A Comparison between Evidence-Generated Transtibial Sockets and Conventional Computer-Aided Designs, from the Patient's Perspective

Abstract

Background: Personalised prosthetic socket design depends upon highly skilled prosthetists. They aim to balance functional human-prosthesis coupling with safe, comfortable load transmission from the prosthesis to the skeleton, through vulnerable skin and soft tissues. Both traditional plaster and Computer Aided Design and Manufacturing (CAD/CAM) methods are iterative, and sharing knowledge is difficult. Evidence-Generated (EG) Sockets derived from past Computer Aided Socket Design (CASD) records could provide a personalised starting point for limb fitting, potentially reducing time spent on basic design and enabling prosthetists to focus on more highly-skilled customisation.

Objective: To assess the comfort of Evidence-Generated sockets, generated from past computer aided socket design records.

Methods: A crossover trial compared EG sockets, derived from 163 previous transtibial devices, to conventional clinician-led CAD/CAM sockets. Non-inferiority was assessed for the Socket Comfort Score (SCS) outcome measure, and semi-structured interviews provided in-depth user analysis. The setting was three United Kingdom National Health Service clinics, with seventeen participants with nineteen transtibial amputations.

Results: Evidence-Generated sockets had no statistically-significant difference in comfort compared to clinician-led Control sockets (median SCS 8.6 for EG sockets and 8.8 for CAD/CAM controls; p=0.38, effect size=0.08), but a lower variability in socket comfort score across the group (95% confidence intervals 8.0-9.0 and 7.5-9.5 for EG and CAD/CAM devices, respectively). Analysis of interviews revealed themes around fitting session experiences, similarities and differences between the Evidence-Generated and CAD/CAM control sockets, and residual limb factors impacting perceptions of socket comfort. These provided insights into the participants' experience of the study and the value of expert prosthetist input in socket design.

Conclusions: Evidence-Generated sockets demonstrated noninferiority to conventional clinical CASD practice in terms of socket comfort. Both quantitative and qualitative results indicated how clinician input remains essential and is valued by prosthesis users. Work is underway to incorporate the Evidence-Generated Sockets into computer aided design software such that they can act as a digital starting point for modification by expert clinicians at fitting, potentially reducing time spent on basic design, enabling prosthetists to focus on more highly-skilled customisation and co-design with their patients.

Trial Registration: clinicaltrials.gov NCT06597266.

Keywords: CAD/CAM; Prosthetic Socket Design; Transtibial; Evidence-Based Practice; Qualitative Research.

Introduction

The lower limb prosthetics community has worked since the 1980s towards computer aided design and manufacturing ('CAD/CAM') technologies to support prosthetic socket design and fabrication workflows[1]. Within CAD/CAM, Computer Aided Socket Design (CASD) is defined as the strategic modification of a 3D digital representation of the residual limb shape in software by an expert human prosthetist, producing a rectified socket shape design. The 'CAM' typically refers to fabricating the socket by producing a corresponding a rigid foam mould carved using a computer numerical controlled (CNC) robotic carver, followed by draping or lamination. CAD/CAM has been described as offering significant potential benefits over conventional plaster of Paris approaches [2], including reduced manual work time and exposure to plaster, an occupational health risk. This could allow clinicians to spend a greater proportion of their time in direct patient interactions, which might enhance patient engagement and facilitate shared decision-making [2]. Early CAD/CAM results were comparable to traditionally-produced sockets but took longer and needed more adjustments [1–4]. However, over the learning curve, today clinicians using computer aided design and manufacturing can achieve clinical results that are comparable whilst saving time and delivering a better quality of life outcome [5–8].

These technologies were also proposed to offer opportunities for evidence-based decision support in socket design [1]. CASD generates a perpetual, quantitative design record, whereas the plaster design is destroyed upon socket fabrication. A digital record has value for education, peer support on complex cases and, if implemented for clinical decision support, further time savings to focus on the most highly skilled and value-added parts of socket personalisation [3,9]. However, despite proposals since the 1980s to augment CAD/CAM by providing the ability to refer to prior design records [10] it appears that the full potential of the benefits offered through these rich datasets to improve the prosthetic rehabilitation process have not been fully exploited.

In particular, data might be used for generating socket design recommendations, which we define as Evidence-Generated (EG) sockets. Since Dean and Saunders in 1985 [11], clinical innovators have considered an alternative to performing CASD in a manner analogous to manual work with plaster, whereby a user could apply averaged rectifications from prior designs as an 'overlay', or select from a database of different size and shape 'primitive' or 'template' sockets, and scale and adjust them to fit to a newly presenting patient's residual limb shape. This has been demonstrated for transtibial [3,9,12–14] and transfemoral socket designs [15,16], and in orthotics for scoliosis braces [17,18]. Recent publications present alternative methods of informing the socket design process by data, including Fuzzy Logic or Inference to map linguistic descriptions of socket design approaches and patient descriptors, for application to new people [19,20], and optimisation for automating transradial socket design [21]. However, these studies are only demonstrated in

research settings and not yet clinically applied. Anecdotally, today most CASD software packages in clinical use define templates as structured design workflows or sequences to guide users in applying their own choice of rectifications and gross design features.

The application of such methods would benefit from systematic study of rectification design practice, though this is limited in the scientific literature [22] since the 'Automated Fabrication of Mobility Aids' (AFMA) project [12]. Recently researchers have begun to leverage high resolution 3D scan and CASD data to investigate rectification sizes in transtibial and transradial design [23–25], and most recently probabilistic methods have been used to derive insights into transtibial socket design strategy through the associations between design features [26]. Building upon those insights, the present study aims to evaluate an Evidence-Generated socket concept developed by Radii Devices Ltd and University of Southampton, with UK service provider Opcare Ltd providing data and expert clinical design insight. The objective was to compare the EG socket design approach to clinician-led CASD, using socket comfort outcome measures and capturing the patients' experiences through qualitative interviews.

Methods

This study was registered at clinicaltrials.gov (NCT06597266) and is reported using the STROBE cross sectional reporting guidelines [27].

Patient and Participant Involvement and Engagement:

The study research question was informed by Patient and Participant Involvement and Engagement (PPIE) group discussions [28], which highlighted how socket comfort is paramount but difficult to achieve, and that delays between assessment and device provision can impair fitting. PPIE contributors also expressed support for sharing knowledge between prosthetics centres to enable service improvement. Collaboration with the Alex Lewis Trust during the study development reinforced this, and provided review and feedback of the study design, recruitment posters, participant information sheets and consent forms. PPIE contributors are also actively involved in disseminating the study findings to patients.

Study Design

The study (Figure 1) used a single-blind, crossover design to assess comfort at socket fitting, followed by a qualitative study of semi-structured interviews. An Evidence-Generated transtibial draped thermoplastic check socket was compared to a control CAD/CAM socket which was designed by a prosthetist using Tracer CASD software (Ohio Willowwood Co, USA) from the same residual limb 3D scan (Figure 2). Participants used the same interface as intended in the definitive device (i.e. liners or socks: see Raw Data file). Quantitative and qualitative data were collected and analysed independently, and interpreted together. This study design was selected to capture the patient's comparative experience of socket fitting from quantitative and qualitative perspectives, developed from a foundational computer

aided design vs. traditional socket comparison study [5] and with recent precedent in clinical assessment of adjustable sockets [29]. This study design was chosen because:

- new digital design and fabrication technologies are often considered in small scale or low technology readiness level trials in the scientific literature but are often not tested in power-sized, blinded or controlled trials, with consideration of qualitative service user experience alongside quantitative outcome measures [22]; and
- it is important to understand the patient's perceived experience. This may relate to socket fit and comfort for which detailed, open descriptions offer more nuanced insights than a simple socket comfort score [30]. It may also relate to the user's perspective of device design and fabrication, to promote shared-decision-making [31] and its potential benefits regarding patient engagement in and understanding of care.

As such the work aligns with recently published perspectives on ethical considerations for development and clinical translation of prosthetic technologies [32].

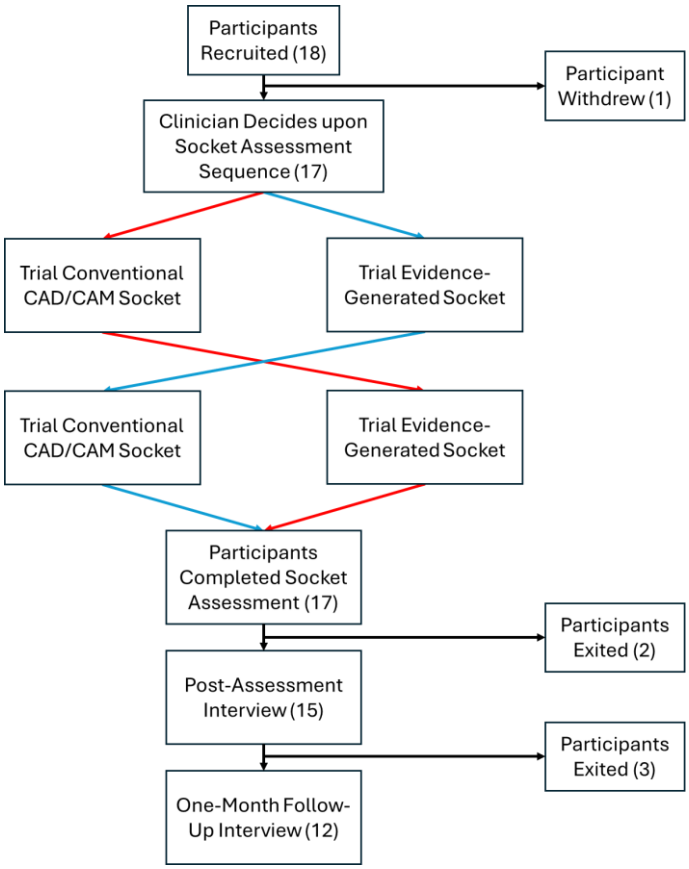

Figure 1: Study design and recruitment diagram

Study Approvals

Ethical approval was granted by Institutional (ERGO 76033.A3) and national review boards (IRAS 313408 / HRA REC 22/YH/0215). Inclusion criteria included people

aged 18 and over, with transtibial amputation, deemed ready for a new prosthetic socket by their prosthetist in their usual clinical pathway, and willing and able to tolerate trialling two sockets at a fitting session. Convenience sampling was used to identify participants at three United Kingdom prosthetic rehabilitation centres.

Evidence-Generated Socket Design Method

A socket generation method based upon evidence of expert practice was applied, building upon previous work [26]. To review briefly, a dataset of 163 transtibial residual limb 3D scans and corresponding socket designs was accessed in .aop format (version AAOP1) including labelled landmarks, exported from Omega software (Ohio WillowWood Co, USA) with cylindrical sampling at maximum 3° spacing on minimum 90 slices. These were produced at a single, large UK physical enablement centre by four prosthetists, all with a minimum BSc qualification. Two had 20+ yrs experience, one 5-10 yrs, and the other was a first year graduate. The corresponding patient characteristics such as gender, age, time since amputation, and reason for amputation were also collated. A Statistical Shape Model (SSM) was generated to describe the residual limb shape and size with a minimal number of dimensions, corresponding to principal 'modes' of variation. The training datasets were aligned with assistance of the landmarks, registered, and a principal component analysis (PCA) was conducted using the full surface shapes of the residual limb scans. Socket design features of local rectifications (patella tendon bar carve, paratibial carves, fibula head build, distal end build, distal tibia build, anterior tibia build, supracondylar carves) and gross volume change were extracted from the dataset. Bayesian inference was applied to analyse the probabilistic association between patient characteristics and principal modes of limb shape variation (inputs), and the extracted design features for the 163 limb-socket pairs. Finally, the same inputs were obtained for the study participants, and check sockets were created by automatically applying modifications to their landmarked residual limb 3D scans, which were predicted using the statistical model.

Quantitative Study:

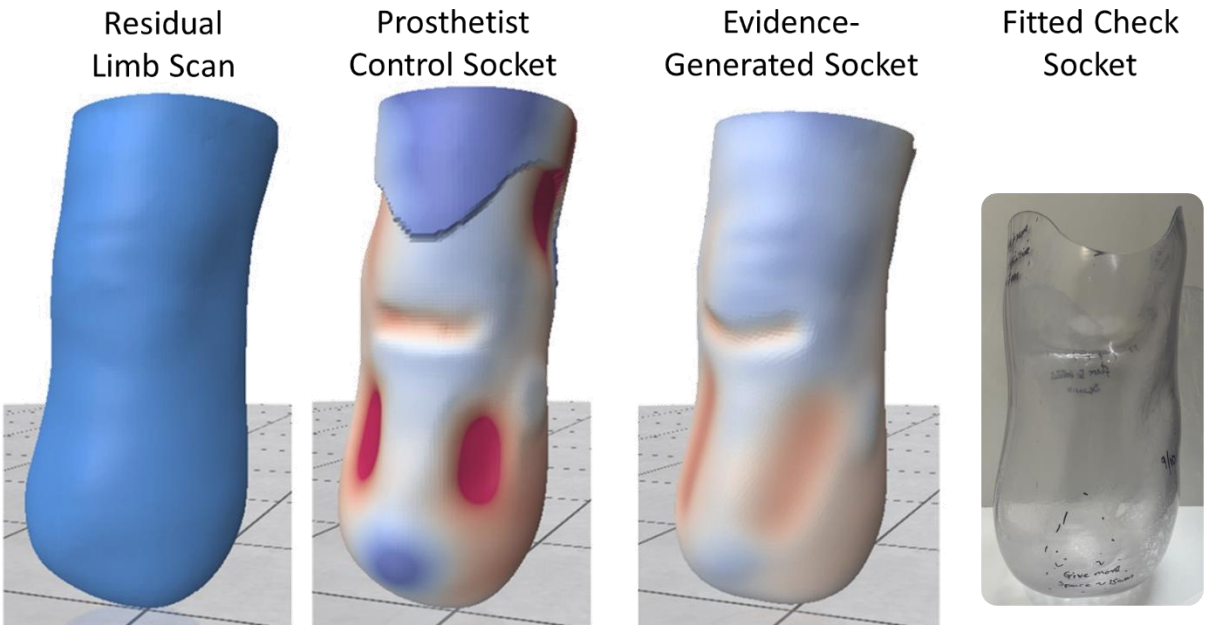

Figure 2, from left to right, for an exemplar participant: the residual limb scan over a sock; the prosthetist's socket rectification design; the evidence-generated design prior to adding brimline; and a fitted check socket. In rectification design maps, red colour represents a carve or press-fit between socket and limb, white represents exact fit, and blue represents buildup or limb-socket gap.

The Evidence-Generated socket design was generated automatically except for the brim line, which the fabrication technician was requested to apply in the same location as the control, prosthetist-designed socket. The prosthetist then worked through their standard fitting and assessment procedure for both sockets (Supplementary File 1), including a Socket Comfort Score (SCS). At the fitting appointment, the prosthetist chose which socket was trialled first, and the patient participant was blinded to which socket was prosthetist-designed CAD/CAM or Evidence-Generated. At the end of the session, the patient participant and their clinician were allowed free choice over which check socket design was to be used for the definitive prosthesis, on the basis of their mutual agreement without any intervention from the researchers.

A power calculation indicated a sample size of 19 was required to test non-inferiority in a crossover trial (power: 0.9, significance level: 0.05, Mean Difference: 0, non-inferiority limit: 1.21 [33], and population SCS standard deviation 1.2 [23]). A Shapiro-Wilk test indicated the control SCS data were not normally distributed ($p=0.01$), so non-parametric descriptive statistics were calculated with confidence intervals using the Bootstrap method [34], and the paired Wilcoxon Signed-Rank test was used to assess the statistical significance of difference between the sockets.

Qualitative Study

Following the quantitative study, two semi-structured interviews were carried out to capture participants' views and experiences of in-clinic fitting of two sockets designed in different ways, and general usability of their new prosthetic socket. The first was immediately after completion of the socket fitting and the second was one month afterwards (Supplementary File 2). Interviews were audio-recorded, anonymised, and transcribed verbatim by a professional transcribing company. A member of the research team (FM) checked a sample of transcripts against the audio recordings for accuracy. The transcripts were analysed using thematic analysis, which provided a flexible approach to ascertain a clear understanding of the comparability of socket comfort and views of the processes [35]. The thematic analysis approach consisted of 1) familiarisation with the data, 2) coding by hand and using NVIVO software (QSR International, Melbourne, Australia), 3) generating initial themes, and 4) reviewing and finalising final themes to capture consistent patterns within the data and key meaning relevant to the research questions [35]. One team member (MDH) led all stages of the analysis. Two other members (FM, JB) coded different sections of the data and together agreed on the final themes, providing verification, and allowing for a range of interpretations.

Results

Recruitment

Seventeen recruited participants with nineteen residual limbs completed the socket assessment study between March and November 2023 (Table 1, Figure 1). Six prosthetists designed control sockets for between one and nine participants. Approval was initially granted to compare transparent check sockets, but due to slow recruitment a study protocol amendment was approved to compare the Evidence-Generated check socket to a definitive CAD/CAM prosthetist-designed socket, reflecting more common practice in the participating clinics.

Table 1: Description of Participants

Side (n=19)	8 Left / 11 Right
Sex (n=17)	1 Female / 16 Male
Age (yrs, n=17)	Median 66, IQR 51 – 73
Time since amputation (yrs, n=19)	Median 4.0, IQR 2.5 – 8.9
Reason for amputation (n=19)	6 Infection / diabetic foot 4 Dysvascularity 3 Trauma 3 Ischaemia / CLTI 1 Sepsis 1 Peripheral Neuropathy 1 Chronic osteomyelitis secondary to trauma
Reason(s) for new socket (n=19)	12 socket too large / limb shrinkage 3 requested new suspension method 2 socket too small / tight

	1 alignment incorrect 3 N/R
Participant Activity Level (n=17) A1: In house walking or transfers only A2: Walking on flat ground only A3: Normal everyday walking A4: Additional high impact/energy activities	1 A1 6 A2 8 A3 0 A4 2 N/R

Notes: N/R denotes 'not reported'. CLTI: critical limb-threatening ischemia. Activity Level as assessed by the participants' normal clinical team.

Two participants exited before completing the post-assessment interview, and a further three were not contactable for the one-month follow-up interview.

Quantitative study findings

The unmodified Evidence-Generated sockets had no statistically significant difference in SCS compared to prosthetist-designed CAD/CAM control sockets (median SCS 8.6 for EG sockets and 8.8 for CAD/CAM controls; p=0.376 and effect size 0.08 in the paired significance test, Figure 3). Lower variability in SCS was observed across the study group for the EG sockets than the control sockets (95% confidence intervals 8.0-9.0 and 7.5-9.5, respectively). Nine of the nineteen EG sockets were given a comfort score within the noninferiority limit (1.21) of the control. Six EG sockets were rated as more comfortable than the CAD/CAM control, by between 2.0 and 3.5 points. Four EG sockets demonstrated lower comfort than the CAD/CAM control, by 1.5 to 2.5 points.

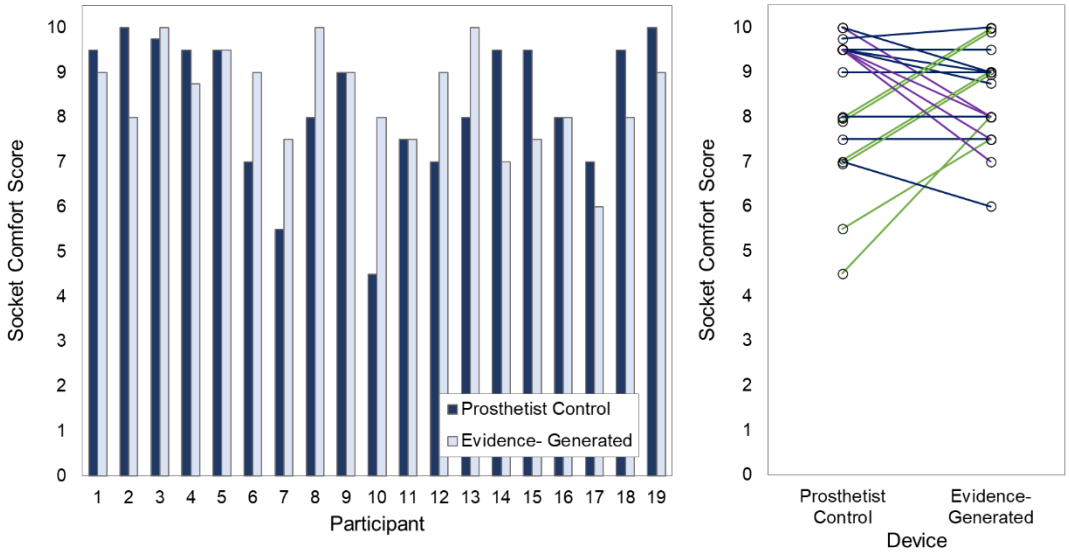

Figure 3: noninferiority crossover study results comparing Socket Comfort Score between the prosthetist control and evidence-generated sockets, for 19 fittings across 17 participants (left) and paired comparison chart (right). Colour coding denotes higher (green), the same (blue) or lower (purple) socket comfort score for evidence-generated than prosthetist control devices, within the noninferiority threshold of 1.21 points.

Qualitative study findings:

Due to the significant impact and diverse experiences related to socket comfort, thematic analysis identified several broader themes that were beyond this paper's objective. Focus is therefore limited to specific themes that offer insights into the participants' views and experiences relating to the sockets produced by the two design approaches (**Error! Not a valid bookmark self-reference.**).

Table 2: Themes identified in semi-structured interviews relating to comparison between comfort of the fitted sockets and reflections on the socket fitting process:

Theme 1	Experiences of the comparative fitting session
Theme 2	Similarity between the compared sockets
Theme 3	Differences between the compared sockets
Theme 4	Residual limb factors impacting on perceptions of socket comfort

Theme 1: Experiences of the comparative fitting session

Both devices were fabricated prior to the fitting session, and when discussing the session participants reflected on several aspects that they felt impacted on their experiences. Several participants described feeling that it went "*well", "fine"* or *"ok",* which illustrated that a process involving two different sockets was not a particular issue. For example, participant 10 (male, 58yrs, amputation following trauma, gel cushion liner) discussed their experience in terms of the output of the session: "*I got something out of it, it looks like this time if you know what I mean. At the end of this fitting there was something that looked like it was ready for me*". Other participants discussed how they felt about comparing the two sockets and commented on how they did not know who designed either of the two sockets, for example "*I didn't know who designed and who produced each socket"* (participant 1, male, 81yrs, infection, sock).

Other participants discussed their experience in terms of their expectations of addressing their specific socket fit issues relating to their residual limb. For example, "*The only thing I've got hope for there is that the bottom of my stump shrinks a lot more before it gets thinner and thinner because that's the only thing that's stopping me having a smaller prosthetic is that stump. It's where they added all the bits on"* (participant 10, male, 58yrs, amputation following trauma, gel cushion liner).

Theme 2: Similarity between the compared sockets

Several participants described not feeling any difference in the level of comfort between the sockets regardless of which design process was used. For some participants, this appeared to be related to feeling that both sockets were equally comfortable, with descriptions of how they found it difficult to decide if one was more comfortable than the other: *"As far as comfort there was very little difference in it really to be honest as far as I could judge at the time"* (participant 19, male, 71yrs, amputation due to ischemia, gel liner). Some participants compared the comfort of

the two new sockets to their previous device. For example: "*I feel a lot more comfortable really than the old one"* (participant 1, male, 81yrs, infection, sock).

This similarity in the level of comfort between the two new sockets was described by some participants in relation to both sockets feeling equally *"firm", "stable", "both fitting well"* and both sockets feeling very *"natural"*, as described by participant 4 (male, 30yrs, elective amputation following trauma, suction liner): "*Absolutely fine. They were both very, very close to being completely natural".* However, for other participants, the similarity between the sockets appeared to be associated with feeling similar levels of pain: "*walking with them as I was walking there was the same amount of pain"* (participant 11, female, 84yrs, peripheral vascular disease, cushion liner).

Theme 3: Differences between the compared sockets

Other participants noticed significant differences in the comfort of the two sockets, from positive and negative perspectives. The reported comparative fitment assessments were associated with some of the factors the participants raised in Theme 2, around similarities in fit, but also included differing, design-related factors such as the height of the socket, local shape details associated with bony prominences, and dynamic fit. Participants mentioned issues such as pressure points, discomfort at the back of the leg, and feelings of tightness. For example: "*One felt really tight. I like it tight when I get a new socket because it lasts longer. One felt a lot more comfortable at the front where my bone is closer to the skin"* (participant 12, male, 40yrs, amputation due to chronic ulcers, seal-in liner).

Differences in the size of the sockets also affected comfort. Participant 4 (male, 30yrs, elective amputation post trauma, suction liner) explained, "*The taller one was a bit more uncomfortable due to how high it was. When you bend your leg down, it hits the back of your leg.*" Some participants felt that the height of the socket made it feel more natural. These differences impacted participants' walking, with one socket feeling easier to walk in than the other: "*One socket was absolutely perfect. The other one had different movement, slightly different, but it seemed like you walked quicker with it. It was a nice, easy movement"* (participant 8, male, 76yrs, ischaemic amputation, pin liner).

Theme 4: Residual limb factors impacting on perceptions of socket comfort

While comparing the two sockets, participants discussed sensitive areas that affected their comfort, such as spots on the crest of the shin and other specific sore areas. These issues were often ongoing and considered by the prosthetist during socket design: *"I've always had this issue. We've had to shave out a bit of the socket to ease the pressure. But I think it's just the shape of my stump, and it's something that will always be an issue and I'm always aware of it"* (participant 13, male, 32yrs, elective amputation post trauma, no interface details recorded). Participant 16/17 (male, 70yrs, diabetic amputations, no interface details recorded) reflected on the adjustment after the fitting process, saying "*I don't know if the second one on the*

right whether it needed any more adjustment. Maybe a little bit but I would say they are fairly comfortable."

Other factors also not necessarily directly related to the design process appeared to impact on the participants' views of which of the two new sockets were more comfortable. For example, participant 6 (male, 51yrs, dysvascular amputation, no interface devices) described how their residual limb had shrunk since their last prosthetic fitting and this led to the new socket feeling more comfortable: *"But it does feel better and that clear one that I had in my old socket … had more movement because the stump had shrunk so much. So, it's just a case of getting used to having this because it's slightly smaller and it's hugging the stump. Perhaps where I had the freedom before where it moves about a lot more … I've got to get used to the new feelings of it."*

Discussion

Principal Results

This study demonstrated noninferiority of the Evidence-Generated socket design method in comparison to conventional clinician-led CAD/CAM socket design at initial fitting. Socket comfort score indicated similar comfort on average, and reduced variability across the cohort, for the evidence-generated sockets. Participant interviews confirmed this assessment and added a more detailed understanding of socket satisfaction.

Thematic analysis also revealed the patients' detailed understanding of the nuances of their prosthesis design and its fit, and demonstrated the importance of ensuring a trained, experienced clinician directs the application of technology-enhanced socket design processes. The comfort results indicated non-inferiority of the EG sockets' fundamental design without any personalised clinician input. However, the qualitative study provided evidence to support clinical usage of EG sockets with an expert human in the loop to make design decisions in response to patients' individual and complex needs [12,23,36]. That might include local design modifications in response to vulnerable sites on that individual's residual limb or accommodating the patient's preferences for tightness of fit. This was identified for the single participant whose EG sockets was rated with SCS below seven (Participant 16/17, male, 70yrs, diabetic amputation), for whom the score of seven was attributed to an unusual tissue sensitivity at a supracondylar site, where the CAD/CAM control socket featured a local modification. The same point may explain the observed trend where all four EG sockets that were rated as less comfortable than the CAD/CAM control were cases where the control scored a socket comfort score of nine to ten, where such personalisation has evidently been successful. Patient-specific local areas of sensitivity and corresponding design changes inherently cannot be generalised, so this justifies the importance of an expert in the design process, who retains clinical responsibility.

Comparison with Prior Work

The complementary evidence provided by this multiple-methods approach demonstrates the value of exploring the participants' experience more deeply through interviewing, to enhance what can be learned from objective measurement [37]. However, this approach is somewhat unusual in the assessment of prosthetics technologies [29]. The study involved a large interdisciplinary team which enabled separation of trial socket design, clinical assessment, interviewing, data analysis and interpretation, in an attempt to minimise potential researcher biases. The combined synthesis of the SCS and interviews revealed the participants' detailed understanding of the influence of residual limb shape and corresponding socket design upon their comfort and function, illustrative of the value of excellent prosthetist-patient communication. These technologies may offer an opportunity to improve patient experience through understanding of their care [38] or even shared decision making [39]. The use of an Evidence-Generated socket design process may enable greater focus on the higher value-added aspects of personalisation, and might be easier to perform in front of the patient [23]. Most notably this observation justifies ongoing work with clinician stakeholders, for example to indicate specific areas in which human input is particularly important for fitting EG sockets to newly presenting individuals, and in development of software interfaces, building upon methods reported by Ngan et al [40].

Limitations

The study included a relatively diverse group of patients accessing prosthetic rehabilitation services except for gender, where the recruited participants were predominantly male (16/17) [41], which may impact the study's generalisability. Women are less likely to have a major amputation and to be successfully fitted with a prosthesis [42], enter prosthetic rehabilitation later [43], and are under-represented in research cohorts [44]. It is not clear why the present study's convenience sampling resulted in an imbalance, but this illustrates the need to ensure that further studies include more diverse gender representation, as the experiences of men and women may be different. However, the distribution of randomly sampled people whose socket designs were used to train the socket design evidence model [26] was representative of the population of people with transtibial amputations, and external validity is supported by their diverse range of ages, reasons for limb absence, activity levels and time since amputation. Further bias may arise from the recruited participants' age profile (IQR 51-73yrs, range 30-84yrs), which was similar on average but narrower in range than the general population of people using prosthetic limbs [41], but matched to the historic socket design dataset (IQR 50-71yrs, IDR 38-77yrs, range 20-94yrs [26]). Finally, the training datasets came from clinicians at a single centre, whose practice may be similar, potentially limiting the diversity of design approaches.

The study also has limitations in its single timepoint and outcome measure, where previous studies comparing computer aided design and manufacturing to plaster design and fabrication considered quality of life [7] and more extensive assessments of comfort, fit, cosmesis, weight and function alongside clinical workload and productivity measures [9]. The study cannot indicate how socket comfort would

develop long-term, and it may be preferable to use the Expanded Socket Comfort Score for Best, Worst and Average Comfort over a longer period [45]. However, this study replicates the clinical assessment of trial and definitive sockets in UK National Health Service settings, and provides additional insight since participants could compare two socket options side-by-side and select their preference, with interviews proceeding a month after fitting. A different comparison, versus plaster socket design methods might provide additional insights but the study was designed to compare with conventional CAD/CAM as the standard of care in the participating centres, and indeed the prevalence of CAD/CAM is rising. Finally, the study was not formally randomised and prosthetists generally fitted their own-design socket first, meaning a carryover effect cannot be excluded. Alongside this limitation, single-blinding could not apply to three participants for whom the EG check socket was compared to a definitive CAD/CAM control socket, instead of comparing two visually-similar check sockets.

Conclusions

Overall, the study findings support wider clinical use of Evidence-Generated transtibial sockets, but also demonstrates the importance of delivering this technology in a way that facilitates prosthetist input in tailoring the design to their individual patients' needs and provides maximal opportunity for their communication. Such an implementation may enable prosthetists to take the advantages offered by technology whilst retaining or ideally enhancing trust through human-centred prosthetic rehabilitation.

Clinical Messages

- Evidence-Generated transtibial prosthetic socket designs compared well to devices produced by conventional CAD/CAM clinical practice, in terms of comfort at socket fitting and patient feedback in semi-structured interviews.
- Qualitative feedback confirmed that clinician input remains essential, to incorporate patient-specific socket design details in response to local sites of sensitivity or tissue vulnerability, or preference: details that cannot be generalised.
- Work is underway to incorporate Evidence-Generated socket designs into computer aided socket design software such that they can be modified at fitting, enhancing evidence-based practice as a support tool to help qualified clinicians to leverage their experience and skill and enable co-design with the prosthesis user.

Acknowledgements

We acknowledge our study participants, patient advisor the Alex Lewis Trust, and kind support from the University of Southampton's Institute for Life Sciences.

This research was funded by the Royal Academy of Engineering (RAEng), grant numbers RF/130 and EF1819\8\24, Innovate UK, grant 10014827, the Higher Education Innovation Fund (HEIF), and The Alan Turing Institute, grant EP/N510129/1. The funders had no role in the design of the study; in the collection,

analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

The study was conducted according to the guidelines of the Declaration of Helsinki, and was granted approval by Institutional (ERGO 76033.A3) and UK national review boards (IRAS 313408 / HRA REC 22/YH/0215). All participants provided written, informed consent and the presented data are selected to avoid identification. The study protocol is registered at clinicaltrials.gov (ID NCT06597266).

The authors specifically contributed to:
FM: data collection, data analysis, data interpretation, writing, editing
MDH: study design, literature search, data analysis, data interpretation, writing, editing
JB: study design, data collection, data analysis, data interpretation, editing
JS: study design, technical design, data analysis, data interpretation, figures, writing, editing
CR: technical design, data analysis, underlying data verification, editing
PW, CO, CM, DH: study design, data interpretation, editing
CW, JK, SS, KM, SG, HH, DHS, VK: study design, data collection, data interpretation, editing
AD: study design, technical design, literature search, data interpretation, figures, writing, editing

The dataset supporting the conclusions of this article is available in the University of Southampton repository, https://doi.org/10.5258/SOTON/D3205 (to be activated upon acceptance).

Conflicts of Interest

Authors FM, MDH, CO, CM, SG, HH, VK have no conflict of interest to declare. Authors JS, JB, CR, AD & PW declare employment and/or shareholding in Radii Devices Ltd. Authors DH, CW, JK, SS, KM, DHS declare employment at Opcare Ltd.

Abbreviations

AFMA: Automated Fabrication of Mobility Aids
CAD/CAM: Computer Aided Design and Manufacturing
CASD: Computer Aided Socket Design
CLTI: Critical Limb-Threatening Ischemia
CNC: Computer Numerical Control
EG: Evidence-Generated
IQR: Inter-Quartile Range
PPIE: Patient and Public Involvement and Engagement
SCS: Socket Comfort Score

References

1 Saunders CG, Foort J, Bannon M, *et al.* Computer aided design of prosthetic sockets for below-knee amputees. *Prosthetics Orthot Int* 1985;**19**:17–22.

2 Köhler P, Lindh L, Netz P. Comparison of CAD-CAM and hand made sockets for PTB prostheses. *Prosthet Orthot Int* 1989;**13**:19–24. doi:10.3109/03093648909079405
3 Topper AK, Fernie GR. An evaluation of computer aided design of below-knee prosthetic sockets. *Prosthet Orthot Int* 1990;**14**:136–42. doi:10.3109/03093649009080339
4 Ruder GK. CAD CAM trans-tibial temporary prosthesis: analysis and comparison with an established technique. *Prosthet Orthot Int* 1992;**16**:189–95.
5 Öberg T, Lilja M, Johansson T, *et al.* Clinical evaluation of trans-tibial prosthesis sockets: A comparison between CAD CAM and conventionally produced sockets. *Prosthet Orthot Int* 1993;**17**:164–71. doi:10.3109/03093649309164377
6 Wong MS, Cheng JCY, Wong MW, *et al.* A work study of the CAD/CAM method and conventional manual method in the fabrication of spinal orthoses for patients with adolescent idiopathic scoliosis. *Prosthet Orthot Int* 2005;**29**:93–105. doi:10.1080/17461550500066782
7 Karakoç M, Batmaz I, Sariyildiz MA, *et al.* Sockets manufactured by CAD/CAM method have positive effects on the quality of life of patients with transtibial amputation. *Am J Phys Med Rehabil* 2017;**96**:578–81. doi:10.1097/PHM.0000000000000689
8 van der Stelt M, Berends B, Papenburg M, *et al.* Evaluating the Effectiveness of Transtibial Prosthetic Socket Shape Design Using Artificial Intelligence: A Clinical Comparison With Traditional Plaster Cast Socket Designs. *Arch Phys Med Rehabil* 2025;**106**:239–46. doi:10.1016/j.apmr.2024.08.026
9 Houston VL, Burgess EM, Childress DS, *et al.* Automated fabrication of mobility aids (AFMA): Below-Knee CASD/CAM testing and evaluation program results. *J Rehabil Res Dev* 1992;**29**:78–124. doi:10.1682/JRRD.1992.10.0078
10 Smith DG, Burgess EM. The use of CAD/CAM technology in prosthetics and orthotics - Current clinical models and a view to the future. *J Rehabil Res Dev* 2001;**38**:327–34.
11 Dean D, Saunders CG. A Software Package for Design and Manufacture of Prosthetic Sockets for Transtibial Amputees. *IEEE Trans Biomed Eng* 1985;**BME-32**:257–62. doi:10.1109/TBME.1985.325445
12 Boone DA, Harlan JS, Burgess EM. Automated fabrication of mobility aids : Review of the AFMA process and VA / Seattle ShapeMaker software design. *J Rehab* 1994;**31**:42–9.
13 Lemaire ED, Johnson F. A Quantitative Method for Comparing and Evaluating Manual Prosthetic Socket Modifications. *IEEE Trans Rehabil Eng* 1996;**4**.
14 Cutti AG, Santi MG, Hansen AH, *et al.* Prosthetist-Specific Rectification Templates Based on Artificial Intelligence for the Digital Fabrication of Custom Transtibial Sockets. *Prosthesis* 2024;**6**:1149–69. doi:10.3390/prosthesis6050083
15 Torres-Moreno R, Foort J, Morrison JB, *et al.* A reference shape library for computer aided socket design in above-knee prostheses. *Prosthet Orthot Int*

1989;**13**:130–9.
16 Fatone S, Johnson WB, Tran L, *et al.* Quantification of rectifications for the Northwestern University Flexible Sub-Ischial Vacuum Socket. *Prosthet Orthot Int* 2017;**41**:251–7. doi:10.1177/0309364616684165
17 Weiss HR, Werkmann M. The ScoliOlogiC Chêneau light™ brace in the treatment of scoliosis. *Scoliosis* 2010;**5**:1–18. doi:10.1186/1748-7161-5-19
18 Bowman GG. The L.A. Brace-Description and discussion. *Physiother Theory Pract* 2011;**27**:68–73. doi:10.3109/09593980903498352
19 Li S, Lan H, Luo X, *et al.* Quantitative compensation design for prosthetic socket based on eigenvector algorithm method. *Rev Sci Instrum* 2019;**90**. doi:10.1063/1.5092743
20 Karamousadakis M, Porichis A, Ottikkutti S, *et al.* A Sensor-Based Decision Support System for Transfemoral Socket Rectification. *Sensors* 2021;**21**. doi:https://doi.org/10.3390/s21113743
21 Gu Y, He L, Zeng H, *et al.* A Data-Driven Design Framework for Structural Optimization to Enhance Wearing Adaptability of Prosthetic Hands. *IEEE Trans Neural Syst Rehabil Eng* 2024;:1–12. doi:10.1109/TNSRE.2024.3430070
22 Oldfrey BM, Morgado Ramirez DZ, Miodownik M, *et al.* A scoping review of digital fabrication techniques applied to prosthetics and orthotics: Part 1 of 2—Prosthetics. *Prosthetics Orthot Int* 2024;**48**:574–89. doi:https://doi.org/10.1097/PXR.0000000000000351
23 Dickinson A, Diment L, Morris R, *et al.* Characterising Residual Limb Morphology and Prosthetic Socket Design based on Expert Clinician Practice. *Prosthesis* 2021;**3**:280–99. doi:https://doi.org/10.3390/prosthesis3040027
24 Nagarajan YR, Farukh F, Silberschmidt V V, *et al.* Shape Analysis of Prosthetic Socket Rectification Procedure for Transtibial Amputees. *Prosthesis* 2024;**6**:157–74. doi:https://doi.org/10.3390/prosthesis6010013
25 Ngan C, Pendse V, Sivasambu H, *et al.* Preliminary Characterization of Rectification for Transradial Prosthetic Sockets. *Sci Rep* 2024;**14**:5759. doi:https://doi.org/10.1038/s41598-024-56333-6
26 Dickinson AS, Steer JW, Rossides C, *et al.* Insights into the spectrum of transtibial prosthetic socket design from expert clinicians and their digital records. *Front Rehabil Sci* 2024;**1354069**. doi:https://doi.org/10.3389/fresc.2024.1354069
27 von Elm E, Altman DG, Egger M, *et al.* The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies. *Bull World Health Organ* 2007;**85**:867–72. doi:10.2471/BLT.07.045120
28 Ostler CM, Donovan-Hall M, Eggbeer D, *et al.* People Powered Prosthetics: Prosthetic Innovation driven by User Needs. 2024.https://www.peoplepoweredprosthetics.com/projects/voices/
29 Sanders JE, Vamos AC, Mertens JC, *et al.* An adaptive prosthetic socket for people with transtibial amputation. *Sci Rep* 2024;**14**:1–15. doi:10.1038/s41598-024-61234-9
30 Turner S, McGregor AH. Perceived Effect of Socket Fit on Major Lower Limb Prosthetic Rehabilitation: A Clinician and Amputee Perspective. *Arch Rehabil*

Res Clin Transl 2020;**2**:100059. doi:10.1016/j.arrct.2020.100059
31 Anderson C, Kittelson A, Wurdeman S, *et al.* Understanding decision-making in prosthetic rehabilitation by prosthetists and people with lower limb amputation: a qualitative study. *Disabil Rehabil* 2023;**45**:723–32. doi:10.1080/09638288.2022.2037745
32 Gavette H, McDonald CL, Kostick-Quenet K, *et al.* Advances in prosthetic technology: a perspective on ethical considerations for development and clinical translation. *Front Rehabil Sci* 2023;**4**:1–9. doi:10.3389/fresc.2023.1335966
33 Hafner BJ, Morgan SJ, Askew RL, *et al.* Psychometric evaluation of self-report outcome measures for prosthetic applications. *J Rehabil Res Dev* 2016;**53**:797–812. doi:10.1682/JRRD.2015.12.0228
34 Efron B. Censored Data and the Bootstrap. *J Am Stat Assoc* 1981;**76**:312. doi:10.2307/2287832
35 Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;**3**:77–101. doi:10.1191/1478088706qp063oa
36 Foort J. Innovation in prosthetics and orthotics. *Prosthet Orthot Int* 1986;**10**:61–71.
37 Dillon MP, Fatone S, Ramstrand N, *et al.* Prosthetics and Orthotics International welcomes qualitative research submissions. *Prosthet Orthot Int* 2019;**43**:366–8. doi:10.1177/0309364619863922
38 Adams RJ. Improving health outcomes with better patient understanding and education. *Risk Manag Healthc Policy* 2010;**3**:61–72. doi:https://doi.org/10.2147/RMHP.S7500
39 Anderson CB, Fatone S, Mañago MM, *et al.* Improving shared decision-making for prosthetic care: A qualitative needs assessment of prosthetists and new lower-limb prosthesis users. *Prosthet Orthot Int* 2023;**47**:26–42. doi:10.1097/PXR.0000000000000142
40 Ngan C, Sivasambu H, Kelland K, *et al.* Understanding the adoption of digital workflows in orthotic & prosthetic practice from practitioner perspectives: a qualitative descriptive study. *Prosthet Orthot Int* Published Online First: 2022. doi:10.1097/PXR.0000000000000107
41 Twiste M. Limbless Statistics Annual Report: 2011/2012. Manchester: 2015.
42 Davie-Smith F, Paul L, Nicholls N, *et al.* The impact of gender , level of amputation and diabetes on prosthetic fit rates following major lower extremity amputation. *Prosthetics Orthot Int* 2017;**41**:19–25. doi:10.1177/0309364616628341
43 Levy J, Kamdar N, Adidharma W, *et al.* Gender Disparities in the Acquisition of Lower Extremity Prosthetics Following Major Limb Amputation. *J Clin Transl Sci* 2024;**8**:75. doi:10.1017/cts.2024.229
44 Ljung J, Iacangelo A. Identifying and Acknowledging a Sex Gap in Lower-Limb Prosthetics Research: A Review. *J Prosthetics Orthot* 2024;**36**:e18–24. doi:10.1097/JPO.0000000000000470
45 Morgan SJ, Askew RL, Hafner BJ. Measurements of Best, Worst, and Average Socket Comfort Are More Reliable Than Current Socket Comfort in Established Lower Limb Prosthesis Users. *Arch Phys Med Rehabil*

2022;**103**:1201–4. doi:10.1016/j.apmr.2021.10.008