Report on the TIDAL Network Plus Feasibility Project: An affordable and flexible prosthetic socket

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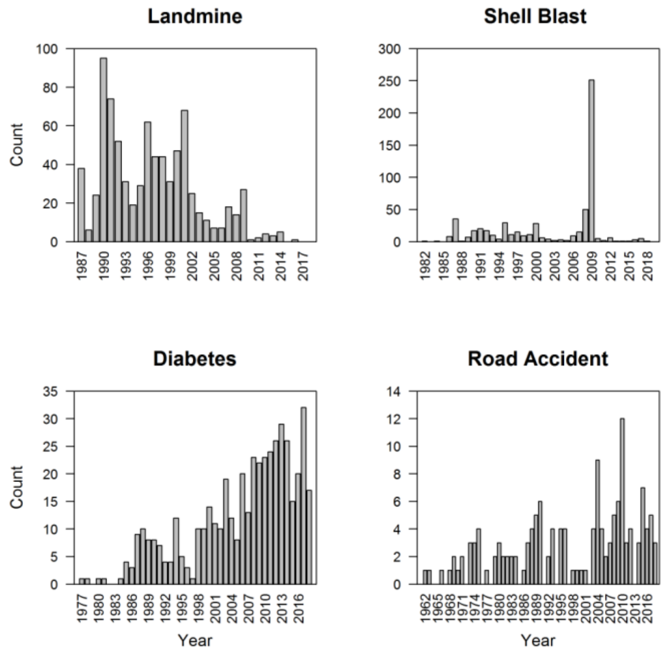
What we set out to discover

Background and research context

Globally, the number of lower limb amputees is on the rise (Cieza et al., 2020). Among lower limb amputees (LLAs), mobility it highly correlated with quality of life, as it enables the prosthetic user to engage in activities such as standing, walking, and carrying loads. Mobility additionally increases employability, aiding to local and global economic growth (Boone, 2019; Musselwhite and Haddad, 2010). The manufacture and delivery of prosthetics in LMICs often falls to humanitarian organisations or charities, with occasional governmental aid (personal communications, TATCOT Tanzania and throughout Sri Lanka). This limits the number of LLAs who can receive a prosthetic. Many LMICs utilize polypropylene prosthetic technology (without liners), which requires a trained prosthetist for socket manufacture, many LLAs go without prosthetics or are stuck with ill-fitting sockets (as small amounts of weight gain/loss can cause problems with prosthetic fit). This can lead to skin lesions due to friction on the residual limb, decreased mobility, and/or prosthetic abandonment. The polypropylene is additionally not recyclable and must be shipped in from foreign countries (e.g., Switzerland), creating a large carbon footprint. A flexible lower limb prosthetic socket, not requiring a prosthetist to manufacture locally, made from sustainable materials would increase LLA mobility, improve LLA quality of life, decrease abandonment, and – if manufactured from local sustainable materials – decrease carbon footprint. As northern Sri Lanka has a large population of LLAs due to their ~30 year mine-based civil war, and have an increasing diabetic amputee population (Fig 1), they are ideal to work with here.

Engineering / research challenge and why it matters



Globally, the number of LLA is on the rise due to road traffic accidents and diabetes mellitus. This is particularly true for many LMICs where diabetic-related amputations are on the rise (e.g., Sri Lanka; Fig 1 unpublished data from the Jaffna Jaipur Centre for Disability Rehabilitation, JJCDR) and affordable motorbikes from China are becoming increasingly popular (e.g., Cambodia, Tanzania; personal communications). Globally, the supply of prosthetics is limited by the number of prosthetists, who – using polypropylene technology – mould sockets to each patient, individually. Given the lifecycle of prosthetics, only an estimated 10% of individuals with lower limb loss have prosthetic devices (Zahedi, personal communications). No flexible socket for LLAs exists in the current market. Given the current unmet demand and increasing lower limb amputee population (Cieza et al., 2020), such a novel device is needed.

Aims and objectives for the project

The primary aim of this research is to design and test a sustainable, environmentally friendly flexible prosthetic socket for lower limb amputees which is locally manufacturable. The device will be co-designed with prosthetists, amputees, and medical professionals in northern Sri Lanka to reduce the risk of abandonment, and ensure the design will be sustainable past the lifetime of this project.

To achieve the same reset the following objectives:

1. Run a digital co-design workshops centred around the ideas of sustainability and affordability
2. Finalize two or more socket designs and create digital computer aided design (CAD) models
3. Create prototypes of the sockets and test their mechanical performance

Designs will be altered and prototyped for improvement but the limited timespan of this project prohibits and substantial iterative design from taking place.

What we did

We set two work packages (WPs), WP1 was a end-user co-design workshop, and WP2 was the creation and testing of the new prosthetic socket designs.

Pre-grant work: After submission and prior to grant outcome, Berthaume ran similar co-design workshops in Sri Lanka focused on the design prosthetic feet. From this workshop, he found results from workshops varied greatly depending on if they included medical professionals or individuals with limb loss. He also discovered severe limitations of what could be done remotely, mostly due to unfamiliarity with the co-design method for the target group, and the state of the government (e.g., economic crisis, president being overthrown in summer 2022) and that it would not be possible to run digital workshops (e.g., lack of devices with video internet, lack of know-how in target group, lack of stable internet). After the grant was awarded, Andrews searched for a design company in Sri Lanka which could run the co-design workshop that was needed, and one could not be identified. The following decisions were then made:

1. As we were gathering data in Sri Lanka in March 2023 for a separate project, it was decided we would run an in-person co-design workshop there as well to gather our data with a decreased carbon footprint.
2. We would team up with Exceed Worldwide to gather end-user data in Cambodia, enabling our design to be informed by more than one LMIC.

Prior to the grants start, we submitted an amendment to our existing ethics both at LSBU and the University of Jaffna to allow for the gathering of data in Sri Lanka. The Cambodia side of the project would first require ethics to be approved by the Cambodian government before LSBU would approve the application. When the grant began (January 2023), my PhD student, Gemma Ranson, suspended her studies to work full-time on the grant and our amendment to our ethics application was approved. Ethics was not approved for the Cambodian research until May.

Pre-workshop: While waiting for the data to be gathered through Sri Lanka, we prepared for the workshop and worked with Cambodia to get ethical approval for this part of the project. We also began a literature review on flexible load bearing prosthetics (published academic literature, patents, companies, etc.) and were invited by the editor of Annals of Biomedical Engineering to submit there. We anticipate this manuscript will be submitted in March 2024.

Sri Lankan workshop: Unfortunately, given the economic state in Sri Lanka, we were only able to recruit 5 people to the workshop, instead of the targeted 15 which we had at the previous workshop. Participants provided useful information (see next section).

Cambodian data: Given the difference in opinions between medical professionals and those with limb-loss, we took a two-prong approach. First, we ran a workshop with medical professionals from three centres across the country. Second, we had our collaborators (hired using the consultancy funds in this grant) conduct interviews with 20 individuals with lower limb loss. Despite receiving ethical approval for the project in May and conveying the urgency of this data to be gathered quickly, the workshop did not take place until 25 September, and interviews are still ongoing. As of 29 November, 7 interviews were complete and 13 outstanding. Part of the reason for the delay is our collaborators are translating the results into English. As such, this information did not inform our designs.

Designs and prototypes: We focused on inspiration from unlikely sources, namely, toys, for our designs and prototypes. CAD models of three prototypes were constructed in April, following the co-design workshop in Sri Lankas, and discussions with others at ISPO in Mexico. Designs were altered in May, and parts were ordered over the next month for construction. Prototypes were finished in July/August for testing.

Testing: Berthaume and Ranson brought the prototypes to Southampton for testing. No standardized testing exists for lower-limb prosthetic sockets. As such, we used a method developed by Dickinson and his colleagues where a model of a residual transtibial limb is placed in the socket and loaded to quantify interfragmentary motion of a residual limb during loading (imaged in Diondo d5 system at The National X-ray Computed Tomography facility, NXCT, free of charge; Figure 1).

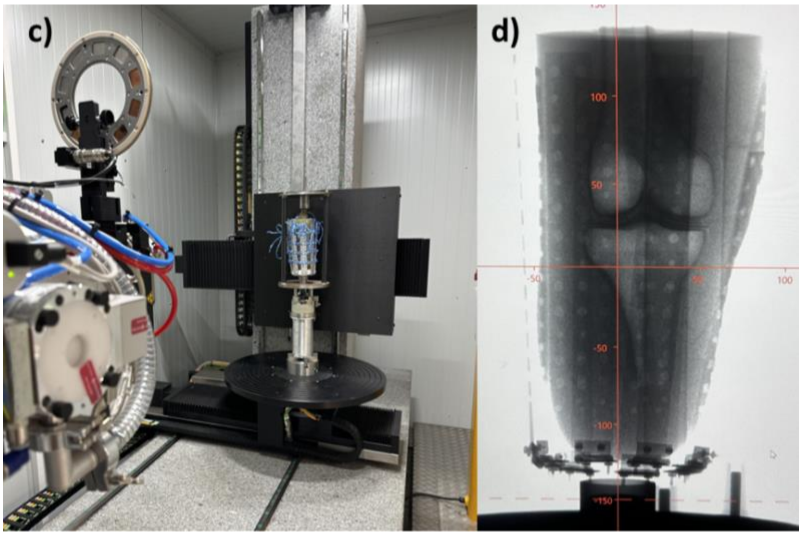


Figure 1: (left) prototype of the flexible socket in the testing rig, (right) image of residual limb in one of the prototypes.

On the day of testing, we discovered some issues:

1. Prototypes were not as structurally sound as anticipated. Namely, a lack of locking washers meant screws/bolts were coming loose.
2. Due to time constraints, FE analyses were not run, and the aluminium used for the prototypes was too loose and bending when loaded.
3. The technician in charge of the scanner was concerned the prototypes may break when loaded and cause damage to the scanner. As such, we were not able to load the prototypes.

What we found

Pre-workshop: We found a wide range of definitions for what people considered "flexible" sockets to be. Most people thought about the socket as two pieces – a hard, rigid outer casing for structural support, and a soft, dampening liner to prevent areas of high pressure from forming. People we discussed the issue with often had difficulty in discussing the socket as a single unit, instead often asking whether we were talking about the outer casing or liner. When we said "both" as they are both parts of the socket, they would often get confused and only answer about one of these components. This was reflected by the literature. While a clear reason developed for why the socket was not a single component (what material/structure could be soft and rigid at the same time?) no reason seemed to emerge for why it was two and not three or more components. For example, it could be a soft liner (comfort) within a dampening mechanism which in turn interacted with the hard liner. Ultimately, any changes in material were often considered as part of the liner, while any changes in morphology were often considered part of the outer casing. Because of this, we ultimately decided to focus on the outer casing moving forward, as we were focusing on morphological changes to the socket. Where possible, we tried to integrate the function of the liner into our design as well.

Our manuscript is well underway, and we are currently finishing the sustainability section. The review will focus on flexible sockets with applications for LMICs.

Sri Lankan workshop: During the foot design workshop in the summer 2022, we discovered our workshop participants were excellent at problem identification (the Discover/Define stages of the Double Diamond approach) but lacked original thinking in the solution phase (Develop/Deliver). As such, we focused on problem identification, and had information discussions that would aid in creating solutions. Major problems with current lower-limb prosthetic socket design included:

1. Sores developing from ill-fitting sockets.
2. A lack of proper liners. Military socks were commonly used as liners, which quickly wore down creating friction instead of dampening in the socket. Too expensive to replace regularly. Regular socks were not as thick or efficient.
3. Materials were unreliable. Polypropylene needed to be imported and given the state of the economy, could not be done so reliably. Local materials would be better.
4. Materials were expensive. Being a charity, which has historically survived primarily on donations, they had issues with financing the socket material, especially 10 years post-civil war when the international community had mostly forgotten them.

The participants thought flexible sockets would be good, both in terms of enabling those with limb-loss the freedom to reduce areas of high pressure and relieving pressures to defiler services from the P&O centre, which was struggling financially. Additionally, the following avenues were discussed as possible solutions:

Figure 2: Wicker prosthetic socket from Cambodia.

1. Creation of cloth-based devices. Approximately 10% of Sri Lankans are employed by the clothing industry, making it a readily available supply in the country. A local charity additionally helped employ amputees in making dresses and clothing for the local community, and this charity could be leveraged.

2. Creation of frond-based sockets. Palm fronds are common in Sri Lanka, and there is a history and tradition of weaving baskets from the fronds. Sockets could be woven, creating a locally manufacturable, organic prosthetic socket.

The second avenue is particularly interesting, and one we wish to investigate further in the future as it aligns with our goals of sustainability in materials, and sustainability in knowledge base (leveraging basket weaving traditions). It may be easier to implement as well, as wicker prosthetic sockets have been used in other SE Asian countries (e.g., Figure 2, photograph courtesy of Kurzman).

Cambodian data: Data from the interviews is currently being gathered. Data from the workshop, aimed at identifying issues and problems with the sockets, has been gathered but not analysed in depth. The main problems identified by the participants (structured as "how might we statements") are:

1. How might we make the socket linear and easy to don and doff?
2. How might we reduce the sweating and smell of the client devices?
3. How might we prevent the breaking of the SACH foot?
4. How might we do to make a prosthesis comfortable during cross-leg sitting?
5. How might we make prosthetics without hearing the knocking sound when the SACH foot broken?

Designs included increasing prosthetic modularity (portions that can be removed and cleaned) and ventilation (creating holes in the hard prosthetic exterior). Much useful information was obtained which can be included in iterative designs.

Designs and prototypes: The three prototypes were based on concepts of self-tightening (based on the Chinese finger trap), modularity (many panels held together by string, tied together like laces on a shoe), and flexibility (based on the design of Roman sandals). All prototypes had an aluminium based to allow the socket to attach to the pylon. A few lessons were learned here:

1. The collapsing portion of the Chinese finger trap was made of nylon strap, which had trouble maintaining its structural integrity when a mock residual limb was not in place. We have ideas on how to improve this for the future
2. The aluminium components used were thin for flexibility, but too thin for the designs. Aluminium was chosen as it is light, transfers heat effectively, and can be readily manufactured from recycled material, like cans.
3. The sockets need to be made from fewer moving components, like screws and bolts. Some, like string (mimicking laces) is appropriate and necessary, as it is meant to be flexible, but components that are not meant to be flexible should be more rigid.

Testing: Two issues came up during testing. The proper risk assessment was not completed before testing took place (which we were unaware was needed), and as such the technician was uncomfortable conducting the tests. Additionally, the sockets were not working well, and we were afraid the aluminium would fail. In lieu of the planned tests, the following data was collected:

1. Testing of standard sockets: standard transtibial sockets (patellar tendon bearing [PTB] and total surface bearing [TSB]) were tested, to see how much the residual bone translated during loading.
2. Imaging of designs (Figure 1): as it can be difficult to image metal using X-ray scanning, we took some preliminary 3D scans to see how much back-scatter there was, and whether we would be able to see interfragmentary motion of a residual limb during loading. We found that, despite backscatter, it was possible, meaning we would be able to conduct successful tests in the future, should better prototypes be made.

What this means

There appears a need for a different, new way of looking at the prosthetic socket. Issues of sustainability in terms of skills, environment, and economics came up in both Sri Lanka and Cambodia. Use of local skills and resources would be beneficial. Problems identified by medical professionals mainly concern comfort and perception (smell, sound), and not functionality. In Sri Lanka, there were issues with prosthetic fit, likely because the one trained prosthetist at the P&O centre quit in April 2022 (which we learned on our trip there), and the technicians making the sockets were not professionally trained but learned from him. The lack of centralized professional bodies ensuring patients are receiving adequate prosthetic care in LMICs likely means this problem is more widespread than just this one charity in northern Sri Lanka. While people at this charity have the option of becoming a trained prosthetist, it would require them living far from home for 3 years, and the increase in pay would not offset the costs for decades, so there is no motivation to become trained.

From both our previous workshop and these ones, we found it is often difficult to discuss prosthetics as individual components. Often, the problems and issues discussed are those most pertinent to the person being talked to, and thus not necessarily related to the part of the prosthetic they are being questioned about (e.g., sound coming from the prosthetic foot when discussing a socket, above). This problem was even more confounded in a workshop we ran with those with limb loss previously when discussing the prosthetic foot, as it became evident the participants viewed the prosthetic device as an extension of their bodies. It therefore become difficult to discuss the object as anything more than the sum of its components.

We found errors with our designs which can be remedied and found that we can conduct effective compression tests using the setup at Southampton. We also learned how to better design the prototypes for this testing in the future.

What next

We have a journal paper which we plan to submit in the next 6 months. We will be continuing gathering data in Cambodia and will analyse the data when gathered. We aim to turn this data into a publication in an international journal. Originally, we planned to publish results from the Sri Lankan workshop in a local journal from the university. However, what we learned at this workshop was of limited value, and as such as have decided against publishing it on its own.

We have kept an eye on the funding landscape, with the aim of identifying a large grant to continue the project. We are currently considering a mid-sized (£100k) grant, due 30 January, to investigate prosthetic design from a historical perspective, as it became obvious from our literature review that flexible sockets used to be much more common (e.g., leather sockets), and our project could benefit from a better understanding of why flexible prosthetic sockets in the past have been replaced.

We additionally plan on applying for additional seed funding, through King's College London's sustainability centre, to refine our designs and prototypes, focusing on the materials from which they are constructed.