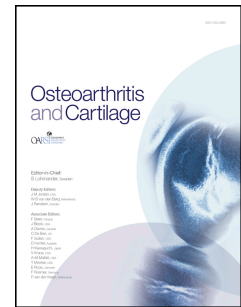


Accepted Manuscript

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PII: S1063-4584(16)30491-5

DOI: [10.1016/j.joca.2016.12.022](https://doi.org/10.1016/j.joca.2016.12.022)

Reference: YJOCA 3925

To appear in: *Osteoarthritis and Cartilage*

Received Date: 9 August 2016

Revised Date: 15 December 2016

Accepted Date: 22 December 2016

Please cite this article as: Gates LS, Bowen CJ, Sanchez-Santos M, Delmestri A, Arden NK, Do foot & ankle assessments assist the explanation of one year knee arthroplasty outcomes?, *Osteoarthritis and Cartilage* (2017), doi: 10.1016/j.joca.2016.12.022.

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Do foot & ankle assessments assist the explanation of one year knee arthroplasty outcomes?

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Abstract

Objective: Whilst a number of risk factors for poor patient reported outcomes (PROMs) following knee arthroplasty (KA) have been identified, unexplained variability still remains. The role of pre-operative foot and ankle status on such outcomes has not been investigated. The aim of this study was therefore to determine the association of clinical foot and ankle assessments with patient reported outcomes one year following KA. Design: One hundred and fifteen participants from the Clinical Outcomes in Arthroplasty Study (COAST), underwent detailed foot and ankle assessments at baseline, prior to KA (2012-2014) and were followed up for self-reported outcomes one year after surgery. Results: Thirty nine percent of subjects reported foot pain at baseline. Mean pre-operative Oxford Knee Score (OKS; 0 [worst] to 48 [best outcome]) was 21 and post-operative OKS score was 38. In fully adjusted analysis pre-operative foot pain was significantly associated with one year outcome (risk ratio (RR) 0.78 95% confidence interval (CI) 0.62, 0.98). No significant association was observed between ankle dorsiflexion or foot posture and outcome. Conclusions: Patients with pre-operative foot pain are more likely to have poorer clinically important outcomes one year following KA than patients without foot pain. Static ankle dorsiflexion and foot posture do not further explain post-operative KA outcomes. Consideration should also be given to address pre-operative foot pain when attempting to achieve a good clinical outcome for KA.

Introduction

Knee Arthroplasty (KA) is considered to be a successful and cost-effective intervention for individuals with severe end stage Osteoarthritis (OA) (1). Growing emphasis is therefore now placed upon Patient Reported Outcome Measures (PROMS) to measure the success of KA (2) and it has become apparent that not all patients are satisfied with their surgery, with dissatisfaction rates ranging from 7% to 32% (3-7).

A number of factors for poor patient reported outcomes following KA have been identified. These include BMI (8, 9), anxiety, depression and social deprivation (10), rheumatoid arthritis (RA) (10, 11), age (10, 12) and musculoskeletal comorbidities (13). Whilst these studies have provided good insight into the explanation of KA outcome, less than 20% of the variability in PROMs of KA has so far been explained (10), suggesting there are other factors still to be identified to improve our ability to recognise patients at risk of poor KA outcomes.

Patients undergoing KA often have other troublesome hips and knees (13). It is acknowledged by clinicians and researchers that there is a relationship between foot, ankle, knee and hip kinematics. Clinical foot and ankle assessments is based on the theory to which, the degree of movement at the foot, subtalar and ankle joint affect the lower limb alignment as movement is transferred proximally. An excess of subtalar joint inversion/eversion is hypothesised to increase external/internal rotation about the tibia, which in turn is said to disrupt the normal mechanics of the tibiofemoral joint (14). 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. 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. Despite the growing body of evidence which has observed the effect of altering biomechanical factors, via the use of foot

interventions, on knee OA related kinematics (15-19), there is little known about the role of the foot and ankle on clinical knee outcomes such as pain and function, in particular following KA.

A study of KA patients found worse post-surgical pain and function in individuals who reported arthritis related symptoms in the ankles/feet/toes (13), these associations were however mediated through depression. Recent findings from a large prospective cohort, enhanced with patients with or at risk of knee OA, show that foot pain adversely affects knee OA related pain and symptom severity as measured by WOMAC and objective measures of physical function (20-meter walk test pace and repeated chair stand pace) (20). Due to the cross-sectional nature of the study no inference could be made as to whether foot pain preceded knee OA or developed subsequent to it.

The aim of this study was therefore to determine if clinical foot and ankle assessments, including pain are associated with patient reported outcomes one year following KA.

Methods

Study population

A subset of participants (n=115) from a prospective cohort of patients listed for KA, known as the Clinical Outcomes in Arthroplasty Study (COAST), underwent detailed foot and ankle assessments. This subset is known as COAST-Foot. COAST is a prospective, dual-centre longitudinal cohort study of patients who were listed for hip and knee arthroplasties across two hospitals; Southampton University Hospital NHS Foundation Trust (UHS) and Nuffield Orthopaedic Centre (NOC), part of the Oxford University Hospital NHS Trust (OUH). 1760 patients recruited for COAST for KA underwent baseline data collection. 1441 at UHS and 319 at the NOC. Full ethical approval was gained (Oxford REC A ref: 10/H0604/91). All participants

provided written informed consent. One hundred and fifteen patients underwent detailed foot and ankle assessments pre-operatively and were prospectively followed up one-year post-operative to allow comparison of pre and 1 year post-operative knee outcomes.

Baseline data collection for COAST-foot ran from 2012-2014 at both sites. All patient characteristics and clinical measures including foot and ankle measures were made during the COAST pre-operative visit, alongside all other measures taken with COAST at baseline. Follow-up patient reported outcomes were collected one year post-operatively. All patients listed for KA at both sites were approached to take part in COAST. Participants were included if above the age of 18, with no upper age limit. The broad inclusion criteria of COAST provided a high level of generalizability. COAST-Foot is a sample of COAST KA participants, randomly selected over a short period for a doctoral study. Participants with Charcots arthropathy or other severe neurological disease, previous knee or ankle arthroplasty or fusion were excluded from COAST-foot.

Covariates

Demographic and clinical data, including age (years) and gender, was collected when enrolling on the COAST study. BMI (Kg/m^2) was measured at baseline pre-operative assessment by the COAST researcher, along with depression (Hospital Anxiety and Depression Score) (21), which was assessed via patient completed questionnaire.

Pre-operative Oxford Knee Score (OKS) (22) was also collected at baseline visit. OKS is a validated patient-administered questionnaire which consists of 12 questions relating to knee pain and physical function limitations during the past 4 weeks. Each question is answered on a five-point Likert scale, and an overall score is calculated by summarising the responses to each

of the 12 questions. This sum score ranges from 0 to 48, where 0 indicates the most severe symptoms and 48 the least severe symptoms.

Main exposures

Disabling foot pain, foot posture and passive ankle dorsiflexion were examined. Objective assessments were chosen based on the findings of an international consensus study (23) and extensive literature review (24). Prior to this the absence of agreement for which assessment measures should be used to assess the foot and ankle in clinical practice was a dilemma for researchers and clinicians and whilst foot and ankle assessment measures were routinely used, the evidence to support their use was weak. Many historically used 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.

The consensus study informed the choice of ankle dorsiflexion range of motion and Foot Posture Index (FPI), which unlike most, have undergone previous investigations for both reliability and clinical validity (25-29) and were selected as two of the most highly recommended measures among a battery of others (23). 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 Manchester Foot Pain and Disability Index (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 (30, 31).

One clinical examiner at each site (research physiotherapist and clinical research nurse) conducted the ankle dorsiflexion measures, after receiving training from an experienced Podiatrist (LG) and all FPI measures at both sites were conducted by LG.

Disabling foot pain was established for either foot using the MFPDI (30) at baseline pre-operative assessment. A practical definition of disabling foot pain (at least one of the 10 FPD function items experienced on most/every day(s)) has been proposed and shown to be sensitive to age and gender differences within the older population (31, 32).

Passive ankle dorsiflexion of the affected limb was also assessed at the pre-operative assessment visit, using a goniometer placed on lateral aspect of calcaneus, one arm bisecting the midpoint of lateral lower leg and other arm orientated at 90°, whilst the participant lay supine with knee extended. The examiner applied pressure to passively dorsiflex the ankle, whilst measuring the movement.

The FPI provides a composite measure of overall foot posture (25). It 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. Total FPI score is the sum of 6 ordinal items with individual scores of -2 to +2. High intra-rater reliability has previously been reported for both of these measures (26-28).

The FPI has undergone testing against the Rasch model to determine its internal construct validity. Ordinal data that fits the Rasch model can be transformed to an interval measurement level using logits as the units of measurement, these logit values has been previously established (33) and prior to analysis the total FPI scores for left and right feet were transformed to their equivalent logit values.

Outcome

The main outcome variable was patient acceptable symptom state (PASS) for one-year Oxford Knee Score (OKS) (≥ 30 points). OKS PASS for one-year OKS was assessed by mail questionnaire one year post-operatively. 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 or no improvement in terms of pain and function, as measured by OKS, they may still be satisfied with surgery (4, 10). Therefore, satisfaction was considered within OKS outcome by using the one-year PASS score. Judge et al (10) previously identified the PASS score cut off of 30 points in the OKS to define a 'satisfactory symptom state' and differentiate between patients with extremely high versus high overall levels of satisfaction with surgery.

Statistical 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.

Baseline characteristics between those who provided follow up data and those who did not and between those with acceptable and non-acceptable PASS scores were compared using Student's t-test and Pearson chi squared tests (table 1 and 2). Due to the increased risk of a type I error (falsely rejecting the null hypothesis) when making multiple statistical tests, Bonferroni corrections were used to adjust probability levels. Complete case analysis was undertaken to ensure homogeneity between foot and ankle assessment groups.

The association between foot pain, ankle dorsiflexion and FPI with KA outcome was assessed using generalized linear models with a log link (Poisson family) to obtain estimates of relative risk (RR) and 95 percent confidence intervals (95% CIs) by using robust standard errors (34). Interaction between foot pain and depression was tested using likelihood ratio test and multicollinearity was assessed by tolerance and variance inflation factor (VIF). The following covariates were used in the adjusted models for foot pain: Pre-operative OKS, age, sex, BMI and depression. Models for ankle dorsiflexion and FPI were adjusted for pre-operative OKS, age, sex and BMI.

We used a directed acyclic graph (DAG) to select covariates needed for an unbiased parametric estimate of the exposures (35). This gave us 2 alternative foot pain models, where two of the covariates could be excluded (BMI and depression). These models resulted in no changes in the estimated risk ratios (data not shown).

Results

248 patients who underwent KA were recruited to the COAST-Foot study. Of these patients 115 (mean age 65.7 ± 10.1 years) completed both pre and one year post-operative OKS and underwent foot and ankle screening and these patients form the cohort used for the analysis of clinically important outcomes (figure 1). No interaction was observed between foot pain and depression and no indication of multicollinearity was found.

Figure 1.

Baseline demographic details of this cohort are described in Table 1. A small number of participants (14.8%) had incomplete follow up OKS scores or were missing complete scores. There were small differences between patients that did and did not respond to the one-year

questionnaire, where those who responded were older, had a lower BMI and were less likely to suffer from anxiety/depression and foot pain. A higher percentage of non-responders were female. There were no significant differences in pre-operative patient characteristics between participants with follow up (responders) and those without (non-responders), apart from pre-operative OKS (mean difference 6.0 95% CI 2.8, 9.2 $P=0.0007$); non-responders had a lower (worse) mean pre-operative OKS score (15.7 ± 6.4) than responders (21.7 ± 6.6).

39% of subjects (from $n=115$) reported foot pain at baseline, with 34% reported disabling foot pain (from $n=115$). Mean pre-operative OKS score (0-48) was 21 and post-operative OKS score was 38. The distribution of OKS at one year was negatively skewed to the left, suggesting the majority of patients achieve improvement in pain and function. However, for difference in scores, whereas most patients showed an improvement in their OKS, a small number (4%) get worse or remain unchanged.

Table 1.

Table 2.

Foot pain

Adjusted model indicated that subjects with pre-operative foot pain were less likely to achieve an acceptable outcome (RR 0.78 95% CI 0.62, 0.98 $p=0.03$) (table 3).

Ankle dorsiflexion

Adjusted regression analysis showed ankle dorsiflexion was not associated to post-operative PASS score (RR 1.00 95% CI 0.99, 1.02) (table 3).

Foot Posture

Adjusted regression analysis showed that a more pronated static foot posture was not associated to outcome (RR 0.98 95% CI 0.95, 1.02) (table 3).

Table 3.

Discussion

Using a subset of participants from a prospective cohort receiving primary KA in Southampton and Oxford, UK, the COASt-Foot study has found that pre-operative foot pain is associated with one-year post-operative patient reported outcome following KA; participants with foot pain had greater risk of having a poorer outcome, as defined by OKS PASS. Objective pre-operative assessments including foot posture and ankle dorsiflexion did not provide further explanation for one-year outcome.

OA related ankle/foot/toe pain, identified from a pain mannequin has shown worse post-operative outcomes in a population of individuals awaiting KA (n=494) (13). 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 and associations were mediated through depression.

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 to first establish if knee OA precedes foot pain.

Whilst there is evidence of investigation into the role of foot structure on knee pain and injuries (36, 37), evidence is often limited to cross sectional design and 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 foot conditions, the high prevalence of foot pain in the COAST-Foot population suggests the association is clinically important. Potential biological mechanisms that may explain the findings are the role of central sensitisation, generalised joint OA and/or mechanical associations.

It is now well established that some patients with painful OA present with pain sensitization (38). The risk of persistent pain after KA has been related to the degree of central sensitisation before surgery. Following finding of a systematic literature review Baert et al (39) suggest that pre-surgical signs of altered central pain modulation, such as joint pain at rest or widespread pain sensitization, may plausibly be associated with more post-surgical pain. In a previous longitudinal study, 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 18 months after TKR (40). If foot pain is a consequence of sensitisation then it may be the sensitisation phenomenon in its entirety that is actually associated to poor outcome and foot pain is merely a part of this.

Multiple joint involvement or polyarticular OA is common (41) and clustering of frequently affected joints has been observed to support this (42). Associations have been found for hand and knee OA (43) and foot, hand and knee OA, with an elevated risk of foot OA in coexisting bilateral disease of other joints (44). 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 findings that foot pain is associated to knee OA 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 (45). 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. Although the 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 (46). Medial knee OA has also been associated with changes in gait patterns attributed to movement-induced nociception (47). Studies have shown relationships between foot, ankle, knee and hip kinematics and it has been suggested that an association between knee OA and foot status is relative to disease led biomechanical changes (14-16).

Findings from COASt-Foot showed no association between foot posture or ankle dorsiflexion with 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 in KA outcomes. However, the relationship between dynamic influences in COASt-Foot is unknown and may potentially play a role in the main findings.

The study made use of carefully chosen valid, reliable and responsive instruments for assessing multiple exposures and outcomes. 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 (48).

Limitations

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 may be over-estimated in this study. However, the loss to follow up rate was relatively low and this was the only variable to show a difference. Whilst the reasons for non-compliance to follow up in these participants is unknown we are able to account for baseline characteristics. Studies often show a difference in more than one characteristic between responders and non-responders and previous evidence has acknowledged the same effect of pre-operative OKS (10, 11, 49).

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 (10, 11, 50). 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 type II error. Whilst it does not invalidate the longitudinal findings it may have underestimated the effects of

foot pain and ankle dorsiflexion on outcome. The effects of confounding were limited by adjustments for a large number of confounders; however, this cannot be fully excluded.

Reliability of clinical measures was not established within this cohort due to the ethical considerations for patients, who had strict time restrictions applied to pre-operative COAST appointments due to lengthy demanding physical assessments and questionnaires. Reliability for the clinical foot and ankle assessments has however been determined in previous studies (25-28).

Clinical assessment of the ankle may be somewhat subjective, particularly when performed passively, as the range of motion depends on the force applied by the tester. However, in this instance it was believed that this would be a superior method to remove the potential for bias that may be introduced from the discrepancies in lower extremity strength and active joint stiffness often seen in patients with severe knee OA. A number of participants had difficulty maintaining a position of non-weight knee flexion during measurements due to discomfort, therefore ankle dorsiflexion with knee extension was used for this analysis to ensure data included was collected systematically. This also reduces the potential for examiner bias which may be introduced when also attempting to ensure the knee remains in a given degree of flexion. The choice of land marking for goniometric measurement may be limited by the fact it is not directly over the anatomical axis of the talocrural joint, however the use of the lateral malleoli was chosen to ensure consistency in identifying anatomical locations for goniometric positioning, to ensure standardisation of the range of motion measurement. A further 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. Unfortunately, due to an absence of foot and ankle x-rays, we were unable to ascertain the role of polyarticular OA in these findings. This would be a valuable consideration for future work to investigate the role of the foot and ankle in knee outcomes.

Conclusion

In conclusion the results of the COASt-Foot study suggest that pre-operative foot pain is associated with poor clinically important knee outcomes one year following KA. Static ankle dorsiflexion and foot posture did not explain post-operative KA outcomes. 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.

Author contributions

LSG, CJB and NKA involved in conception and design of the study. LSG was involved in the acquisition and management of data. LSG, CJB, MTSS, AD and NKA were involved in management, statistical analysis and interpretation of the data. LSG drafted the manuscript. All authors reviewed the manuscript with critical revision of the article for important intellectual content and approved the final manuscript. LSG, CJB and NKA took the responsibility for the integrity of the work as a whole, from inception to finished article.

Potential conflicts of interests:

N Arden has received consultancy from Merck, Smith & Nephew, Flexion, Freshfields, Bioberica and Regeneron. All other authors declare that they have no conflict of interest.

Informed consent: Informed consent was obtained from all individual participants included in the study.

Funding:

The recruitment of the Clinical Outcomes in Arthroplasty Study (COAST) was funded by a program grant for applied research from the National Institute of Health and Research (NIHR; 10064) and COAST-Foot was further supported by Southampton Rheumatology Trust (Grant no SRT/GEN/2012/1). LSG is the recipient of an Arthritis Research UK Allied Health Professional Training Research Fellowship (Award no: 19875).

Acknowledgments:

The Clinical Outcomes in Arthroplasty Study was made possible by the contribution of many people, including the original investigators and the diligent team who recruited the participants and who continue working on follow up. We would like to express our gratitude to the number of Southampton and Oxford based residents who participated in the study. For the recruitment and study coordination we would especially like to thank Senior Research Nurse Carole Ball from Southampton University Hospital Trust.

References

1. Jordan KM, Arden NK, Doherty M, Bannwarth B, Bijlsma JWJ, Dieppe P, et al. EULAR Recommendations 2003: an evidence based approach to the management of knee osteoarthritis: Report of a Task Force of the Standing Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT). *Annals Of The Rheumatic Diseases*. 2003; 62(12):1145-1155

2. Williams DP, Blakey CM, Hadfield SG, Murray DW, Price AJ, Field RE. Long-term trends in the Oxford knee score following total knee replacement. *Bone & Joint Journal*. 2013;95-B(1):45-51
3. Noble P, Conditt M, Cook K, Mathis K. The John Insall Award: Patient expectations affect satisfaction with total knee arthroplasty. *Clinical Orthopaedics & Related Research*. 2006;452:35-43
4. Baker P, Van Der Meulen J, Lewsy J, Gregg P. The role of pain and function in determining patient satisfaction after total knee replacement. *The Journal of Bone & Joint Surgery*. 2007;89(7):893-900
5. Nilsdotter AK, Toksvig-Larsen S, Roos EM. Knee arthroplasty: are patients' expectations fulfilled? *Acta Orthopaedica*. 2009;80(1):55-61
6. Bourne R, Chesworth B, Davis A, Mahomed N, Charron KJ. Patient Satisfaction after Total Knee Arthroplasty: Who is Satisfied and Who is Not? *Clinical Orthopaedics and Related Research*. 2010;468(1):57-63
7. Scott C, Howie C, Macdonald D, Biant L. Predicting dissatisfaction following total knee replacement: a prospective study of 1217 patients. *Journal of Bone and Joint Surgery*. 2010;92-B:1253-1258
8. Zeni JA, Snyder-Mackler L. Early Postoperative Measures Predict 1- and 2-Year Outcomes After Unilateral Total Knee Arthroplasty: Importance of Contralateral Limb Strength. *Physical Therapy*. 2010;90(1):43-54
9. Baker P, Muthumayandi K, Gerrand C, Kleim B, Bettinson K, Deehan D. Influence of Body Mass Index (BMI) on Functional Improvements at 3 Years Following Total Knee Replacement: A Retrospective Cohort Study. *PLoS ONE*. 2013;8(3):e59079
10. Judge A, Arden N, Cooper C, Javaid K, Carr A, Field R et al. Predictors of outcomes of total knee replacement surgery. *Rheumatology*. 2012;51:1804-1813

11. Hawker GA, Badley EM, Borkhoff CM, Croxford R, Davis AM, Dunn S et al. Which Patients
Are Most Likely to Benefit From Total Joint Arthroplasty? *Arthritis & Rheumatism*.
2013;65(5):1243-1252
12. Nilsson A-K, Petersson IF, Roos EM, Lohmander LS. Predictors of patient relevant
outcome after total hip replacement for osteoarthritis: a prospective study. *Annals of The
Rheumatic Diseases*. 2003;62(10):923-930
13. Perruccio AV, Power JD, Evans HMK, Mahomed SR, Gandhi R, Mahomed NN et al. Multiple
joint involvement in total knee replacement for osteoarthritis - effects on patient-reported
outcomes. *Arthritis Care & Research*. 2012;64(6):838-846
14. Tiberio D. The effect of excessive subtalar joint pronation on patellofemoral mechanics: a
theoretical model. *The Journal Of Orthopaedic And Sports Physical Therapy*.
1987;9(4):160-165
15. Levinger P, Menz HB, Morrow AD, Feller JA, Bartlett JR, Bergman NR. Foot kinematics in
people with medial compartment knee osteoarthritis. *Rheumatology*. 2012;51:2191-8
16. Bennell KL, Bowles KA, Payne C, Cicuttini F, Williamson E, Forbes A et al. Lateral wedge
insoles for medial knee osteoarthritis: 12 month randomised controlled trial. *British
Medical Journal*. 2011;342:d2912
17. Butler R, Marchesi S, Royer T, Davis I. The effect of a subject-specific amount of lateral
wedge on knee mechanics in patients with medial knee osteoarthritis. *Journal of
Orthopaedic Research*. 2007;25(9):1121-7
18. Butler RJ, Barrios JA, Royer T, Davis IS. Effect of laterally wedged foot orthoses on rearfoot
and hip mechanics in patients with medial knee osteoarthritis. *Prosthetics And Orthotics
International*. 2009;33(2):107-116
19. Hinman RS, Bennell KL. Advances in insoles and shoes for knee osteoarthritis. *Current
Opinion in Rheumatology*. 2009;21(2):164-170 10.1097/BOR.0b013e32832496c2
20. Paterson KL, Hinman RS, Hunter DJ, Wrigley TV, Bennell KL. Impact of Concurrent Foot
Pain on Health and Functional Status in People with Knee Osteoarthritis: Data From the
Osteoarthritis Initiative. *American College of Rheumatology*. 2015;67(7):989-995

21. Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. *Acta Psychiatr Scand.* 1983;67(6):361-70.
22. Dawson J, Fitzpatrick R, Murray D, Carr A. Questionnaire on the perceptions of patients about total knee replacement. *Journal of Bone & Joint Surgery, British Volume.* 1998;80-B(1):63-9
23. Gates LS, Bowen C, Arden NK. Clinical Measures of Musculoskeletal Foot and Ankle Assessment: An International Consensus Statement. *International Journal of Health Sciences and Research.* 2015; 5(2):91-105
24. Gates L, Arden NK, McCulloch LA, Bowen CJ. An evaluation of musculoskeletal foot and ankle assessment measures *Working Papers in the Health Sciences.* 2015;1(11): 1-17
25. Redmond AC, Crosbie J, Ouvrier RA. Development and validation of a novel rating system for scoring standing foot posture: the Foot Posture Index. *Clinical Biomechanics (Bristol, Avon).* 2006;21(1):89-98
26. Cornwall MW, Mcpoil TG, Lebec M, Vincenzino B, Wilson J. Reliability of the modified Foot Posture Index. *Journal Of The American Podiatric Medical Association.* 2008;98(1):7-13
27. Bennell KL, Talbot R, Wajswelner H, Wassana T, Kelly D. Intra-rater and inter-rater reliability of a weight-bearing lunge measure of ankle dorsiflexion. *Australian Physiotherapy.* 1998;44(3):175-180
28. Krause DA, Cloud BA, Forster LA, Schrank JA, Hollman JH. Measurement of Ankle Dorsiflexion: A Comparison of Active and Passive Techniques in Multiple Positions. *Journal Of Sport Rehabilitation.* 2011;20(3):333-344
29. Menz HB, Tiedemann A, Kwan MM-S, Latt MD, Sherrington C, Lord SR. Reliability of clinical tests of foot and ankle characteristics in older people. *Journal Of The American Podiatric Medical Association.* 2003;93(5):380-387
30. Garrow AP, Papageorgiou AC, Silman AJ, Thomas E, Jayson MI, Macfarlane GJ. Development and validation of a questionnaire to assess disabling foot pain. *Pain.* 2000;85(1-2):107-13

31. Roddy E, Muller S, Thomas E. Defining disabling foot pain in older adults: further examination of the Manchester Foot Pain and Disability Index. *Rheumatology*. 2009;48:992–996
32. Menz HB, Tiedemann A, Kwan MM, Plumb K, Lord SR. Foot pain in community-dwelling older people: an evaluation of the Manchester Foot Pain and Disability Index. *Rheumatology*. 2009;45:863–867
33. Keenan A, Redmond AC, Horton M, Conaghan PG, Tennant A. The Foot Posture Index: Rasch analysis of a novel, foot-specific outcome measure. *Archives of Physical Medicine & Rehabilitation*. 2007;88(1):88-93
34. Zou G. A Modified Poisson Regression Approach to Prospective Studies with Binary Data. *American Journal of Epidemiology*. 2004;159(7):702-6
35. Shrier I, Platt RW. Reducing bias through directed acyclic graphs. *BMC Medical Research Methodology*. 2008;8(1):70
36. Barton CJ, Menz HB, Crossley KM. The immediate effects of foot orthoses on functional performance in individuals with patellofemoral pain syndrome. *British Journal Of Sports Medicine*. 2011;45(3):193-197
37. Levinger P, Menz H, Fotoohabadi M, Feller J, Bartlett J, Bergman N. Foot posture in people with medial compartment knee osteoarthritis. *Journal of Foot and Ankle Research*. 2010;3(1):29
38. Lluch E, Torres R, Nijs J, Van Oosterwijck J. Evidence for central sensitization in patients with osteoarthritis pain: a systematic literature review. *European Journal of Pain*. 2014;18:1367–75.
39. Baert IA, Luch E, Mulder, Niis J, Noten S, Meeus M. Does pre-surgical central modulation of pain influence outcome after total knee replacement? A systematic review. *Osteoarthritis and Cartilage*. 2016;24(2):213-23.
40. Lundblad H, Kreicbergs A, Jansson KÅ. Prediction of persistent pain after total knee replacement for osteoarthritis. *The Journal of Bone & Joint Surgery*. 2008;90(2):166-171

41. Carroll GJ, Breidahl WH, Jazayeri J. Confirmation of two major polyarticular osteoarthritis (POA) phenotypes – differentiation on the basis of joint topography. *Osteoarthritis and Cartilage*. 2009;17(7):891–895
42. Cooper C, Egger P, Coggan D, Hart DJ, Masud T, Cicuttini F et al. Generalised osteoarthritis in women: pattern of joint involvement and approaches to definition for epidemiological studies. *Journal of Rheumatology*. 1996;23:1938–1942
43. Englund M, Paradowski PT, Lohmander LS. Association of Radiographic Hand Osteoarthritis With Radiographic Knee Osteoarthritis After Meniscectomy. *Arthritis and Rheumatism*. 2004;50(2):469–475
44. Wilder FV, Barrett JP, Farina EJ. The association of radiographic foot osteoarthritis and radiographic osteoarthritis at other sites. *Osteoarthritis and Cartilage*. 2005;13:211–215
45. Hannan MT, Felson DT, Pincus T. Analysis of the discordance between radiographic changes and knee pain in osteoarthritis of the knee. *Journal of Rheumatology*. 2000;27(6):1513–7
46. Lidtke RH, Muehleman C, Kwasny M, Block JA. Foot center of pressure and medial knee osteoarthritis. *Journal of American Podiatric Medical Association*. 2010;100:178–84
47. Rosland T, Gregersen LS, Eskehave TN, Kersting UG, Arendt-Nielsen L. Pain sensitization and degenerative changes are associated with aberrant plantar loading in patients with painful knee osteoarthritis. *Scandinavian Journal of Rheumatology*. 2015;44(1)
48. Vickers AJ, Altman DG. Analysing controlled trials with baseline and follow up measurements. *BMJ*. 2001;323(7321):1123–1124
49. Fortin PR, Clarke AE, Joseph L, Liang MH, Tanzer M, Ferland D et al. Outcomes of total hip and knee replacement: preoperative functional status predicts outcomes at six months after surgery. *Arthritis Rheum*. 1999;42:1722–8
50. Kiran A, Bottomley N, Biant LC, Javaid K, Carr AJ, Cooper C et al. Variations In Good Patient Reported Outcomes After Total Knee Arthroplasty. *The Journal of Arthroplasty*. 2015;30:1364–1371

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Table I. Baseline clinical descriptive and statistical comparisons of pre-operative variables between those with and without complete data and those with and without 1 year follow up

Characterisitcs	Baseline (n=135)	Without complete data (n=42)	P-value	With one year follow up (n=115)	Without one year follow up (n=20)	P-value
Age, mean (S.D), years	65.7 (10.1)	68.3 (9.0)	0.1336	65.8 (10.1)	65.1 (10.1)	0.7773
BMI, mean (S.D), Kg/m2	31.5 (5.3)	33.7 (5.9)	0.0482	31.4 (4.8)	32.4 (7.6)	0.5562
Sex, n (%) female	72 (53.3%)	19 (45.2%)	0.230	58 (50.4%)	14 (70.0%)	0.083
Disabling Foot Pain n (%) present	46 (34.1%)	12 (32.4%)	0.852	38 (33.0%)	8 (40.0%)	0.545
Ankle Dorsiflexion, mean (S.D), degrees of motion	10.4 (8.3)	9.1 (6.0)	0.3330	10.5 (8.4)	10.0 (8.4)	0.7838
Foot posture, mean (S.D), higher score/pronated	1.7 (2.4)	3.1 (2.6)	0.0123	1.7 (2.4)	1.9 (2.7)	0.8033
Pre-operative OKS, mean (S.D), 0-48 with lower score worse	20.8 (6.9)	21.7 (10.0)	0.6312	21.7 (6.6)	15.7 (6.4)	0.0007*
Depression (%) present	26 (19.3%)	5 (21.7%)	0.782	20 (17.4%)	6 (30.0%)	0.187

Student's t-tests were used for continuous variables and χ^2 tests for categorical variables.

Fisher's exact test is used where expected counts were <5

α set with Bonferonni adjustment for multiple testing at a $P < 0.0062$

Table II. Baseline clinical descriptive and statistical comparisons of pre-operative variables between those with acceptable and non-acceptable 1 year PASS score

Characteristics	Baseline inclusions (n=115)	Acceptable PASS score (n=94)	Unacceptable PASS Score (n=21)	P-value
Age, mean (S.D), years	65.8 (10.1)	66.1 (9.08)	64.5 (14.1)	0.6314
BMI, mean (S.D), Kg/m ²	31.4 (4.8)	31.1 (4.8)	32.5 (4.8)	0.2569
Sex, n (%) female	58 (50.4%)	48 (51.1%)	10 (47.6%)	0.775
Disabling Foot Pain n (%) present	38 (33.0%)	26 (27.7%)	12 (57.1%)	0.009
Ankle Dorsiflexion, mean (S.D), degrees of motion	10.5 (8.4)	10.9 (7.9)	8.8 (10.3)	0.3784
Foot posture, mean (S.D), higher score/pronated	1.7 (2.4)	1.6 (2.4)	2.2 (2.3)	0.3079
Pre-operative OKS, mean (S.D), 0-48 with lower score worse	21.7 (6.6)	22.4 (6.6)	18.8 (5.9)	0.0192
Depression (%) present	20 (17.4%)	15 (16.0%)	5 (23.8%)	0.391

Student's t-tests were used for continuous variables and X² tests for categorical variables.

Fisher's exact test is used where expected counts were <5

α set with Bonferroni adjustment for multiple testing at a P<0.0062

Table III. Foot pain, ankle dorsiflexion and foot posture as factors for achieving an acceptable clinical post-operative knee outcome (PASS)

N=115	RR	95% CIs	P-value
Disabling Foot pain (present) [°]	0.78	0.62, 0.98	0.033*
Ankle dorsiflexion (higher degrees) [¥]	1.00	0.99, 1.02	0.454
Foot Posture (more pronated) [¥]	0.98	0.95, 1.02	0.393

[°] Models are adjusted for pre-operative OKS, age, sex, BMI and depression.

[¥] Models are adjusted for pre-operative OKS, age, sex and BMI

OKS, Oxford Knee Score; BMI, Body Mass Index

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

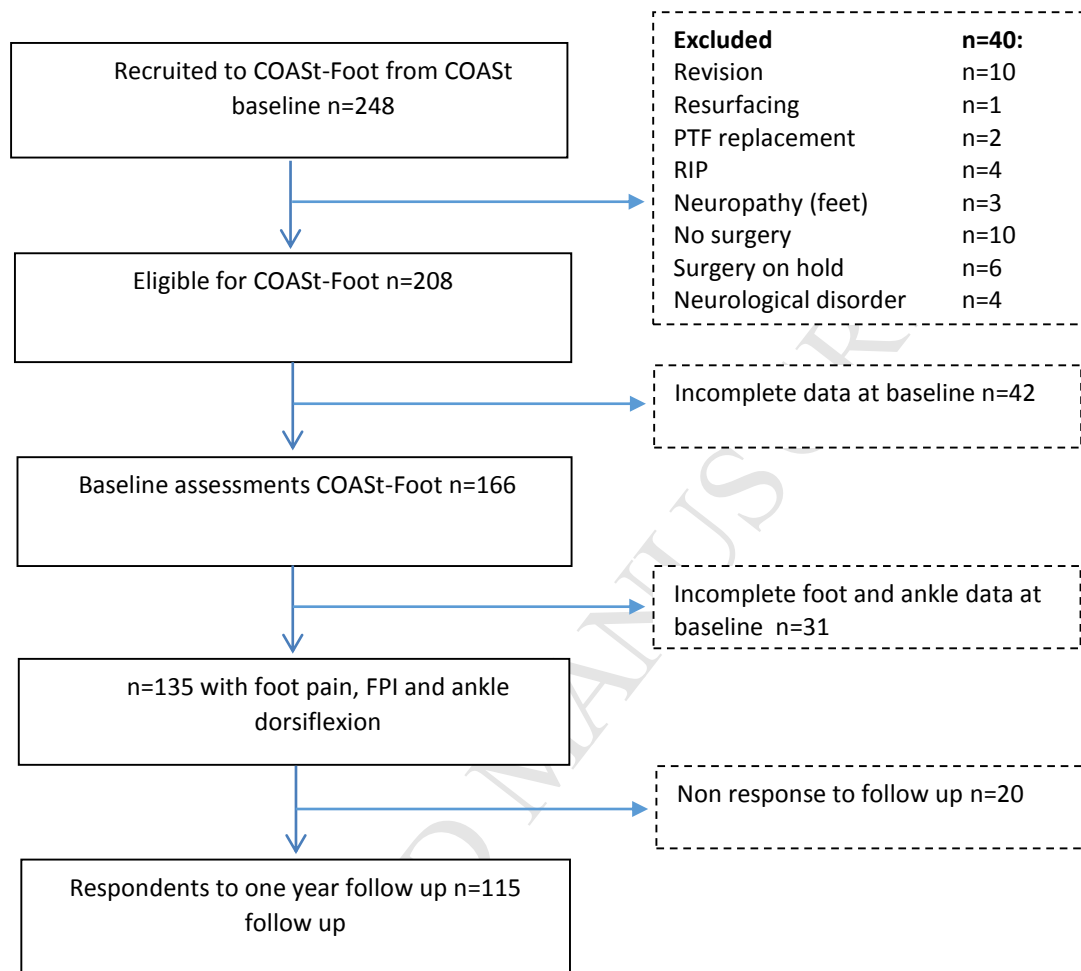


Figure I. Exclusion process for COAST-Foot cohort