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Do Clinical Foot and Ankle Assessments Improve the Prediction of Patient Reported Outcomes in Knee Arthroplasty?

by

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Abstract

Knee arthroplasty (KA) has been considered to be a successful and cost-effective intervention for individuals with severe end stage Osteoarthritis (OA). A number of clinically important predictors of outcomes following KA have been established, however there are still other factors to be identified to improve our ability to recognise patients at risk of poor KA outcomes. Although the relationship between foot, ankle and knee kinematics has become widely accepted, it is not known whether foot and ankle status affect KA outcomes. This thesis therefore aims to determine whether clinical foot and ankle measures are useful in predicting patient reported outcomes following KA. A formal literature review was firstly undertaken to identify current methods of assessing musculoskeletal foot and ankle status. Findings of the review revealed an absence of a standardised assessment protocol and a lack of agreement and validity for many current clinical measures. In response to this an international expert consensus study was undertaken to produce an agreed set of objective clinical musculoskeletal foot and ankle assessment measures to form a new protocol. Two measures identified from the review, and agreed via expert consensus, as the most robust assessment methods- the Foot Posture Index (FPI) and ankle dorsiflexion, were introduced to a large prospective cohort of patients awaiting knee arthroplasty, in addition to foot pain questions. Results show that ankle dorsiflexion and foot posture were not associated with one year knee outcomes, however pre-operative foot pain was associated to outcome; the presence of foot pain increased the risk of a poor post-operative clinical outcome. Findings suggest that it would be beneficial to address foot pain prior to surgery to reduce the risks associated with a poor outcome. Further work would be beneficial to establish the sequential link between foot pain and knee OA in order to inform the most appropriate method of the conservative management.

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Academic Thesis: Declaration of Authorship

I, Lucy Gates declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

'Do Clinical Foot and Ankle Assessment Improve the Prediction of Patient Reported Outcomes in Knee Arthroplasty?'

I confirm that:

This work was done wholly or mainly while in candidature for a research degree at this University;

Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;

Where I have consulted the published work of others, this is always clearly attributed;

Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;

I have acknowledged all main sources of help;

Where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself*;

Parts of this work have been published as listed previously (please list references below);

Signed: …….

Date: …….

*This thesis was nested in a larger programme of study known as the "Clinical Outcomes in Arthroplasty Study (COASt)" led by Chief Investigator Professor Nigel Arden.

The baseline and one year follow up data used within this thesis is part of COASt. I was responsible for collecting baseline and one year follow up data relevant to the foot and ankle, alongside Specialist Research Nurse Carole Ball and Research Physiotherapists Jennifer Rowe and Adam Toner.

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Abbreviations

COASt	Clinical Outcomes in Arthroplasty Study
FPI	Foot Posture Index
HAD	Hospital Anxiety and Depression score
IMFAA	International Musculoskeletal Foot & Ankle Assessment
KA	Knee Arthroplasty
OA	Osteoarthritis
OKS	Oxford Knee Score
MFPDI	Manchester Foot Pain and Disability Index
NDORMS	Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences
NIHR	National Institute for Health Research
NOC	Nuffield Orthopaedic Centre
RA	Rheumatoid Arthritis
SCBR	Southampton Centre for Biomedical Research
SOR	Strength of Recommendation
SUHT	Southampton University Hospitals Trust
KA	Knee Arthroplasty
WTCRF	Wellcome Trust Clinical Research Facility

Research staff abbreviations

CAB	Carole Ball (Senior Research Nurse, Southampton University Hospitals Trust)
AT	Adam Toner (Research Physiotherapist, Nuffield Orthopaedic Centre)
JR	Jennifer Rowe (Research Physiotherapist, Nuffield Orthopaedic Centre)
LM	Louise McCulloch, Podiatrist (University of Southampton)

Publications, presentations & awards

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- Hooper L, Bowen C, **Gates L**, Culliford D, Arden N and Edwards C 2014 Comparative distribution of ultrasound-detectable forefoot bursae in patients with osteoarthritis and rheumatoid arthritis. *Arthritis Care & Research* Vol. 66 (6): 869–877
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- Hooper L, Bowen C, **Gates L**, Culliford D, Ball C, Edwards C.J and Arden NK 2012 Prognostic indicators of foot related disability in patients with RA: results of a prospective three-year study. *Arthritis Care & Research*, 64: 8.
- Hooper L, Bowen C, **Gates L**, Culliford D, Ball C, Edwards C and Arden N. Forefoot Bursae are a Novel Prognostic Indicator of Foot Related Disability in Patients with RA: Results of a Prospective Three-Year Study. Oral Presentation. *The British society of Rheumatology Conference 2012 Annual Conference*
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1 Chapter One

Introduction

1.1 Introduction

This document is submitted in consideration of examination for PhD. Findings will be presented of an epidemiological study to identify the influence of foot and ankle measures on knee arthroplasty (KA) outcomes. A comprehensive literature review and consensus study was completed prior to this to establish a musculoskeletal foot and ankle assessment protocol to include within the study. The need to establish a definitive set of measures arose from the primary aim of the proposed thesis; to investigate the role of foot and ankle assessment in predicting patient reported KA outcomes.

Podiatrists regularly receive referrals from orthopaedic departments for patients who have undergone lower limb KA. From clinical experience many of those attending Podiatry are there due to worse than expected outcomes from KA surgery, although this has not yet been prospectively evaluated. It has been reported that in the general population of KA patients, 18-19% are not satisfied with their primary arthroplasty (Baker et al 2007; Bourne et al 2010; Judge et al 2012). Other data suggests as many as 46.5% patients report a bad outcome following KA (Hawker et al 2013).

Knee related referrals to Podiatry are often to request orthotic intervention to alter the alignment of the foot in a way which may influence the frontal plane mechanics of the knee. Some referrals are made to podiatry with the intention of adjusting for any leg length discrepancy which may have resulted from surgery, whilst others simply indicate a trial of an in shoe device in an attempt to relieve pain at the knee. Evidence to support the use of orthotic prescription in knee pathology, in particular osteoarthritis, is increasing but varied (Rubin & Menz 2005; Bennell et al. 2007; Hinman et al. 2008; Hinman et al. 2012) and the therapeutic effects of such interventions are not entirely understood.

A patient attending a podiatry clinic following their KA will have often not been seen within the department prior to their joint surgery. It is therefore difficult to ascertain whether any potentially influential discrepancy in foot and ankle characteristics may have been present prior to knee surgery. This therefore raises the question that if such discrepancies were previously apparent, would addressing these prior to knee surgery have influenced the patients KA outcome?

A number of clinically important predictors of pain and functional outcomes following KA have been identified, including pre-operative pain, function, anxiety, social deprivation, age and gender (Judge et al 2012a). Hawker et al (2013) suggested that factors including pre-operative pain and function, co morbidity, severity of arthritis and number of multiple troublesome knees/hips affect the probability of a good outcome as defined by improvements in overall knee pain or disability.

Whilst these studies provide good insight into predictors of KA outcome other predictive factors are yet to be identified. From a review of the literature there is no evidence to determine if foot and ankle pain, pathology or characteristics, have an influence on the outcomes of KA. This therefore led to the main research question;

“Do clinical foot and ankle assessments inform the prediction of patient reported outcomes in knee arthroplasty?”

To answer this question a set of informed clinical foot and ankle assessment measures were firstly required. Clinical and research experience within the field and preliminary literature searching identified a distinct lack of agreed and valid foot and ankle assessments. It was therefore anticipated that a formal literature review and expert consensus study would be required in order to define a core set of clinically applicable foot and ankle assessment measures to be utilised within the main study. The measures established would then inform the musculoskeletal foot and ankle assessments to be used within a prospective cohort study of patients awaiting knee arthroplasty, known as the Clinical Outcomes in Arthroplasty Cohort (COASt). A description of COASt is detailed below.

1.1.1 COASt

COASt is a prospective, dual-centre longitudinal cohort study of patients who are listed for hip and knee arthroplasties across two hospitals Southampton University Hospital NHS Foundation Trust (UHS) and Nuffield Orthopaedic Centre (NOC), which is the part of the Oxford University

Hospital NHS Trust (OUH). National Institute of Health and Research (NIHR) funded study (NIHR Programme Grant for Applied Research 10064) set up to assess a strategy for predicting patients at risk of poor functional outcome following lower limb joint arthroplasty. The main aim of the programme is to design and implement a strategy, for use within the NHS, for predicting patients at risk of poor functional outcome. The study collects baseline, intra-operative and follow-up information for up to five years after their surgery. It also collects patients' pre-operative, intra-operative and one and/or two to five years' post-operative samples.

The number of patients consented for COASt, across both hip and knee, was n=3,711 (Oxford, n= 2,970, Southampton n= 741). Of these 1,441 knees were recruited in Southampton and 319 in Oxford.

1.2 Research Question

Do clinical foot and ankle assessments inform the prediction of patient reported outcomes in knee arthroplasty?

1.3 Main Aims

The primary aim of the thesis is to determine whether clinical foot and ankle assessments are useful in predicting patient reported outcomes following KA. This will be informed by three experimental studies which specifically aim to:

1) Critically review the literature to identify existing musculoskeletal measures of foot and ankle status

2) Conduct an expert consensus study to produce a core set of objective clinical musculoskeletal foot and ankle assessment measures in order to predict patient related outcomes.

3) Determine the influence of these assessment measures, with the addition of foot pain assessment, in the prediction of patient related outcomes in KA by applying a number of these to a prospective cohort known as COASt.

2 Chapter Two

Background & Literature Review

2.1 Introduction

This chapter provides a critical overview of the literature underpinning the epidemiology of knee arthroplasty (KA), the risk factors for poor outcomes and the outcome measures currently utilised to measure the success of KA. Literature is further reviewed to provide insight into the potential role that the foot and ankle may play on the above related knee factors.

2.1.1 Knee Arthroplasty

KA is considered to be a successful and cost-effective intervention for individuals with severe end stage Osteoarthritis (OA) (Liang et al 1986; Chang et al 1996; Rissanen et al 1997; Jordan et al 2003; Ethgen et al 2004). When the joint becomes damaged through the degradation of cartilage, development of cysts, erosion of bone and osteophyte formation, malalignment can occur, causing potentially high stress across the joint. Depending on the location and extent of disease a surgeon may opt for either a total knee arthroplasty or a unicompartmental arthroplasty (Carr et al 2012). Unicompartmental knee replacements can be completed in medial, lateral, or patello-femoral compartments of the knee. Only the most affected parts are replaced, by contrast with total arthroplasty in which the whole joint is replaced (Saccomanni 2010). There is a general consensus that total knee arthroplasty substantially changes the kinematic profile of the knee compared to unicompartmental arthroplasty, likely due to the severity and widened location of pre-existing pathology and loss of ligament integrity often seen in patients requiring total replacement (Patil et al 2005).

Evidence using population based data from the Clinical Practice Research Database (CPRD), formerly the General Practice Research Database (GPRD)- a database of longitudinal primary care medical records, containing over 3 million active patient records drawn from approximately 400 primary care practices in the UK (www.gprd.com) has highlighted the increasing future burden that KA will have on healthcare.

Using CPRD data Culliford et al (2012) investigated the lifetime risk of undergoing KA in the UK between 1991 and 2001. Findings suggested that the lifetime risk estimated at between 5 and 10%. There was an upward trend in risk for this period, with KA rising from 2.9 to 10.6% for women and from 1.8 to 7.7% for men. Culliford et al (2010) identified 23,843 primary KAs within the UK between 1996 and 2006, reporting the estimated age- standardised primary KA rates have increased by over three times over a ten year period.

Recent evidence using CPRD over a 20-year period (1990-2010) and accounting for changes in age, gender and BMI has estimated the number of KAs performed in the UK in 2035 to be 118,666 (Culliford et al 2015). With an additional assumption of a change in future BMI, this distribution increases further. Projected counts were higher for women than men and distributions increased with the assumption of a change in BMI. Culliford et al (2015) suggest these long-term estimates

Are likely neither plausible nor sustainable in terms of NHS capacity and funding levels.

2.1.2 Joint Arthroplasty Survivorship

A report from the National Joint Registry (NJR) in 2010 noted that out of the 77, 545 KA procedures submitted to the register in England and Wales, 4,456 were revision procedures. With a rising requirement for knee joint replacements and an increasing lifetime of the elderly population, there has been a continual rise in the rate of KA revision (Platzer et al 2010). The survival of KA in particular, has often been assessed using revision of replacement as the end point, limitations of such data are those numbers lost to follow up. Factors identified which may influence KA survivorship are summarised in table 1.

Table 1. Factors associated with KA survivorship

Implant Survivorship factors	*Effect*	*Author*
Component loosening	Poor Survivorship	Furnes et al. 2007; Gupta et al. 2007; NJR, 2010
Peri-prosthetic fracture	Poor Survivorship	Platzer et al. 2010
Mal-alignment	Poor Survivorship	Fang et al. 2009; Keene et al. 2006; Parvizi et al. 2004; Ridgeway et al. 2002
Infection	Poor Survivorship	Jamsen et al. 2009
Pain	Poor Survivorship	Furnes et al. 2007; Lygre et al. 2010
Age	Younger age=lower survival rate	Harrysson et al. 2004; Julin et al. 2010; NJR, 2010; Rand et al. 2003
Gender	No difference in survival between genders	Gill & Joshi 2001
	Higher survivorship in women	Rand et al. 2003
BMI	Poor survivorship in obese population	Amin et al. 2006
	No difference in survivorship between obese and non-obese	Yeung et al. 2011
	Increase demand with higher BMI	Culliford et al 2015
Implant design	Survival of tricompartmental KA is superior to that of unicompartmental knee replacements	Furnes et al. 2007
	Unicompartmental knee replacements superior to tricompartmental KA	Berger et al. 1999; Murray & Frost 1998
	Better survivorship for cemented prosthesis compared with uncemented	Rand et al. 2003
	No difference in survivorship between cemented and non-cemented.	Baker et al. 2007

Component loosening (Furnes et al 2007; Gupta et al 2007; NJR 2014), peri-prosthetic fracture (Platzer et al 2010), mal-alignment (Fang et al 2009), infection (Jämsen et al 2009) and pain (Furnes et al 2007; Lygre 2010) are some reasons identified as a requirement for revision of knee replacement.

In concurrence with the most recent publications from the NJR 7th Annual report (2014) a reduction of implant survival has been identified in younger patients (under 65 years old) (Harrysson et al 2004), this has been linked to an increase in activity levels noted in younger patients. Rand et al (2003) reported a prosthetic survivorship of 83% for patients fifty-five years of age or less compared with 94% for those older than seventy years of age at ten years was ($p < 0.0001$). Similarly Gill and Joshi (2001) showed age at surgery was significant (log-rank test, $p = 0.001$), with younger patients (55 years and younger) faring worse (21% revision rate) as compared with the older age group (above 55 years, 3% revision rate), at endpoint defined by revision.

The role of gender as an influence on KA survival has received conflicting findings; some studies have reported no difference in gender with rates of KA success at endpoint of revision or removal (Gill & Joshi 2001), whilst others have found a significantly higher survivorship of KA in women than men, with survivorship of 93% (95% CI, 92% to 94%) for women and 88% (95% confidence interval, 86% to 89%) for men ($p < 0.0001$) (Rand et al 2003). Differences in findings are likely due to length of follow up; survivorship figures for the latter study were taken at ten years, unlike the former which used revision or removal as end point.

Higher BMI has been linked to poorer results of primary KA at five years, with survivorship based on revision and pain at 72.3% in an obese group compared to 97.6% in a non-obese group (Amin et al 2006). However a case control study of obese and non-obese patients, (Yeung et al 2011) found no difference in mid-term KA survival rate at ten years between obese and no obese patients.

Implant design has also been identified as a risk factor for primary KA failure. An observational study of the Norwegian arthroplasty register from 1994-2004 suggests survival of tricompartmental KA is superior to that of unicompartmental knee replacements (Furnes et al., 2007). This study however was unusual as in case mix studies of arthroplasty, especially using joint registries, do not usually adjust for type of procedure. Studies from specialized centres (Murray et al 1998; Berger et al 1999) have shown a significant difference in survivorship at ten

years between cemented prosthesis (92%, 95% CI 91% to 93%) and cement less prosthesis (61%, 95CI 54% to 68%) (P<0.0001) (Rand et al 2003). Laxity and pre and post-operative limb alignment have also been identified as risk factors for early failure of KA at 5 and 6 years (Ridgeway et al 2002; Parvizi et al 2004).

2.1.3 Arthroplasty Outcomes

The main problems of modern survival analysis, which use revision as endpoint is that revision does not account for patient satisfaction and may therefore not be a true representation of arthroplasty success. Price et al (2010) found that with revision as endpoint, the total knee arthroplasty (TKA) survival rate in a younger group (<60 years) was 82.2% at a minimum of 12 years. However many of the patients who did not undergo revision had a less than satisfactory outcome. A combined endpoint including revision, poor function and significant pain drastically reduced the survival rate for the KA, suggesting that an accurate representation of the success of KA should include endpoints of pain and function.

Objective clinical measures are increasingly considered less representative of the outcome from the patient's perspective (Bullens et al 2001). Growing emphasis is therefore now placed upon Patient Reported Outcome Measures (PROMS) to measure the success of KA (Williams et al 2013). It has become apparent that not all patients are satisfied with their surgery, with dissatisfaction rates ranging from 7% to 32% (Bullens et al 2001; Noble et al 2006; Baker et al 2007; Nilsdotter et al 2009; Bourne et al 2010; Scott et al 2010).

Following the release of the Darzi report (Department of Health 2008), which indicated a need for understanding success rates of treatments from a patients perspective, the UK government and the National Joint Registry have adopted the mandatory use of the Oxford Knee Score (OKS) (Dawson et al 1998; Murray et al 2007) and EuroQol (EQ-5D) as validated outcome measures of pain, function and health status in KA.

Questions have recently arisen regarding appropriateness of using the OKS as a single measure of outcome. In a study to address the effects of age on PROMs in KA, Williams et al (2013) found that overall outcome is comparable across ages, with a trend for greater improvement in the younger cohort. However, the addition of satisfaction outcome shows a higher rate of dissatisfaction in those aged <55 years. This is especially of concern as post-operative OKS and EQ-5D scores in this group were among the highest of all age groups studied, implying that a satisfactory outcome in

clinical symptoms has been achieved. Findings suggest that outcome scores such as OKS and EQ-5D alone might therefore not accurately reflect the true outcome in all age groups, and consideration is required for satisfaction outcomes. Baker et al (2007) have shown that even if a patient reports a bad outcome in terms of pain and function, as measured by OKS, they may still be satisfied with surgery. The exclusion criteria for the current cohort study (COASt) contain no age cut off and utilises a variety of additional objective and patient reported outcomes, including satisfaction.

In a previous study by Judge et al (2012), 54.6% of KA patients who completed outcome surveys reported being satisfied with surgery, even though according to their OKS scores they had no change in symptoms or their symptoms had worsened six months after surgery. Judge et al therefore identified thresholds that represent whether or not a patient achieved a clinically meaningful outcome, rather than looking at satisfaction alone. The Patient Acceptable Symptom State (PASS) score thresholds were identified for the OKS in order to define a 'satisfactory symptom state' therefore differentiate between patients with extremely high versus high overall levels of satisfaction with surgery. For six-month post-surgery OKS of 30 points or more show the highest level of satisfaction.

It is important to consider the factors that may influence such outcomes and increasing attention is being paid to identifying such factors. Previously established predictors of satisfaction and outcome following KA are summarised in Table 2.

Table 2. Predictors of KA satisfaction and outcome

Predictors	*Outcome*	*Authors*
BMI	Higher BMI linked to poor functional outcomes in KA	Amin et al (2006) ; Foran et al (2004); Gandhi et al (2010); Zeni & Snyder-Mackler (2010); Yeung et al (2011)
BMI	Equivalent functional benefit following KA with high and low BMI. Lower satisfaction with higher BMI	Baker et al (2013)
BMI	BMI not a clinically important predictor of KA outcome (in relation to satisfaction)	Judge et al (2012)
BMI	Equivalent KA satisfaction between obese and non-obese	Yeung et al (2011)
Pre-operative Pain/function	Pre-operative Pain/function were the strongest determinants of KA outcome: those with less severe pre-operative disease obtain the best absoloute outcomes	Judge et al (2012)
Pre-operative Pain/function (as per WOMAC)	Worse pre-op WOMAC summary scores had higher probability of better KA outcome	Hawker et al (2013)
Pre-operative expectation	Patient expectations of pain relief was an independent predictor of improved functional outcomes and satisfaction following KA.	Mohamed et al (2002)
Disease	KA patients with RA showed better outcomes than those with OA	Judge et al (2012)
Disease	KA patients with OA (Vs RA) had higher probability of better outcome	Hawker et al (2013)
Anxiety/depression	Worse pre-operative anxiety/depression led to worse pain in KA patients	Judge et al (2012)

Deprivation	KA patients living in more deprived areas had worse outcomes	Judge et al (2012)
Age	Age specifically associated with function in KA patients	Judge et al (2012)
Age	Younger patients (<55 years) gain greater improvement in pain and function but report lower satisfaction	Williams et al (2013)
Gender	Gender specifically associated with function after KA	Judge et al (2012)
Other pathological joints	KA patients with fewer troublesome hips/knees had higher probability of better outcome	Hawker et al (2013)
Co-morbidities	Those with fewer co-morbidities had higher probability of better outcome	Hawker et al (2013)

BMI has received increasing interest in its association with KA outcomes. Higher BMI has been linked to poor functional outcomes in knee arthroplasty up to 2 years (Gandhi et al 2010; Zeni & Snyder-Mackler 2010), 5 years (Foran et al 2004; Amin et al 2006) and 10 years (Yeung et al 2011). However equivalent satisfaction results have been reported between obese and non-obese populations at 10 years post op (Yeung et al 2011). Results of a cohort study shows that although BMI is associated to statistically important outcome, it is not a predictor of clinically important outcome, which is anchored to patient satisfaction (Judge et al 2012). Baker et al (2013) also showed obese patients gain as much functional benefit from KA as those with lower BMI for up to 3 years after surgery. It is therefore important to consider that whilst BMI may be associated with function it may not influence clinically important outcomes linked to satisfaction. The potential confounding of BMI was therefore addressed when evaluating outcomes of pain, function and satisfaction within the current thesis.

Judge et al (2012) have identified a number of clinically important predictors of pain and functional outcomes following KA. Importantly, within the context of patient expectation, it was reported that predictors of pain were not necessarily the same as functional outcomes. Pre-operative pain and function were the strongest determinants of outcome, with the best outcomes seen from those with less severe pre-operative disease. Patients with RA showed better outcomes than those with OA and diagnosis of RA was associated with pain. Those living in more deprived areas had worse outcomes, likewise those with worse pre-operative anxiety/depression led to worse pain. Age and gender were specifically associated with function. These findings have important implications, showing that age and BMI should not be a barrier to KA surgery and even where some groups may have poorer functional outcomes it does not indicate these patients do not benefit from surgery.

Williams et al (2013) demonstrated that good early outcomes, as measured by the OKS and EQ-5D, can be anticipated following knee replacement regardless of the patient's age, although younger patients gain greater improvement. These younger patients (<55 years) do however report lower satisfaction. Once again these findings suggest that clinically important and patient interpretable satisfaction outcomes should not be represented entirely by pain and functional outcomes.

Depression and/or anxiety has also been associated with worse pain outcomes at 1 year (Brander et al 2003), 2 years, with 1.4 higher odds (95% CI 1.0, 2.0) of moderate to severe index knee pain and at 5 years with 1.7 higher odds (95% CI 1.1, 2.5) (Singh and Lewallen 2013).

A more recent cohort study of patients undergoing KA identified four main variables associated with arthroplasty outcome (Hawker et al 2013). Good outcome was defined as an improvement in Western Ontario and McMaster Universities OA Index (WOMAC) summary score greater than or equal to the minimal important difference (where the minimal important difference represented one-half of the SD of the difference between pre-total joint arthroplasty summary score and post-total joint arthroplasty summary score). The WOMAC is a questionnaire to evaluate pain, stiffness and function specific to joints affected by OA (Bellamy et al 1988). The probability of a good outcome was greater with worse pre – joint replacement KA WOMAC summary scores, fewer pathological hips/knees, OA (Vs Rheumatoid Arthritis) and fewer co-morbidities. This study also showed a much lower joint replacement satisfaction rate than any previous cohort studies, with only half achieving a good KA outcome, defined as improved pain and disability these findings may be due to the ceiling effect that can occur with bound outcomes such as WOMAC.

It is difficult to confidently compare KA outcome results from the most recent cohort studies due to the use of different outcome measures and the variation in defining good and poor outcomes. Hawker et al (2013) used the WOMAC OA Index to report pain, function and stiffness in 202 participants (KA=133 AND Total hip replacement=69), 6.9 % of whom were diagnosed with inflammatory arthritis. Judge et a (2012) used both the OKS (an instrument validated for the examination of patients specifically undergoing KA, which is not limited in validity to OA specific populations) and satisfaction scores on a sample of 1991 participants undergoing primary KA (93.7% diagnosed with OA, 2.9% rheumatoid arthritis and 3.3% unspecified other pathology).

The larger sample and the use of both statistically and clinically important outcomes relative to satisfaction are strength of the earlier cohort study by Judge et al (2012). It identified predictors of both statistically important outcomes using the 6-month OKS, and clinically important outcomes by identifying a cut-point for the 6-month OKS related to satisfaction with surgery. As recognised by Judge et al (2012), there are potential problems when using a change in score (between pre and post op score) as outcome for all PROMs instruments; floor and ceiling effects are an important consideration in this circumstance as patients with poor pre-operative scores may have had more room for improvement than those with better pre op scores, indicating potential ceiling effects on fixed-end scales such as the OKS.

Whilst both studies provide good insight into predictors of KA outcome, <20% of the variability in PROMs of KR was explained (Judge et al 2012), suggesting there are other predictive factors still to be identified to improve our ability to recognize patients at risk of poor KA outcomes. The

predictive value of distal joints such as the foot and ankle, upon KA outcomes, has yet to be investigated.

2.1.4 Multi- Joint Approach

Patients undergoing KA often have other troublesome hips and knees (Hawker et al 2009; Perruccio et al 2012). Multiple-site joint problems are a common occurrence among patients visiting both primary and secondary care musculoskeletal departments (Keene et al 2006). The management of both single and multiple joints via treatment of a distal or proximal joint is a growing approach, especially for the lower limb. Although there is a gradual increase in investigations to support this, more robust clinical investigations are required.

In a review of 2429 participants reporting pain in the previous year in at least one hip, knee, or foot, it was found that over 50% reported multiple joint pains (Peat et al 2006). In addition, the severity of pain at one joint was shown to increase as the number of joints affected increased. Due to the cross sectional methodology the cause and effect relationships of one site on another were not established; however the findings do support the importance of a multi joint approach to treatment.

Sayre et al (2010) reported an association between severity of OA in a knee or hip joint and severity of OA in the contralateral knee or hip with odds ratios ranging from 9.2 (95% CI 7.1, 11.9) to 225.0 (95% CI 83.6, 605.7). Interestingly they noted an association in radiographic OA with the other joint on the same limb from the one being observed (i.e. hip or knee). These findings suggest a link between weight bearing joints affected by OA, indicating a multi-joint assessment approach for management of pathology such as OA.

A study investigating the relationship between lower back pain and knee OA concluded that any single musculoskeletal pain location external to the knee was associated with a higher knee pain score; of these lower back pain and ipsilateral foot pain were significantly associated with knee pain (Suri et al 2010). This highlights the potential effect that foot pain and/or pathology may have on knee symptoms, either mechanically or via either phenomena's such as central sensitisation.

Arendt-Nielsen et al. (2010), who highlighted the significance of central sensitisation as an important manifestation in knee OA. Central sensitisation is the phenomenon that occurs with

tissue injury or repeated nociceptive stimulation, as may be seen in OA (Bonica 1990). This leads to changes in nerve endings, with lowered stimulation threshold and prolonged and enhanced response to stimulation (Hucho and Levine 2007). Initially this hypersensitivity is found at the site of damage; however when the disease process is not controlled, such as in patients with OA, the central nervous system undergoes plastic changes that are responsible for sustaining chronic pain. These changes may also occur at sites distant from the OA affected knee (Imamura et al 2008).

Evidence to suggest the role of foot pain on KA outcomes is very limited. A population based study of KA patients found worse patient reported outcomes in individuals who reported pain in the ankles/feet/toes. This was however pain associated with osteoarthritis at that joint, therefore suggesting that the association is determined by the presence of foot and ankle osteoarthritis (Peruccio et al 2012).

Recent findings from a large prospective cohort, which was enriched with patients with or at risk of knee Osteoarthritis, show that foot pain adversely affects knee OA related pain and symptom severity (WOMAC) and objective measures of physical function (20-meter walk test pace and repeated chair stand pace)($P<0.05$) (Paterson et al 2015). The data used was cross-sectional therefore no inference can be made to whether foot pain developed subsequent to knee OA or prior to it.

It is widely acknowledged by health care clinicians and researchers that there is a relationship between foot, ankle, knee and hip kinematics (Andrews et al 1996; Guichet et al 2003; Pierrynowski et al 2003; Reilly et al 2006; Reilly et al 2009). The effects of altering biomechanical factors at the distal limb has received increasing attention in managing knee osteoarthritis (Cornwall & McPoil 1995; Rubin & Menz 2005; Bennell et al 2007; Butler et al 2007; Butler et al 2009; Hinman & Bennell 2009). However it is not known whether foot, ankle and knee kinematics are associated with KA outcomes.

Work utilising multi-segmental joint models for motion analysis within the laboratory setting has facilitated understanding of lower limb biomechanical factors (Grood & Suntay 1983; Cornwall & McPoil 1999; Leardini et al 1999). Such methods can be very complex, costly, require lengthy examination periods and are not typically transferable to clinical settings. Clinical foot and ankle assessments performed by podiatrists follow a structured assessment based on a series of hypotheses developed in the early 1970s (Root et al. 1971; Root et al. 1977).

Clinical Podiatric biomechanical assessment is based on the theory to which, the degree of movement at the foot and subtalar joint affect the lower limb alignment as movement is transferred proximally to the tibia. An excess of subtalar joint inversion/eversion is hypothesised to increase external/internal rotation about the tibia (Inman 1976), this in turn is said to disrupt the normal mechanics of the tibio femoral joint (Tiberio 1987). Mal-rotation is coupled with mal-alignment (Eckhoff 1994), both of which have been suggested to have a relationship to the risk (Brouwer et al 2007; Janakiramanan et al 2008) and development (Sharma et al 2001) of knee OA. These axial links between the subtalar and tibiofemoral joint indicate that foot and ankle kinematics may play an influential role on the both the transverse rotational and frontal measures about the knee (Inman 1976; Tiberio 1987), such attributes, as previously stated, are known risk factors for the development of mechanical stress derived pathology such as OA and the early failure of KA. Such theories remain limited in their evidence base, likely due to the difficulty in assessing dynamic anatomical forces and motion within the intricate articulations around the foot and ankle joints. Further investigation is required to determine any potential relationships between foot and ankle and knee, and to investigate the effect such a relationship may have upon the outcomes of procedures such as KA.

From this introductory review of the literature evidence has yet to be found to investigate the relationship between foot and ankle characteristics and KA outcomes.

Studies investigating the use of foot orthoses in the treatment of knee conditions such as OA (Rubin and Menz 2005; Baker et al 2007; Bennell et al 2007; Butler et al 2009; Hinman and Bennell 2009; Bennell et al 2011; Parkes et al 2013; Jones et al 2014) are more prevalent than those for hip OA (Ohsawa & Ueno 1997). The majority of foot orthoses/knee OA studies remain observational. The National Institute for Health and Clinical Excellence guidelines (2008) suggest that foot orthoses and footwear advice may be useful for patients with lower limb OA. However, there is little investigation of the role of musculoskeletal foot assessment and the principles underpinning the use of these devices. The majority of studies investigating the use of foot orthoses in the treatment of lower limb OA do not examine the foot prior to orthotic provision (Bennell et al 2007; Butler et al 2009; Hinman et al 2009). This may be due to a lack of reliable evidenced protocols for foot orthotic prescription and this clearly limits evaluation of their use as an intervention for knee OA.

It is likely this has been influenced by the lack of valid clinical foot function and gait assessment measures. Many of the clinical foot and ankle assessments are subjective, lacking in reliability,

reportedly difficult to validate and outdated (Keenan & Bach 1996). The development of the Foot Posture Index (FPI) (Redmond et al 2006) attempted to address the need for a clinically useful and repeatable evaluation tool. The FPI is a method for quantifying static standing foot posture. It is a clinician assessed 6 point scale which allows for assessment across the three planes of the foot without the need for sophisticated equipment (Redmond et al 2006). It offers a score based upon 6 criteria which, when summated, provide a score to determine foot posture classification. To date it appears the FPI is the most rigorously tested clinical foot and ankle assessment tool available. Validation of the tool has been somewhat hindered by a limitation in gold standard comparative techniques and caution has been advised when interpreting the results of FPI-6 due to only moderate levels of inter rater reliability (Cornwall et al 2008).

A recent investigation by (Levinger et al 2010) utilised the FPI to observe differences of foot posture in people with knee OA. Their findings suggest that those with medial knee OA exhibit particular characteristics of a more pronated foot type in stance. Similarly a previous study (Reilly et al 2006) observing the relationship between foot posture, using the FPI and medial knee OA showed differences in foot type between people with medial compartment OA of the knee, OA of the hips and healthy controls. A follow up investigation (Reilly et al 2009) concluded that the FPI is a sufficiently sensitive tool to demonstrate the differences between patients with hip OA, medial knee OA and healthy controls. The findings indicated that patients with medial knee OA demonstrate extremes of the normal range of ankle dorsiflexion and foot posture.

Although a suggestion was made that foot posture types may lead to the use of subtly different knee movements, the study findings are limited in that kinematic measures across the knee joint were not used and foot measures were of static alignment rather than dynamic function. A limitation in the use of static clinical foot and ankle assessments, such as the FPI, is the lack of representation of dynamic gait. Results for FPI-6 indicated the FPI scores predicted 64% of the variation in the static ankle joint position during stance, but only 41% of the dynamic variation in midstance foot position (Redmond et al 2006).

Although interventions for the foot and ankle aim to reduce pain and increase function there is surprisingly little investigation into the association between clinical musculoskeletal foot and ankle assessments and outcomes such as pain or patient function (activity participation/lifestyle). The majority of foot and ankle assessment techniques including: first ray passive range of motion (ROM), 1st metatarsal phalangeal joint (MTPJ) ROM, arch height, navicular height, rear/forefoot, ankle, subtalar joint (STJ) and foot posture have usually been examined for validity against other

objective measures such as radiography (Saltzman et al 1995; Williams & McClay 2000; Scharfbillig et al 2004; McPoil et al 2008b; Hegedus et al 2010), 3D motion analysis (McPoil & Cornwall 2005; Halstead & Redmond 2006; Redmond et al 2006) and mechanical devices (Glasoe et al 2002; Noakes & Payne 2003; Cornwall et al 2004; Glasoe et al 2005; Kim et al 2008). From the few investigations that have assessed clinical foot and ankle measures against pain or function, so far only measures of ankle dorsiflexion and toe plantarflexor strength have been found to be independent predictors of balance, function and falls although these findings are limited to the older population (Menz et al 2005; Menz et al 2006).

In order to confidently assess the predictive ability of foot and ankle measures on KA outcomes an essential element is to know the relationships between clinical foot and ankle assessments and outcomes of pain and function. Consensus on which foot and ankle assessments should be used is required among investigators so that comparisons between studies can be made more readily. Agreement would facilitate the development of a standard protocol for the assessment of the foot and ankle that has the ability to universally evaluate musculoskeletal foot and ankle status.

Research has so far identified <20% of the variability in patient-reported outcomes of KA (Judge et al 2012). The development of a clinical model including foot and ankle assessment, such as that being developed within the COASt study, may enable better prediction of KA patient reported and functional outcomes and it would provide an opportunity to phenotype more prognostic indicators. Determining whether musculoskeletal foot and ankle assessment influence the prediction of KA outcome could provide valuable information required to improve outcomes. Such information could have potential implications on the management of patients requiring KA. If association is shown between particular foot and ankle status and poor KA outcome further interventional investigation would be required. This may determine if KA outcome could be improved in patients with a higher risk of poor outcome due to the foot/ankle status by managing the foot and ankle prior to surgery.

3 Chapter Three

Methodology

3.1 Introduction

The initial literature review (chapter two) has identified limited investigation of the role of foot and ankle assessment on the outcome of KA. To date little is known about the relationship between the foot and ankle and KA. This is coupled with a lack of valid foot and ankle assessment measures (chapter four), and therefore challenges the investigation of the primary research question:

Do clinical foot and ankle assessments inform the prediction of patient reported outcomes in knee arthroplasty?

This chapter discusses the philosophical approach and research methodology used for the investigations that form this thesis to answer the primary research question.

3.2 Aims and Objectives

To answer the main research question it was necessary to firstly achieve the following:

1) To identify existing reliable/valid musculoskeletal measures of foot and ankle status.

2) To identify a core set of objective clinical musculoskeletal foot and ankle assessment measures in order to predict patient related outcomes.

3) To determine the influence of these assessment measures in the prediction of patient related outcomes in knee arthroplasty.

The methods for the completion of these studies were designed to address the following objectives:

1) To administer a consensus study to produce a set of objective clinical musculoskeletal foot and ankle assessment techniques, to inform a core set of measures. This study is to include an initial formal literature review to identify existing clinical measures of foot and ankle status (Chapter 4) and an expert Delphi exercise to provide consensus on the appropriate foot and ankle assessments to include (Chapter 5).

2) To apply a number of the identified foot and ankle assessment measures to a prospective knee arthroplasty cohort to determine the influence of these assessment measures in the prediction of patient related outcomes (Chapter 6).

3.3 Study Design

A deductive research approach allowed for the establishment of a hypothesis by the use of theory, driven by current evidence and expert opinion. Data collection on a cohort of knee arthroplasty patients confirmed or rejected the hypothesis. A mixed methods approach was taken to the thesis (figure 1).

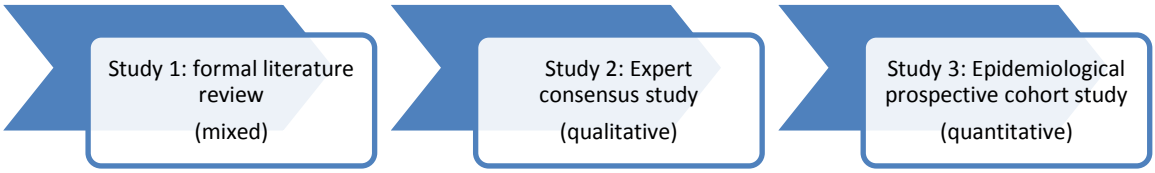

Figure 1. Thesis study designs

The stages in the approach to answering the main research question can be seen in figure 2. The initial stage was the evaluation of current evidence, which informed a need to investigate the role of foot and ankle assessment in predicting KA outcomes. In order to test the hypothesis which emerged a literature review was conducted to identify and evaluate current musculoskeletal foot and ankle assessments (chapter four). The purpose of a review was to interpret, summarise and evaluate all available research evidence to facilitate decision making on the requirement of further investigation.

The findings of the review confirmed the need for an additional study. Further investigation was required to address the need for agreement of a suitable set of foot and ankle measures to be

used within the investigation of predictors of KA outcome. Due to a lack of valid foot and ankle assessment measures and an absence of agreement on suitable foot and ankle clinical measures, it was necessary to develop an evidence driven approach to gain consensus on an appropriate set of musculoskeletal foot and ankle measures from a group of international foot and ankle experts (chapter 5).

The findings of the first two studies informed the introduction of a number of foot and ankle assessments into a prospective cohort of patients awaiting knee arthroplasty. Patients were prospectively followed up to compare to the pre-operative foot and ankle assessments to one year post-operative knee outcomes (chapter 6).

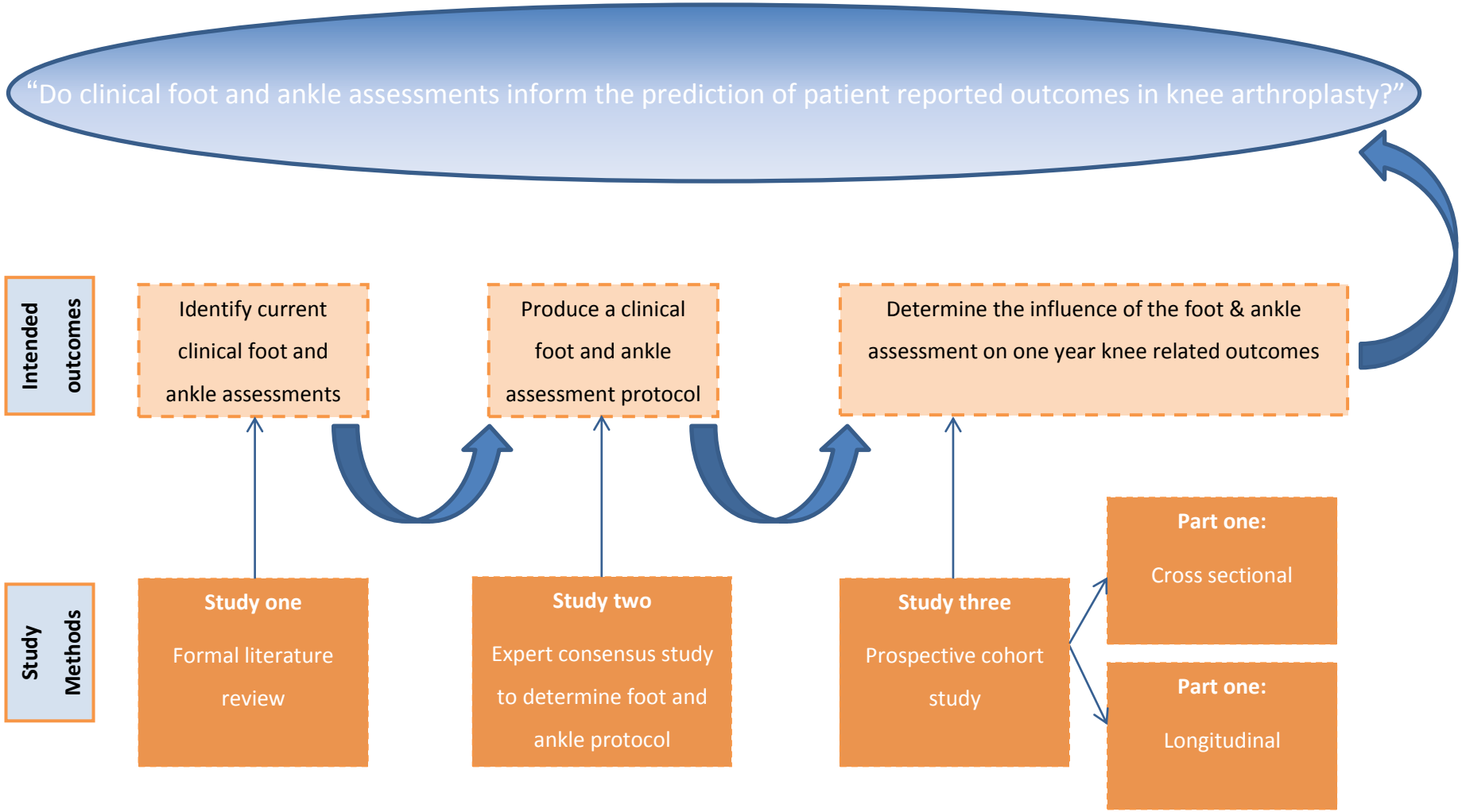

Figure 2. Stages of Study progression

3.4 Study specific research aims, objectives and methodological design

3.4.1 Experimental study one (chapter 4)

The main aim of study one was to examine the validity and reliability of current individual clinical assessment measures and to establish whether a foot and ankle assessment protocol currently exists. The following objectives were set in order to achieve this aim:

1) To complete a comprehensive literature review to:
    a. Identify all current clinical musculoskeletal foot and ankle assessments within the literature
    b. Identify whether a comprehensive musculoskeletal foot and ankle assessment protocol exists
    c. Evaluate the cross sectional criterion validity, longitudinal predictive validity (against pain and function) and the reliability of each measure as defined within the literature
    d. Identify which assessments, if any, are clinically valid and reliable, to use within the current study

Study one was a formal critical literature review of current and previous literature. A detailed systematic search strategy was used to obtain a comprehensive overview and summary of the available literature for the proposed area. The key literature was critically appraised with a narrative approach due to the majority of level III evidence.

3.4.2 Experimental study two (chapter 5)

Based on the findings of study one, a decision had to be made either to use a current assessment instrument, if one existed, or alternatively develop a new set of assessment measures. The following objectives were set in order to achieve this aim:

1) To administer a consensus study to identify a core set of objective musculoskeletal foot and ankle assessment measures that will be appropriate for use in a prospective cohort study.

Study two was an international foot and ankle expert consensus study, which utilised a Delphi Technique to identify expert opinions relevant to foot and ankle assessment measures.

3.4.3 Experimental study three (chapter 6)

The main aim of this study was to determine the influence of a number of the agreed foot and ankle assessment measures (from study one and two) on the prediction of 'patient reported outcomes' in knee arthroplasty. The following objectives were set in order to achieve this aim:

1) To introduce a number of agreed foot and ankle assessment measures (physical and subjective) pre-operatively to a prospective cohort of patients awaiting KA
2) To observe differences in baseline foot and ankle characteristics
3) To observe patient reported outcomes one year post TA
4) To compare baseline pre-operative foot and ankle assessments with one year post-operative knee patient reported outcomes

Experimental study three was a prospective cohort study of clinical foot and ankle assessments in patients pre and post KA. Baseline (pre-op assessment), and one year post-operative data were collected on patients who underwent primary UKR or TKR within the established COASt cohort.

3.5 Quality Assurance and control

Throughout this thesis, care has been taken to identify, consider, adjust for and interpret potential errors or biases inherent with the design of the studies. The following section documents the potential sources of error or bias and the methods used to negate these.

3.5.1 Agreement in data collection

Estimations of reporting error, as a consequence of longitudinal researcher variability, have been calculated for the completion of the FPI by the main research (LG). The term agreement has been used throughout the following text to refer to the quantifiable extent to which scores taken by two researchers are the same or differ.

3.5.1.1 Agreement in FPI data

The FPI data was collected by the lead investigator (LG). However, on occasion when this was not possible, the COASt research nurse was required to undertake this assessment. The FPI requires a semi-quantitative scoring of multiple joint alignments to derive a final composite score. The

subjective nature of scoring alignment may introduce observer bias to the study results thus inter-examiner agreement of FPI scores was established.

A subset of 31 participants, consecutively recruited from COASt, was examined at the same time by the lead investigator (LG) and senior research nurse (SRN). The participant remained in the same standing position and both observers remained blind to each other's records.

Inter-rater agreement was demonstrated by calculation of the mean difference between scores (estimated bias), with the range of disagreement expressed as +/- 2 standard deviations (the fluctuations around this mean). The standard error of the mean was calculated to provide 95% confidence intervals for the likely mean disagreement between scores for each observer. The results of the FPI agreement analysis are presented using Bland-Altman plot (figure 3), which aid in the identification of any systematic difference between the measurements (i.e., fixed bias) and to identify possible outliers (Bland and Altman 1986).

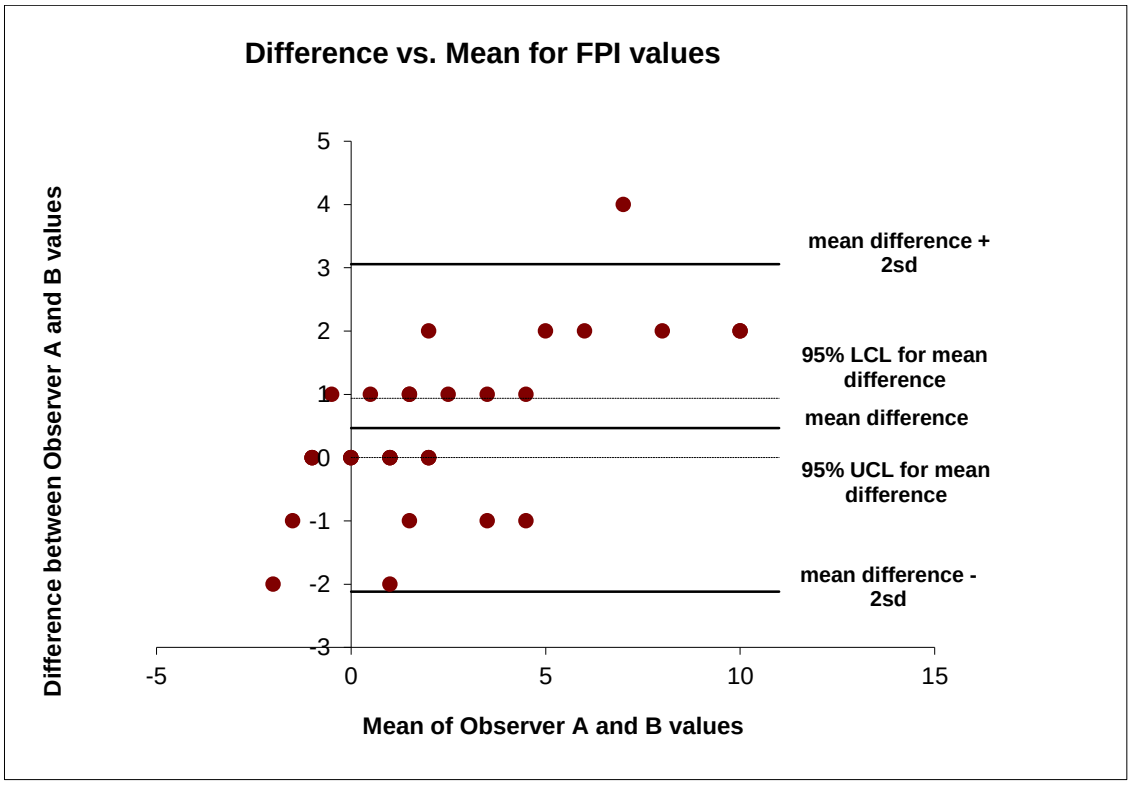

Figure 3. FPI Inter-rater reliability

Bland-Altman plot demonstrating inter-rater reliability between observer A (LG) and observer B (SRN) for FPI scores for left and right foot

The mean difference is 0.5 and limits of agreement are wide at 3.1 and -2.1. The 95% confidence interval for this estimation is 0.00-0.94 and the standard error of mean difference between scores of observer A and B is 0.23, across a score range of -3 to 11. A number of scores are close to, on or over the upper and lower limits of agreement. The differences in measurement vary in a somewhat systematic way, showing a degree of proportional error, with greater differences between lower and higher FPI scores. Due to a lack of agreement between observers only measurements made by the lead investigator (LG) were included within analysis.

3.5.2 Confounding and interactive effects

3.5.2.1 Confounding

It is possible that spurious relationships (statistically inferred relationship between two variables when in fact no relationship exists), may be demonstrated when investigating associations between total joint replacement outcomes and explanatory variables, as illustrated in figure 4. Consequently the identification of putative risk factors (most likely explanatory variables) and investigation of confounders (explanatory, equally associated variables) was completed as part of the statistical analysis process.

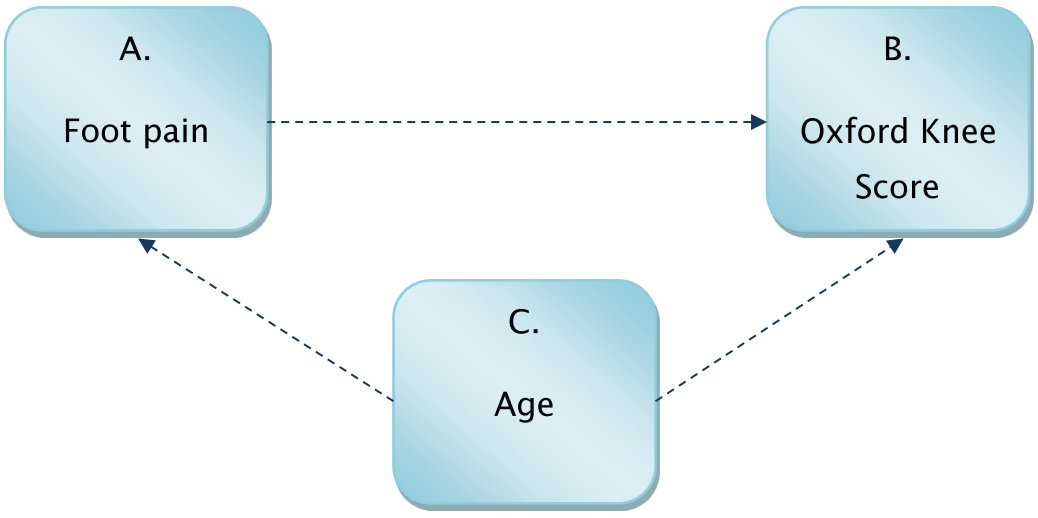

Figure 4. The identification of confounding variables

Where A = Exposure/risk factor of interest (e.g. foot pain), B = outcome of interest (e.g. OKS), C = possible confounding risk factor (e.g. age). Image authors own.

The determination of a confounding variable was made on the basis of a known statistical relationship or a biologically plausible relationship. The potential for biological plausibility of variables was decided with members of the clinical research team.

The exploration of literature suggests that a number of potential confounders needed to be considered within the analysis of foot and ankle assessment and knee outcome. The following variables will be discussed according to each statistical model within chapter 6:

- *Depression*
- *Pain in other joints*
- *Rheumatoid Arthritis (RA)*

Where evidence was not available to suggest the existence of associations between relevant variables and our exposure and/or outcome variables of interest, it was necessary to run potentially plausible variables within stepwise analysis to identify confounding relationships that may have influenced our findings in the final analysis. The following variables are discussed and tested according to each statistical model within chapter 6:

- *Pre-operative knee pain and function*
- *Pre-operative ankle dorsiflexion*
- *Foot pain and FPI*

3.5.2.2 Interaction

Interaction occurs when an association between two variables is modified due to the effect of a third variable (Marston, 2010). Potential interactions or effect modifiers must be considered as they may produce a greater or lesser effect than the sum of the effects of each factor acting on its own. For example foot pain is a possible risk factor for poor outcome following KA and consideration needs to be given if there is an interactive effect of another factor, for example depression, on this potential relationship. Effect modifiers are statistically tested within the relevant model in study three (chapter 6).

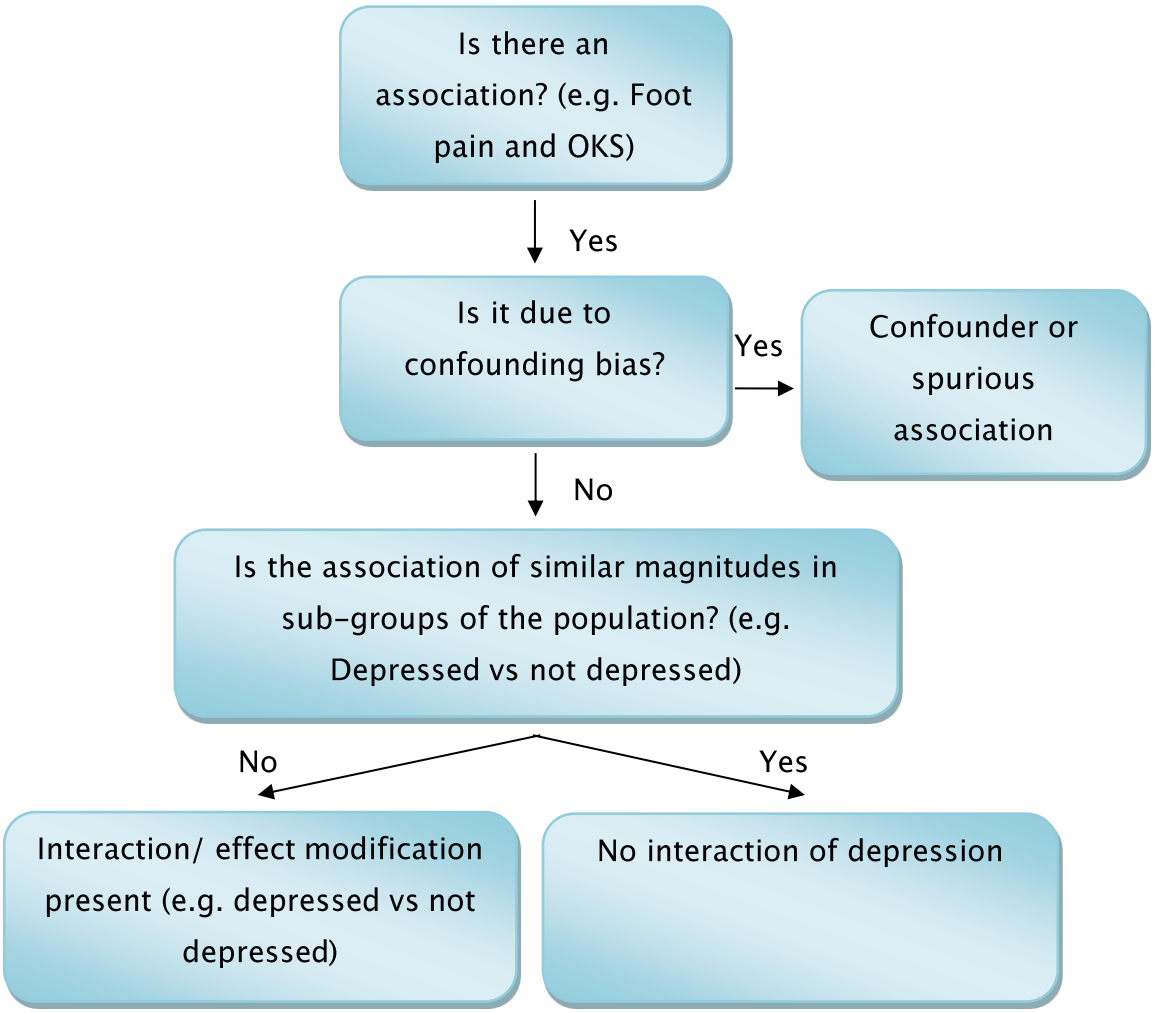

Figure 5. The conceptual framework for determining interactive effect.

In this example it is assumed that Depression is the effect modifier. Image (authors own) adapted from Campbell and Machin (1999).

Further detail on study design, ethical considerations, study specific considerations, study population and study outcome measures are discussed within the respective studies (Chapters four, five and six).

3.6 Overview of Statistical Methodologies

The following section provides an overview of the information processing techniques used for data entry, checking and analysis. All techniques were completed by the study investigator (LG) and reviewed by a senior statistician.

3.6.1 Data preparation and analysis software

For study three Microsoft Excel (Microsoft Corporation, 2010) was used for data entry. All variable data was entered relevant to each COASt participant number, including participant demographics, pre-operative HAD, pre and post-operative foot and knee pain, foot, ankle and knee physical assessment, post-operative knee pain and function patient reported outcomes. Data was then imported into the primary database, held at the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), in a staggered approach, using set inclusion criteria per data entry. All baseline and year one data was double entered by COASt data entry personnel located at NDORMS, where both North (Oxford) and South (Southampton) COASt data was centralised. Data was checked for errors, inconsistencies, outliers and missing information by assigned data inputting staff. Identified errors were checked against the original hard copy data sheets. Where information was confirmed as missing this was noted as such within the database, with reasoning where possible.

Prior to statistical analysis data distribution was checked for normality using histograms or scatter plots, the findings of which were used to inform statistical test selection.

3.6.2 Descriptive Statistics

<u>Study two</u>

Medians were used for clinical and research strength of recommendation scores and tertiles were calculated to categorise these scores: not recommended, recommended or highly recommended. Box & Whisker Plots illustrated median SORs and fences of each measure for clinical and research circumstances.

Study three

The demographical and clinical characteristics of the study participants are presented as the mean, standard deviation (SD) and frequencies, dependent upon data distribution.

3.6.3 Inferential Statistics

Statistical analysis was completed by the lead investigator (LG) using Stata (Version 13.0, Statacorp, College Station, Texas, USA).

Study three

Two methods were used to identify predictors of (i) statistically important outcomes using the one year OKS and (ii) clinically important outcomes using a patient acceptable symptom state cut off, anchored on satisfaction, for one year post-operative OKS.

Prior to regression analysis potential interactions were statistically tested. These had been decided a priori.

For the first outcome correlation coefficients were calculated to identify potential predictors of one year OKS, firstly by univariable models to examine the association between each predictor and the outcome. A multivariable linear regression model was then fitted including all predictor variables. Due to potential ceiling effects of the outcome, regression diagnostics were checked to ensure the assumptions underlying the linear regression model were met.

For outcome two, odds ratios were calculated using logistic regression modelling to identify predictors of the binary one year patient acceptable symptom state score. Regression diagnostics were checked to ensure the assumptions underlying the logistic regression model were met. Exploratory analysis was conducted to determine the need for stratification of the data. This was based on the potential influence that a particular dichotomised variable may have on the results, and were decided a priori; actual procedure undertaken (UKR or TKR) and presence of RA.

4 Chapter Four

A Review of Clinical Musculoskeletal Foot and Ankle Assessment Measures

4.1 Introduction

To ensure the use of valid and rigorously investigated foot and ankle assessment measures, a comprehensive literature review was undertaken to identify all current clinical measures used within foot and ankle assessments and to highlight the degree of validation and reliability for each measure.

The review synthesizes the results of primary investigations by using a comprehensive search of all potential relevant articles. A detailed systematic search strategy is outlined to obtain a comprehensive overview and summary of the available literature for the proposed area. Study findings are discussed and appraised and results are interpreted.

4.2 Aim of review

The literature review aimed to provide an overview of musculoskeletal foot and ankle assessments used within clinical practice. The review focused on particular musculoskeletal measures excluding those which involve the use of sophisticated equipment or PROMs, likewise assessments specific to disease or particular pathology were not included.

4.3 Background

Population representative meta-analysis has reported a 20% prevalence of foot and ankle pain in adults of middle and old age, with two-thirds reporting moderate or worse disability with daily activities (Thomas et al 2011). There is also increasing evidence to show that foot problems are highly prevalent in patients who have musculoskeletal disease (Katz et al 2006; Otter et al 2010; Otter et al 2012; Roddy et al 2013; Rome et al 2009; Rome et al 2012; Van Der Leeden et al 2010; Williams et al 2013) and despite advances in musculoskeletal disease management, a large proportion of patients remain significantly impaired by foot problems. The emergence of disease

led foot and ankle research brings with it the demand for high quality interventional studies to investigate optimal methods of managing foot and ankle pathologies. In the first instance a method for assessing the physical musculoskeletal status of the foot and ankle is required to provide a way of observing baseline characteristics and subsequent change.

At present there is no consensus on the ideal method for assessing the musculoskeletal status of the foot and ankle, this may be due to the number of domains that require assessment. Furthermore there is a requirement for future studies to adopt a consistent definition of foot pain and a standardised method of clinical assessment to explore the contribution of common foot disorders to the development of foot symptoms (Thomas et al 2011).

Clinical measures of the foot and ankle are an essential component of the assessment of foot function; facilitating treatment and providing a method for monitoring lower limb pathologies. Many individual physical techniques have been identified to measure characteristics of the foot, (Buell et al 1998; Cornwall and McPoil 2004; Cornwall et al 2004; Hegedus et al 2010; Hunt et al 2000; Kim et al 2008; McPoil et al 2008; Nawoczenski et al 1999; Redmond et al 2006; Williams and McClay 2000), however it is unclear if a valid comprehensive clinical assessment protocol currently exists. Findings from a review of foot type classification methods have shown that despite the fact clinicians regularly perform static lower extremity measurements on their patients; little research has been published to support their predictive ability to functional measures and injury (Razeghi & Batt 2002). Whilst the review provided good insightful discussion into the concerns of using many static lower limb examinations to assess function and injury, it did not discuss the relationship of these measurements to pain. Also, additional assessments have since been introduced and it is unclear whether these assessment techniques are associated with clinical outcomes.

The purpose of this review was to examine the literature and provide a summary of what is known about clinical foot and ankle assessment measures and to identify if a comprehensive protocol exists. To effectively evaluate clinical assessments it is necessary to determine if they are associated with clinical outcomes. This review summarises evidence which investigates the association of foot and ankle assessments to outcomes such as pain, function and other measures which are deemed to be more superior. Where evidence is available for cross sectional criterion validity and longitudinal predictive validity against pain and function, these have been discussed.

Clinical decision making is often formed on the basis of chair side assessment measures and whilst it is essential to explore the methods used to establish validity it is also important for clinicians to know the degree of measurement error for these measures and to know what the clinically important differences are. The reliability of assessments is also an important consideration when identifying appropriate use of measures within an assessment protocol.

Within the evidence identified intra-class correlation coefficient (ICC) and kappa agreement (K) have been the standard forms of reported reliability analysis. Where reliability is discussed arbitrary bench marks for Intra-class correlation coefficient (ICC) and Kappa (K), provided by (Landis & Koch 1977), shall be referred to for consistency (see tables 3 and 4). There are limitations to the use of benchmarks due to the variation in thresholds seen across different types of studies. Values from 0.40 to 0.75 have been described as “fair to good” (Fleiss, 1986). Whereas Streiner and Norman (2003) recommend values > 0.75 for continuous scales used in health research. DeMast (2007) has described these criterial levels as “hopelessly arbitrary. Ultimately, irrespective of the choice of threshold, the recommendation is that confidence intervals accompany reliability coefficients as measures of precision (Van Ness et al 2008). Sample size formulae have been provided for the kappa and intraclass correlation coefficients, to ensure reliability studies can be correctly powered (Walter, Eliasziw, & Donner, 1998).

Where available the standard error of measurement (SEm) is discussed. In the current context the SEm- the standard deviation of errors of measurement- estimates how repeated measures of a person using the same instrument tend to be distributed around the true score (Harvill et al 1991). The true score represents an average score if the test was repeated infinitely. It is related to the reliability of a test; the larger the SEm, the less precision there is in the measures taken and scores obtained. Where confidence intervals are included this informs the reader of the probability that the examinee’s true score lies within a given range of scores.

Table 3. Arbitrary bench marks for Intra-class correlation coefficients (Landis & Koch 1977)

ICC Values:	Representative benchmark:
< 0.20	Poor
0.21-0.40	Fair
0.41-0.60	Moderate
0.61-0.80	Substantial
0.81 to 1.00	almost perfect

Table 4. Arbitrary bench marks for Kappa values (Landis & Koch 1977)

Kappa Agreement:	Representative benchmark:
< 0	Less than chance agreement
0.01– 0.20	Slight agreement
0.21–0.40	Fair agreement
0.41-0.60	Moderate agreement
0.61-0.80	Substantial agreement
0.81-0.99	Almost perfect agreement

Although this review aimed to identify only musculoskeletal assessments that avoid the use of sophisticated equipment, where evidence uses such equipment for validation purposes these articles have been included and will be discussed within the review.

4.4 Methods

4.4.1 Search Strategies and outcomes

CINAHL and MEDLINE electronic databases were searched with limitations applied to the searches in terms of language (English), age of paper (published between January 1980 – December 2012) and human participants. The main concepts of the search, search terms and synonyms were determined by members of a foot and ankle expert steering group-established for the international consensus study (chapter 5) -so as to reduce bias potentially introduced with only one person. Keywords were refined using Boolean operators and truncation, to reduce the specificity of search terms and ensure a broad initial search of the literature. Alternative spellings for terms were considered (see appendix 1 for search terms and truncations).

All accepted full text articles were then hand searched for further relevant articles. The reference lists from the hand search were also screened. This hand screening process continued until all potential articles were exhausted.

Previous research (Bennell et al 2007; Razeghi & Batt 2002) has highlighted problems regarding the lack of National Health Medical Research Council level I – III-1 trials (systematic randomisation to pseudorandomisation) (NHMRC 2009) in fields similar to this which is also problematic in this area. Therefore no restrictions were placed on the type of study included. The review aimed to highlight all current clinical musculoskeletal foot and ankle assessments; therefore only clinical assessment measures were included within the search.

4.4.2 Inclusion Criteria

4.4.2.1 Inclusions

- musculoskeletal (foot and ankle) assessment methods/measures
- studies which use dynamic measures (including gait analysis and foot pressure systems), PROMs or devices to assess the validity of a clinical foot and ankle assessment, so long as the focus of the article is based upon the clinical assessment.
- Articles that are evaluating a foot and ankle assessment, not just those papers which propose one.
- Reliability studies of particular clinical musculoskeletal foot and ankle assessment
- Participants of any age
- English language

4.4.2.2 Exclusions

- PROMs/self-reported assessments
- Gait analysis
- Foot pressure systems and pedography
- Mechanical measures with instrumentation as primary clinical measure
- Radiographic measures
- Assessments specific to a pathology or disease or surgery
- Non-MSK assessment (including vascular and neurological assessment)

4.5 Critical appraisal of Literature

Due to an exceptionally low number of interventional studies and a majority of observational evidence, a critical appraisal tool based on adaption of Critical Appraisal Skills Programme (CASP) tool was used to appraise the literature (Weightman et al. 2004) (appendix 2). This provided the appropriate quality checklist according to the level of evidence, including:

I Systematic review (including at least one RCT)

II Randomized controlled trial

III Other experimental study

IV Observational study or economic analysis

V Expert opinion

Each article was critically appraised according to which level of evidence it attempted to fulfil. This review aimed to highlight all clinical musculoskeletal foot and ankle assessments; therefore no articles were excluded based on the findings of critical appraisal. Although appraisal of articles revealed some were not worthy of their intended level of evidence due to a lack of robustness or questionable methodology, these were still included within the review and discussed accordingly.

4.6 Data extraction, synthesis and analysis

The following data were extracted from the full text articles: study design, sample size and characteristics (age, gender, pathology if appropriate), number of examiners, profession and experience of examiners, method of examination, blinding, outcomes measured, results, conclusion. Data extraction was carried out by two reviewers (LG and LM), with meetings to gain consensus on any disagreements.

Due to large quantity of type IV evidence narrative synthesis was conducted on all retrieved articles.

4.7 Results

An initial search identified 2374 potential articles. Following the removal of articles based on title; those not specific to foot and ankle or assessment measures, abstract and full text content, 15 articles were retrieved. 34 additional articles were identified from hand searching of references. 49 articles were selected for inclusion in the review (figure 6).

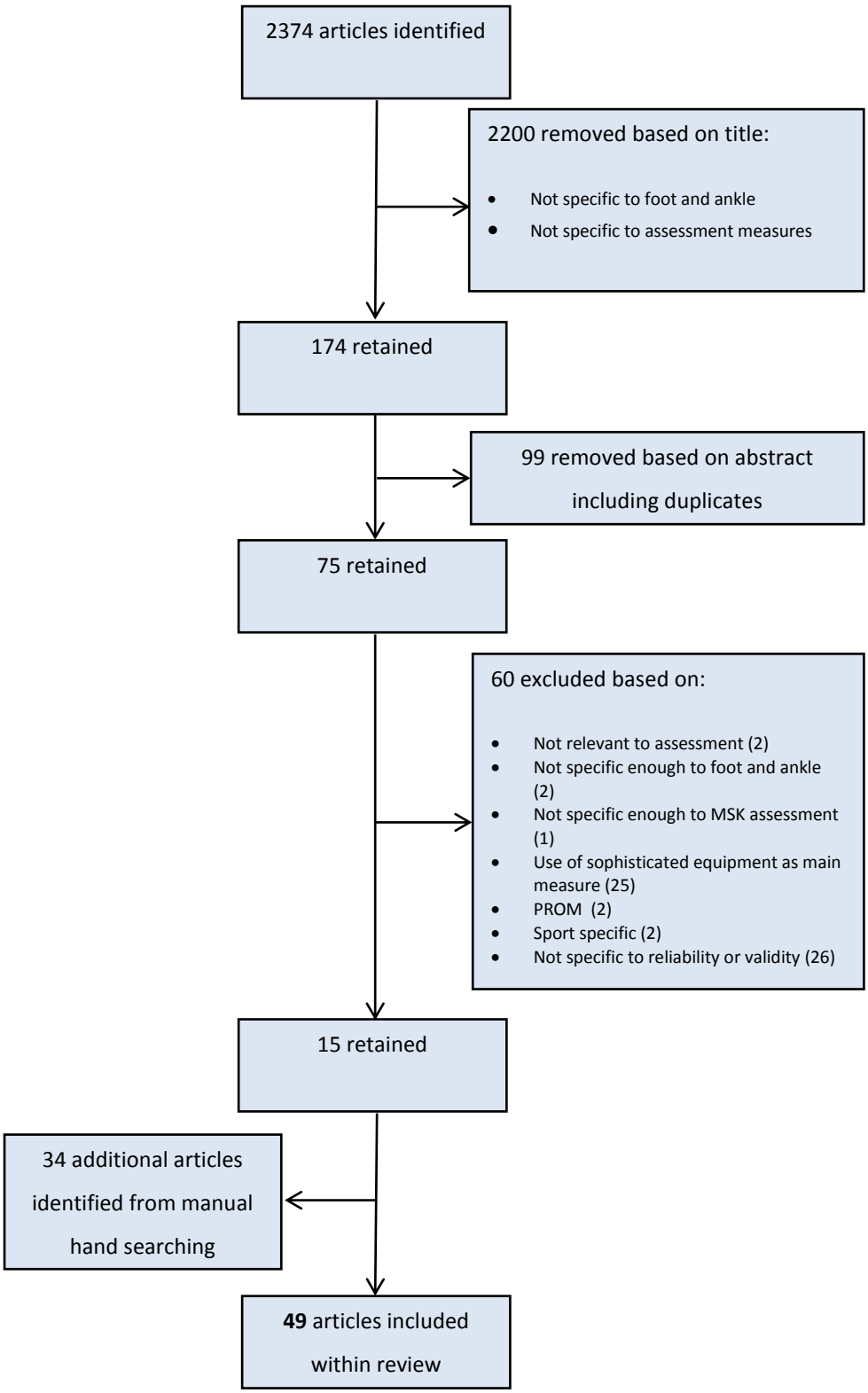

Figure 6. Process of Article Exclusion

4.7.1 Types of Evidence

From the 83 articles retrieved for the final review, a high number of these were representative of observational evidence; cross sectional (64) and case controls (8), with a limited number representative of opinions/reports (4) and reviews (4) and a minority as intervention without randomisation (3). There were none representative of type I (Systematic review, including at least one RCT) or type II (Randomized controlled trial).This diversity is displayed in figure 7.

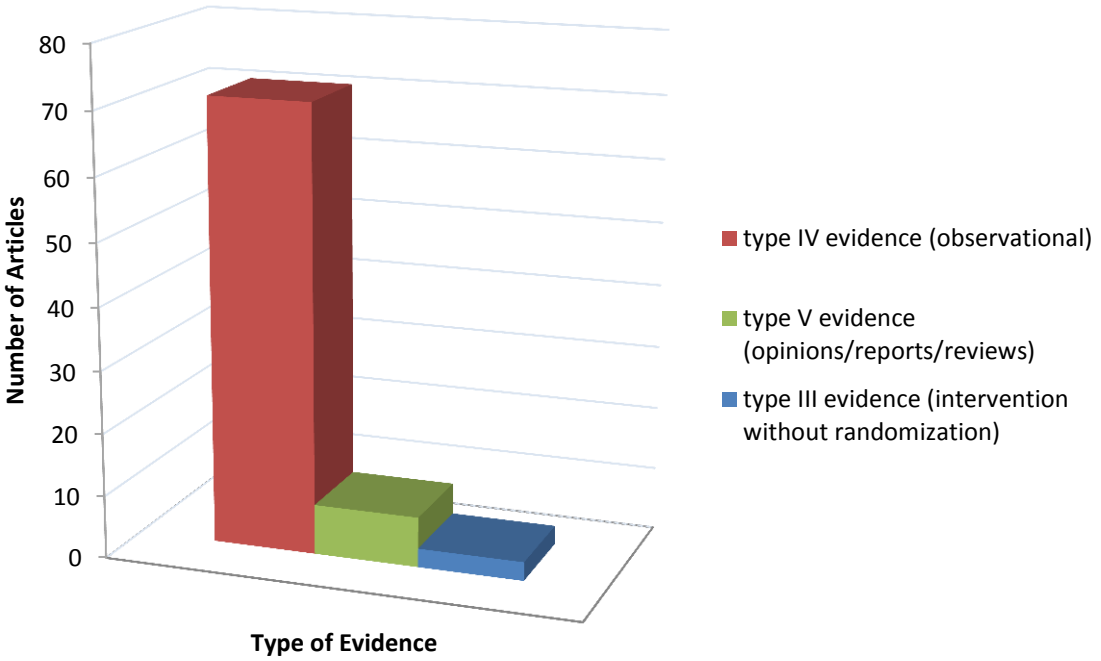

Figure 7. Type of evidence included within systematic literature review

4.8 Assessment Categories

From the review ten individual categories of foot and ankle assessment categories were identified; these can be seen in table 5.

Table 5. Categories of foot and ankle measures identified from the literature

Foot and ankle assessment measures:	
1)	Arch Measures
2)	Navicular Measures
3)	Forefoot Measures
4)	Rearfoot Measures
5)	Subtalar Joint (Neutral) Measures
6)	Goniometry
7)	Manual Supination
8)	1st MTPJ
9)	1st Ray motion
10)	Ankle Joint Dorsiflexion

Of these only five provided evidence of investigation against outcomes of pain or function (arch measures, navicular measures, ankle dorsiflexion, foot posture index and first metatarsal phalangeal joint measures (table 6). A limited number of measures reported an association with particular functional tests, these include navicular height, ankle flexibility, first metatarsal phalangeal joint range of movement, FPI (Menz and Munteanu, 2005; McPoil and Cornwall, 2005; Redmond et al 2006), however only FPI has a reported association with pain. The review did not identify evidence to support the existence of a comprehensive clinical musculoskeletal foot and ankle assessment protocol. Therefore evidence for the reliability and validity is discussed according to each individual measure. Where evidence is available for cross sectional criterion validity and longitudinal predictive validity against clinical outcomes of pain and function these have been reported and summarised in table 6.

Table 6. Summary table of evidence for cross sectional and longitudinal validity

Measure	Cross sectional Validity (against pain and function)	longitudinal (predictive) validity
Arch measures	None shown (Mcpoil & Cornwall 2005; Menz & Munteanu 2005)	No evidence identified
Navicular measures	Maximum balance range (r = 0.154, P<0.05) Alternate step test (r = 0.194, *P* < 0.01) Sit to stand test (r = 0.156, *P* < 0.05) Walking speed (r = 0.183, *P* < 0.05) (Mcpoil & Cornwall 2005; Menz & Munteanu 2005; Menz et al 2005)	No evidence identified
Ankle dorsiflexion	Sway (r = 0.226 and 0.301, *P* < 0.01) Maximum balance range (r = 0.513, *P* < 0.01) Co-ordinated stability (r = 0.540, *P* < 0.01) Alternate step test (r = 0.545, *P* < 0.01) Sit-to-stand (r = 0.511, *P* < 0.01) Walking speed (r = 0.550, *P* < 0.01) (Menz & Munteanu 2005; Menz et al 2005)	No evidence identified
First metatarsal phalangeal joint measurements	Yes Sway (r = 0.160, *P* < 0.05) Maximum balance range (r = 0.219, *P* < 0.01) Walking speed (r = 0.176, *P* < 0.05) (Menz & Munteanu 2005; Menz et al 2005)	No evidence identified

Foot Posture Index	Valgus Index (R2=0.59, P < 0.001) Rear foot position (R2=0.64, p < 0.001) (Redmond et al 2006) Medial knee osteoarthritis (P<0.02) (Levinger et al 2010) Some parameters of dynamic foot function in individuals with patella femoral pain; greater peak forefoot abduction (r = 0.502, p = 0.013) and earlier peak rearfoot eversion (r = -0.440, p = 0.031) (Barton et al 2011)	Variation in walking ankle joint complex function (R2=0.41, P < 0.001) [10]. Risk of foot and ankle overuse injuries in footballers (p = 0.008) (Cain et al 2007)
Rearfoot measures	No evidence identified	No evidence identified
First ray measures	No evidence identified	No evidence identified
Subtalar joint measures	No evidence identified	No evidence identified
Forefoot measures	No evidence identified	No evidence identified
Manual supination test	No evidence identified	No evidence identified

4.8.1 Arch measures

The clinical measures of arch height that have received the most attention to date are the arch ratio (AR) (Williams & McClay 2000), the longitudinal arch angle (LAA) (Dahle et al 1991), the modified arch ratio (MAR) (Hegedus et al 2010). The results showed that reliability and validity of these measures was generally reported as high, although methods between studies varied greatly.

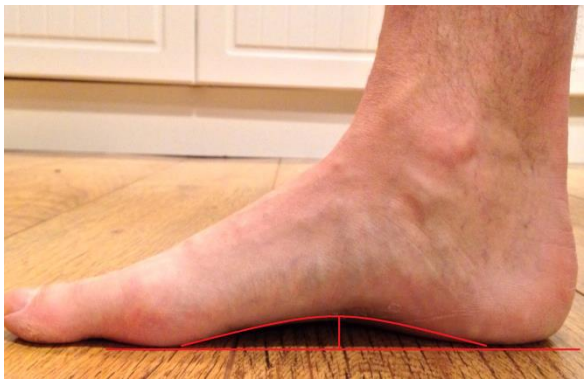

Figure 8. Arch height observation (image authors own)

Reliability

Substantial to almost perfect inter-rater agreement has been reported for the LAA, with ICCs of 0.67 and an SEm of 1.3 for both raters, which is less than 1% of the mean (McPoil and Cornwall 2005). Johnson & Gross (1997) report an ICC of 0.81, however no SEm of confidence intervals are provided. Intra-rater reliability of LAA remained almost perfect between three studies with ICCs (and 95% CIs where reported) of 0.98 (0.91, 0.099) (Hegedus et al 2010), 0.95 and 0.96 (McPoil and Cornwall 2005) and 0.90 (Johnson & Gross 1997).

High inter-rater reliability has also been reported for the AR with ICCs of ≥0.81 (Williams & McClay 2000), 0.98, SEm 0.04 (McPoil et al 2008) and ≥0.93 (Williams and McClay 2000). Whilst there is no evidence for the inter-rater agreement of the MAR, high intra-rater ICCs (0.96, 95% CI 0.85, 0.99) have been reported (Hegedus et al 2010).

Findings suggest good reliability of the arch measures, however examiners and their experience varied between the studies; Williams & McClay (2000) utilised 2 examiners with varied experience of three and twenty years, likewise McPoils' (2008) three physical therapy examiners had between two and thirty years' experience. McPoil and Cornwall (2005) used two experienced

examiners; therefore reports of high reliability are representative only in those experienced to that which constituted them as such. Hegedus et al (2010) only included one examiner, therefore limiting the extent of reliability to only one person's ability to repeat the measure.

Poor agreement between examiners has been found for measures of arch height from the ground to the top of the arch. Weiner-Ogilvie et al (1998) reported mean differences between observers of between 37-61%, whilst Cowan et al (1994) reported Kendalls tau coefficients of 0.35. The latter included four orthopaedic surgeons and two podiatrists, although level experience of these clinicians was not reported.

Validity

Significant discrepancy has been reported between the clinician observed foot morphology and the radiographic appearance. Noting that several feet that appeared clinically flat, were actually classified as high arched from lateral radiographs (Benink 1985). High validity has been reported in a pilot sample (n=10) for both LAA (r=0.885) and mAR (r=0.827) when compared to lateral weight bearing x-rays with equal weight distribution. Unfortunately no confidence intervals were provided to infer these results, which would be essential considering the small sample (Hegedus et al 2010).

Findings from these studies indicate that use of the longitudinal arch angle, dorsal arch height and truncated foot length as clinical measures are reliable however the representations of these clinical measures to osseous arch height cannot be concluded.

Conversely, reports were mixed regarding arch height as a measure of foot function. No associations were found between maximum eversion movement and arch height (r=0.059) during running (Nigg et al 1993). However static LAA at 50% weight bearing reportedly explained more than 90% of the variance associated with the LAA around midstance of walking (r=0.97) (McPoil and Cornwall 2005).

Differences in conditions, specific measures of arch height, artefacts due to displacement of markers during kinematic measurements and sample size between these studies do make firm direct comparisons difficult. The lack of measure of error within agreements further compounded interpretation of findings. Studies have utilised a variety of populations including pathological (Hegedus et al 2010), orthopaedic (Saltzman et al. 1995), older (Menz and Munteanu 2005) and

healthy (Williams and McClay 2000; McPoil et al 2008) and a range of examiners form orthopaedic surgeons to physical therapists with varying experience.

Despite findings for the radiographic validity of clinical measures of arch height a study, limited to the older population, has shown no significant association (P > 0.05) between the arch index and disabling foot pain (Menz and Morris 2005), balance and function (Menz et al 2005) or falls (Menz et al 2006).

4.8.2 Navicular measures

Navicular height has been represented as both a single and component measure of arch height and position of the subtalar joint. Navicular drop was introduced to gain a more dynamic representation of foot measures from static assessment (Brody 1983).

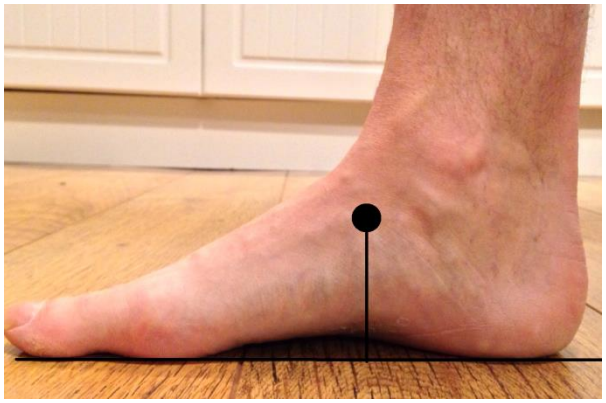

Figure 9. Navicular height assessment (Image authors own)

Reliability

Navicular Height

Substantial to high intra-rater reliability of measuring navicular height has been reported with ICCs from 0.64 (95% CI 0.38–0.81) (Menz et al 2003a), to 0.90 (95% CI 0.82-0.95) (Saltzman et al 1995) and ≥0.92 (Williams and McClay 2000) in examiners of varying experience, however confidence intervals are relatively wide.

High inter-rater ICCs for navicular height have been reported in adolescents (0.72 95% CI 0.58–0.76) (Evans et al 2003) and adults (0.76 95% CI 0.71–0.84 and 0.74 95% CI 0.55, 0.87) (Evans et al 2003 and Saltzman et al 1995, respectively). Only moderate inter-rater reliability has been reported when measuring navicular height on children (ICC= 0.52 95% CI 0.46–0.69) (Evans et al 2003). Williams and McClay (2000) report varying inter-rater ICCs for navicular height measured at varying percentages of weight bearing; 10% weight bearing ICC = 0.924, 90% weight bearing ICC= 0.608, navicular height divided by foot length at 10% WB ICC = 0.872 and navicular height divided by foot length at 90% ICC = 0.706. Unfortunately no confidence intervals or SEms were provided. As well as test subject population variations, studies utilised a variety of clinicians (physical therapists, foot health clinicians) of differing experience, or failed to report either.

Navicular Displacement

Intra-rater ICCs have ranged from almost perfect (ICC=0.83, SEms 1.5-1.9mm) in experienced examiners (Sell et al 1994), to moderate-substantial (ICC= 0.61, SEm=2.6mm and ICC=0.79, SEM=1.9mm), with higher SEms, in less experienced examiners (Picciano et al 1993).

Moderate inter-rater reliability (ICC = 0.57) with high SEms (2.7mm) have been reported for measures of navicular drop taken by less experienced examiners (Picciano et al 1993) and substantial reliability (ICC = 0.73) with lower, yet still substantial SEms (1.4-2.3mm) reported in more experienced examiners (Sell et al 1994). Moderate-substantial inter-rater reliability was also reported for navicular drop between podiatric examiners with a minimum of 3 years' experience (ICC= 0.72, SEm 1.27 and ICC= 0.73, SEm 1.17), with even lower inter-rater ICC values for measures of navicular drift (ICC=0.50, SEm ICC=0.57, SEm) (Vinicombe et al 2001).

<u>Validity</u>

Navicular Height

Clinical measurements of navicular height (normal and truncated) have been shown to be strongly associated with navicular height measures obtained from radiographs ($r=0.777$ and 0.753, $P<0.01$, respectively) (Menz & Munteanu 2005).

Interestingly Menz et al (2003) found a significant association between navicular height and foot length ($r=0.57$, $p<0.01$), suggesting therefore navicular height would need to be adjusted for foot size if comparisons are to be made between subjects.

Clinical measurements of navicular height have shown to be associated with particular tests of balance and function, including maximum balance range ($P<0.05$), alternate step test ($P < 0.01$), sit to stand test and walking speed ($P < 0.05$) (Menz et al 2005). Results are limited to the older population and comprehensive inference is restricted by an absence of confidence intervals, which prevents further information of the likely range of possible values for the true effect. No significant association was found between navicular height and foot pain ($P > 0.05$) (Menz and Morris 2005) or falls ($P > 0.05$) (Menz et al 2006).

Navicular Displacement

Measurements taken from the displacement of the navicular, such as navicular drop and drift, which indicate the effect of altered foot position on the talonavicular joint, suggest only moderate reliability, with often large measurement error (Vinicombe et al 2001). Measures of navicular height in adults as an independent component show more promising reliability both within and between examiners (Menz et al 2003; Saltzman et al 1995; Williams & McClay 2000).

It is possible that the contributing factors to the moderate to poor levels of inter-rater reliability for measures of navicular drop and drift may be the difficulty in consistently placing the foot in subtalar joint neutral position. This latter technique is criticised as being difficult to repeat and lacking in validity (Smith-Oricchio & Harris 1990; Menz 1995; Pierrynowski et al 1996).

4.8.3 Forefoot measures

Measurement of the forefoot predominantly revolves around the measure of two frontal plane positions; forefoot varus and forefoot valgus. Firstly, investigation into the prevalence of either position within the normal population has revealed contrasting results; figures as high as 44.8% (McPoil et al 1988) and as low as 8% and 8.75% (Buchanan and Davis 2005; Garbalosa et al 1994) have been reported for forefoot valgus. Conversely forefoot varus has been reported in as many as 83.67% and 92% of Garbalosa et al 1994 and Buchanan and Davis 2005) and as little as 8.6% (McPoil et al 1988) of the normal population. A potential reason for such disparity is the wide variation in the method of measurement.

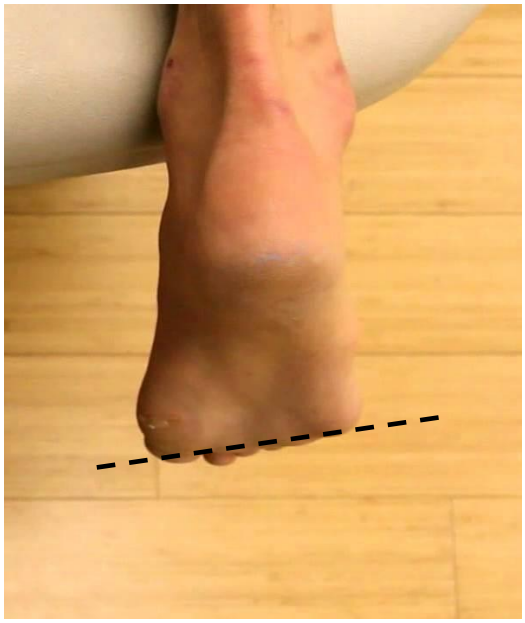

Figure 10. Forefoot observation

Reliability

Substantial intra-rater reliability for the goniometric measure of forefoot alignment has been reported in non-experienced examiners (ICC=0.65) (Somers et al 1997). Reports are varied within more experienced examiners, with intra-rater ICCs of 0.81 (Somers et al 1997) and 0.82-0.92 (Astrom & Arvidson 1995). Moderate to substantial inter-rater reliability has been reported between clinicians with varying experience, with ICCs of 0.45 and SEms of 3.4 ^{o} (Van Gheluwe et al 2002) and ICCs of 0.68 (Astrom & Arvidson 1995).

The review identified evidence with highly varied results for the reliability of forefoot measurement when taken using a goniometer, particularly with stark differences measurement techniques and examiner experience between studies. There was no evidence of investigation for the association of forefoot measures to pain or function.

4.8.4 Rear Foot Measures

Clinical methods for measuring rearfoot position may involve measures of the static weight bearing or non-weight bearing calcaneal positions, often with a goniometer. Normal values are limited to research in females, where 83.6% standing rearfoot varus has been reported in healthy participants (McPoil et al 1988). Two weight bearing methods for determining rear foot position,

often reported as direct measures of the sub-talar joint, are the resting calcaneal stance position (RCSP) and the neutral calcaneal stance position (NCSP).

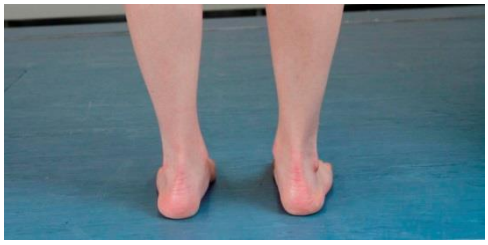

Figure 11. Rear foot measurement (image authors own)

Reliability

Non weight bearing

Fair to moderate inter-rater reliability of non-weight bearing calcaneal inversion (ICC=0.42) and eversion (ICC= 0.25) were reported, via measures of posterior calcaneus and lower leg bisection (Smith-Oricchio & Harris 1990). No confidence intervals or SEms were reported to support findings.

Weight bearing

Almost perfect intra-rater reliability (ICC=0.950) was reported for the measure of rearfoot angle in relaxed standing, when measured in relation to the lower leg (Cornwall & McPoil 2004). Likewise substantial-almost perfect intra-rater reliability (ICCs=0.61-0.90) has been reported when measuring resting stance calcaneal angle in relation to the ground (Sobel et al 1999).

Substantial to almost perfect inter-rater reliability has been reported for weight bearing measures of rear foot angle in resting stance, measured from calcaneus-lower leg, with ICCs of 0.86 (Johnson & Gross 1997) 0.91 (Smith-Oricchio & Harris 1990). Once again a lack of confidence intervals or SEms fails to support study generalisability.

Validity

Clinical rear foot valgus, as measured with a goniometer has been reported to correlate with radiographic measures of lateral talometatarsal angle (r=0.356, p=0.026), lateral talocalcaneal angle (r=0.336, p=0.036), and first metatarsal-cuneiform height (r=-0.439, p= 0.005) (Coughlin &

Kaz 2009). Unfortunately there was no reported investigation of an association to radiographic frontal plane rear foot alignment.

Weak correlations have been reported between static calcaneal deviation and the range of inversion-eversion during the stance phase of walking ($r = 0.03$, $p = 0.90$) (Hunt et al 2000) and no significant differences in rearfoot motion were reported between groups where participants were classified with inverted and everted rear feet ($P>0.05$) (Cornwall & McPoil 2004).

Findings report higher reliability of weight bearing calcaneal measurements than non-weight bearing (Smith-Oricchio & Harris 1990; Johnson & Gross 1997; Sobel et al 1999; Cornwall & McPoil 2004). The potential for static rearfoot measures to represent dynamic motion has not been confirmed (Hunt et al 2000; Cornwall & McPoil 2004). The review identified no evidence for the investigation of rear foot measures association to pain.

4.8.5 Subtalar Joint Measures

The two most frequently defined methods of determining subtalar joint neutral (STJN) are that based on a 2:1 ratio of supination to pronation (Root et al 1971) and that where the head and body of the talus is palpated for greatest congruity between it and the navicular and calcaneus (Wernick & Langer 1971). Both positions have been reported as significantly different from one another, suggesting therefore that the two methods cannot be inferred as the same determinant measure (Ogilvie et al 1997). Subtalar Joint range of motion is mostly represented by measures of the rear foot (see section 4.8.5 for reliability and validity of this measurement technique). Apart from difficulties is ensuring isolation of the STJ when measuring passive range of motion, measurements are largely based on STJN being a reference for zero; a method for measuring such has yet to be proven accurate or reliable between testers (Chen et al 2008; Elveru et al 1988a and Picciano et al 1993).

<u>Reliability</u>

Poor and substantial inter-rater reliability has been reported for both NWB measures of STJN via talar head palpation (ICC=0.25 and 0.60) (Elveru et al 1988a; Elveru et al 1988b; Smith-Orrichio & Harris. 1990, respectively) and WB measures of STJN (ICC= 0.15, SEm= 2.43^{o} and ICC=0.68, SEm=1.8^{o}) (Picciano et al 1993 and Sell et al 1994).

Experienced foot care clinicians and novice students placed the rearfoot within 2 degrees of subtalar joint neutral (represented as of zero inversion/eversion) only 72.3% and 47.6% of the time, respectively. Corresponding values within 1 degree of STJN were even lower at 41.3% and 25.0% (Pierrynowski et al 1996).

Validity

On the basis that the neutral position of a joint is where the articulating surfaces are completely congruent, cadaveric maximum talonavicular and calcaneocuboid congruency has been reported to occur at the midpoint of the joint range of motion, subsequently diminishing and at extremes of range of motion (Inman 1976). Chen et al (2008) reported cadaveric measures of 10 ^{o} abduction, 20^{o} dorsiflexion and 10^{o} eversion to represent this position. The review failed to identify any evidence of investigation for the association of subtalar joint assessment to pain or function.

It is difficult to compare findings of reliability and validity for the measure of STJ, which is represented by a variety of morphological characteristics, including talus palpation, calcaneal alignment and navicular measures; none of which have been confirmed as a valid clinical representation of the anatomical subtalar joint position. Validity of determining STJ position via talar head palpation is also questionable as palpation is of the superior aspect of talus, not at the talocalcaneal articulation (STJ) (Garbalosa et al 1994).

4.8.6 Goniometry

Goniometry provides a method for providing quantitative joint angles. Questions have repeatedly arisen over the reliability of goniometric measures, both between and within examiners at all joints, in particular regarding measures about the lower limb. Details of goniometric measures of particular foot and ankle joints are also discussed within their separate categories within the review.

STJ

The ability to effectively measure both STJ ROM and neutral positioning has received attention as described 4.8.5. The inherent difficulty lies in the validity of such measures, with much

investigation based upon the historical hypothesis that the subtalar joint can be directly represented from frontal plane measures of the calcaneus.

As previously highlighted, the use of goniometry as a clinical measure of the subtalar joint is highly questionable due to varied inter-rater reliability. One particular finding of high clinical concern was the poor reliability reported (ICC=0.35) for therapists agreement on the general position of the rearfoot when in STJN; where 15 out of 50 paired therapists did not agree whether the rearfoot was in varus, valgus or zero (Elveru et al 1988b).

Ankle

Reductions from intra-rater (ICC=0.78-0.96) to inter-rater (ICC=0.28) reliability have been reported in active ankle range of motion measures with a universal goniometer (Youdas et al 1993). A large variation in intra-rater reliability (ICCs=0.284-0.902) has been reported for a selection of measures which used different landmarks and ways of assisting measurement (Bohannon et al 1989). The use of different foot and ankle landmarks can provide varying results and should therefore be standardised for reliability.

Forefoot & Rearfoot

High intra-rater reliability of forefoot measures via goniometer has been reported in both experienced examiners (ICCs=0.81-0.92) (Astrom & Arvidson. 1995 and Somers et al 1997) and non-experienced examiners (ICC=0.66-0.78) (Somers et al. 1997). Reliability of forefoot goniometric measures between examiners was however somewhat more varied with ICCs between 0.45, with high SEm of 3.4 ^{o} (Van Gheluwe et al 2002) and 0.68 (Astrom & Arvidson. 1995).

Only fair to moderate inter-rater reliability of non-weight bearing calcaneal measures with goniometer has been reported (ICC=0.25-0.42) (Smith-Oricchio & Harris 1990). Whereas for weight bearing goniometric measures of rear foot position, high intra-rater reliability (ICC=0.61-0.95) (Sobel et al 1999; Cornwall & McPoil 2004; Haight et al 2005) has been reported. Inter-rater reliability was however more varied with ICCs ranging from 0.50-0.91 (Smith-Oricchio & Harris 1990; Johnson & Gross 1997; Haight et al 2005).

First MTPJ & First Ray

High intra-rater reliability has been reported for static methods of assessing 1st MTPJ extension ROM with a goniometer (ICCs= 0.76-0.98) (Hopson et al 1995). However poor inter-rater reliability has been reported for the measurement of first ray dorsiflexion and plantarflexion with a goniometer, with ICCs ranging from 0.14 to 0.21 and reasonable high SEMs of 1.5-3.2 (Van Gheluwe et al 2002). A lack of detail in measurement methods makes comparison of similar studies difficult.

Goniometric measurement at the foot and ankle can be adequately reliable if repeated by the same examiner, however the clinical usefulness of such measures are questionable with, at best, only moderate reliability between examiners (Elveru et al 1988a, Haight et al 2005, Somers et al 1997, Van Gheluwe et al 2002 and Youdas et al 1993). Validity of goniometric foot and ankle measures cannot be established from the evidence included within this review.

4.8.7 Manual supination resistance test

Abnormal pronation about the subtalar joint has traditionally been considered to place the foot at increased risk for tissue damage (Noakes & Payne 2003). (Kirby & Green 1992) described a manual resistance test used to estimate the force needed to supinate the foot about the subtalar joint, which in turn may inform the force required from an orthotic device for interventional purposes. This review identified only one investigation for this test. However this is not an indication of the extent to which the test is used within the clinical setting.

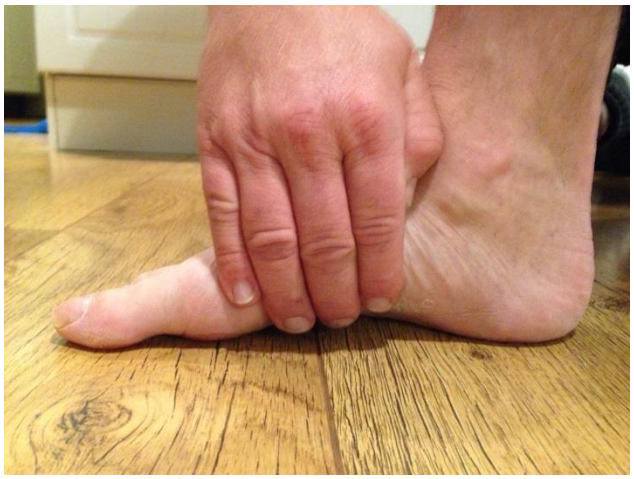

Figure 12. Manual supination test (image authors own)

Reliability

Higher intra-rater reliability was reported in experienced clinicians (0.82 [95% CI 0.72, 0.88] and 0.78 [95% CI 0.69, 0.86]) than in in-experienced clinicians (0.56 [95% CI, 0.32–0.71] and 0.62 [95% CI, 0.41–0.75]). Substantial inter-rater reliability was reported 0.89 (95% CI 0.85, 0.92) (Noakes & Payne, 2003).

Validity

The clinical manual supination test was poorly correlated to the value obtained from a mechanical supination device (r=0.57) (Noakes & Payne 2003). The ability of the mechanical device to accurately measure the required force is however unclear and there is no apparent evidence available to show its tested validity. The review identified no evidence to investigate the association of the clinical manual supination test to pain or function.

4.8.8 First Metatarsal Phalangeal Joint Measurements

Adequate function of the first metatarsal phalangeal joint (MTPJ), particularly dorsiflexion, has been stipulated as a necessity for normal functioning of the foot and continuing proximal lower limb. First MTPJ ROM can be measured in non-weight bearing or weight bearing via visual or goniometric measurement.

Figure 13. Passive first MTPJ measurement (image authors own)

Reliability

High intra-rater ICCs of 0.91-0.95 (Hopson et al 1995) and 0.99 (SEm= 1.77^{o}) (Nawoczenski et al 1999) have been reported for non-weight bearing first MTPJ ROM. Similarly high intra-rater ICCs of 0.95-0.98 (Hopson et al 1995) and 0.97-0.99 (SEms of 1.46-2.30^{o}) have been reported for weight bearing active and passive measures of first MTPJ ROM. Unfortunately inter-rater reliability was not reported.

Validity

Fair to good associations have been shown between clinical and radiographic measurements of non-weight bearing first MTPJ ROM (Buell et al 1988). However clinical and radiographic information was not measured simultaneously and correlation coefficient values were not provided, therefore the quantitative degree of association is unclear.

Strong correlations have been reported between first MTPJ motion during gait and active weight bearing first MTPJ measures including active heel raise (r=0.87) and the active range of motion with participants weight bearing (r=0.80, p<0.001) (Nawoczenski et al 1999). Lower correlations were reported for passive 1st MTPJ ROM in weight bearing and non-weight bearing (r=0.61 and r= 0.67, P<0.001 respectively) (Nawoczenski et al 1999). Halstead and Redmond (2006) report no significant relationship between passive static 1st MTPJ ROM and dynamic 1st MTPJ ROM (r = 0.186, P = 0.325).

Foot posture, in particular indicators of a more pronated foot, has been reported to be associated with reduced 1st MTPJ dorsiflexion in stance (Munteanu & Bassed 2006). Significant differences in weight bearing hallux dorsiflexion have been reported between differing degrees of rearfoot positioning (P=0.05) although there was no evidence of confidence intervals (Harradine & Bevan 2000). A significant negative correlation has been reported between maximal hallux dorsiflexion and navicular drop; a suggested indicator of pronation (r= -0.474, P<0.05) (Paton 2006). To note, these findings are based on results using a goniometer; the method of measurement which has previously been shown to have at best, only moderate reliability.

No significant association (P > 0.05) has been reported between first metatarsal phalangeal joint range of movement and disabling foot pain (Menz & Morris, 2005) and no significant difference was reported in first metatarsal phalangeal joint range of movement between fallers and non-fallers (P > 0.05) (Menz et al 2006). First metatarsal phalangeal joint range of movement was

significantly associated with measures of balance such as sway ($P < 0.05$), maximum balance range ($P < 0.01$), coordinated stability ($P < 0.05$) and walking speed ($P < 0.05$) in older people (Menz et al 2005).

4.8.9 First Ray

First ray hypermobility was first suggested as a mechanical aetiology of many foot pathologies by Morton (1930). The first ray has been described as the first metatarsal and corresponding medial cuneiform (Glasoe et al 2002; Bevans 2003; Cornwall et al 2004; Grebing & Coughlin 2004). Many of the investigations identified in the current review clinically assess the movement of the first ray via measurement of first metatarsal excursion alone (Lee & Young 2001; Glasoe et al 2002; Voellmicke & Deland 2002; Bevans 2003; Cornwall et al 2004; Grebing & Coughlin, 2004; Shirk et al 2006; Kim et al 2008;).

Reliability

Low intra and inter-rater agreement for first ray position (K= 0.21 [experienced] and 0.27 [inexperienced] and K=0.12 [experienced] and 0.11 [inexperienced]) and mobility (K=0.03 [experienced] and 0.26 [inexperienced] and K=0.12 [experienced] and 0.14 [inexperienced]) has been reported (Shirk et al 2006). Likewise poor reliability between examiners was reported when using a ruler (ICC = 0.05; 95% CI, –0.23-0.40; SEM = 1.23 mm) (Glasoe et al 2005) and poor agreement with use of passive mobility and observation by eye (12.5% and 34.1%) (Cornwall et al 2004). Conversely no significant difference between or within examiners ($r=0.76$ and 0.80, $P>0.05$) was reported for measurement of first ray mobility using a two bit ruler device, which measures the vertical displacement of the first ray against the corresponding lesser metatarsals (Kim et al 2008).

Validity

No significant correlation ($r=-0.21$, $P<0.05$) was reported between assessment of first ray mobility by manual displacement and testing with a previously validated mechanical device (Glasoe et al 1999; Glasoe et al 2002). In an evaluation of the EMC device, results showed no significant difference between the measures from EMC device and Klaue device ($r= 0.92$, $P=0.118$).

Generally low reliability has been reported for first ray measures within and between examiners, with the exception of the EMC device. Despite the relatively apparent simplicity of such a device, accessibility to such a product within multidisciplinary clinical settings is questionable. The validity of 1st ray measurements appears uncertain, as whilst correlations have been reported for the EMC device, the validity of the mechanical devices used in its evaluation are unclear. No evidence has been identified to investigate the association of first ray measures to pain or function.

4.8.10 Ankle Dorsiflexion Range of Motion (ADROM)

Examiners rely upon the assessment of ankle range of motion, in particular dorsiflexion, to determine whether ankle joint range of motion is sufficient for adequate function and ambulation (Bohannon et al 1989; Tiberio et al 1989). Despite the lack of clinical reliability in identification of subtalar joint neutral, many studies addressing measures of ankle dorsiflexion rely on the addition of locating and maintaining the subtalar joint neutral in order to limit potential STJ influences on ankle measurements.

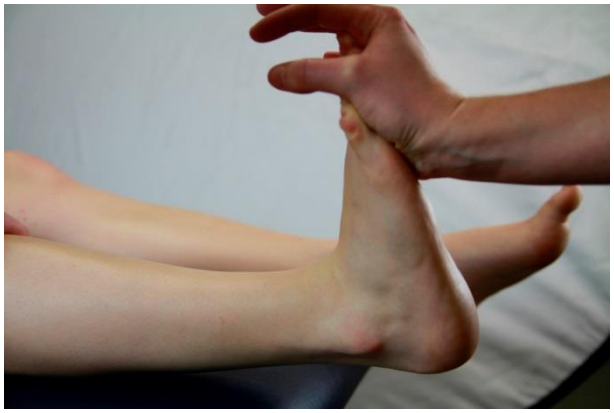

Figure 14. Passive ankle dorsiflexion assessment (image authors own)

<u>Reliability</u>

High intra-rater reliability has been reported for both weight bearing and non-weight bearing measures of ADROM among examiners of varied experience; ICCs of 0.94 (Thoms et al 1997), 0.97-0.98 (SEm= 0.5-1.1cm) (Bennell et al 1998) and ICCs=0.68-0.89 (SEm=2.1-2.9 ^{o}) (Krause et al 2011). Contrary to this one study reported a high variance in intra-rater reliability (ICCs 0.28-0.90)

(Bohannon et al 1989), however the study failed to define the examiners experience and the addition of locating the STJN was applied to the ADROM assessment; this measure has already be shown to be unreliable. Equally high inter-rater ICCs of 0.82 (SEm=2.82^{o}) (Krause et al 2011), and 0.99 (SEm=0.4cm) and 0.97 (SEm=1.4 ^{o}) (Bennell et al 1998) have been reported for standing lunge measures of ADROM with an inclinometer. Inter-rater reliability was less (ICCs=0.55-79, SEMm=2.58-3.70^{o}) for non-weight bearing measures of ADROM (Krause et al 2011).

Evidence suggests significant differences (P<0.001) in the results of maximum ADROM, dependent upon the use of different conditions and landmarks (Bohannon et al 1989). Similarly, the test may be conducted with different patient positioning. Higher mean active dorsiflexion values have been reported with the patient sitting (11.67^{o}), rather than in supine (6.59 ^{o}) or prone (6.45 ^{o}) (Thoms & Rome 1997).

From the literature it appears that weight bearing methods such as lunge tests may provide superior reliability to non-weight bearing assessment methods, further work may be useful to establish the use of the universal goniometer as an alternative to the inclinometer in weight bearing ADROM.

Ankle flexibility has been shown to be associated with balance and functional tests in older people, including sway, maximum balance range, co-ordinated stability, alternate step test, sit-to-stand and walking speed ($P < 0.01$) (Menz et al 2005). It is also significantly different between fallers and non-fallers ($P < 0.05$) (Menz et al 2006), with a reduction in flexibility in fallers. Ankle flexibility was not significantly associated with disabling foot pain ($P > 0.05$) (Menz & Morris, 2005).

4.8.11 Foot Posture Index

The FPI was initially developed to address the limitations of clinical methods of appraising foot posture (Redmond et al 2001). The original version of the FPI consisted of eight criteria: talar head palpation, curves above and below the malleoli, inversion/eversion of the calcaneus, bulge at the region of the talonavicular joint, congruence of the medial longitudinal arch, abduction/adduction of the forefoot on rearfoot, congruence of the lateral border of the foot and Helbings sign. Following one of the more rigorous validation processes of all the included foot and ankle assessment measures, the latter two criteria were removed to provide the FPI-6 (Redmond et al. 2006).

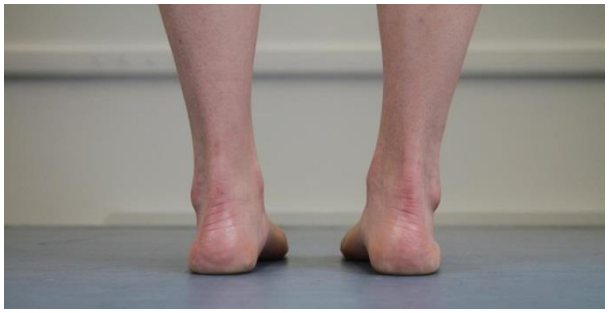

Figure 15. Positional standing for FPI test (image authors own)

Reliability

Moderate-substantial reliability was reported for the original FPI-8, with inter-rater ICCs of 0.62 (95% CI 0.47–0.74) in children, 0.74 (95% CI 0.66–0.82) in adolescents and 0.58 (95% CI 0.39–0.72) in adults (Evans et al 2004). Slight higher intra-rater reliability was reported for the FPI-6 in adults; ICC= 0.928 (95% CI 0.893–0.952)- 0.937 (95% CI 0.907–0.958), however inter-rater reliability was no better (ICC=0.56, 95% CI 0.452–0.671) (Cornwall et al 2008). The main difficulty in comparing the reliability of FPI-8 and FPI-6 is the difference in analysis. The items of FPI-8 were analysed individually, whereas FPI-6 was analysed as a total score.

Validity

A coefficient of 0.53 was reported for the original FPI-8 and the Valgus index scores (Redmond et al 2001). Poor correlations (r= -0.28-0.42) have been reported for four criteria from FPI against radiographic angles, including: talar head palpation, congruence of lateral border of foot, abduction and adduction of rearfoot and forefoot and congruence of the medial longitudinal arch (Scharfbillig et al 2004).

Six components of the original FPI-8 demonstrated validity against an electromagnetic tracking device (EMT) (Redmond et al 2006). The components of measuring lateral border congruence and Helbings sign did not show adequate concurrent validity and were therefore rejected from the final draft, resulting in the FPI-6 item version. Results for FPI-6 indicated the FPI-6 scores predicted 64% of the variation in the static ankle joint position during stance (supporting the validity of FPI-6), but only 41% of the dynamic variation in midstance foot position (Redmond et al

2006). Reports from Rasch analysis showed that the FPI-6 has good psychometric properties, good individual item fit and good overall fit of the six criteria (Keenan et al 2006).

An association has been shown between the Foot Posture Index and walking function (R^2=0.64, P < 0.001) (Redmond et al 2006), medial knee OA (P<0.02) (Levinger et al 2010), risk of foot and ankle overuse injuries in football (P = 0.008) (Cain et al 2007) and some parameters of dynamic foot function in individuals with patella femoral pain; greater peak forefoot abduction (r = 0.502, P = 0.013) and earlier peak rearfoot eversion (r = -0.440, P = 0.031) (Barton et al 2011). No association has been found between FPI-6 and disabling foot pain (P > 0.05) (Menz & Morris 2005), balance or functional tests in older people (Menz et al 2005). Neither was there any significant difference in FPI between groups of fallers and non-fallers (P > 0.05) (Menz et al 2006).

4.9 Discussion

This review has identified ten categories of clinical musculoskeletal foot and ankle measures, investigated over the last two decades. No evidence was identified of a comprehensive clinical musculoskeletal foot and ankle assessment protocol for use in either the clinical or research environment. Only independent foot and ankle assessment techniques have been identified and for many of these a lack of standardised technique across study protocols has made comparison difficult. Many of the foot and ankle measures show considerable variability in clinical reliability and for many measures there is an absence of investigation for their association to clinically important outcomes such as pain and function.

Inconsistencies in reporting parameters such as confidence intervals, standard error of measure and correlation coefficients have made it extremely difficult to interpret results. A variation in the populations used, examiner experience and examiner professions between studies made study results challenging to compare.

The main objective of clinical foot and ankle assessment is to provide information to guide appropriate intervention. Interventions often aim to facilitate a reduction in pain and an increase in function, however this review has revealed limited investigation into the association between clinical musculoskeletal foot and ankle assessments and outcomes of pain and function (Nigg et al 1993; Menz et al 2003; Menz and Munteanu 2005; Menz et al 2005; Menz et al 2006). Only ankle dorsiflexion, Foot Posture Index, arch, navicular and first metatarsal phalangeal joint measures have been investigated for an association with such outcomes.

Of these assessment measures, none have shown an association with foot pain. Navicular height, ankle dorsiflexion, first metatarsal phalangeal joint range of movement were associated with functional tests that include balance, stability, walking speed, sit to stand and stepping. Inferences of these associations was however limited to the older population, raising a question over the clinical justification for the use of many of these assessment measures in the general adult and child populations. Further investigation of the identified measures across age groups and disease cohorts is recommended for the clinical justification of their use. It would be useful to investigate the association of pain (in particular foot pain) and function against the remaining measures.

Ankle dorsiflexion assessed in weight bearing was the only assessment where reported values remained almost perfect for both intra and inter-examiner reliability across at least three studies (Bennell et al 1998; Menz et al 2003; Krause et al 2011). All other foot and ankle measures displayed highly variable or low reliability values across observational studies. Regardless of reliability, if assessments are not associated to the outcomes that treatment aims to facilitate, for instance pain, then the value of the assessment is questionable. The disparity in reliability may partly be explained by the variability in study design. Examples of differences in study designs were apparent by the variation in the number of examiners, experience of examiners, number of conditions, sample size, assessment technique and degree of control within the techniques.

Measures including navicular drop, ankle dorsiflexion, rearfoot position and forefoot position have relied upon techniques which include the determination of subtalar joint neutral position. This is likely to have influenced the variation of reliability values across studies because, apart from difficulties in ensuring isolation of the subtalar joint when measuring passive range of motion, measurements are largely based on subtalar joint neutral being a reference for zero; a method for measuring this has yet to be proven accurate or reliable between testers (Elveru et al 1988; Picciano et al 1993; Chen et al 2008).

An example of this variation is seen in the differences between the reliability of navicular drift and the foot line test, where the latter, which does not require judgement of the subtalar joint neutral position, showed markedly higher reliability values (Picciano et al 1993 ; Evans et al 2003; Vinicombe et al 2001; Brushøj et al 2007). A difference in reliability was also reported between rearfoot measures made in resting calcaneal stance position and those with a reference to an apparent neutral position; those referenced to neutral showed a higher frequency of poorer values (Dahle et al 1991; Youdas et al 1993; Sell et al 1994; Cornwall et al 2004; Scharfbillig et al 2004; Cornwall et al 2008). This highlights the potential error effect that may be introduced by

attempting to ascertain an apparent neutral position. Additionally, determining subtalar joint neutral position is influenced by examiner experience; experienced examiners have been reported to position the rearfoot into $+1^{o}$ of subtalar joint neutral position 41.3% of the time, compared to only 25% for untrained physiotherapy students (Pierrynowski et al 1996).

The difference in reported results is further highlighted by the limited use of confidence intervals and standard error of measurement. ICC quantifies reliability or consistency in a measurement; however it does not provide a quantification of the magnitude of the error. Evaluating the smallest detectable change is an important aspect of a reliability study (Muir et al 2010). For continuous data, SEMs provide useful information (De Vet et al 2006; Kottner et al 2011) and without the inclusion of appropriate inferences it is not possible to establish the level of reliability within that population (Ellaszlw et al 1994). We suggest where ICCs are used within future investigations SEMs be included. Consideration may also be given to the use of the limits of agreement method (Bland and Altman 1986) within future investigations as a method of standard reporting. Additionally interval estimates, such as confidence intervals, should be reported alongside all point estimates to inform the reader of the possible range of values for the true effect.

Findings suggest that, of those clinical measures tested against “gold standard measures” for validity (FPI, first ray and first metatarsal phalangeal joint assessment, manual supination resistance test, arch and navicular measures); only FPI, navicular height and arch height have shown any degree of concurrent validity (see supplementary tables). It appears the FPI is the most rigorously tested clinical foot and ankle assessment tool available. Validation of the tool has been hindered by a limitation in gold standard comparative techniques, a problem that has also restricted the validation of other foot and ankle assessment measures. FPI has been shown to predict 41% of variance in midstance of walking (Redmond et al 2006), however the large amount of unexplained variance does mean that FPI values cannot infer those structures during gait. The authors offer caution when interpreting FPI results, due to only moderate levels of inter examiner reliability.

When interpreting the findings of this review, several limitations need to be considered. Only English language articles published were included due to the lack of translation services. Literature was not searched from inception as the aim of the review was to identify current assessment methods. The authors believed duration of three decades would be suitable to expose investigation into the assessments currently used. Whilst the agreement between

reviewers for the inclusion of articles was established via consensus meetings, the level of agreement was not quantified.

A full systematic review and meta-analysis was not appropriate for this review due to the low level and heterogeneous nature of the studies (e.g. different populations, different outcome measures and methods). All relevant articles were considered, despite the methodological quality. This was to ensure the inclusion of all foot and ankle assessments that may be utilised within the clinical and research setting. Whilst narrative synthesis of lower quality evidence makes comparison of findings more difficult to interpret, the authors believe it was important to identify all potential assessment methods and consider the limitations of all evidence rather than forfeit the inclusion of particular assessment methods.

Conclusion

It is clear that there is currently no comprehensive clinical protocol for the musculoskeletal assessment of the foot and ankle. A limited number of foot and ankle measures have shown an association with functional tests (navicular height, ankle flexibility, first metatarsal phalangeal joint range of movement), however no association has been shown between any of the foot and ankle measures identified and pain. For the majority of measures identified there is no evidence of investigation against outcomes of pain and function. The review highlights a requirement for the identification of standardised set of clinical foot and ankle assessment measures. Due to the limited number of assessment measures which have been robustly investigated for their association to clinical outcomes it would be necessary to use a valid and structured approach to decide in the first instance, which assessments should be taken forward to develop a new protocol.

5 Chapter Five

An International Consensus Study to Determine a Core Set of Objective Musculoskeletal Foot and Ankle Assessment Measures

5.1 Introduction

Findings from study one show that at present there is no consensus on the ideal method for assessing the musculoskeletal status of the foot and ankle, a reason for which is due to the lack of clinically valid and reliable measures. Findings of study one supported the use of the Foot Posture Index as the most rigorously tested individual clinical measure. Furthermore the limitations highlighted from a previous meta-analysis have shown the requirement for future studies to adopt a consistent definition of foot pain and a standardised method of clinical assessment to explore the contribution of common foot disorders to the development of foot symptoms (Thomas et al, 2011). These results confirm the requirement for a more comprehensive approach to address the second aim of this thesis:

"To determine a core set of objective clinical musculoskeletal foot and ankle assessment measures for multidisciplinary use for clinical and research purposes"

Taking into consideration that clinicians and researchers routinely use assessments to facilitate interventions, which aim to influence outcomes such as pain and function, it appears many of the foot and ankle measures identified have yet to be validated against such outcomes. A standardised quantifiable measurement system for the assessment of the foot and ankle will enable the appropriate evaluation of clinical and research outcomes. In turn also meeting the governments' current objectives set out in the Department of Health document (DOH 2010) for the NHS to be accountable against evidence based clinical outcomes.

In the absence of data appropriate to define a core set of clinical foot and ankle assessments, a first stage in the development of measurement definitions is to employ a systematic approach which relies on the available evidence (from chapter four), complemented with expert opinion. Experts examine the evidence and reach consensus (Boulkedid et al 2011). Following on from

established consensus, agreed measures may be formed into a core set and further investigated to evaluate their sensitivity and specificity.

The Delphi technique has been widely used for quality-indicator development in healthcare. Studies endorsed by EULAR and OARSI have successfully applied the Delphi technique as a method of gaining consensus to develop rheumatology based diagnostic guidelines and assessment protocols (Zhang et al 2008; Mosca et al 2010; Zhang et al 2010b; Hunter et al 2011; Fransen et al. 2012).

The Delphi technique is a structured process which uses a series of rounds to collect information; these rounds are repeated until consensus is reached (Powell 2003). It allows the inclusion of a large number of individuals from diverse locations and professions, who can remain anonymous to others, thus avoiding domination of the consensus process by particular experts (Jairath & Weinstein 1994).

5.2 Aims

To gain expert consensus to determine a core set of objective, clinical foot and ankle musculoskeletal assessment measures, applicable for multidisciplinary use in both clinical and research settings.

5.3 Objectives

1) To administer a Delphi exercise to identify a core set of objective musculoskeletal foot and ankle assessment measures.

5.4 Priorities of Consensus Study

1) To identify important measures that should be included in an objective musculoskeletal foot and ankle assessment.
2) To determine which existing assessment instruments, if any, best represent these chosen measures.
3) To agree upon a new or adapted set of measures if there is no existing instrument which represents all of the agreed measures.

5.5 Outcome

The determination of a core set of musculoskeletal foot and ankle assessment measures; existing or new, which comprise a selection of agreed features, which are applicable across health related professions.

Pilot Study

A pilot study was initially conducted to test the proposed study design, to provide feedback on the understanding of the task requested and the ability of the exercise to gather the correct foot and ankle information.

5.5.1 Pilot Participant Sample

Five musculoskeletal podiatrists from the local NHS trust, with 1-10 years' experience, took part in the pilot study. Consideration was taken that this was a homogenous group that did not constitute both academic and clinical expertise. Therefore the aim was not to determine the potential contents of a final list, but to determine understanding of the Delphi process for this topic of clinical foot and ankle assessments.

5.5.2 Pilot Methods

The members were briefed as a group and a presentation was administered which set out the aims of the main study, and the aims and objectives of the pilot study. All members were advised this would not constitute a complete Delphi exercise however it would reflect an initial round. Members were then asked to provide an infinite list of the measures they believed would be essential to use within a musculoskeletal foot and ankle assessment. Exclusion criteria were set out in the presentation. These included:

- Self-reported measures
- Pathology specific measures
- Measures which involve the use of sophisticated devices which are not readily available within a standard NHS clinical setting

5.5.3 Pilot Results

Results of the pilot study can be seen below in table 7. Twenty four foot and ankle measures were suggested, however four were deemed inappropriate as they did not meet the inclusion criteria set out in the initial presentation.

Table 7. Results of Pilot Study: suggested assessment measures

Suggested Assessment Measures:		No. of times measure suggested
Ankle joint Dorsiflexion		III
Ankle joint ROM-Lunge test		I
Forefoot alignment		II
Rearfoot alignment		II
RCSP		II
NCSP		I
STJ ROM		II
STJ alignment		I
Talar head palpation in stance (STJN)		I
Manual supination resistance		II
Arch height measures		I
Hubscher test		III
First ray ROM		I
1st MTPJ dorsiflexion		I
Static foot position (pronation/supination end range in stance)		I
Active ROM		I
Passive ROM		I
Muscle length		I
Muscle strength		I
Maximum Pronation		I
Single /double leg toe raise		II
Assessment Suggestions that did not meet inclusion criteria	Reason for not including	No of times suggested
Technological Gait analysis	Clinically Unquantifiable	IIII
VAS scale	PROMs	II
Activity of Daily Living		I

5.5.4 Pilot study findings

The pilot study highlighted the importance of making clear the initial exclusion criteria to avoid the addition of unnecessary suggestions. Also findings confirm the importance of using a heterogeneous group of experts to provide profession diverse measures.

Considerations and/or changes made to the Delphi study as a result of the pilot study findings include:

- Explicit and clear explanation of exclusion criteria
- Well defined “expert” criteria
- Group to include a number of experts from a variety of professions

Consensus Study

Following the pilot study the final study design, participant sample and methods of data collection were formed.

5.6 Study Design

An electronic Delphi technique was chosen to address the lack of agreement of musculoskeletal foot and ankle measures found from the first phase of this investigation (chapter four). In the current study the rounds focussed on gaining opinions of "what measures of foot and ankle are essential to incorporate within a core set of clinical musculoskeletal foot and ankle assessment measures". Each subsequent round is developed based on the results of the previous round, where the experts can observe the findings of other experts involved in the study.

5.7 Expert Sample

In order to gain the desired expert homogeneity participants with an informed knowledge of foot and ankle assessment, with both clinical and research experience were considered. This was generalised across musculoskeletal professions to limit bias that may evolve from the education and professional development of specific clinical professions.

5.8 Inclusion Criteria

The group of experienced professionals meet defined expert criteria (table 8).

Table 8. Criteria for inclusion of experts within foot and ankle consensus study

Clinical Expert Participants (Any two of the following criteria)
10 years clinical experience in lower limb musculoskeletal pathology
Health Care Professions Council Registered OR General Medical Council Registered
Clinical practice including lower limb assessment and management within last 2 years
Research/Publication record on lower limb musculoskeletal topic

5.9 Participant Recruitment

Expert clinicians/researchers with known and demonstrable experience and expertise in the field of foot and ankle musculoskeletal pathology and management were purposively sampled according the set inclusion criteria. Professions included: Podiatry; Rheumatology; Orthopaedics; General Practice; Podiatric Surgery and Physiotherapy.

Twenty six individuals were identified as potential study experts and were approached to allow for an expression of interest. They were emailed the main aims of the study and the potential responsibilities of being an expert representative. Twenty five experts initially agreed to take part, these included individuals from the following profession: Podiatry (12), Orthopaedics (2), Rheumatology (5), Sports Medicine (1), Physiotherapy (3) and General Practice with specialist interest (2). Letters of collaboration support can be seen in appendix 3.

5.10 Data Collection-The Delphi Exercise

Findings from the literature review (chapter 4) were presented to the expert panel members prior to the completion of the Delphi questionnaires. The presentation including these findings, plus the aims of the Delphi technique was uploaded to the University of Southampton's online teaching and learning repository EdShare, which can be accessed at: http://www.edshare.soton.ac.uk/9061/.

The Delphi exercise consisted of four rounds of factor identification and refinement. A schematic of these rounds can be seen in figure 8. Each round consisted of a questionnaire which was sent via email to the expert representatives. The Internet rounds were followed by a meeting in which

all experts that contributed to the study were invited to give strength of recommendation scores for each measure in light of both a research and clinical set of measures and to discuss future research agendas.

There are a number of potential methods used to achieve consensus around selected indicators. A review by Boulkedid et al (2011) has shown discrepancy in these methods. A number of studies have used indicators scales where median scores above a predefined threshold are used. Others have used the proportion of experts, such as the proportion of experts who rated the indicator within the highest region of the scale had to be greater than a predefined threshold (Boulkedid et al 2011). International studies to drive healthcare guidelines have been known to use a given percentage of experts votes to include each indicator (Hunter et al 2011). Also used are ranking methods, often using a 9-point Likert scale, where only a limited number of members can rate the indication outside a certain point region (i.e. 3 point region) containing the median (Jones and Hunter 1995). In accordance with previous OARSI Delphi exercises to define OA diagnostic criteria (Hunter et al. 2011), voting for measures within each round was based on the following: ≥60% votes led to inclusion and ≤20% votes led to exclusion of the measure. Those between these values were discussed and another round of voting followed.

5.11 Method and Results: Factor Identification and Refinement

The epistemological basis for the Delphi Technique can cross the qualitative and quantitative divides (Critcher & Gladstone 1998). It is therefore difficult to make clear conclusions about the paradigmatic assumptions underpinning this technique.

Some however, present the Delphi technique as subjective and qualitative in nature (Fitzsimmons & Fitzsimmons 2001). This is because the aim of the Delphi technique is to achieve consensus through a process of iteration, based on opinions, ideas and words (Stewart 2001). The Delphi techniques' main advantage is gaining achievement of consensus in a given area of uncertainty, lack of empirical evidence or incomplete knowledge (Murphy et al 1998). The Delphi technique allows for anonymous inclusion of a large number and variety of individual experts. Other methods of reaching consensus, such as face to face meetings of committees, are recognized to be prone to domination by powerful individuals (Murphy et al 1998). The anonymous approach of the Delphi avoids potential domination of the consensus process by particular experts (Jairath & Weinstein 1994). The Delphi technique incorporates a successive ranking technique, via a series of

questionnaires/rounds, in order to gain consensus. It is process used to collect and refine the judgements/opinions of experts (Linstone & Turoff 2002).

The agreement of important features required within a foot and ankle assessment enables an informed universal method of examination throughout health and medical professions. This may not only form a method of assessment that can be used in every day clinical situations to monitor patient foot and ankle status and progression, but will also allow for the capture and analysis of data for research purposes.

Within the current study four rounds of factor identification and refinement were completed. The entire consensus process is displayed in figure 16 and the results from each round are detailed table 9.

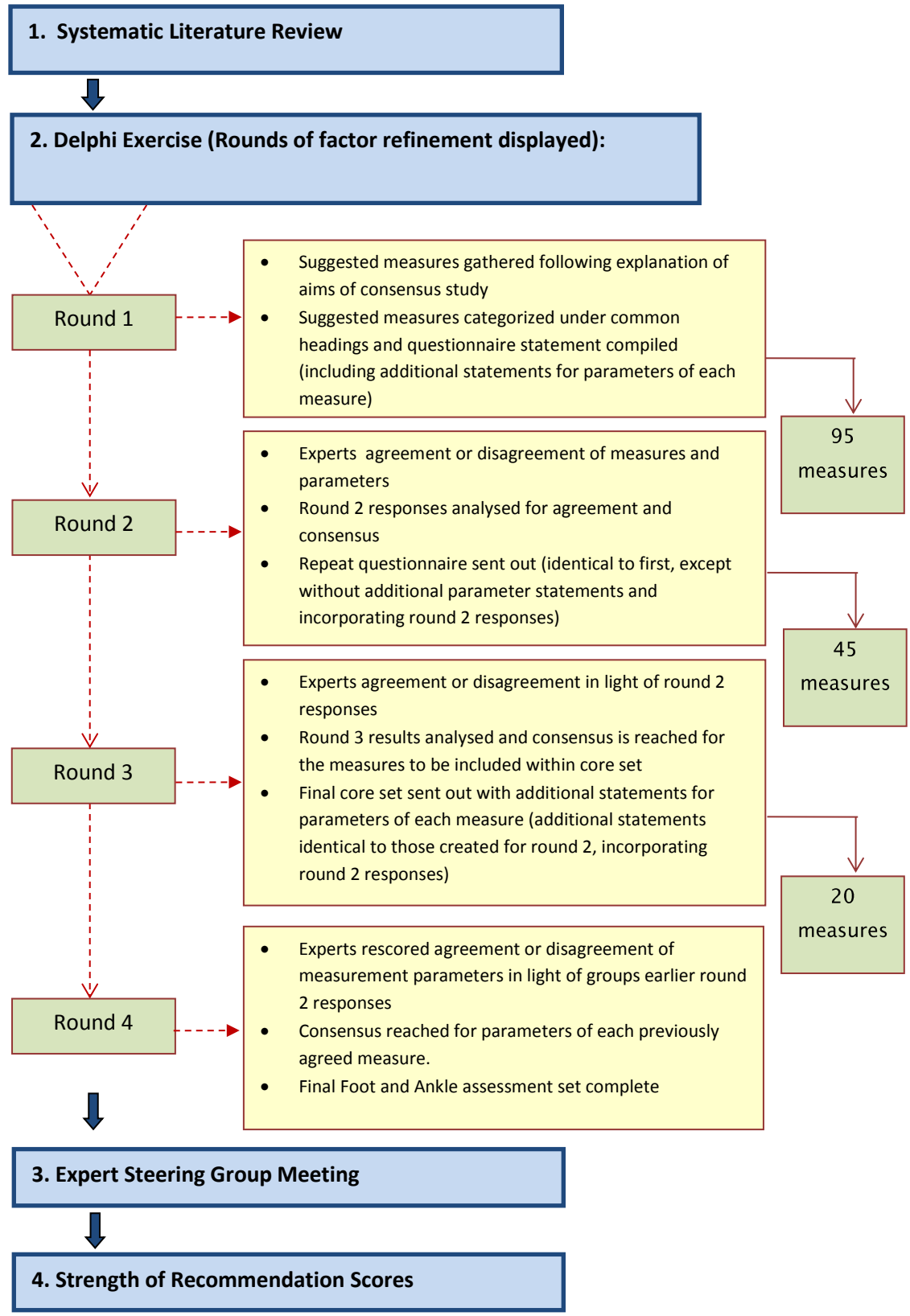

Figure 16. Consensus Study Process

5.11.1 Round One

The first round was sent via email, with the findings of the systematic literature review via the online presentation and a corresponding explanatory letter (see appendix 4). Round one consisted of two open ended questions:

Q1) Are there any important foot and ankle measures we have failed to identify from the literature review?

Q2) Which objective measures do you believe are important to be included within a musculoskeletal foot and ankle examination?

-Please include a brief description of the measure and a reason for your choice

Responses were compiled to form an inclusive list of measures and categorised according to type of measure.

Seventeen experts responded to round one. Responses were compiled to form an inclusive list of ninety five measures. Each measure was categorised according to its type of measure.

5.11.2 Round Two

Round two comprised the inclusive list of expert responses from round one (see appendix 5 for full questionnaire and collated responses). Similar measures or terms were merged to avoid repetition and measures that did not meet the inclusion criteria set out in round one instructions were not included. Experts were asked to reject or accept each assessment measure and to clarify their accepted assessment method. Experts were also given the opportunity to merge features accordingly. Individual results were collated and all accepted answers were calculated to provide a total of experts who agreed upon each measure.

Measures receiving >60% of votes were accepted, <20% of votes rejected and those in between were added to discussion within the following round.

Eighteen experts responded to round two. A total of thirteen measures were accepted, two merged and twenty rejected. Forty five measures were left to revote in round three.

5.11.3 Round Three

Once again experts were shown total votes from the previous round (see appendix 6 for full questionnaire). Experts were asked to reject or accept each measure for revote. They were not asked to contribute any further to the descriptions of measures at this stage, as it was decided that further input on this may prove confusing and unnecessary at this stage and would be more beneficial to revisit once the final list of measures had been decided.

Each measure was once again accepted based on previous criteria of >60% of votes: Measure Accepted, <20% of votes: Measure Rejected, 20-60% of Votes: Measure undecided.

Nineteen experts responded to round three. Round three comprised the list of forty five measures from round two (appendix 6).

Following further merging of measures including ankle/rear foot/subtalar inversion/eversion and rear foot alignment/ rear foot alignment to leg/in resting stance in round three, twenty one measures were accepted and categorised accordingly. Consensus on measures to be included had been reached at this point, with no further increase in agreement over the majority of measures. Also, it has been recommended that a Delphi should be completed within three rounds (Boulkedid et al 2011) as a large amount of rounds may cause participant fatigue and steep drop out (Schmidt 1997). This selection of measures was therefore concluded as the final list.

5.11.4 Round Four

Round three informed the final list of measures to be included within the core set. The aim of round four was to return the focus to methods of measurement and recording, in order to determine the measurement parameters for each foot and ankle measures. Experts were sent the final list of measures along with a choice of measurement parameters appropriate to each individual measure. Experts were also shown the total votes of these parameters from round 2. They were also provided with supportive evidence, where applicable, for evidenced measurement techniques to inform decision making (see appendix 7 for questionnaire).

Nineteen experts responded with opinions on the methodological parameters for each measure. Due to a majority decision to measure rear foot alignment against the lower leg, in relaxed standing, the two measures of rearfoot alignment were merged into one, to create “rearfoot to

leg alignment in relaxed standing". Therefore a total of ***twenty*** measures were included within the final set:

Observation of:

1. swollen (tender) joints
2. skin/nail changes and/or lesions
3. general foot morphology
4. hallux valgus
5. lesser toe deformities

Palpation of:

6. achilles tendon
7. proximal plantarfascia insertion

Passive range of motion of:

8. ankle dorsiflexion (non-weight bearing) knee extended
9. ankle dorsiflexion (non-weight bearing) knee flexed
10. metatarsal phalangeal joints
11. midfoot /midtarsal
12. first metatarsal phalangeal joint
13. subtalar joint represented as rearfoot inversion/eversion

Muscle tests of:

14. gastrocnemius /soleus
15. tibialis posterior

Alignment of:

16. rearfoot to leg in relaxed stance

Static foot posture:

17. foot Posture Index

Indirect assessment of:

18. leg length
19. footwear
20. gait parameters.

The collation of round four responses can be seen in appendix 7.

The intention for the final consensus of measurement parameters was once again based on a minimum of 60% expert acceptance. For each individual measure, where the vote for descriptive or categorical reporting was closer to 50% these were combined to create a categorical reporting style made up of a choice of common descriptors. This can be seen for observation of general foot morphology and palpation of Achilles and plantarfascia insertion.

Table 9. Factor identification (round one) and refinement (rounds 2-3)

Measures suggested from Round 1		Measures rejected or accepted/for revote (✓) in Round 2	Measures rejected or accepted/for revote (✓) in Round 3
Observation:			
1	Swollen (tender) joints	✓	✓
2	Skin/nail changes	✓	✓
3	Asymmetry	✓ 3&4 merged	✓ 3&4 merged
4	general foot morphology	✓	✓
5	forefoot width	✓	
Palpation:			
6	General swelling	✓	✓ Merged to 1
7	Swollen joints	✓ Merged to 1	✓ Merged to 1
8	Temperature	✓	
Range of Motion:			
9	Ankle Dorsiflexion		
10	▪ Ankle Dorsiflexion with knee extended (NWB)	✓	✓
11	▪ Ankle Dorsiflexion with knee flexed (NWB)	✓	✓
12	▪ Ankle Dorsiflexion weight bearing Lunge Test	✓	
13	Ankle (non-specific)		
14	Ankle/rearfoot		
15	▪ inversion/eversion	✓	✓ 15 & 18 Merged
16	▪ Passive motion of rear foot in 6 directions to determine rigidity/flexibility		
17	Subtalar		
18	▪ Represented as rearfoot inversion/eversion	✓	✓ 15 & 18 Merged
19	▪ **Pronation/supination**	✓	
20	Midfoot /midtarsal	✓	✓

21	▪ Calcaneocuboid joint	✓	
22	• Talonavicular joint	✓	✓
23	▪ Inter-tarsal accessory movements		
24	▪ Passive motion of mid foot in 6 directions to determine rigidity/flexibility	✓	
25	Forefoot		
26	▪ 1st MTPJ	✓	✓
27	▪ Metatarsal phalangeal joints	✓	✓
28	▪ Inter metatarsal phalangeal joints	✓	
29	▪ Passive motion of forefoot in 6 directions to determine rigidity/flexibility		
30	1st Ray	✓	
31	Joint stability		
32	Quality of joint motion (from one or more of the above joints)	✓	
33	Direction of joint motion (from one or more of the above joints)		
Alignment:			
34	Rear foot alignment to leg alignment:		
35	• To leg	✓	✓ 35 & 39 Merged
36	• To ground	✓	
37	• To fore foot (NWB)	✓	
38	• In neutral stance	✓	
39	• In relaxed stance	✓	✓ 35 & 39 Merged
40	Subtalar joint		
41	• neutral position		
42	• axis position	✓	
43	Frontal plane tibial position		
44	Midtarsal joint sagittal plane inclination		
45	First ray neutral position in relation to forefoot	✓	
46	Forefoot alignment	✓	

Static Posture:			
47	foot posture (Nonspecific)	✓	
48	Foot posture index (FPI): composite	✓	✓
49	• Talar head palpation		
50	• Curves above and below the malleoli		
51	• calcaneal inversion/eversion		
52	• talonavicular prominence		
53	• medial arch height		
54	• forefoot ab/adduction		
55	Arch height	✓	
56	Arch Index	✓	
57	Transverse arch		
58	Navicular height	✓	
59	Normalised navicular height truncated		
Other:			
60	supination resistance test		
61	maximum pronation test		
Muscle Tests:			
62	Gastrocnemius	✓ 62 & 63 merged	✓ 62 & 63 merged
63	soleus	✓ 62 & 63 merged	✓ 62 & 63 merged
64	Plantaris		
65	Tibialis posterior	✓	✓
66	Flexor digitorum longus	✓	
67	Flexor hallucis longus	✓	
68	Tibialis anterior	✓	
69	Extensor digitorum longus	✓	
70	Extensor hallucis longus	✓	
71	Peroneus tertius		
72	Peroneus longus	✓ 72 & 73 merged	

73	Peroneus brevis	✓	
74	strength generalised to movement (i.e. inversion/eversion)	✓	
75	muscle strength assessed using hand held dynamometer	✓	
Indirect measures:			
76	leg length	✓	✓
77	balance measures		
78	one leg stance with eyes open/closed	✓	
79	postural sway in anterior-posterior and medial-lateral direction with eyes open/closed	✓	
80	foot wear examination	✓	✓
81	Knee ROM with goniometer		
82	gait - parameters including walking velocity, cadence, double support, step and stride length	✓	✓
Specific to Pathology:			
83	observation of deformity using semi-objective rating	✓ 83&84 merged	
84	Observation of forefoot and digital deformity with Foot structure index	✓	
85	Platto Index for deformity		
86	observation of lesser toe deformities	✓	✓
87	hallux valgus presence	✓	✓
88	hallux valgus assessment with goniometer		
89	hallux valgus assessment via x-ray		
90	standing heel raise to assess tibialis posterior- noted as full/limited/none	✓	✓
91	Ankle ligament tests, in particular ATFL and deltoid via drawer and tilt	✓	
92	Palpation of plantarfascia insertion	✓	✓
93	Palpation of Achilles tendon	✓	✓
94	Achilles tendon rupture: Simmonds test	✓	✓
95	Mortons neuroma- mulders sign	✓	✓

5.11.5 Response and Drop Out

Twenty five experts initially agreed to participate in the Delphi exercise. Two experts withdrew prior to round one due to work load commitments (n=23). Two additional experts were included following round one after expressing an interest in the study (n=25). Expert response rate to each round, based upon the figure of those who initially agreed (n=25) can be seen in figure 17 (see appendix 8 for individual professions contributions throughout rounds).

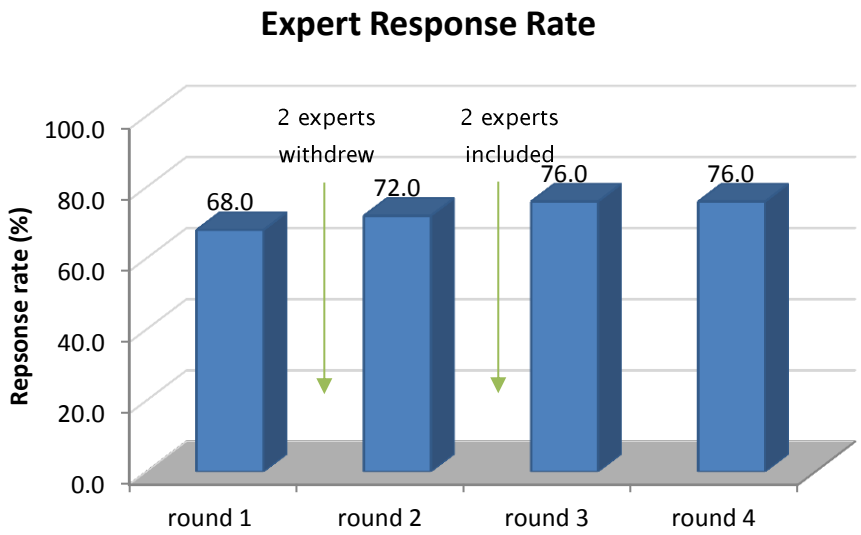

Figure 17. Graph to illustrate expert response rates through each Delphi round

5.11.6 Expert Meeting & Strength of Recommendation Scores

Upon analysis of parameter consensus there were particular measures for which both descriptive and categorical reporting were chosen. Acknowledging the benefits of both, within given circumstances, the potential for two core sets of measures was recognised: one for clinical use and one for use in research. The core set applicable for research would make use of predominantly categorical parameters, whereas a clinical set would allow for a higher degree of descriptive reporting. A final meeting of nine experts was convened to agree upon the parameters within each core set. All experts included in the consensus study at the final round were invited to attend. See appendix 9 for the main discussion points from the meeting

Clinical and research strength of recommendation (SOR) values based on each measure were obtained from the experts present at the meeting (n=9) and the remainder (n=10) via email correspondence (table 10). SOR values are based upon a numerical rating scale from 1-10, where higher values are representative of stronger strength of recommendation and lower values for lesser strength of recommendation. Strength of recommendation values were categorised into tertiles of the mean. Categories included: not recommended (mean of 0-3.3), recommended (mean of 3.4-6.6) highly recommended (mean of 6.7-10).

Table 10. Level of recommendation for each measure, based upon clinical and research strength of recommendation values

	Clinical Measure	Mean (SD)	Research Measure	Mean (SD)
6.7-10 (highly recommended)	Swollen/Tender Joints	7.8 (2.6)	Swollen/Tender Joints	7.1 (2.6)
	HAV presence	7.6 (2.3)	HAV presence	7.5 (2.6)
	Ankle DF knee flexed	6.8 (2.4)	Ankle DF knee flexed	6.7 (2.7)
	Ankle DF knee extended	7.5 (1.9)	Ankle DF knee extended	7.0 (2.3)
	First MTPJ	7.5 (1.9)	First MTPJ	6.9 (2.4)
	FPI	7.6 (2.6)	FPI	8.2 (2.0)
3.4-6.6 (recommended)	Skin Nail	6.0 (2.2)	Skin Nail	4.4 (2.6)
	General foot morphology	5.1 (2.9)	General foot morphology	4.3 (2.9)
	Lesser toe deformities	6.5 (2.5)	Lesser toe deformities	5.8 (3.1)
	Plantarfascia palpation	5.8 (2.8)	Plantarfascia palpation	4.1 (3.2)
	Achilles palpation	5.4 (2.9)	Achilles palpation	3.8 (3.0)
	Rearfoot	6.3 (2.1)	Rearfoot	5.6 (2.6)
	Midfoot	5.0 (2.4)	Midfoot	5.1 (2.8)
	Lesser MTPJ	4.9 (2.2)	Lesser MTPJ	4.5 (2.7)
	Gastrocnemius	3.9 (2.6)	Gastrocnemius	3.8 (2.6)
	Standing heel raise	5.6 (2.7)	Standing heel raise	5.4 (2.6)
	Rearfoot to leg alignment	5.1 (2.5)	Rearfoot to leg alignment	4.6 (2.4)
	Leg length	5.1 (2.5)	Leg length	4.6 (2.7)
	Footwear	6.2 (3.0)	Footwear	5.3 (3.1)
	Gait	6.6 (3.2)	Gait	6.4 (3.4)
0-3.3 (not recommended)	NA	NA	NA	NA

5.11.7 The International Musculoskeletal Foot and Ankle Assessment

Agreement was made between the main investigator and experts to name the 20 items the International Musculoskeletal Foot and Ankle Assessment (IMFAA). IMFAA has been produced into a tabular format (table 11) for ease of recording and is provided with guidelines for users (appendix 10). A number of measures included are depicted in figure 18.

Table 11. Expert derived International Musculoskeletal Foot and Ankle Assessment (IMFAA) record sheet

Observation		Left			Right		
1. Swollen (tender) joints	1st MTPJ	Yes		No	Yes		No
	2nd MTPJ	Yes		No	Yes		No
	3rd MTPJ	Yes		No	Yes		No
	4th MTPJ	Yes		No	Yes		No
	5th MTPJ	Yes		No	Yes		No
	Midfoot	Yes		No	Yes		No
	STJ	Yes		No	Yes		No
	Ankle	Yes		No	Yes		No
2. Skin/nail changes and/or lesions	Skin changes:						
	Nail changes:						
3. General foot morphology	Abnormal	Yes		No	Yes		No
	Asymmetrical	Yes		No	Yes		No
4. Hallux valgus presence		Yes		No	Yes		No
5. Lesser toe deformities			No of toes affected			No of toes affected	
	Hammer	Yes		No	Yes		No
	Mallet	Yes		No	Yes		No
	Retracted	Yes		No	Yes		No
	Clawed	Yes		No	Yes		No

Palpation		**Left**				**Right**			
6. Achilles Tendon		Tender		Thickened		Tender		Thickened	
	T-A Junction	Yes	No	Yes	No	Yes	No	Yes	No
	Mid Tendon	Yes	No	Yes	No	Yes	No	Yes	No
	Enthesis	Yes	No	Yes	No	Yes	No	Yes	No
7. Proximal plantarfascia insertion	Tender	Yes		No		Yes		No	

Passive Range of Motion	**Left**				**Right**			
8. Ankle dorsiflexion with knee extended	Hypermobile	Normal	Limited	Fixed	Hypermobile	Normal	Limited	Fixed
9. Ankle dorsiflexion with knee flexed	Hypermobile	Normal	Limited	Fixed	Hypermobile	Normal	Limited	Fixed
10. Rearfoot inversion/eversion	Hypermobile	Normal	Limited	Fixed	Hypermobile	Normal	Limited	Fixed
11. Midfoot /midtarsal	Hypermobile	Normal	Limited	Fixed	Hypermobile	Normal	Limited	Fixed
12. 1st MTPJ	Hypermobile	Normal	Limited	Fixed	Hypermobile	Normal	Limited	Fixed
13. Metatarsal phalangeal joints	Hypermobile	Normal	Limited	Fixed	Hypermobile	Normal	Limited	Fixed

Muscle Tests	**Left**						**Right**					
14. Gastrocnemius /soleus (MRC Scale)	0	1	2	3	4	5	0	1	2	3	4	5
15. Single Limb Heel Raise (Tibialis posterior)	Able	Limited	Unable				Able	Limited	Unable			

Alignment	**Left**			**Right**		
16. Rearfoot to leg in relaxed stance	Inverted	Linear	Everted	Inverted	Linear	Everted

Static Posture		**Left**					**Right**				
17. Foot Posture Index (FPI)	Talar head palpation	-2	-1	0	+1	+2	-2	-1	0	+1	+2
	Curves above and below malleoli	-2	-1	0	+1	+2	-2	-1	0	+1	+2
	Calcaneal inversion/eversion	-2	-1	0	+1	+2	-2	-1	0	+1	+2
	Talo-navicular prominence	-2	-1	0	+1	+2	-2	-1	0	+1	+2
	Medial arch height	-2	-1	0	+1	+2	-2	-1	0	+1	+2
	Forefoot ab/adduction	-2	-1	0	+1	+2	-2	-1	0	+1	+2
	Total										

Indirect Assessment	Left	Right
18. Leg length	ASIS-MM (mm) :	ASIS-MM (mm) :

19. Footwear	Shoe Type with % worn in average week	Trainer	%	Boot	%	Oxford/ lace	%	Court	**%**
		Slip on	**%**	Sandal	**%**	Bespoke	**%**	slipper	**%**

	Heel Height in average week (If yes to court, slip on or boot)	0-2.5cm	2.6-5cm	>5cm
20. Gait parameters	Walking aid	Yes	No	
	Lower Limb Asymmetry	Yes	No	
	Antalgic Gait	Yes	No	
	Ataxic Gait	Yes	No	
	Festinating gait	Yes	No	
	Hemiplegic	Yes	No	
	Spastic Gait	Yes	No	
	10m walk time (secs):			

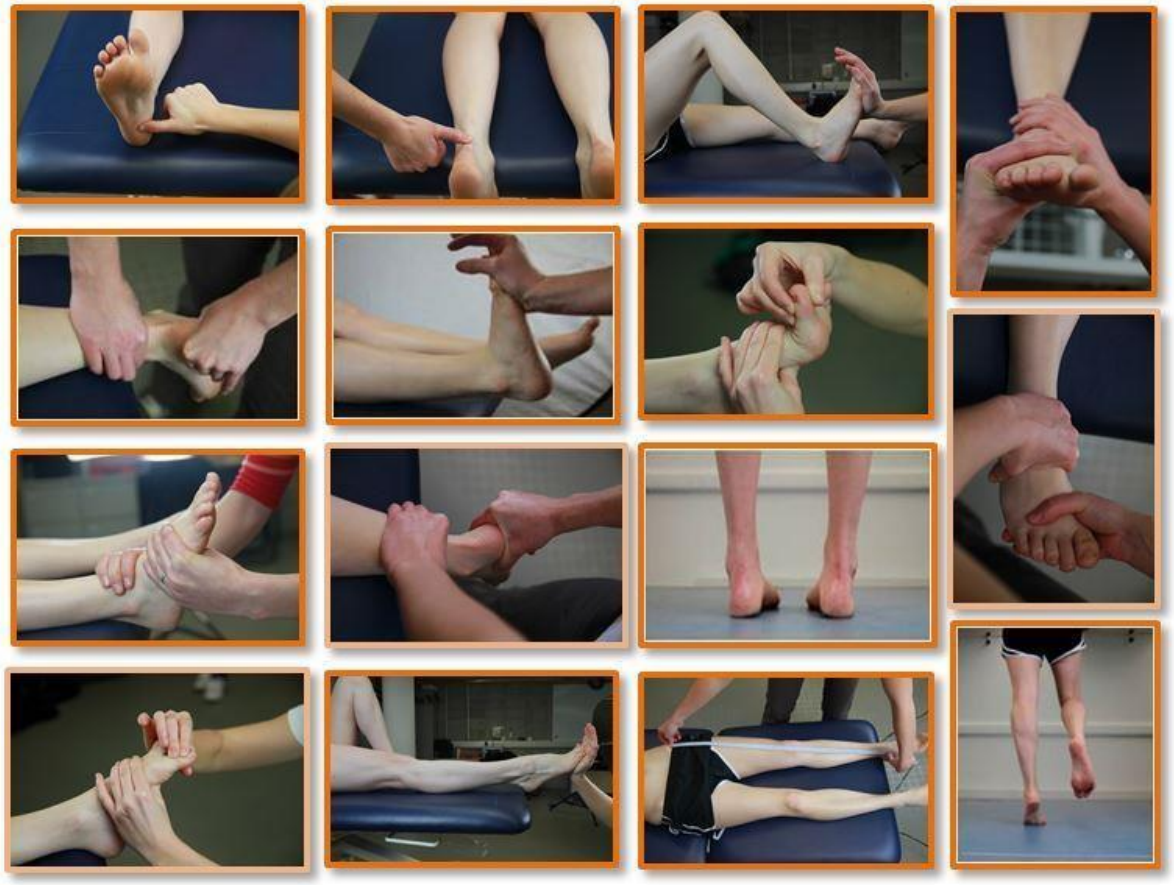

Figure 18. Photo examples of IMFAA

Permission was granted from volunteers within photos to use these pictures. Photos were authors own.

5.12 Discussion

Through an international consensus exercise we have established a core set of objective foot and ankle assessment measures to inform a standard protocol for future research and clinical evaluation. From this the IMFAA has been formed.

The IMFAA is unique as to our knowledge there is no evidence of a current standardised comprehensive musculoskeletal foot and ankle assessment protocol for clinical or research application. Clinical foot and ankle assessment is important to inform the management of lower limb conditions and disease. The absence of agreement for which assessment measures should be used to assess the foot and ankle in clinical practice is a current dilemma for researchers and

clinicians (Jarvis et al 2012). Whilst clinicians routinely use foot and ankle assessment measures, the evidence to support their use is weak, as highlighted by the finding in chapter four. Assessment protocols used within clinical settings are difficult to standardize because they are based on the clinicians subjective experience of what represents a significant clinical finding. This lack of standardisation makes any observation of clinical change difficult over time, between patients or between clinicians.

The development of many currently used clinical methods of assessing musculoskeletal foot and ankle status have no reliable objective foundations. Many of which are driven by the historical work of Root et al (1977), which suggests "normal" foot morphology is characterised and referenced to a neutral position of the subtalar joint at midstsance phase of gait. This theory is now contested as it has yet to be proven and the accuracy and reliability for measuring subtalar joint neutral has yet to be demonstrated (Picciano et al 1993; Chen et al 2008).

A variety of methods have since been theorised and developed including, but not limited to, Rose's Valgus Index (Rose 1991), Staheli's Plantar Arch Index (Staheli 1987), Platto' Structural Index (Platto et al 1991), longitudinal arch angle (Dahle et al 1991), the arch ratio (William and McClay 2000). These measures are limited in that associations to clinical outcomes such as foot pain or function have yet to be reported and as such the clinical relevance and minimally important clinical change values have not been established. Likewise to clinical validity, chapter four results showed questionable reliability in many historically used foot and ankle assessment.

FPI and ankle dorsiflexion were somewhat exceptions to this. Ankle dorsiflexion assessed in weight bearing was the only assessment where reported values remained almost perfect for both intra and inter-examiner reliability across at least three studies (Bennell et al 1998; Menz et al 2003; Krause et al 2011). An association was shown between the FPI and walking function (Redmond et al 2006), medial knee OA (Levinger et al 2010), some parameters of dynamic foot function in individuals with patella femoral pain (Barton et al 2011) and risk of foot and ankle overuse injuries in football (Cain et al 2007). Moreover these individual measures of foot ankle status do not provide clinicians or researchers with a comprehensive multi-dimensional assessment protocol. Instead each focuses upon a specific element of the foot and ankle alone, for example arch anatomy, forefoot structure or foot posture. A standardised comprehensive foot and ankle assessment protocol such as IMFAA that includes a variety of measures, which are not

limited to one parameter (i.e. movement, morphology and deformity), has potential to improve screening and the measurement of intervention success/failure.

Standardised assessment protocols have already been identified for OA of the knee (Cibere et al 2004) and hip (Cibere et al 2008) and for musculoskeletal disorders of the upper limb (Harrington et al 1998; Palmer et al 2000; Walker-Bone et al 2002). Consensus statements have been used to develop examination schedules for the diagnosis and classification of musculoskeletal disorders of the upper limb (Harrington et al 1998), recommendations for the diagnosis of knee and hand OA (Roddy et al 2005; Zhang et al 2005), the management of gout (Zhang et al 2006) and the classification criteria in systemic sclerosis (Fransen et al 2012).

The results of the consensus exercise provide the first step in the development of a standardised protocol for clinical musculoskeletal foot and ankle assessment measures, which may now be taken forward for validation. Validation will be of particular importance when considering the results of chapter four, in which a number of measures chosen to be included with IMFAA have previously shown limited validity and/or reliability, some have limited investigation for these constructs all together and a limited number were not identified within the literature review. It is likely the latter concern was due to the limitations of using expert opinion to inform search terms, which was ultimately done to reduce bias but may have inadvertently lost the potential for maximum coverage of terms.

As part of the initial validation process strength of recommendation scores were collected to provide a level of recommendation for clinical and research use of each measure based on a 1-10 scale (10 being the strongest recommendation). These findings suggest that observation of swollen/tender joints, HAV presence, ankle dorsiflexion with the knee flexed and extended, first metatarsal phalangeal joint range of movement and Foot Posture Index be highly recommended for use within musculoskeletal assessment of the foot and ankle in both clinical and research circumstances. The range of scores for all measures was consistently wide. This reflects limitations in using many current measures, particularly in research, and support the requirement to further test the validity of these measures. The strength of recommendation scores build upon the foundational findings from chapter four, which suggest FPI and ankle dorsiflexion are at least the most robustly tested measures, to provide a basis of suggestion for the measures to be included within musculoskeletal foot and ankle assessment.

It has been agreed that the IMFAA protocol should be used for screening purposes. It should be viewed as a core set of items that provide the minimal important information to determine musculoskeletal status and can be added upon depending upon clinical circumstance. At present a global scoring system is not recommended due to the lack of similarity between measurement categories, potential ambiguities of summation scoring and limitations of weighting scores based on a number of potentially unreliable measures and limited evidence to support others.

The IMFAA provides a standard approach to allow the inclusion of the foot and ankle within clinical research models. A standardised protocol such as the IMFAA will help to overcome the current difficulties we have in comparing foot and ankle status and studies. It has been agreed that all twenty measures require cross sectional and longitudinal validation and that use of the measures within IMFAA would help to ensure that future investigations involving the foot and ankle are comparable and data sets can be combined across studies. If the IMFAA is introduced to future cohorts it will provide the standardised method required to investigate the role of the foot and ankle.

The IMFAA also has valuable clinical applications. It may be used as a screening tool for the foot and ankle within different conditions, alongside other joint assessments. It will enable clinicians to standardise at least one part of an entire assessment process to monitor changes (progress or deterioration) between visits, following intervention and importantly between clinicians; this will be a valuable formality to ensure best practice where patients are often seen by a variety of clinicians over time. It may also be a potential clinical risk indicator following its validation across particular populations.

Strengths and Potential Limitations

While a range of consensus methods exists, two techniques have a long predominant history, namely the Delphi and the Nominal Group Techniques (NGT) (Fink et al 1984). The NGT tends to be limited to a smaller number of experts (usually 9-12), unlike the Delphi where there is no rule to govern the number of participants included (Jones and Hunter 1995). Unlike NGTs, the feature of anonymity within the Delphi allows members to express their opinions privately, potentially reducing the effects of social pressures from dominant characters or the majority within the group (Fransen et al 2012). Although compared to the NGT the Delphi technique is time consuming the main benefit, particularly in the current study where worldwide, multi-

professional input was vital, is that the Delphi does not have geographical limitations, making it ideal for international input.

The identification of experts has been a source of debate in the use of the `Delphi' (Keeney et al 2001). Whilst the selection of the expert panel is the vital first stage of the consensus process, it also raises methodological concerns. Studies have criticised the use of experts (Mckenna 1994), claiming the feature of the `Delphi' to represent valid expert opinion as scientifically overstated. There is also a clear potential for bias in the selection as the exact composition of the panel can affect the results obtained (Keeney et al 2001). To limit potential bias within this study, more than one inclusion criteria was applied, allowing for a variety of academic and clinical expertise. It also ensured the inclusion of experts from a variety of medical disciplines to reduce potential biases in assessment selections that may have been introduced between professions.

The application of the modified Delphi, which differs to the conventional Delphi by introducing a meeting within the process, may also be portrayed as a limitation. It has been stated that having a physical meeting contradicts one of the basic rules of the Delphi procedure, which is avoidance of situations that might allow one or more panel members to dominate the consensus process (Boulkedid et al 2011). The benefits of a meeting however are the face-to-face exchange of information, such as clarification of reasons for disagreement (Walker & Selfe 1996). In the case of the current study a meeting following the conclusion of the Delphi rounds allowed for the proposal of a future research agenda within a structured environment, which ensured clarity and provided an opportunity for expert feedback. This also allowed for expert confirmation in regard to the importance of gathering strength of recommendation scores.

5.13 Conclusion

The international consensus statement, using a Delphi technique, has provided a successful method of gaining expert agreement for a core set of musculoskeletal foot and ankle assessment measures, known as the Musculoskeletal Foot and Ankle Assessment. Observation of swollen/tender joints, hallux abducto valgus presence, ankle dorsiflexion with the knee flexed and extended, first metatarsal phalangeal joint range of movement and Foot Posture Index are highly recommended for use within musculoskeletal assessment of the foot and ankle for both clinical and research circumstances. It is recommended that the assessment measures be used for screening purposes. Face validity has been acquired and strength of recommendation values provided a level of recommendation for the use of measures. Further work is proposed to validate

the IMFAA across a variety of populations to cover the extremes of foot types and pathologies including normal, rheumatology, neurological and sporting populations.

6 Chapter Six

The relationship between musculoskeletal foot and ankle assessment on the prediction of outcomes in knee arthroplasty

6.1 Introduction

Study one and two (chapters 4 and 5) have informed the choice of two of the foot and ankle assessments; the FPI and ankle dorsiflexion. These were selected, by expert agreement, as the most highly recommended measures to be included within a battery of other physical knee assessments and were identified as the most robustly tested measures currently available. These measures were introduced to the COASt-Foot cohort, which is a subset of patients enrolled on the main COASt cohort (patients awaiting KA), with the addition of a foot pain questionnaire to address the main research question of this thesis:

"Can we use clinical foot and ankle assessment to improve the prediction of patient reported outcomes in knee arthroplasty?"

Attention is currently focused on the use of PROMS and the assessment of satisfaction. It is known that patients who are satisfied with their surgery may actually report poor scores on well-validated health outcomes questionnaires, as shown in the reported series on satisfaction after KA from the Swedish Knee Registry (Robertsson et al 2000). Therefore both functional/pain outcomes and satisfaction must be considered to allow for the interpretations of complete clinically meaningful outcome.

A number of predictors of outcome following KA have been identified. These include BMI (Foran et al 2004; Amin et al 2006; Gandhi et al 2010; Zeni & Snyder-Mackler 2010; Judge et al 2012; Baker et al 2013), anxiety, depression and social deprivation (Judge et al 2012), RA (Judge et al 2012; Hawker et al 2013), age (Nilsdotter et al 2003; Williams et al 2003 Judge et al 2012), and the number of troublesome joints and musculoskeletal comorbidities (Nilsdotter et al 2003; Hawker et al 2009; Perruccio et al 2012; Hawker et al 2013).

Whilst these studies have provided good insight into predictors of KA outcome, less than 20% of the variability in PROMs of KA has so far been explained (Judge et al 2012), suggesting there are other predictive factors still to be identified to improve our ability to recognise patients at risk of poor KA outcomes.

The one known study to observe the foot/ankle pain within the predictive context of KA outcomes was a cohort study by Peruccio et al (2012). Pain was however limited to joint with OA. Using a homunculus to determine the influence of more than one painful joint, Peruccio et al (2012) found individuals awaiting KA who reported painful or problematic ankles/feet/toes, that were affected by arthritis, had worse post-surgery WOMAC pain (β 1.24 95% CI 0.48, 2.00) and physical function scores (β 3.14 95% CI 0.69, 5.59). To the authors knowledge there is no other evidence for the role of foot pain, independent of foot OA, in KA outcomes.

To the thesis authors' knowledge there is no evidence to investigate the role of physical foot status in outcomes of KA. Study two established a core set of foot and ankle assessment measures via an evidence based approach, complimented with expert opinion. Together with MFPDI, these measures provide a standardised method of assessing of the foot and ankle across populations and over time and importantly informed the use of the foot posture index and ankle dorsiflexion within COASt-Foot, which aims to determine the influence of foot and ankle clinical assessments in the prediction of patient related outcomes in knee arthroplasty.

An additional measure of foot pain was introduced to COASt-Foot due to the importance of pain within disease. A measurement of foot pain that has often been used in epidemiology is the MFPDI. The MFPDI can be used for foot pain in different populations, with or without the presence of musculoskeletal disease. It has been validated in both the rheumatology and general population (Garrow et al 2000; Muller and Roddy 2009; Roddy et al 2009).

6.2 COAST-Foot Study aims and Objectives

The main aim of study was to determine the influence of a number of the agreed foot and ankle assessment measures on the prediction of 'patient reported outcomes' in knee. The following objectives were set in order to achieve this aim:

1) To conduct foot and ankle assessment measures (FPI, ankle dorsiflexion and MFPDI) to a prospective cohort of patients awaiting KA (COASt)

2) To determine baseline cross sectional characteristics of patients awaiting KA and determine how these are related to foot pain
3) To determine patient reported knee outcomes one year post KA surgery
4) To compare baseline pre-operative foot and ankle assessments with 1 year post-operative patient reported knee outcomes

6.3 Hypothesis

The decision to accept or reject the following null hypothesis will be determined by findings of the longitudinal study (part two):

H_0 Clinical foot and ankle assessment, including foot pain, does not affect patient reported outcomes following knee arthroplasty

H_1 Clinical foot and ankle assessment, including foot pain, has a positive or negative effect on patient reported outcomes following knee arthroplasty

6.4 Materials & methods

6.4.1 Study Design

COASt-Foot was a longitudinal prospective study to test the predictive ability of pre-operative clinical foot and ankle assessments, on post-KA outcomes. It was a subset sample from the COASt cohort, which is described in chapter one (section 1.1). Figure 19 depicts the COASt-Foot patient pathway within COASt and figure 20 provides a schematic outline of study three data collection. This chapter will be divided into two parts; part one is a pre-operative cross sectional study to observe the pre-operative characteristics of patients and determine how foot pain relates to these. This study includes all the pre-operative variables used in part two. Part two is a longitudinal study to determine the influence of the foot and ankle assessments in predicting patient reported outcomes one year following knee arthroplasty. Separate discussions are made for part one and two. Both studies were conducted on the same population, therefore recruitment, exclusions and demographics remain the same and will all be discussed within the following section.

6.4.2 Ethical considerations

University Hospital Southampton NHS Foundation Trust agreed sponsorship of the patient related studies relative to the Clinical Outcomes in Arthroplasty Study in June 2010 (see appendix 11 for

all correspondence related to ethical approval). University of Southampton professional indemnity insurance was also granted at this time. The programme of work was accepted onto the National Institute for Health Research (NIHR) Clinical Research Portfolio in April 2008. The study was also registered with the UK central research network at this time in accordance with the declaration of Helsinki of the World Medical Association (2008). Full ethical approval for the programme of work entitled "COASt - Clinical Outcomes in Arthroplasty Study- A study to assess a strategy for predicting patients at risk of poor functional outcome following lower limb joint arthroplasty" was obtained from Oxfordshire Research Ethics Committee A in December 2010. Approval was gained from Southampton University Hospitals NHS Trust Research and Development in January 2011. The study was accepted for completion at the Southampton Centre for Biomedical Research (SCBR), (formerly Wellcome Trust Clinical Research Facility (WTCRF)) in December 2010. Full approval from the local research and development department within Southampton University Hospitals NHS Trust was obtained in January 2011.

Subsequent to the submission of a substantial amendment request , approval for the addition of the Manchester Foot Pain and Disability Index questionnaire, was sought from the Oxfordshire Research Ethics Committee A and granted in October 2011 (Oxford REC A Reference: 10/H0604/91).

The following considerations were identified as potential ethical issues applicable to the investigation to date.

6.4.2.1 Consent

Human participants were involved within experimental research study three. Therefore informed consent procedures were adhered to.

6.4.2.2 Confidentiality

Data collected contained personal information regarding assessment findings and surgical procedure. However, only clinicians and researchers actively involved in the study had access to the data collected. All data collection phases utilised participant coding methods. Patient anonymity continues to be observed in all publications arising from this study. All data was stored in a lockable filing cabinet or on an encrypted password access device. The investigators duties as a researcher did not conflict with duties as a health care professional.

6.4.2.3 Participant Feedback

Results of COASt-Foot (part one) have been made fully available to all participants. Results of COASt-Foot (part two) will be made included within the next COAst newsletter, and have been freely available at the request of any participant. If there was any obvious requirement for podiatric input the appropriate referral was offered to be made into the local primary care podiatry service.

6.4.2.4 Potential risks and burdens to Participants

Participants were required to stand and lay for a period of time during physical assessments. Participants were given the opportunity to use an external aid for support such as a stick or crutch if this was normal to do so. When required standing assessment was staggered either side of that laying down in order to minimise the length of time standing for one given period. At least one clinician/researcher was available at all times to oversee the participant and give full explanations of procedures involved.

6.4.2.5 Withholding of intervention or procedure

This was a non-interventional observation study, as such no interventions considered part of routine care, were withheld and there was no requirement for the provision of further intervention.

6.4.2.6 Participant benefits

Participant involvement in this study provided no direct personal benefit or gain. Involvement or withdrawal from the study was fully discussed, was optional at any time, and had no direct consequence to the participants on-going medical care.

6.4.2.7 Withdrawal of Participants

Participants were able to withdraw for the study at any time. This was made clear in all patient and participant information sheets. They were reminded this at the time of consent. This had no effect on their on-going clinical care or involvement in other research studies.

6.4.3 Study population

Participants included within COASt-Foot study are a subset of patients successfully prospectively recruited onto the COASt study at either study site (Southampton or Oxford), awaiting primary KA.

6.4.4 Inclusion and Exclusion Criteria

Inclusion Criteria

- Enrolled on COASt study requiring primary KA (UKR or TKR)
- Signed informed consent gained from the potential participant
- Participant is at least 18 years of age on the day of signing the consent form.
- The participant is cognitively intact and sufficiently literate to complete the questionnaires and comply with study protocol

Exclusion Criteria

- Charcots arthropathy or other severe neurological disease
- Previous knee or ankle arthroplasty or fusion
- Inability to gain informed consent
- Revision of KA

6.4.5 Main outcome variables

- 1 year post-operative OKS (on 0-48 point scale)
- Patient acceptable symptom state (PASS) for one-year OKS (≥30 points)

6.4.6 Main Predictor variables

- Foot pain (either foot: defined as present or absent by MFPDI)
- Index limb foot posture Index Items:
    - Eversion/inversion of calcaneus
    - Medial longitudinal arch
    - Talonavicular Joint (TNJ) bulge
    - Curves above and below lateral mal
    - Talar head palpation

    - Ab/add forefoot

- Index limb ankle dorsiflexion (degrees)

6.4.7 Covariates

- Age (years)
- Gender
- BMI (Kg/m^2)
- Fixed Flexion Deformity (fixed position over 0 degrees knee flexion whilst in relaxed extension)
- Other joint pain (back pain)
- Pre op index knee pain (OKS 48 point score)
- Depression (Hospital Anxiety and Depression Score [HAD])

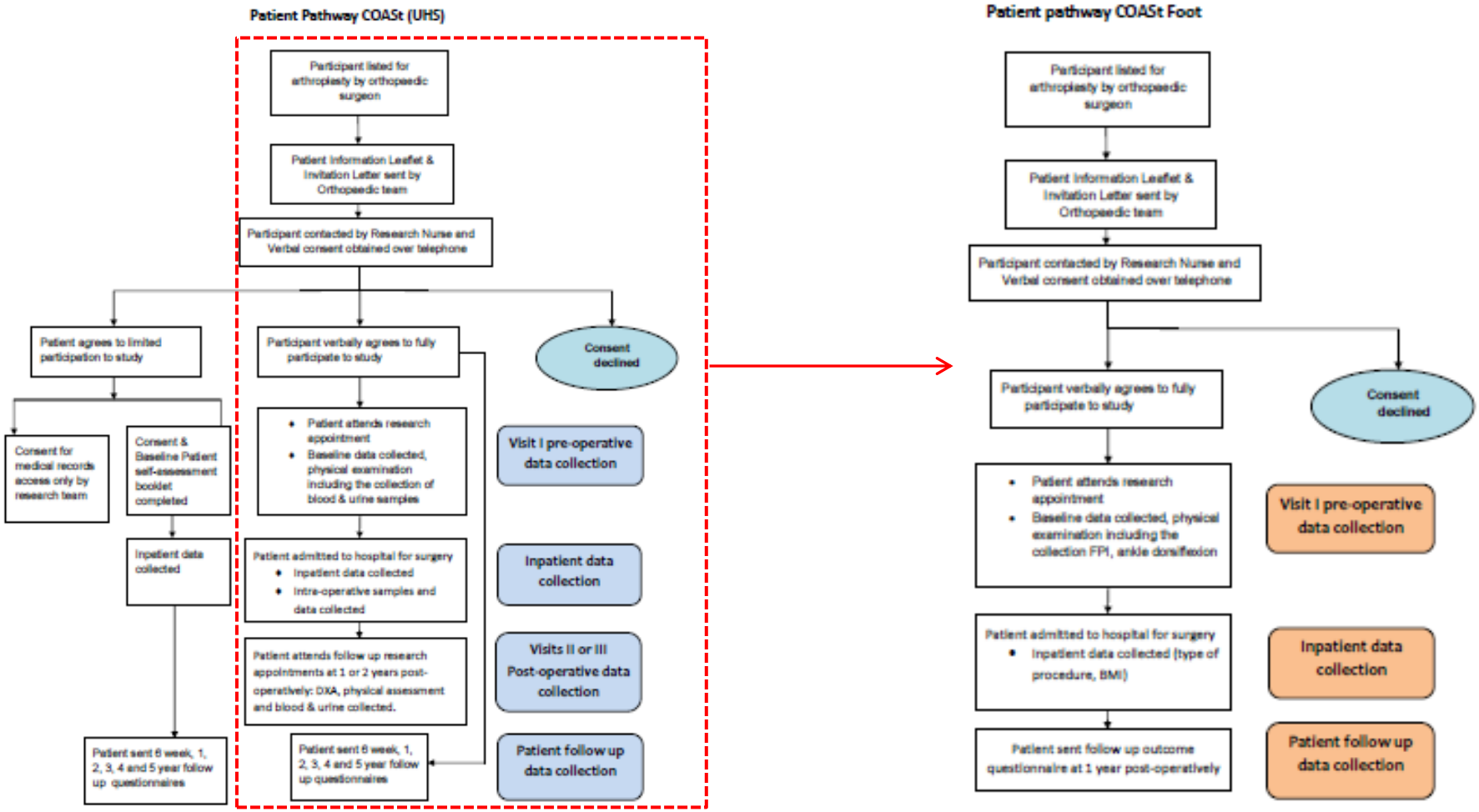

Figure 19. Patient pathway of study three within COASt. Adapted from COASt 5 year report with permissions

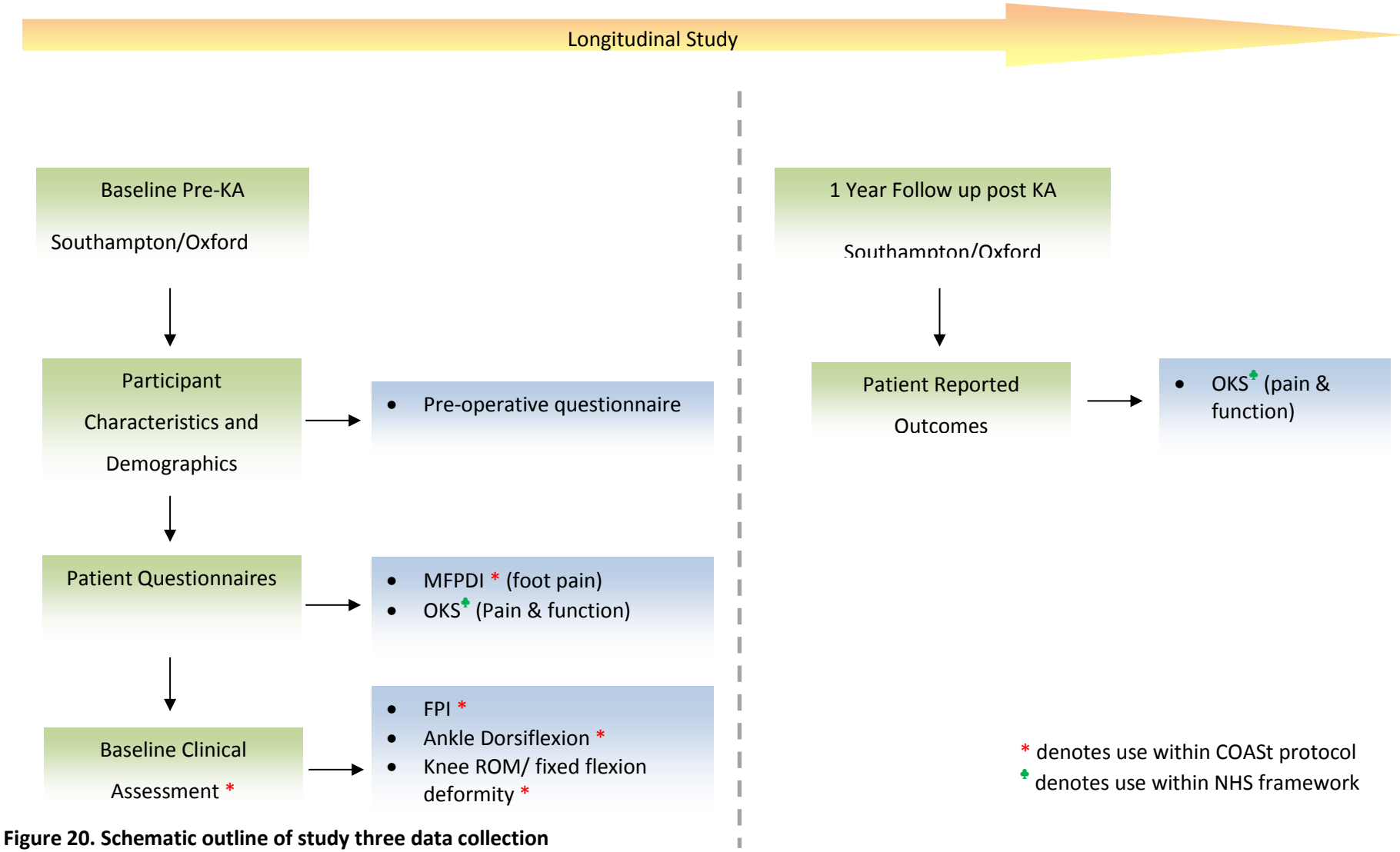

Figure 20. Schematic outline of study three data collection

6.4.8 Sample Size Determinants

Power calculations indicated that a sample size of 113 KA participants would be sufficient to detect a correlation coefficient of 0.275 with 80% power and 2-sided significance at the 5% level (including an adjustment factor for 10% loss to follow up).

In the absence of evidence within literature to suggest significance, a moderate association between OKS and Foot Posture Index was anticipated. Cohen (1988) suggests a correlation coefficient of 0.30 is suitable as a moderate effect size.

For regression equations using six or more predictors, an absolute minimum of 10 participants per predictor variable is appropriate (with outcome of interest) (Hosmer & Lemeshow 2003; Wilson et al 2007). Therefore a sample size of n=70 would be sufficient to detect an adequate effect size for those who achieve a post-operative OKS PASS (see section 6.4.13 for full description) in the foot pain model consisting 7 degrees of freedom.

6.4.9 Data Collection and Outcome Measures

The COASt-Foot study utilised the following information, which was also collected as part of COASt: participant phenotypic, demographic, clinician assessed knee alignment and function, patient reported knee scores (pre-operative OKS), patient reported foot pain (MFPDI), clinician assessed foot and ankle measures including FPI and ankle dorsiflexion. All were collected during the patients COASt pre-operative assessments. Other measures back pain and HAD score.

PROMs were repeated at one year following operation. This included OKS as the primary outcome (See figure 21 for study three data collection process and the authors contributions).

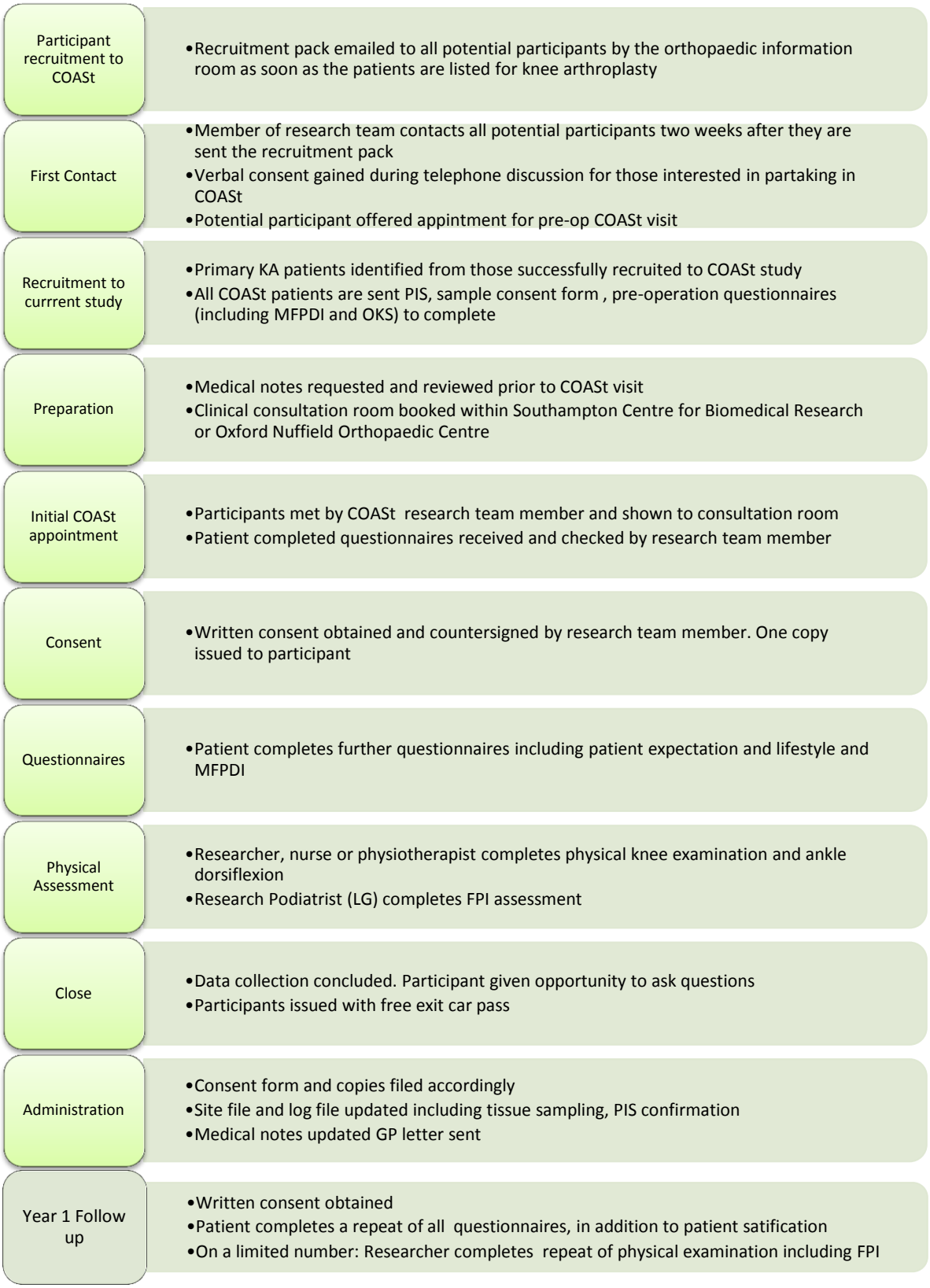

Figure 21. Study three data collection process

6.4.10 Demographical, participant characteristic and anthropometric information

Data collected for the COASt study and incorporated in COASt-Foot study included: age, gender, BMI, underlying arthritic condition (including severity and identification of other affected joints), co-morbid medical pathologies (i.e. neurological disorders), foot pain, knee, back pain, previous foot and ankle trauma or surgery, surgical history, HAD score.

Demographical data was collected when enrolling on the COASt study (appendix 14 includes an example of the pre-operation booklet sent to KA patients to collect this information). Participant characteristics were collected at pre-operation assessments in Southampton by Senior Research Nurse Carole Ball (CAB) and in Oxford by Research Physiotherapists Adam Toner (AT) or Jennifer Rowe (JR). OKS was collected at this time, and at one year post surgery via post (appendix 15). Additional foot and ankle data was collected at this time for purposes of the COASt-Foot study. Permissions to use outcome measures, including those above, were attained automatically via the universities association with ISIS Innovations, Oxford (see appendix 16 for email correspondence).

6.4.11 Clinical Foot and Ankle Assessments

All clinical foot, ankle and knee assessments were carried out by a trained member of the COASt clinical research team in Southampton (LG and CAB) and Oxford (LG, AT and JR). Particulars of the foot and ankle assessment method were ascertained from experimental study one and two (chapters 4 & 5). As an addition to MFPDI (appendix 17), the inclusion of which in COASt-Foot had been decided a priori, the foot Posture Index (appendix 18) and ankle dorsiflexion (appendix 19) were identified as the most appropriate assessments. These were conducted on each participant during their COASt pre-operative visit.

6.4.11.1 Ankle Dorsiflexion

Ankle Dorsiflexion was assessed using a goniometer placed on lateral aspect of calcaneus, one arm bisecting the midpoint of lateral lower leg and other arm orientated at 90^{O}, whilst the participant lays supine. The examiner applies pressure passively dorsiflexes the ankle, whilst measuring the movement with the goniometer. The measurement is made twice; once with the knee extended and once with it flexed to approximately 30^{O} flexion.

6.4.11.2 The Foot Posture Index (FPI)

The FPI provided a composite measure of overall foot posture (Redmond et al 2001). The FPI consists of six criteria: talar head palpation, curves above and below the malleoli, inversion/eversion of the calcaneus, bulge at the region of the talonavicular joint, congruence of the medial longitudinal arch and abduction/adduction of the forefoot on rearfoot (see table 12 FPI reference score sheet).

Total FPI score is the sum of 6 ordinal items. This is an ambiguous total which is difficult to interpret due to the clinical variation in the 6 individual items. For example in a foot that is largely clinically representative of a neutral posture, one item such as congruence of the medial longitudinal arch may be scored as -2 due to a cavoid medial foot type, whilst all other items may be scored at 0. This would summate to an overall total of -2, actually suggesting a supinated, rather than neutral foot type. The COASt-Foot study modelled and analysed each FPI item individually, not as a total score.

Individual FPI item scores are based on an ordinal scoring system. For pragmatic representation the original individual scores of -2 to +2 were categorised into three categories by merging the definitions on either side of 0 (table 13).

Table 12. FPI item scoring

Rearfoot Score	**-2**	**-1**	**0**	**1**	**2**
Talar head palpation	Talar head palpable on lateral side/but not on medial side	Talar head palpable on lateral side/slightly palpable on medial side	Talar head equally palpable on lateral and medial side	Talar head slightly palpable on lateral side/ palpable on medial side	Talar head not palpable on lateral side/ but palpable on medial side
Curves above and below the malleoli	Curve below the malleolus either straight or convex	Curve below the malleolus concave, but flatter/ more shallow than the curve above the malleolus	Both infra and supra malleolar curves roughly equal	Curve below malleolus more concave than curve above malleolus	Curve below malleolus markedly more concave than curve above malleolus
Calcaneal inversion/eversion	More than an estimated 5° inverted (varus)	Between vertical and an estimated 5° inverted (varus)	Vertical	Between vertical and an estimated 5° everted (valgus)	More than an estimated 5° everted (valgus)
Forefoot Score	**-2**	**-1**	**0**	**1**	**2**
Talo-navicular congruence	Area of TNJ markedly concave	Area of TNJ slightly, but definitely concave	Area of TNJ flat	Area of TNJ bulging slightly	Area of TNJ bulging markedly
Medial arch height	Arch high and acutely angled towards the posterior end of the medial arch	Arch moderately high and slightly acute posteriorly	Arch height normal and concentrically curved	Arch lowered with some flattening in the central portion	Arch very low with severe flattening in the central portion – arch making ground contact
Forefoot abd/adduction	No lateral toes visible. Medial toes clearly visible	Medial toes clearly more visible than lateral	Medial and lateral toes equally visible	Lateral toes clearly more visible than medial	No medial toes visible. Lateral toes clearly visible

(Downloaded from: http://www.leeds.ac.uk/medicine/FASTER/z/pdf/FPI-Reference-sheets.pdf on 01/04/2015)

Table 13. FPI item scoring transformations- authors own

Original item scoring	-2	-1	0	+1	+2
New Categories	0		1	2	
Talar head palpation original score	Talar head more palpable on lateral side		Talar head equally palpable medial and lateral side	Talar head more palpable on medial side	
Curves above & below malleoli	Curve below malleolus flatter or more convex than curves above		Infra and supra curves roughly equal	Curves below malleolous more convex than curves above	
Calcaneal inversion/eversion	Inverted		Vertical	Everted	
Talonavicular congruence	Area of TNJ concave		Area of TNJ flat	Area of TNJ bulging	
Medial arch height	Arch height higher than normal		Arch height normal	Arch lower than normal	
Ab/adduction of forefoot	Medial toes more visible than lateral		Medial and lateral toes equally visable	Lateral toes more visible than medial	

Prior to analysis the foot posture index items were explored. It was observed that zero participants scored 0 (supinated) within the items ab/adduction of forefoot. To address the potential modelling issues which arise when a group includes zero participants were categorised both items into the two most biologically plausible scoring categories: 0 (supinated) and 1 (neutral) were combined to one category (0) whilst 2 (pronated) remained as the other (1). This categorisation was also performed for curves above and below the malleolous, which had particularly low numbers in one group.

6.4.11.3 Manchester foot Pain and Disability Index

The MFPDI is a self-administered, questionnaire consisting of 19-items assessing foot pain and disability. It contains three constructs (four subscales) which reflect disabilities associated with foot pain and two additional items relating to work and leisure. The three constructs identified within the MFPDI are:

- Functional limitation (10 items)
- Pain intensity (7 items)
- Personal appearance (2 items)

Responses are recorded on a three point scale:

- None of the time
- On some days
- On most /every day(s)

(Garrow et al 2000)

<u>Foot pain</u>

Every patient was questioned whether they had current foot pain. If so they were requested to complete the Manchester Foot Pain and Disability Index questionnaire. Presence of foot pain is confirmed where one of the 19 items of the questionnaire is selected as “on some days or on most /every day(s)” (Roddy et al 2009; Menz et al 2011). The use of the MFPDI would allow for further exploration of the type of foot pain dependant on results of initial analysis.

6.4.12 Clinical Knee Assessments

Clinical knee assessments were carried out by CAB in Southampton or AT/JR in Oxford within the same appointment to that of foot and ankle assessments. Fixed flexion deformity was based upon a standardised method of examination to measure the degrees of knee extension with a goniometer (appendix 20). Fixed flexion deformity was present if the patient was unable to extend the knee to 0 degrees whilst in supine lying position. The amount of fixed flexion was measured from 0 degrees and over.

6.4.13 Clinical Questions

6.4.13.1 Hospital Anxiety and Depression Score (HAD)

A score for each subscale (anxiety and depression) can range from 0-21 with scores categorized as follows: normal (0-7), mild (8-10), moderate (11-14), severe (15-21) (Zigmond & Snaith 1983). Via a systematic review of a large number of studies, Bjelland et al (2002) identified a cut-off point of 8/21 for anxiety or depression. This was therefore used as a cut off for depression.

6.4.13.2 Rheumatoid Arthritis

The presence of rheumatoid arthritis was based on the patient answering the question: “Do you have Rheumatoid arthritis” Yes/No. 11% of patients reported having RA. RA and OA are commonly confused within the general public; therefore the medical records of every patient reporting RA were checked by the thesis author and adjudicated with the specialist rheumatology research nurse. Eight patients reporting RA had no evidence for the condition within their medical records and this was therefore changed accordingly within the study database.

6.4.13.3 Oxford Knee Score

The OKS is a 12-item questionnaire that addresses pain and functional disability in relationship to the patient’s knee problems (Murray et al 2007). In each case, item responses have five categories and are Likert scaled. The COASt study used the original OKS, where scores from each question were added so that the overall figure lies between 12 and 60, with 12 being the best outcome (Dawson et al 1998). This scoring system has since been modified to a system whereby each question has been scored between 0 and 4, with 4 being the best outcome, produces overall scores running from 0 to 48, with 48 being the best outcome (Murray et al 2007). The 60 to 12 system may be converted to the 0 to 48 score and vice versa by subtracting the score from 60

(Weale et al 2001). To account for the requirement to attain a clinically meaningful outcome the OKS scores within the COASt-Foot study were converted to from the 12-60 to the 0-48 score.

6.4.13.4 Post-operative OKS Outcome

The COASt-Foot study aimed to use thresholds that represent whether a patient has or has not achieved a clinically meaningful outcome. Even if the patient reports a bad outcome in terms of pain and function, as measured by OKS, they may still be satisfied with surgery (Baker et al 2007) therefore satisfaction must be considered within OKS outcome. In a previous study by Judge et al (2012), 54.6% of KA patients who completed outcome surveys reported being satisfied with surgery, even though according to their OKS scores they had no change in symptoms or their symptoms had worsened six months after surgery. Judge et al therefore identified thresholds that represent whether or not a patient achieved a clinically meaningful outcome, anchored on satisfaction.

The Patient Acceptable Symptom State (PASS) score threshold was identified for the OKS in order to define a 'satisfactory symptom state' therefore differentiate between patients with extremely high versus high overall levels of satisfaction with surgery. For the six-month OKS, 96.7% of patients were satisfied using a score of 30 points or above, compared with 70.1% of patients not meeting the threshold (Judge et al 2012).

The outcome was split into categories based on patient satisfaction. Judge et al (2012) suggested a cut-off point of 30 in the OKS at six-months as optimal since it maximised sensitivity (77.8%) and specificity (78.2%), identified via the 45 degree line on the ROC curve (AUC = 0.85). However, this cut-off point was estimated based on data from patients following a primary TKR, using a threshold of 50 out of a total possible score of 100 in a VAS satisfaction question answered by patients six months after their operation.

The use of such a score in COASt-Foot study was dependant on the validity of PASS at one year after KA. Unpublished work was recently undertaken by research members of the COASt study group to replicate the method followed by Judge et al (2012) on the HES-PROMs data. This allowed for the estimation of more robust cut-off points derived from a much larger and representative sample, using satisfaction at one year following surgery as the anchor, and identifying patients as 'satisfied' when their answer to the question 'How would you describe the results of your operation?' were 'Excellent', 'Very good' or 'Good', leaving as dissatisfied those who answered 'Fair' or 'Poor'. Data from 95,349 patients undergoing a primary KA were used to

estimate a cut-off point after primaries, whilst data from 3,068 patients who underwent a revision KA were used to estimate a separate cut-off point following revisions. The cut-off in the OKS anchored in satisfaction one year after surgery was estimated to be 30 for primary KAs (sensitivity=80.7%, specificity=82.0%, AUC=0.89). This finding shows that the 6 month post-operative OKS cut-off identified by Judge et al (2012) is representative of a satisfaction based one year cut-off. The current study therefore adopted a PASS score of 30 or above as a cut-off for a clinically meaningful good outcome.

6.4.14 Analysis

All analysis was completed in Stata version 13.0 (Stata Corp, College Station, Texas, USA). Prior to analysis, data distributions were checked for inconsistencies, outliers and missing information.

For part two (longitudinal study) two methods were used to identify predictors of (i) statistically important outcomes using the one year OKS and (ii) clinically important outcomes using a PASS cut off for one year post-operative OKS. Within each method there were three models (six models in total) to test the relationships between the independent variables i) foot pain ii) ankle dorsiflexion and iii) foot posture index items against each outcome (figure 22).

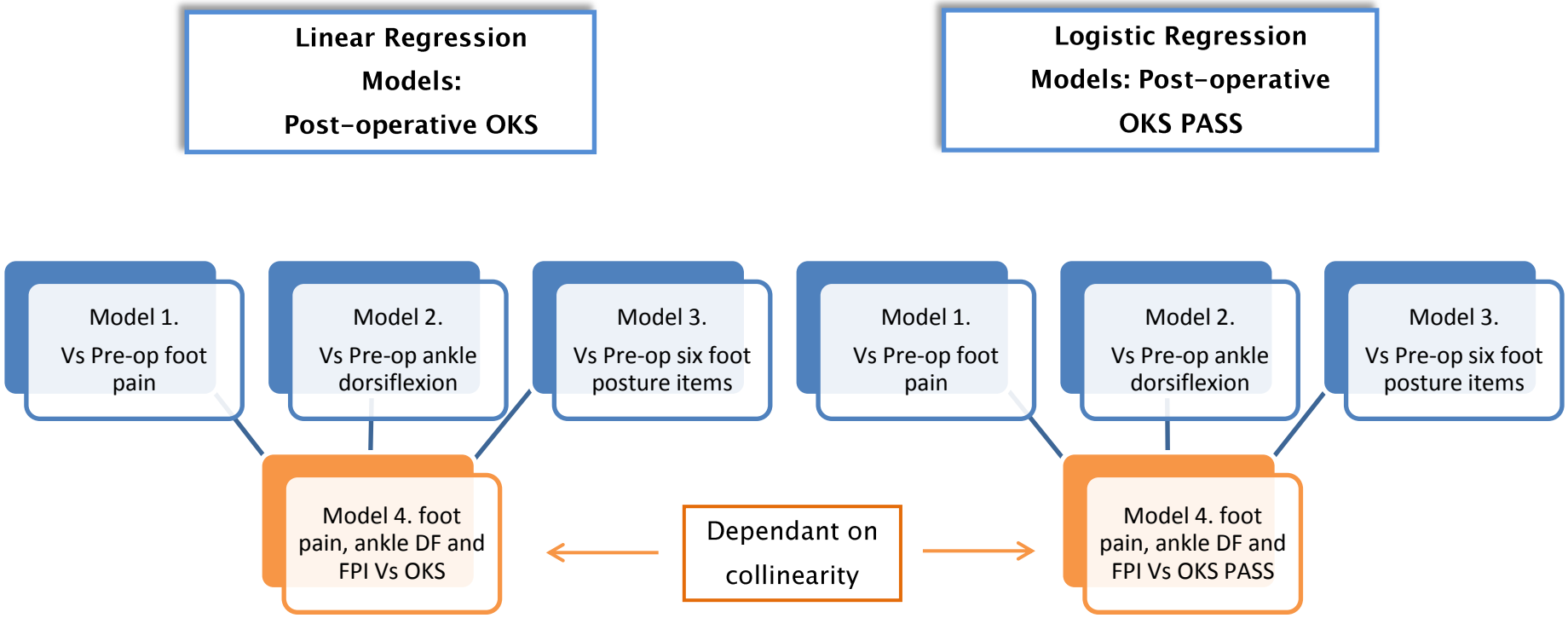

Figure 22. Statistical Modelling- Longitudinal Study

6.4.14.1 Descriptive statistics

Descriptive statistics were used to gain an understanding of the distribution of data for each variable. Distributions of variables were explored by creating histograms and frequency tables. The demographic and clinical characteristics of the study participants are presented as the mean, standard deviation (SD) and frequencies.

6.4.14.2 Univariable Analysis

Univariable analysis was undertaken to test the association of one explanatory variable at a time with the outcome (unconditional association).

6.4.14.3 Testing of collinearity

If two of the explanatory variables were highly correlated with each other, they may have caused problems during multivariable analysis because they would potentially be explaining almost the same variability in the outcome. Therefore it was necessary to examine associations/correlation between explanatory variables and exclude one of the pair, or in the case of the main study variables, separate them into separate multivariable analysis. Within the current analysis there was little requirement to test this for the majority of covariates as they were clinically independent of one another with little-to-no similarity in clinical factors. It was however necessary to determine any relationship between the main study variables (foot pain, ankle dorsiflexion and foot posture items) to ensure the most appropriate modelling. Linear and Logistic regression was used to determine the relationship between these variables.

Linear regression indicates that the presence of foot pain was not associated with a reduction in ankle dorsiflexion (β -2.95, CI -6.11, 0.21 P=0.067). Having a difference in foot posture, indicated by a malleolar curvature score of 1 compared to 0 was not associated with an increase in ankle dorsiflexion (β -2.88 CI -5.10, 0.23, P=0.069). A change in foot posture score, in any of the other five items was not associated with a change in ankle dorsiflexion (P>0.05) (Table 14). Logistic regression indicates that the odds of foot pain are not statistically higher or lower with a difference in any of the six foot posture items (P>0.05) (table 15).

Results suggest no significant association between foot pain, ankle dorsiflexion and foot posture. These variables could therefore be modelled together (figure 22, above).

Table 14. Linear regression to test -association of foot and ankle assessments

Predictors		Pre-op ankle dorsiflexion Univariable Coefficient (95% CI)	P-value
Foot Pain		- 2.95 (-6.11, 0.21)	0.067 *
Index limb Talar head palpation	1 (Talar head equally palpable medial and lateral side) compared to 0 (Talar head more palpable on lateral side)	1.78 (-4.15, 7.70)	0.59
	2 (Talar head more palpable on medial side) compared to 0	0.53 (-5.18, 6.23)	0.18
Index limb Curves above and below lat malleolus[¥]	0 (Area of TNJ concave or Area of TNJ flat) compared to 1 (Area of TNJ bulging medially)	-2.88 (-5.10, 0.23)	0.069
Index limb Eversion/inversion of calcaneus	1 (calcaneus vertical) compared to 0 (calcaneus inverted)	-2.88 (-7.65, 1.89)	0.234
	2 (calcaneus everted) compared to 0	-3.50 (-8.70, 1.69)	0.184
Index limb Talonavicular Joint bulge	1 (Area of TNJ flat) compared to 0 (Area of TNJ concave)	1.90 (-3.58, 7.38)	0.493
	2 (Area of TNJ bulging) compared to 0	-0.62 (-6.21, 4.96)	0.826
Index limb Medial longitudinal arch height	1 (Arch height normal) compared to 0 (Arch height higher than normal)	3.17 (-2.78, 9.13)	0.293
	2 (Arch lower than normal) compared to 0	2.05 (-4.11, 8.20)	0.511
Index limb Abbduction/adduction of forefoot on rearfoot[¥]	1 (Lateral toes more visible than medial) compared to 0 (Medial toes more visible than lateral or Medial and lateral toes equally visable)	-0.57 (-3.72, 2.59)	0.723

[¥]further categorised due to lack of observations in one group
*Denotes statistical significance at P=<0.05

Table 15. Logistic regression to test -association of foot and ankle assessments

Predictor Variables		Pre-op foot pain (present) Univariable OR (95% CI)	P-value
Index limb Talar head palpation	1 (Talar head equally palpable medial and lateral side) compared to 0 (Talar head more palpable on lateral side)	1.26 (0.28, 5.63)	0.766
	2 (Talar head more palpable on medial side) compared to 0	1.81 (0.43, 7.66)	0.417
Index limb malleolar curvature[¥]	0 (Area of TNJ concave or Area of TNJ flat) compared to 1 (Area of TNJ bulging medially)	1.63 (0.76, 3.47)	0.209
Index limb calcaneal inclination	1 (calcaneus vertical) compared to 0 (calcaneus inverted)	1.22 (0.37, 3.98)	0.742
	2 (calcaneus everted) compared to 0	1.67 (0.47, 5.96)	0.432
Index limb Talonavicular Joint bulge	1 (Area of TNJ flat) compared to 0 (Area of TNJ concave)	0.74 (0.19, 2.88)	0.688
	2 (Area of TNJ bulging) compared to 0	1.91 (0.49, 7.42)	0.351
Index limb Medial longitudinal arch height	1 (Arch height normal) compared to 0 (Arch height high)	1.12 (0.26, 4.91)	0.879
	2 (Arch lower than normal) compared to 0	1.73 (0.38, 7.86)	0.480
Index limb Ab/adduction of forefoot on rearfoot[¥]	1 (Lateral toes more visible than medial) compared to 0 (Medial toes more visible than lateral or Medial and lateral toes equally visible)	0.57 (0.26, 1.23)	0.151

[¥]further categorised due to lack of observations in one group

*Denotes statistical significance at P=<0.05

6.4.14.4 Multivariable Analysis

Associations between exploratory variables and the outcome were tested after accounting for other variables and confounders. In addition to the variables found to be significant in the univariable analysis (and not highly correlated with each other), biological confounders (variables that have been shown to be associated with the outcome as well as exposure or study variable/s in previous studies, or are likely to confound the association between the exposure and outcome) were also included in the stepwise multivariable modelling process, whether or not they were unconditionally associated with the outcome.

Forward multivariable regression modelling was chosen. Significance (α-level) was set at 0.05. This model allowed all variables to be fit individually into a regression model, then kept or discarded dependant on meeting the significance level and providing an effect size change of at least 20% (Hosmer and Lemeshow, 2000).

Backward regression (model is fitted with all potential predictors, then variables are removed) was not chosen due to the modest size of the data set in relation to the number of potential variables to include (i.e. the analysis would begin with a model which has more than 1 variable for every 10 observations, therefore making the model unstable).

6.4.14.5 Variable selection

Forward selection was used, starting with a null model then adding one variable at a time, retaining a variable if it was significant. Exposure/study variables and known confounders, if any, were included in all the step wise models.

Continuous outcome (Longitudinal study only)

Post-operative OKS was used on a continuous scale of 0-48 (48 being the best outcome).

Binary outcome (Longitudinal study only)

An established OKS PASS score cut-point of ≥30 was used to identify those patients who achieved a good or poor outcome based on pain and function, anchored to satisfaction (section 6.4.13.4).

The outcome is a binary variable, based on whether or not the patient achieved a PASS at one year. Logistic regression modelling was used to identify predictors of the one year PASS score.

6.4.14.6 Diagnostics

Regression diagnostics were checked to ensure assumptions underlying the regression models were met, particularly due to the potential ceiling effects seen in post-operative OKS.

Linear Regression diagnostics:

Residuals (differences between observed and fitted values) were assessed for normality using histograms and QQ-plots. Homoscedasticity (variance of residuals) was assessed using a scatter plots. The assumption of homoscedasticity is that the variance around the regression line is the same for all values of the predictor variable. If this assumption is violated there will be an unequal variation of points around the regression line along the x-axis.

Logistic Regression diagnostics:

The Hosmer-Lemeshow Goodness of fit test was used to indicate how well the logistic regression model fits the data. This was used to test whether the observed binary responses (Y= OKS PASS), conditional on a vector of covariates (risk factors and confounding variables) were consistent with predictions from the logistic regression model. It is a test of the null hypothesis that the fitted model is correct (in other words it indicates the extent to which the model fits the data) (Hosmer and Lemeshow, 2000). H^0= there is no difference between observed and model-predicting values.

The aims of COASt-Foot study (study three) were:

1) To describe the prevalence of foot characteristics in patients awaiting arthroplasty and determine the relationship of foot pain to other pre-operative variables (cross-sectional).

2) To determine the influence of a number of the agreed foot and ankle assessment measures on the prediction of patient reported outcomes in knee arthroplasty (longitudinal).

The following section of this chapter is therefore divided into two parts:

Part 1) cross sectional study to observe the pre-operative characteristics of patients with and without foot pain prior to knee arthroplasty

Part 2) longitudinal study to determine the influence of the foot and ankle assessments in predicting patient reported outcomes one year following knee arthroplasty.

Separate methods, results and discussions are provided part one and two.

Part one:

Cross sectional study: Foot and ankle characteristics in patients awaiting Knee Arthroplasty

The relationship of foot pain to pre-operative variables such as age, gender, knee pain and function, back pain is unknown. It would be beneficial to understand these relationships to inform the characteristics of patients who are to be treated with knee arthroplasty. This cross sectional case-control study was therefore undertaken, within a subset of cohort study (COASt), to determine if particular pre-operative characteristics were associated with foot pain.

6.4.15 Study cohort characteristics

In a prospective cohort study of patients awaiting total knee arthroplasty (COASt), a consecutive subset of patients completed a baseline foot pain questionnaire (MFPDI) and had foot and ankle assessments undertaken (FPI and ankle dorsiflexion). A summary of the demographic and clinical characteristics of the study participants is shown in table 16.

6.5 Aim

The aim of this study was to determine the relationship of pre-operative characteristics and foot pain in patients awaiting knee arthroplasty.

6.5.1 Outcome

- Foot pain (present/absent)

6.5.2 Exposures

- Age (years)
- Gender
- BMI (Kg/m2)
- Fixed Flexion Deformity (fixed position over 0 degrees knee flexion)
- Back pain
- Pre op index knee pain and function (OKS 48 point score)
- Depression (HAD >8 cut off)
- Ankle dorsiflexion (degrees)

- Eversion/inversion of calcaneus
- Medial longitudinal arch congruence
- TNJ bulge
- Curves above and below lat mal
- Talar head palpation
- Ab/add forefoot

6.6 Results

6.6.1 Exclusions and loss to follow up

Reasons for exclusions in COASt-Foot and the number of participants lost to one-year follow up are shown in table 16.

Table 16. Reasons for exclusion and loss to follow up

Reasons for exclusion	**Southampton**	**Oxford**	**Total**
Revision	5	5	10
Resurfacing	1	0	1
PTF replacement	2	0	2
Neuropathy	2	1	3
Neurological disorder	3	0	3
Death	4	0	4
No Surgery	10	0	10
Surgery on hold/delayed	7	0	7
			40
Reasons for loss to follow up	**Southampton (n=104)**	**Oxford (n=29)**	**Total**
No Follow up returned	8	0	8
Incomplete FU	0	4	4
Passed inclusion for inputting schedule	7	0	7
	n=89	n=25	19

6.6.2 Participant Recruitment Procedure

Participants were recruited from the COASt study criteria; patients awaiting primary KA, identified from pre-existing data held at Southampton General Hospital or Oxford NOC. Potential participants were sent a participant information sheet (appendix 12) and a postal letter of invitation (appendix 13) that describes the study protocol, their proposed involvement and

additional questionnaire based involvement. Participants were contacted by an associated research nurse a minimum of two weeks following this, to allow sufficient time to consider participation. On receipt of participants initial verbal intention to be involved the COASt research nurse agreed a mutually convenient time for the participant to attend a pre-assessment appointment, in order to complete baseline measures, clinical assessments and questionnaire completion. Participants were given the opportunity to discuss details of the study with the chief investigator of COASt (NKA).

6.6.3 Recruitment – COASt-Foot Study

Recruitment for COASt-Foot can be seen in figure 23.

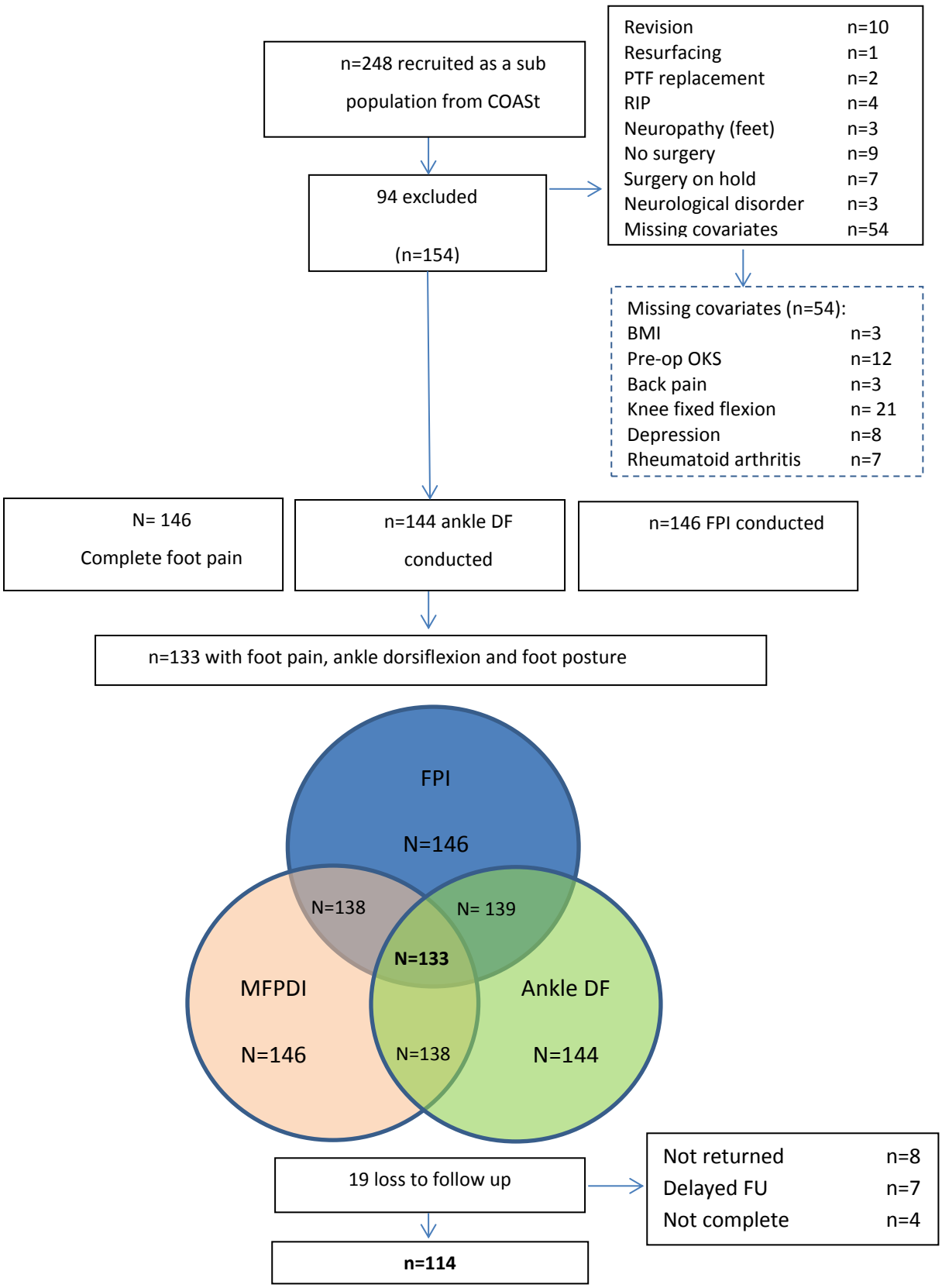

Figure 23. Patient recruitment schematic

Differences in baseline demographic and clinical characteristics were explored between those with and without foot pain. Descriptive summaries were produced for all variables (table 17) based on the appropriate statistical method for the distribution of each variable (figures 24-27). These variables were then compared between those with and without foot pain using Welch's test (for unequal variance) and relationships of certain variables with foot pain were examined using Chi-squared tests or Fishers Exact (table 18). Box & Whisker Plots were provided to illustrate differences between continuous exposure variables (figures 28-31). This was followed by logistic regression analysis to identify the degree of relationship between pre-operative characteristics and foot pain (table 19).

Table 17. Descriptive summaries of baseline demographics and clinical characteristics

Variables		**Baseline (n=114)**
Age, mean (S.D), years		65.70 (10.10)
BMI, mean (S.D), Kg/m^2		31.36 (4.81)
Gender, n (%)	Male Female	57 (50.00) 57 (50.00)
Back pain, n (%)	Present Absent	47 (41.23) 67 (58.77)
Index leg fixed flexion deformity , n (%)	Present Absent	60 (52.63) 54 (47.37)
Depression, n (%)	Present Absent	20 (17.54) 94 (82.46)
Self-reported (adjudicated) RA	Present Absent	7 (6.14) 107 (93.86)
Index limb Ankle Dorsiflexion, mean (S.D), degrees		10.52 (8.41)
Pre-operative OKS, mean (S.D)		21.63 (6.62)
Foot Pain n (%)	Present Absent	45 (39.47) 69 (60.53)
Pre-operative index limb Talar head palpation, n (%)	0 (score category) 1 (score category) 2 (score category)	10 (8.77) 40 (35.09) 64 (56.14)
Pre-malleolar curves, n (%)	0 1 2	4 (3.51) 60 (52.63) 50 (43.86)

Pre-operative index limb calcaneal inclination, n (%)	0 1 2	15 (13.16) 66 (57.89) 33 (28.95)
Pre-operative index limb talonavicular Joint bulge, n (%)	0 1 2	11 (9.65) 57 (50.00) 46 (40.35)
Pre-operative index limb medial longitudinal arch height, n (%)	0 1 2	9 (7.89) 64 (56.14) 41 (35.96)
Pre-operative index limb ab/adduction of forefoot, n (%)	0 1 2	0 (0.00) 64 (56.14) 50 (43.86)

6.6.3.1 Foot Posture categorisation:

As can be seen in table 17, zero participants scored 0 (supinated) within the items ab/adduction of forefoot and only 4 score 0 for malleolar curvature. To address the potential modelling issues which arise when a group has a particularly low frequency both items were categorised into the two most biologically plausible scoring categories: 0 (supinated) and 1 (neutral) were combined to one category (0) whilst 2 (pronated) remained as the other (1). This categorisation was applied from here on.

Normality of data was assessed using Kernal density plots. Pre-operative OKS, age, BM and ankle dorsiflexion are normally distributed as shown by Figures 18-21

Pre-operative OKS

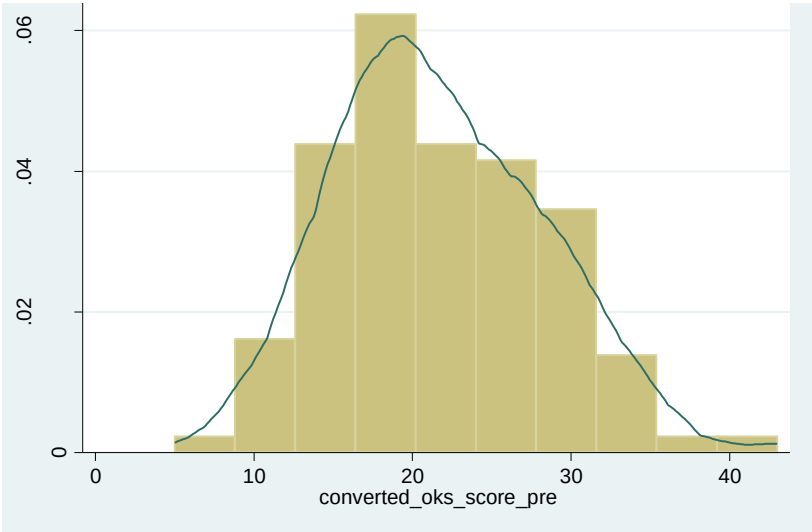

Figure 24. Distribution of pre-operative OKS score

Age

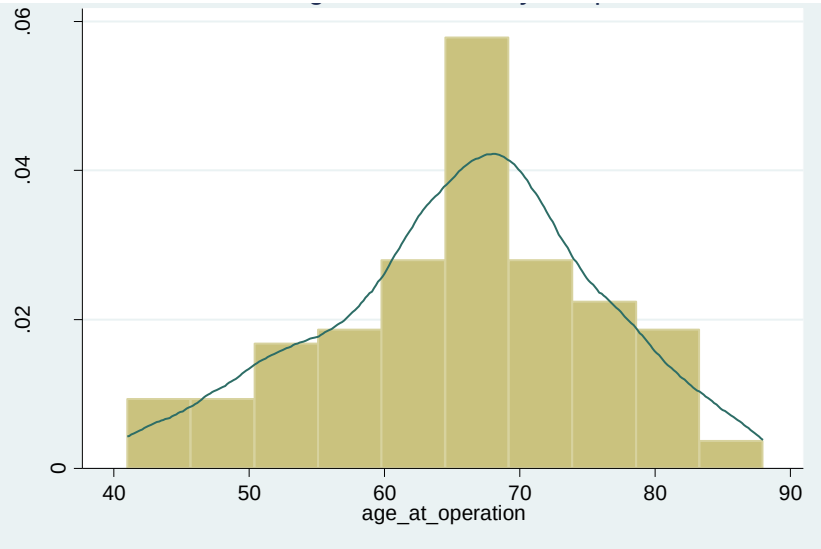

Figure 25. Distribution of age

BMI

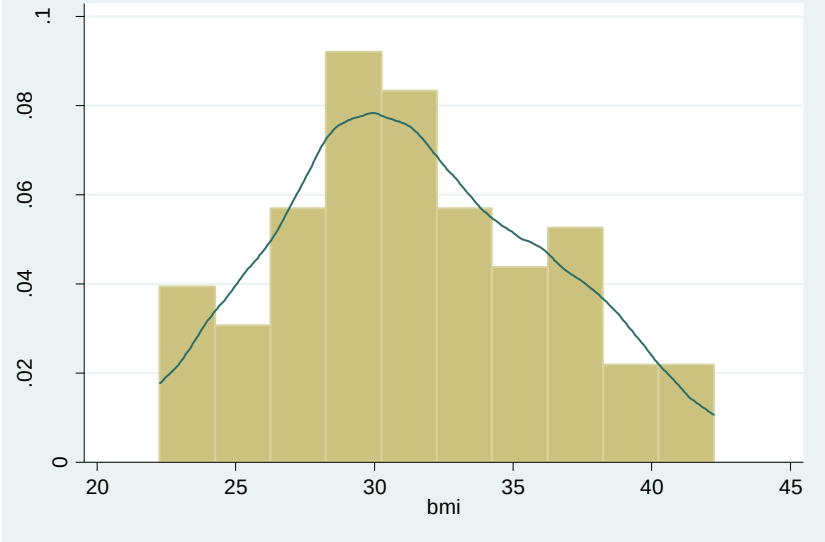

Figure 26. Distribution of BMI

Index limb range of ankle dorsiflexion

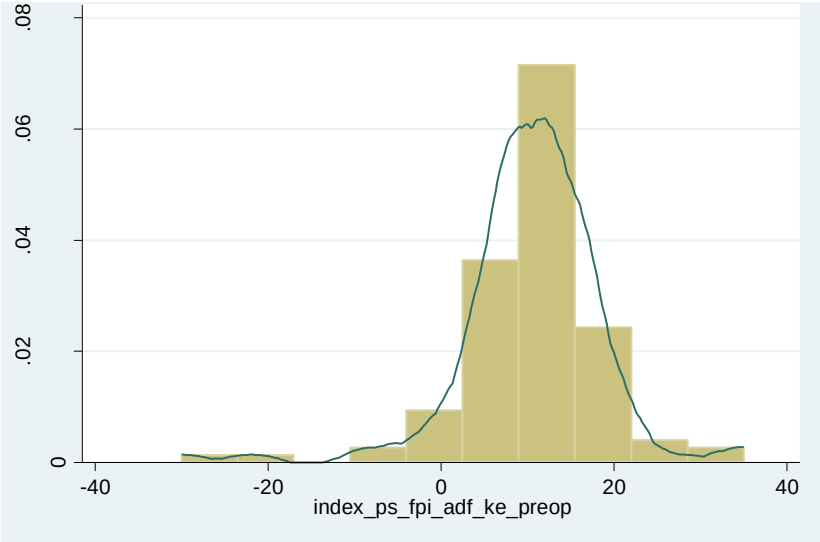

Figure 27. Distribution of range of ankle dorsiflexion

6.6.4 Univariable analysis

The prevalence of pre-operative foot pain in the COASt-Foot study was 39.47%. Mean age was 65.70 ± 10.10 years and BMI 31.36 ± 4.81 Kg/m^2. 50% were male.

Women had a significantly higher probability of having foot pain than men, with 56% of women reporting foot pain compared to only 23% of men (P<0.003).

Paired t-tests showed no significant difference in age, BMI, pre-operative OKS score or index limb ankle dorsiflexion between those with foot pain and those without (P>0.003).

Chi-squared test showed no relationship between type of procedure, back pain, depression, fixed flexion deformity, presence of RA or any foot posture items with foot pain (P>0.003).

Regression analyses was undertaken to investigate the degree of association of these variables to foot pain and account for the possible effects of confounding.

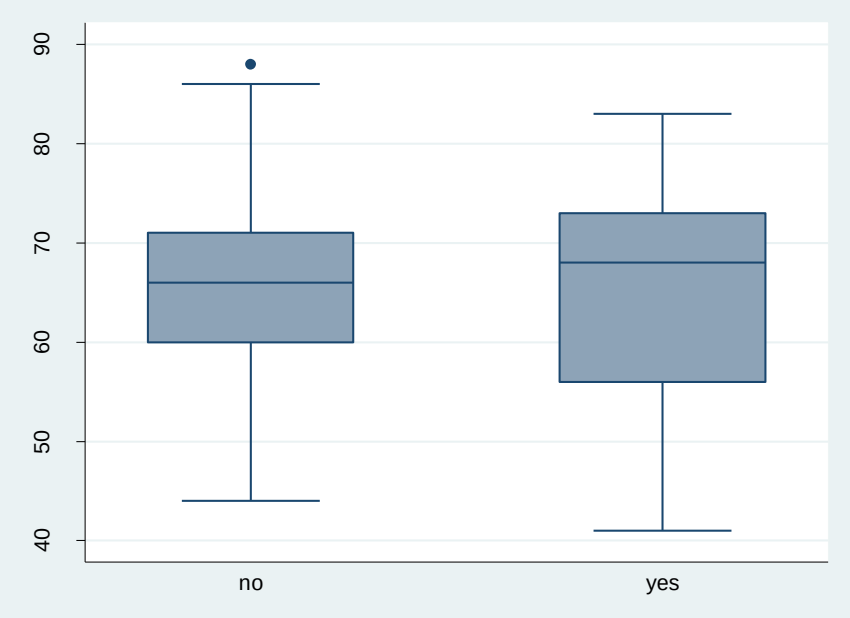

Figure 28. Box & Whisker Plot- Age across foot pain

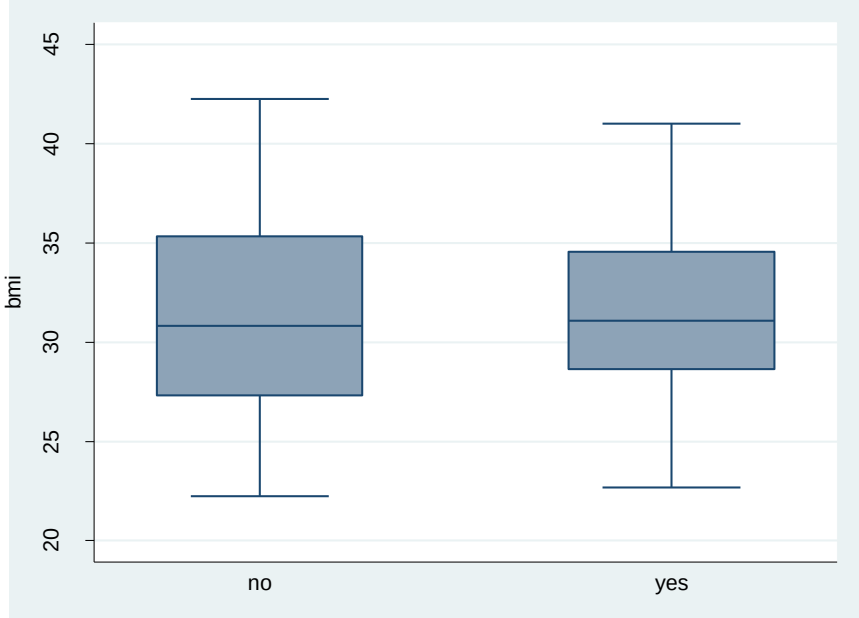

Figure 29. Box & Whisker Plot- BMI across foot pain

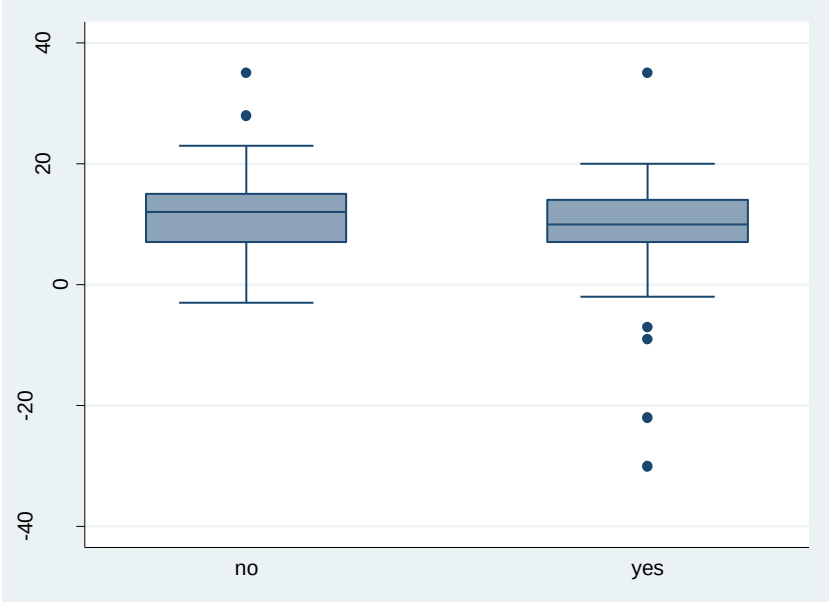

Figure 30. Box & Whisker Plot- Ankle dorsiflexion across foot pain

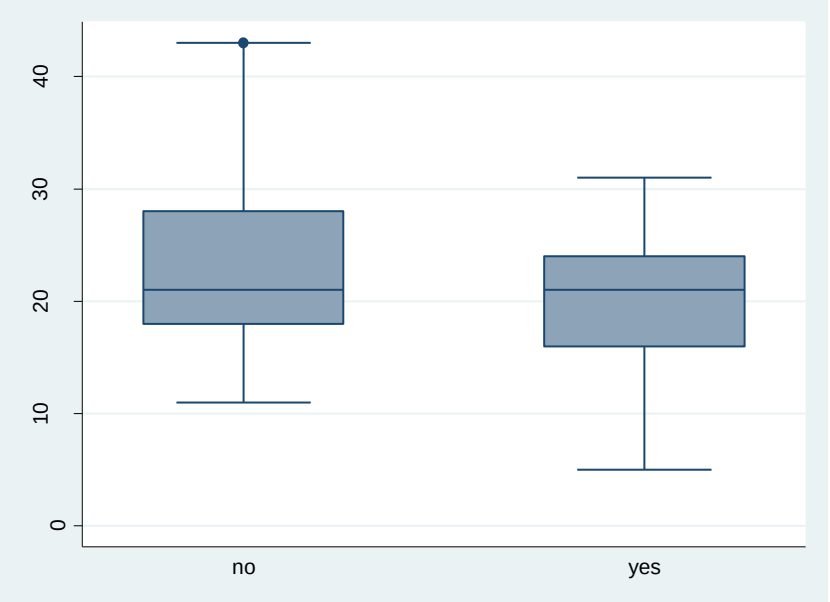

Figure 31. Box & Whisker Plot- Pre-operative OKS across foot pain

Table 18. Univariable analysis- Statistical differences of pre-operative variables between participants with/without foot pain

		No Foot pain (n=69)	Foot pain (n=45)	Difference in means	95% CIs	P-value
		Welch t test (for unequal variance):				
Age, mean (S.D), years		65.70 (9.37)	65.71 (11.25)	0.02	-4.04, 4.00	0.994
BMI, mean (S.D), Kg/m2		31. 14 (4.98)	31.70 (4.59)	0.55	-2.36, 1.25	0.545
Index limb Ankle Dorsiflexion, mean (S.D), degrees		11.68 (6.66)	8.73 (10.38)	2.95	-0.53, 6.43	0.095
Pre-operative OKS, mean (S.D)		22.75 (6.97)	19.91 (5.70)	2.84	0.48, 5.21	0.019
		Chi-squared test of independence:		**Chi-squared statistic:**		
		No foot pain	**Foot pain**			
Gender, n (%)	Female Male	25 (43.86) 44 (77.19)	32 (56.14) 13 (22.81)	13.254		0.001*
Actual procedure, n (%)	TKA UKA	44 (57.89) 25 (65.79)	32 (42.11) 13 (34.21)	2.856		0.091
Back pain, n (%)	Absent Present	45 (67.16) 24 (51.06)	22 (32.84) 23 (48.94)	2.997		0.083
Depression, n (%)	Absent Present	60 (63.83) 9 (45.00)	34 (36.17) 11 (55.00)	2.447		0.118
Index leg fixed flexion deformity	Absent Present	27 (50.00) 42 (70.00)	27 (50.00) 18 (30.00)	4.758		0.029

		Fishers exact test:		Test statistic:	P-Value
		No foot pain	Foot pain		
Self-reported Rheumatoid Arthritis	Absent Present	67 (62.62) 2 (28.57)	40 (37.38) 5 (71.43)	NA[◊]	0.084
Pre-operative index limb talar head palpation, n (%)	0 1 2	7 (70.00) 26 (65.00) 36 (56.25)	3 (30.00) 14 (35.00) 28 (43.75)	NA[◊]	0.567
Pre-operative malleolar curves, n (%)	0 1	42 (65.63) 27 (54.00)	22 (34.38) 23 (46.00)	NA[◊]	0.143
Pre-operative index limb calcaneal inclination, n (%)	0 1 2	10 (66.67) 41 (62.12) 18 (54.55)	5 (33.33) 25 (37.88) 15 (45.45)	NA[◊]	0.682
Pre-operative index limb prominence of TNJ , n (%)	0 1 2	7 (63.64) 40 (70.18) 22 (47.83)	4 (36.36) 17 (29.82) 24 (52.17)	NA[◊]	0.072
Pre-operative index limb medial longitudinal arch height, n (%)	0 1 2	6 (66.67) 41 (64.06) 22 (53.66)	3 (33.33) 23 (35.94) 19 (46.34)	NA[◊]	0.537
Pre-operative index limb ab/adduction of forefoot, n (%)	0 1	35 (54.69) 34 (68.00)	29 (45.31) 16 (32.00)	NA[◊]	0.105

Welch's t-test for unequal variance were used for continuous variables and X^2 tests for categorical variables. Fisher's exact test was used where expected counts were <5.

[◊]Fishers exact test does not provide a test-statistic

*α set with Bonferonni adjustment for multiple testing at a P<0.003

6.6.5 Logistic Regression analysis

Univariable logistic regression analysis was run for each variable. The core multi variable model included biological covariates of age, BMI and gender. These three covariates were included within all multivariable analysis from here on. This decision was made by subject matter experts including epidemiologists and statisticians from within the relevant faculties at both Southampton and Oxford University, who were part of the COASt research team.

Results of univariable analyses show significant associations of foot pain by depression, pre-operative OKS and index limb ankle dorsiflexion. These were therefore also included within the multivariable model of foot pain.

In a fully adjusted multivariable logistic regression model participants with a higher (better) pre-operative OKS score were 8% less likely to have foot pain (Odds Ratio=0.92 95% CI 0.85, 0.99 P=0.031). Men were 75% less likely to have foot pain (Odds Ratio =0.25 95% CI 0.11, 0.60 P=0.002) and participants with index knee fixed flexion deformity were 66% less likely to have foot pain (Odds Ratio= 0.34 95% CI 0.14, 0.82 P=0.016). No other covariates significantly affected the odds of foot pain. A pseudo r-squared value of 0.1495 shows that this model explains 15.0% of the variability.

Table 19. Logistic regression model to identify the association of foot pain to pre-operative variables

Predictor Variables		**Pre-op foot pain Univariable OR (95% CI)**	**P-value**	**Pre-op foot pain Multivariable OR mutually adjusted for confounders (95% CI)**	**P-value**
Age		1.00 (0.96, 1.04)	0.994	1.00 (0.96, 1.04)	0.997
BMI		1.02 (0.95, 1.11)	0.548	0.97 (0.88, 1.07)	0.524
Gender	Male	0.23 (0.10, 0.52)	<0.001*	0.25 (0.11, 0.60)	0.002*
Pre-op OKS score		0.93 (0.88, 0.99)	0.028*	0.92 (0.85, 0.99)	0.031*
Index limb ankle dorsiflexion		0.96 (0.91, 1.01)	0.079	NA	NA
Depression	Present	2.16 (0.81, 5.73)	0.123	NA	NA
Self-reported RA	Present	4.19 (0.78, 22.60)	0.096	NA	NA
Fixed flexion deformity	Present	0.43 (0.20, 0.92)	0.031*	0.34 (0.14, 0.82)	0.016*
Actual procedure	TKA	1.40 (0.62, 3.14)	0.417	NA	NA
Back pain	Present	1.96 (0.91, 4.22)	0.085	NA	NA
Index limb Talar head palpation	1 (Talar head equally palpable both sides) compared to 0 (More palpable on lateral side) 2 (More on medial side) compared to 0	1.26 (0.28, 5.63) 1.82 (0.43, 7.66)	0.766 0.417	NA	NA

Predictor Variables		Pre-op foot pain Univariable OR (95% CI)	P-value	Pre-op foot pain Multivariable OR mutually adjusted for confounders (95% CI)	P-value
Index limb malleolar curvature[¥]	0 (both infra and supra curves equal or infra curve more shallow than supra curve) compared to 1 (infra curves more concave)	1.63 (0.76, 3.47)	0.209	NA	NA
Index limb calcaneal inclination	1 (calcaneus vertical) compared to 0 (calcaneus inverted) 2 (calcaneus everted) compared to 0	1.22 (0.37, 3.98) 1.67 (0.47, 5.96)	0.742 0.432	NA	NA
Index limb talonavicular Joint bulge	1 (Area of TNJ flat) compared to 0 (Area of TNJ concave) 2 (Area of TNJ bulging) compared to 0	0.74 (0.19, 2.88) 1.91 (0.49, 7.42)	0.668 0.351	NA	NA
Index limb Medial longitudinal arch height	1 (Arch height normal) compared to 0 (Arch height higher than normal) 2 (Arch lower than normal) compared to 0	1.12 (0.26, 4.91) 1.73 (0.38, 7.86)	0.879 0.480	NA	NA
Index limb Ab/adduction of forefoot on rearfoot[¥]	1 (Lateral toes more visible than medial) compared to 0 (Medial toes more visible than lateral or Medial and lateral toes equally visible)	0.57 (0.26, 1.23)	0.151	NA	NA

[¥]further categorised due to lack of observations in one group

*Denotes statistical significance with α set at P=<0.05

6.7 Discussion

Over one third of participants in the COASt-Foot study reported foot pain (39.47%). This figure is comparative to that of a larger cohort study, which reported a 36% prevalence rate in foot, toe or ankle pain prior to KA (Peruccio et al 2012). These figures are higher than those from general population studies, which report foot pain prevalence of 17% across age groups (Hill et al 2008) and 8.9%-24% in middle and older age groups reflective of those in COASt-Foot (Picavet & Scouten 2003; Thomas et al 2004; Thomas et al 2011).

Results of multivariable analysis showed gender, fixed flexion deformity and knee pre-operative pain were associated with foot pain. Men were less likely to have foot pain, as were participants with fixed flexion deformity or better pre-operative OKS. Due to the cross sectional nature of this study, cause and effect cannot be established, however existing evidence can be drawn upon.

It is known that 50% patients with pain in at least one hip, knee, or foot are more likely to report pain in multiple joints (Peat et al 2006). Patients undergoing KA often have other pathological hips and knees (Hawker et al 2009; Perruccio et al 2012). It is unknown whether this is due to mechanical factors associated with altered gait or due to central pain mechanisms, referred pain or generalised OA.

Arendt-Nielsen et al. (2010) highlighted the significance of central sensitisation as an important manifestation in knee OA. Central sensitisation refers to the changes that central nervous system undergoes after persistent nociceptive input, from an osteoarthritic joint for example (Hucho and Levine 2007). Imamura et al (2008) have demonstrated that these central changes, measured by decreased pressure pain thresholds over superficial and deep structures, occurred also in sites distant from the knee area. Bajaj et al (2001) found that knee OA patients experienced stronger pain and larger referred pain areas to experimental muscle stimulation outside the affected joint, which is another indicator of central sensitization. It is unknown how many patients awaiting KA may suffer with central sensitisation and there appears to be no evidence to investigate the role of other joints such as the foot in central sensitisation secondary to knee OA.

Previous evidence indicates that foot pain in older people is related to pain and OA in other body regions and therefore may be a component of a general chronic pain syndrome; foot pain has been associated with symptomatic hand and knee OA in older women (Leveille et al 1998) and older subjects with disabling foot pain have been reported as more likely to report OA in the spine, hips, hands or wrists, and feet (Menz & Morris 2005).

The role of central sensitisation is supported by the cross-sectional findings from the COAST-Foot study, which show a relationship between severity of pre-operative knee pain/function and the presence of foot pain. Patients affected by central sensitisation secondary to chronic knee OA related pain may be more susceptible to heightened foot pain. This is further reinforced by the high prevalence of patients with pre-operative back pain (41%), 49% of whom also had foot pain.

Patients with OA also show manifestations of referred pain (Bajaj et al 2001). Whilst referred pain has been advocated as an important consideration in the diagnosis of knee OA (Zhang et al 2010), the role of referred pain in hip OA has received the more attention than that of the knee; hip OA referred pain distributions have been shown to be associated with total hip arthroplasty component failure (Khan & Woolson 1998) and arthroplasty outcome (Street et al 2005). To the current authors knowledge no evidence exists to show if pain referred from knee OA is likely to manifest in the foot or ankle. The known referred pain pattern from hip OA into the knee suggests that this is possible. The findings of the current study also support this.

It is also possible that foot pain in the COASt-Foot population may be linked to a degree of foot OA, however the prevalence of foot OA these patients is unknown. The overall prevalence of symptomatic radiographic OA in the general population has been reported as 16.7% (Roddy et al 2013) and was significantly greater in women than men. Therefore in a population such as COASt-Foot this figure could potentially be higher. OA-related foot pain could be part of a polyarticular form of generalized OA, similar to that found for hand and knee OA (Hirsch et al 1996; Englund et al 2004). Peruccio et al (2012) found that individuals who reported OA related pain in the ankles/feet/toes had worse post-surgery pain (1.24 95% CI 0.48, 2.00) and physical function scores (3.14 95% CI 0.69, 5.59). The association of multiple joint OA has also been shown between sides; Sayre et al. (2010) reported an association between severity of OA in one knee or hip and in the contralateral knee or hip, with odds ratios ranging from 9.2 (95% CI 7.1, 11.9) to 225.0 (95% CI 83.6, 605.7). The association of single joint OA on foot OA has yet to be investigated.

The problems of foot pain in older persons has been highlighted in a study by Menz et al (2006), whose results indicate that disabling foot pain was significantly and independently associated with falls after accounting for physiological falls risk factors and age. Both knee OA in older men (Campbell et al 1989), self-reported OA (Arden et al 1999) and widespread musculoskeletal pain in older women (Leveille et al 2002) has been shown to be a substantial risk factor for falls. The combination of multi-joint pain and OA should be of importance to the clinician concerned with a patient's risk of falls. In order to inform current care pathways further research is required to

establish whether a combination of foot pain and lower limb OA increases a patient's risk of falling. This is of particular importance prior to arthroplasty as this could affect the decision to treat surgically, potentially delay surgery or affect outcome of surgery.

Similar to previous evidence from a systematic review and meta-analysis (Thomas et al 2011), findings of COASt-Foot suggest that women were more likely to report foot pain than men. Other work has shown the prevalence of overall body pain is also higher in women than men (Picavet & Scouten 2003), suggesting this is not a phenomenon specific to pre-operative arthroplasty population.

The findings from COASt-Foot show that foot pain is not associated with ankle dorsiflexion range of motion. Similarly Menz & Morris (2005) found ankle flexibility is not associated with disabling foot pain in an older population ($P > 0.05$). The importance of reduced ankle flexibility has been highlighted in factors other than pain in the older population. It is a significant and independent predictor of balance and functional test performance (Menz et al 2005) and a risk factor for falls (Menz et al 2006). This emphasises the need to consider the role of ankle dorsiflexion in longitudinal clinical and functional outcomes, particularly in the older and potentially at risk population such as those undergoing knee arthroplasty in the current study.

Foot pain was not associated with the presence of self-reported RA. Very wide confidence intervals suggest that COASt-Foot was likely to have been lacking the power to determine the true association RA and foot pain, exacerbated by the limited number of RA positive participants in the sample. It is acknowledged that patients with RA often suffer with foot pain, with foot and ankle symptoms reported in 62.1% in RA patients, this rose 93.5% for those who reported foot and ankle symptoms at some point during the course of RA disease (Otter et al 2010). Similar rates were observed in COASt-Foot, where 64.29% of patients with RA reported foot pain.

Interestingly participants with index knee fixed flexion deformity were less likely to report foot pain. There is currently no evidence to suggest how fixed flexion deformity affects foot pain in any population. There are a number of reasons for this finding; power, confounding, bias or biological plausibility.

Chi squared tests with Bonferonni adjustment (due to multiple hypotheses testing) revealed no association of foot pain to fixed flexion deformity. Although logistic regression showed an effect of foot pain to fixed flexion deformity, wide confidence intervals suggest uncertainty in the precision of the effect. It is therefore possible that the effect seen was due to a type I error

(falsely rejecting the null). Confounding was accounted for, however there may be other variables that were not available, that had an effect on the exposure and outcome.

A number of biologically plausible reasons for this effect were 1) Participants with fixed flexion deformity have a higher pain threshold and therefore do not report foot pain 2) an antalgic gait, secondary to knee severe OA, was driving a mechanical change in foot loading. A patient's necessity to reduce weight bearing onto a pathological knee may reduce the normal forces through the entire limb, therefore reducing the chance of mechanical foot pain 3). Fixed flexion deformity itself therefore limits frontal plane motion, reducing efficiency and speed of gait and therefore restricting the normal weight bearing.

Fixed flexion deformity is a potential surrogate for knee OA severity (Harato et al 2008). In further analysis of fixed flexion deformity, t-tests showed that pre-operative OKS was not significantly different between participants with and without foot pain (P= 0.557). This suggests that the effect of fixed flexion deformity on foot pain may not be related to pain threshold, if it were a difference in reported knee pain between these participants would be expected.

Fixed flexion deformity has been estimated to occur in up to 60% of patients undergoing total knee arthroplasty (Su 2012). Similarly index knee fixed flexion deformity was present in 53% of participants within the COASt-Foot study cohort. Previous studies using gait analysis have demonstrated the effect of fixed flexion deformity on abnormal gait mechanics; reducing both stride length and velocity (Cerny et al 1994; Kagaya et al 1998). In addition, fixed flexion may influence movements in other body parts such as the hip and ankle joints (Cerny et al 1994).

No association was found between any of the six foot posture items and foot pain in the current study. These results are reflective of a previous study, which also found no association between FPI-6 and disabling foot pain ($P > 0.05$) in an older population (Menz & Morris, 2005).

Subjects with pes cavus foot type have reported a higher proportion of foot pain (60%) compared to subjects with a normal foot type (23%) ($P = 0.009$), as defined by a total foot posture index score of ≤ -2 (Burns et al 2013). Pes cavus was both idiopathic and neurogenic. A case control study of participants with chronic heel pain (mean age 52.3 ± 11.7 years), these participants were more likely to have a pronated foot posture ($P < 0.01$) than asymptomatic patients (Irving et al 2007). Pronated foot posture was defined as a total FPI score of ≥ 4; although cited, this is not reflective of the categorisation of pronated foot posture set in the original FPI development

manuscript (Redmond et al 2006), which suggests 0 to 5 is normal, ≥6 pronated. This has important and limiting implications for researchers attempting to compare study results.

Total FPI score is an arbitrary approach to defining foot status, which does not reflect the foot position at individual segments; it averages these segments to provide a total foot status. For example, a person defined as having a pronated foot posture by a total foot posture score of ≥ 6, may actually have three out of 6 items scored as 2 (pronated), but the remaining items scored at 0 each (representing neutral). It is therefore important to consider each item individually.

Previous evidence for the association between static foot posture and chronic heel pain was inconclusive (Irving et al 2003). The systematic review revealed that although increased weight and age demonstrated some evidence of an association with chronic plantar heel pain in a non-athletic population, this association was absent in an athletic population. These findings suggest that association of standard variables such as age and BMI on foot pain may be population specific and may be dependent on physical activity levels. The current study also found no significant association of BMI or age with foot pain, unfortunately levels of physical activity were not considered to determine the influence of this factor. This is surprising in comparison to the well-known relationship between both BMI and increasing age and foot pain within the normal population (Menz and Morris 2005; Hill et al 2008; Tanamas et al 2012; Gay et al 2014). It is possible that foot pain was under represented in this study because the participants main outcome and reason for inclusion on the study was knee not foot related factors. Alternatively it may be because foot pain is associated with central sensitisation mechanisms, which may not be affected by BMI and age.

Unadjusted and adjusted analyses showed that although no significant association was found between foot pain and back pain the direction of association was the same for that of RA; the presence of back pain indicated increased odds of foot pain. Wide confidence intervals indicate that little knowledge about the effect, and that further information is needed, possibly with a greater sample.

There were some potential limitations to the data within COASt-Foot that were explored. The missing values of foot pain, ankle dorsiflexion and foot posture variables can be accounted for. Both ankle dorsiflexion and foot posture were conducted during the participants pre-operative research visit. Foot posture was not measured in all participants because the principal investigator

was not present at a number of earlier patient visits. There are a number of ankle dorsiflexion values missing because this measurement was introduced to the cohort slightly later at one site.

Individual foot pain question were taken from a self-reported questionnaire during pre-operative appointment. The missingness for a number of foot pain questions was not monotone as not all foot pain variables were missing per patient. Where individual question values are missing, but the remaining questions are complete for that participant, multiple imputation was considered, however not enough independent variables within the data sets contains a completely full set of values in order to complete the multiple imputation effectively. Also at the advice of collaborative statisticians, multiple imputation would be too unstable with such a low sample. Complete case analysis was therefore chosen.

In conclusion, this cross sectional study has shown that in patients awaiting knee arthroplasty; foot pain is associated with gender, fixed flexion deformity and pre-operative knee pain and function. Men are less likely to have foot pain, and patients with fixed flexion deformity and better pre-operative knee pain and function are also less likely to have foot pain. It is unknown whether these relationships are due to mechanical factors, central pain mechanisms, referred pain or generalised OA. Further longitudinal investigation may help to inform this. The findings from this cohort of patients awaiting surgery suggest that the decision to treat knee OA with KA is being taken without regard to the level of foot pain.

Part two:

Longitudinal study of pre-operative foot and ankle characteristics versus post-operative KA patient reported outcomes

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6.8 Longitudinal data collection

Knee pain and function (OKS) was measured at one year following KA to determine the influence of the pre-specified foot and ankle measures on patient reported outcomes. Characteristics of all baseline and follow up variables can be seen in table 20.

6.8.1 Main outcome variables

- Post-operative OKS (continuous) adjusted for pre-operative OKS
- Patient acceptable symptom state (PASS) for post-operative OKS (binary) = >30 cut off pain/function score anchored to satisfaction.

6.8.2 Main risk factors variables

- Foot pain (present/absent)
- Foot Posture Index Items:
    - Eversion/inversion of calcaneus
    - Medial longitudinal arch
    - TNJ bulge
    - Curves above and below lateral mal
    - Talar head palpation
    - Ab/add forefoot
- Ankle dorsiflexion (degrees)

6.8.3 Covariates

- Age (years)
- Gender
- BMI (Kg/m2)
- Fixed Flexion Deformity (fixed position over 0 degrees knee flexion)

- Back pain (yes/no)
- Pre-operative index knee pain and function (OKS 48 point score)
- Depression (HAD- cut off 8>)
- RA (self-reported, clinician adjudicated)

6.8.4 Exclusions and loss to follow up

Exclusions and loss to follow up are described previously in section 6.6.1

6.8.5 Recruitment – COASt-Foot Study

Recruitment for COASt-Foot can be seen previously in section 6.6.2.

6.9 Results

Baseline clinical foot and ankle assessments, including foot pain and one year post-operative outcomes were explored. Descriptive summaries are produced for all variables (Table 20).

In the first instance follow up analysis was conducted to determine if differences existed in participant characteristics between those who were followed up with one year post-operative outcomes (n=114) (responders) and those who were not (n=19) (non-responders). Statistical comparisons of pre-operative variables between responders and non-responders were made using Welch's paired t-tests and Chi-squared or Fishers exact tests (table 21).

To determine if there was a need to stratify the decision was made, based on biological importance and because of large differences in group numbers, to explore type of procedure and the presence of RA. Any differences in post-operative outcomes were statistically explored, using Welch's t-test, Mann-Whitney test, (due to distribution of data) and relationships of variables with type of procedure and RA were examined using Chi-squared or Fishers exact tests (table 22 & 23, respectively). Box & Whisker plots were provided to illustrate differences between continuous and categorical exposure variables (Figures 32-41).

Potential effect modifiers were discussed a priori within the COASt research group. The decision of which to explore was made based on biological plausibility. These were explored with consideration to each model. Statistical differences between restrictive and less restrictive models were tested using likelihood ratio tests (tables 24-26) and depicted in figures 42-50.

Univariable and multivariable linear regression was conducted to test the effects of foot and ankle assessments, including foot pain on one year post-operative OKS outcomes. Separate linear regression models were conducted for three different risk factors (foot pain, ankle dorsiflexion and foot posture) including confounders, against post-operative OKS outcome (table 27-30). Regression diagnostics were checked for each model to ensure assumptions underlying the linear regression model were met. Distribution of residuals was assessed using histograms (figure 54, 57 and 60) and QQ-plots (figure 55, 58 and 61). Variance of residuals was assessed using a scatter plots (figure 56, 59 and 62).

Univariable and multivariable logistic regression was conducted to test the significant effects of foot and ankle assessments, including foot pain on one year post-operative OKS PASS outcomes. Separate linear regression models were conducted for three different risk factors (foot pain, ankle dorsiflexion and foot posture) including confounders, against post-operative OKS PASS outcome (tables 31-34). Regression diagnostics were checked to test whether observed binary responses were consistent with predictions from the logistic regression model.

Table 20. Descriptive summaries of baseline and follow up demographics and clinical characteristics

		Mean (SD) (n=114)
Age, mean (S.D), years		65.70 (10.10)
BMI, mean (S.D), Kg/m^2		31.36 (4.81)
Gender, n (%)	Male	57 (50.00)
	Female	57 (50.00)
Back pain, n (%)	Present	47 (41.23)
	Absent	67 (58.77)
Index leg fixed flexion deformity, n (%)	Present	60 (52.63)
	Absent	54 (47.37)
Depression, n (%)	Present	20 (17.54)
	Absent	94 (82.46)
Self-reported (adjudicated) RA	Present	7 (6.14)
	Absent	107 (93.86)
Foot Pain n (%)	Present	45 (39.47)
	Absent	69 (60.53)
Index limb Ankle Dorsiflexion, mean (S.D), degrees		10.52 (8.41)
Pre-operative OKS, mean (S.D)		21.63 (6.62)
Pre-operative index limb Talar head palpation, n (%)	0	10 (8.77)
	1	40 (35.09)
	2	64 (56.14)
Pre-malleolar curves, n (%)	0	4 (3.51)
	1	60 (52.63)
	2	50 (43.86)
Pre-operative index limb calcaneal inclination, n (%)	0	15 (13.16)
	1	66 (57.89)
	2	33 (28.95)
Pre-operative index limb talonavicular Joint bulge, n (%)	0	11 (9.65)
	1	57 (50.00)
	2	46 (40.35)
Pre-operative index limb medial longitudinal arch height, n (%)	0	9 (7.89)
	1	64 (56.14)
	2	41 (35.96)
Pre-operative index limb ab/adduction of forefoot, n (%)	0	0 (0.00)
	1	64 (56.14)
	2	50 (43.86)
Post-operative OKS, mean (S.D)		37.71 (9.07)
Post-operative PASS score n (%)	Achieved	93 (81.58)
	Not achieved	21 (18.42)

*further categorisation of foot posture scores due to lack of observations in one group

6.9.1 Loss to follow-up analysis

A small number of participants (14.3 %, n=19) had incomplete follow up OKS scores or were missing complete scores. It was important to determine whether there are any differences in characteristics between these participants, to limit the potential bias that may be introduced when missing participants are not included.

Results of Welch's t-tests and Chi-squared or Fishers Exact tests shows there were no statistical differences in pre-operative patient characteristics between participants with follow up (responders) and those without (non-responders), apart from pre-operative OKS (mean difference 6.37 95% CI -9.60, -3.14 P=0.0001); non-responders had a lower (worse) mean pre-operative OKS score (15.26 ± 6.30) than responders (21.63 ± 6.62) (table 21).

Table 21. Statistical comparisons of pre-operative variables between participants who were followed up and those who were not

Predictor Variables		**Baseline (n=133)**	**Responders (n=114)**	**Non-responders (n=19)**	**P-value**
		Welch t test (for unequal variance):			
Age, mean (S.D), years		65.68 (10.06)	65.70 (10.11)	65.58 (10.16)	0.961
BMI, mean (S.D), Kg/m^2		31.53 (5.32)	31.36 (4.82)	32.56 (7.76)	0.521
Index limb Ankle Dorsiflexion, mean (S.D), degrees		10.38 (8.39)	10.52 (8.41)	9.53 (8.40)	0.638
Pre-operative OKS, mean (S.D)		20.72 (6.92)	21.63 (6.62)	15.26 (6.30)	0.0001*
		Chi squared:			
Foot Pain n (%)	Present Absent	53 (39.85) 80 (60.15)	45 (84.91) 69 (86.25)	8 (15.09) 11 (13.75)	0.828
Rheumatoid arthritis, n (%)	Present Absent	8 (6.02) 125 (93.98)	1 (87.50) 107 (85.60)	7 (12.50) 18 (14.40)	0.680
Back pain, n (%)	Present Absent	53 (39.85) 80 (60.15)	47 (88.68) 67 (83.75)	6 (11.32) 13 (16.25)	0.426
Index leg fixed flexion deformity	Present Absent	72 (54.14) 61 (45.86)	60 (83.33) 54 (88.52)	12 (16.67) 7 (11.48)	0.394
Depression (%)	Present Absent	26 (19.55) 107 (80.45)	20 (76.92) 13 (87.85)	6 (23.08) 94 (12.15)	0.153

Predictor Variables		**Baseline (n=133)**	**Responders (n=114)**	**Non-responders (n=19)**	**P-value**
		Fishers exact test:			
Operation type, n (%)	TKR UKR	91 (68.42) 42 (31.58)	76 (83.52) 38 (90.48)	15 (16.48) 4 (9.52)	0.215
Gender, n (%)	Female Male	71 (53.38) 62 (46.62)	57 (80.28) 57 (91.94)	14 (19.72) 5 (8.06)	0.046
Rheumatoid arthritis, n (%)	Present Absent	8 (6.02) 125 (93.98)	1 (87.50) 107 (85.60)	7 (12.50) 18 (14.40)	0.680
Index limb Talar head palpation, n (%)	0 1 2	12 (9.02) 45 (33.83) 76 (57.14)	10 (83.33) 40 (88.89) 64 (84.21)	2 (16.67) 5 (11.11) 12 (15.79)	0.749
Index limb malleolar curve, n (%)[¥]	0 1	75 (56.39) 58 (43.61)	64 (85.33) 50 (86.21)	11 (14.67) 8 (13.79)	0.886
Index limb calcaneal inclination, n (%)	0 1 2	17 (12.78) 76 (57.14) 40 (30.08)	15 (88.24) 66 (86.84) 33 (82.50)	2 (11.76) 10 (13.16) 7 (17.50)	0.775
Index limb talonavicular Joint bulge, n (%)	0 1 2	14 (10.53) 68 (51.13) 51 (38.35)	11 (78.57) 57 (83.82) 46 (90.20)	3 (21.43) 11 (16.18) 5 (9.80)	0.416

Index limb Medial longitudinal arch height, n (%)	0 1 2	10 (7.52) 71 (53.38) 52 (39.10)	9 (90.00) 64 (90.14) 41 (78.85)	1 (10.00) 7 (9.86) 11 (21.15)	0.204
Index limb ab/adduction of forefoot on rearfoot, n (%)[¥]	0 1	75 (56.39) 58 (43.61)	11 (14.67) 8 (13.79)	64 (85.33) 50 (86.21)	0.886

Welch's t-test for unequal variance were used for continuous variables and X^2 tests for categorical variables. Fisher's exact test is used where expected counts were <5

[¥]further categorised due to lack of observations in one group

*α set with Bonferonni adjustment for multiple testing at a P<0.003

6.9.2 Stratification

It was important to consider any variables within the COASt-Foot subset that may yield a potential need to stratify data. Type of procedure and presence of RA were identified a priori as two variables with large differences in group numbers, which also have known difference in their effects on outcome dependant on each end of their dichotomised status. UKA has been shown to give better early patient-reported outcomes (OKS) than TKA, with UKA patients were more likely to achieve excellent results (OR 1.59, 95% CI 1.47 to 1.72, $p < 0.001$) and to be highly satisfied (OR 1.27, 95% CI 1.17 to 1.39, $p < 0.001$) (Liddle et al 2015). Differences in outcome were also observed for patients with RA, where those with RA had better outcomes (OKS) than those without (OR 2.17, 95% CI 1.02, 4.60) (Judge et al 2012).

6.9.3 Exploratory analysis: Differences between total knee arthroplasty (TKA) and uni knee arthroplasty (UKA) participants?

6.9.3.1 Methods

The cohort of participants included both UKA (n=38) and TKA (n=76) participants. In order to determine the potential requirement for stratification of data it was pertinent to investigate any potential differences in characteristics, in particular outcomes, between TKA and UKA participants. Differences in baseline and follow up demographic and clinical characteristics were explored between those participants who underwent TKA and those who underwent UKA. Differences in continuous variables were depicted in figures 32-36. Any differences in post-operative outcomes were statistically explored, using Welch's t-test (due to unequal variances), Mann-Whitney test, (due to distribution of data) and relationships of variables with type of procedure were examined using Chi-squared tests or Fishers Exact (table 22).

6.9.3.2 Results

Participants who underwent UKA were significantly younger than those who underwent TKA (mean difference= 6.14 years, 95% CI 2.23, 10.06 P=0.003). There were no significant differences or relationships between other pre and-post operative variables and type of procedure (P>0.003).

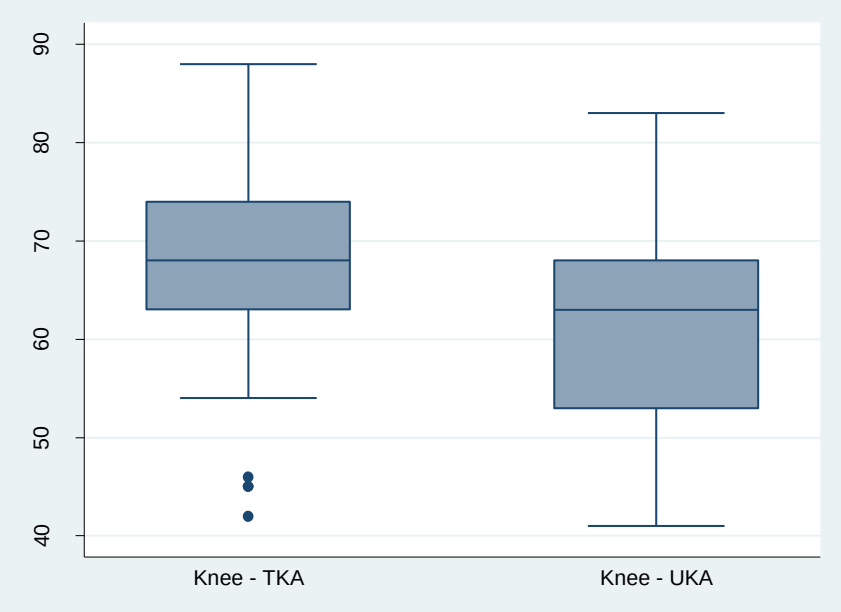

Figure 32. Box & Whisker Plot - age across actual procedure

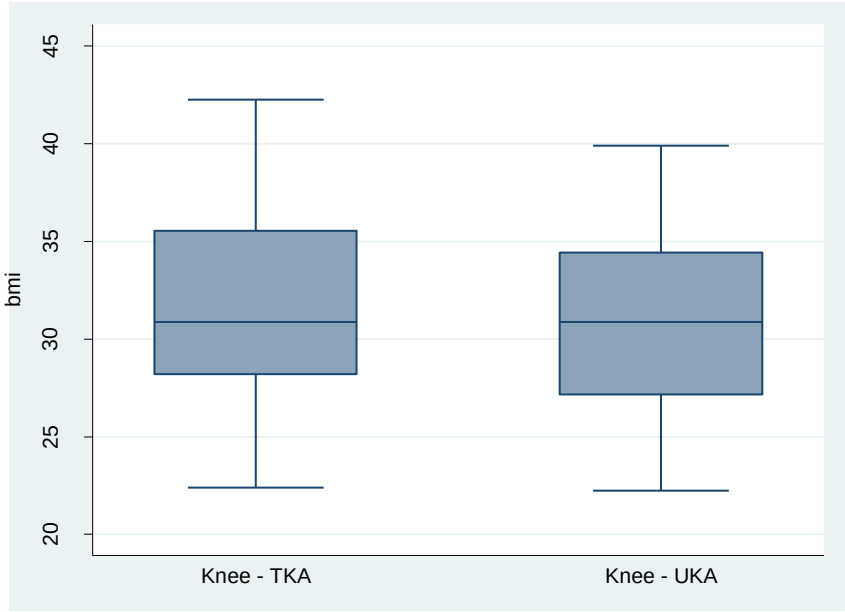

Figure 33. Box & Whisker Plot- BMI across actual procedure

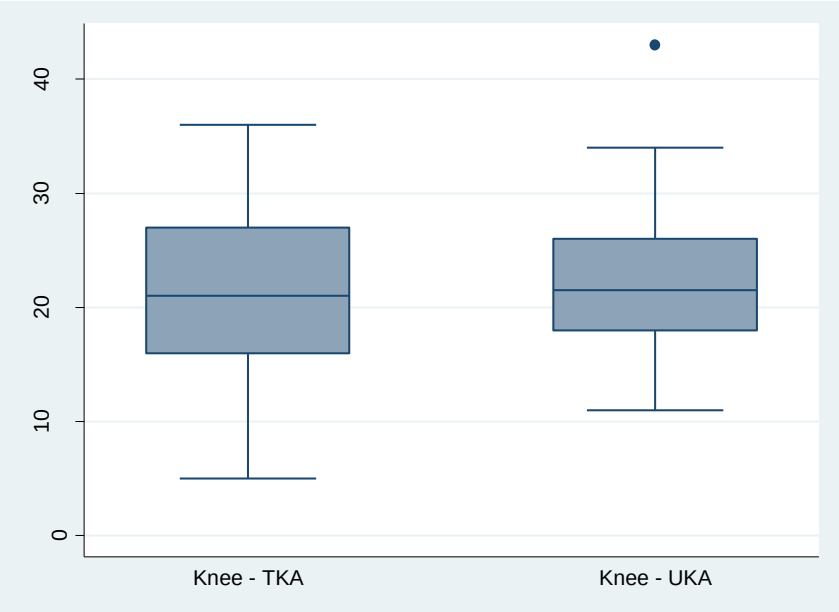

Figure 34. Box & Whisker Plot - pre-op OKS score across actual procedure

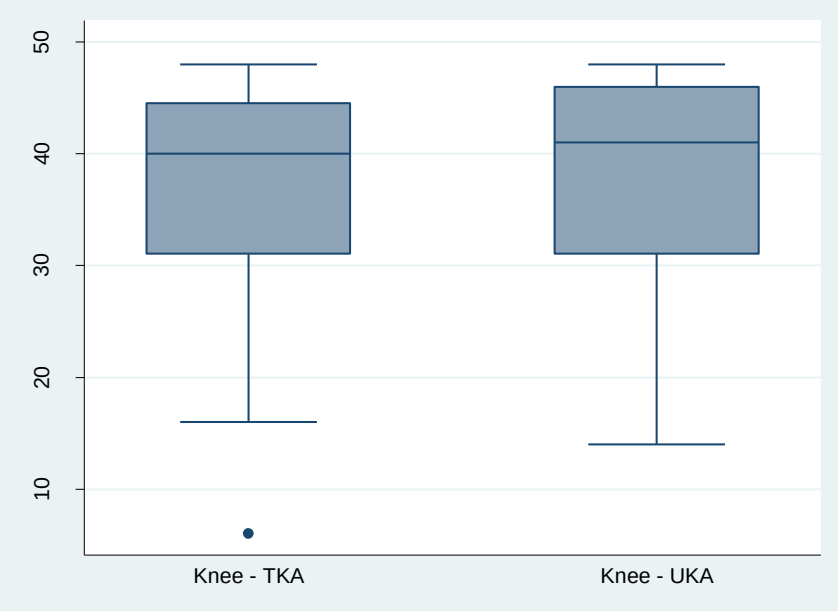

Figure 35. Box & Whisker Plot post-op OKS across actual procedure

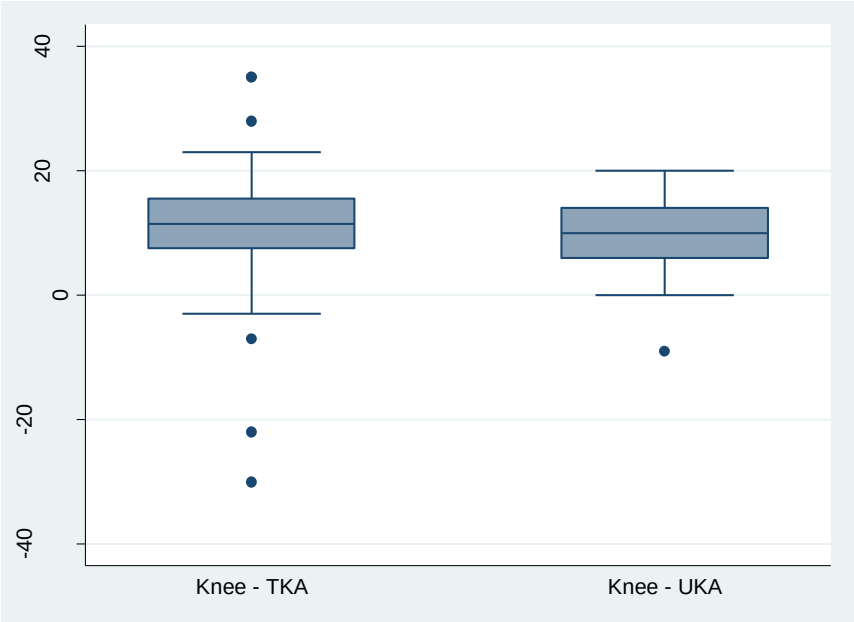

Figure 36. Box & Whisker Plot - index limb ankle dorsiflexion across actual procedure

Table 22. Statistical comparisons of pre and post-operative variables in participants who underwent TKR or UKR

		TKR (n=76)	UKR (n=38)	Difference in means	95% CIs	P-value
		Welch t test (for unequal variance):				
Age, mean (S.D), years		67.77 (9.56)	61.61 (10.05)	6.14	2.23, 10.06	0.003*
BMI, mean (S.D), Kg/m2		31.55 (4.88)	31.00 (4.742)	0.55	-1.34, 2.44	0.565
Index limb Ankle Dorsiflexion, mean (S.D), degrees		11.04 (9.48)	9.47 (5.69)	1.57	-1.26, 4.3	0.275
Pre-operative OKS, mean (S.D)		21.30 (6.56)	22.29 (6.77)	0.99	-3.64, 1.67	0.461
		Mann-Whitney test:				
Post-operative OKS, n (%)		37.59 (8.98)	37.95 (9.37)	NA	NA	0.658
		TKR	**UKR**	**Chi-squared statistic**		**P-value**
		Chi-squared test:				
Post-operative OKS PASS score, n (%)	Not achieved Achieved	15 (71.43) 61 (65.59)	6 (28.57) 32 (34.41)	0.263		0.608
Gender, n (%)	Female Male	36 (63.16) 40 (70.18)	21 (36.84) 17 (29.82)	0.632		0.427
Back pain, n (%)	Absent Present	46 (68.66) 30 (63.83)	21 (31.34) 17 (36.17)	0.290		0.590
Depression, n (%)	Absent Present	64 (68.09) 12 (60.00)	30 (31.91) 8 (40.00)	0.485		0.486
Index leg fixed flexion deformity	Absent Present	39 (72.22) 37 (61.67)	15 (27.78) 23 (38.33)	1.425		0.233
Foot pain, n (%)	No Yes	44 (63.77) 32 (71.11)	25 (36.23) 13 (28.89)	0.661		0.416

		TKR	UKR	Chi-squared statistic	P-value
		Chi-squared test:			
Index limb malleolar curves[¥]	0 1	46 (71.88) 30 (60.00)	18 (28.13) 20 (40.00)	1.781	0.182
Index limb Ab/adduction of forefoot on rearfoot[¥]	0 1	44 (68.75) 32 (64.00)	20 (31.25) 18 (36.00)	0.285	0.593
		TKR	**UKR**		**P-value**
		Fishers exact test:			
Self-reported RA, n (%)	Absent Present	71 (66.36) 5 (71.43)	36 (33.64) 2 (28.57)	NA[◊]	0.571
Index limb Talar head palpation	0 1 2	8 (80.00) 31 (77.50) 37 (57.81)	2 (20.00) 9 (22.50) 27 (42.19)	NA[◊]	0.085
Index limb calcaneal inclination	0 1 2	12 (80.00) 43 (65.15) 21 (63.64)	3 (20.00) 23 (34.85) 12 (36.36)	NA[◊]	0.582
Index limb talonavicular Joint bulge	0 1 2	8 (72.73) 40 (70.18) 28 (60.87)	3 (27.27) 17 (29.82) 18 (39.13)	NA[◊]	0.594
Index limb Medial longitudinal arch height	0 1 2	5 (55.56) 46 (71.88) 25 (60.98)	4 (10.53) 18 (28.13) 16 (39.02)	NA[◊]	0.437

[¥] Welch's t-test for unequal variance and Mann-Whitney non-parametric tests were used for continuous variables. X^2 tests were used for categorical variables and Fisher's exact test were used where expected counts were <5. [¥]further categorised due to lack of observations in one group [◊]Fishers exact test does not provide a test-statistic *α set with Bonferonni adjustment for multiple testing at a P<0.003

6.9.4 Exploratory analysis: Differences between participants with and without rheumatoid Arthritis?

6.9.4.1 Methods

The COASt-Foot subset cohort included participants with self-reported diagnosed rheumatoid arthritis. In order to determine the potential requirement for stratification potential differences in characteristics and outcomes were explored between rheumatoid (n=7) and non-rheumatoid (n=107) participants. Differences in post-operative outcomes were statistically explored, using Welch's t-test, Mann-Whitney test and relationships of certain variables with RA diagnosis were examined using Chi-squared or Fishers Exact tests (table 23) and illustrated for particular variables in figures 37-41.

6.9.4.2 Results

There were no significant differences or relationships between any pre and post-operative variables and RA diagnosis (P>0.003).

N= 5 RA participants underwent TKA and n=2 RA participants underwent UKA

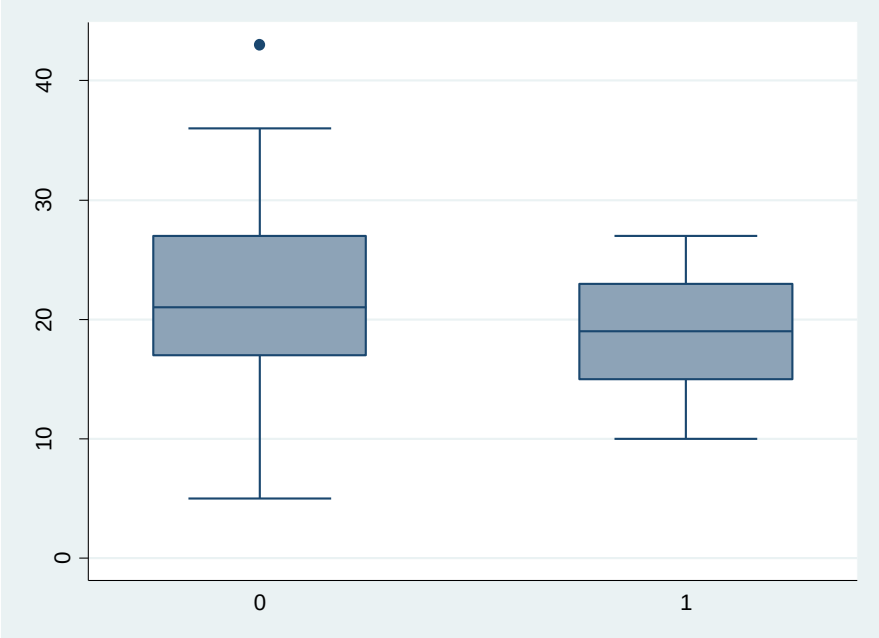

Figure 37. Box & Whisker Plot- pre-op OKS score across presence of RA op OKS score (1= present)

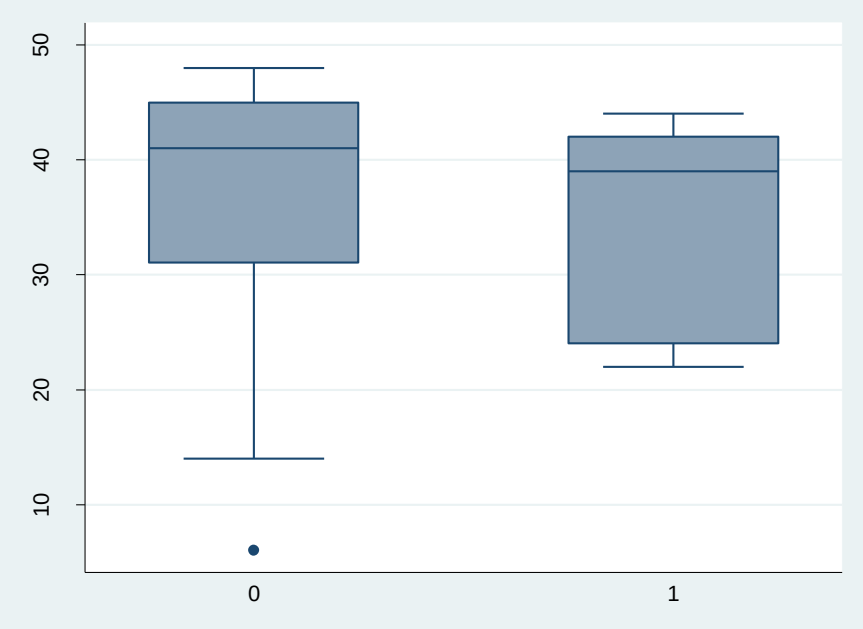

Figure 38. Box & Whisker Plot- converted post-op OKS score across post-

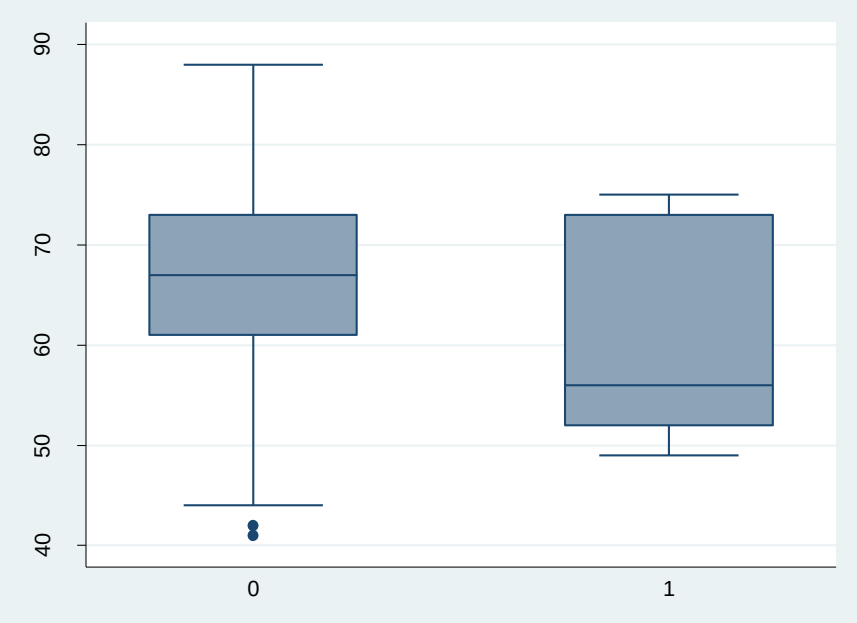

Figure 39. Box & Whisker Plot- age across presence of RA

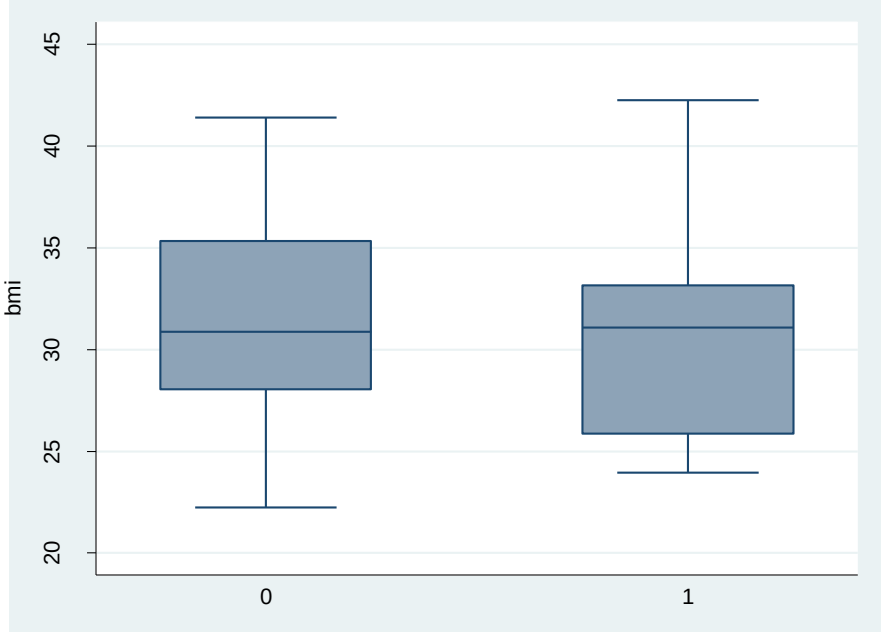

Figure 40. Box & Whisker Plot- BMI across presence of RA

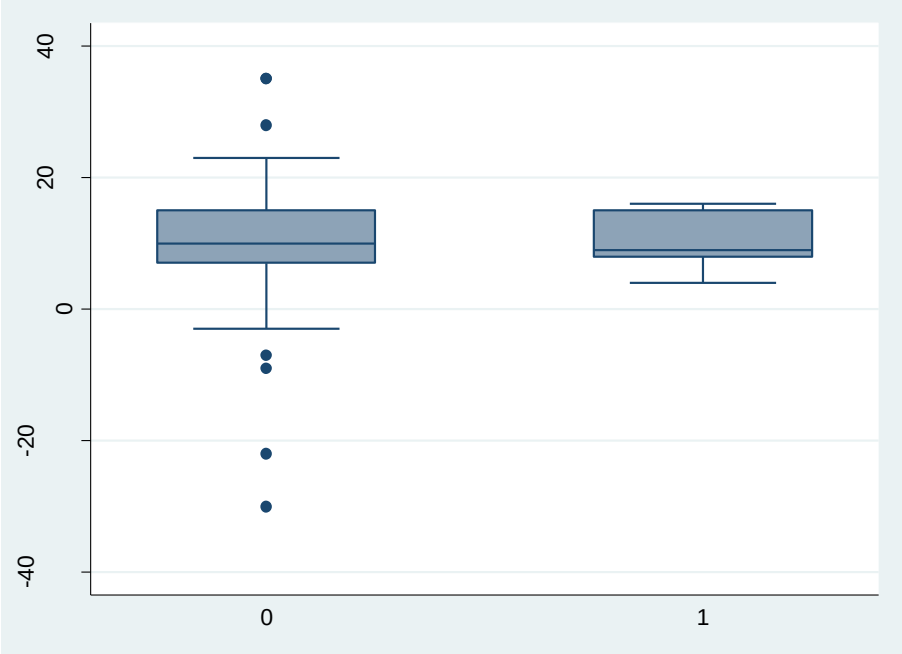

Figure 41. Box & Whisker Plot- pre-op ankle dorsiflexion across presence of RA

Table 23. Statistical comparisons of pre and post-operative variables in participants with and without RA

		RA (n=7)	Non-RA (n=107)	Difference in means	95% CIs	P-value
		Welch t test (for unequal variance):				
Age, mean (S.D), years		59.29 (10.36)	66.12 (10.00)	6.84	-2.70, 16.37	0.134
BMI, mean (S.D), Kg/m2		30.89 (5.94)	31.39 (4.77)	0.50	-4.97, 5.98	0.833
Index limb Ankle Dorsiflexion, mean (S.D), degrees		10.71 (4.39)	10.50 (8.62)	-0.21	-4.32, 3.90	0.912
Pre-operative OKS, mean (S.D)		18.71 (5.62)	21.82 (6.66)	3.11	-2.07, 8.28	0.201
		Mann-Whitney test:				
Post-operative OKS, n (%)		7 (6.14)	107 (93.86)	NA	NA	0.2018
		Non RA	**RA**			**P-value**
		Fishers exact test:				
Post-operative OKS PASS score, n (%)	Not achieved Achieved	19 (90.48) 88 (94.62)	2 (9.52) 5 (5.38)	NA◊		0.381
Gender, n (%)	Female Male	55 (96.49) 52 (91.23)	2 (3.51) 5 (8.77)	NA◊		0.219
Back pain, n (%)	Absent Present	64 (95.52) 43 (91.49)	3 (4.48) 4 (8.51)	NA◊		0.309
Depression, (%)	Absent Present	89 (94.68) 18 (90.00)	5 (5.32) 2 (10.00)	NA◊		0.355
Index leg fixed flexion deformity	Absent Present	51 (94.44) 56 (93.33)	3 (5.56) 4 (6.67)	NA◊		0.559
		Non RA	**RA**			**P-value**
		Fishers exact test:				

Foot pain, n (%)	No Yes	67 (97.10) 40 (88.89)	2 (2.90) 5 (11.11)	NA[◊]	0.084
Index limb Talar head palpation	0 1 2	10 (100.00) 37 (92.50) 60 (93.75)	0 (0.00) 3 (7.50) 4 (6.25)	NA[◊]	1.000
Index limb Malleolar curves[¥]	0 1	62 (96.88) 45 (90.00)	2 (3.13) 5 (10.00)	NA[◊]	0.131
Index limb calcaneal inclination	0 1 2	14 (93.33) 62 (93.94) 31 (93.94)	1 (6.67) 4 (6.06) 2 (6.06)	NA[◊]	1.000
Index limb Talonavicular Joint bulge	0 1 2	10 (90.91) 53 (92.98) 44 (95.65)	1 (9.09) 4 (7.02) 2 (4.35)	NA[◊]	0.619
Index limb Medial longitudinal arch height	0 1 2	9 (100.00) 60 (93.75) 38 (92.68)	0 (0.00) 4 (6.25) 3 (7.32)	NA[◊]	1.000
Index limb Ab/adduction of forefoot on rearfoot[¥]	0 1	61 (95.31) 46 (92.00)	3 (4.69) 4 (8.00)	NA[◊]	0.364

[¥] Welch's t-test for unequal variance and Mann-Whitney non-parametric tests were used for continuous variables. X^2 tests were used for categorical variables and Fisher's exact test were used where expected counts were <5. [¥]further categorised due to lack of observations in one group [◊]Fishers exact test does not provide a test-statistic *α set with Bonferonni adjustment for multiple testing at a P<0.003

6.9.5 Effect modification

In this section potential interaction terms, decided a priori, for relevant models were tested and likelihood ratio tests run against the restrictive and less restrictive (one with interaction term added) models. If the difference was statistically significant, then the less restrictive model fit the data significantly better than the more restrictive model. Effect sizes (coefficients or odds ratios), P-values and 95% confidence intervals are given for each potential interaction term within each model (tables 24-26). These are depicted in predictive margin plots (figures 42-50).

6.9.5.1 Effect modifiers within Pre-op foot pain vs post-op OKS model

Potential interactions for foot pain vs post-operative OKS are depicted in figures 42-45. Results for the tests of effect modification can be seen in table 24.

Back pain

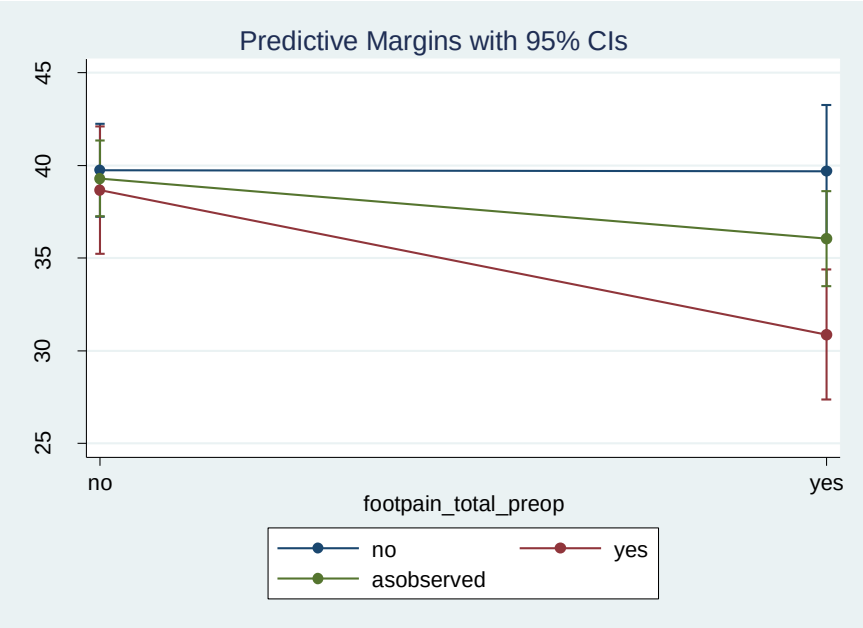

Figure 42. Margin plot for the effect modification of back pain

Actual Procedure (TKR/UKR)

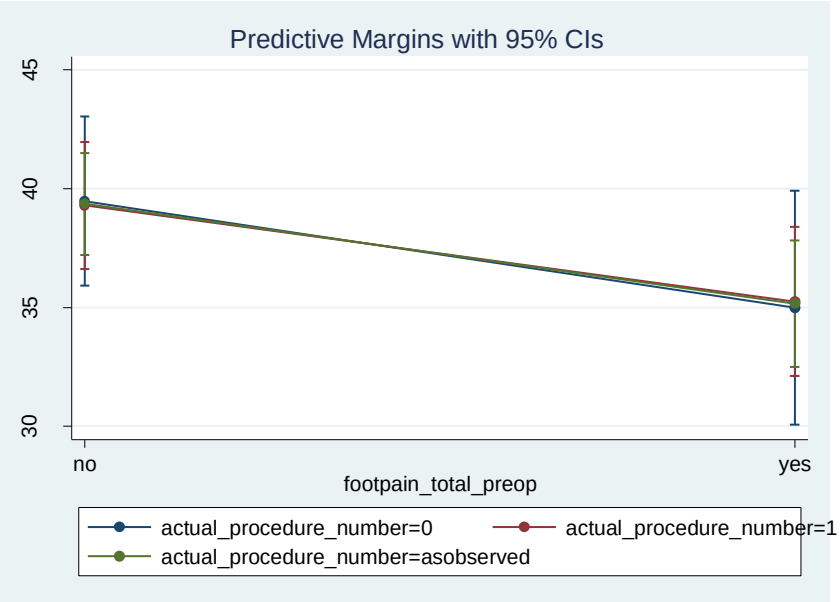

Figure 43. Margin plot for the effect modification of TKR/UKR procedure

Depression and anxiety

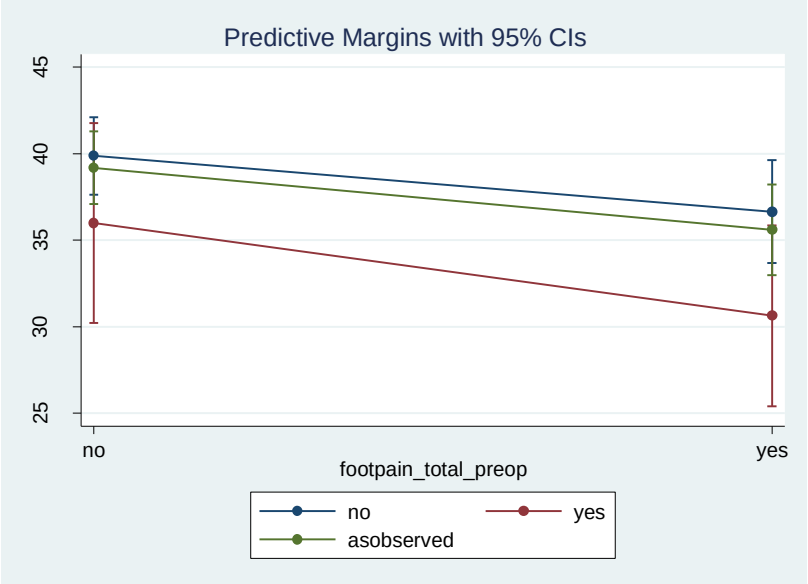

Figure 44. Margin plot for the effect modification of depression

Arthritis (RA/OA)

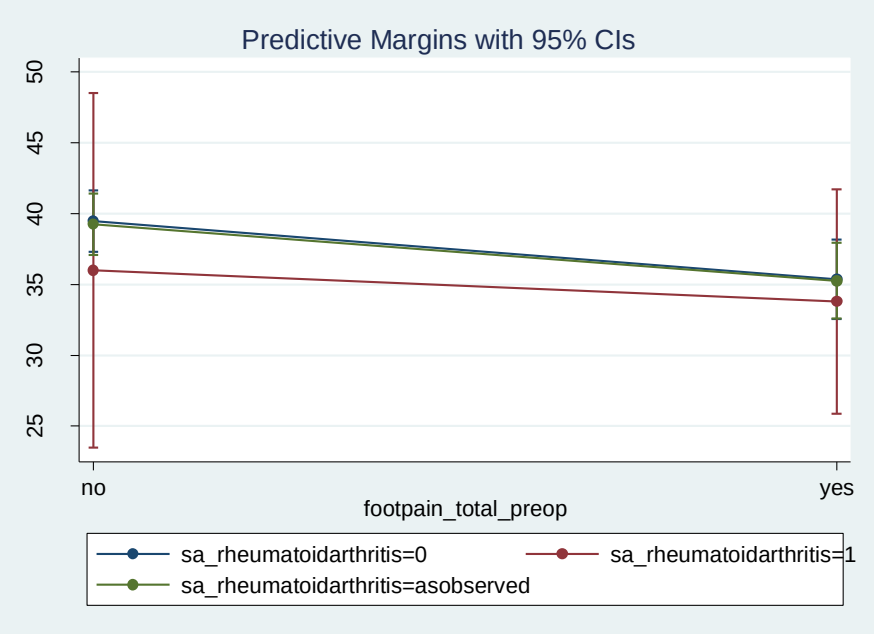

Figure 45. Margin plot for the effect modification of RA

Table 24. Effect modifiers within pre-op foot pain vs post op OKS score model

Interaction Term	Interaction Term Coefficient	P-Value	95% CIs	Likelihood ratio test P-value
Depression	-2.14	0.623	-10.77, 6.49	0.616
Back pain	-7.75	0.021*	-14.32, -1.17	0.019*
Type of procedure	0.43	0.907	-6.90, 7.77	0.905
RA	1.91	0.804	-13.33, 17.15	0.800

Depression diagnosis based on a HAD cut off score of 8/21 (Bjelland *et al* 2002).

*Significant at <0.05.

Back pain was a significant effect modifier in the relationship between foot pain and post-operative OKS, showing a trend for those with back pain to have a steeper negative relationship between foot pain and post-operative OKS scores compared to those without back pain (figure 36). Likelihood ratio test suggested the less restrictive model (including back pain as an

interaction term) fitted the data better. Depression, type of procedure and RA were not significant effect modifiers. Back pain was therefore included as an interaction term within further analysis.

Tests for interactions were repeated in multivariable models (not shown), adjusting for pre-operative OKS, age, gender and BMI. The same results were found with regard the direction of effect and significance; back pain was the only significant effect modifier).

6.9.5.2 Effect modifiers within pre-operative foot posture vs Post-operative OKS model

Potential interactions for foot posture vs post-operative OKS are depicted in figure 46. Results for the tests of effect modification can be seen in table 25.

Back Pain

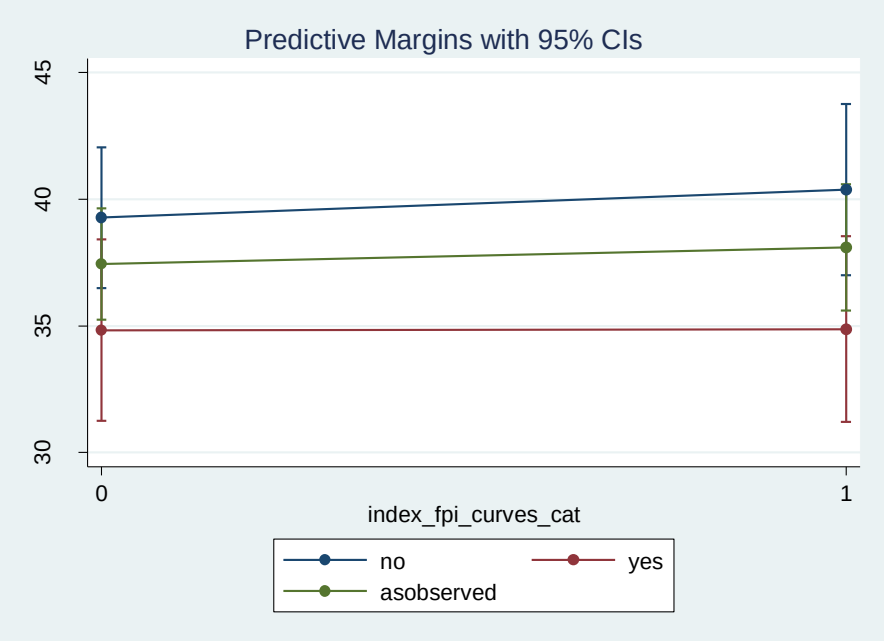

Figure 46. Margin plot for the effect modification of back pain

Table 25. Effect modification within pre-operative foot posture vs post-operative OKS model

Interaction Term	Interaction Term Odds Ratio	P-Value of interaction	95% CIs	Likelihood ratio test P-value
Back pain	-1.06	0.756	-7.79, 5.67	0.751

Back pain did not modify the effect of pre-operative foot posture on post-operative OKS.

The test for interaction was repeated in a multivariable model (not shown), adjusting for pre-operative OKS, age, gender and BMI. The same results were found with regard to significance; back pain was not a significant effect modifier.

6.9.5.3 Effect modification in pre-op foot pain vs post op OKS PASS model

Potential effect modifiers within the foot pain vs post-operative OKS PASS model are depicted in figures 47-50. Results for the tests of effect modification can be seen in table 26.

Depression

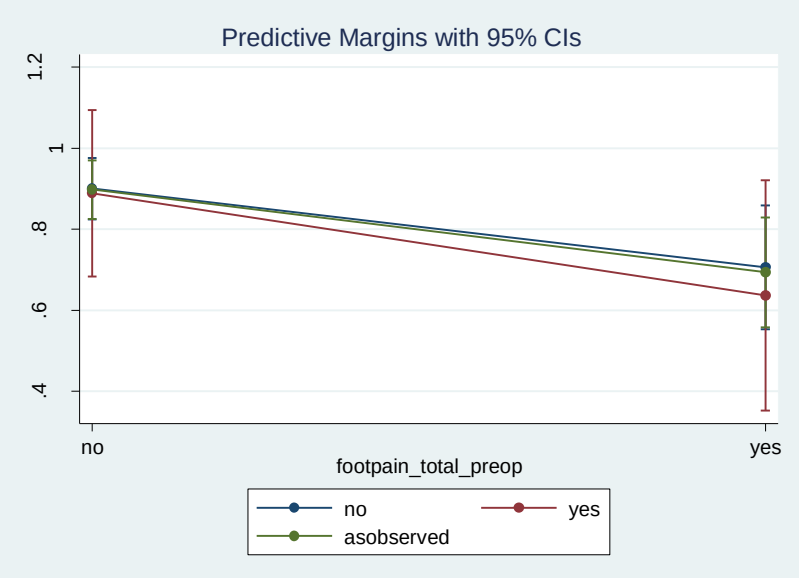

Figure 47. Margin plot for the effect modification of depression

Back pain

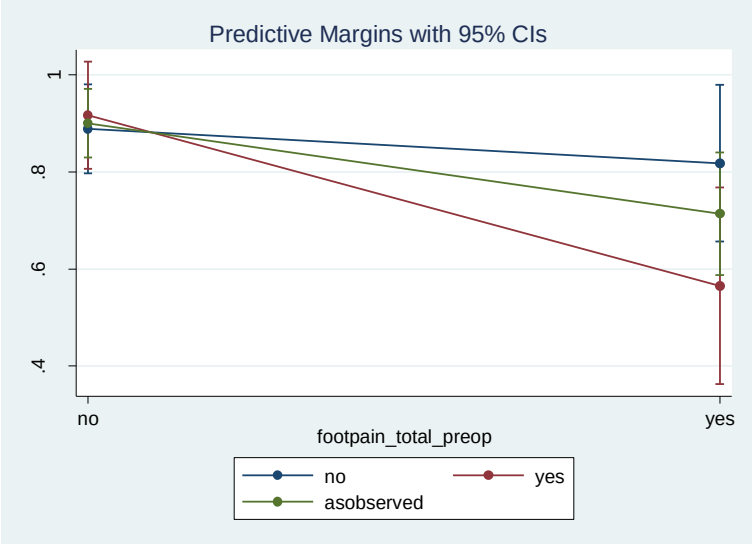

Figure 48. Margin plot for the effect modification of back pain

Actual procedure

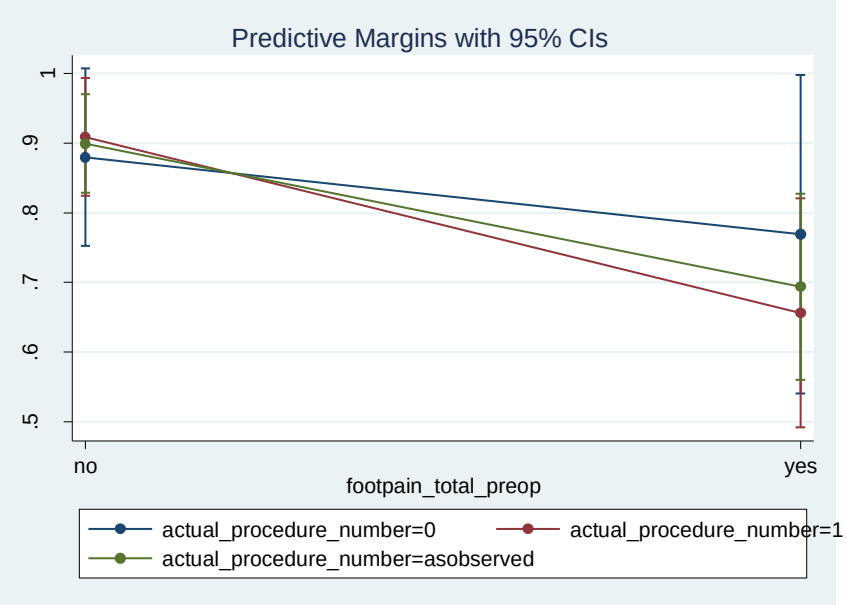

Figure 49. Margin plot for the effect modification of UKR/TKR procedure

Rheumatoid Arthritis

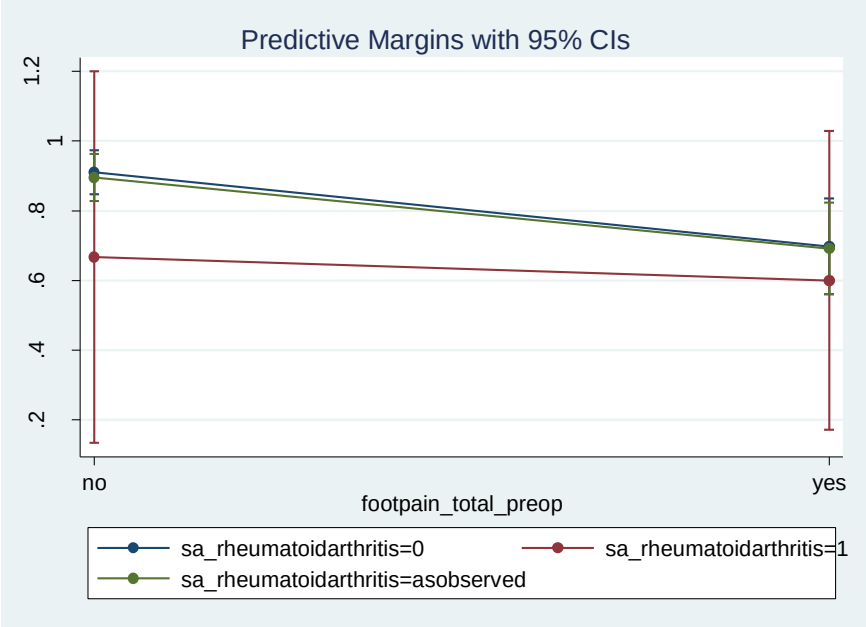

Figure 50. Margin plot for the effect modification of RA

Table 26. Effect modification within foot pain vs post op OKS PASS score model

Interaction Term	Interaction Term Odds Ratio	P-Value of interaction	95% CIs	Likelihood ratio test P-value
Depression	0.82	0.884	0.06, 11.75	0.883
Back pain	0.21	0.163	0.02, 1.88	0.149
Type of procedure	0.42	0.433	0.05, 3.78	0.433
RA	NA*			

* Omitted due to low frequency of RA participants not achieving PASS (n=2), making test unstable

Depression, back pain, type of procedure and RA diagnosis did not significantly modify the effect of foot pain on post-operative OKS PASS. There was a trend for those with foot pain to have a steeper negative relationship with post-operative OKS scores in those with back pain compared to those without back pain (figure 48).

The tests for interactions were repeated in a multivariable analysis (not shown), adjusting for pre-operative OKS, age, gender and BMI. The same results were found with regard to significance; depression, back pain, type of procedure and RA diagnosis were not significant effect modifiers.

6.9.6 Confounding

Variables that have been shown to be associated with the outcome as well as exposure in previous studies, or were decided a priori as likely to confound the association between the exposure and outcome based on biological plausibility, were initially considered as confounders within the forward selection multivariable regression models. These are discussed for each separate model. Due to their known biological cofounding effects on post-operative outcome age, gender and BMI were included as confounders within every model.

6.9.6.1 Exposure 1 (pre-operative Foot pain) Vs post-operative OKS

A number of factors have shown to be associated with KA outcome in populations reflective of the COASt-Foot. These include age, gender, BMI, other symptomatic joints (including back pain), pre-operative knee pain, and depression (Nilsdotter et al. 2003; Yeung et al. 2011; Judge et al. 2012a; Baker et al. 2013; Hawker et al. 2013; Williams et al. 2013). These factors have previously been shown to have an association with foot pain (Garrow et al 2004; Menz and Morris 2005; Menz et al 2006; Hill et al 2008). These variables, except for back pain which has already been identified as an effect modifier, were therefore considered a priori and will be treated as confounders in the COASt-Foot study.

6.9.6.2 Exposure 2 (pre-operative ankle dorsiflexion) Vs post-operative OKS

The evidence for associations between ankle flexibility and common covariates is lacking, as is robust evidence for normative values of ankle dorsiflexion across age groups. Ageing has shown to be associated with significant changes in foot characteristics such as reduced range of motion of the ankle (Scott et al 2007) and one study has shown that the range of ankle dorsiflexion is less for older women than for older men (Nigg et al 1992). Ankle flexibility has shown no association with foot pain (Menz and Morris, 2005). Foot pain may be viewed as a potential confounder however it is more likely this will be on the causal pathway and will therefore not be included for potential confounding effects. It is unclear if fixed flexion deformity, RA and back pain play a confounding role; therefore the statistical relationships to both ankle dorsiflexion and OKS outcome were explored within the following regression analysis.

6.9.6.3 Exposure 3 (pre-operative Foot posture index items) Vs post-operative OKS

As previously discussed there is now a good understanding of the associations between KA outcome and factors such as age, gender, BMI, other pathological joints, pre-operative knee pain, and depression. There is also evidence available to suggest associations, or lack of, between some of these (namely BMI, age and gender) and total FPI score (Redmond et al 2008 Menz and Morris 2005).

Studies observing the individual items of foot posture characteristics have shown that obese women presented flatter feet (according to the medial longitudinal arch height) while obese men presented more pronated feet (according to the entire foot posture), indicating a relationship between high BMI values and postural characteristics of the feet (Aurichio et al 2011). Other findings indicate that ageing is associated with significant changes in foot characteristics such as flatter/more pronated feet (Scott et al 2007). Age, gender and BMI were therefore treated as biological confounders.

6.9.7 Linear Regression Analysis- Outcome 1 (Oxford Knee Score)

Normality of data was assessed using Kernal density plots. Pre-operative OKS is normally distributed (figure 51). Post-operative OKS is negatively skewed (figure 53) suggesting the majority of participants achieve improvement in pain and function. However the histogram of the difference in scores (figure 52) highlights that whereas some got better, others got worse or received no improvement.

Pre and post-operative OKS

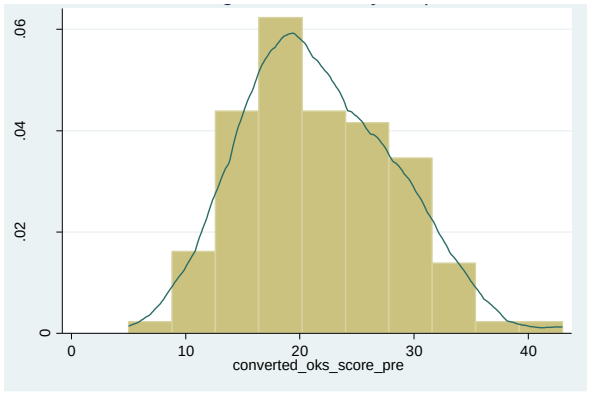

Figure 52. Distribution pre-operative OKS score

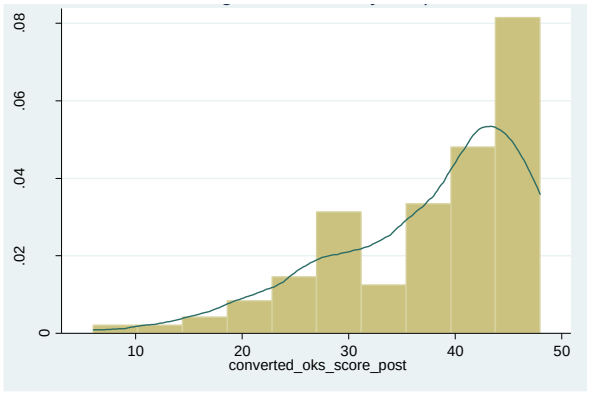

Figure 53. Distribution of post-operative OKS scores

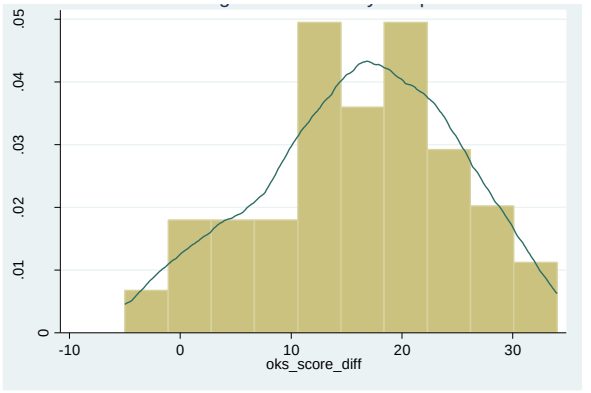

Figure 51. Distribution of difference between pre and post-operative OKS

6.9.7.1 Analysis

Collinearity was previously examined (section 6.4.14.3) between the main study predictor variables; foot pain, ankle dorsiflexion and six foot posture items. The lack of association found between these variables indicated that one variable should not swamp the effect of another, therefore permitting each to be modelled either together or separately. Univariable analysis was undertaken on each predictor against the outcome of post-operative OKS score. Each of the three main predictors was then included within separate multivariable regression analysis alongside all potential confounders, which were confirmed based upon their statistical association via forward selection process. A final fourth model combined the three main predictors alongside confounders.

6.9.7.2 Univariable Analysis- Foot pain

The presence of foot pain predicted a significant reduction (worse) post-op OKS (β-4.18, 95% CI - -7.55, -0.814, P=0.015). An R-squared value of 0.0513 showed that foot pain explained 5.1% of the variability of post-operative OKS score.

6.9.7.3 Univariable Analysis - Ankle dorsiflexion

Ankle dorsiflexion did not predict a better or worse post-operative OKS score (β 0.11, 95% CI -0.09, 0.31 P=0.283).

6.9.7.4 Univariable Analysis - Talar head palpation

A talar head palpation score of 1 (talar head equally palpable on medial and lateral side) (β -0.7 95% CI -7.07, 5.67 P=0.828) or 2 (talar head more palpable on medial side) (β -2.75 95% CI -8.87, 3.37 P=0.375) had no greater prediction on post-operative OKS than a talar head palpation score of 0 (talar head more palpable on lateral side).

6.9.7.5 Univariable Analysis –Malleolar curves

A lateral malleolar curves score of 1 (infra curves more concave) had no greater prediction on post-operative OKS than a score of 0 (both infra and supra curves equal or infra curve more shallow than supra curve) (β 0.23 95% CI -3.18, 3.64 P=0.894).

6.9.7.6 Univariable Analysis – Calcaneal position

An inversion/eversion of the calcaneus score of 1 (vertical) (β -3.02 95% CI -8.17, 2.13 P=0.248) or 2 (everted) (β -1.41 95% CI -7.02, 4.19 P=0.619) had no greater prediction on post-operative OKS than a score of 0 (inverted).

6.9.7.7 Univariable Analysis – Prominence of the talonavicular joint

A talonavicular joint score of 1 (area of TNJ flat) (β 1.24 95% CI -4.59, 7.07 P= 0.675) or 2 (area of NJ bulging) (β -2.92 95% CI -8.87, 3.02 P=0.331) had no greater prediction on post-operative OKS than a score of 0 (area of TNJ concave).

6.9.7.8 Univariable Analysis – Congruence of medial longitudinal arch

A medial longitudinal arch score of 1 (normal) (β 3.94 95% CI -2.46, 10.35 P=0.225) or 2 (arch more lowered) (β 2.31 95% CI -4.31, 8.93 P=0.491) had no greater prediction on post-operative OKS than a score of 0 (arch high and angled).

6.9.7.9 Univariable Analysis – Ab/adduction of the rearfoot on forefoot

An ab/adduction of the rearfoot on forefoot score of 1 (medial toes more visible) had no greater prediction on post-operative OKS than a score of 0 (medial and lateral toes equally visible or lateral toes more visible) (β 0.12 95% CI -3.28, 3.53 P=0.943).

6.9.7.10 Univariable Analysis – Age

Age did not predict a better or worse post-operative OKS (β 0.03 95% CI -0.14, 0.20 P=0.707).

6.9.7.11 Univariable Analysis – Gender

Gender did not predict a better or worse post-operative OKS (β 1.14 95% CI -2.24, 4.52 P=0.505).

6.9.7.12 Univariable Analysis – BMI

BMI predicted a significant reduction (worse) in post-operative OKS (β -0.52, 95% CI -0.85, -0.18 P=0.003). An R-squared value of 0.0749 showed that BMI explained 7.5% of the variability of OKS score post-operatively.

6.9.7.13 Univariable Analysis – pre op oks

Greater (better) pre-operative OKS score predicted a significantly greater post-operative OKS score (β 0.54, 95% CI 0.30, 0.77 P=0.001). An R-squared value of 0.1539 shows that pre-op OKS explained 15.4% of the variability of post-op OKS score.

6.9.7.14 Univariable Analysis – Depression

Depression predicted a significant reduction (worse) in post-op OKS score (β -5.65, 95% CI -9.97, -1.33 P=0.011). An R-squared value of 0.0566 showed that depression explained 5.7% of the variability of post-op OKS score.

6.9.7.15 Univariable Analysis – Fixed flexion deformity

Pre-operative index knee fixed flexion deformity did not predict a better or worse post-operative OKS score (β 0.04 95% CI -0.21, 0.29 P=0.738).

6.9.7.16 Univariable Analysis – Back pain

Back pain predicted a significant reduction (worse) in post-op OKS score (β -4.87, 95% CI -8.18, -1.55 P=0.004). An R-squared value of 0.0703 showed that back pain explained 7.0% of the variability of post-op OKS score.

6.9.7.17 Univariable Analysis – Rheumatoid Arthritis

Univariable linear regression shows that RA did not predict a better or worse post-op OKS score (β -3.50, 95% CI -10.51, 3.52 P=0.325).

6.9.8 Multivariable Analysis- 1) foot pain Vs post op OKS score

Forward selection regression was conducted to assess the importance of a priori decided biological and known confounders (from existing evidence); age, gender, BMI, pre-operative knee pain, depression, fixed flexion deformity and ankle dorsiflexion. Back pain was already identified as an effect modifier within this model and was therefore included as an interaction term. Within the forward selection process age, gender, BMI, fixed flexion deformity, ankle dorsiflexion and depression had no significant effect on outcome (and coefficient did not change more than 20%). Fixed flexion deformity and depression were therefore removed from the final multivariable

regression model. Age, gender and BMI were retained in every model due to biological plausibility and known clinical relevance.

Fully adjusted linear regression showed higher pre-operative OKS score predicted a significantly higher (better) post-op OKS score (β 0.38, 95% CI 0.13, 0.63 P=0.003). No other pre-operative variables significantly predicted post-operative OKS score (table 27). An adjusted r-squared value of 0.2310 shows that this model explained 23.10% of the variability of post-operative OKS-score.

Table 27. Unadjusted and adjusted linear regression analysis of foot pain as a predictor of post-operative knee outcome (OKS)

Predictor Variables	Post op OKS Univariable Coefficient (95% CI)	P-value	Post op OKS Multivariable adjusted for biological confounders Coefficient (95% CI)	P-value
Age	0.03 (-0.14, 0.20)	0.707	-0.08 (-0.24, 0.08)	0.307
Gender	1.14 (-2.24, 4.52)	0.505	-1.93 (-5.18, 1.31)	0.240
BMI	-0.52 (-0.85, -0.18)	0.003*	-0.34 (-0.68, 0.01)	0.055
Foot pain (Yes)	-4.18 (-7.55, -0.814)	0.015*	-0.14 (-4.22, 4.50)	0.949
Pre-op OKS	0.54 (0.30, 0.77)	0.000*	0.38 (0.13, 0.63)	0.003*
Depression	-5.65 (-9.97, -1.33)	0.011*	NA	NA
Fixed flexion deformity	0.04 (-0.21, 0.29)	0.738	NA	NA
Rheumatoid Arthritis	-3.50 (-10.51, 3.52)	0.325	NA	NA
Back pain	-4.87 (-8.18, -1.55)	0.004*	-6.98 (-13.38, -0.58) As interaction term	0.033*
Index limb Ankle dorsiflexion	0.11 (-0.09, 0.31)	0.283	NA	NA

*Denotes statistical significance with α set at P=<0.05

6.9.8.1 Regression diagnostics (Model 1- Foot pain)

Regression diagnostics were checked to ensure assumptions underlying the linear regression model were met, particularly due to the potential ceiling effects seen in post-operative OKS. Residuals (differences between observed and fitted values) were first assessed for normality using a histogram (figure 54) and QQ-plot (figure 55), which showed a normal distribution. Variance of residuals was assessed using a scatter plot (figure 56). The presence of homoscedasticity (variance of the residuals is constant) was questionable in this plot; there was evidence of heteroscedasticity (variance of the residuals is not constant) with minor funnelling of higher values on the x-axis towards the regression line suggests the prediction of post-operative OKS score is more consistent with higher values.

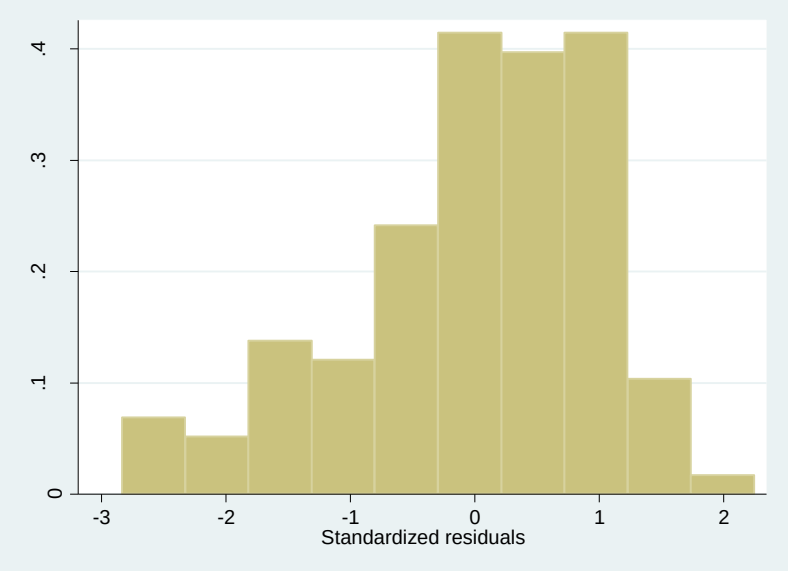

Figure 54. Distribution of residuals for model 1 (foot pain Vs post op OKS)

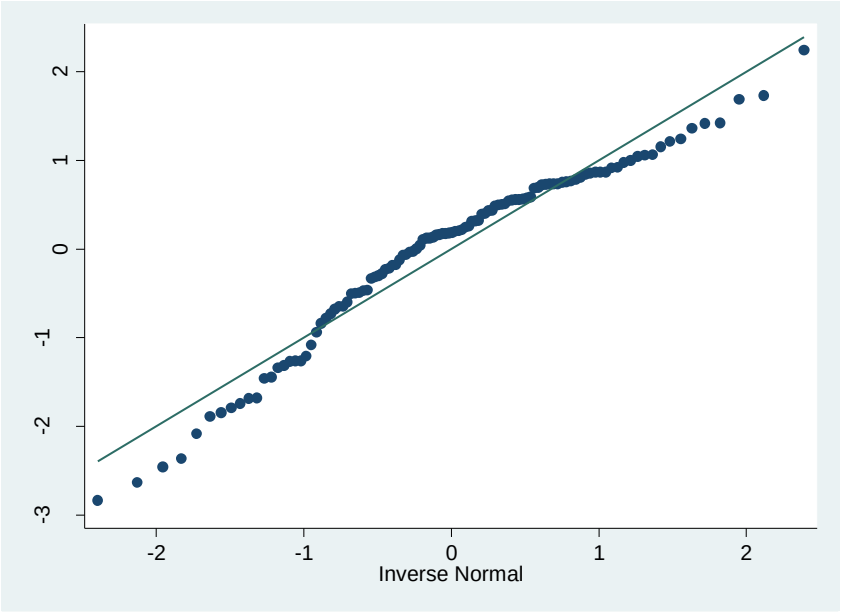

Figure 55. QQ-plot: Distribution of residuals (model 1)

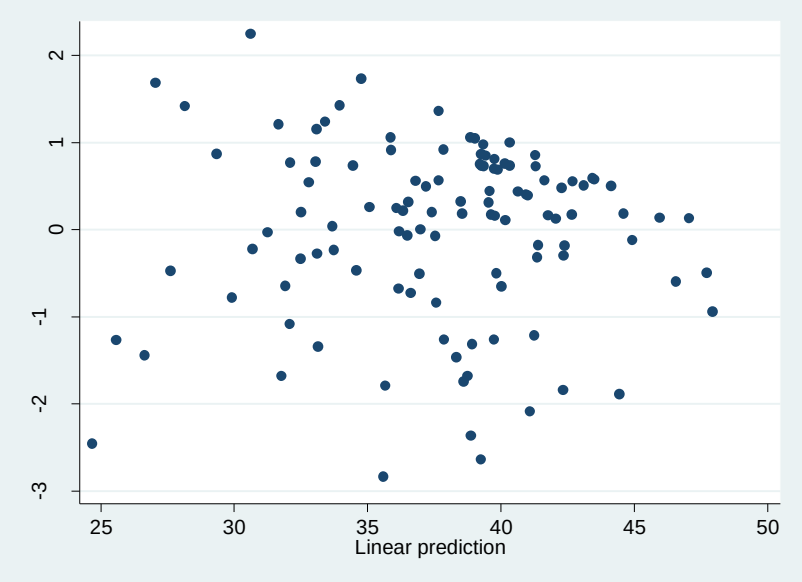

Figure 56. Variance of residuals (model 1)

6.9.9 Multivariable Analysis- 2) Ankle Dorsiflexion Vs post op OKS score

Within the forward selection regression fixed flexion deformity and rheumatoid arthritis had no significant effect on outcome and these were therefore removed from the final multivariable regression model.

Fully adjusted linear regression showed that higher pre-operative OKS score predicted a significant increase (better) in post-op OKS score (β 0.44, 95% CI 0.18, 0.70 P=0.001) and the presence of back pain predicted a significant reduction (worse) in post-op OKS score (β -4.15 95% CI -7.33, -0.98 P=0.011). No other pre-operative variables significantly predicted post-operative OKS score. An adjusted r-squared value of 0.1809 shows that this model explained 18.09% of the variability of post-operative OKS score (table 28).

Table 28. Unadjusted and adjusted linear regression analysis of ankle dorsiflexion as a predictor of post-operative knee outcome (OKS)

Predictor Variables	Post op OKS Univariable Coefficient (95% CI)	P-value	Post op OKS Multivariable adjusted for biological confounders Coefficient (95% CI)	P-value
Age	0.03 (-0.14, 0.20)	0.707	-0.04 (-0.20, 0.11)	0.595
Gender	1.14 (-2.24, 4.52)	0.505	-1.39 (-4.60, 1.82)	0.329
BMI	-0.52 (-0.85, -0.18)	0.003*	-0.30 (-0.66, 0.05)	0.090
Index limb Ankle dorsiflexion	0.11 (-0.09, 0.31)	0.283	0.01 (-0.18, 0.20)	0.932
Pre-op OKS	0.54 (0.30, 0.77)	0.000*	0.44 (0.18, 0.70)	0.001*
Fixed flexion deformity	0.04 (-0.21, 0.29)	0.738	NA	NA
Rheumatoid Arthritis	-3.50 (-10.51, 3.52)	0.325	NA	NA
Back pain	-4.87 (-8.18, -1.55)	0.004*	-4.15 (-7.33, -0.98)	0.011*

*Denotes statistical significance with α set at P=<0.05

6.9.9.1 Regression diagnostics (Model 2- Ankle Dorsiflexion)

Regression diagnostics were checked to ensure assumptions underlying the linear regression model were met, particularly due to the potential ceiling effects seen in post-operative OKS. Residuals (differences between observed and fitted values) were first assessed for normality using a histogram (figure 57) and QQ-plot (figure 58), which showed a normal distribution. Variance of residuals was assessed using a scatter plot (figure 59). There was evidence of heteroscedasticity (variance of the residuals is not constant) with funnelling as the predictive post-operative OKS score got higher, suggesting the prediction is more consistent with higher values.

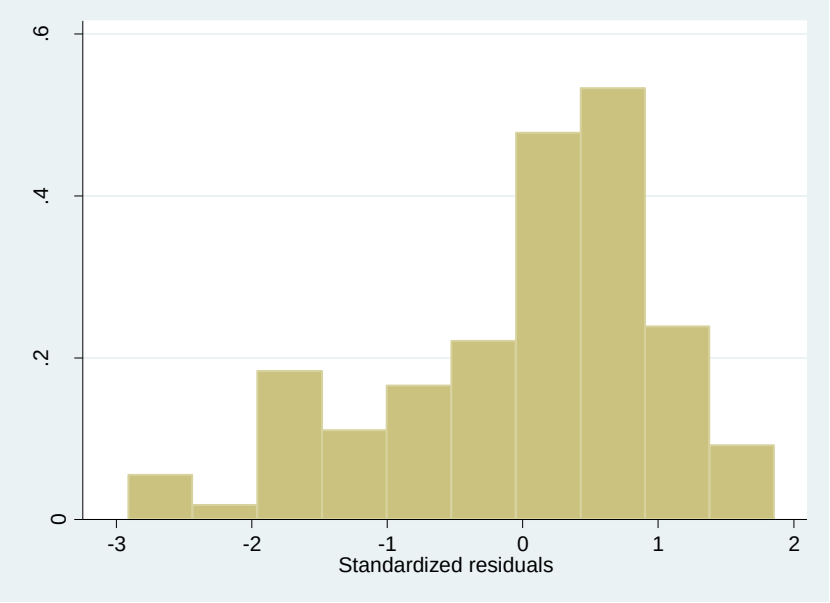

Figure 57. Distribution of residuals for model 2 (ankle dorsiflexion)

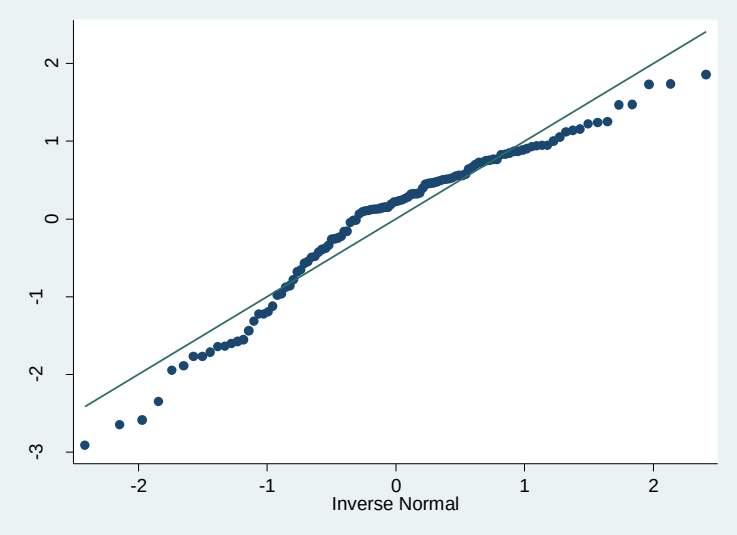

Figure 58. QQ-plot: Distribution of residuals

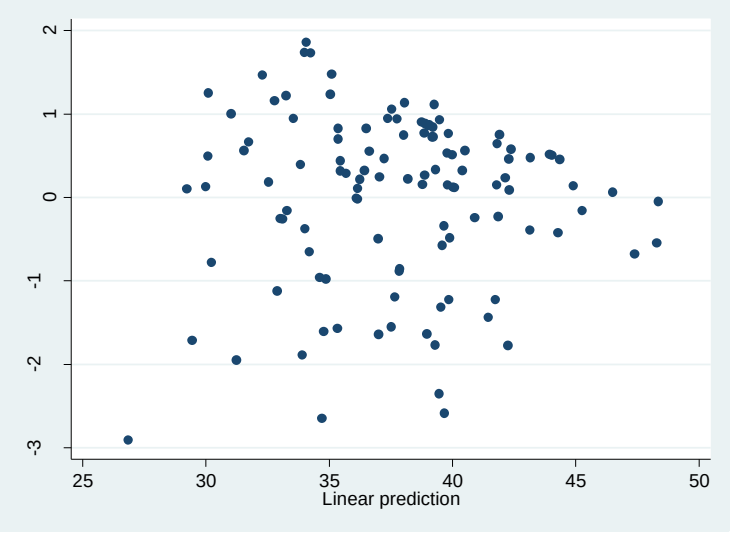

Figure 59. Variance of residuals (model 2)

6.9.10 Multivariable Analysis- 3) Foot Posture Items Vs post op OKS score

Within the forward selection process, variables including fixed flexion deformity and rheumatoid arthritis had no significant effect on outcome and these were therefore removed from the final multivariable regression model.

Fully adjusted linear regression showed that higher pre-operative OKS score predicted a significant increase (better) in post-op OKS score (β 0.44, 95% CI 0.18, 0.69 P=0.001) and the presence of back pain predicted a significant reduction (worse) in post-op OKS score (β -4.92 95% CI -8.20, -1.64 P=0.004). No other pre-operative variables significantly predicted post-operative OKS score. An adjusted r-squared value of 0.2175 showed that this model explained 21.75% of the variability of OKS score post-op (table 29).

Table 29. Unadjusted and adjusted linear regression analysis of foot posture as a predictor of post-operative knee outcome (OKS)

Predictor Variables		Post op OKS Univariable Coefficient (95% CI)	P-value	Post op OKS Multivariable adjusted for biological confounders Coefficient (95% CI)	P-value
Age		0.03 (-0.14, 0.20)	0.707	-0.08 (-0.24, 0.08)	0.316
Gender		1.14 (-2.24, 4.52)	0.505	-2.32 (-5.67, 1.03)	0.172
BMI		-0.52 (-0.85, -0.18)	0.003*	-0.32 (-0.68, 0.03)	0.075
Pre-op OKS		0.54 (0.30, 0.77)	0.000*	0.44 (0.18, 0.69)	0.001*
Index knee fixed flexion deformity		0.04 (-0.21, 0.29)	0.738	NA	NA
Back pain		-4.87 (-8.18, -1.55)	0.004*	-4.92 (-8.20, -1.64)	0.004*
Rheumatoid Arthritis		-3.50 (-10.51, 3.52)	0.325	NA	NA
Index limb talar head palpation	1 (neutral) compared to 0 (supinated)	-0.7 (-7.07, 5.67)	0.828	-7.01 (-13.69, -0.34)	0.040*
	2 (pronated) compared to 0 (supinated)	-2.75 (-8.87, 3.37)	0.375	-7.89 (-14.60, -1.17)	0.022*
Index limb malleolar curves[¥]	0 (neutral or supinated) compared to 1 (pronated)	0.23 (-3.18, 3.64)	0.894	2.50 (-1.40, 6.41)	0.206
Index limb calcaneal inclination	1 (neutral) compared to 0 (supinated)	-3.02 (-8.17, 2.13)	0.248	-2.25 (-7.75, 3.26)	0.420
	2 (pronated) compared to 0	-1.41 (-7.02, 4.19)	0.619	0.55 (-5.91, 7.01)	0.866

Predictor Variables		Post op OKS Univariable Coefficient (95% CI)	P-value	Post op OKS Multivariable adjusted for biological confounders Coefficient (95% CI)	P-value
Index limb talonavicular Joint prominence	1 (neutral) compared to 0 (supinated)	1.24 (-4.59, 7.07)	0.675	0.05 (-6.45, 6.54)	0.988
	2 (pronated) compared to 0 (supinated)	-2.92 (-8.87, 3.02)	0.331	-2.71 (-9.83, 4.42)	0.453
Index limb Medial longitudinal arch height	1 (neutral) compared to 0 (supinated)	3.94 (-2.46, 10.35)	0.225	6.62 (-0.28, 13.53)	0.060
	2 (pronated) compared to 0 (supinated)	2.31 (-4.31, 8.93)	0.491	5.93 (-1.60, 13.46)	0.121
Index limb Ab/adduction of forefoot on rearfoot[¥]	0 (neutral or supinated) compared to 1 (pronated)	0.12 (-3.28, 3.53)	0.943	-1.10 (-4.64, 2.43)	0.537

[¥]further categorised due to lack of observations in one group

*Denotes statistical significance with α set at P=<0.05

6.9.10.1 Regression diagnostics (Model 3- FPI items)

The variance of residuals plot (figure 62) shows evidence of heteroscedasticity (variance of the residuals is not constant) with funnelling as the prediction gets higher, suggesting the prediction is more consistent with higher values.

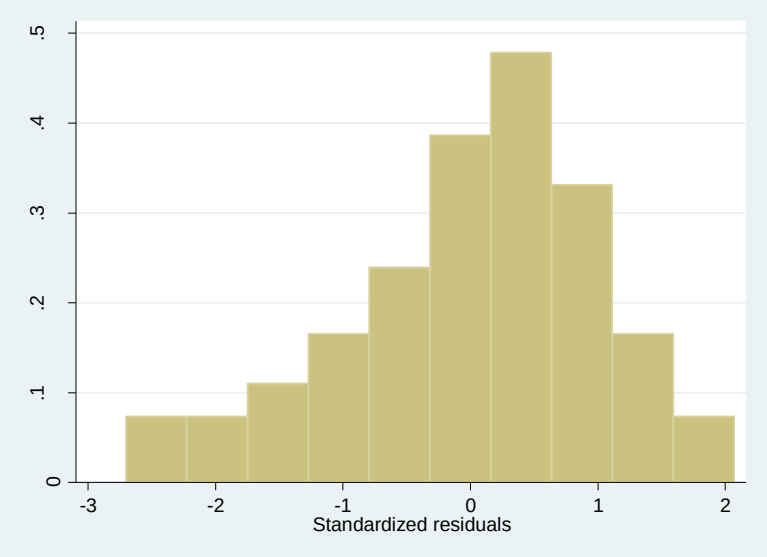

Figure 60. Distribution of residuals for model 3 (foot posture model)

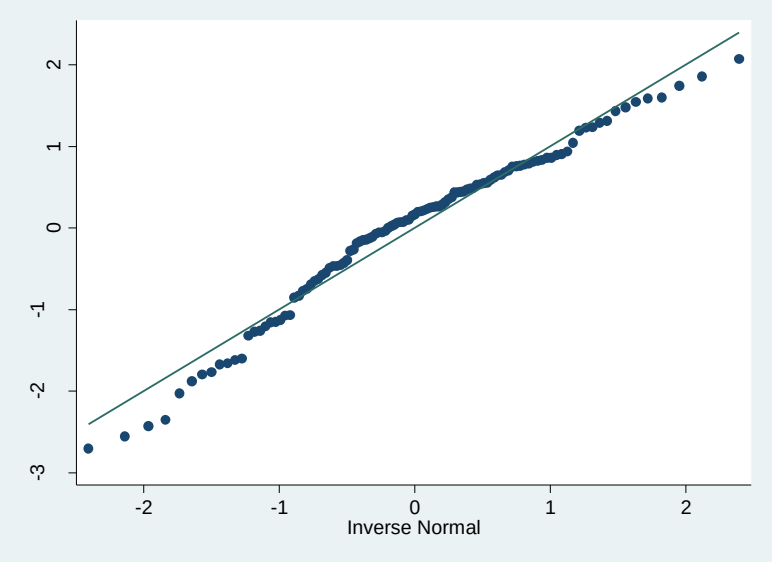

Figure 61. QQ-plot: Distribution of residuals (model 3)

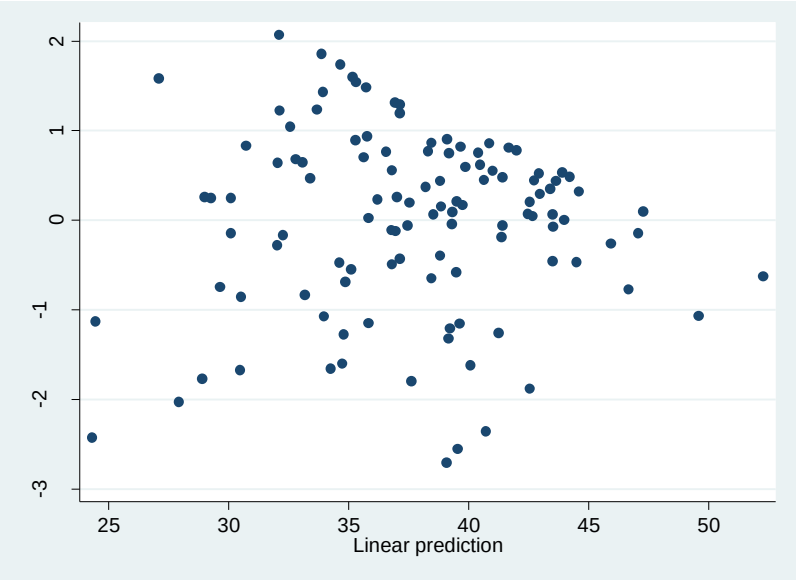

Figure 62. Variance of residuals (model 3)

6.9.11 Multivariable Analysis- 4) Foot pain, ankle dorsiflexion and foot posture Vs post-operative OKS score (loaded model)

Forward selection regression was conducted. Fixed flexion deformity, depression and rheumatoid arthritis had no significant effect on outcome and these were therefore removed from the final multivariable regression model. Back pain remained in the model as a potential effect modifier

Fully adjusted linear regression showed that increased BMI predicted a significant reduction (worse) in post-op OKS score (β -0.36, 95% CI -0.71, 0.01 P=0.045) and a higher pre-operative OKS score predicted and significant increase (better) in post-op OKS score (β 0.44, 95% CI 0.17, 0.70 P=0.001). Index limb talar head palpation score of 1 (β -7.20, 95% CI -13.81, -0.59 P= 0.033) or 2 (β -7.47, 95% CI -14.13, -0.81 P= 0.028) predicted a significant reduction in post-op OKS score, however confidence intervals were very wide, therefore this is less likely to be a true association. No other pre-operative variables significantly predicted post-operative OKS score. An adjusted r-squared value of 0.2421 showed that this model explained 24.21% of the variability of post-operative OKS score (table 30).

Table 30. Fully adjusted linear regression analysis to identify foot and ankle assessment predictors of post-operative knee outcome (OKS) (loaded model)

Predictor Variables		Post op OKS Multivariable adjusted for biological confounders Coefficient (95% CI)	P-value
Age		-0.11 (-0.27, 0.05)	0.172
Gender		-2.96 (-6.48, 0.55)	0.098
BMI		-0.36 (-0.71, -0.01)	0.045*
Foot pain		-0.46 (-5.07, 4.16)	0.845
Ankle dorsiflexion		0.02 (-0.18, 0.22)	0.844
Index limb talar head palpation	1 (neutral) compared to 0 (supinated) 2 (pronated) compared to 0 (supinated)	-7.20 (-13.81, -0.59) -7.47 (-14.13, -0.81)	0.033* 0.028*
Index limb malleolar curves¥	0 (neutral or supinated) compared to 1 (pronated)	2.36 (-1.52, 6.24)	0.230
Index limb calcaneal inclination	1 (neutral) compared to 0 (supinated) 2 (pronated) compared to 0 (supinated)	-2.61 (-8.15, 2.94) 0.39 (-6.02, 6.80)	0.353 0.904
Index limb talonavicular Joint prominence	1 (neutral) compared to 0 (supinated) 2 (pronated) compared to 0 (supinated)	0.05 (-6.48, 6.57) -1.78 (-8.92, 5.36)	0.989 0.621
Index limb Medial longitudinal arch height	1 (neutral) compared to 0 (supinated) 2 (pronated) compared to 0 (supinated)	6.40 (-0.56, 13.36) 5.94 (-1.67, 13.55)	0.071 0.125
Index limb Ab/adduction of forefoot on rearfoot¥	0 (neutral or supinated) compared to 1 (pronated)	-1.55 (-5.11, 2.01)	0.390
Pre-op OKS		0.44 (0.17, 0 .70)	0.001*
Index knee fixed flexion deformity		0.14 (-0.12, 0.40)	0.274

¥further categorised due to lack of observations in one group
*Denotes statistical significance with α set at P=<0.05

6.9.11.1 Regression diagnostics - 4) Foot pain, ankle dorsiflexion and foot posture Vs post-operative OKS

The variance of residuals plot (figure 63) shows evidence of heteroscedasticity (variance of the residuals is not constant) with funnelling as the prediction gets higher, suggesting the prediction is more consistent with higher values.

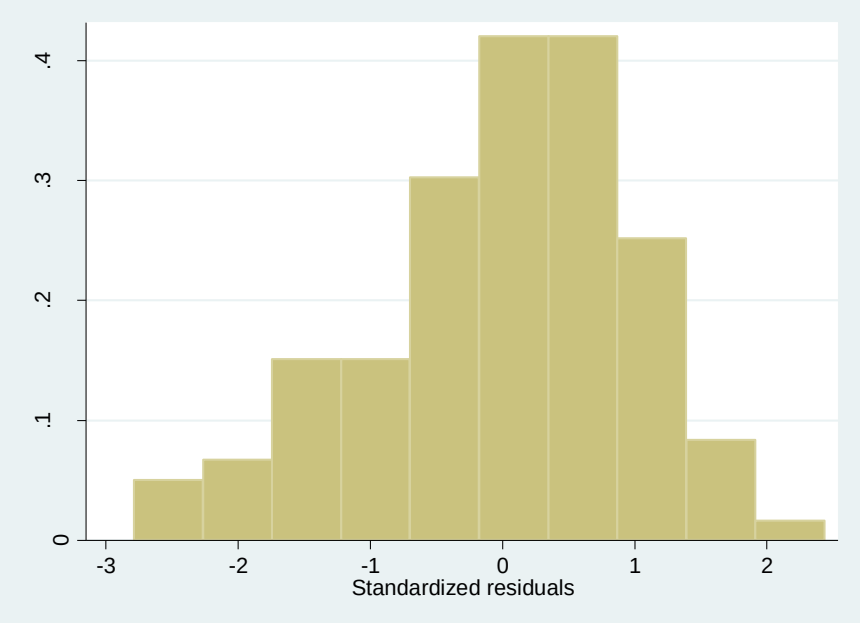

Figure 63. Distribution of residuals for model 4 (foot pain, ankle dorsiflexion and foot posture)

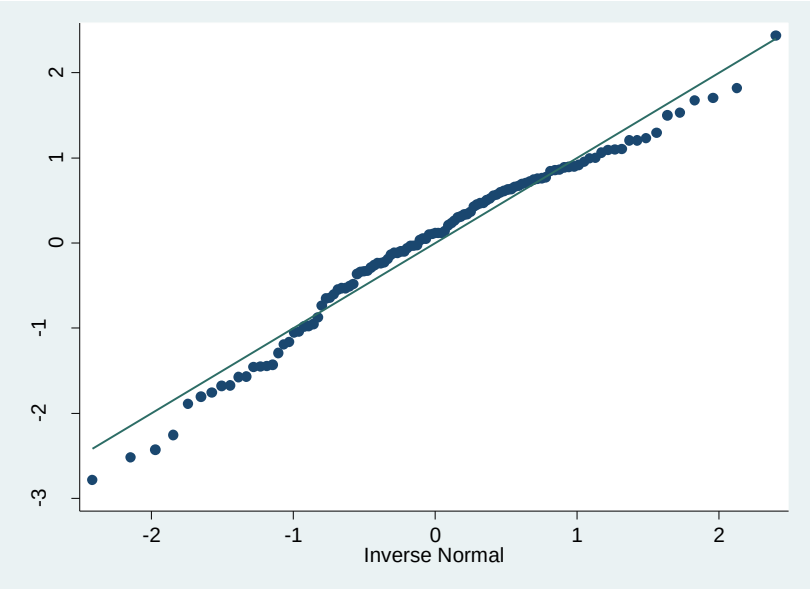

Figure 64. QQ-plot: Distribution of residuals (model 4)

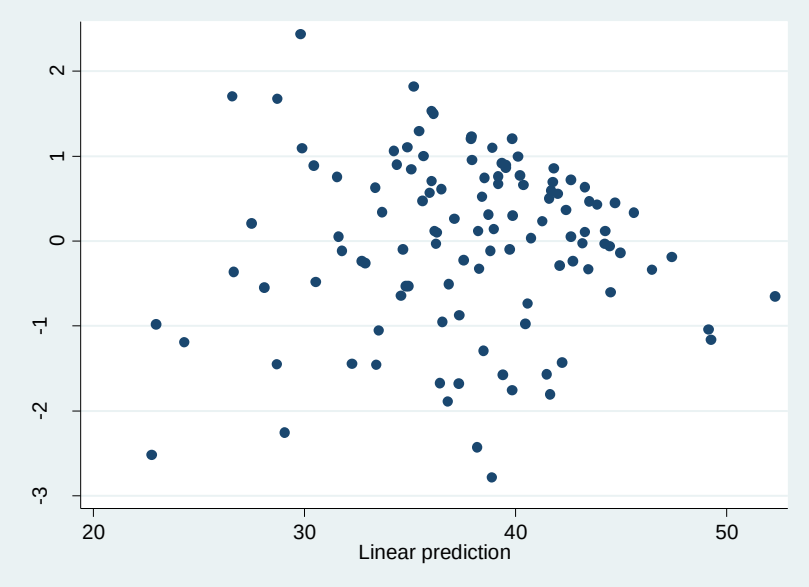

Figure 65. Variance of residuals (model 4)

6.9.12 Comparison of linear regression diagnostics for all four models

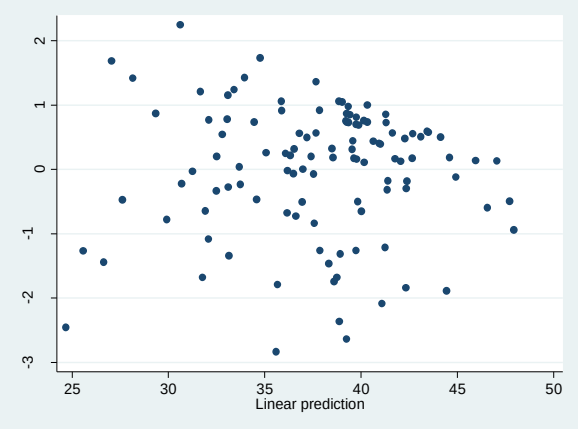

Figure 66. Variance of residuals (model 1- foot pain)

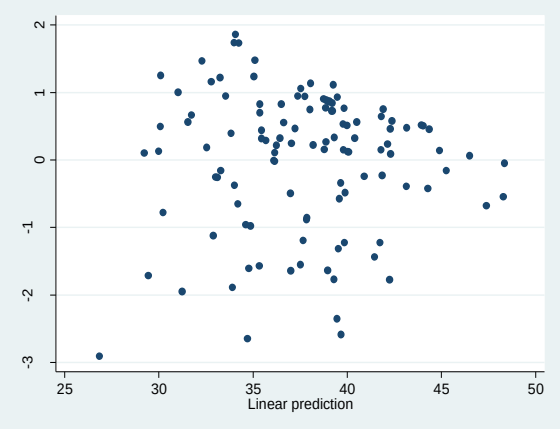

Figure 67. Variance of residuals (model 2- ankle dorsiflexion)

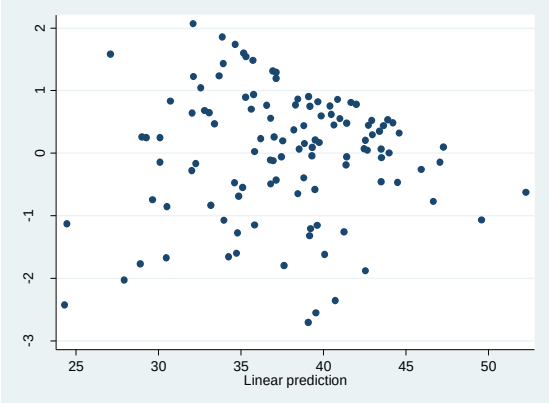

Figure 68. Variance of residuals (model 3- foot posture)

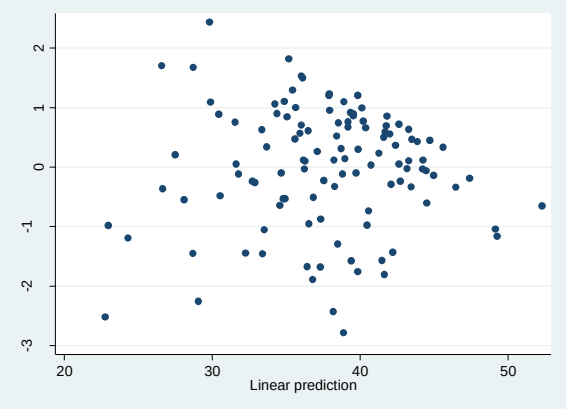

Figure 69. Variance of residuals (model 4- loaded)

Results of the variance of residuals show that all plots (figures 66-69) exhibit heteroscedasticity, where in all instances, the variance of residuals get larger as the prediction moves from large to small, suggesting therefore that prediction of post-operative OKS score may be less consistent as values lower. This indicates a less than perfect fit to each linear model, which implies either the models require improvement or a non-linear analysis would be more appropriate.

6.9.13 Linear Regression summary

Univariable and multivariable linear regression coefficients and 95% confidence intervals are shown for each model (foot pain, ankle dorsiflexion and foot posture Vs post-operative OKS) in figure 70.

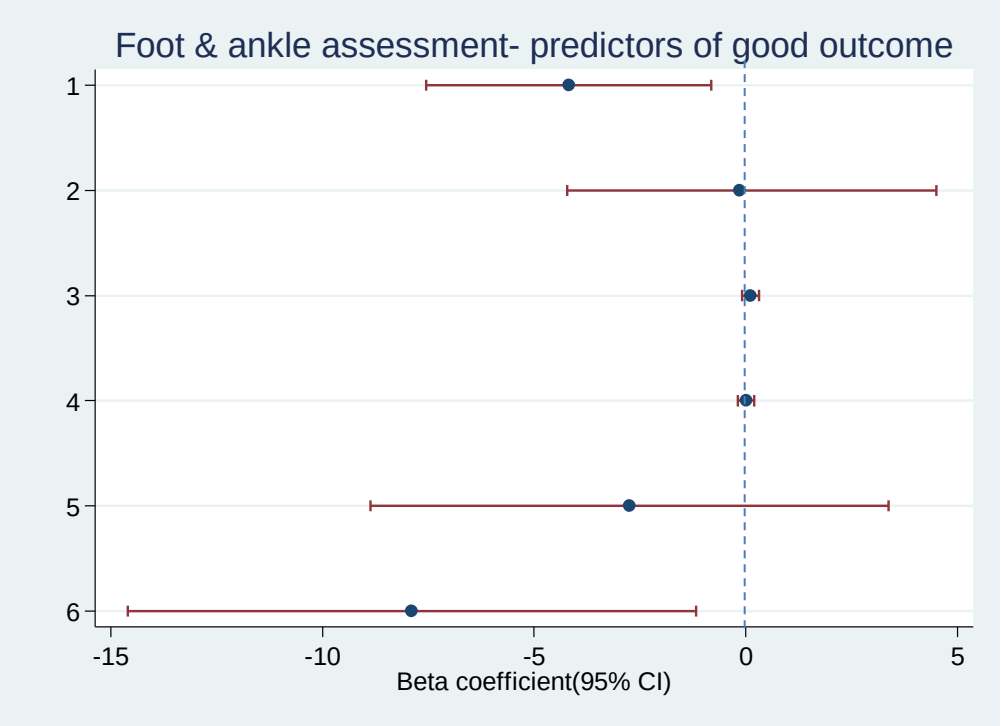

Figure 70. Point estimate and confidence interval plot to show level of prediction for foot and ankle assessments on better outcome (OKS score) following knee arthroplasty*Y Axis denotes 1: Multivariable foot pain model 2: Univariable foot pain model 3: Multivariable ankle dorsiflexion model 4: Univariable ankle dorsiflexion model 5: Mulitvariable foot posture model 6: Univariable foot posture model.

Adjusted r-square values (the percentage of post-operative OKS outcome variation that is explained by the linear model) for each model are shown in table 31.

Table 31. Adjusted R-squared values

Model	Adjusted R-squared values	% variation of post-op OKS explained by model predictors
1) foot pain Vs post op OKS score	0.2310	23.10
2) Ankle Dorsiflexion Vs post op OKS score	0.1809	18.09
3) Foot Posture Items Vs post op OKS score	0.2175	22.75
4) Foot pain, ankle dorsiflexion and foot posture Vs post-operative OKS score	0.2421	24.21

6.9.14 Logistic regression analysis- Outcome 2 (patient acceptable symptom state (PASS) for one year OKS)

The main study predictor variables; foot pain, ankle dorsiflexion and six foot posture items were firstly modelled separately, then combined. Univariable analysis was undertaken for each predictor against the outcome of post-operative OKS score. Each were then included within their separate multivariable regression analysis alongside other confounders, which were confirmed via forward selection.

6.9.14.1 Univariable Analysis- Foot pain

Participants with pre-operative foot pain were 75% less likely to achieve a good outcome (represented by an acceptable PASS score) (odds ratio [OR] 0.25 95% CI 0.09, 0.68 P= 0.007).

6.9.14.2 Univariable analysis- Ankle dorsiflexion

The odds achieving an acceptable PASS score (good outcome) were not significantly increased with greater range of ankle dorsiflexion (OR 1.03 95% CI 0.98, 1.09 P= 0.294).

6.9.14.3 Univariable Analysis Talar head palpation

The odds of achieving an acceptable PASS score were not significantly reduced with a pre-operative talar head palpation score of 1 (OR 0.63, 95% CI 0.07, 5.92 P= 0.686) or 2 (OR 0.40, 95% CI 0.046, 3.40 P= 0.399) compared to 0.

6.9.14.4 Univariable Analysis – Curves above and below the lateral malleolus

The odds of achieving an acceptable PASS score were not significantly increased with a pre-operative curves above and below the lateral malleolus score of 1 (OR 1.38, 95% CI 0.51, 3.53 P= 0.556) compared to 0.

6.9.14.5 Univariable Analysis – Inversion/eversion of the calcaneus

The odds of achieving an acceptable PASS score were not significantly reduced with a pre-operative inversion/eversion of the calcaneus score of 1 (OR 0.57, 95% CI 0.12, 2.83 P= 0.493) or 2 (OR 0.86, 95% CI 0.15, 5.04 P= 0.869) compared to 0.

6.9.14.6 Univariable Analysis – Prominence of the talonavicular joint

The odds of achieving an acceptable PASS score were not significantly increased with a pre-operative talonavicular joint prominence score of 1 (OR 1.59 95% CI 0.28, 8.90 P= 0.599) or reduced with a score of 2 (OR 0.63 95% CI 0.12, 3.34 P= 0.587) compared to 0.

6.9.14.7 Univariable Analysis – Congruence of medial longitudinal arch

The odds of achieving an acceptable PASS score were not significantly increased with a pre-operative congruence of the medial longitudinal arch score of 1 (OR 1.54 95% CI 0.28, 8.53 P= 0.619) or 2 (OR 1.02 95% CI 0.18, 5.77 P= 0.986) compared to 0.

6.9.14.8 Univariable Analysis – Ab/adduction of the rearfoot on forefoot

The odds of achieving an acceptable PASS score were not significantly reduced with a pre-operative ab/adduction of the forefoot score of 1 (OR 0.66, 95% CI 0.25, 1.70 P= 0.386) compared to 0.

6.9.14.9 Univariable Analysis – Age

The odds of achieving an acceptable PASS score were not significantly increased with age (OR 1.01 95% CI 0.97, 1.06 P=0.553).

6.9.14.10 Univariable Analysis – Gender

The odds of achieving an acceptable PASS score were not significantly reduced with gender (OR 0.89 (95% CI 0.34, 2.30 P=0.809).

6.9.14.11 Univariable Analysis – BMI

The odds of achieving an acceptable PASS score were not significantly reduced with higher BMI (OR 0.94 95% CI 0.85, 1.04 P=0.239).

6.9.14.12 Univariable Analysis – pre op OKS

Better pre-operative OKS score significantly increased the odds of achieving an acceptable PASS score by 9% (OR 1.09 95% CI= 1.01, 1.19 P=0.031).

6.9.14.13 Univariable Analysis – Depression

The odds of achieving an acceptable PASS score were not significantly reduced with the presence of depression (OR 0.62 95% CI 0.20, 1.94 P=0.406).

6.9.14.14 Univariable Analysis – back pain

The odds of achieving an acceptable PASS score were not significantly reduced with the presence of back pain (OR 0.45 95% CI 0.17, 1.18 P=0.106).

6.9.14.15 Univariable Analysis – knee fixed flexion deformity

The odds of achieving an acceptable PASS score were not significantly reduced with the presence of index knee fixed flexion deformity (OR 1.05 95% CI 0.97, 1.15 P=0.232).

6.9.14.16 Univariable Analysis – Rheumatoid Arthritis

The odds of achieving an acceptable PASS score were not significantly reduced with the presence of rheumatoid arthritis (OR 0.54 95% CI 0.10, 2.99 P=0.481).

6.9.15 Multivariable Analysis- 1) foot pain vs OKS PASS

Forward selection regression was conducted to assess the significance of potential confounders; pre-operative knee pain, back pain and depression.

In a fully adjusted model the odds of achieving an acceptable PASS score are reduced by 81% if foot pain was present (OR 0.19 95% CI 0.06, 0.61 P=0.005). No other variables significantly affected the odds of achieving an acceptable PASS score (P>0.05) (table 32).

Table 32. Unadjusted and adjusted logistic regression analysis of foot pain as a risk factor for poor clinical post-operative knee outcome (PASS)

Predictor Variables	Post op OKS PASS score Univariable OR (95% CI)	P-value	Post op OKS PASS score Multivariable OR mutually adjusted for biological confounders (95% CI)	P-value
Age	1.01 (0.97, 1.06)	0.553	1.01 (0.96, 1.06)	0.698
Gender (male)	0.89 (0.34, 2.30)	0.809	0.36 (0.11, 1.14)	0.083
BMI	0.94 (0.85, 1.04)	0.239	0.96 (0.85, 1.08)	0.451
Foot pain (present)	0.25 (0.09, 0.68)	0.007*	0.19 (0.06, 0.61)	0.005*
Pre-op OKS	1.09 (1.01, 1.19)	0.031*	1.08 (0.98, 1.18)	0.104
Depression (present)	0.62 (0.20, 1.94)	0.406	NA	NA
Back pain (present)	0.45 (0.17, 1.18)	0.106	NA	NA
Rheumatoid Arthritis (present)	0.54 (0.10, 2.99)	0.481	NA	NA

*Denotes statistical significance with α set at P=<0.05

6.9.15.1 Regression diagnostics (Foot pain vs Post-operative OKS PASS)

Goodness of fit:

The Hosmer-Lemeshow goodness of fit test was used to test whether observed binary responses (Y= OKS PASS), conditional on a vector of p covariates (x= risk factors and confounding variables) are consistent with predictions from the logistic regression model.

H^0= there is no difference between observed and model-predicting values

Stata output:

```
Logistic model for oks_pass, goodness-of-fit test

       number of observations =       114
 number of covariate patterns =       114
            Pearson chi2(108) =       123.68
                  Prob > chi2 =         0.1437
```

The H-L goodness of fit test statistic is non-significant (P=0.1437), therefore failing to reject the null hypothesis, indicating the model prediction is not significantly different from observed values, implying that the models estimates fit the data at an acceptable level.

6.9.16 Multivariable Analysis- 2) Ankle Dorsiflexion vs OKS PASS

In a fully adjusted model increased ankle dorsiflexion did not increase the odds of achieving an acceptable PASS score (OR 1.01 95% CI 0.95, 1.07 P=0.748). No other variables statistically effected the odds of achieving an acceptable PASS score (P>0.05) (table 33).

Table 33. Unadjusted and adjusted logistic regression analysis of ankle dorsiflexion as a risk factor for poor clinical post-operative knee outcome (PASS)

Predictor Variables	Post op OKS PASS score Univariable OR (95% CI)	P-value	Post op OKS PASS score Multivariable OR mutually adjusted for biological confounders (95% CI)	P-value
Age	1.01 (0.97, 1.06)	0.553	1.01 (0.96, 1.06)	0.754
Gender (male)	0.89 (0.34, 2.30)	0.809	0.65 (0.23, 1.80)	0.402
BMI	0.94 (0.85, 1.04)	0.239	0.98 (0.87, 1.10)	0.718
Pre-op OKS	1.09 (1.01, 1.19)	0.031*	1.09 (0.99, 1.19)	0.069
Back pain (present)	0.45 (0.17, 1.18)	0.106	NA	NA
Index limb Ankle dorsiflexion	1.03 (0.98, 1.09	0.294	1.02 (0.96, 1.08)	0.579
Index knee fixed flexion deformity (present)	1.05 (0.97, 1.15	0.232	NA	NA

*Denotes statistical significance at P=<0.05

6.9.16.1 Regression diagnostics (Ankle dorsiflexion vs post-operative OKS PASS)

Goodness of fit, stata output:

```
Logistic model for oks_pass, goodness-of-fit test

       number of observations =       114
 number of covariate patterns =       114
            Pearson chi2(108) =       109.33
                  Prob > chi2 =         0.4461
```

The H-L goodness of fit test statistic is non-significant (P=0.4461), therefore failing to reject the null hypothesis, indicating the model prediction is not significantly different from observed values, implying that the models estimates fit the data at an acceptable level.

6.9.17 Multivariable Analysis- 3) foot posture items vs OKS PASS

In a fully adjusted model higher (better) pre-operative OKS score significantly increased the odds of achieving an acceptable PASS score (OR 1.10 95% CI 1.00, 1.21, P=0.042). No other variables statistically effected the odds of achieving an acceptable PASS score (P>0.05) (table 34).

Table 34. Unadjusted and adjusted logistic regression analysis of foot posture as a risk factor for poor clinical post-operative knee outcome (PASS)

Predictor Variables		**Post op OKS Univariable OR (95% CI)**	**P-value**	**Post op OKS Multivariable adjusted for biological confounders OR (95% CI)**	**P-value**
Age		1.01 (0.97, 1.06)	0.553	1.00 (0.95, 1.06)	0.939
Gender (male)		0.89 (0.34, 2.30)	0.809	0.55 (0.17, 1.78)	0.314
BMI		0.94 (0.85, 1.04)	0.239	0.98 (0.87, 1.10)	0.711
Pre-op OKS		1.09 (1.01, 1.19)	0.031*	1.10 (1.00, 1.21)	0.042*
Index knee fixed flexion deformity (present)		1.05 (0.97, 1.15	0.232	NA	NA
Back pain (present)		0.45 (0.17, 1.18)	0.106	NA	NA
Index limb talar head palpation	1 (neutral) compared to 0 (supinated)	0.63 (0.07, 5.92)	0.686	0.25 (0.02, 3.37)	0.229
	2 (pronated) compared to 0 (supinated)	0.40 (0.046, 3.40)	0.399	0.20 (0.02, 2.59)	0.218
Index limb malleolar curves[¥]	0 (neutral or supinated) compared to 1 (pronated)	1.38 (0.51, 3.53)	0.556	3.79 (0.86, 16.78)	0.079

Predictor Variables		Post op OKS Univariable OR (95% CI)	P-value	Post op OKS Multivariable adjusted for biological confounders OR (95% CI)	P-value
Index limb calcaneal inclination	1 (neutral) compared to 0 (supinated)	0.57 (0.12, 2.83)	0.493	0.44 (0.06, 3.35)	0.424
	2 (pronated) compared to 0 (supinated)	0.86 (0.15, 5.04)	0.869	0.98 (0.09, 10.13)	0.986
Index limb talonavicular Joint prominence	1 (neutral) compared to 0 (supinated)	1.59 (0.28, 8.90)	0.599	1.43 (0.16, 12.68)	0.747
	2 (pronated) compared to 0 (supinated)	0.63 (0.12, 3.34)	0.587	0.57 (0.06, 5.60)	0.626
Index limb Medial longitudinal arch height	1 (neutral) compared to 0 (supinated)	1.54 (0.28, 8.53)	0.619	4.29 (0.38, 47.80)	0.237
	2 (pronated) compared to 0 (supinated)	1.02 (0.18, 5.77)	0.986	2.51 (0.38, 34.71)	0.492
Index limb Ab/adduction of forefoot on rearfoot[¥]	0 (neutral or supinated) compared to 1 (pronated)	0.66 (0.25, 1.70)	0.386	0.36 (0.09, 1.41)	0.143

[¥]further categorised due to lack of observations in one group
*Denotes statistical significance with α set at P=<0.05

6.9.17.1 Regression diagnostics (foot posture vs post-operative OKS PASS)

Goodness of fit, stata output:

```
Logistic model for oks_pass, goodness-of-fit test

       number of observations =       114
 number of covariate patterns =       114
             Pearson chi2(99) =       109.97
                  Prob > chi2 =         0.2121
```

The H-L goodness of fit test statistic is non-significant (P=0.2121), therefore failing to accept the null hypothesis, indicating the model prediction is not significantly different from observed values, implying that the models estimates fit the data at an acceptable level.

6.9.17.2 Multivariable Analysis- 4) Foot pain, ankle dorsiflexion and foot posture Vs post-operative OKS PASS (loaded model)

Fully adjusted logistic regression showed that foot pain significantly reduced the odds of a good outcome (β 0.15, 95% CI 0.04, 0.56 P=0.004). No other pre-operative variables significantly affected the odds of a good outcome (P>0.05) (table 35).

Table 35. Fully adjusted logistic regression analysis to identify foot and ankle assessment risk factors for poor post-operative knee outcome (PASS) (loaded model)

Predictor Variables		**Post op OKS Multivariable adjusted for biological confounders Coefficient (95% CI)**	**P-value**
Age		1.00 (0.95, 1.05)	0.996
Gender (male)		0.25 (0.06, 1.03)	0.055
BMI		0.96 (0.85, 1.09)	0.568
Foot pain		0.15 (0.04, 0.56)	0.004*
Ankle dorsiflexion		1.01 (0.95, 1.08)	0.727
Index limb talar head palpation	1 (neutral) compared to 0 (supinated) 2 (pronated) compared to 0 (supinated)	0.24 (0.02, 3.51) 0.15 (0.01, 2.08)	0.299 0.157
Index limb malleolar curves[¥]	0 (neutral or supinated) compared to 1 (pronated)	4.12 (0.88, 19.30)	0.072
Index limb calcaneal inclination	1 (neutral) compared to 0 (supinated) 2 (pronated) compared to 0 (supinated)	0.53 (0.07, 3.99) 1.47 (0.13, 16.09)	0.541 0.753
Index limb talonavicular Joint prominence	1 (neutral) compared to 0 (supinated) 2 (pronated) compared to 0 (supinated)	1.02 (0.10, 10.59) 0.58 (0.05, 6.99)	0.989 0.672

Predictor Variables		**Post op OKS Multivariable adjusted for biological confounders Coefficient (95% CI)**	**P-value**
Index limb Medial longitudinal arch height	1 (neutral) compared to 0 (supinated) 2 (pronated) compared to 0 (supinated)	4.28 (0.30, 60.78) 2.91 (0.15, 56.15)	0.283 0.480
Index limb Ab/adduction of forefoot on rearfoot[¥]	0 (neutral or supinated) compared to 1 (pronated)	0.28 (0.06, 1.20)	0.085
Pre-op OKS		1.09 (0.98, 1.21)	0.102

[¥]further categorised due to lack of observations in one group
*Denotes statistical significance with α set at P=<0.05

6.9.18 Regression diagnostics - 4) Foot pain, ankle dorsiflexion and foot posture Vs post-operative OKS PASS

Goodness of fit, stata output:

```
Logistic model for oks_pass, goodness-of-fit test

       number of observations =       114
 number of covariate patterns =       114
             Pearson chi2(97) =       181.50
                  Prob > chi2 =         0.0000
```

The H-L goodness of fit test statistic is highly significant (P=0.0000), indicating the model prediction is significantly different from observed values, implying that the models estimates do not fit the data. This model was therefore not acceptable. It is likely this model does not have a sample size large enough to detect an appropriate effect size for this number of degrees of freedom (23), therefore violating assumptions of the model and increasing the chance of a type II error (false negative) (Kirkwood and Sterne 2003). Transformations would not be appropriate, therefore this analysis was rejected.

6.9.19 Logistic Regression summary

Univariable and multivariable logistic regression odds ratios and 95% confidence intervals are shown for each model (foot pain, ankle dorsiflexion and foot posture Vs post-operative OKS) in figure 71.

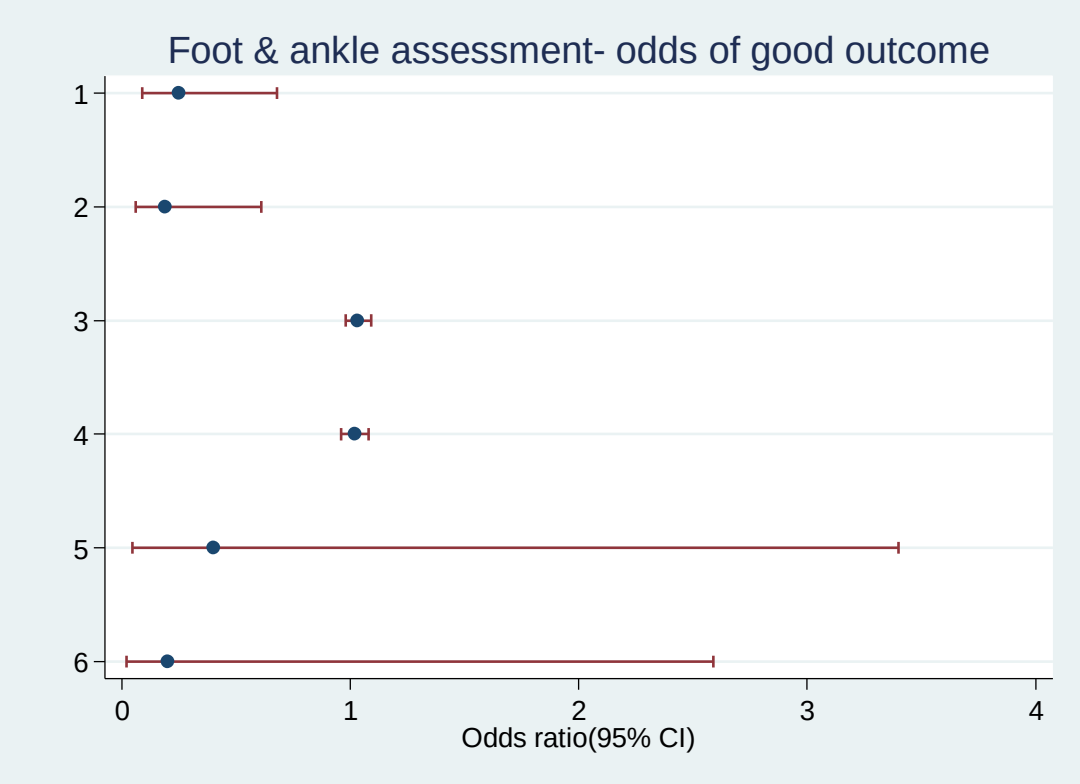

Figure 71. Point estimate and confidence interval plot to show odds of good clinical knee arthroplasty outcome (OKS PASS). Y Axis denotes 1: Multivariable foot pain model 2: Univariable foot pain model 3: Multivariable ankle dorsiflexion model 4: Univariable ankle dorsiflexion model 5: Multivariable foot posture model 6: Univariable foot posture model.

6.10 Results summary

Findings from linear regression diagnostics indicate a likely absence of homoscedasticity within the models, suggesting that prediction of post-operative OKS score may be less consistent as values lower. The apparent heteroscedasticity suggests the estimates of the standard errors of the models may be biased, which leads to questionable inferences within the population. This implies that either the models may have been improved by adding variables or increasing power, or that a non-linear analysis would be more appropriate.

Regression diagnostics for each logistic regression models implies that the models estimates fit the data at an acceptable level. Logistic models showed the presence of pre-operative foot pain reduced odds of a good outcome and higher pre-op OKS increased the odds of a good outcome.

Findings advocate rejection of the null hypothesis, for foot pain only;

H^0 clinical foot and ankle assessment, including foot pain does not affect patient reported outcomes following knee arthroplasty

6.10.1 Relationship between foot pain specific outcomes

A difference in significant findings was seen between foot pain and specific outcomes (OKS continuous OKS PASS). Although associations were in the same direction; this was only significant for OKS PASS. This may be attributable to the heteroscedasticity of residuals observed in the OKS models.

A residual plot shows the prediction made by the linear regression on the x-axis and the accuracy of the prediction (residual) is on the y-axis. The distance from the line at 0 is how poor the prediction was for that value. Assumptions of homoscedasticity are that variance of error is unrelated to a predictor and is constant. In other words the points in a residual plot are symmetrically distributed in a random dispersion around the horizontal axis. If a trend is seen then the errors are heteroscedastic and more work needs to be done to the model or a non-linear model is more appropriate. A trend suggests that the estimates of the coefficient are inefficient and ignoring the heteroscedasticity may lead to biased estimates in the standard errors and therefore questionable inferences within the population (Hayes and Cai 2007).

The residual plot (figure 72) shows a non-random dispersion, with a funnelling in the variance of residuals at higher scores. This shows that the prediction of post-operative OKS score was less consistent at lower predicted OKS values, indicating a less than perfect fit the linear model. Therefore at lower values the model may underestimate the effect of foot pain on OKS.

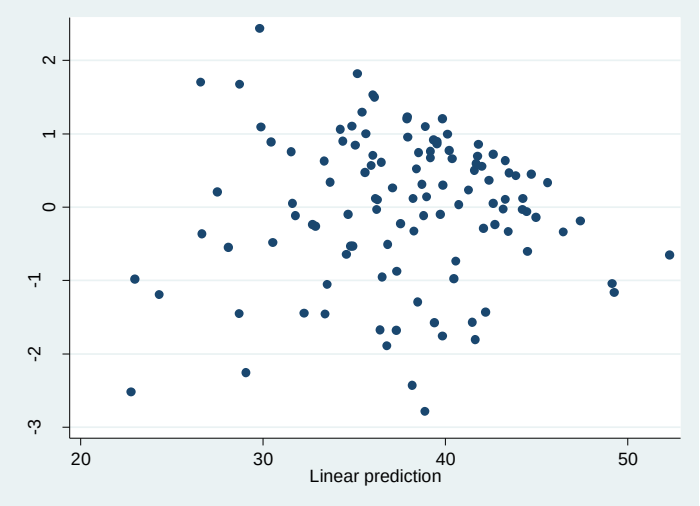

Figure 72. Variance of residuals

Heteroscedasticity can be the result of modelling bounded outcome variables. Bounded outcome data are known to exhibit non-normal data distributions (Tsonaka et al 2006). Post-operative OKS is an example of this; Kernal density plots (figure73-75) show post-operative OKS is negatively skewed, suggesting a ceiling effect of OKS. The lack of normality, induced by boundary constraints, could adversely affect fitting and estimation of linear models and therefore the prediction (Hutmacher et al 2011).

In such an instance logistic models are more appropriate, where coefficients estimates vary less from sample to sample and the logistic model makes no assumptions regarding distribution. This may therefore explain why logistic regression analysis found a significant effect of pre-operative foot pain on post-operative outcome but linear regression did not.

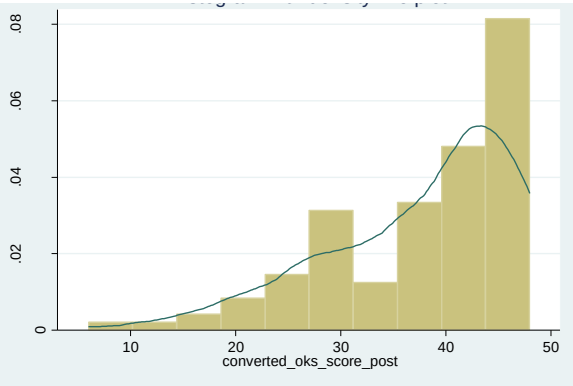

Figure 73. Distribution of post-operative OKS

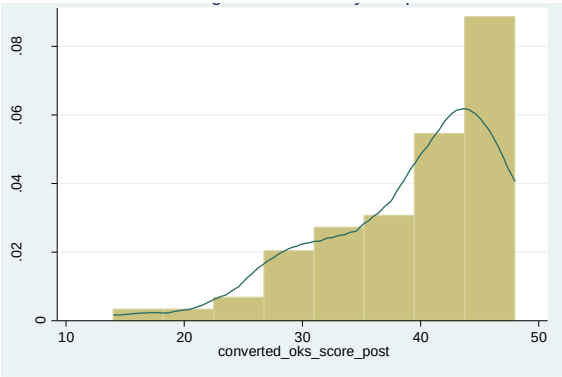

Figure 74. Distribution of post-operative OKS in non-foot pain population

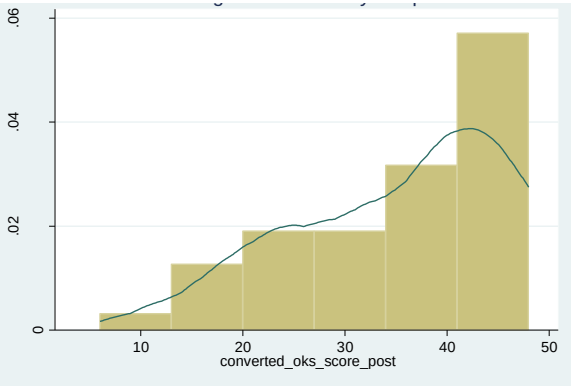

Figure 75. Distribution of post-operative oks in foot pain population

6.11 Discussion

Using a subset of participants from a prospective cohort receiving primary knee arthroplasty in Southampton and Oxford, the COASt-Foot study has found that pre-operative foot pain was one of the strongest determinants of one year post-operative patient reported outcome; participants with foot pain were more likely to have poorer outcomes, as defined by OKS PASS. Pre-operative ankle dorsiflexion and foot posture did not predict one year outcome, however they did improve the percentage explanation of outcome variation for their respective linear models. The main findings from COASt-Foot are summarised in table 36.

Cross sectional results of COASt-Foot showed gender, fixed flexion deformity and knee pre-operative pain were associated with foot pain. Men were less likely to have foot pain, as were participants with fixed flexion deformity or better pre-operative OKS.

Longitudinal results of COASt-Foot identified a number of statistically and clinically important predictors of outcome. The strongest determinants of statistically important outcomes, measured by post-operative OKS, include pre-operative knee pain and function-the better a patient was prior to surgery the better their post-operative score; back pain-participants with back pain had worse outcomes; and BMI-those with higher BMI had worse outcomes. Foot posture and ankle dorsiflexion were not significant predictors of outcome. The significance of the regression coefficients may be underestimated in this population and may be increased with improved power.

In addition to foot pain, pre-operative knee pain and function score (OKS) was also a determinant of clinically important outcomes, defined by a OKS PASS - better pre-operative OKS predicted a good outcome.

The difference observed in the relationships between foot pain and specific outcomes in the COASt-Foot study may be attributable to the heteroscedasticity of residuals observed in the OKS models. A non-linear relationship between foot pain and outcome was also a possibility. Linear regression assumes that the relationship between variables is linear, therefore if a relationship is non-linear, the statistics may underestimate the strength of the relationship, or fail to detect the existence of a relationship.

Table 36. Summary of findings from COASt-Foot study

Outcome	**Main findings for the pre –operative predictors/risk factors of outcome**	
OKS (statistically important outcome)	Foot and ankle assessments	Foot pain, ankle dorsiflexion and foot posture did not predict OKS
OKS PASS (clinically important outcome)	Foot pain (In foot pain model)	Presence of foot pain reduced odds of a good outcome Pre-op OKS was a significant confounder
	Foot and ankle assessments	Ankle dorsiflexion and foot posture did not predict OKS Pass outcome
Cross sectional findings	**Pre-operative outcomes**	
Foot pain	Pre-operative knee pain & function	Participants with better knee pain and function were less likely to have foot pain
	Gender	Men were less likely to have foot pain
	Fixed flexion deformity	Participants with index knee fixed flexion deformity were less likely to have foot pain
	Foot posture index and ankle dorsiflexion did not predict foot pain in participants with knee OA awaiting KA	

6.11.1 Comparison to the literature

Similar results have been found in a large population of individuals awaiting KA (n=494), using statistically but not clinically important outcomes in the form of the Likert version of WOMAC (Peruccio et al 2012). Individuals who reported problematic or painful ankles/feet/toes with OA had worse post-surgery WOMAC pain (1.24 95% CI 0.48, 2.00) and physical function scores (3.14 95% CI 0.69, 5.59). The problematic or painful joints reported were those also affected by arthritis, therefore whilst these results may inform the influence of pain on post-surgery outcome the findings are limited to effects of OA affected joints only. Whilst Peruccio et al adjusted for baseline pre-operative scores, it was unclear if potential effect modifiers were tested for and included within analysis. The importance of including interaction terms has been shown in the COASt-Foot study, particularly when considering other symptomatic joints. Neglecting to acknowledge interactions within a model will lead to potential differences in effect sizes and significance, therefore increasing the chance of type I error.

Results of (Peruccio et al 2012) also showed that individuals reporting symptomatic ankles/feet/toes had significant worse post-surgery anxiety scores compared to those not reporting pain at these joint sites, suggesting the influence of symptomatic ankles/feet/toes on post-surgical pain and function was in part mediated through depression. The COASt-Foot study found no association of pre-op foot pain and depression, nor depression and post-operative outcome in mutually adjusted analysis. However the direction of effect indicated that the presence of pre-operative depression was associated with poor outcome. Additionally univariate analysis showed a significant effect of depression on outcome indicating this may be representative of type II error.

Findings from the Osteoarthritis Initiative (OAI)- a prospective cohort of patients with or at risk of knee OA- demonstrated that foot pain adversely affects knee OA–related pain and symptom severity (WOMAC), health-related quality of life (SF-12) and depressive symptoms (CES-D), and objective measures of physical function (20-meter walk test pace and repeated chair stand pace) (Paterson et al 2015). Although Paterson et al theorise that foot posture and function may influence knee biomechanics and joint load, and therefore link foot and knee pain in people with symptomatic knee OA, the study did not assess foot posture or physical foot status and the data used were cross-sectional, therefore could not infer whether foot pain developed subsequent or prior to knee OA.

COASt-Foot study suggests foot pain increases the likelihood of a poor outcome and it is important to consider the potential drivers behind foot pain to inform pre-operative management advice. To determine whether foot pain is independent of mechanical or biological factors of knee OA a lengthened pre-operative longitudinal study would be required. Findings from the cross sectional study indicate that foot pain was associated with worse pre-operative knee pain and function, however we cannot infer a causal relationship of the two. Whilst there is evidence of investigation into the role of foot structure on knee pain and injuries (Kaufman et al 1999; Barton et al 2011; Levinger et al 2010), investigation into the association of foot pain and knee pain appears to have been overlooked.

Whilst foot pain may be due to direct symptoms and local conditions, the high prevalence of foot pain in the COAST-Foot population suggests the association is clinically important. It must be considered whether findings are due to bias, confounding or biological plausibility. Selection bias was unlikely in this prospective cohort as the research question regarding foot pain was not known to the participants, who were recruited under the premise of investigation of knee outcomes as a priority. Recall bias is also unlikely for the same reasons and also that the most important exposure and outcome variables were collected contemporaneously. The effects of follow up bias are limited as the rates of follow up were high and by the fact that there was a difference between responders and non-responders in only one variable and the difference found did not reach a minimally important change. The effects of confounding were limited by adjustments for a large number of confounders; however this cannot be fully excluded.

There are four potential biological mechanisms that may explain the cross sectional and longitudinal findings of COASt –Foot:

- The role of central sensitisation
- Referred pain
- Generalised joint OA
- Mechanical associations

It is now well established that some patients with painful OA have pain sensitization (Arendt-Nielsen et al 2010; King et al 2013; Suokas et al 2012; Finan et al 2013; Lluch et al 2014). Central sensitisation also plays a role in other chronic pain disorders, such as back pain (Flor et al 1997; O'neil et al 2007). 41% of participants in COAST-Foot reported pre-operative back pain. Estimates of back pain in the normal population suggest that the prevalence of chronic low back pain is

lower than in COASt-Foot at around 23% (Airaksinen et al 2006). Within the current study over half of all participants with foot pain also reported back pain (51%). Findings suggest that both back pain and foot pain are highly prevalent in patients awaiting KA. Pre-operative knee pain was associated with foot pain and post-operative knee pain was associated with back pain. Combined, these factors support the role of central sensitisation in these patients awaiting KA.

Foot pain predicted a worse outcome following surgery in COASt-foot. The risk of persistent pain after KA has been related to the degree of central sensitisation before surgery. After adjusting for pre-operative pain, participants with a high pre-operative pain at rest and a low pain threshold (features which may reflect a central sensitisation mechanism) showed less favourable outcome in terms of pain relief (VAS) 18 months after TKR (Lundblad et al 2008).

Findings from Graven-Nielson et al (2012) support the notion of widespread central sensitisation in patients with knee OA. They undertook pain assessments in patients with symptomatic knee OA and age and gender matched pain-free healthy controls. Pressure-pain thresholds at the knee and at sites away from the knee were reduced in OA patients compared with healthy pain-free control subjects ($P < 0.0001$). Conditioned pain modulation (pain inhibition) was assessed by recording the increase in pressure-pain thresholds in response to experimental arm pain; these were decreased in OA patients as compared with the healthy controls ($P < 0.05$). What's more, only 5-28 weeks following joint replacement in the OA patients, there was a normalization of conditioned pain modulation and pressure-pain thresholds at all sites were significantly increased after surgery as compared with the values before surgery ($F[1,1] = 4.36$, $P < 0.04$ by ANOVA; $P < 0.0001$). These findings support the theory of central sensitisation in knee OA and the potential for foot pain in these individuals, however suggest that the effects of such may be normalised prior to one year follow up from surgery. Although KA may have removed the knee as a source of pain, if foot pain was still present sensitisation may continue.

Referred pain is a known presentation in OA (Bajaj et al 2001), however the degree of foot symptoms referred from knee OA is not well evidenced. Referred pain, particularly in hip OA, has been known to manifest distally, even in the absence of pain in the pathologically affected joint. Findings from the cross sectional study -that there is an association between pre-operative foot pain and knee pain support the theory that foot pain may manifest as referred pain from symptomatic knee OA (but not from non-symptomatic knee OA). However findings from the longitudinal study- that there is an association between pre-operative foot pain and post-

operative outcome- inform the direction of this association. If foot pain was a secondary manifestation, referred from the knee, then one would expect the knee to affect the foot, not visa versa. Therefore pre-operative referred foot pain was unlikely play a role in the outcome of knee intervention with KA. However if referred pain was a surrogate for pre-operative severity, similar to central sensitisation, then this may be the inhibitory factor on outcome, and foot pain a part of it.

Multiple joint involvement or polyarticular OA is common (Carroll et al 2009) and clustering of frequently affected joints has been observed to support this (Cooper et al 1996; Hirsch et al .1996). Associations have been found for hand and knee OA (Hirsch et al 1996; Englund et al 2004) and foot, hand and knee OA, with an elevated risk of foot OA in coexisting bilateral disease of other joints (Wilder et al 2005). Foot pain in the COASt-Foot population may be linked to a degree of foot OA, however the prevalence of foot OA in these patients is unknown. The COASt-Foot cross sectional and longitudinal findings that foot pain is related to knee OA related symptoms and outcomes would support this theory in the presence of symptomatic foot OA.

Evidence suggests discordance between radiographic OA and clinical symptoms, with less than 50% of patients with radiographic OA reporting symptoms (Hannan et al 2000). This would indicate that either participants with foot pain in the COASt-Foot study represent only half of patients with foot OA or that this theory may not support the association of foot pain to knee OA related symptoms and outcomes in COASt-Foot. If the former were true this indicates that almost 80% of patients within COASt-Foot would have had foot OA. Despite the likelihood of the number of individuals with foot OA being greater in COAST-Foot, there is currently no evidence to support such a high prevalence of radiographic foot OA.

Recent findings from a the Clinical Assessment Study of the Foot (CASF) cohort showed an overall population prevalence of 16.7% for symptomatic radiographic foot OA in a normal population of adults aged >50 years (Roddy et al 2013). However the prevalence of non-symptomatic foot OA was not reported and the only other evidence of radiographic foot OA is a systematic review, which revealed wide variation in prevalence estimates of OA specific to the 1st MTPJ, ranging from 6.3% to 39% (Tivedi et al 2010). It is not clear whether these figures were inclusive of symptomatic radiographic OA. Although a reasonable presence of foot OA is likely in the COASt-Foot population, particularly those with foot pain, it is difficult to confirm the role of polyarticular OA in these findings without radiographic evidence.

Another consideration for the findings in COASt-Foot is the potential of mechanical associations. In knee OA changes in loading patterns have been identified throughout the lower extremity as it acts as a linked kinetic unit with adaptations seen in distal body segments (Lidtke et al 2011; Rosland et al 2015). Medial knee OA has also been associated with changes in gait patterns attributed to movement-induced nociception (Mundermann et al 2005; Henriksen et al 2006).

Studies have shown relationships between foot, ankle, knee and hip kinematics (Andrews et al 1996; Guichet et al 2003; Pierrynowski et al 2003; Reilly et al 2006; Reilly et al 2009) and it has been suggested that an association between knee OA and foot status is relative to disease led biomechanical changes. This has been shown in cross-sectional studies, where in individuals with medial knee OA who have a more pronated, less mobile foot type (Levinger et al 2010; Levinger et al 2012; Reilly et al 2009). The radiographic distribution of knee OA was unknown in COAST-Foot.

Cross sectional and longitudinal findings from COASt-Foot showed no association between foot posture or ankle dorsiflexion with pre or post-operative knee pain and function. These findings suggest that although foot pain is related to knee pain and function, objective clinical foot and ankle status is not and therefore static mechanical influences may not be a key driver in the relationship between foot pain and knee OA symptoms. However, the relationship between dynamic influences in COASt-Foot is unknown and may potentially play a role in the main findings.

There are advantages of longitudinal studies over the cross sectional studies that overwhelm podiatric literature. For example a cross sectional study by Levinger et al (2010) concluded that people with medial compartment knee OA exhibit a more pronated foot type (according to total FPI score) compared to asymptomatic age-matched healthy controls. Whilst these results may show a relationship between foot posture and medial knee OA, they cannot infer cause and effect; therefore this does not confidently inform clinical management. Levinger recommended that the potential influence of foot structure and function on the efficacy of foot orthoses in the management of medial compartment knee OA be further investigated. However it is not known whether foot posture changes as a consequence of knee OA or as an effect (protective or detrimental).

A number of previous cross sectional studies exist to investigate the role of orthoses in reducing external knee adduction moment (EKAM)- a frequently used surrogate measure of medial joint loading. EKAM has been correlated to higher levels of pain in individuals with medial knee OA (Kito et al 2010) and a theory has developed that reduction of medial loading may result in pain

relief. However what remains overlooked or undetermined is whether pain is a result of increased medial joint loading or a risk factor for it and whether increased EKAM precedes OA progression or occurs as a consequence of knee increasing OA disease severity (either protective or destructive). Therefore an important question remains; Is altering these forces actually beneficial or detrimental to the progression of the disease?

Studies continued to attempt to reduce EKAM and despite favourable effects on medial loading, they have not found a reduction in knee pain with the use of lateral wedge insoles (Baker et al 2007; Bennell et al 2011; Parkes et al 2013; Jones et al 2014). If a change in foot and ankle status occurs as a consequence of knee OA, either to reduce forces acting upon a symptomatic knee or due to increasing mechanical load on the foot, then attempting to alter this change may not only be of little effect but may be detrimental to a pathological knee. These findings confirm the need for more longitudinal studies to further the findings of COASt-Foot and to determine whether foot pain precedes knee OA or develops secondary to it. This would inform the potential for the use of foot and ankle intervention i.e. orthoses, to improve outcomes of KA.

BMI was a weak statistical predictor of post-operative knee pain and function, with a small effect size. It was not associated with PASS outcome. A previous study of knee arthroplasty outcomes also found that whilst higher BMI was a statistical predictor of poorer function, it was not associated with 6 month PASS (Judge et al 2012). Others have also found an association to function (Baker et al 2013) and equivalent satisfaction between those with lower and higher BMI (Yeung et al 2011). Lash et al (2013) report that although patients with higher BMI had worse pre-operative and post-operative functional scores, there was no difference in the benefit received from surgery at one year between patients with higher and lower BMI. These findings also have important clinical implications, suggesting that BMI and back pain should not be a barrier to KA surgery, where some groups may have poorer functional outcomes it does not indicate these patients do not benefit from surgery. This is however in the context of patient outcomes and consideration should also be given to the risk of prosthesis failure and post-operative complication.

Better pre-operative pain and function was found to be a significant predictor of post-operative outcome. Previous evidence has observed better 6 month post-operative outcome derived from OKS (Judge et al 2012) and WOMAC (Fortin et al 1999; Hawker et al 2013) and better 2 year outcome (Lingard et al 2004). Findings suggest that pre-operative pain and function is an important predictor of both short and long term follow up. These findings have important

implications for timing of surgery; surgery that is delayed until pain and functional severity of knee OA is worse is likely to result in poorer short and long term postoperative outcomes.

One of the first studies to identify predictors of clinically important attained pain and function post KA surgery by deriving a PASS to define outcome found the predictors of pain were not necessarily the same as for functional outcomes (Judge et al 2012). The COASt-Foot study did not separate pain and function domains of OKS as it is designed to be used as a total score. Judge et al (2012) found that being older and female predicted worse functional outcomes, but not pain. Similar to findings of the COASt-Foot study gender was not associated with PASS, when using total OKS score.

Others have shown that younger patients (<55 years) gain greater improvement in pain and function but report lower satisfaction (Williams et al. 2013). Contrary to COASt-Foot, Judge et al found that patients with RA had better pain outcomes compared to those with OA, suggesting this may be related to the potential for more improvement due to the worse pain and function observed in RA patients at the time of surgery. The COASt-Foot study did not find RA to be a predictor of statistically or clinically important KA outcome, also no difference in pre-operative knee pain and function was observed between those with RA and those without.

6.11.2 Strengths & Potential Limitations

The strengths of this study were the use of a relatively large cohort, the use of carefully chosen valid, reliable and responsive instruments for assessing multiple exposures and outcomes, and the prospective data collection. Surgery was completed at two sites, within a standard NHS setting by multiple surgeons; findings were therefore generalizable and representative of the general UK orthopaedic practice.

Selection bias was minimised as the outcome was unknown during collection of exposure data and recall bias was limited as all questions were based on current status, requiring no long term retrospective consideration. Reporting bias was unlikely as participants were not recruited based on foot pathology therefore there was less reason to over or under report foot symptoms.

Another strength of this study was the use of one year post-operative OKS as the outcome, adjusting for baseline score. This is an unbiased method of analysis and it is known to be the most precise (Vickers and Altman 2001).

Limitations of the analysis described in this chapter are related to the use of OKS total score, the potential effects of missing data, follow up bias and limitations of the FPI.

It is possible that the significance of the regression coefficients within the linear regression models (OKS outcome) is underestimated. Regression diagnostics indicated a less than perfect fit of all linear regression models. Although this does not bias the estimate it does bias the standard error, which in turn makes inference questionable. Therefore the significance of the predictive relationships found in the OKS models cannot be confidently inferred and the effect of some variables (i.e. foot posture and ankle dorsiflexion) on outcome may have been underestimated.

Pain and function domains of OKS were not separated, therefore we do not know if particular covariates such as age, gender and BMI may be more sensitive to one than the other. The OKS was designed to be used as a total score and although it would be relatively easy to separate domains, this is not necessarily advocated (Judge et al 2012). A scoring tool, designed to measure outcomes for individual domains of pain and function, may have been suitable. The WOMAC OA index (Bellamy et al 1988) is known to be a reliable, valid and responsive instrument for examining outcomes in patients with OA undergoing arthroplasty (Bellamy 2002). However this is validated for OA specific population and COASt allowed for the inclusion of all rheumatology diseases.

It was important for complete comparisons to include participants with all three of the main study variables (foot pain, ankle dorsiflexion and foot posture) to allow for valid comparisons to be made. In some instances one or two of these variables were not collected, mostly due to time restraints within the clinical pre-operative assessment. Complete case analysis was therefore undertaken. If individual group analysis had been completed irrespective of these missing covariates, the sample size would have been higher but varied for each group. This method would therefore make analysis between groups difficult as different populations would be studied.

If observations were missing these were probably missing at random (i.e. the chance of data being missing was unrelated to any of the variables involved in the analysis), therefore whilst complete case analysis is not optimally efficient, as it does not include the data from incomplete cases and reduces power, it is at least unbiased and allows for between group comparisons.

Follow up bias may play a role in this study as participants who were followed up had better pre-operative knee pain and function scores than those who did not, hence the true effects of this predictor may be over-estimated in this study. However the loss to follow up rate of 14% was

good and this was the only variable to show a difference. Studies often show a difference in more than one characteristic between responders and non-responders and previous evidence has acknowledged the same predictive effect of pre-operative OKS (Fortin et al 1999; Judge et al 2012a; Hawker et al 2013).

Differences in follow up were seen between the two centres, where Southampton had an overall loss to follow up of 15 and Oxford 4. This is due to a number of factors. Firstly there was a large difference in the total number of study participants included from each centre (Southampton n=89, oxford n=25, after exclusions prior to loss to follow up), due to recruitment limitations and logistical issues for the main investigator under taking assessments at each site. Southampton site had 8 participants not return follow up data compared to 0 in oxford (see table 10). This is likely because an ethical amendment to the protocol was later made in order to contact participants by telephone who had not returned follow up questionnaires. This was introduced a later time point, more concurrent with Oxford follow ups. Likewise a number of Southampton participants follow up were scheduled at a date beyond the most recent data inputting cut off, therefore these participants were censored for the current study.

Based on findings of previous studies-a limited number of which actually report variances between responders and non-responders- this difference in pre-operative OKS was not expected (Judge et al 2012; Hawker et al 2013; Kiran et al 2015). Evidence has shown conflicting results in respondent differences, with some showing responders were older (Judge et al 2012; Kiran et al 2015), had lower BMI and were less likely to be depressed (Judge et al 2012). Conversely, Hawker et al (2013) showed respondents were younger, however data did include hip arthroplasty patients and non-responders included patients who were excluded due to non-elective surgery, revision joint arthroplasty or death. The difference in pre-operative OKS between responders and non-responders does not affect cross sectional findings. Non-responders had, on average, lower (worse) mean pre-operative OKS score than responders, suggesting that a group of patients with worse severity of post-operative symptoms were not accounted for and there was therefore a higher chance of a false positive (type II error). Whilst it does not invalidate the longitudinal findings it may have underestimated the findings of foot posture and ankle dorsiflexion against outcomes.

Minimally important change (MIC) estimate for the OKS, applicable for assessment of individual patients, is 6.5 points. For a single group (e.g. cohort studies) it is 9 points (Beard et al 2015). The mean difference in pre-operative OKS between responders and non-responders in the current

study is 6 points. This is therefore well below the average mean change estimate applicable to an MIC for a cohort over time.

A difficulty encountered within data analysis was due to the use of the foot posture index to define objective foot status. The FPI scoring system uses the total of all six item scores on an ordinal 5-point Likert-type scale where lower scores represent a more supinated foot position and higher scores a more pronated position. As discussed previously this approach to scoring the foot position is rather arbitrary and the concerns with using this have been highlighted from examples of the data in discussion section (6.4.11.2). The small numbers of patients within particular scoring categories created difficulties when modelling this categorical data and it is likely that this played a role in the wide confidence intervals that were commonly seen across foot posture findings. Another limitation is pre-operative foot pain was not measured specific to one side in all participants, therefore laterality of foot pain according to knee symptoms could not be addressed.

6.11.3 Conclusion

In conclusion the results of the COASt-Foot study suggest that patients with pre-operative foot pain are more likely to have poorer clinically important knee outcomes one year following KA than patients without foot pain. Clinical foot and ankle assessments of ankle dorsiflexion and foot posture did not predict post-operative KA outcomes, however these findings may be due to power. Findings suggest that at present the intention to treat knee OA with KA is made irrespective of foot pain. If the objective of treating with KA is to achieve a good a clinical outcome –based on pain reduction, function and satisfaction improvement- then consideration should be given to reducing pre-operative foot pain.

7 Chapter Seven

Summary Discussion

The following chapter draws together findings from the investigative phases conducted within this thesis and suggests how these inform further research.

7.1 Main findings

The main findings of this thesis are summarised in table 37.

Table 37. Summary of main findings

Main Findings
• A critical literature review identified a lack of validated clinical musculoskeletal foot and ankle assessment measures. The FPI was the most rigorously tested assessment. • The review confirmed the absence of and thus the requirement to establish a clinical musculoskeletal foot and ankle assessment protocol. • An international consensus study, in the form of a Delphi technique, was undertaken to gain expert agreement on the most important foot and ankle assessments to include in a new protocol. • Twenty foot and ankle measures were identified to include within a new protocol. • FPI and ankle dorsiflexion were the most highly recommended. These items were therefore introduced to the COASt-Foot study. • In a population of patients undergoing knee arthroplasty (COASt-Foot), men were less likely to have foot pain and the presence of pre-operative fixed flexion deformity and better pre-operative-OKS scores reduced the odds of foot pain. • Pre-operative foot posture and ankle dorsiflexion did not predict pre-operative foot pain. • Longitudinal findings showed the presence of pre-operative foot pain reduced the odds of a good patient reported outcome one year after KA • Pre-operative ankle dorsiflexion and foot posture did not predict one year outcome

The influence of foot and ankle assessment on KA outcomes was previously unknown; therefore the primary aim of the thesis was to determine whether clinical foot and ankle measures can help inform the prediction of patient reported outcomes following KA. To address this aim the objectives of this thesis were to introduce a set of clinical foot and ankle assessments to a prospective cohort of patients awaiting knee arthroplasty and observe the effects they had on knee related patient reported outcomes.

Through clinical and research experience it was anticipated that a valid and comprehensive foot and ankle assessment protocol did not exist. Therefore a critical review was undertaken (study 1) to determine if a protocol existed and if not which existing individual foot and ankle measures were valid and reliable enough to use.

The review revealed an absence of a comprehensive foot and ankle assessment protocol and lack of validated clinical musculoskeletal foot and ankle assessment measures. There was an absence of agreement for the use of many. Findings supported the use of the Foot Posture Index as the most rigorously tested methods for quantifying static standing foot posture. Results of the review confirmed the absence of and thus the requirement to define a core set of objective clinical musculoskeletal foot and ankle assessment measures.

In the absence of an existing foot and ankle protocol to implement into a cohort of KA patient, a new one needed to be established. The first stage in this development was to capture the opinions of experts within the field of foot and ankle assessment and gain consensus on the most appropriate clinical foot and ankle measures to be included within the protocol. An international consensus study in the form of a Delphi technique was undertaken, which included a series of sequential rounds, interspersed by feedback, seeking to gain consensus of opinion of a group of experts.

Twenty foot and ankle measures were defined from the Delphi Technique. Strength of recommendation scores revealed the FPI and ankle dorsiflexion were the most highly recommended of these twenty. These were therefore introduced pre-operatively to a subset of patients (COASt-Foot) taken from a cohort awaiting KA (COASt).

Pre-operative cross sectional findings showed that men awaiting knee arthroplasty were less likely to have foot pain and participants with index knee fixed flexion deformity and better pre-

operative knee pain/function were less likely to have foot pain. Pre-operative foot posture and ankle dorsiflexion did not predict pre-operative foot pain.

A longitudinal comparison of pre-operative foot and ankle assessments and one year post-operative patient reported outcomes showed that the presence of pre-operative foot pain reduced the odds of a good outcome. Although the direction of effect was the same for pre-operative ankle dorsiflexion and foot posture, these did not significantly affect outcome.

The primary aim of this thesis has been met and findings have informed the answer to the thesis research question:

"Do clinical foot and ankle assessments inform the prediction of patient reported outcomes in knee arthroplasty?"

Subjective assessment of foot pain does inform the prediction of clinically important patient reported outcomes following KA. Objective clinical assessment; foot posture and ankle dorsiflexion, do not inform the prediction of outcomes.

This thesis is unique and is the first to draw together foot and ankle assessment procedure to investigate outcomes of KA. Although findings of this thesis showed that foot posture and ankle dorsiflexion did not affect KA outcome, a larger study may find an important clinical effect. Also there may be other foot and ankle measures that could predict outcome better. It would be useful to address these considerations by applying a number of other foot and ankle assessments, for example the remaining 18 measures in IMFAA or dynamic measures, to a larger sample of participants awaiting KA.

Cross sectional findings from COASt-Foot showed that foot pain was associated with worse pre-operative pain and function. The lack of association between *foot alignment* and pre-operative knee pain, combined with the associations of *foot pain* to pre-operative knee pain, strengthens the previously discussed theories based upon central sensitisation and/or generalised OA.

Longitudinal findings showed that foot pain was associated with worse post-operative outcomes. It is biologically plausible that central sensitisation played a role in this finding. In the case of central sensitisation, patients with knee OA may be more susceptible to foot pain due to lowered pain thresholds. It is possible that these individuals, who experience heightened pain, are at greater risk of worse post-operative outcomes because of the prolonged but reversible increase in

the excitability of neurons in central nociceptive pathways that is known in central sensitization (Woolf 2011). However as discussed in section 6.11.1, it is questionable whether central sensitisation will still influence outcomes as far as one year post operatively.

It is not known if foot pain in this population was associated to foot OA, however if it were then it would be possible that ongoing pain or altered mechanical function secondary to foot OA influenced knee outcomes.

Findings may also be due to mechanical factors related to a symptomatic foot and ankle which may alter gait or increase inhibitory forces around the knee, predisposing an individual to poor outcomes.

Of course it is also possible that these findings are result of a combination of these factors. Patients who have poor outcomes following KA may be reflective of a population of individuals with a combination of generalised OA; where the foot may also be affected by OA and/or varying degrees or central sensitisation and/or mechanical influences; which may be primary factors or may be secondary due to prolonged pain (related to the foot or knee) or even foot OA.COASt-Foot is the first study that has conducted work to investigate the longitudinal influence of foot structure assessments or foot pain on KA outcomes. To the authors knowledge only one other study has observed longitudinal effects of foot and assessment, these were conducted to determine the risk factors for falls (Menz et al 2006). With the exception of a few studies, which observed longitudinal effects of orthoses on knee OA (Baker et al 2007; Hinman et al 2008; Bennell et al 2011), all other studies relevant to knee OA and foot pain (Leveille et al 1998; Menz et al 2013), to knee OA and orthoses (Kito et al 2010; Jones et al 2013; Alshawabka et al 2014; Jones et al 2014), to knee OA and foot posture (Reilly et al 2009; Levinger et al 2010; Abourazzak et 2014) and to other knee pathology and foot posture (Barton et al 2010; Barton et al 2011) has been cross sectional.

This study did not find an association between objective foot and ankle assessment and post-operative PROMS. Aside from possible issues of power this finding may also be due to the limitations of assessing an outcome based on patient perception based upon the use of an objective measure. It is questionable whether a static physical foot and ankle assessment may match a patient reported outcome in any circumstance and this is somewhat supported from the lack of association between the two in both the cross sectional and longitudinal findings. Whislt previous studies have found an association between static tests of navicular height, ankle

dorsiflexion, first metatarsal phalangeal joint range of movement with functional tests that include balance, stability, walking speed, sit to stand and stepping, none have shown a relationship to pain.

To build upon these findings it would be beneficial to validate this study in another, larger cohort, using additional foot and ankle assessment measures to help inform the prediction of KA outcomes and increase the percentage of KA outcome variation that is explained (R^2). By increasing the duration of pre-operative data collection this would help to inform the mechanisms linking the foot and ankle to knee OA related symptoms and post-operative outcomes. This information would be useful to inform future intervention and to aid patients and surgeons in making decisions to operate.

7.2 Thesis strengths & limitations

This thesis was the first investigation to use an evidence driven, expert consensus approach to develop a clinical foot and ankle assessment protocol. Such protocols exist for knee and hip but the absence of one for foot and ankle has been a long standing key limitation in the progression of foot and ankle epidemiological research. In the first instance the expert consensus has provided face validity.

The longitudinal nature of COASt-Foot has enabled confirmation of the findings from previously limited evidence; that foot pain is important in long term conditions. It has also highlighted the lack of association for certain physical foot and ankle assessments and long term outcomes, or the need for greater power to improve the precision of these findings.

An additional strength arose from the cross sectional COASt-Foot study, which confirmed a previously reported absence of association between foot and ankle assessment and foot pain, bringing into question the potential validity of such measures in foot and ankle care.

There were a number of limitations of this thesis. Firstly twenty foot and ankle measures were defined from the Delphi Technique. Not all of these could be implemented into the COASt-Foot study for ethical reasons; time restrictions were applied for pre-operative clinical assessment and considerations given for examination fatigue as foot and ankle measures were in combination with a battery of other knee examinations and clinical measures.

The core set of twenty defined measures included a number of items which were not identified within the critical literature review. These include swollen joints, skin/nail changes, general foot morphology, HAV presence, lesser toe deformities, plantarfascia and Achilles palpation, midfoot and MTPJ ROM, gastrocnemius muscle testing and standing heel rise, measures of leg length, foot wear and gait. The possible explanation for the absence of particular measures from the review was due to limitations within the searches. Search terms were informed with expert input, however not every expert included within the study responded with the provision of search terms. Also a number of professions including orthopaedics may have been under-represented within the consensus study due to problems with drop out.

Foot pain was not assessed specific to side, the extent of the influence of index limb foot pain in therefore unknown. Knowledge of affected side may have provided further information on the relationship between foot pain and knee OA and KA outcomes. The duration of foot pain in relation to symptomatic knee OA was also unknown. Therefore inference cannot be made as to which came first.

It was beyond the scope of this thesis to determine the prevalence of foot OA in this population however this would have been useful to inform the question of the existence of the polyarticular form of generalized OA.

Dynamic foot and ankle assessment was not assessed within this thesis. This was not included because in line with the aim of the thesis, all findings were required to be clinically applicable. Although it would have been interesting to know if dynamic walking parameters were associated with KA outcome, any such results would not have facilitated a change in clinical practice as such methods are not routinely used or available for clinicians.

Implications for clinical practice

This thesis has provided clinicians with a new foot and ankle assessment protocol for use either in its entirety or as individual measures. IMFAA provides clinicians with a clinical screening tool or a method to assess and monitor conditions. It can also be used in conjunction with additional measures specific to pathology. This has strong implications for clinical practice as it provides clinicians with the ability to standardise foot and ankle assessment between clinicians and between repeated patient visits. This limits the issues often seen in clinical situations, where clinicians use different measurements or different methods of undertaking the same

measurement, making it difficult to compare findings, in particular when comparing assessment results prior to and following intervention.

Findings from this thesis suggest that foot pain is an important consideration in the intention to treat knee OA with arthroplasty. If foot pain is present, particularly in addition to other risk factors such as low pre-operative knee pain and function scores, this informs the surgeon that the patient is at a higher risk of poor outcome. With this information the surgeon can decide whether to continue with arthroplasty, delay arthroplasty until a number of risk factors have been addressed or consider an alternative treatment.

8 Chapter Eight

Future research recommendations

A clinical foot and ankle assessment protocol has been developed, via expert opinion. The protocol now requires validation. It would be useful to determine if these measures are associated with both short and long term pain and functional outcomes, across a variety of conditions and populations. In the first instance it would be important to determine each measures association with foot and ankle pain in the normal population to decide which measures are useful within clinical assessment.

IMFAA has already been introduced to a female only community based cohort (Chingford 100 women), where measures of foot pain, function and structure are also being ascertained via questionnaires, physical protocols and foot x-rays. This is due to be repeated within a male counterpart cohort (Nottingham cohort). It has also been introduced to a neurological cohort of patients, defined by history of parkinsons or stroke. The aim of this is to determine which measures are useful in defining outcomes for these patients, which measures are useful for determining the effects of footwear intervention and which measures are sensitive to characteristics specific to this neurological condition.

Considering the likely differences in foot type and presenting symptoms between particular disease led populations, it is likely that certain measures from IMFAA may be more useful or sensitive in some populations than others, for example rheumatology or neurological conditions. A future recommendation is therefore to introduce IMFAA to a variety of rheumatology populations, including those affected by foot OA, rheumatoid arthritis, systemic lupus erythematosus (SLE) and other sero-negative disease where foot conditions a common yet varied.

Once the most clinically important measures -driven by pain and clinical function- have been identified within different populations, these may be developed into a clinical tool. It may then be useful, however not essential, to determine if any measures are representative of dynamic movement. It should be highlighted that IMFAA was not developed to represent dynamic systems, however within the literature there has been much attention given to attempting to establish a

correlation between static assessment and dynamic foot function. This is largely due to the requirements of clinicians to have a simplistic clinical measure to diagnose gait derived pathology.

COASt-Foot has investigated the clinically relevant predictors of KA outcome. To build upon these findings, another larger cohort study is recommended, using additional foot and ankle assessment measures that may not be applicable to clinical practice in the short term, but may help inform the predictive model. Measures of pain sensitivity and dynamic assessment would assist in this validation. Additionally a longitudinal study introducing foot and knee assessments to a normal population from baseline, with ongoing follow-up long enough to detect sufficient cases of incident knee OA would help to determine the mechanisms behind foot status, in particular pain, and knee OA . It is likely that an existing population cohort may already have the data at relevant time points to facilitate this. This would inform the requirement to focus knee OA related management on the knee, foot or both. An interventional trial may then be considered to determine if the management of foot and ankle can improve arthroplasty outcomes.

9 Chapter Nine

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Appendices

Appendix 1: Search terms

Primary Keywords for literature search:

Primary keywords:
Foot Synonyms: feet, (f**t) Associated: Calcaneus, heel, talus , tarsal(s), metatarsal(s), “metatarsal phalangeal (joint)”, navicular, hallux, subtalar (joint), rearfoot, “rear foot”, hindfoot “hind foot”, forefoot
Ankle Synonyms: talocrural (joint)
Assessment Synonyms: measure(ment), exam(ination) Associated: physical, clinical, podiat(ric), ortho(paedic) (examination/assessment/measurement), clinical (examination/assessment/measurement), “foot posture”

Keywords given above were then refined using Boolean operators and truncation, to reduce the specificity of search terms and ensure a broad initial search of the literature. Alternative spellings for terms were considered.

Preliminary search terms, with truncation and Boolean operators:

Truncated Search terms with Boolean operators
(1) Foot OR feet OR ankle* OR talocrural* OR joint OR calcaneus OR heel OR talus OR tarsals OR navicular OR hallux OR metatarsal* OR metatarsal phalangeal * OR subtalar OR rearfoot OR hindfoot OR forefoot AND **(2)** Assessment* OR measure* OR exam* OR physical OR Clinical OR podiat* OR ortho* OR posture

Appendix 2: Critical Appraisal tool (Weightman et al. 2004)

Health Evidence Bulletins - Wales: Questions to assist with the critical appraisal of a randomised controlled trial (Type II evidence)

Adapted from the CASP questions (taken from Guyatt *et al.* Users' guides to the medical literature. II How to use an article about therapy or prevention. *Journal of the American Medical Association*. 1993; **270**: 2598-2601 and **271**: 59-63; Barker, JM. Project for the enhancement of the Welsh Protocols for Investment in Health Gain. Project Methodology. Cardiff: Duthie Library. UWCM, 1996; Egger *et al.* How important are comprehensive literature searches and the assessment of trial quality in systematic reviews? *Health Technology Assessment* 2003; **7(1)**

Paper details **Authors:**

Title:

Source:

A/ What is this trial about and can I trust it?
Screening questions.

	Yes	Can't tell	No
1. Is the trial relevant to the needs of the Project?			
2. Did the trial address a clearly focused issue? In terms of: • the population studied, • the intervention given, • the outcomes considered.			
3. Was there concealment of allocation? Note whether: • the randomisation process was described explicitly eg the use of random number tables or coin flips; • there was some form of centralised randomisation scheme eg central allocation or use of sealed opaque envelopes.			
4. Were all the patients who entered the trial properly accounted for at its conclusion? • Was follow-up obtained for 80-100% of subjects? Note % follow-up. • Were patients analysed in the groups to which they were randomised?			
5. Were patients, health workers and study personnel 'blind' to treatment? • Patients? • Health workers? • Study personnel?			
6. Were the groups similar at the start of the trial? In terms of all the factors that might be relevant to the outcome: age, sex, social class, life style etc.			
	Yes	Can't tell	No

7. Aside from the experimental intervention, were the groups treated equally?			

Is it worth continuing?

B/ What did they find?

8. How large was the treatment effect? • What outcomes were measured? • Take a note of the result(s) (eg odds ratio, number needed to treat) if provided.	**Result(s):**
9. How precise was the estimate of the treatment effect? • What are the confidence limits? • Do you feel confidence in the authors' use of statistics?	

C/ Are the results relevant locally/to me?

	Yes	Can't tell	No
10. Can the results be applied to the local population? Do you think the patients covered by the trial are similar enough to your population? Consider culture, geography etc.			
11. Were all important outcomes considered? If not, does this effect the conclusion(s)?			
12. Is any cost information provided?		N/A	
13. Accept for further use as Type II evidence?		Refer to Team Leader	

Comments:

In the draft statement Remember to include the relevant target group (age range, sex etc.);the duration of the study, the measured outcomes/benefits with quantitative information if available and whether: 1. Treatment allocation was concealed; 2. An intention-to-treat analysis was carried out (include % follow-up); and 3. The trial was double (or triple) blind.

Health Evidence Bulletins - Wales: Questions to assist with the critical appraisal of an interventional study without randomisation (Type III evidence)

Sources used: Critical Appraisal Skills Programme (CASP, Anglia and Oxford RHA) questions. NHS Centre for Reviews & Dissemination, Guidelines for those carrying out or commissioning reviews. CRD report No. 4, 1996. Polgar A, Thomas SA. Chapter 22: Critical evaluation of published research in Introduction to research in the health sciences. 3rd edition. Melbourne: Churchill Livingstone, 1995.

Paper details **Authors:**

Title:

Source

A/ What is this paper about?

	Yes	Can't tell	No
1. Is the study relevant to the needs of the Project?			
2. Does the paper address a clearly focused issue? Are the aims of the investigation clearly stated?			

B/ Do I trust it?

	Yes	Can't tell	No
3. Is the choice of study method appropriate? • Has an acceptable method been chosen (eg interventional without randomisation, before-and-after study)? • Are the inclusion/exclusion criteria given? • Is the choice of control group (if included) adequate?			

C/ What did they find?

	Yes	Can't tell	No
4. Are tables/graphs adequately labelled and understandable?			
5. Are you confident with the authors' choice and use of statistical methods, if employed?			
6. What are the results of this piece of research? Are the authors' conclusions adequately supported by the information cited?			

D/ Are the results relevant locally?

	Yes	Can't tell	No
7. Can the results be applied to the local situation? Consider differences between the local and study populations (eg cultural, geographical, ethical) which could affect the relevance of the study.			
8. Were all important outcomes/results considered?			
9. Accept for further use as Type III evidence?		Refer to Team Leader	

Comments:

Draft Statement (if appropriate):
(Remember to include the relevant target group (age range, sex etc.); the measured outcomes/benefits with quantitative information if available; and the health gain notation)

Health Evidence Bulletins - Wales: Questions to assist with the critical appraisal of an observational study eg cohort, case-control, cross-sectional. (Type IV evidence)

Sources used: Critical Appraisal Skills Programme (CASP, Anglia and Oxford RHA) questions and Polgar A, Thomas SA. Chapter 22. Critical evaluation of published research in Introduction to research in the health sciences. 3rd edition. Melbourne: Churchill Livingstone, 1995; Undertaking systematic reviews of research on effectiveness. University of York: NHS Centre for Reviews & Dissemination, 2001; Weightman AL, Barker, JM, Lancaster J. Health Evidence Bulletins Wales Project Methodology 3. Cardiff: UWCM, 2000.

Paper details Authors:

Title:

Source

A/ What is this paper about?

	Yes	Can't tell	No
1. Is the study relevant to the needs of the Project?			
2. Does the paper address a clearly focused issue? In terms of • the population studied? • (case-control study only) is the case definition explicit and confirmed? • the outcomes considered? • are the aims of the investigation clearly stated?			

B/ Do I trust it?

	Yes	Can't tell	No
3. Is the choice of study method appropriate?			
4. Is the population studied appropriate? • (cohort study) Was an appropriate control group used – ie were groups comparable on important confounding factors? • (case-control study) Were the controls randomly selected from the same population as the cases?			
5. Is confounding and bias considered? • Have all possible explanations of the effects been considered? • (cohort study) Were the assessors blind to the different groups? • (cohort study) Could selective drop out explain the effect? • (case-control study) How comparable are the cases and controls with respect to potential confounding factors? • (case-control study) Were interventions and other exposures assessed in the same way for cases and controls? • (case-control study) Is it possible that overmatching has occurred in that cases and controls were matched on factors related to exposure?			

6. (Cohort study) Was follow up for long enough? • Could all likely effects have appeared in the time scale? • Could the effect be transitory? • Was follow up sufficiently complete? • Was dose response demonstrated?			

C/ What did they find?

	Yes	Can't tell	No
7. Are tables/graphs adequately labelled and understandable?			
8. Are you confident with the authors' choice and use of statistical methods, if employed?			
9. What are the results of this piece of research? Are the authors' conclusions adequately supported by the information cited?			

D/ Are the results relevant locally?

	Yes	Can't tell	No
10. Can the results be applied to the local situation? Consider differences between the local and study populations (eg cultural, geographical, ethical) which could affect the relevance of the study.			
11. Were all important outcomes/results considered?			
12. Is any cost-information provided?			
13. Accept for further use as Type IV evidence?		Refer to Team Leader	

Comments:

Draft Statement (if appropriate):
(Remember to include the relevant target group (age range, sex etc.); the measured outcomes/benefits with quantitative information if available; and the health gain notation)

Appendix 3: Letters of collaboration

Professor Christopher Nester
BSc (Hon) PhD

Director,

Centre for Health, Sport and Rehabilitation Sciences Research

Associate Head for Research & Innovation,

School of Health, Sport and Rehabilitation Sciences Research

The University of Salford
Brian Blatchford Building
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c.j.nester@salford.ac.uk

1.3.11

Miss Lucy Gates
Podiatry Research Assistant
Rheumatology Research Department
Mailpoint 63, G Level, West Wing
Southampton General Hospital
Tremona Road
Southampton SO16 6YD

Dear Lucy,

Re: Consensus Study: To determine foot and ankle assessments used across multidisciplinary professions

I write to confirm that I would be willing to collaborate on the above referenced study, which as part of an NIHR fellowship application is component of a project to predict patient reported outcomes of knee arthroplasty. As we have discussed, this offers real promise to take advantage of the iFAB initiative and become an international effort/study.

Yours sincerely

Professor Christopher Nester
Director,
Centre for Health, Sport and Rehabilitation Sciences Research
Associate Head for Research & Innovation,
School of Health, Sport and Rehabilitation Sciences Research

Andrew Price
Consultant Knee Surgeon
Reader in Musculoskeletal Science
Telephone: +44(0) 1865 737539 Fax: +44(0) 1865 227671
E-mail: andrew.price@ndorms.ox.ac.uk
PA: Sandra Regan, sandra.regan@ndorms.ox.ac.uk

Nuffield Department of Orthopaedics,
Rheumatology and Musculoskeletal Sciences
University of Oxford
Nuffield Orthopaedic Centre
Windmill Road
OXFORD, OX3 7LD

Miss Lucy Gates
Podiatry Research Assistant
Rheumatology Research Dept.
Mailpoint 63, G Level, West Wing
Southampton General Hospital
Tremona Road
Southampton
SO16 6YD

April 1st 2011

Dear Miss Gates,

Re: Expression of Collaboration – Can we use clinical foot and ankle assessment to improve the prediction of patient reported outcomes in total knee arthroplasty?

Further to our prior correspondence, I am writing to confirm that I would be happy to collaborate on your study to predict outcomes of knee replacement.

Yours sincerely,

Andrew Price MA DPhil FRCS(Orth)
Reader in Musculoskeletal Science
Consultant Orthopaedic Surgeon

Hylton B. Menz, *PhD, BPod(Hons), HonFCPod*
Professor and Director
Musculoskeletal Research Centre
La Trobe University

Miss Lucy Gates
Podiatry Research Assistant
Rheumatology Research Department
Mailpoint 63, G Level, West Wing
Southampton General Hospital
Tremona Road
Southampton SO16 6YD

Saturday, 12 March 2011

Dear Lucy,

Re: *Consensus Study: To determine foot and ankle assessments used across multidisciplinary professions*

I write to confirm that I would be willing to collaborate on the above referenced study, which as part of an NIHR fellowship application is a component of a project to predict patient reported outcomes of knee arthroplasty.

Yours sincerely,

Prof Hylton B. Menz

Musculoskeletal Research Centre
La Trobe University, Bundoora, Victoria 3086, Australia
Ph. +61-3-9479 5801, Fax. +61-3-9479 5415
Email: h.menz@latrobe.edu.au
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James Woodburn PhD, MPhil, BSc
Professor of Rehabilitation
Glasgow Caledonian University
Glasgow, UK
T: +44(0)141-331-8484
E: jim.woodburn@gcu.ac.uk

23-02-11

To whom it may concern,

Re: NIHR Fellowship application, Ms Lucy Gates

Can we use Clinical Foot and Ankle Assessment to Improve the Prediction of Patient Reported Outcomes in Total Knee Arthroplasty?
Clinical Outcomes of Arthroplasty Study (COASt).

I write to confirm that I would be willing to collaborate on the above referenced NIHR Fellowship application for Ms Lucy Gates.

Yours sincerely,

Prof. Jim Woodburn PhD, MPhil, BSc
Professor of Rehabilitation

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Faculty of Health Sciences

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10th March 2011

Miss Lucy Gates
Podiatry Research Assistant
Rheumatology Research Department
Mailpoint 63, G Level, West Wing
Southampton General Hospital
Tremona Road
Southampton SO16 6YD

Dear Lucy,

Re: Consensus study – to determine foot and ankle assessments used across multidisciplinary professions

I write to confirm that I am willing to collaborate on the above referenced study, which, as part of an NIHR fellowship application is component of a project to predict patient-reported outcomes of knee arthroplasty.

Yours sincerely,

Karl B Landorf *PhD*
Senior Lecturer and Research Coordinator

9.2

Appendix 4: Delphi Round 1

Faculty of Health Sciences
Building 45
University of Southampton
Southampton
SO17 1BJ
Tel: 02380 598832
Email: lsg105@soton.ac.uk

Re: Important measures within musculoskeletal foot and ankle assessment

Dear

Thank you once again for joining our international panel of experts for our Delphi exercise.

The Delphi exercise is a structured process that uses a series of questionnaires or 'rounds' to gather and refine information until consensus is reached. If you have not already done so, please refer to the consensus study video via the link: http://www.edshare.soton.ac.uk/9061/. This includes the aims of the study and the main findings from a recent systematic literature review. We anticipate the formal literature review will be available in July, however should you require any further information from our findings to date please do not hesitate to contact me.

The Delphi exercise will consist of three rounds of factor identification and refinement. The first round questionnaire is enclosed with this letter and consists of two open ended questions. We anticipate this will take you 15-30 minutes to complete.

Responses from the first round will be compiled to form a second questionnaire that will ask you to rate the importance of those features listed by all panel members. The third round will ask you to re-rate the features in light of the average results from all experts. A final list of foot and ankle measures will be formed dependant on all expert ratings; you will be given the opportunity to contribute further comments before completion. I shall include instructions with each subsequent round.

Your responses will remain anonymous throughout the rounds.

Please can you complete the attached questionnaire and return it to lsg105@soton.ac.uk by **Friday 13th July**.

Should you wish to discuss any aspect of this project, please feel free to contact me.

Thank you Kindly for completing this questionnaire.

Yours Sincerely

Lucy Gates
Arthritis Research UK PhD Fellow

Arthritis Research UK
Providing answers today and tomorrow

Objective measures to be included within a musculoskeletal foot and ankle examination

Instructions

1. Please answer the questions in the space provided below
2. There are no right or wrong answers
3. There is no limit to the number of features that you can list, please list all features you believe are essential
4. Do not discuss your response with any of your colleagues or anyone else who you think might be participating in the Delphi exercise. We are after your expert opinion
5. After completing the questionnaire please save a copy and return it to lsg105@soton.ac.uk
6. If you would prefer to print this off to complete it please return it to the address at the top of the letter

Q1: Are there any important foot and ankle measures we have failed to identify from the literature review?

A:

Q2: Which objective measures do you believe are important to be included within a musculoskeletal foot and ankle examination?

-Please include a brief description of the measure and a reason for your choice

A:

Appendix 5: Delphi Round 2 Questionnaire

Faculty of Health Sciences
Building 45
University of Southampton
Southampton
SO17 1BJ
Tel: 02380 598832
Email: lsg105@soton.ac.uk

Re: Round 2 Delphi – Foot and Ankle Consensus Study

Dear

Welcome to round 2 of the Delphi exercise. Thank you for your participation in Round 1, from which, all experts results have been collated and are presented within this document ready for completion of round 2.

Within this round you will be shown the list of foot and ankle measures suggested by all experts. You will be asked to "accept, reject or merge" each measure according to which you feel should be included within foot and ankle musculoskeletal assessment. Please consider this is *not* a disease specific or injury specific tool. Measurement items receiving ≥60% of acceptance vote will be retained and those receiving ≤20% will be removed. Those in the middle will be further discussed until consensus is reached.

In round 3 you will be able to review the results of every measure. Where applicable a summary table of supporting evidence from the systematic literature review will be introduced with each of the suggested measures. You will also have access to the entire findings of the systematic review at this stage. You will then be given the opportunity to re-rate each item based upon the informed evidence and opinions of fellow experts provided.

We are hopeful that the suggested changes and amalgamations of foot and ankle measures will enable us to reach sufficient consensus to close the Delphi exercise following round 3, failing this an additional round will be included.

Please can you complete the attached questionnaire and return it to lsg105@soton.ac.uk by ***7th September 2012***. Should you wish to discuss any aspect of this project, please feel free to contact me.

Thank you Kindly for completing this round.

Yours Sincerely

Lucy Gates
Arthritis Research UK PhD Fellow

Round 2 Delphi – Objective measures to be included within a musculoskeletal foot and ankle examination

Instructions:

Please make your choice on all listed foot and ankle measures by placing an ***X*** following ***accept*** or ***reject***. Once complete please save and return to lsg105@soton.ac.uk
Do not discuss your response with anyone else.
If you are accepting a measure please clarify your method by selecting one or more of the relevant choices, which are represented by a coded number or letter within the comment box. Should your preferred method not be included please add to comments box.
Should you wish to merge measures please note the measures corresponding numbers (to left of table) within the relevant box. See example below:

Example:

Notes:

- Similar measures or terms may have been amalgamated to avoid repetition.
- Measures that did not meet the inclusion criteria set out in round 1 instructions are not included.

Range of Motion:		Number of times item selected	Accept	Reject	Merge	**Measurement Technique**			**Recording**		
						Active =A	**Passive =P**	**Ruler =1**	**Gonio meter =2**	**Visual-full/limited/none =3**	**Visual-rigid/normal/flexible =4**
10	▪ **Ankle Dorsiflexion with knee extended (NWB)**	**II**	**x**		**10 & 11**	**A, P**		**3**			
11	▪ **Ankle Dorsiflexion with knee flexed (NWB)**	**II**	**x**								

Appendix 5: Delphi round 2 responses

Observation:		Number of times item selected (rnd 1)	Accept	Reject	Merge	Recording		
						Descriptive =1	Categorical (i.e. present/absent) = 2	Other = 3
1	**observation of swelling (tender) joints**	**IIIIIII**						
2	**observation of skin/nail/colour changes and/or lesions**	**IIII**						
3	**observation of asymmetry**	**I**						
4	**general foot morphology**	**I**						
5	**forefoot width**	**I**						

Palpation:		No.	Accept	Reject	Merge	Recording		
						Descriptive =1	Categorical (i.e. present/absent) =2	Other =3
6	**General swelling**	**I**						
7	**Swollen joints**	**I**						
8	**Temperature**	**I**						

Please indicate your choice/s from **both** measurement technique and recording:

Range of Motion:		**No.**	**Accept**	**Reject**	**Merge**	**Measurement Technique**		**Recording**			
						Active =A	Passive =P	Ruler =1	Goniometer =2	Visual-full/limited/none =3	Visual-rigid/normal/flexible =4
9	**Ankle Dorsiflexion**	**IIIIII**									
10	▪ **Ankle Dorsiflexion with knee extended (NWB)**	**II**									
11	▪ **Ankle Dorsiflexion with knee flexed (NWB)**	**II**									
12	▪ **Ankle Dorsiflexion weight bearing Lunge Test**	**I**									
13	**Ankle (non-specific)**	**IIIIII**									
14	**Ankle/rearfoot**	**III**									
15	▪ **inversion/eversion**	**I**									
16	▪ **Passive motion of rear foot in 6 directions to determine rigidity/flexibility**	**I**									
17	**Subtalar**	**IIIIIIIII**									
18	▪ **Represented as rearfoot inversion/eversion**	**I**									
19	▪ **Pronation/supination**	**II**									
20	**Midfoot /midtarsal**	**IIII**									

Range of Motion continued:		No.	Accept	Reject	Merge	Measurement Technique		Recording			
						Active =A	Passive =P	Ruler =1	Goniometer =2	Visual-full/limited/none =3	Visual-rigid/normal/flexible =4
21	▪ Calcaneocuboid joint	I									
22	▪ Talonavicular joint	I									
23	▪ Inter-tarsal accessory movements	I									
24	▪ Passive motion of mid foot in 6 directions to determine rigidity/flexibility	I									
25	Forefoot	II									
26	▪ 1st MTPJ	IIIIIIIII									
27	▪ Metatarsal phalangeal joints	II									
28	▪ Inter metatarsal phalangeal joints	I									
29	▪ Passive motion of forefoot in 6 directions to determine rigidity/flexibility	I									
30	1st Ray	II									
31	Joint stability	I									
32	Quality of joint motion (from one or more of the above joints)	IIII									
33	Direction of joint motion (from one or more of the above joints)	II									

Alignment:		No.	Accept	Reject	Merge	Measurement technique		Recording	
						Weight bearing =WB	Non-weight bearing =NWB	Goniometer =1	Visually =2
34	Rear foot alignment to leg alignment	IIII							
35	• To leg	IIII							
36	• To ground								
37	• To fore foot (NWB)	I							
38	• In neutral stance	I							
39	• In relaxed stance	II							
40	Subtalar joint								
41	• neutral position	III							
42	• axis position	III							
43	Frontal plane tibial position	I							
44	Midtarsal joint sagittal plane inclination	I							
45	First ray neutral position in relation to forefoot	I							
46	Forefoot alignment	I							

Static Posture:			No.	Accept	Reject	Merge	comments
47	foot posture (Nonspecific)		III				
48	Foot posture index (FPI): composite		IIIII				
49	FPI Individual Components	• Talar head palpation	I				
50		• Curves above and below the malleoli	I				
51		• calcaneal inversion/eversion	I				
52		• talo-navicular prominence					
53		• medial arch height	I				
54		• forefoot ab/adduction	I				
55	Arch height		II				
56	Arch Index		IIIII				
57	Transverse arch		I				
58	Navicular height		I				
59	Normalised navicular height truncated		II				

Other:		No.	Accept	Reject	Merge	Comments
60	supination resistance test	I				
61	maximum pronation test	I				

Muscle tests:		No.	Accept	Reject	Merge	Reporting	
						full/limited/none =1	MRC scale =1
Indirect foot and ankle assessment:		**No.**	**Accept**	**Reject**	**Merge**	**Comments**	
63	**soleus**	**I**					
64	**Plantaris**	**I**					
65	**Tibialis posterior**	**II**					
66	**Flexor digitorum longus**	**I**					
67	**Flexor hallucis longus**	**I**					
68	**Tibialis anterior**	**I**					
69	**Extensor digitorum longus**	**I**					
70	**Extensor hallucis longus**	**I**					
71	**Peroneus tertius**	**I**					
72	**Peroneus longus**	**I**					
73	**Peroneus brevis**	**I**					
74	**strength generalised to movement (i.e. inversion/eversion)**	**I**					
75	**muscle strength assessed using hand held dynamometer**	**I**					

leg length	**I**				
balance measures					
• **one leg stance with eyes open/closed**	**I**				
• **postural sway in anterior-posterior and medial-lateral direction with eyes open/closed**	**I**				
foot wear examination	**II**				
Knee ROM with goniometer	**I**				
gait - parameters including walking velocity, cadence, double support, step and stride length	**IIIII**				

	Specific to pathology	No.	Accept	Reject	Merge	Comments
1	observation of deformity using semi-objective rating					
2	Observation of forefoot and digital deformity with Foot structure index	I				
3	Platto Index for deformity	II				
4	observation of lesser toe deformities	III				
5	hallux valgus presence	III				
6	hallux valgus assessment with goniometer	I				
7	hallux valgus assessment via x-ray	I				
8	standing heel raise to assess tibialis posterior- noted as full/limited/none	I				
9	Ankle ligament tests, in particular ATFL and deltoid via drawer and tilt	I				
10	Palpation of plantarfascia insertion	II				
11	Palpation of Achilles tendon	I				
12	Achilles tendon rupture: Simmonds test	I				
13	Mortons neuroma- mulders sign	I				

Appendix 5: Delphi Round 2 collated results

	>60% accepted		10.2 (11 and over accepted)						
	Less than 20% accepted=reject		3.4 (3 or less rejected)			17 responses			
	Between 20%-60% accepted								
	Observation:	**Accept**	**Total accepted**	**% accepted**	**Reject**	**Merge**	**Recording**		
							Descriptive 1	Categorical (i.e. present/absent) 2	Other 3
1	**observation of swelling (tender) joints**	xxxxxxxxxxxxx xx	15	88	xx	1,7: 1,2: 1,2: 1,6	xx	xxxxxxxxxxxxx	
2	**observation of skin/nail/colour changes and/or lesions**	xxxxxxxxxxxx	13	76	xxxx		xxxxxxxx	xxxxxx	
3	**observation of asymmetry**	xxxxxxxx	8	47	xxxxxxxxx	3,4,6: 3,4:	xxx	xxxxxx	
4	**general foot morphology**	xxxxx	5	29	xxxxxxxxxxx	4,5:	xxxx	xx	
5	**forefoot width**	xxxx	4	24	xxxxxxxxxxx		xxx	x	x
	Palpation:	**Accept**	**Total accepted**	**% accepted**	**Reject**	**Merge**	**Recording**		
							Descriptive 1	Categorical 2	Other 3
6	**General swelling**	xxxxxxxxx	9	53	xxxxxxxx	6,7: 6,7,1: 6,7	xx	xxxxxxx	
7	**Swollen joints**	xxxxxxxxxx	10	59	xxxxxxx	1,7		xxxxxxxxx	
8	**Temperature**	xxxxxxxx	8	47	xxxxxxxxxx		xxx	xx	x

	Range of Motion:	Accept	Total accepted	% accepted	Reject	Merge	Measurement Technique		Recording		
							Active	Passive	Ruler 1	Goniometer 2	Categorical 3
9	Ankle Dorsiflexion	xxxxxxxxxxxxx	15	88	xx	9,10,11: 9,10,11	xxxxxxxx	xxxxxxxxxxx		xxxxxx	xxxxxxxxx
10	▪ Ankle Dorsiflexion with knee extended (NWB)	xxxxxxxxxxx	11	65	xxxxx	10,11,12:10,11,	xxxx	xxxxxxxx		xxx	xxxxxx
11	▪ Ankle Dorsiflexion with knee flexed (NWB)	xxxxxxxxxxxx	12	71	xxxx		xxxx	xxxxxxxxx		xxx	xxxxxxx
12	▪ Ankle Dorsiflexion weight bearing Lunge Test	xxxxxxx	7	41	xxxxxxxxxx		xxxxx	x		xxxxxx	
13	Ankle (non-specific)	xxx	3	18	xxxxxxxxxxx		x	xxx			xxx
14	Ankle/rearfoot	xxxxx	5	29	xxxxxxxxxx	14, 15: 14,15:		xxx			xx
15	▪ inversion/eversion	xxxxxxxxx	9	53	xxxxxxxx	15,16:	xxx	xxxxx		x	xxxxxx
16	▪ Passive motion of rear foot in 6 directions to determine rigidity/flexibility	x	1	6	xxxxxxxxxxxxx			x			x
17	Subtalar	xxxxxxxxxxxxx	14	82	xxx	17, 18, 19: 17,18	x	xxxxxx			xxxxxxxx
18	▪ Represented as rearfoot inversion/eversion	xxxxxxxxx	9	53	xxxxxx	18,19:	xxx	xxxxxxx		xx	xxxxxxx
19	▪ Pronation/supination	xxxxx	5	29	xxxxxxxxx		x	xxx			xxxx

20	Midfoot /midtarsal	xxxxxxxxxxx	11	65	xxx		x	xxxxxxx			xxxxxxxxx
21	▪ Calcaneocuboid joint	xxxx	4	24	xxxxxxxxxxxx		x	xxxx			xxxx
22	▪ Talonavicular joint	xxxx	4	24	xxxxxxxxxxxx	22,23	x	xxxx			xxxx
23	▪ Inter-tarsal accessory movements	xx	2	12	xxxxxxxxxxxxx			x			xx
24	▪ Passive motion of mid foot in 6 directions to determine rigidity/flexibility	xxx	3	18	xxxxxxxxxxx	21-24; 24,26					
25	Forefoot	xxxxx	5	29	xxx	25,26	x	xxx			xxx
26	▪ 1st MTPJ	xxxxxxxxxxxxx	17	#			xxxx	xxxxxxxxxxxxxx		xxxxxx	xxxxxxxxx
27	▪ Metatarsal phalangeal joints	xxxxxxxx	8	47	xxxxxxxx		xx	xxxxxxx			xxxxxxxxx
28	▪ Inter metatarsal phalangeal joints	xxxxx	5	29	xxxxxxxxxx		xx	xxxxx			xxxxx
29	▪ Passive motion of forefoot in 6 directions to determine rigidity/flexibility	xx	2	12	xxxxxxxxxxx	26-29:					
30	1st Ray	xxxxxxx	7	41	xxxxxxxxx		x	xxxxx			xxxxxx
31	Joint stability	xx	2	12	xxxxxxxxxxxx			xxx			x
32	Quality of joint motion (from one or more of the above joints)	xxxxxxx	7	41	xxxxxxxxx			xxxxx			xxxx
33	Direction of joint motion (from one or more of the above joints)	xx	2	12	xxxxxxxxxxxx			x			

	Alignment:	Accept	Total accepted	% accepted	Reject	Merge	Measurement		Recording	
							Weight bearing	Non-weight bearing	Goniometer 1	Visually 2
34	Rear foot alignment to leg alignment	xxxxxxxxxxx	12	71	xxxxx	34,35:	xxxxxxxxxx	xxx		xxxxxxxxx
35	• To leg	xxxxxxxxxx	10	59	xxxxxx		xxxxxxxx	x	x	xxxxxxxx
36	• To ground	xxxx	4	24	xxxxxxxxxx		xxx		x	xxx
37	• To fore foot (NWB)	xxxxx	5	29	xxxxxxxxxx		xxxx	x	x	xxxx
38	• In neutral stance	xxx	3	18	xxxxxxxxxxx		xxx		xx	xx
39	• In relaxed stance	xxxxxxxxx	9	53	xxxxxxx		xxxxxxx		xxx	xxxxxx
40	Subtalar joint	xxx	3	18	xxxx		x		x	x
41	• neutral position	xxxxxxx	7	41	xxxxxxxx		xxxx	xxxx	xx	xxxxx
42	• axis position	xxxx	4	24	xxxxxxxxxx		xxxx			xxxx
43	Frontal plane tibial position	xx	2	12	xxxxxxxxxxx		xx			xx
44	Midtarsal joint sagittal plane inclination	x	1	6	xxxxxxxxxxxxx		x			x
45	First ray neutral position in relation to forefoot	xxxx	4	24	xxxxxxxxx		xxx	x		xxxx
46	Forefoot alignment	xxxx	4	24	xxxxxxxxx	37,46:	xx	x		xxxx

	Static Posture:	Accept	Total Accepted	% accepted	Reject	Merge	comments
47	foot posture (Nonspecific)	xxxxxx	6	35	xxxxxxxxx		WB descritptive
48	Foot posture index (FPI):	xxxxxxxxxxxxx	14	82	xxx	48-54; 48-54	
49	• Talar head palpation	xxxxxxx	7	41	xx		
50	• Curves above and below the malleoli	xxxxxxx	7	41	xx		
51	• calcaneal inversion/eversion	xxxxxxx	7	41	xx		
52	• talo-navicular prominence	xxxxxxx	7	41	xx		
53	• medial arch height	xxxxxxx	7	41	xx		
54	• forefoot ab/adduction	xxxxxxx	7	41	xx		
55	Arch height	xxxx	4	24	xxxxxxxxxx		
56	Arch Index	xxxxxxx	7	41	xxxxxxxx		
57	Transverse arch	xx	2	12	xxxxxxxxxxxxxx		
58	Navicular height	xxxxx	5	29	xxxxxxxxxx		measured in mm
59	Normalised navicular height truncated	xxxx	3	18	xxxxxxxxxx		measured in mm
	Other:	Accept	Total accepted	% accepted	Reject	Merge	Comments
60	supination resistance test	x	1	6	xxxxxxxxxxxxx		
61	maximum pronation test	x	1	6	xxxxxxxxxxxxx		

	Muscle tests	Accept	Total accepted	% accepted	Reject	Merge	Reporting		
							full/limited/none 1	MRC scale 1	
62	Gastrocnemius	xxxxxxx	7	41	xxxxxxx	62,63,64:	xxx	xx	As clinically indicated
63	soleus	xxxxxx	6	35	xxxxxxxx		xxx	xx	As clinically indicated
64	Plantaris	xxx	3	18	xxxxxxxxxx		x	x	As clinically indicated
65	Tibialis posterior	xxxxxx	6	35	xxxxxxxx		xxx	xx	As clinically indicated
66	Flexor digitorum longus	xxxxxx	6	35	xxxxxxxx		xxx	xx	As clinically indicated
67	Flexor hallucis longus	xxxxxx	6	35	xxxxxxxx		xxx	xx	As clinically indicated
68	Tibialis anterior	xxxxxxx	7	41	xxxxxxx		xxx	xx	As clinically indicated
69	Extensor digitorum longus	xxxxxxx	7	41	xxxxxxx		xxx	xx	As clinically indicated
70	Extensor hallucis longus	xxxxxx	6	35	xxxxxxxx		xxx	xx	As clinically indicated
71	Peroneus tertius	xxx	3	18	xxxxxxxxxx	71,72,73	xx		As clinically indicated
72	Peroneus longus	xxxxxx	6	35	xxxxxxxx		xxx	xx	As clinically indicated
73	Peroneus brevis	xxxxx	5	29	xxxxxxxxx		xxx	x	As clinically indicated
74	strength generalised to movement (i.e. inversion/eversion)	xxxxx	5	29	xxxxxxxx		xx		As clinically indicated
75	muscle strength assessed using hand held dynamometer	xxxx	4	24	xxxxxxxxxx		xx	x	As clinically indicated

	Indirect foot and ankle assessment:	Accept	Total accepted	% accepted	Reject	Merge	Comments
76	leg length	xxxxxxxx	8	47	xxxxxxxx		ONLY FOR PURPOSE OF DETECTING LARGE (>1CM) DIFFERENCES
77	balance measures	xxx	3	18	xxxxxxx		SIMPLE STANDING ON ONE LEG
78	• one leg stance with eyes open/closed	xxxx	4	24	xxxxxxxxxxx		
79	• postural sway in anterior-posterior and medial-lateral direction with eyes open/closed	xxx	3	18	xxxxxxxxxxx		
80	foot wear examination	xxxxxxxxxxxx	13	76	xxx		observe heel wear, type of shoe frequently worn. Menz scoring system
81	Knee ROM with goniometer	xx	2	12	xxxxxxxxxxx		
82	gait - parameters including walking velocity, cadence, double support, step and stride length	xxxxxxxxxxxxx	14	82	xxx		SIMPLE VISUAL OBSERVATION. Without instrumented walk way just use walking speed

	Specific to pathology	Accept	Total accepted	% accepted	Reject	Merge	Comments
1	observation of deformity using semi-objective rating	xxxxx	5	29	xxxxxxxx	1,2,3,4	IF THERE IS AN OBJECTIVE DISEASE SPECIFIC MEASURE
2	Observation of forefoot and digital deformity with Foot structure index	xxxxxx	6	35	xxxxxxxxx	2,3,4: 2,4	
3	Platto Index for deformity	xxxxx	5	29	xxxxxxxxxx		
4	observation of lesser toe deformities	xxxxxxxxxxxx	13	76	xx		
5	hallux valgus presence	xxxxxxxxxxxxx	14	82	x		Mancheter scale
6	hallux valgus assessment with goniometer		0	0	xxxxxxxxxxxxxx		
7	hallux valgus assessment via x-ray		0	0	xxxxxxxxxxxxxx		
8	standing heel raise to assess tibialis posterior- noted as full/limited/none	xxxxxxxx	8	47	xxxxxxx		AS A MEASURE OF SYMETRY TO DETERMINE SIDE SPECIFIC DEFICIT
9	Ankle ligament tests, in particular ATFL and deltoid via drawer and tilt	xxxxxx	6	35	xxxxxxxx		IF IN CONTEXT OF REPORTED CONDITION
10	Palpation of plantarfascia insertion	xxxxxxxxxx	11	65	xxxx		
11	Palpation of Achilles tendon	xxxxxxxxxx	10	59	xxxxx	11,12	IF IN CONTEXT OF REPORTED CONDITION
12	Achilles tendon rupture: Simmonds test	xxxxxx	6	35	xxxxxxxxx		IF IN CONTEXT OF REPORTED CONDITION
13	Mortons neuroma- mulders sign	xxxxx	5	29	xxxxxxxxxx		IF IN CONTEXT OF REPORTED CONDITION

Appendix 6: Delphi Round 3 Questionnaire

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Southampton
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Re: Round 3 Delphi – Foot and Ankle Consensus Study

Dear

Thank you for your participation in this study to date. Consensus gained from your input so far has successfully reduced the original list of 95 foot and ankle assessment measures to a definite 13 and 45 to further revote. A number have been rejected, whilst others merged.

We now wish to refine this list further, with the ultimate aim to provide an ideal assessment tool which can be used in a timely and efficient manor within the clinical setting. With this in mind for the following round, please do consider what has already been accepted within each section to avoid repetition of similar measures.

Within this shorter round you will see the list of accepted/rejected foot and ankle measures, and those which require a revote. **You will be asked to simply "accept or reject" each measure which requires a revote**. Once again measurement items receiving ≥60% of acceptance vote will be retained and those receiving ≤20% will be removed. Those in the middle may be further discussed until consensus is reached.

For the current round we have not included the methods of measuring and recording each assessment parameter as in previous stages, this will revisited at the final stage. We anticipate the requirement of a further round to gain consensus on this completed list, where applicable in the final round, supportive evidence shall be introduced with each suggested measure.

As this should be a relatively quick round please can I request that you complete the attached questionnaire and return it to lsg105@soton.ac.uk by **Friday 16th November 2013**. Should you wish to discuss any aspect of this project, please feel free to contact me. Thank you Kindly for completing this round.

Yours Sincerely

Lucy Gates

ARUK AHP Training Research Fellow

Instructions: Please mark and X to accept or reject each measure which is NOT already shaded in. Those shaded in have already been accepted.

		Round 2 Results:		Round 3. To Revote:	
	Observation:	**Total Votes**		**Accept**	**Reject**
1	Swollen (tender) joints	16			
2	observation of skin/nail/colour changes and/or lesions	14			
3	general foot morphology and assymetry	9			
4	forefoot width	4			
	Palpation:	**Total**		**Accept**	**Reject**
5	General swelling	10			
6	Temperature	8			
	Range of Motion:	**Total**		**Accept**	**Reject**
7	Ankle Dorsiflexion with knee extended (NWB)	12			
8	Ankle Dorsiflexion with knee flexed (NWB)	13			
9	Ankle Dorsiflexion weight bearing Lunge Test	7			
10	Ankle inversion/eversion	9			
11	Subtalar Joint represented as rearfoot inversion/eversion	10			
12	Subtalar Joint represented as Pronation/supination	6			
13	Midfoot /midtarsal	11			
14	Calcaneocuboid joint	5			
15	Talonavicular joint	5			
16	Passive motion of mid foot in 6 directions to determine rigidity/flexibility	4			
17	1st MTPJ	18			
18	Metatarsal phalangeal joints	9			
19	Inter metatarsal phalangeal joints	6			
20	1st Ray	8			
21	Quality of joint motion (from one or more of the above joints)	7			

	Alignment:	Total		Accept	Reject
22	Rearfoot to leg	11			
23	Rearfoot to ground	4			
24	Rearfoot to fore foot (NWB)	5			
25	Rearfoot in relaxed stance	10			
26	Rearfoot in neutral position	7			
27	Rearfoot axis position	4			
28	First ray neutral position in relation to forefoot	5			
29	Forefoot alignment	5			
	Static Posture:	Total		Accept	Reject
30	foot posture (Nonspecific)	7			
31	Foot posture index (FPI): composite	14			
32	Arch height	5			
33	Arch Index	7			
34	Navicular height	5			
	Muscle test	Total		Accept	Reject
35	Gastrocnemius /soleus	8			
36	Tibialis posterior	7			
37	Flexor digitorum longus	7			
38	Flexor hallucis longus	7			
39	Tibialis anterior	8			
40	Extensor digitorum longus	8			
41	Extensor hallucis longus	7			
42	Peroneus longus and brevis	7			
43	strength generalised to movement (i.e. inversion/eversion)	6			
44	muscle strength assessed using hand held dynamometer	4			

	Indirect foot and ankle assessment:	Total		Accept	Reject
45	leg length	9			
46	One leg stance with eyes open/closed	4			
47	postural sway in anterior-posterior and medial-lateral direction with eyes open/closed	4			
48	foot wear examination	14			
49	gait - parameters including walking velocity, cadence, double support, step and stride length	15			
	Specific to pathology			Accept	Reject
50	Observation of forefoot and digital deformity with Foot structure index	5			
51	observation of lesser toe deformities	14			
52	hallux valgus presence	15			
53	standing heel raise to assess tibialis posterior- noted as full/limited/none	9			
54	Ankle ligament tests, in particular ATFL and deltoid via drawer and tilt	6			
55	Palpation of Achilles tendon	11			
56	Achilles tendon rupture: Simmonds test	7			
57	Mortons neuroma- mulders sign	6			
58	Palpation of plantarfascia insertion	12			

Appendix 6: Delphi Round 2 & 3 results collated

Round 2 & 3 Results/Accepted (shaded)

	Observation:	Total Votes Round 2	Total votes round 3	Accepted (shaded) & To Discuss:
1	Swollen (tender) joints	16		
2	observation of skin/nail/colour changes and/or lesions	14		
3	general foot morphology and assymetry	9	12	

Total of 21 accepted

27 to Discuss

	Palpation:	Round 2	Round 3	
4	General swelling	10	10	
5	Temperature	8	6	

	Range of Motion:	Round 2	Round 3	
6	Ankle Dorsiflexion with knee extended (NWB)	12		
7	Ankle Dorsiflexion with knee flexed (NWB)	13		
8	Ankle Dorsiflexion weight bearing Lunge	7	5	

	Test			
9	Ankle inversion/eversion	9	9	
10	Subtalar Joint represented as rearfoot inversion/eversion	10	16	
11	Midfoot /midtarsal	11		
12	Talonavicular joint	5	5	
13	1st MTPJ	18		
14	Metatarsal phalangeal joints	9	13	
15	Inter metatarsal phalangeal joints	6	7	
16	1st Ray	8	10	
17	Quality of joint motion (from one or more of the above joints)	7	6	

	Alignment:	Round 2	Round 3	
18	Rearfoot to leg	11		
19	Rearfoot in relaxed stance	10	16	
20	Rearfoot in neutral position	7	5	
21	Forefoot alignment	5	8	

	Static Posture:	Round 2	Round 3	

22	Foot posture index (FPI): composite	14		
23	Arch Index	7	5	

	Muscle test	Round 2	Round 3	
24	Gastrocnemius /soleus	8	11	
25	Tibialis posterior	7	10	
26	Flexor digitorum longus	7	7	
27	Flexor hallucis longus	7	9	
28	Tibialis anterior	8	10	
29	Extensor digitorum longus	8	7	
30	Extensor hallucis longus	7	8	
31	Peroneus longus and brevis	7	8	
32	strength generalised to movement (i.e. inversion/eversion)	6	8	

	Indirect foot and ankle assessment:	Round 2	Round 3	
33	leg length	9	13	
34	foot wear examination	14		
35	gait - parameters including walking velocity, cadence, double support, step and stride length	15		
36				
	Specific to pathology	Round 2	Round 3	

	observation of lesser toe deformities	14			
37	hallux valgus presence	15			
38	standing heel raise to assess tibialis posterior- noted as full/limited/none	9	14		
39	Ankle ligament tests, in particular ATFL and deltoid via drawer and tilt	6	8		
40	Palpation of Achilles tendon	11	14		
41	Achilles tendon rupture: Simmonds test	7	6		
42	Mortons neuroma- mulders sign	6	5		
43	Palpation of plantarfascia insertion	12			

Appendix 7: Delphi round 4 Questionnaire

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Re: Final Round Delphi – Foot and Ankle Consensus Study

Dear

I am pleased to announce that we have now successfully reached consensus on the particular measures to be included within a musculoskeletal foot and ankle assessment tool. I thank you once again for your valuable contributions which have made this possible.

We now require your input on the final short round to confirm the recording parameters of the each measure. Please indicate your choice on the attached list, taking into account the formerly made expert choices. Supportive evidence from our initial literature review has been introduced, where applicable. Please find this attached as a separate word document.

It has become clear that there is the potential for two final assessment tools: one for clinical use and one for research. In order to confirm which measures would be suitable in each we believe a face to face expert meeting would be most beneficial. We would therefore like to hold a separate meeting at the British Rheumatology Society (BSR) Conference 2013, in Birmingham. Should you be intending to visit the UK around this time, we would like to invite you to attend the meeting. We can offer to subsidise internal travel and accommodation for a short period. If this is something you would like to consider please let me know.

Could I request you complete the attached final round and return it to lsg105@soton.ac.uk by Friday 21st December 2012. Should you wish to discuss any aspect of this please feel free to contact me. Thank you kindly for your input in this study.

Yours Sincerely

Lucy Gates

ARUK Training Research Fellow

Total votes from round 2:

(Shaded measures were not not applicable for voting at round 2):

TO COMPLETE: Please indicate your choice of measurement method with an X.

	Observation:	Recording		Recording	
		Descriptive	Categorical (i.e. present/absent)	Descriptive	Categorical (i.e. present/absent)
1	Swollen (tender) joints	2	14		
2	observation of skin/nail/colour changes and/or lesions	8	6		
3	general foot morphology and assymetry	4	6		
4	lesser toe deformities				
5	hallux valgus presence				

	Palpation:	Recording		Recording	
		Descriptive	Categorical (i.e. present/absent)	Descriptive	Categorical (i.e. present/absent)
6	Palpation of Achilles tendon				
7	Palpation of plantarfascia insertion				

	Range of Motion:	Recording		Measurement Technique		Recording		Measurement Technique (More than one choice can be made)	
		Goniometer	Categorical	Active	Passive	Goniometer	Categorical	Active	Passive
8	Ankle Dorsiflexion with knee extended (NWB)	3	6	4	8				
9	Ankle Dorsiflexion with knee flexed (NWB)	3	7	4	9				
10	Subtalar Joint represented as rearfoot inversion/eversion	2	7	3	7				
11	Midfoot /midtarsal	0	9	1	7				
12	1st MTPJ	5	10	4	14				
13	Metatarsal phalangeal joints	0	10	2	7				

	Alignment:	Recording		Measurement Technique		Recording		Measurement Technique (More than one choice can be made)	
		Goniometer	Categorical	Weight bearing	Non weight bearing	Goniometer	Categorical	Weight bearing	Non weight bearing
14	Rearfoot to leg	1	8	8	1				

	Alignment:	Recording		Recording		Measurement Technique	
		Goniometer	Categorical	Goniometer	Categorical	Rearfoot to leg	Rearfoot to ground
15	Rearfoot in relaxed stance	3	6				

	Static Posture:	Recording
16	Foot posture index (FPI): composite	

	Muscle test:	Recording		Recording	
		Categorical	MRC Scale (1-5)	Categorical (Full/limited/none)	MRC Scale (1-5)
17	Gastrocnemius /soleus	3	2		
18	standing heel raise to assess tibialis posterior- noted as full/limited/none				

19	leg length		
20	foot wear examination		
21	gait - parameters including walking velocity, cadence, double support, step and stride length		

Appendix 7: Delphi Round 4 collated responses

	Observation:		Recording	
			Descriptive	Categorical (i.e. present/absent)
1	Swollen (tender) joints		2	16
2	observation of skin/nail/colour changes and/or lesions		13	6
3	general foot morphology and assymetry		10	8
4	lesser toe deformities		3	10
5	hallux valgus presence		2	11
	Palpation:		Recording	
			Descriptive	Categorical (i.e. present/absent)
6	Palpation of Achilles tendon		7	7
7	Palpation of plantarfascia insertion		5	9

	Range of Motion:	Recording		Measurement Technique (More than one choice can be made)	
		Goniometer	Categorical	Active	Passive
8	Ankle Dorsiflexion with knee extended (NWB)	6	13	9	16
9	Ankle Dorsiflexion with knee flexed (NWB)	6	12	8	15
10	Subtalar Joint represented as rearfoot inversion/eversion	1	18	2	17
11	Midfoot /midtarsal	0	16	2	16
12	1st MTPJ	4	14	2	17
13	Metatarsal phalangeal joints	2	17	3	17

	Alignment:	Recording		Measurement Technique (More than one choice can be made)	
		Goniometer	Categorical	Weight bearing	Non weight bearing
14	Rearfoot to leg		17	16	5

	Alignment:	Recording		Measurement Technique	
		Goniometer	Categorical	Rearfoot to leg	Rearfoot to ground
15	Rearfoot in relaxed stance	1	16	9	9

	Static Posture:				
16	**Foot posture index (FPI): composite**				
	Muscle test:		**Recording**		
			Categorical (Full/limited/none)	**MRC Scale (1-5)**	
17	**Gastrocnemius /soleus**		**12**	**4**	
18	**standing heel raise to assess tibialis posterior- noted as full/limited/none**		**9**		
	Indirect foot and ankle assessment:		**Please Specifiy method of Measurement:**		
19	**leg length**		**Tape measure (3) while sitting and standing/ASIS to MM (2)/NWB umbilicus-MM/subjective view of malleoli, patella and asis (2)**		
20	**foot wear examination**		**Descriptive/ Barton et al footwear (3)**		
21	**gait - parameters including walking velocity, cadence, double support, step and stride length**		**Observation/ gaitrite (3)/video analysis over ground and treadmil. Matscan and fscan**		simple full/limited/none and description
					simple with stopwatch over 10m

Appendix 8: Delphi Expert Involvement

Professional Specialism		Initial Consent to Delphi	Withdrew prior to round 1	Consent after round 1	Input at round 1	Input at round 2	Input at round 3	Input at round 4
1	Podiatry	YES	NO		YES	YES	YES	YES
2	Podiatry	YES	NO		YES	YES	YES	YES
3	Podiatry	YES	NO		YES	YES	YES	YES
4	Podiatry	YES	NO		YES	YES	YES	YES
5	Podiatry	YES	NO		YES	YES	YES	YES
6	Podiatry	YES	NO		YES	YES	YES	YES
7	Podiatry	YES	YES					
8	Podiatry	YES	NO		YES	YES	YES	YES
9	Podiatry	YES	NO		YES	YES	YES	YES
10	Podiatry	YES	NO		YES	YES	YES	YES
11	Orthopaedics	YES	YES					
12	Orthopaedics	YES	NO		NO	NO	NO	NO
13	Rheumatology	YES	NO		YES	YES	YES	YES
14	Rheumatology	YES	NO		YES	YES	YES	YES
15	Rheumatology	YES	NO		YES	YES	YES	YES
16	Rheumatology	YES	NO		YES	YES	YES	YES
17	Rheumatology	YES	NO		NO	NO	NO	NO
18	Podiatry	YES	NO		NO	NO	NO	NO
19	Podiatry	YES	NO		YES	NO	YES	YES
20	Physiotherapy	YES	NO		YES	YES	YES	YES
21	Physiotherapy	YES	NO		YES	YES	YES	YES
22	Physiotherapy	YES	NO		YES	YES	YES	YES
23	GP/Sports medicine	YES	NO		NO	NO	NO	NO
24	General Practice	YES	NO		NO	NO	NO	NO
25	General Practice	YES	NO		NO	NO	NO	NO
26	Podiatry			YES		YES	YES	YES
27	Orthopaedics			YES		YES	YES	YES
	27	25	2	2	17	18	19	19

Appendix 9: Expert meeting

Expert Meeting

The foot and ankle assessment consensus study expert meeting was held on 23rd April 2013 (13.00-15.00) at the ICC, Birmingham, during the British Society of Rheumatology conference

Experts present:

N=9

Discussion points:

Experts and Lead Investigator (LG): Confirmation that the main aim of consensus study was to develop a core set of expertly derived foot and ankle assessment measures to inform research, that are applicable for use within the clinical setting.

LG: The aim of meeting was to gain a level of recommendation for each of the 20 measures and from this, provide a suggestions for the applicability of each measure to be included within a research and clinical assessment. This will be published as suggestions for measures to be included within musculoskeletal foot and ankle assessment.

Experts and LG: These measures are not to be classed as generic tool for foot and ankle diagnosis, but a core set of items that could be added on depending upon circumstance. All present agreed the set of measures are for screening purposes not diagnosis.

Experts and LG: There was a strong group agreement for no scoring system to be applied to the set of measures at present, especially no requirement for a global score.

Final comments:

Experts and LG: This is a list of parameters to make a good broad generic foot and ankle assessment.

Experts and LG: Suggestions made to use it across institutions in its current draft state. Use the draft to determine efficacy of the tool itself then move forward from there.

Research priorities:

The list forms twenty measures with Strength of Recommendation (SOR) scores applied individually to each. These is a recommendation for validation and a need to consider if validation will be clinically or scientifically led i.e. against gold standard MRI or outcomes of pain and function.

SOR scores were collected via email from the remaining experts who could not attend the meeting.

Strength of Recommendation (SOR):

SOR values were taken for each individual measure for both a clinical and research circumstance. SOR values are based upon a numerical rating scale from 1-10, where higher values are representative of stronger strength of recommendation and lower values for lesser strength of recommendation.

Appendix 10: International Musculoskeletal Foot and Ankle Assessment ©

Observation		**Left**			**Right**		
1. Swollen (tender) joints	1st MTPJ	Yes		No	Yes		No
	2nd MTPJ	Yes		No	Yes		No
	3rd MTPJ	Yes		No	Yes		No
	4th MTPJ	Yes		No	Yes		No
	5th MTPJ	Yes		No	Yes		No
	Midfoot	Yes		No	Yes		No
	STJ	Yes		No	Yes		No
	Ankle	Yes		No	Yes		No
2. Skin/nail changes and/or lesions	Skin changes:						
	Nail changes:						
3. General foot morphology		Normal		Abnormal	Normal		Abnormal
	Symmetrical	Yes/No					
4. Hallux valgus presence		Yes		No	Yes		No
5. Lesser toe deformities			No of toes affected			No of toes affected	
	Hammer	Yes		No	Yes		No
	Mallet	Yes		No	Yes		No
	Retracted	Yes		No	Yes		No
	Clawed	Yes		No	Yes		No

Palpation		Left				Right			
6. Achilles Tendon		Tender		Thickened		Tender		Thickened	
	T-A Junction	Yes	No	Yes	No	Yes	No	Yes	No
	Mid Tendon	Yes	No	Yes	No	Yes	No	Yes	No
	Enthesis	Yes	No	Yes	No	Yes	No	Yes	No
7. Proximal plantarfascia insertion	Tender	Yes		No		Yes		No	

Passive Range of Motion	Left				Right			
8. Ankle dorsiflexion with knee extended	Hypermobile	Normal	Limited	Fixed	Hypermobile	Normal	Limited	Fixed
9. Ankle dorsiflexion with knee flexed	Hypermobile	Normal	Limited	Fixed	Hypermobile	Normal	Limited	Fixed
10. Rearfoot inversion/eversion	Hypermobile	Normal	Limited	Fixed	Hypermobile	Normal	Limited	Fixed
11. Midfoot /midtarsal	Hypermobile	Normal	Limited	Fixed	Hypermobile	Normal	Limited	Fixed
12. 1st MTPJ	Hypermobile	Normal	Limited	Fixed	Hypermobile	Normal	Limited	Fixed
13. Metatarsal phalangeal joints	Hypermobile	Normal	Limited	Fixed	Hypermobile	Normal	Limited	Fixed

Muscle Tests	Left						Right					
14. Gastrocnemius /soleus (MRC Scale)	0	1	2	3	4	5	0	1	2	3	4	5
15. Single Limb Heel Raise (Tibialis posterior)	Able	Limited	Unable				Able	Limited	Unable			

Alignment		Left			Right		
16. Rearfoot to leg in relaxed stance		Inverted	Linear	Everted	Inverted	Linear	Everted

Static Posture		Left					Right				
17. Foot Posture Index (FPI)	Talar head palpation	-2	-1	0	+1	+2	-2	-1	0	+1	+2

	Curves above and below malleoli	-2	-1	0	+1	+2	-2	-1	0	+1	+2
	Calcaneal inversion/eversion	-2	-1	0	+1	+2	-2	-1	0	+1	+2
	Talo-navicular prominence	-2	-1	0	+1	+2	-2	-1	0	+1	+2
	Medial arch height	-2	-1	0	+1	+2	-2	-1	0	+1	+2
	Forefoot ab/adduction	-2	-1	0	+1	+2	-2	-1	0	+1	+2
	Total										

Indirect Assessment	Left	Right
18. Leg length	ASIS-MM (mm) :	ASIS-MM (mm) :

19. Footwear	Shoe Type with % worn in average week	Trainer	%	Boot	%	Oxford/ lace	%	Court	%
		Slip on	%	Sandal	%	Bespoke	%	slipper	%
	Heel Height in average week (If yes to court, slip on or boot)	0-2.5cm		2.6-5cm		>5cm			
20. Gait parameters	Walking aid	Yes		No					
	Lower Limb Asymmetry	Yes		No					
	Antalgic Gait	Yes		No					
	Ataxic Gait	Yes		No					
	Festinating gait	Yes		No					
	Hemiplegic	Yes		No					
	Spastic Gait	Yes		No					

	10m walk time (secs):	

Guidelines for use

Unless pathology or disability dictates otherwise, to ensure optimum standardisation of the assessment, measures should be conducted with the patient in the following positions:

Measure	Patient Position
Observation:	
Swollen (tender) joints	Sitting
Skin/nail changes and/or lesions	Sitting
General foot morphology and asymmetry	Sitting
Lesser toe deformities	Sitting
Hallux valgus presence	Sitting
Palpation:	
Achilles tendon	Prone Lying
Proximal plantarfascia insertion	Prone Lying
Passive Range of Motion:	
Ankle dorsiflexion with knee extended (NWB)	Supine Lying
Ankle dorsiflexion with knee flexed (NWB)	Supine Lying
Rearfoot inversion/eversion	Supine Lying
Midfoot /midtarsal	Supine Lying
1st MTPJ	Supine Lying
Metatarsal phalangeal joints	Supine Lying
Muscle Tests:	
Gastrocnemius /soleus	Supine Lying
Tibialis posterior (Heel raise)	Standing*
Alignment:	
Rearfoot to leg in relaxed stance	Standing*
Static Foot Posture:	
Foot posture index (FPI)	Standing**
Indirect Measures:	
leg length	Supine Lying
Gait	Standing*
Footwear	Patient unshod

*During standing measures the patient should adopt a relaxed stance position and should be instructed to remain looking forward so as not to alter foot position.

**Please refer to the Foot Posture Index Reference Manual (Redmond , 1998). Further information can be found on-line at: http://www.leeds.ac.uk/medicine/FASTER/FPI

Equipment required: Tape Measure

The techniques below are provided as a guide to ensure the standardisation of assessment.

Observation:

1. **Swollen (Tender) Joints**

- Patient in sitting with legs extended on the couch
- Indicate the presence of swollen tender joints for the following:
    - 1^{st}, 2^{nd}, 3^{rd}, 4^{th} and 5^{th} metatarsal phalangeal joints
    - Midfoot (talonavicular joint medially to the calcaeocuboid joint laterally)
    - Subtalar (from the upper border of calcaneus anterior to the lateral malleolus, to the medial side at the sustentsculum tali)
    - Ankle joint (along the distal ends of the tibia and fibula and the taus).

2. **Skin/Nail Changes and/or Lesions**

- Patient in sitting with legs extended on the couch
- Describe any apparent skin and/or nail changes and/or lesions. These may include pathological nail conditions, acute trauma to tissue, chronic frictional callus or corns etc.

3. **General Foot Morphology and Asymmetry**

- Patient in sitting with legs extended on the couch
- Indicate if general foot morphology appears normal or abnormal, observing the structure, form and alignment of the foot.
- Indicate if there is symmetry between left and right foot (if applicable).

4. **Hallux Valgus Presence**

- Patient in sitting with legs extended on the couch
- Indicate the presence of Hallux Abducto Valgus deformity. This is characterized by abnormal lateral deviation of the hallux from the metatarsalphalangeal joint (> 15^{o}), with/without apparent bony changes at the metatarsal phalangeal joint (figure 1) .

Figure 76. Example of HAV presence

5. Lesser Toe Deformities

- Patient in sitting with legs extended on the couch.
- Indicate the presence of any of the following deformities and specify the number of toes affected:
    - hammer toe (figure 2)
    - mallet toe (figure 3)
    - retracted toe (figure 4)
    - clawed toe (figure 5)

Hammer toe is characterised by:

- Dorsiflexion at MPJ
- Marked plantarflexion at proximal IPJ
- Dorsiflexion, marked dorsiflexion or plantar flexion at distal IPJ

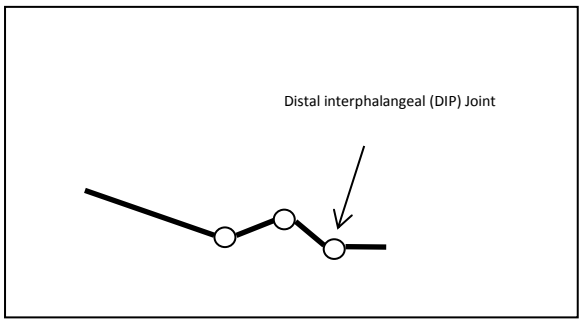


Figure 77 Hammer toe

Mallet toe is characterised by:

- Marked plantarflexion of the distal interphalangeal joint of the lesser toe.

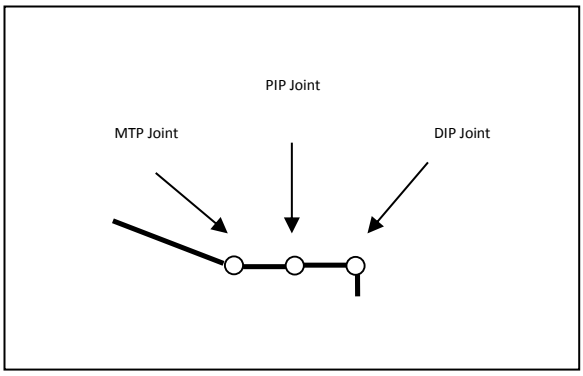


Figure 78 Mallet toe

Claw toe is characterised by:

- dorsiflexion at MPJ
- plantarflexion at proximal IPJ
- Marked plantar flexion at distal IPJ

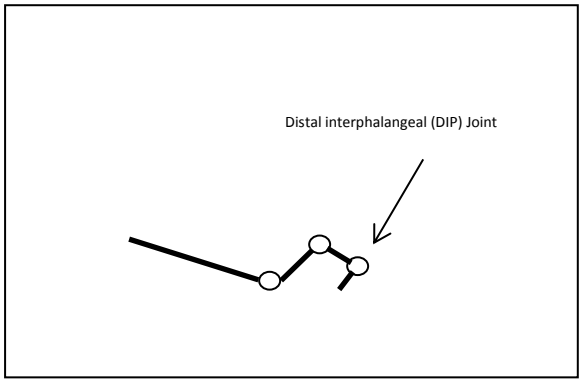


Figure 79 Claw toe

Retracted toe is characterised by:

- Marked dorsiflexion at MTPJ
- Plantarflexion at proximal IPJ
- Plantarflexion at distal IPJ with elevation

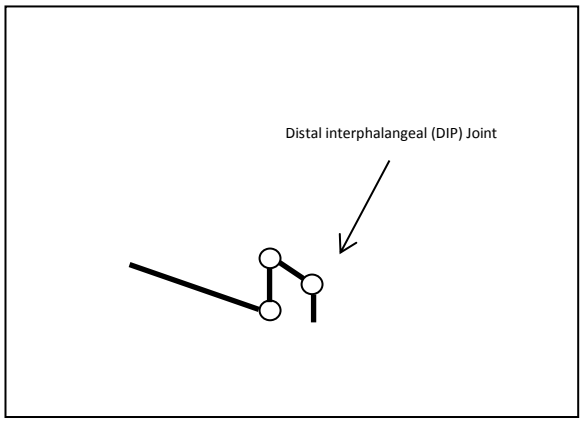


Figure 80 Retracted toe

Palpation:

6. Achilles tendon

- Patient in prone lying position on the couch, knees extended feet over the end.
- Palpate the Achilles tendon from the tendo-Achilles junction, through the mid portion of the tendon to the attachment at the enthesis.
- Indicate the presence of tenderness or thickening and the site at which either was palpated (figure 6-8)

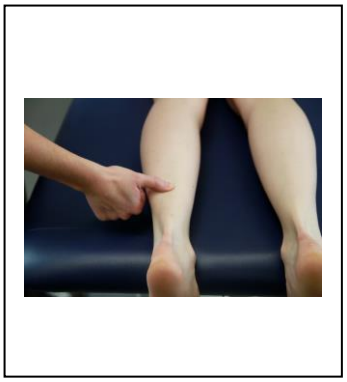


Figure 81 Tendo-Achilles junction

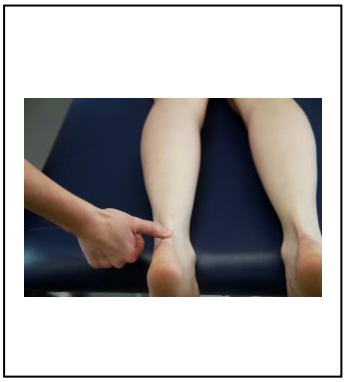


Figure 82 Achilles tendon

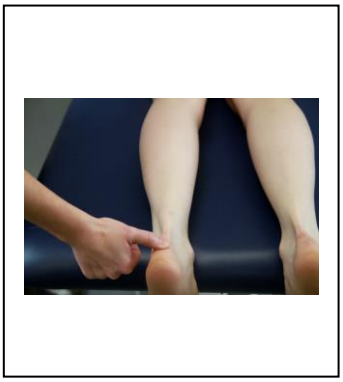


Figure 83 Achilles enthesis

7. Proximal Plantarfascia insertion

- Patient in the prone lying position on the couch, knees extended and feet over the end.
- Extend digits 1-5 with one hand whilst palpating the proximal plantarfascia where it inserts on the calcaneal tuberosity (figure 9).
- Indicate if pain is present (It may be useful to compare left to right in the first instance to establish normal levels of sensitivity around this area).

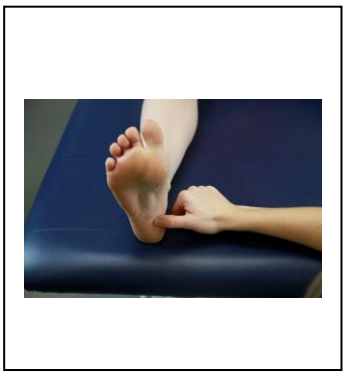


Figure 84 Plantarfascia insertion

Passive Range of Motion:

Using the following criteria, indicate if the range of motion of each joint is:

- Fixed
- Reduced
- Normal
- Hypermobile

8. Ankle dorsiflexion with knee extended (NWB)

- Patient in supine lying position on the couch with knees relaxed and extended
- Using the whole hand against the dorsum of the foot, apply a linear force to create a dorsiflexion movement, limiting any potential eversion.

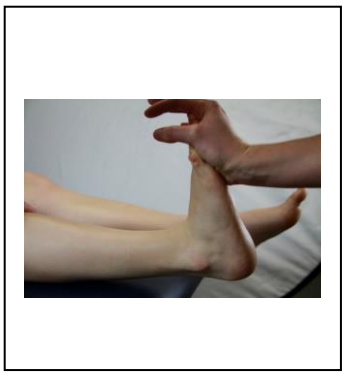


Figure 85 Ankle dorsiflexion (knee extended)

9. Ankle dorsiflexion with knee flexed (NWB)

- Patient in supine lying position on the couch with knee in 90 degrees of flexion
- Using the entire hand against the dorsum of the foot, apply a linear force to create a dorsiflexion movement, limiting any potential eversion

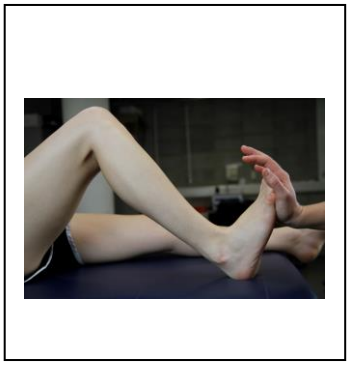


Figure 86 Ankle dorsiflexion (knee flexed)

10. Rearfoot inversion/eversion

- Patient in prone lying position on the couch, knees extended and feet over the end.
- Stabilise the lower leg with on hand and grasp the calcaneus the other entire. Move the calcaneus through its frontal plane range of motion.

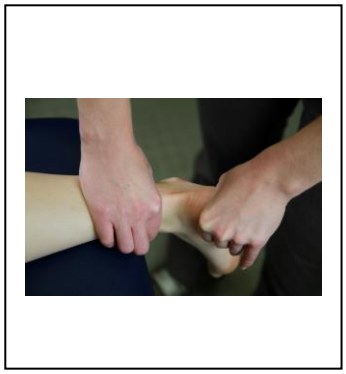


Figure 87 Rearfoot inversion

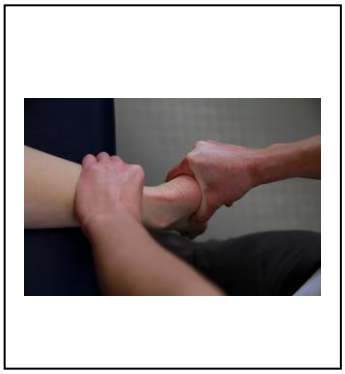


Figure 88 Rearfoot eversion

11. Midfoot and Midtarsal

- With the patient in supine lying position on the couch, knees extended and feet over the end, move the midfoot/ tarsometatarsal joint (where the five metatarsals articulate with the three cuneiforms and cuboid) through all three planes of motion (figure 14).
- Transfer both hands proximally to surround and move the midtarsal joint (comprising the talo-navicular medially and calcaneo-cuboid joints laterally) (figure 15)

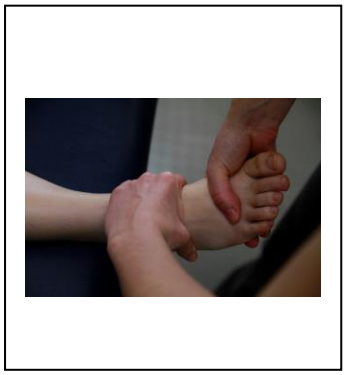


Figure 89 Midfoot

Figure 90 Midtarsal

12. First MTPJ

- With the patient in supine lying position on the couch, knees extended and feet over the end, grasp above and below the MTPJ. Dorsiflex (figure 16) and plantarflex (figure 17) the joint to the end of range

Figure 91 First MTPJ dorsiflexion

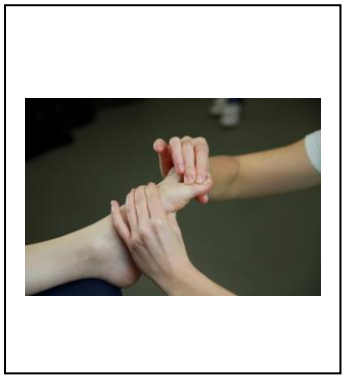


Figure 92 First MTPJ plantarflexion

13. Metatarsal phalangeal joints

- Complete the same as above for each individual MTPJ

Muscle Tests:

Based on Medical Research Council (MRC) grading system:

The patient's effort is graded on a scale of 0-5:

- Grade 5: Muscle contracts normally against full resistance.
- Grade 4: Strength reduced but muscle contraction can still move joint against resistance.
- Grade 3: Strength further reduced such that the joint can be moved only against gravity with the examiner's resistance completely removed.
- Grade 2: Muscle can move only if the resistance of gravity is removed
- Grade 1: Only a flicker of movement in the muscle
- Grade 0: No movement observed.

14. Gastrocnemius

- Patient in supine lying position on the couch, with legs extended.
- Patient attempts to plantarflex the ankle whilst examiner applies resistance to the forefoot.
- Attention must be paid to ensure the patient is not facilitating or substituting plantarflexion with eversion of the foot.
- Indicate the patients' grade of effort using the MRC scale above

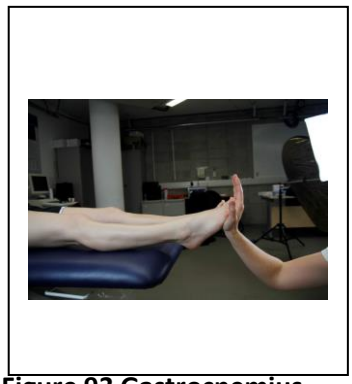


Figure 93 Gastrocnemius

15. Tibialis posterior (single heel rise)

- Patient adopts single limb stance
- Patient attempts to raise the rearfoot of the weight bearing limb whilst maintaining forefoot contact with the ground
- Indicate if the patient is able to, if there is difficulty or if they are complete unable to perform the *single-limb* heel-rise

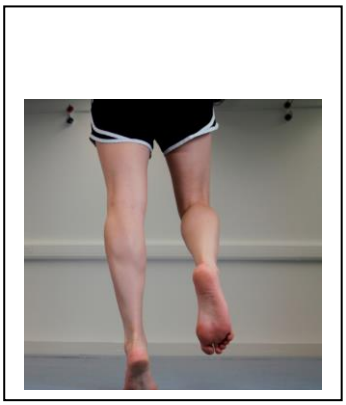


Figure 94 Single limb heel raise

Alignment:

16. Rearfoot to leg in relaxed stance

- The patient should be in a relaxed standing position, in double limb support, looking forward. Whilst observing the posterior aspect of the calcaneus, indicate its vertical position relative to the posterior lower leg. Dependent upon the approximate bisection of the two, indicate if the calcaneus is everted (figure 20), linear (figure 21) or inverted (figure 22).

Figure 95 Rearfoot everted

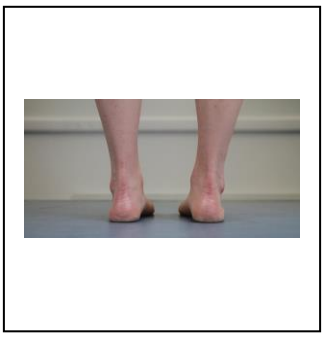


Figure 96 Rearfoot linear

Figure 97 Rearfoot inverted

Static Foot Posture:

17. Foot posture index (FPI)

- Please refer to the Foot Posture Index Reference Manual (Redmond , 1998). Further information can be found on-line at: http://www.leeds.ac.uk/medicine/FASTER/FPI

Indirect Measures:

18. leg length

- Patient in supine lying. Ensure both legs run parallel to the corresponding centre line of the body
- Identify the Anterior Superior Iliac Spine (ASIS) as the first bony prominence felt by palpation proximally along the inguinal ligaments (figure 23)
- On the same side identify the distal tip of the medial malleoli (figure 24)
- Measure from the anterior superior iliac spine (ASIS) to the distal tip of the medial malleolus using a tape measure (figure 25)

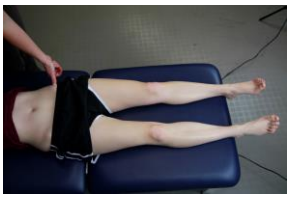


Figure 98 Identifying ASIS

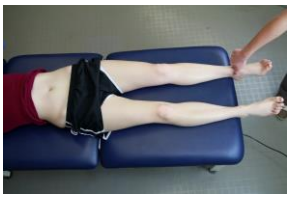


Figure 99 Medial malleoli

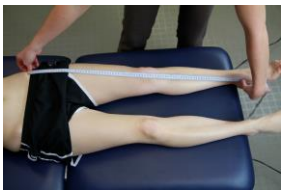


Figure 100 Measure length

19. Footwear

- Observe and discuss patients footwear and indicate the:
    - Type of shoe with percentage worn in average week
    - Heel height

20. Gait Parameters

- Observe patient walking (barefoot where possible)
- Indicate the presence of the following gait parameters:
    - Walking aid- Including Sticks, crutches, frame, AFO etc
    - Lower Limb Symmetry- Similar movement patterns of both lower limbs throughout the three planes of movement
    - Antalgic Gait- A limp adopted to avoid pain on weight-bearing structures, characterized by a very short stance phase
    - Ataxic Gait- Unsteady, uncoordinated, wide based gait, with the feet thrown out. Irregular lurching steps result in lateral veering and if severe, falling
    - Festinating gait- Involuntarily movement with short, accelerating steps, often on tiptoe
    - Hemiplegic- Unilateral weakness and spasticity with the upper extremity held in flexion and the lower extremity in extension. The foot is in extension so the leg is "too long" therefore, the patient will have to circumduct or swing the leg around to step forward.
    - Spastic Gait- The legs are held together and move in a stiff manner, the toes seeming to drag and catch

10 meter walk:

- Mark two lines on the floor 10 meters apart (with a chair at the end if required)
- Have the patient standing at the first line ready (use a static standing start)
- Instruct usual or comfortable pace be used
- Time from one line to the other
- Calculate time in metres per second: 10 (metres) divided by time (seconds)

Appendix 11: Ethical approval documentation

Southampton University Hospitals NHS Trust NHS

Please reply to: Research and Development
Duthie Building (Trust) MP138
Southampton General Hospital
Tremona Road Southampton SO16 6YD

Telephone: 02380 794245
Fax: 02380 798678
E-mail: Victoria.McArdell@suht.swest.nhs.uk

Professor Nigel Arden
Rheumatology Research Unit
Mailpoint 63
Level G, West Wing
Southampton General Hospital
Tremona Road
SO16 6YD

16 June 2010

Dear Professor Arden

ID: RHM MED0938 A study to assess a strategy for predicting patients at risk of poor functional outcome following lower limb joint arthroplasty

Re: NHS Research Governance and Identification of Nominated Research Sponsor

I am writing to confirm that Southampton University Hospitals NHS Trust is prepared to act, in principle, as sponsor for this study under the terms of the Department of Health Research Governance Framework for Health and Social Care.

SUHT's final acceptance of sponsorship responsibilities is dependent on full R&D approval, which will incorporate evidence of adequate funding to conduct your study.

SUHT fulfills the role of research sponsor in ensuring management, monitoring and reporting arrangements for research. I understand that you will be acting as the principal investigator responsible for the daily management for this study, and that you will be providing regular reports on the progress of the study to the Trust on this basis.

I would like to take this opportunity to remind you of your responsibilities under the terms of the Research Governance Framework for researchers, principal investigators and research sponsors, that it is a requirement of the terms and conditions of approval that you become fully conversant with the Research Governance Framework on Health and Social Care document which is available from : http://www.dh.gov.uk/en/Policyandguidance/Researchanddevelopment/index.htm

Please do not hesitate to contact us should you require any additional information or support.

May I also take this opportunity to wish you every success with your research.

Yours sincerely

Victoria McArdell
Research Governance Officer

UNIVERSITY OF Southampton

Dr. Nigel Arden
School of Medicine
Medical Research Council
MP 95
Southampton General Hospital
Tremona Road
Southampton
SO16 6YD

RGO REF - 7661
NHS R&D RHM - MED0938
REC No - 10/H0604/91

04 November 2010

Dear Dr. Arden

Professional Indemnity and Clinical Trials Insurance

Project Title COASt - Clinical Outcomes in Arthroplasty Study

Participant Type:	No Of Participants:	Participant Age Group:	Notes:
Patients	3000	Adults	Oxford
Patients	3000	Adults	Southampton

Thank you for forwarding the completed questionnaire and attached papers.

Having taken note of the information provided, I can confirm that this project will be covered under the terms and conditions of the above policy, subject to written informed consent being obtained from the participating volunteers.

I would also advise that it is a condition of the University's insurance that any incidents that could eventually result in a claim are reported immediately. Serious adverse events, suspected unexpected serious adverse reactions and similar fall into this category and should also be reported to me at the same time as they are reported under the Protocol. Failure to do this could invalidate the insurance.

Insurance will only be activated when we have received a copy of the Ethics Committee approval and you must not begin your project prior to this. Please forward a copy of the Ethics Committee approval letter as soon as it is to hand to complete the insurance placement.

If there are any changes to the above details, please advise us as failure to do so may invalidate the insurance.

Yours sincerely

Mrs Ruth McFadyen
Insurance Services Manager

Tel: 023 8059 2417
email: hrm@soton.ac.uk

cc: File

NHS
National Research Ethics Service
Oxfordshire REC A
Room 002
TEDCO Business Centre
Rolling Mill Road
Jarrow
NE32 3DT

Telephone: 0191 428 3561
Facsimile: 0191 428 3432

10 December 2010

Professor Nigel Arden
Professor in Rheumatic Diseases & Consultant Rheumatologist
University of Southampton & University of Oxford
MRC Epidemiology Resource Centre
MP 95, Southampton General Hospital
Tremona Road
Southampton
SO16 6YD

Dear Professor Arden

Study Title:	**COASt - Clinical Outcomes in Arthroplasty StudyA study to assess a strategy for predicting patients at risk of poor functional outcome following lower limb joint arthroplasty**
REC reference number:	**10/H0604/91**
Protocol number:	**RHM MED0938**

Thank you for your letter of 26 November 2010, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research

University of Southampton

Southampton NHS
University Hospitals NHS Trust

wellcome trust

Wellcome Trust Clinical Research Facility
Mailpoint 218
C Level, West Wing
Southampton General Hospital
Tremona Road
Southampton
SO16 6YD

Tel: 023 8079 4989
Fax: 023 8079 5023

22 December 2010

Professor Nigel Arden
MRC Epidemiology Resource Centre
MP 095
SGH

Dear Professor Arden

Re: Study No **RHM MED0938 – PLEASE NOTE THAT THE WTCRF IS NO LONGER ISSUING CRF IDENTITY NUMBERS**

Project title: **COAST – Clinical Outcomes of Arthroplasty Study**

I am pleased to inform you that your recent application to conduct a study in partnership with the Wellcome Trust Clinical Research Facility has been accepted. We look forward to receiving a copy of SUHT Research and Development final approval before study commencement.

This study will be subject to recovery of costs in line with WTCRF policy. Please contact Enrico Tambellini if you require further clarification.

A member of the Nursing Team will contact you shortly to determine your exact requirements. This meeting is a necessary part of the study initiation process and must take place before your study can commence in the WTCRF.

If any aspect of your study alters before commencement, eg through protocol amendments or significant time lag to approval, the WTCRF reserves the right to review the study requirements and our capability to support it.

Facility space and nursing time will be allocated to you according to availability. This is due to increased activity within the WTCRF and the need to utilise our resources optimally. Your study Research Nurse will work with you to ensure that your preferences are met as closely as possible.

I enclose our Guidelines for Users for further information about using the Facility.

Thank you for your interest in the WTCRF. We look forward to working with you on this study.

Yours sincerely

Saul Faust
Director

or

Chris Edwards
Associate Director

G:\MANAGEMENT\Secretarial\SAB files\SAB letter templates\letters 600-649\MED0938_accepted, R&D reqd.doc

Southampton University Hospitals NHS Trust

Please reply to: Research and Development
Duthie Building (Trust) MP138
Southampton General Hospital
Tremona Road Southampton SO16 6YD

Telephone: 02380 794901
Fax: 02380 798678
E-mail: danny.pratt@suht.swest.nhs.uk

Professor Nigel Arden
Rheumatology Research Unit
Mailpoint 63
Level G, West Wing
Southampton General Hospital
Tremona Road
SO16 6YD

21 January 2011

Dear Professor Arden

ID: RHM MED0938 **A study to assess a strategy for predicting patients at risk of poor functional outcome following lower limb joint arthroplasty (COAST)**

EudraCT:

Thank you for submitting all the required documentation for Trust R&D approval. I write to inform you that your study has full SUHT R&D approval. Please find attached the Conditions of Trust R&D approval which you are obliged to adhere to.

You are required to keep copies of all your essential documents relating to this study. Please download a copy of the relevant Investigator Site File template from the R&D website: http://tinyurl.com/3xtxv66.

Your project is subject to R&D monitoring and you will be contacted by our office to arrange this.

Please note: A condition of approval is that any changes need to be timeously notified to the R&D office. This includes providing copies of:

. All NRES substantial amendments and favourable opinions;
. All Serious Adverse Events (SAEs);
. NRES Annual Progress Reports;
. Annual MHRA Safety Reports;
. NRES End of Study Declaration;
. Notifications of significant breaches of GCP or protocol

Please quote the above RHM No. on any correspondence with our office.

Should you, or any of your team, require training in any of the policies and procedures required to ensure compliance with the conditions of approval, please refer to the R&D Training website http://tinyurl.com/prkd65 for an up-to-date calendar of training events.

Yours sincerely

Danny Pratt
Research Governance Officer

NHS
National Research Ethics Service
NRES Committee South Central - Oxford A
South West Research Ethics Committee Centre
Whitefriars
Level 3 Block B
Lewins Mead
Bristol
BS1 2NT

Tel: 01173421331
Fax: 01173420445

20 October 2011

Prof Nigel Arden
Professor of Rheumatology
The Botnar Research Centre
University of Oxford
Rm /Bdg 45, Highfield
Southampton
SO17 1BJ

Dear Prof Arden

Study title:	**COASt - Clinical Outcomes in Arthroplasty StudyA study to assess a strategy for predicting patients at risk of poor functional outcome following lower limb joint arthroplasty**
REC reference:	**10/H0604/91**
Protocol number:	**RHM MED0938**
Amendment number:	**2**
Amendment date:	**01 September 2011**

The above amendment was reviewed on 14 October 2011 by the Sub-Committee in correspondence.

Ethical opinion

The Committee Members were content with the changes made.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
COASt CRF 007 Post-Operative One Year Follow Up: Knee	3.0	01 September 2011
COASt CRF 002 Pre-Operative Procedure Specific Assesment:Knee	2.0	01 September 2011
COASt CRF 003 Pre-Operative Procedure Specific Assesment: Hip	2.0	01 September 2011
COASt CRF 018 Pre-Operative Patient Self Assesment: Hip	2.0	01 September 2011
COASt CRF 017 Pre-Operative Patient Self Assesment:Knee	2.0	01 September 2011

NHS
Health Research Authority

NRES Committee South Central - Oxford A
Bristol Research Ethics Committee Centre
Whitefriars
Level 3 Block B
Lewins Mead
Bristol
BS1 2NT

Tel: 0117 342 1331
Fax: 0117 342 0445

25 February 2013

Prof Nigel Arden
Professor of Rheumatology
The Botnar Research Centre
University of Oxford
Rm /Bdg 45, Highfield
Southampton
SO17 1BJ

Dear Prof Arden

Study title:	**COASt - Clinical Outcomes in Arthroplasty StudyA study to assess a strategy for predicting patients at risk of poor functional outcome following lower limb joint arthroplasty**
REC reference:	**10/H0604/91**
Protocol number:	**RHM MED0938**
Amendment number:	**SA3.0**
Amendment date:	**12 November 2012**
IRAS project ID:	**65920**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The Committee Members approved:

The main purpose of this amendment is to invite patients back for a research appointment one year after their operation.

There are also minor formatting and grammatical corrections, along with small alterations for the purpose of clarification, to the Patient Information Sheet (PI 006) and Protocol.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

Appendix 12: Patient Information Sheet

OMB
OXFORD MUSCULOSKELETAL BIOBANK

University Hospital Southampton NHS
NHS Foundation Trust

COASt

Clinical Outcomes in Arthroplasty Study

Chief Investigator: Professor Nigel Arden
MRC Epidemiology Resource Centre
Southampton Hospital

Oxford REC A (REC Ref: 10/H0604/91)

Patient Information Sheet

Introduction

We are inviting you to take part in a research project. Before you decide whether to take part it is important for you to know why the research is being done, and what it will involve for you. Please take time to read the following information carefully to decide whether you wish to take part. Please feel free to talk to others about the study if you wish.

What is the Research Project about?

Hip and knee replacements are the most common elective orthopaedic operations performed in the National Health Service (NHS). The aim of this research is to gain a better understanding of the mechanisms and risk factors underlying musculoskeletal diseases in order to develop new methods of assessment, diagnosis and treatment.

This is a joint study between University Hospital Southampton and the Nuffield Orthopaedic Centre in Oxford. Patients who are waiting for hip and knee replacements and revision surgery are being invited to take part in the COASt study.

Do I have to take part?

No. Your participation in this study is entirely voluntary. You are free to decline to enter or withdraw from the study at any time without having to give a reason. If you choose not to enter the study, or withdraw once entered, this will in no way affect your medical care or alter the treatment your doctors have already planned.

What will it involve if I decide to take part?

If you decide you would like to participate in the study, you will be contacted by a member of the research team who will answer any questions relating to the study that you may have. A research appointment will be made for you to attend Southampton General Hospital at your convenience.

You may be sent a patient self assessment questionnaire which will include social/medical history and aspects of your lifestyle to complete at home. You will be asked to bring the completed questionnaire with you when you come to your research appointment. During your research appointment you will be asked to sign a Study Consent Form. You will also be asked to provide blood, urine and/or tissue samples. You will be given a copy of your signed consent from and patient information sheet, copies of these will also be retained in your

hospital records.

The following additional tests will also be undertaken: a whole body bone density scan (DEXA) and physical assessment. These tests will all be performed during your research appointment. We would also like to have access to copies of any images (x-rays etc.) that have been taken during the course of your treatment. You can expect to be at the hospital for approximately one to two hours for this appointment.

Information will be collected from your hospital records following your surgery. All information will be retained in your research folder and recorded onto a password protected database.

You will be asked to complete a postal questionnaire at 6 weeks after your operation and then yearly for the next 5 years. You are free to decline to answer any of the questions at any time without giving a reason.

How will the information I provide be used?

Once the results of the study have been gathered and analysed, we will present this data at national and international scientific meetings and publish the results in medical journals so that other can read about and learn from them. This kind of research helps us to plan more efficiently and effectively for the National Health Service.

What are the advantages and disadvantages of taking part?

There are no disadvantages in contributing to this study. Blood samples are usually taken at the time of routine investigation/follow up. If you are having an operation then the tissue samples used for research are only taken from any tissue that is being removed in the normal course of surgical treatment: no additional tissue is removed.

There are no advantages to you, but the results of research using samples of tissue taken from you and others may help patients in the future. You are asked to donate your tissue freely for research and you will not receive a financial reward either now or in the future. Your samples will not be sold for profit to other researchers. Your samples may be used for research that may lead to the development of new assessment tools, drugs or therapies, which may eventually be marketed, and companies may sell these for profit.

What will happen to any samples that I give?

We will store your tissue, blood, urine samples and data at the Oxford Musculoskeletal BioBank (OMB) which is based in Oxford and licensed by the Human Tissue Authority and approved by a research ethics committee. The OMB is a tissue and data facility for a number of research projects that study diseases of bone, joint and other soft tissues.

Samples and data will be stored by the OMB for use by the COASt study. Upon completion of the COASt study any remaining samples and associated data will become available to other ethically approved projects, many of which are not yet known and will depend on the development of new research techniques in the future. However all research projects will be subject to approval by a Research Ethics Committee and access to samples and data will be controlled.

Scientists who are experts in genetics may perform tests on your samples – the results of these tests may provide information on which genes cause arthritis and other musculoskeletal diseases and whether it responds to certain treatments. Samples and data collected may be transferred for the purpose of research and analysis to associated investigators within/outside the European Economic Area.

Will my taking part in the project be kept confidential?

All information regarding your medical records will be treated as strictly confidential. The data will initially be stored at SUHT and transferred to the OMB database at Oxford for permanent storage. Participation in this study will in no way affect your legal rights.

Personal data, which may be sensitive (e.g. name, date of birth) will be collected and processed but only for research purposes in connection with this study. All data will remain confidential, and no personal details will be made available to any third parties. Details about you will be stored on a computer during this research project. Information on you, your clinical history and biological samples will be coded so that these are all anonymous.

With your permission, if specific COASt investigations indicate any medically important results, we will inform your general practitioner (GP) who will contact you to discuss the findings.

What if something goes wrong?

We do not believe that you will be harmed by taking part in this research study but in the event that something does go wrong. If this is due to someone's negligence, then you may have grounds for legal action for compensation against Southampton University Hospital Trust, but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you. As the Chief Investigator is an employee of the University of Southampton, additional professional indemnity and clinical investigation insurance is in place. Regardless of this, any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed.

Please raise your concerns in the first instance with the Chief Investigator, Professor Nigel Arden. If you wish to make a more formal complaint, please contact the hospital's Patient Advice and Liaison Service (PALS) on 023 8079 8498 (available 9 am to 4:30 pm Monday to Friday, out of hours there is an answer phone). Email PALS@uhs.nhs.uk or write to PALS, C Level, Centre Block, Southampton General Hospital, Tremona Road, Southampton, SO16 6YD.

Where can I find out more about research in general?

INVOLVE is a national advisory group, funded by the National Institute for Health Research (NIHR). Its role is to support and promote active public involvement in NHS, public health and social care research, http://www.invo.org.uk/ or Wessex House, Upper Market Street, Eastleigh, Hampshire, SO50 9FD. Telephone: 02380 651088 or email admin@invo.org.uk.

Who is organising and funding the research?

This study is being funded by the National Institute of Health Research (NIHR). The researchers in this study conduct research on a time basis and are paid a fixed salary which is independent of whether you participate in the study or not.

Who has reviewed and approved the study?

This study has been reviewed and approved by Oxford REC A (REC Ref: 10/H0604/91).

Oxford Musculoskeletal BioBank has been approved by Oxford REC C(REC Ref: 09/H0606/11, 3rd March 2009) and is regulated and licensed by the Human Tissue Authority (Licence No: 12217).

Research enquiries:

If you have any questions, concerns or complaints about the study, please contact the research team.

Southampton Research Team:

Professor Nigel Arden	Tel:01865 227357
(Chief Investigator)	
Nuffield Department of	Email:
Orthopaedic, Rheumatology and Musculoskeletal Sciences	Nigel.arden@ndorms.ox.ac.uk
Botnor Research Centre,	
Old Road,	
Oxford, OX3 7LD	
Carole Ball	Telephone: 02380 795279
(Specialist Research Nurse)	
Mailpoint 63,	Email:
G Level West Wing	Carole.Ball@uhs.nhs.uk
Southampton General Hospital,	
Tremona Road	
Southampton, SO16 6YD	

Oxford Research Team:

Stefanie Garden **(Research Nurse Coordinator)**	Telephone: 01865 737258
Nuffield Department of Orthopaedics, Rheumatology & Musculoskeletal Sciences Nuffield Orthopaedic Hospital Windmill Road, Headington, Oxford OX3 7LD	Email: Stefanie.garden@ndorms.ox.ac.uk
Karolina Kliskey **(Oxford Musculoskeletal BioBank Coordinator)**	Telephone: 01865 737418
Nuffield Department of Orthopaedics, Rheumatology & Musculoskeletal Sciences Nuffield Orthopaedic Hospital Windmill Road, Headington, Oxford OX3 7LD	Email: Karolina.kliskey@ndorms.ox.ac.uk

SAMPLE CONSENT FORM

If you wish to take part in the study you will be asked to confirm your agreement with the following statements.

1	I confirm that I have read, understood and have had time to consider the Patient Information Sheet (Version 2.0, dated 26/11/10) and have been given a copy to keep. I have had the opportunity to ask questions about this project.
2	I understand that my participation is voluntary and that I am free at any time to withdraw, without giving any reason, without my medical care or legal rights being affected.
3	I understand that relevant sections of my medical notes and data collected, during the study, may be looked at by individuals from the sponsor, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
4	I agree to give samples of blood, urine and tissue for COASt as detailed in the information Sheet.
5	I agree to have a physical assessment.
6	I agree to have a bone density scan (DEXA).
7	I agree to take part in the long term follow up of COASt.
8	I understand results from research tests on my samples might be medically important to me. I agree to my GP being informed of my participation in the study and that relevant experimental findings can be discussed with them.
9	I agree that the sample(s) I have given and the information gathered about me can be stored for use in future projects, subject to ethical approval, which may include genetics studies as described in Patient Information Sheet. I understand that some of these projects may be carried out be researchers working abroad or for commercial companies.
10	I agree that the sample(s) of blood, urine and tissue I have given and the information gathered about me can be stored by the Oxford Musculoskeletal BioBank (OMB) in an anonymised format for the duration of the study.
11	Once the study is complete, I agree to gift the samples, and the information gathered about me can be stored by the Oxford Musculoskeletal BioBank (OMB) for possible future research projects. If a commercial product were developed as a result of this study I will not profit financially from such product.

Appendix 13: Postal letter of invitation

University Hospital Southampton NHS
NHS Foundation Trust

Southampton General Hospital
Mailpoint 63, G Level, West Wing
Tremona Road
Southampton
SO16 6YD

Telephone: 02380 795279
Email: carole.ball@uhs.nhs.uk

COASt

Clinical Outcomes in Arthroplasty Study

Dear Sir/Madam

We are writing to invite you to take part in an important medical research project. You have been chosen because you have recently attended an orthopaedic clinic and been placed on the waiting list for a hip/knee replacement or revision surgery.

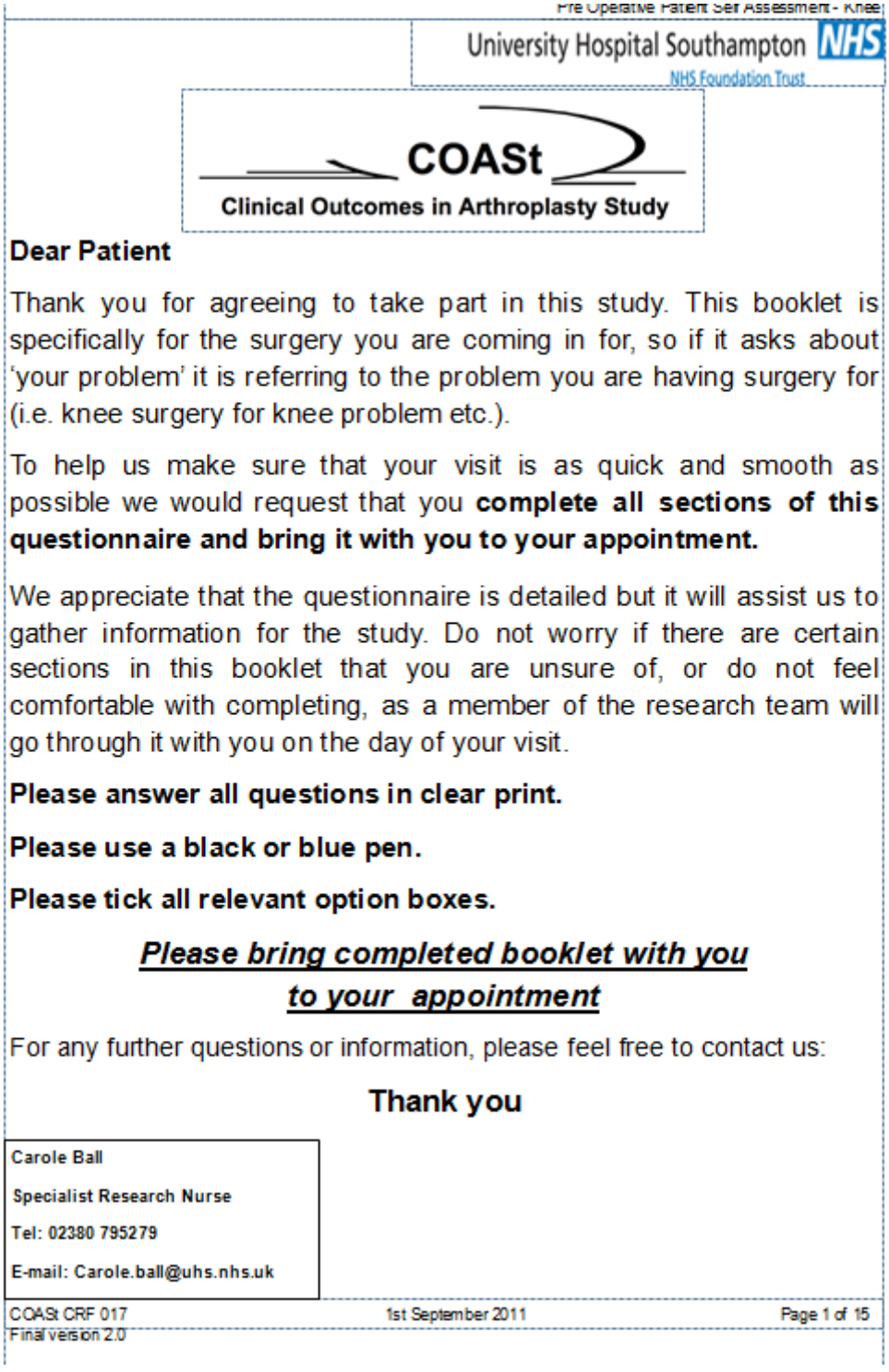
Before you decide whether to take part, it is important for you to understand why the research is being done, and what it will involve. Please take time to read the Patient Information Sheet enclosed and feel free to discuss it with family and friends. Please be assured that taking part in this study is voluntary and if you decide to decline this will not affect your medical care, or the surgery, in any way.

If you do NOT wish to take part in this project, please contact us by: telephone on 02380 795279 or email at carole.ball@uhs.nhs.uk. We will contact you by telephone, within two weeks, to discuss the project if we do not hear from you. Please feel free to contact our office if you require any further information.

Yours sincerely,

Professor N Arden
Chief Investigator

Appendix 14: Pre-operation booklet sent to KA patients



University Hospital Southampton NHS
NHS Foundation Trust

COASt
Clinical Outcomes in Arthroplasty Study

Dear Patient

Thank you for agreeing to take part in this study. This booklet is specifically for the surgery you are coming in for, so if it asks about 'your problem' it is referring to the problem you are having surgery for (i.e. knee surgery for knee problem etc.).

To help us make sure that your visit is as quick and smooth as possible we would request that you **complete all sections of this questionnaire and bring it with you to your appointment.**

We appreciate that the questionnaire is detailed but it will assist us to gather information for the study. Do not worry if there are certain sections in this booklet that you are unsure of, or do not feel comfortable with completing, as a member of the research team will go through it with you on the day of your visit.

Please answer all questions in clear print.

Please use a black or blue pen.

Please tick all relevant option boxes.

Please bring completed booklet with you to your appointment

For any further questions or information, please feel free to contact us:

Thank you

Carole Ball
Specialist Research Nurse
Tel: 02380 795279
E-mail: Carole.ball@uhs.nhs.uk

Patient Self Assessment for Inpatient Surgery

Patients: Please be sure to complete the following ...

1. All square sections within this booklet.

Patient personal details

1.1 Study Number: _____

1.2 Date of Birth _____

1.3 Address _____

_____ 1.4 Post code _____

1.5 Gender: Male ☐ i Female ☐ ii

1.6 Civil state: Single ☐ i Married ☐ ii Widowed ☐ iii Divorced ☐ iv Separated ☐ v

2.1 **General Practitioner's (GP) Name** _____

2.2 Surgery address _____

2.3 Post code _____ 2.4 Tel. No. _____

3.1 **At what age did you leave school?** _____

3.2 Did you have any further education after you finished school (please tick applicable box)?

None ☐ i GCSE / O level ☐ ii A level ☐ iii

Further education ☐ iv Higher education (diploma / degree / PHD) ☐ v

4. How long have you suffered with this problem?

Days ☐☐ i Weeks ☐☐ ii Months ☐☐ iii Years ☐☐ iv

5.1 **Current work status**

Employed ☐ i Full time ☐ ii Part time ☐ iii Unemployed ☐ iv

Retired ☐ v Disability benefit ☐ vi Housewife ☐ vii

Student ☐ viii Full time ☐ ix Part time ☐ x

5.2 If employed, what is your occupation? _____

5.3 What is your partners' occupation? _____

6.1 **Have you taken any time off work for this problem?** Yes ☐ No ☐

6.2 If yes, how much time have you taken off in the past six months?

Days ☐☐ Weeks ☐☐ Months ☐☐

7. **Is there anything that may affect your understanding during your care (e.g. confusion, speech impediment, language etc.)?**

Please state _____

8.1 **Do you have any specific dietary needs?** Yes ☐ No ☐

8.2 If yes, please specify _____

Recording of ethnic group information for patients

Please note: We are not asking about citizenship or nationality, but about the ethnic group to which you feel you belong. Please complete the form below by ticking the box of the ethnic group you feel you belong to. If you feel you are descended from more than one group, please tick the one you feel you belong to more, or choose the 'Any other ethnic group' option.

9.1	A	**White**	British	☐
9.2	B		Irish	☐
9.3	C		Any other White Background	☐
9.4	D	**Mixed**	White and Black Caribbean	☐
9.5	E		White and Black African	☐
9.6	F		White and Asian	☐
9.7	G		Any other Mixed Background	☐
9.8	H	**Asian or British Asian**	Indian	☐
9.9	I		Pakistani	☐
9.10	J		Bangladeshi	☐
9.11	K		Any other Asian Background	☐
9.12	L	**Black or Black British**	Caribbean	☐
9.13	M		African	☐
9.14	N		Any other Black Background	☐
9.15	O	**Other Ethnic Groups**	Chinese	☐
9.16	P		Any other Ethnic Group	☐

17.1 **Have you ever had any history of angina / chest pain?** Yes ☐ No ☐

17.2 If yes, do you get angina / chest pain at rest or minimal exertion? Yes ☐ No ☐

17.3 If yes, how far can you walk on a flat surface before the symptoms start?

Yards OR Metres

17.4 If yes, please specify _____

_____

18.1 **Have you ever had a MI (heart attack)?** Yes ☐ No ☐

18.2 If yes, which year? ☐☐☐☐

18.3 If yes, please specify _____

_____

19.1 **Have you ever had a history of heart failure or other cardiac diseases (including congenital heart disease)?** Yes ☐ No ☐

19.2 If yes, please specify _____

20.1 **Have you ever had a pacemaker fitted?** Yes ☐ No ☐

20.2 If yes, record date when it was last checked or changed? ☐☐/☐☐ month / year

20.3 Have you had any faints or blackouts since your last pacemaker check? Yes ☐ No ☐

20.4 Please specify _____

21.1 **Have you ever had a history of liver problems or jaundice?** Yes ☐ No ☐

21.2 If yes, please specify _____

_____

22.1 **Have you ever been diagnosed with diabetes?** Yes ☐ No ☐

22.2 If yes, which form of treatment do you use?

Diet ☐ Tablets ☐ Insulin injections ☐

22.3 If yes, please specify _____

_____

23.1 **Have you ever had a DVT / PE (blood clot) in your leg/s or lung/s?** Yes ☐ No ☐

23.2 If yes, please specify _____

_____

23.3 **Have you ever experienced unusual bruising or bleeding?** Yes ☐ No ☐

23.4 If yes, please specify _____

_____

10.1 **Do you have any problems with your hearing?** Yes ☐ ' No ☐ "

10.2 If yes, please specify _____

10.3 If you wear a hearing aid, in which ear do you wear it?

Right ☐ ' Left ☐ " Both ☐ "

11. **Please list <u>all allergies</u> and what reaction they cause (incl. food, drugs, metals etc.).**

11.1 _____

11.2 _____

11.3 _____

11.4 _____

12. **Please list all <u>intolerances</u> and what reaction they cause (incl. food, drugs, metals etc.).**

12.1 _____

12.2 _____

12.3 _____

13.1 **Have you ever had an anaesthetic?** Yes ☐ ' No ☐ "

13.2 Have you ever had any problems with anaesthetic (e.g. Adverse reaction, difficult intubation and heart or lung problems? Yes ☐ ' No ☐ "

13.3 Please specify _____

14.1 **Have you ever had a history of hypertension (high blood pressure)?** Yes ☐ ' No ☐ "

14.2 If yes, are you on medication? Yes ☐ ' No ☐ "

14.3 If yes, approximately when did you first start medication for high blood pressure? ☐☐☐☐ Year

14.4 Please specify _____

15.1 **Have you ever had a TIA / CVA (stroke or mini stroke)?** Yes ☐ ' No ☐ "

If yes, when? _____

If yes, which side of your body did it affect? Right ☐ ' Left ☐ " Both ☐ "

15.2 Please specify _____

16.1 **Have you ever been told you have a heart murmur or suffered with rheumatic fever?** Yes ☐ ' No ☐ "

16.2 If yes, approximately which year? ☐☐☐☐

16.3 If yes, is it associated with any of the following?

Fainting ☐ ' Dizziness ☐ " Unusual breathlessness ☐ "

Sweating ☐ " Chest pain ☐ "

16.4 Please specify _____

24.1 **Have you had any lung problems or shortness of breath (e.g. asthma, emphysema, TB, bronchitis, bronchiectasis etc.)?** Yes ☐ No ☐

24.2 If yes, please specify _____

24.3 If you suffer with asthma / COPD, have you been admitted to hospital for it? Yes ☐ No ☐

24.4 If you suffer with asthma / COPD, is it well controlled? Yes ☐ No ☐

24.5 If no, please specify _____

25.1 **Do you smoke?** Yes ☐ No ☐

25.2 If yes, please tick relevant: Cigarettes[i] ☐ Cigars[ii] ☐ Pipes[iii] ☐ Other[iv] ☐

25.3 If yes, how many do you smoke a day? ☐☐ / day

25.4 How many years have you been smoking? ☐☐ years

25.5 Do you have your first cigarette within 20 minutes of waking up? Yes ☐ No ☐

25.6 Are you using any treatment other than Nicotine Replacement Therapy? Yes ☐ No ☐

25.7 How successful has it been? _____

25.8 If you still smoke, would you like help with stopping? Yes ☐ No ☐

26.1 **Have you ever had any other problems (e.g. circulation, skin conditions, epilepsy, blood disorders such a haemophilia / sickle cell / anaemia)?** Yes ☐ No ☐

26.2 If yes, please specify _____

27.1 **Have you ever had a history of alcoholism/alcohol abuse?** Yes ☐ No ☐

27.2 **How much alcohol do you drink per week** (e.g. Pint=two units, small glass of wine=one unit, Single shot of spirits = one and a half units)? ☐☐ Units/week ☐ Not applicable

27.3 If yes, please specify _____

28.1 **Have you ever had a history of substance abuse?** Yes ☐ No ☐

28.2 If yes, please specify _____

29.1 **Have you ever had problems with your bowels?** Yes ☐ No ☐

29.2 If yes, please specify _____

30.1 **Have you ever had a history of renal problems?** Yes ☐ No ☐

Have you been treated for renal failure, or had renal surgery? Yes ☐ No ☐

30.2 If yes, please specify _____

31.1 **Do you have a history of urine infections?** Yes ☐ No ☐

31.2 **Are you currently suffering from any other urinary problems, including the following?**

Urgency ☐ Frequency ☐ Pain / Discomfort ☐

Incontinence ☐ Do you get up at night to use the toilet ☐

31.3 Please specify _____

31.4 Do you suffer with: Faecal Incontinence ☐ Not applicable ☐

31.5 If yes, please specify _____

32.1 **Have you ever been treated for anxiety?** Yes ☐ No ☐

32.2 If yes, please specify _____

33.1 **Have you ever been treated for depression?** Yes ☐ No ☐

33.2 If yes, are you currently taking antidepressants? Yes ☐ No ☐

33.3 If yes, are they "no cheese" drugs? Yes ☐ No ☐

33.4 If yes, please specify _____

34.1 **Have you ever had an operation to your head, neck or mouth?** Yes ☐ No ☐

34.2 If yes, please specify _____

35.1 **Have you ever had radiotherapy above your chest?** Yes ☐ No ☐

35.2 If yes, please specify _____

36.1 **Have you ever been diagnosed with Rheumatoid Arthritis?** Yes ☐ No ☐

If yes, please specify _____

If yes, does it affect your neck? Yes ☐ No ☐

36.2 If yes, please specify _____

37.1 **Medication**

- Please list all the medications you are currently taking and the reason for taking them OR
- Bring your latest prescription sheet with you to your research appointment

A. Medication Name	B. Dose and Frequency (please copy from label)	C. Reason for taking it

38.2 **Have you been on steroids during the past two years?** Yes ☐ No ☐

38.3 If yes, please specify _____

39. **Do you suffer from any of the following?**

Please tick and note which areas are affected (e.g. hands, knees, ankles and sides etc.) and dates diagnosed.

39.1 **Osteoarthritis** Yes ☐ Not to my knowledge ☐

If yes, please specify (including dates and area affected) _____

_____

39.2 **Septic Arthritis (e.g. infection of the joint)** Yes ☐ Not to my knowledge ☐

If yes, please specify (including dates and area affected) _____

_____

39.3 **Gout / Pseudo gout** Yes ☐ Not to my knowledge ☐

If yes, please specify (including dates and area affected) _____

_____

39.4 **Any other inflammatory and/or other joint problems (e.g. Ankylosing spondylitis, Bursitis etc.)** Yes ☐ Not to my knowledge ☐

If yes, please specify (including dates and area affected) _____

_____

39.5 **Avascular Necrosis** Yes ☐ Not to my knowledge ☐

If yes, please specify (including dates and area affected) _____

_____

39.6 **Paget's Disease** Yes ☐ Not to my knowledge ☐

If yes, please specify (including dates and area affected) _____

_____

39.7 **Childhood conditions (e.g. Developmental Dysplasia of Hip (DDH), Perthes' Disease, SUFE etc.)** Yes ☐ Not to my knowledge ☐

If yes, please specify (including dates and area affected) _____

_____

39.8 **Trauma (accidents / incidents)** Yes ☐ Not to my knowledge ☐

If yes, please specify (including dates and area affected) _____

_____

40.1	**Have you ever been diagnosed with Osteoporosis?**	Yes ☐	No ☐
	If yes, specify, including dates: _____		
40.2	**Have you ever been diagnosed with high cholesterol?**	Yes ☐	No ☐
	If yes, specify, including dates: _____		
40.3	**Have you ever been diagnosed with Multiple Sclerosis?**	Yes ☐	No ☐
	If yes, specify, including dates: _____		
40.4	**Have you ever been diagnosed with Parkinson's disease?**	Yes ☐	No ☐
	If yes, specify, including dates: _____		
40.5	**Have you ever had any other neurological (nerve) conditions?**	Yes ☐	No ☐
	If yes, specify, including dates: _____		
40.6	**Do you currently suffer from back pain?**	Yes ☐	No ☐
	If yes, specify, including dates: _____		
40.7	**Have you ever suffered with sciatica?**	Yes ☐	No ☐
	If yes, please tick which side is / was affected?	Left ☐ Right ☐	Both ☐
	If yes, specify, including dates: _____		
40.8	**Have you ever had surgery to your back?**	Yes ☐	No ☐
	If yes, specify, including dates: _____		
40.9	**Have you had any falls, near falls or stumbles in the last year?**	Yes ☐	No ☐
	If yes, how many? _____		
40.10	**Have you ever fractured (broken) any bones?**	Yes ☐	No ☐
	If yes, which bone/s, including dates: _____		
40.11	**Do you suffer from muscle spasms?**	Yes ☐	No ☐
	If yes, specify, including dates: _____		
40.12	**Do you suffer from joint contracture?**	Yes ☐	No ☐
	If yes, specify, including dates: _____		

40.13 **Please write down any other relevant medical and surgical history:** _____

_____

_____

_____

_____

41. **Have you used any of the following services, listed below, in the last 12 months for problems related to your musculoskeletal problem. (If yes, please indicate NHS or Private and how many times you have seen them):**

41.1 **General Practitioner (GP)**

Yes ☐ i No ☐ ii No. of times seen in NHS ☐☐ iii No. of times seen privately ☐☐ iv

41.2 **Hospital Doctor:**

Yes ☐ i No ☐ ii No. of times seen in NHS ☐☐ iii No. of times seen privately ☐☐ iv

41.3 **Physiotherapist:**

Yes ☐ i No ☐ ii No. of times seen in NHS ☐☐ iii No. of times seen privately ☐☐ iv

41.4 **Nurse/Practitioner:**

Yes ☐ i No ☐ ii No. of times seen in NHS ☐☐ iii No. of times seen privately ☐☐ iv

If yes, please state type of nurse/practitioner seen _____

_____

41.5 **Alternative practitioners (e.g. Chiropractor, Osteopath etc.)**

Yes ☐ i No ☐ ii No. of times seen in NHS ☐☐ iii No. of times seen in privately ☐☐ iv

If yes, please state type of practitioner seen _____

_____

41.6 **Accident and Emergency (A & E)**

Yes ☐ i No ☐ ii No. of times seen ☐☐ iii

If yes, please specify _____

_____

41.7 **Home Care**

Yes ☐ i No ☐ ii Hours a week by Social Services: _____

Hours a week paid by yourself: _____

41.8 **Other NHS services or health care professionals**

Yes ☐ i No ☐ ii

If yes, please state type of service or professional seen _____

_____

42. **Have you had any of the following treatments for this problem in the last 12 months?**

42.1 **Intra-articular steroid injection (into this joint)?**

Yes ☐ ' No ☐ ' No. of times ☐☐ "

42.2 **Intra-articular hyaluronic acid injection (into this joint)?**

(often called oil, lubricant, artificial synovial fluid)

Yes ☐ ' No ☐ ' No. of times ☐☐ "

42.3 **Soft tissue injection (into muscle, arm, buttock etc. because of this joint)?**

Yes ☐ ' No ☐ ' No. of times ☐☐ "

42.4 **Arthroscopy (keyhole surgery) for and because of this problem?**

Yes ☐ ' No ☐ ' No. of times ☐☐ "

42.5 **Treated for an infection for this problem?**

Yes ☐ ' No ☐ ' No. of times ☐☐ "

42.6 **Have you had any X-rays for this problem?**

Yes ☐ ' No ☐ ' No. of times ☐☐ "

42.7 **Have you been admitted to hospital for this problem?**

Yes ☐ ' No ☐ ' No. of times ☐☐ "

43. **Has your mother, father, brothers and / or sisters suffered from any of the following?**

43.1 **Osteoporosis?** Yes ☐ ' No ☐ '

43.2 **Osteoarthritis?** Yes ☐ ' No ☐ '

43.3 **Rheumatoid Arthritis?** Yes ☐ ' No ☐ '

43.4 **Joint Dysplasia (dislocation)?** Yes ☐ ' No ☐ '

43.5 **Deep Vein Thrombosis (Blood clots)?** Yes ☐ ' No ☐ '

44. PainDETECT

painDETECT™

PAIN QUESTIONNAIRE

Date: Patient: Last name: First name:

How would you assess your pain **now**, at this moment?

0 1 2 3 4 5 6 7 8 9 10

none max.

How strong was the **strongest** pain during the past 4 weeks?

0 1 2 3 4 5 6 7 8 9 10

none max.

How strong was the pain during the past 4 weeks **on average**?

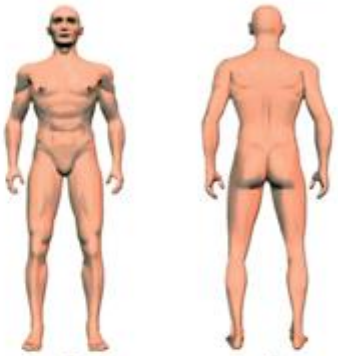
0 1 2 3 4 5 6 7 8 9 10

none max.

Mark the picture that best describes the course of your pain:

-  **Persistent pain with slight fluctuations** ☐
-  **Persistent pain with pain attacks** ☐
-  **Pain attacks without pain between them** ☐
-  **Pain attacks with pain between them** ☐

Please mark your **main area of pain**



Does your pain radiate to other regions of your body? yes ☐ no ☐

If yes, please draw the direction in which the pain radiates.

Do you suffer from a burning sensation (e.g., stinging nettles) in the marked areas?

never ☐ hardly noticed ☐ slightly ☐ moderately ☐ strongly ☐ very strongly ☐

Do you have a tingling or prickling sensation in the area of your pain (like crawling ants or electrical tingling)?

never ☐ hardly noticed ☐ slightly ☐ moderately ☐ strongly ☐ very strongly ☐

Is light touching (clothing, a blanket) in this area painful?

never ☐ hardly noticed ☐ slightly ☐ moderately ☐ strongly ☐ very strongly ☐

Do you have sudden pain attacks in the area of your pain, like electric shocks?

never ☐ hardly noticed ☐ slightly ☐ moderately ☐ strongly ☐ very strongly ☐

Is cold or heat (bath water) in this area occasionally painful?

never ☐ hardly noticed ☐ slightly ☐ moderately ☐ strongly ☐ very strongly ☐

Do you suffer from a sensation of numbness in the areas that you marked?

never ☐ hardly noticed ☐ slightly ☐ moderately ☐ strongly ☐ very strongly ☐

Does slight pressure in this area, e.g., with a finger, trigger pain?

never ☐ hardly noticed ☐ slightly ☐ moderately ☐ strongly ☐ very strongly ☐

(To be filled out by the physician)

never	hardly noticed	slightly	moderately	strongly	very strongly
☐ x 0 = 0	☐ x 1 = ☐	☐ x 2 = ☐☐	☐ x 3 = ☐☐	☐ x 4 = ☐☐	☐ x 5 = ☐☐

Total score ☐☐ **out of 35**

R. Freynhagen, R. Baron, U. Gockel, T.R. Tölle, Current Medical Research and Opinion vol 22 (10) 2006; 1911-1920

Thank you for completing this booklet.

45. Oxford Knee Score

1. *During the past 4 weeks .....*
How would you describe the pain you usually have from your knee?

None	Very mild	Mild	Moderate	Severe
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. *During the past 4 weeks .....*
Have you had any trouble with washing and drying yourself (all over) because of your knee?

No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. *During the past 4 weeks .....*
Have you had any trouble getting in and out of a car or using public transport because of your knee (whichever you tend to use)?

No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. *During the past 4 weeks .....*
For how long have you been able to walk before pain from you knee becomes severe (with or without a stick)?

No pain/More than 30 minutes	16 to 30 minutes	5 to 15 minutes	Around the house only	Not at all - pain severe on walking
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. *During the past 4 weeks .....*
After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your knee?

Not at all painful	Slightly painful	Moderately painful	Very painful	Unbearable
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. *During the past 4 weeks .....*
Have you been limping when walking, because of your knee?

Rarely/Never	Sometimes or just at first	Often, not just at first	Most of the time	All of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. *During the past 4 weeks .....*
Could you kneel down and get up again afterwards?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

8. *During the past 4 weeks .....*
Have you been troubled by pain from your knee in bed at night?

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

9. *During the past 4 weeks .....*
How much has pain from your knee interfered with your usual work (including housework)?

Not at all	A little bit	Moderately	Greatly	Totally
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

10. *During the past 4 weeks .....*
Have you felt that your knee might suddenly 'give way' or let you down?

Rarely/Never	Sometimes or just at first	Often, not just at first	Most of the time	All of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. *During the past 4 weeks .....*
Could you do the household shopping on your own?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

12. *During the past 4 weeks .....*
Could you walk down one flight of stairs?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

46. EQ-5D

By placing a tick in one box in each group below, please indicate which statement best describes your own health state today.

1.	**Mobility**	
	I have no problems in walking about	☐ 1
	I have some problems in walking about	☐ 2
	I am confined to bed	☐ 3
2.	**Self-Care**	
	I have no problems with self-care	☐ 1
	I have some problems washing or dressing myself	☐ 2
	I am unable to wash or dress myself	☐ 3
3.	**Usual Activities**	
	(e.g. Work, study, housework, family or leisure activities)	
	I have no problems with performing my usual activities	☐ 1
	I have some problems with performing my usual activities	☐ 2
	I am unable to perform my usual activities	☐ 3
4.	**Pain/Discomfort**	
	I have no pain or discomfort	☐ 1
	I have moderate pain or discomfort	☐ 2
	I have extreme pain or discomfort	☐ 3
5.	**Anxiety/Depression**	
	I am not anxious or depressed	☐ 1
	I am moderately anxious or depressed	☐ 2
	I am extremely anxious or depressed	☐ 3

Hospital Anxiety and Depression Scale (HADS)

GL assessment
the measure of potential

Name: _____ Date: _____

Clinicians are aware that emotions play an important part in most illnesses. If your clinician knows about these feelings he or she will be able to help you more.

This questionnaire is designed to help your clinician to know how you feel. Read each item below and **underline the reply** which comes closest to how you have been feeling in the past week. Ignore the numbers printed at the edge of the questionnaire.

Don't take too long over your replies, your immediate reaction to each item will probably be more accurate than a long, thought-out response.

FOLD HERE

A	D			A	D
		I feel tense or 'wound up'			
3		Most of the time			
2		A lot of the time			
1		From time to time, occasionally			
0		Not at all	**I feel as if I am slowed down**		
			Nearly all the time	3	
			Very often	2	
			Sometimes	1	
			Not at all	0	
		I still enjoy the things I used to enjoy			
	0	Definitely as much			
	1	Not quite so much			
	2	Only a little			
	3	Hardly at all	**I get a sort of frightened feeling like 'butterflies' in the stomach**		
			Not at all		0
			Occasionally		1
			Quite often		2
			Very often		3
		I get a sort of frightened feeling as if something awful is about to happen			
3		Very definitely and quite badly			
2		Yes, but not too badly			
1		A little, but it doesn't worry me			
0		Not at all	**I have lost interest in my appearance**		
			Definitely		3
			I don't take as much care as I should		2
			I may not take quite as much care		1
			I take just as much care as ever		0
		I can laugh and see the funny side of things			
	0	As much as I always could			
	1	Not quite so much now			
	2	Definitely not so much now			
	3	Not at all	**I feel restless as if I have to be on the move**		
			Very much indeed		3
			Quite a lot		2
			Not very much		1
			Not at all		0
		Worrying thoughts go through my mind			
3		A great deal of the time			
2		A lot of the time	**I look forward with enjoyment to things**		
1		Not too often	As much as I ever did		0
0		Very little	Rather less than I used to		1
			Definitely less than I used to		2
			Hardly at all		3
		I feel cheerful			
	0	Never			
	1	Not often	**I get sudden feelings of panic**		
	2	Sometimes	Very often indeed		3
	3	Most of the time	Quite often		2
			Not very often		1
			Not at all		0
		I can sit at ease and feel relaxed			
0		Definitely			
1		Usually	**I can enjoy a good book or radio or television programme**		
2		Not often	Often		0
3		Not at all	Sometimes		1
			Not often		2
			Very seldom		3

Now check that you have answered all the questions

A	D

TOTAL

Appendix 15: Oxford Knee Score

PROBLEMS WITH YOUR KNEE

During the past 4 weeks..

✓tick one box for every question

1	*During the past 4 weeks.....* How would you describe the pain you usually have from your knee? None ❑ Very mild ❑ Mild ❑ Moderate ❑ Severe ❑
2	*During the past 4 weeks.....* Have you had any trouble with washing and drying yourself (all over) because of your knee? No trouble at all ❑ Very little trouble ❑ Moderate trouble ❑ Extreme difficulty ❑ Impossible to do ❑
3	*During the past 4 weeks.....* Have you had any trouble getting in and out of a car or using public transport because of your knee? (whichever you would tend to use) No trouble at all ❑ Very little trouble ❑ Moderate trouble ❑ Extreme difficulty ❑ Impossible to do ❑
4	*During the past 4 weeks.....* For how long have you been able to walk before pain from your knee becomes **severe**? *(with or without a stick)* No pain/ More than 30 minutes ❑ 16 to 30 minutes ❑ 5 to 15 minutes ❑ Around the house only ❑ Not at all - pain severe when walking ❑
5	*During the past 4 weeks.....* After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your knee? Not at all painful ❑ Slightly painful ❑ Moderately painful ❑ Very painful ❑ Unbearable ❑
6	*During the past 4 weeks.....* Have you been limping when walking, because of your knee? Rarely/ never ❑ Sometimes, or just at first ❑ Often, not just at first ❑ Most of the time ❑ All of the time ❑

/P.T.O

During the past 4 weeks...

✓tick one box for every question

7 *During the past 4 weeks.....*

Could you kneel down and get up again afterwards?

Yes, Easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
❑	❑	❑	❑	❑

8 *During the past 4 weeks.....*

Have you been troubled by pain from your knee in bed at night?

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
❑	❑	❑	❑	❑

9 *During the past 4 weeks.....*

How much has pain from your knee interfered with your usual work *(including housework)*?

Not at all	A little bit	Moderately	Greatly	Totally
❑	❑	❑	❑	❑

10 *During the past 4 weeks.....*

Have you felt that your knee might suddenly 'give way' or let you down?

Rarely/ never	Sometimes, or just at first	Often, not just at first	Most of the time	All of the time
❑	❑	❑	❑	❑

11 *During the past 4 weeks.....*

Could you do the household shopping on your own?

Yes, Easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
❑	❑	❑	❑	❑

12 *During the past 4 weeks.....*

Could you walk down one flight of stairs?

Yes, Easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, Impossible
❑	❑	❑	❑	❑

Appendix 16: Outcome measure ISIS approval

To:
M

Stefanie Garden stefanie.garden@ndorms.ox.ac.uk]]

Cc:
M

Gates L.S.

14 December 2012 07:54

You replied on 14/12/2012 11:30.

Hi Stef/Lucy

The Manchester Foot Pain is owned by Isis and by nature of Isis' relationship with the University we and other academic colleagues (under the banner OU) already have (automatic) permissions to use the ISIS outcome measures in our studies for non-commercial purposes, so, a licence is not required.

Isis have been informed that we plan to use the Index (along with various other outcome measures) and they are very helpful. When I informed them that we planned to use their measures I was thinking only of Chingford, but their emails suggest our permissions to use their measures (based on us being part of the University of Oxford) also reaches to studies we run in conjunction with other centres (such as Southampton).
I think it is the non-commercial part they are most interested in.

Hope that helps Lucy, if you have any other questions, feel free to ask.

Best Wishes

Alison
Alison Turner

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Nuffield Dept. of Orthopaedics, Rheumatology and Musculoskeletal Sciences
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Appendix 17: Manchester foot pain & disability Index

Section 8: Foot Symptoms

Foot symptoms Part 1.
Below are some statements about problems people have **because of pain in their feet.** For each statement indicate if this has applied to you **during the past month.** If so, was this only on some days or on most or every day in the past month?

PLEASE TICK A BOX FOR EACH STATEMENT.

	During the past month this has applied to me		
Because of pain in my feet:	None of the time	On some days	On most / every day (s)
I avoid walking outside at all	☐	☐	☐
I avoid walking long distances	☐	☐	☐
I don't walk in a normal way	☐	☐	☐
I walk slowly	☐	☐	☐
I have to stop and rest my feet	☐	☐	☐
I avoid hard or rough surfaces when possible	☐	☐	☐
I avoid standing for a long time	☐	☐	☐
I catch the bus or use the car more often	☐	☐	☐
I need help with housework/shopping	☐	☐	☐
I get irritable when my feet hurt	☐	☐	☐
I feel self-conscious about my feet	☐	☐	☐
I feel self-conscious about the shoes I have to wear	☐	☐	☐
I still do everything but with more pain and discomfort	☐	☐	☐
I have constant pain in my feet	☐	☐	☐
My feet are worse in the morning	☐	☐	☐
My feet are more painful in the evening	☐	☐	☐
I get shooting pains in my feet	☐	☐	☐

Because of pain in my feet:	None of the time	On some days	On most / every Day(s)	Not applic able
I am unable to carry out my previous work	☐	☐	☐	☐
I no longer do all my previous activities (sport, dancing, hill walking etc)	☐	☐	☐	☐

TICK HERE WHEN YOU HAVE READ ALL THE STATEMENTS ON THIS PAGE ☐

Appendix 18: Foot Posture Index

THE FOOT POSTURE INDEX©
FPI-6

Reference Sheet

The patient should stand in their relaxed stance position with double limb support. The patient should be instructed to stand still, with their arms by the side and looking straight ahead. It may be helpful to ask the patient to take several steps, marching on the spot, prior to settling into a comfortable stance position. During the assessment, it is important to ensure that the patient does not swivel to try to see what is happening for themself, as this will significantly affect the foot posture. The patient will need to stand still for approximately two minutes in total in order for the assessment to be conducted. The assessor needs to be able to move around the patient during the assessment and to have uninterrupted access to the posterior aspect of the leg and foot.

If an observation cannot be made (e.g. because of soft tissue swelling) simply miss it out and indicate on the datasheet that the item was not scored.

If there is genuine doubt about how high or low to score an item always use the more conservative score.

Rearfoot Score	**-2**	**-1**	**0**	**1**	**2**
Talar head palpation	Talar head palpable on lateral side/but not on medial side	Talar head palpable on lateral side/slightly palpable on medial side	Talar head equally palpable on lateral and medial side	Talar head slightly palpable on lateral side/ palpable on medial side	Talar head not palpable on lateral side/ but palpable on medial side
Curves above and below the malleoli	Curve below the malleolus either straight or convex	Curve below the malleolus concave, but flatter/ more shallow than the curve above the malleolus	Both infra and supra malleolar curves roughly equal	Curve below malleolus more concave than curve above malleolus	Curve below malleolus markedly more concave than curve above malleolus
Calcaneal inversion/eversion	More than an estimated 5° inverted (varus)	Between vertical and an estimated 5° inverted (varus)	Vertical	Between vertical and an estimated 5° everted (valgus)	More than an estimated 5° everted (valgus)
Forefoot Score	**-2**	**-1**	**0**	**1**	**2**
Talo-navicular congruence	Area of TNJ markedly concave	Area of TNJ slightly, but definitely concave	Area of TNJ flat	Area of TNJ bulging slightly	Area of TNJ bulging markedly
Medial arch height	Arch high and acutely angled towards the posterior end of the medial arch	Arch moderately high and slightly acute posteriorly	Arch height normal and concentrically curved	Arch lowered with some flattening in the central portion	Arch very low with severe flattening in the central portion – arch making ground contact
Forefoot abd/adduction	No lateral toes visible. Medial toes clearly visible	Medial toes clearly more visible than lateral	Medial and lateral toes equally visible	Lateral toes clearly more visible than medial	No medial toes visible. Lateral toes clearly visible

For further information, manuals and extra datasheets see: www.leeds.ac.uk/medicine/FASTER/FPI/

Foot Posture Index Datasheet

Patient name	ID number

	FACTOR	PLANE	SCORE 1 Date_____ Comment_____		SCORE 2 Date_____ Comment_____		SCORE 3 Date_____ Comment_____	
			Left -2 to +2	Right -2 to +2	Left -2 to +2	Right -2 to +2	Left -2 to +2	Right -2 to +2
Rearfoot	Talar head palpation	Transverse						
	Curves above and below the lateral malleolus	Frontal/ transverse						
	Inversion/eversion of the calcaneus	Frontal						
Forefoot	Prominence in the region of the TNJ	Transverse						
	Congruence of the medial longitudinal arch	Sagittal						
	Abd/adduction forefoot on rearfoot	Transverse						
	TOTAL							

Reference values
Normal = 0 to +5
Pronated = +6 to +9, Highly pronated 10+
Supinated = -1 to –4, Highly supinated –5 to -12

Foot Posture Index Datasheet

Patient name	ID number

	FACTOR	PLANE	SCORE 1 Date_____ Comment_____		SCORE 2 Date_____ Comment_____		SCORE 3 Date_____ Comment_____	
			Left -2 to +2	Right -2 to +2	Left -2 to +2	Right -2 to +2	Left -2 to +2	Right -2 to +2
Rearfoot	Talar head palpation	Transverse						
	Curves above and below the lateral malleolus	Frontal/ transverse						
	Inversion/eversion of the calcaneus	Frontal						
Forefoot	Prominence in the region of the TNJ	Transverse						
	Congruence of the medial longitudinal arch	Sagittal						
	Abd/adduction forefoot on rearfoot	Transverse						
	TOTAL							

Reference values
Normal = 0 to +5
Pronated = +6 to +9, Highly pronated 10+
Supinated = -1 to –4, Highly supinated –5 to -12

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www.leeds.ac.uk/medicine/FASTER/FPI

Appendix 19: Ankle dorsiflexion SOP

Taken from: ***Study Specific SOP: Performing the Pre operative limb Assessment and completion of the procedure specific document for WTCRF-BRU Study RHM MED0938***

30. ANKLE DORSIFLEXION

Participant lying supine, legs outstretched on the couch. Goniometer centre placed on lateral aspect of calcaneus, one arm bisecting the midpoint of lateral lower leg and other arm orientated at 90^{O}.

Apply pressure to the plantar aspect of the mid tarsal joint causing the ankle to dorsiflex. Move second arm of goniometer to position of maximum ankle dorsiflexion achieved. Record this value as 90^{O}+ additional i.e. 90+5= ***95^{O}***

Steps 2 – From that position ask the patient to bend their knee to approx 30^{O} flexion. Repeat application of plantar pressure and record angle of dorsiflexion as above

Repeat on opposite foot.

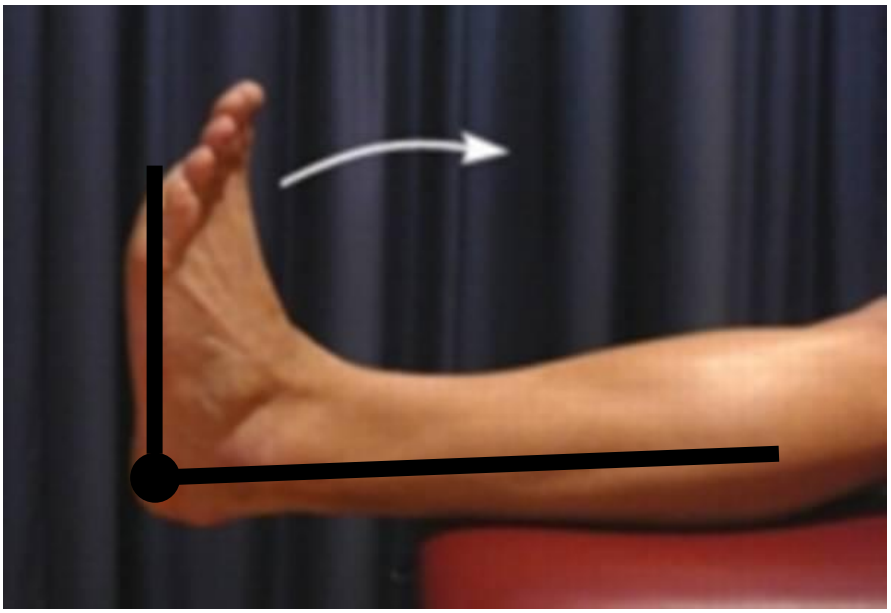

Figure 27

Appendix 20: Fixed flexion deformity measurement

Taken from: ***Study Specific SOP: Performing the Pre operative limb Assessment and completion of the procedure specific document for WTCRF-BRU Study RHM MED0938***

4. KNEE ALIGNMENT

Background: Evaluations of knee alignment are useful in the diagnosis of arthritic conditions affecting the knee joint and also as a guide for conservative management and surgical planning.

Equipment: Extending Goniometer

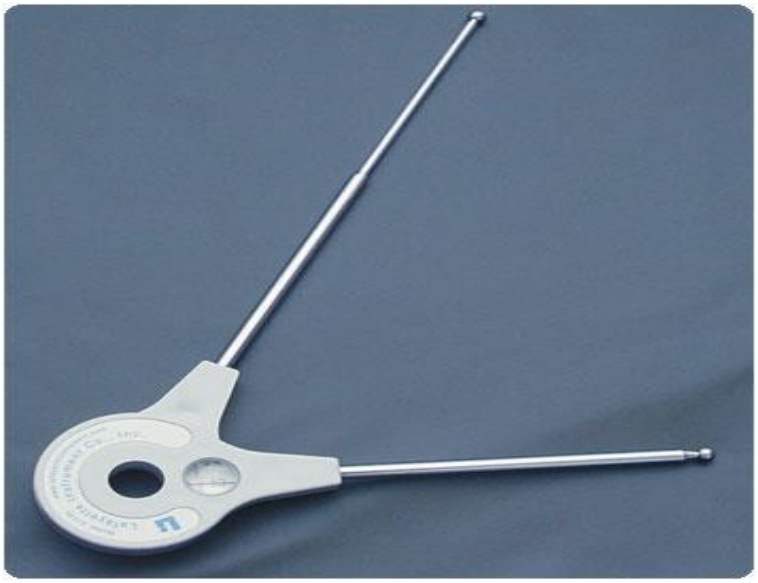

Figure 4