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Innovation Insights

Digital Fabrication of Lower Limb Prosthetic Sockets

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Highlights

- Globally, only 5-15% of people who need a lower limb prosthetic have access.
- There is a lack of service access in LMICs. Digital fabrication of prosthetic sockets could decrease the burden on existing clinics in LMICs and overcome the lack of service points, however unanswered questions about the feasibility of this approach remain.
- 3D scanning is mature and has standalone clinical and technical benefits. It could begin to be introduced to P&O training as a first step in training for a digital workflow.
- An understanding of the training burden for a full digital workflow is lacking, and there is potential to do more than harm than good in attempting to alter the practices of LMIC clinics. It is crucial therefore to fully understand the challenges of large-scale implementation.
- If the reliability of print & material quality can be proven and accepted by the community, while still keeping cost low, then additive manufacture could transform service delivery models in low resource settings.
- Without larger scale trials & research on quality control and durability, the prosthetist community will remain sceptical. Consensus is needed on valid approaches to testing and scaling digital fabrication technologies.

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Summary

This innovation insight discusses current approaches to digital fabrication of lower limb prosthetics (LLP) sockets aimed at low resourced settings. Digital fabrication of LLPs sockets has been researched for a number of decades, yet these technologies are not widely adopted, and most of the activities within this domain reside in high-income settings. However, the majority of amputees are in LMICs where there is a severe lack of access to services. It is in LMICs then, that the advantages that digital technologies offer could be of particular benefit however little to no progress in digital workflow adoption has been made to date.

Introduction

Digital fabrication technologies have been transforming manufacturing for many decades. However, it is only recently that they have become affordable enough to disrupt the craft practices of assistive technology manufacture. Prosthetic sockets are almost exclusively handmade due to the uniqueness of shape, size and tissue composition of each prosthesis wearers' residual limb. The craft process starts with a well-trained prosthetist measuring the dimensions of the limb, and manually palpating the skin surface to assess the tissue make-up of the stump. The prosthetist's expertise of how the wearer's physiology, such as weight, and the intended use of the prosthesis, be it more sedentary or highly active, all affect the final fit of the socket.

The predominant craft methods for prosthetic socket fabrication are moulding and casting techniques. Further fittings and adjustments are typically made to the socket and other components during a series of tweaks, until the wearer finds the socket and prosthesis comfortable. When done by a trained prosthetist, this iterative fitting process is highly effective, but time consuming which can mean high labour costs. Along with a shortage of personnel, service units and health rehabilitation infrastructures (Sexton, 2016), this results in only 5-15% of amputees in LMICs having access to a prosthesis (World Health Organisation, 2017).

Socket manufacture is a crucial part of providing appropriate prosthetic service to lower limb amputees - once made other components of the prosthetic can be tailored to it, resulting in a life changing assistive device. If the socket fits poorly, the results are chafing, bleeding, bruising, pressure sores and pain. These problems can reduce the amputee's functional ability, compromise their long term health, decrease independence, and increase costs to society (Engsberg et al. 2006).

Digital technology is increasingly used to speed up socket fabrication and

some approaches have been in use for some time in HICs, such as 'CAD/CAM': where a 3D scanner is used to measure the stump geometry, which is converted to a digital design using specialist software; this is then 'carved' using a CNC (Computer

Numerical Control) machine to produce a mould, and a socket is produced using traditional fabrication methods.

Additive manufacture (AM), with 3D printers which can repeatably and accurately convert these digital designs into printed sockets promises to complete the digital workflow and transform the fabrication process in the clinic. In this Innovation Insight we focus on the potential that a full digital fabrication workflow has to disrupt the manufacture of sockets for lower limb prostheses (LLP) in LMICs, with a view to overcoming barriers to service access.

While there is high interest among research groups, adoption of AM socket fabrication in practice in high-income countries (HICs) is low. The technology has yet to receive wide acceptance from both users and prosthetists. Access to available prosthetists in HICs is high so there is little pressure for change, and the service provision is mostly well met and received. The upfront costs of equipment and re-training to change to a full digital workflow are just not seen as worthwhile for an approach that is not yet a trusted option - as there is a lack of evidence regarding efficiency improvements, quality & cost effectiveness.

It is estimated that 64% of amputees reside in LMICs (McDonald C., 2017) where the situation is quite different from the one found in HICs. In LMICs, one of the major barriers to effective provision of prosthetics is the low number of trained prosthetists compared to the number of patients. Where there is access to service, workloads are high, meaning long waiting lists. This and variable socket fit quality, which is highly dependent on adequate training, contribute to high abandonment rates. What is required in most LMICs is a prosthetic service delivery model which can match socket quality and consistency when compared to traditional fabrication methods, as well as reducing the fabrication time. Thus it is in LMICs in which digital scanning, design and printing of prosthetic sockets could have a large potential impact on the outcomes achieved for patients. However assessment of whether this is an appropriate technology is complex and unanswered questions remain over whether it really can solve some of these issues.

Stages of Digital Fabrication

Here we will discuss the phases of potential digital workflows, going from 3D scanning, digital socket design followed by either CNC carving (CAD/CAM) and traditional fabrication or additive manufacture (AM). Fig 1 gives a summary of the workflows as compared to the traditional method.

Traditional Workflow	Casting the stump to make a negative mould	Filling the negative mould with plaster to make a positive mould	Manually rectifying the positive mould based on stump physiology		Socket manufacturing e.g. manual draping or vacuum forming	Post processing, assemble & align other componentry	Final adjustments / corrections before & during gait training until comfortable
CAD/CAM Workflow	Scanning the stump to give digital stump model		Virtually rectifying the model based on stump physiology	CNC Machine Positive Mould on Carver	Socket manufacturing e.g. manual draping or vacuum forming	Post processing, assemble & align other componentry	Final adjustments / corrections before & during gait training until comfortable
AM Workflow	Scanning the stump to give digital stump model		Virtually rectifying the model based on stump physiology		Automated additive manufacture of socket	Post processing, assemble & align other componentry	Final adjustments / corrections before & during gait training until comfortable

Fig 1. A comparison of workflows of socket manufacture

3D Scanning

There are a range of scanning options available which vary greatly in features, price, and employ different types of imaging technology. A recent review of the scanners relevant to prosthetics, found the most relevant scanner for prosthetic socket production are handheld devices that can be moved around the patient's residuum to take high resolution recordings of the surface geometry (see Fig 2) (Golovin, Marusin, and Golubeva 2018). In HIC clinics, fixed scanners are also used for a few different purposes. For example, the scanning of positive moulds (1:1 replicas of a stump) to allow digital manufacturing techniques based on a traditionally obtained limb cast, or for the recording of limb data for future use in fabrication and clinical analysis. Additionally, there have been recent innovations on reducing price barriers to scanning by using smartphone-based scanning apps, for example *Trnio*, which is advantageous to very low resource settings. In-depth research on these for use in prosthetics is limited, however work exists such as a low cost and accessible smartphone photogrammetry method for digitising prosthetic socket interiors has been described by Hernandez & Lemaire (Hernandez, Lemaire, 2016). This method is just one of the potential other use cases beyond actual socket design, that 3D scanning allows within the clinic - such as socket replication/recording and monitoring stump change over time.

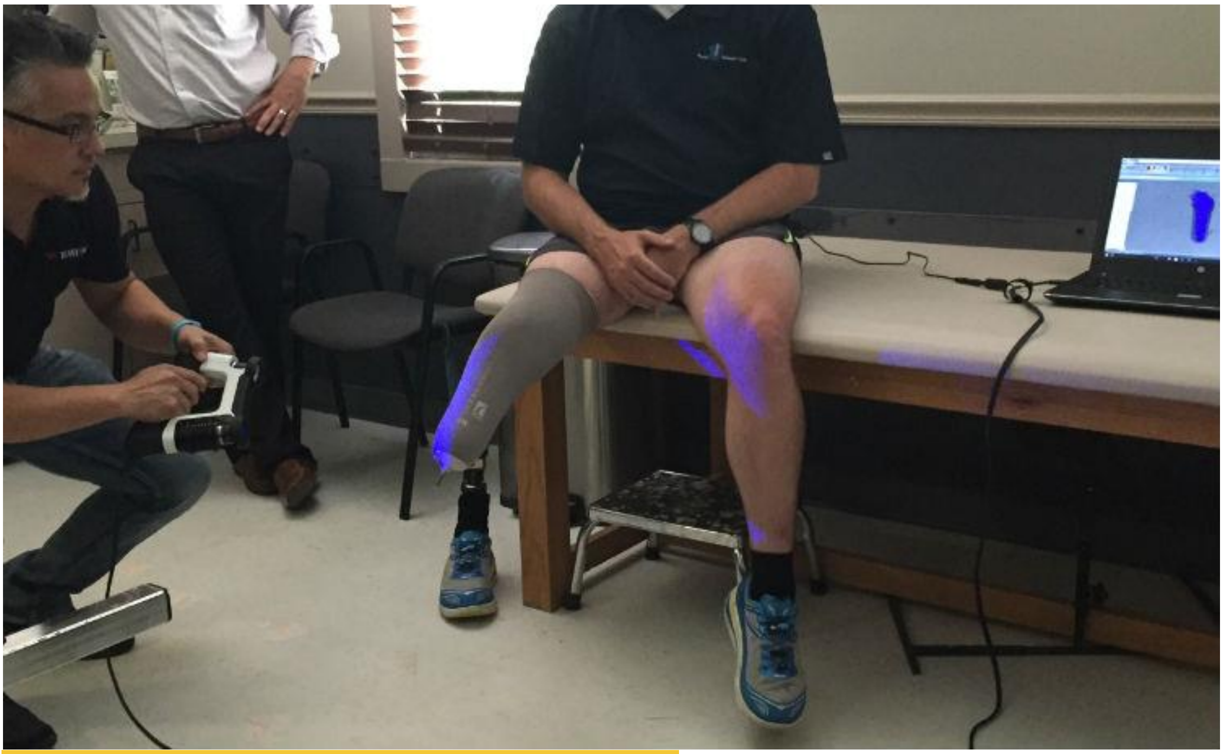


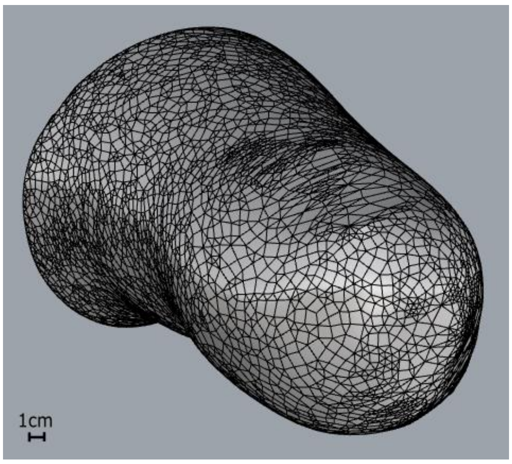
Fig 2. Operation of a hand held 3D scanner at Horton's O&P Clinic, USA (https://www.hortonsoandp.com/)

A potential benefit of 3D scanning technologies to LMIC scenarios is that with sufficient portable power, the scanning could be done anywhere, allowing it to occur outside a Prosthetics & Orthotics (P&O) clinic. However, a criticism of 3D scanning is that it does not account for differences in limb composition, which are typically identified through palpation of the limb by a trained prosthetist. The prosthetist uses this hands-on information to alter the socket design, addressing pressure-relief and pressure-transfer areas of the socket. Therefore, for scanners to appropriately enable task shifting away from trained prosthetists, careful consideration is required.

Nevertheless, scanning technology is in a sufficient state of maturity that useful surface scanning is a realistic option. In most cases, as the maintenance is low for these devices, while the lifespan is high (5-10+ years), the technology itself does not present a barrier to use. However the training required to operate the socket design software for interpreting scans and producing socket designs, while effectively incorporating hands-on information, could be a barrier to adoption. Correct choice of scanner is also essential, and adequate benchmarking is needed to select an appropriate technology for the intended application (Dickinson et al, 2020).

A recent LMIC study concluded that scanning technology could be of use now in LMIC settings to monitor residual limb volume and shape change to understand changes in socket fit over time and optimise the process (Dickinson et al. 2019). Key metrics such as these could be rapidly obtained with high accuracy and low process time for clinicians - ‘the foundation would then be in place for clinic or community-based CAD/CAM at a central fabrication facility, once appropriate fabrication technology is identified’ (Dickinson et al. 2019).

Fig 3. A digitally scanned stump (Oldfrey B et al, 2020)



Digital Socket Design

When shifting to a digital approach to socket design, instead of making a cast and the respective rectifications by hand, the prosthetist uses scan information to create a 3D digital model of the residuum on a computer. Rectifications are therefore achieved virtually, and can be tweaked ad infinitum. Multiple companies have developed prosthetic oriented CAD software packages, however, there has been minimal published research on the processes involved. This lack of transparency is most likely to protect intellectual property and potential competitive edge, however it could reduce confidence and acceptance of the technology in clinical settings. Broadly, it seems the software available has the required features to allow effective preparation of a 3D printable socket. However, research into effective training would be highly beneficial for clinics and policy makers. This could be combined with a co-design/engagement process of the software with prosthetic workshop teams to optimise workflow and software design.

A notable opportunity of digital workflows for socket design lies in exploring digital socket manufacture as a ‘telefabrication’ method. Using a telefabrication approach, scanned limb files from a remote location with limited resources could be sent to trained prosthetists in a central location, who can undertake the digital design of the socket, as well as potentially the actual socket fabrication. To ensure this model builds local capacity however, capacity within country or region must be made for the final design work, and the logistics of delivering the fabricated sockets are also an important additional barrier to consider.

CNC Carving

For the CAD/CAM approach, the design for the positive mould (a 1:1 replica) of the stump, with virtually applied rectifications (adjustments for fit made by the prosthetist), is physically reproduced. A specialist CNC machine carves the required geometry from a block of material, such as polyurethane foam, and a traditional method is then used to fabricate the socket using the mould. Technologies for this approach are available from multiple companies such as Vorum and Rodin4D, and can achieve equivalent outcomes to conventional plaster, however the labour time reductions are more limited than with a full digital workflow. Additionally this approach, which can be described as 'subtractive manufacture', is materially wasteful and results in higher material costs than for plaster casting, as well as having high costs associated with the machinery and ongoing maintenance. These costs however may not be an insurmountable barrier if scale can be achieved with centralised fabrication. Limited investigation for its use in low resource settings has been done, however it is discussed as an option for LMICs in this recent paper (Dickinson et al, 2019).

Additive Manufacture

The final stage of a full digital workflow is the printing. There are many different 3D Printing (AM) approaches available to rapidly manufacture LLP sockets. A recent review of these methods found that results are varied, and are still hampered by low success rates, a wide range of print quality and uncertainty of mechanical properties. Added to which, fit and comfort optimization of the socket are difficult due to the limited utility of modelling approaches developed so far (Bikas, Stavropoulos, and Chryssolouris n.d.).

Fig 4. An LLP socket using FDM printing (Nia Technologies)

The majority of research groups investigating 3D printing of sockets are using fused deposition techniques (FDM). FDM printers incrementally build up layers of extruded molten thermoplastic to form a product, such as that shown in Figure 4 from Nia Technologies. There have been some advances using more expensive and less available technologies and techniques such as: laser sintering (SLS), Polyjet and the much newer multi-jet fusion (MJF). These give higher resolution and more reliable print quality, albeit with a much higher price tag. However, as technologies advance they are likely to become more affordable, as has been the case with FDM printers. As with CNC carving, the potential upfront and ongoing costs are a major concern. Whatever technology is used it is imperative that strength is proven, as the structural integrity of

AM produced devices is not equivalent to other production methods like injection moulding or vacuum forming using the same material. There is an inherent potential weakness arising from the layer by layer building of a product and 'persistent concerns regarding the strength and durability of 3D-printed prosthetic sockets are a barrier to clinical adoption of 3D-printing technologies in prosthetic socket fabrication' (Nickel et al, 2020). Unfortunately though the ISO 10328 standard that is often used to test & verify technologies is not explicitly designed to test sockets, which does not help with building definitive trust in a given approach. Groups replicate the loads & procedures aimed at testing whole prostheses to conduct strength testing for sockets, for example recent work comparing 3D printed sockets with standard sockets by Owen & Desjardin. They state that 'although the ISO 10328 testing standard was sufficient to complete these evaluations, the method lacked some socket-specific measures and loading conditions that could have improved comparisons between socket types', (Owen, DesJardin, 2020).

Modes of Delivery

There are many modes of delivery through which these manufacturing processes could be enabled – we discuss 3 key scenarios: (1) Fabrication on-site at the P&O clinic; (2) Printing using a subcontracted 3D printing bureau; and (3) Fabrication using mobile setups.

In-Clinic Fabrication

A highly desired approach is to have the whole process done on-site in full control of the P&O team, replicating the traditional approach. This potentially allows very fast delivery times, possible within 5-15 hours, with no device shipping issues. However it brings significant upfront expenditure on equipment, and for more than one socket to be in process at any one time, multiple machines will be required, increasing costs further (to note with traditional methods, the workshop is able to parallelise some processes). With full control, comes full responsibility - maintenance and troubleshooting all rest with the P&O team, which represent significant costs and training burden, and potential breakdowns could stop production entirely until fixed. Unreliable power supply is also common place in LMICs, which could represent a serious barrier for 3D printing in particular, which needs long periods of continuous power if a print is to be successful. With all this in mind, it is not clear yet whether a full in-clinic digital workflow really does save costs & time or if it just brings a different set of issues.

Progress on this delivery mode has been made by Nia Technologies, a Toronto based non-profit social enterprise founded in 2015 who specifically aims at making a low-cost fully digital AM workflow for socket fabrication in low resource settings, called 3D PrintAbility (3DPA). After initial prototyping and 3D printing trials using PLA (Polylactic Acid), they moved to Nylon due to its improved printability and higher strength. During trials in Cambodia with prosthetic wearers who stood in rice paddies, they found problems with the nylon being too hydrophilic - compromising the integrity of the devices due to absorption of water. They also found sockets manufactured with this approach to be abrasion resistant - making them difficult to post-process. They eventually moved to 3D printing polypropylene (PP) and PET-G, since both can be fairly easily modified using a heat gun by a prosthetist to improve the fit and comfort. Lower limb transtibial devices using this improved material and fabricated using 3DPA have been demonstrated to meet ISO 10328 Standards. In 2017, Nia Technologies completed evaluation studies aimed at assessing 3DPA using the International Committee of the Red Cross (ICRC) technology. In their studies across Cambodia, Tanzania and Uganda, prosthetists and orthotists produced a total of 120 printed devices for clients, 61 of these were transtibial prostheses, the rest were Ankle Foot Orthoses (AFOs). Overall, devices produced with the 3DPA system and the standard ICRC system both scored highly and almost uniformly in crucial categories, such as overall satisfaction with the device, ability to walk with the device, overall comfort while wearing the device and overall pain experienced while using the device (Southwick 2019). However when socket failures did occur, the mechanism was brittle fracture for the 3D printed sockets - which is a sudden cracking of the socket and poses much more of a risk to users compared to ductile fracture (warping or deformation) which is the more common failure mechanism found with traditionally draped sockets. This is due to the striated structure of layer by layer manufacture which is inherent to AM – the layers can delaminate from each other. To combat socket failure, Nia increased the thickness of the sockets, which is a common requirement of FDM sockets if they are to be durable enough. This extra thickness compared to traditional sockets of the same material is a downside however as it adds weight and the socket brim line (the top rim of the socket) is more visible through clothes, which is not desirable, especially in some LMIC cultures.

Subcontracted Printing Bureaus

In this delivery option the 3D printing of the devices is performed at a dedicated facility. This allows for the use of top spec printers in the hands of specialists, thus promising reliable, high-quality socket production. The maintenance and operating requirements of the printers are taken care of as well. This means much less burden on the P&O team, who would only need to be trained in the scanning and design software, unlocking their time to see more patients. With high quality, reliable sockets comes significantly higher cost per unit however, which is a major barrier currently. To note though, it must be kept in mind that the upfront & ongoing costs are much lower than for in-clinic fabrication, making direct comparison difficult. Subcontracting does bring potential logistics and shipping challenges, and if the central bureau is in a different country to the P&O clinic, it could lead to risks such as sockets being stuck in customs. Modification to the design of a socket is also problematic if there are problems with fit - a modified socket might need to be re-printed, significantly increasing cost and wait time. If the costs and logistics challenges are appropriately addressed however, this mode of delivery could greatly unlock the time constraints faced by P&O teams in LMICs, increase service access, and deliver state-of-the-art products.

Fig 5. The Optimal Socket from Prosfit using Multi Jet Fusion (www.prosfit.com)

Prosfit, a company based in Sofia (Bulgaria) founded in 2013 by Alan and Chris Hutchinson with the specific aim of developing a digital scanning and 3D printing solution for prosthetic sockets. They began printing using FDM and launched their *Original* below knee socket, which was rated to 100kg, in 2016. In 2018, they launched the *Optimal* version available for above knee and below knee, which is printed using a HP service bureau using Multi Jet Fusion in HP High Reusability PA12- and is rated to 125kg, these can be seen in Figure 5. Prosfit state that the finished socket is significantly lighter than a traditional socket. They have also developed PandoFit, a full proprietary software platform based in the cloud, with a range of subscription plans.

Clinics are able to order sockets directly through the platform, streamlining the process even further.

In 2016 Humanity and Inclusion (H&I) completed a pilot study of the 3D printing service delivery model for lower limb prosthetics developed by Prosfit in Togo, Madagascar and Syria. For the technological component of the study, the 3D printed sockets underwent a structural performance test as recommended by ISO 10328, and a pre-clinical trial with 5 volunteers who evaluated the socket's comfort and their experience throughout the fitting process. Results were compared to standard PP sockets manufactured with traditional methods. Findings show that overall, the structural performance of the 3D printed sockets was comparable to the traditionally manufactured ones, but again the socket failure mechanism was brittle fracture for the 3D printed sockets (nb. these were still FDM sockets) and ductile fracture for the traditional PP sockets. All five participants in the pre-clinical trial found the ProsFit 3D printed socket more comfortable than the polypropylene socket and they were also more satisfied with the novel fitting process. The clinical portion of the study involved 17 participants with transtibial amputation (6 Togo, 8 Madagascar, 3 Syria) who were already LLP wearers. Results showed that the 3D printed sockets were associated with a higher increase in comfort and mobility but the small sample size and variability between participants made it impossible to form statistically meaningful results. To note also, these reports were only given immediately after fitting, and no longer term study was done. The 3D printing method showed significantly reduced active work time for the prosthetist. Despite the advantages offered by the service delivery system linked to 3D printed ProsFit sockets, unfortunately the cost of materials and shipping for this trial (approximately $ 2500 per unit vs $1600 per unit in Togo and $1900 per unit vs $800 in Madagascar – more details see reference below) was found to be prohibitive for most low-resourced settings (Tan D et al, 2017). To note however, these costs would likely reduce at scale, and could open up this option.

Remote Camps

The reduced labour time and increased workflow efficiency of digital manufacturing has the potential to be highly suitable for fitting devices in remote locations such as mountain or island communities, refugee camps and during humanitarian crises. This could be achieved by using models similar in nature to either in-clinic or bureau approaches, depending on the specific barriers the scenario presents. The full equipment needed could be transplanted in mobile units. Considerable thought would be required on the correct ground personnel with the right skill sets to deliver appropriate service provision, and to adequately fit and train the prosthetic users. Resources for both socket fabrication and assembly of the other components would be required, with a reliable power source. If these challenges can be adequately addressed, fabrication in the field would allow provision to occur there and then, which could be highly advantageous for hard to access locations, where shipping is unlikely to be easily optimised or might just not be possible. If the question marks over quality can be answered, FDM printing in particular opens up this approach as small sized machines are available, compared to other methods.

Alternatively, if shipping is not a major barrier, fast and lean services tasked with gathering scan data could be deployed, and design & fabrication achieved elsewhere, with devices shipped in from a subcontracted bureau or central location.

Insights

- Digital fabrication of prosthetic sockets promises to decrease the labour burden on clinics and increase the reach of prosthetic clinics, whilst improving user experience. However, to date, this potential has not yet been realised into 'normal' practice. However, the foundations for 'telefabrication' of lower limb prosthetics exist.
- 3D scanning technology is mature and a potentially cost-effective way to support the work of P&O clinics in LMIC settings and improve outcomes. Increased capacity building with scanners could be a low-risk route to unlock future adoption of digital fabrication methods., while retaining the traditional hands-on methods. This would bring added benefits to the clinic, such as digital records.
- There are many varying approaches to each stage of digitally fabricating prosthetic sockets, and the differing cost structure, benefits & challenges of in-clinic vs centralised fabrication means comparison is complex. This makes clarity, and therefore widely achieved trust, difficult to obtain.
- Although digital fabrication of sockets using 3D printing bureaus has been shown to be effective, the price per socket at present is too high for LMICs. If the costs could be brought down, and shipping was reliable - this centralised

approach could greatly unburden P&O teams, and enable an increased number of service points.

- If the technologies required are optimised effectively, in particular FDM printing, then digital fabrication methods could open up a range of service delivery models across low resource settings that are not achievable currently with traditional methods.
- A future possibility is to combine the advantages of both in-clinic and bureau approaches by development of dedicated medically-orientated printing facilities that could house digital fabrication specialists. These could be handling the physical production requirements of a multitude of both AT and other medical products in one facility locally.

Questions unanswered

- There is a lack of published comparative trials larger than a single subject (i.e. n=1), however a 72 person-study (n=72) comparing the outcomes of traditional & CAD/CAM sockets on users has been carried (Karakoç et al. 2017). This highlighted the need for more large-scale randomized controlled studies to assess the efficacy of different methods used in manufacturing sockets.
- A major design problem to be addressed is the need to eliminate the brittle failure mode of the 3D printing of sockets which has been highlighted by multiple trials. This is a barrier to the widespread implementation of digital fabrication, and poses risks in trials (Pousett, Lizcano, and Raschke 2019)

- It is unfortunate that not more of the trials being conducted are included in the formal published literature, particularly as this makes separating out conflicts of interest from literature originating from in-house studies more difficult. It would be beneficial for this to be addressed and would require further collaborations between research institutions and industry.
- The issues identified by the LMIC trials discussed show the need for user trials to be conducted in the context that the technology is aimed at, as well as allowing infrastructure and technological literacy to be adequately assessed as a barrier to adoption.
- The risk of harm from any adverse events however is potentially much higher in LMICs, due to the subjects' circumstances and ability to resolve encountered issues. Sufficient initial study conducted in high income settings before continuing in LMICs is therefore preferable when possible.

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