Unlocking Sustainable and Resilient Assistive Technology Innovation and Delivery Ecosystems: Personalised Co-creation of Locally Produced Prosthetics

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Introduction

The World Health Organisation (WHO) estimates that while in high-income countries a median of 64% of people who need assistive products, e.g. prosthetics, wheelchairs and hearing aids, have access to them, in medium and low -income countries, the rates of access are much lower at 33% and 11% respectively [1].

Assistive technology (AT) is the umbrella term for the combination of assistive products (APs) and the services needed to ensure safe assessment, distribution and use of APs. An AP is any physical or digital device which is external to the human body, whose primary purpose is to maintain or improve an individual's functioning and independence and thereby promote their well-being [2]

Globalisation, particularly the pairing of mass production and global supply chains, is a hugely effective model for providing manufactured assistive products, vital for AT provision. However, this has produced monopolies with one-size-fits-all solutions and limited access to parts. This leads to barriers to repair strategies and reduced context-specific innovation, making more local service provision elements harder to implement or improve for many low-income countries [4]. Within the AT2030 Programme, funded by the Foreign Commonwealth and Development Office and led by Global Disability Innovation Hub, our project, situated in Nepal, aims to examine where more localised product and service innovation that complements global systems could unlock more sustainable, resilient AT innovation and delivery ecosystems [5] .

Understanding the in-country context is key to building sustainable production and provision systems [6,7] . In Nepal, available data states that 2.2% of people have some form of disability, however as compared to global averages, this is assumed to be hugely underestimated, and may be higher than the global average, due to injury rates [8–10]. Healthcare and technological innovation are just advancing, and given the geographical and economic conditions, the need for local production of assistive products is high.

In Nepal there are several institutions - NGOs, INGOs, governmental agencies, private clinics and P&O centres actively working to provide AT and rehabilitation. While the manufacturing sector is small in Nepal, multiple innovators have attempted or are currently innovating assistive products for the Nepali market. These innovations often address a specific contextual need such as the extremely challenging, mountainous terrain, internal logistics and/or that the available imported products are often not fit for purpose or simply unavailable. Another factor is that product material access issues point towards local resource use as a potential for improving access due to difficult logistics and import duty barriers [4].

Innovating in these settings is difficult, yet great effort is still put into striving for success - these innovations and the Nepali context display the wider global need for multiple models of sustainable AT design, production and delivery, with both mass-produced routes and smaller scall local actions [5,6].

Holloway et al. (2021) have analysed in-depth the existing strategies and processes that have been applied to improving access to AT [3]. As well as other findings, they found two themes that showed as opportunity areas – that of open innovation (OI) and radical & disruptive innovation. They highlight that innovation systems themselves are complex systems, involving a collaborative process between several stakeholders including research institutions, companies and universities [11]. A systems approach is therefore key to understanding and strengthening AT provision and innovation. A systems approach is also needed for AT to be equitably allocated across the population and life course [3,12]. The recent WHO Global Report on AT has put forth ten significant recommendations for nations, calling for increased collaboration and specifically research and investment into the enabling ecosystem around AT innovation [13] .

In this paper we present a description and reflections on our innovation journey so far on chosen elements within the AT2030 Local Systems Strengthening project where we aim to develop and support the AT innovation ecosystem in Nepal.

We describe:

- The development of a global-local community that has set the directions of our work
- An overview of the workstreams set by this community of practice
- From this community, the construction of an interdisciplinary innovation team looking at bespoke product developments in Kathmandu
- Preliminary results on two ongoing bespoke product development cases

Through these two product development cases we will discuss how we aim to address individualised needs and achieve quality processes throughout, as well as understanding how global and local expertise can efficiently collaborate to enable innovation that might not easily fit in many business models.

Current Assistive Technology Provision in Nepal

Nepal has come a long way in recognizing the vital role of assistive technology in the realm of disability rehabilitation. However, it was only in 2015 that the Ministry of Health and Population took a significant step forward by designating the then Leprosy Division as the central unit responsible for disability-related matters within the health sector. Following the devastating earthquake that same year, there was a growing awareness of the pressing need for rehabilitation services [14]. Initially, rehabilitation primarily focused on physiotherapy, which has seen notable improvements over time [14,15]. However, the realization that assistive technology forms an integral part of rehabilitation has been gradually taking root, though there is still progress to be made in fully meeting this need [16].

Under the leadership of the now named Leprosy Control and Disability Management Section, commitment is evident through the creation of various pivotal policy documents and strategic frameworks, such as the National Standards for Assistive Technology, and a Priority Assistive Product list. Notably, they have been actively formulating a Disability Management Policy, a comprehensive Strategy, and a 10-year Action Plan. The provision of training programs, such as Disability Management and Rehabilitation training for primary care health professionals, and the Training on Assistive Product (TAP) initiative, serve as essential building blocks in fostering awareness and understanding of assistive technologies at the national level.

Currently, a situation prevails where both goods and individuals are reliant on imports from abroad, even for basic raw materials, which threatens long-term stability due to increased dependency [13]. Accessing accessory services now often requires individuals to bear the financial burden themselves [13,17]. In Nepal, while the Social Welfare Council has allocated some budgetary resources to offer free services through select service providers, local government municipalities have also begun providing certain financial support [17]. Nonetheless, the development of proper mechanisms for achieving Universal Health Coverage (UHC) remains a work in progress.

From the perspective of current or potential AT users, there is difficulty finding service providers and limited or no access to knowledge on what products are available to them [8,17,18]. There is also a misconception that simply getting a physical product or technology is the journey done. This often disregards the individualised needs of the person, rehabilitation, training and service elements that are crucial to the successful outcome of AT provision [14] . Where provision does occur, AT users have difficulty getting the right product and the right fit, or devices suitable for the terrain [17,18 People] struggle to maintain the products they use – e.g. fixing wheelchairs, repairing prosthetics – whether personally or through employed services [17,19]. Ultimately this results in devices being unusable and abandoned, with people likely losing faith in the potential benefit of AT on their lives [13].

For service providers, supply of products and materials is always a limiting factor for provision. There is also a lack of improved or updated technologies to produce appropriate products, while at the same time the misplaced view that 3D printing and advanced technologies are catch-all solutions can hinder some developments [5] . Imported products dominate the market, and while these products are a crucial part of the puzzle, too often they are found to be inappropriate and not fit for purpose, and limit the potential for service innovation. While there are innovators working to develop local technologies, the ecosystem around them, both locally and globally, is restrictive. There are strong signals of action to improve this, and we look to enable the ecosystem with grassroots innovation leadership to tackle this national problem.

Approaches for AT Innovation

As said, a systems approach is key to understanding and strengthening AT provision and innovation [3]. However, trying to enact change at the system level brings many challenges. Holloway et al. (2021) discuss 'Path dependence' [20] – a prevalent concept in the innovation literature [21] – which may be used to explain resistance to change within a system [3]. As noted by Ussitalo et al (2020) [22] past decisions have "been found to lock organisations onto pathways that constrain future choices and limit their ability to respond to changes." For instance, path dependency has been used to explain inadequate healthcare policies[23].

We can see this path dependency on a grander scale at play in the current manufacturing systems prevalent globally. Mass manufacture has driven the global technological advancement that was seen in the 20th century and present day, however as this mode of production has monopolised the global economy, it has also inadvertently made our systems hostile to any other model.

Increased localisation of production brings the potential to vastly increased resource efficiency through the move to a more circular economy (CE). Oldfrey et al. (2021) discuss at the opportunities that thinking around CE could address issues that are currently outstanding in global assistive technology provision [5]. Resource management strategies are extremely difficult to achieve when design and manufacture occurs overseas [5]. CE thinking demands that the whole production value chain and product life span be the object of innovation, rather than just the product. If the 'system' is just as much the barrier as the design of available products is, then our innovation practices should reflect this.

A critical aspect of AT provision that is highly challenging and often completely unaddressed for low resource settings is the provision of devices that address complex needs - due to a lack of local innovation and manufacturing capacities. If a device needs to be made either fully or partially bespoke, there is no product to mass-manufacture and import. Likely only through local capacity building that can be retained into the long term, and therefore have the opportunity to mature that these challenges can really be addressed, however this is a huge systems problem. Innovation cannot easily be achieved in a vacuum, it requires a large enabling environment for an idea to have a chance of growing into a solid market offering.

Discussing trends in distributed manufacturing systems, Matt et al. (2015) state that in the future, long-established paradigms of production must continue to change to meet the demand for even more individuality, customer-specific product variants and shortest delivery times combined with sustainable and human manufacturing processes [24] . They go on to say that new and innovative ways of organizing production operations will be needed to address the increasingly loud requests for sustainable and ecologically healthy production and distribution - decentralized manufacturing systems show an ideal approach because the production occurs closer to the customer [24]. For these reasons, innovation must bring the flexibility that is needed to deliver these demands, as well as respond to unstable market conditions. A route to flexibility is through likely through more open modes of innovation and production [25] .

Moving the discussion back to innovation practices now, Holloway et al. found that Open Innovation (OI) is frequently used as a strategy by adjacent to AT initiatives, however, it appeared lacking from the AT sector as a whole. OI can often be confused with open-source innovation. OI does not mean cost-free; OI typically means incentives, such as license fees, would be paid between actors [26]. OI was defined as the use of "purposeful inflows and outflows of knowledge to accelerate internal innovation and expand the markets or external use of innovation respectively" [27]. It has been described as a paradigm shift which assumes internal and external ideas should be used to create innovations within products, supply and provision. Inherent to OI is the need to collaborate.

The need for multi-stakeholder innovation approaches in assistive technology has been recognised for some time [28], however this does not mean in reality that this is fully established practice. Oldfrey et al. (2024), in reviewing the study designs of available literature on digital fabrication of prosthetics and orthotics showed that there is a surprising lack of obvious clinician input to many early-stage prosthetics and orthotics innovation, let alone direct influence from users themselves [29]. Many articles cite only engineers as present in the team. It is at these early stages that fundamental design principles are embedded, and cannot as easily be modified later on. Boger et al. discusses this for other AT, arguing for the move to 'transdisciplinary' developments [28]. Collaboration involving experts from multiple relevant areas working together is more likely to result in a more comprehensive understanding of the problem space by enabling access to diverse perspectives and new ways of thinking that would be unknown or not considered by a single-discipline group [28].

In previous periods, development of AT often failed to adequately include AT users – the people who are ultimately the ones who will rely on the technology to live their day to day lives [30]. However, codesign with AT users is now becoming much more common place, with a growing body of literature and with many groups now stating that user-involvement in design is not optional [31–35]. However, for LMIC focused product development, this often still means foreign design teams (potentially academic only for concept stages of development) + local user groups, likely with a translator being required, who's only role is direct translation. This is sub-optimal, particularly where there may be large language and cultural barriers. For the automobile industry or mobile phones maybe, this might adequately reflect the delivery of products to consumers. However, for assistive technology, there are a myriad other vital stakeholders that come in-between simply an engineer designing an assistive product and a user using it[34,36]. Better bridging could help to more fully allow user engagement in the design process, and occupational therapists in particular could help facilitate this, as well as bringing their valuable expertise[36,37].

In a well-functioning AT provision system, as found in various high-income countries, the user would likely first engage with an allied health professional, ie. a community health worker, and referral may be made to a occupational therapist or physiotherapist. In the case of prosthetics, the user may go directly to a prosthetist for guidance, fitting and provision. They would likely then return to longer term engagement with an occupational therapist or physiotherapist for monitoring and continued rehabilitation and guidance.

This is huge simplification, with different needs requiring completely different service pathways, however the list of job roles will likely be the same and specialisms within those job roles changing accordingly. The need for higher focus on product-service innovation is growing – many industries are moving to models that support consumers beyond initial purchase. Core mobility product provision, ie. prosthetics, orthotics and wheelchairs is already aimed to be a 'product-service'. Most devices need custom fitting in some way, and training and rehabilitation is needed for a product to be used effectively or at all.

We advocate in this work for building innovation teams that have more hope of achieving systems-based solutions, that reflect an ideal provision process. We see this lack of full value chain thinking as being highly problematic for AT, where a product is intrinsically linked to the system of provision, as well as the system of innovation.

This inevitably creates problems in itself however as a larger team is much harder to operate than a smaller one. Literature on 'team science' has grown in recent years, which investigates this, and we will discuss what we found to be the challenges that this creates [38,39] . Boger et al. discuss this, stating that the complexities associated with assembling and managing a transdisciplinary group should be weighed carefully against its necessity because there are many problems that may be solved as a multi-, inter-, or even intra-disciplinary team. In general, the more simple, well-defined, and static (or linear) a problem is, the less it will require many disciplines or sectors to solve it, particularly if there are clear directions to probable solutions.

There has been much recent work on strategies to allow the end users of assistive technology to collaborate and access making facilities and expertise, with digital design and fabrication being important tools to make that happen. As a result, so called 'DIY-AT' approaches that result from this is an interesting new model by which various APs can be made [31,40,41]. These are often less formal, concerning products that don't require a clinician to fit and particularly which would be difficult to commercialise anyway. University settings, by virtue of often having multiple digital fabrication and clinical experts in training as well as a population of students with disabilities, provide exciting opportunities for creating and refining interdisciplinary collaborative processes for creating DIY-ATs [42,43]. They argue that although makerspaces have the potential to support the democratization of AT development [42–45]. Research has shown that historically these spaces are often not inclusive and can recreate systems of oppression [46]. Higgins et al. (2023) makes the case however, also working through a transdisciplinary approach, that co-designing DIY-AT is a way to investigate questions of social justice [42].

This leaves us with questions of how these models can interact. On the spectrum from traditional, formal production of certified APs fitted in clinics, to these informal 'DIY-AT' endeavours, multiple articles point to there being a middle ground. Newer expert-level generalised digital fabrication services and existing traditional manufacturing capacities could be linked to the formal provision system, with appropriate clinical oversight and rehabilitation planning. If inefficiencies could be overcome, this ecosystem approach could safely fill gaps in service. With these ideas and philosophies on what a local system of AT innovation could look like and achieve, we move on to describing our work that aims to do this.

Community Building with Enabling Fridays Consortium

Methods

To track progress in our community and team development and facilitate evaluation of the various stages of activity described in this article, all group sessions were recorded and documented manually with the consent of all participants involved.

The relationship between Zener Technologies, a digital manufacturing and innovation company in Kathmandu and the GDI Hub started during the covid pandemic, on a different FCDO programme, aimed at locally producing medical devices across 6 countries, which resulted in the production of 20000+ products in Nepal [47]. When this programme finished, and the focus of the personnel involved was placed back on AT and the AT2030 programme, this highly successful partnership was seen as a strong opportunity to develop innovation projects with a focus on local production systems.

It was a major aim that a resilient ecosystem be developed building on existing capacities that already exist in Nepal, but might not currently work together. It was important that the directions for work were developed with the community, so that the right, context specific objectives were developed and the ownership of the project was shared.

To begin this, a global-local community was formed, The Enabling Fridays Community (EFC) which aimed to bring together local and global expertise working in the AT sector to identify routes that would unlock local innovation and improve current gaps in service. We convened our initial stakeholder group over 4 2-hour sessions to collectively define problem indicators and set an agenda for what the next steps should be.

Our aim was to create a forum that brought together local actors and stakeholders to discuss ways forward. There was a large variety of ideas that the group came up with, but clear was the desire to move to some actionable work quickly to test and develop the collaboration format.

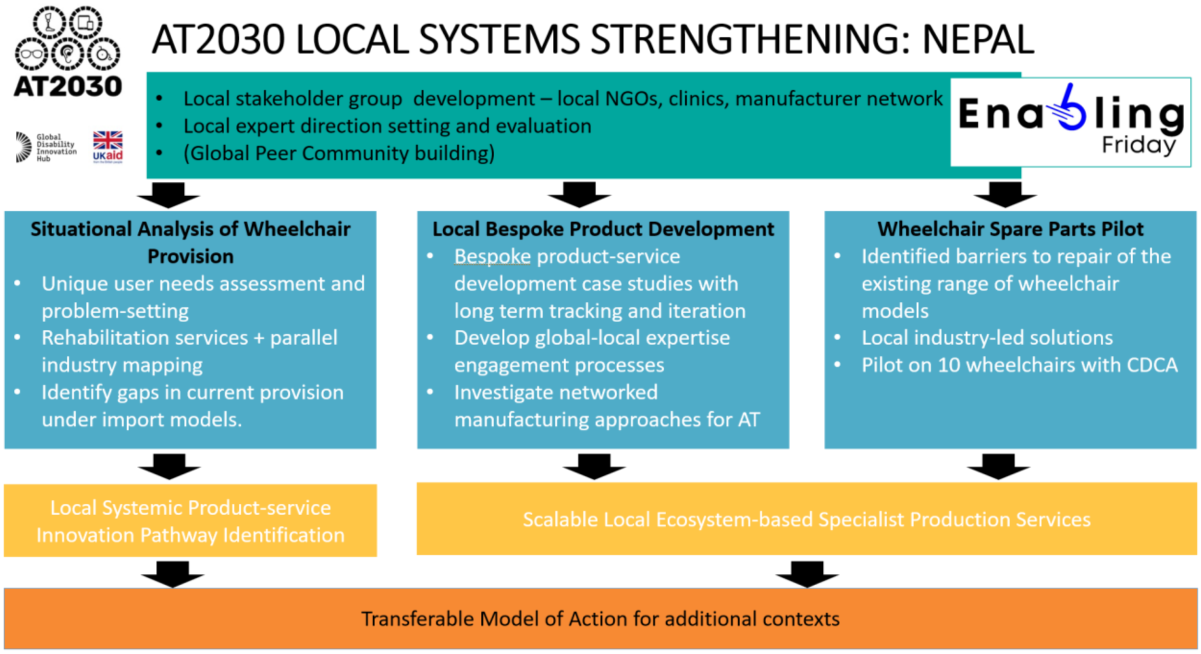

Figure 1: An overview of the initial workstreams of the Local Systems Strengthening Project

Regardless of what the specific projects are there were some clear directives that the EFC wanted to see. There was a strong desire to look at the whole provision process, not just innovation, looking at what already exists, but needs development and support, rather than jumping to brand new technologies. Service delivery should be centred around clinical expertise rather than replacing them. And the community decision making process should be inclusive of people of disabilities, providers and producers working together to develop skills and solutions.

From the EFC sessions, 3 work streams were devised, with specific aims in each, which can be seen in Figure 1. The following sections will give some key details of the bespoke product developments.

Global-Local Innovation Team Development

From the EFC community a global-local innovation team was defined, and additional members recruited. These comprised key elements:

- Engineering – local academic & local industry
- Clinical Prosthetist – Established Local Clinic
- Occupational Therapist – Established local practice and global expert
- Global AT Innovation Specialists

Two individual cases were identified within the Kathmandu area. The case studies were chosen to address an individual user need now, with the longer term goal of building the team's capacity to work together and address further innovation challenges. Crucial to this long term picture is the development of what the team needs to attract and retain funding sources to enable the resilient continued expansion and retention of innovation and mature service delivery capacity. Evidencing the developed capacities is a key part of enabling this needed funding.

Through initial goal setting and ideation sessions, the team decided upon a set of key objectives that we would focus upon in order to keep both the short term and long term aims in mind throughout the work. These are summarised in Figure 2.

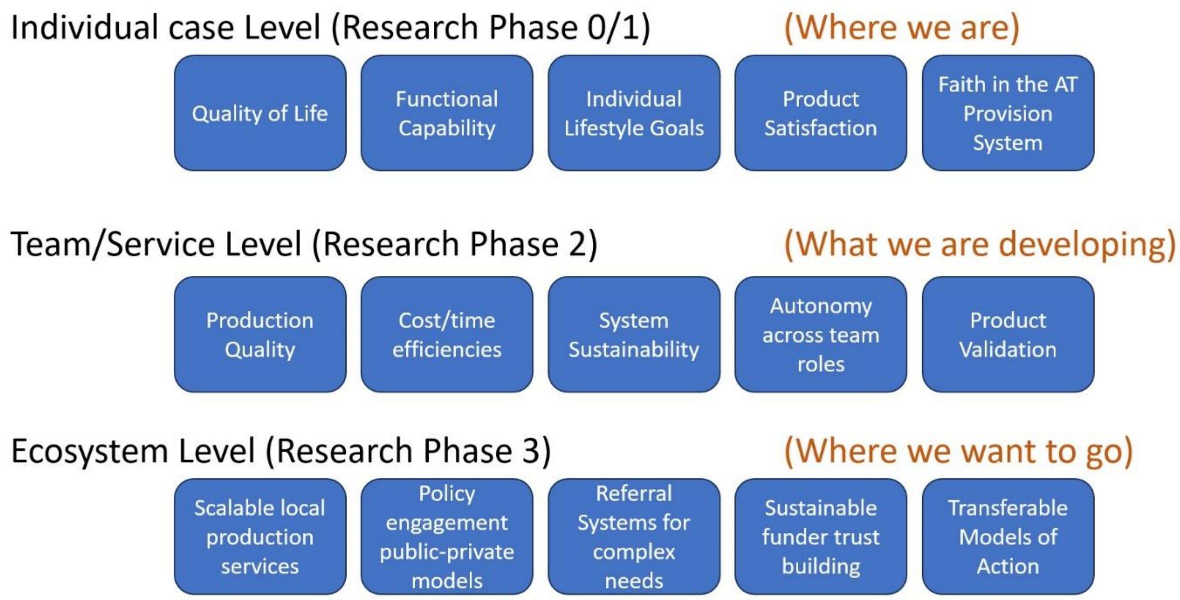

Figure 2: A breakdown of the key objectives across the project

Individual Case Level

The most prioritised intentions of the work must first centre on the participants and our duty of care towards them. The needs and outcomes for the chosen participants, directed by them, with the support of the team. These aims were summarised as:

- Quality of Life
- Functional Capability
- Individual Life Goals
- Product Satisfaction
- Faith in the AT provision System

In order to achieve these goals, a person-centred approach was used. We do this by understanding the person's narrative /story, the context or environment in which they live and work to match solutions into everyday living, at the right time. with the best solution and built in follow up mechanisms to support successful assistive product use, which promotes sustainable use of the assistive technology that is meaningful and fulfilling to the individual's life. An important additional aim for the team was the creation of faith that the AT provision system will continue to provide for their needs. Without this faith, disillusionment and abandonment are commonly seen, with users not seeking further AT as an option for their lives[37,48].

Team/Service Level

With the individual case priorities set, the outcomes for team development with a view to service delivery comes next in terms of importance, with the intention following these product developments to increase team efficacy. 5 key areas were identified that represent this:

- Production Quality
- Cost/time efficiencies
- System sustainability
- Autonomy across team roles
- Product Validation

It was recognised very quickly that the way the team will work together during these first pilot phases would not be the way a service delivery would be achieved, although it could be viewed as a self-directed training period. In later phases, that implement product delivery with the designs complete, team processes will be developed that better emulate service delivery.

Ecosystem Level

Work such as this does not happen in isolation. The state of the ecosystem in which the team operates is hugely influential. Finally the longest term priorities therefore lie in the development of an ecosystem that can continue to support various workstreams. The goals at this level encompass work from other workstreams, but can be discussed in terms of the product developments. Aims in the long term comprise:

- Scalable local production services
- Policy Engagement & Public-Private Models
- Referral Systems for complex needs
- Sustainable funder trust building
- Transferable Models of Action

Design and Tracking Process Overview

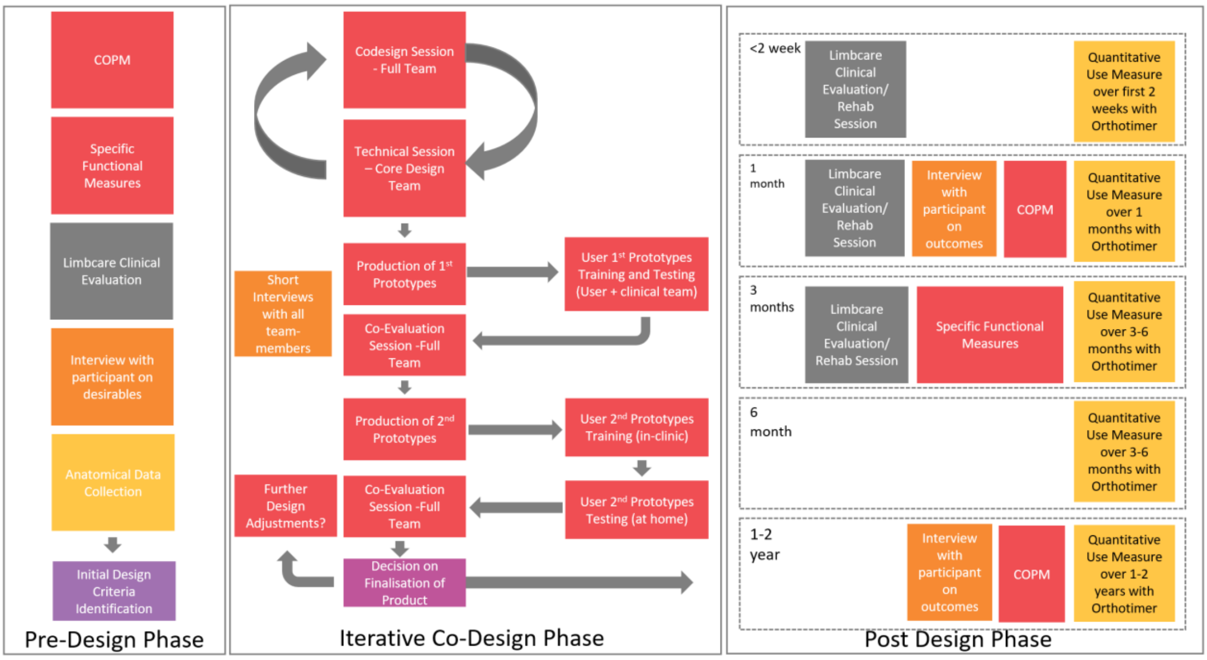

Figure 3: Intended innovation and Investigation Process Breakdown

An overview of the intended design, production, and testing phases is given in Figure 3. These begin with a pre-design phase for data collection concerning the case. Following this pre-design phase, within the first whole group design session. The initial data collection was discussed and broken down further into key design criteria for the products.

Case Studies

Methods

For the bespoke product developments, a range of qualitative and quantitative methods are being used to both inform design processes and evaluate outcomes. These comprised Initial qualitative interviews, the Canadian Occupational Performance Measure (COPM), Patient Specific Functional Scale (PSFS), Plus-M Test, Amp Pro, 2 Minute Walk Test (2MWT), 4 Square step test, and Timed-Up-And-Go (TUG) test, These tests and the continued input of the participants were used to inform a series of multi-stakeholder cocreation sessions which were then conducted, followed by quantitative and qualitative outcome tracking. A selection of these that have been used for preliminary results will be discussed here, with further technical publications to come which will report these in fuller detail. Following this 3 devices were fabricated using a mix of traditional and digital fabrication methods.

Case Study 1

Overview

The first case is a 54-year-old man with a lisfranc amputation, which leaves the heel intact, but with the majority of the foot beyond the ankle removed, due to diabetes. We have developed a digitally fabricated solution tailored to the patient, that is potentially. We first however provided the participant with a locally produced device that is manually carved from foams, and buffalo& goat leathers- however this takes ~6 days to make. This meant that the participant was quickly provide for, while we designed the potentially more efficient solution. This will also allow us to directly compare the two solutions, both functionally and in terms of their service potential.

Participant Profile

Participant 1 is 54 years old who has spent most of his life driving as his primary occupation. He has diabetes for the past 20 years and takes medications for the same. Although aware that diabetes might have secondary complications like poor wound healing, while driving, he pricked his left greater toe, which led to its amputation followed by two more toes amputation within a week, and on the 13th day, he underwent left foot amputation surgery (Lisfranc Amputation).

Lisfranc amputation is a type of partial foot amputation, specifically disarticulation at tarsometatarsal joint. The complications of this amputation are the muscle imbalance the residual limb will have; equinus/equinivarus deformities resulting in excessive pressure in anterodistal area of the stump. It often leads to ulceration, necrosis of Incision line, and delayed healing recurrent ulceration which lead to further proximal amputation.

He reported that his amputation led to a decreased quality of life. His activities of daily living like self-care: lower body dressing, toileting; and mobility has been compromised as seen in the Functional Independence Measure(FIM) scale. He is no longer able to drive which was his primary source of income and which he found meaningful and purposeful. His recreational activities included playing with his grandchildren which he is unable to do post amputation.

His physical activity has significantly reduced after his surgery. He reported that he cannot stand for long due to pain in the stump and long walks increases swelling in the leg. He currently uses a crutch which is cumbersome and painful both. He once measured for a prosthetic foot but has not been able to wear due to improper fit, his wound and swelling.

He currently spends his time helping with small chores like cutting vegetables, cleaning for his small family business of a snack shop. Social participation has reduced drastically after his amputation since he used to visit his friends while driving around. He visits the hospital on a motorbike which his son drives.

He wants to be able to provide for his family by resuming driving, play with his grandchildren, send them to school, perform self-care independently, cook, visit around the community.

On observation, it was noted that poor stump and wound management education and counselling has led to improper stump shape and tightness in his muscles. Hypoaesthesia was observed in his residual limb. Perceived mood was sad, and he had a low arousal level. He had a distal open wound of 1cm*1cm during the initial clinical assessment. There was edema (swelling), but no phantom pain and sensation were present. Though no discharge was seen, the amputee was counselled for daily wound care. On initial clinical engagement, the wound was protecting with bandages and auxiliary crutches provided, to allow walking without weight bearing. He can walk without crutch support but balance was not good.

Participant 1 worked with the occupational therapist to identify his occupational performance problems (OPPs) and rated their importance, his performance and satisfaction. Five OPPs were identified and rated as following:

Occupational Performance Problems (OPP)	Importance	Performance T1	Satisfaction T1
1. Driving vehicles	10	0	0

2. Toileting	10	6	5
3. Pain on using crutches	10	3	4
4. Community management	8	5	5
5. Playing with grandkids	8	5	5
TOTAL SCORE (∑=1+2+3+4+5)	46	19	19
Average Score (∑/number of OPPs)	9.2	3.8	3.8

Figure 4: COPM Outcome Scores for Participant 1 prior to provision

Manual Solution Design & Fabrication

For the local conventional approach, the amputee was first cast during full weight bearing with 4" plaster of paris bandage, and a positive mould was produced with reference lines for the anterior and posterior marked - plaster was then removed in the pressure tolerant areas.

A plastazote liner was pulled over the positive mould with a forefoot filler to restore the normal profile of the foot. The plastazote is 6mm thick and the forefoot filler was filled with high density EVA foam with plastazote on the metatarsal area for smooth rollover. The opening was made at the posterior aspect of the prosthesis, as the Anteroposterior diameter was greater than Mediolateral. Additionally, an orthotimer chip was embedded at the skin interface to track resultant daily wear.

During Initial fitting the patient donned the prosthesis and observational gait analysis was performed. From this, adjustments are made to the design is achieved, in this case with the addition of a lateral wedge. When the prosthetist and client is happy with this, in terms of comfort, gait and perceived skin health, the design is complete.

The final prosthesis was covered with Goat leather overall and with Buffalo leather on the bottom to prevent slippage. Velcro straps were added to secure the prosthesis.

Figure 5: A manually fabricated bespoke partial foot prosthesis solution produced by the prosthetist in ~ 6 days

From start to finish, the process takes ~6 days to complete, and produces a visually pleasing, comfortable, and functional device.

Digital Solution Design & Fabrication

There were a variety of approaches discussed in the first ideation session, with existing/traditional approaches scoped beforehand to aid this. The team, including the user, quickly thought that a digital approach that used a mirror of the opposing foot, and took advantage of additive manufacturing of soft, flexible material was very promising. Version 1 (v1) was designed using a 3D scan of the left stump and a mirrored scan of the fully intact right foot. These were merged in meshmixer (with a 6mm offset on the residual foot scan to make space for a silicone or EVA liner) to match the stance of the opposing limb (not necessarily the correct alignment, but a start for further iteration). These can be seen in Figure 6.

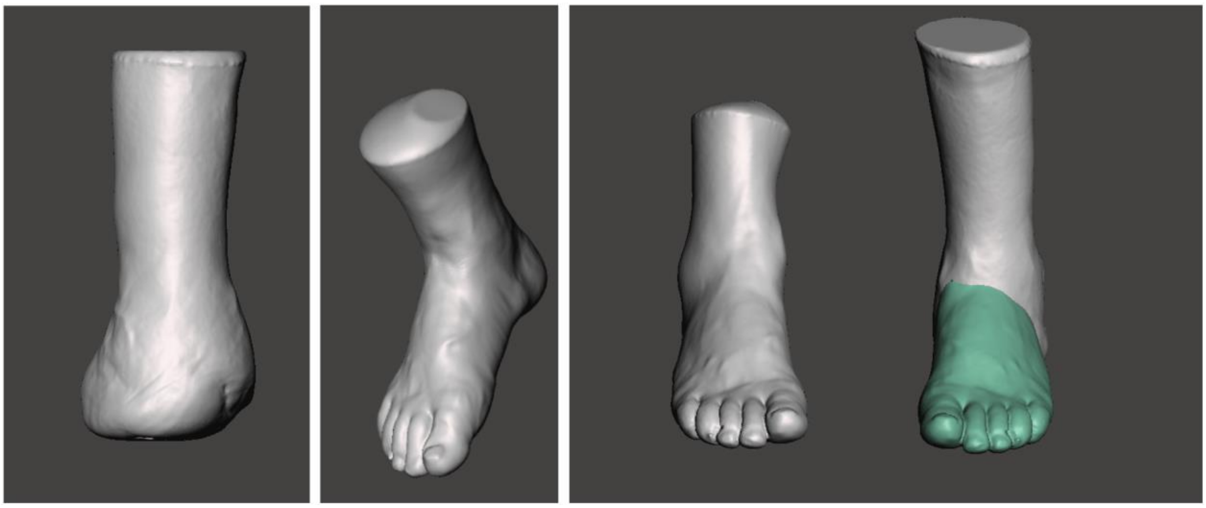

Figure 6: a/b) Scans of Participant 1's residual and opposing limbs; c) Merging of scans to form the basis of design

A reduced 1:5 v1 was printed for quick physical testing in the flexible thermopolyurethane (TPU) filament, which can be seen in Figure 7. The stump looked angled to the posterior and the cutting option was a lateral cut on the inner part like a boot with zips but this hindered the donning and doffing of the model limb.

Figure 7: 1:5 Scaled production for design testing

Effective design adjustments such as toe break angle, slopes, inclination vary greatly across patients and are not likely to be within the expertise of most engineers. The prosthetist suggested angling further towards the anterior and moving to a cut on the ankle. This cut was then added digitally to the design, and this was printed as v2 in 1:2, to get a more accurate validation of the fit and interaction test.

Once deemed viable, v2 was printed 1:1. Here an idea to fill the inside of the front foot portion to increase stiffness with PU spray form and then stitch it together with the shoemaker was proposed and tested. As seen in Figure 8, the two parts were joined, glued and stitching around the joint at a local cobbler shop, and filled with PU foam.

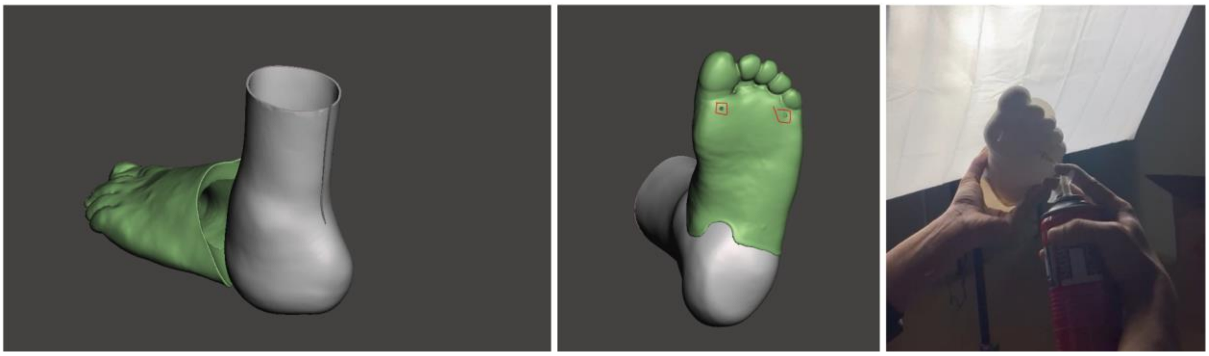

Figure 8: v2 using a 2-part foam filled approach: a)2-part split with a hollow interior; b) digitally designed holes for foam filling; c) manual foam filling

After the application of 5mm thick EVA foam at the socket base v2 was fitted and tested with the prosthetist in clinic, as seen in Figure 9 below.

Figure 9. Fitting of v2 and Functional Tests

Feedback and Outcomes on v2:

1. Due to its natural looks and light weight, this digital solution was preferred by the user to the manual solution - if the drawbacks were addressed, however the sizing of the device needs to be scaled down and a sleeker design is required.
2. The residual foot has a tendency to incline towards the left side (Figure 10b)

3. Toe break angle of about 13 to 20 degrees should be incorporated in the design, as the flexibility that the PU foam gives is too high and needs reducing (Figure 10c blue)
4. The slope at the top surface from socket part to front toe must be steeper and with less volume for better control as well as ease for putting a shoe on top. (Figure 10a/c red)

Figure 10 a) Size Reduction Marks; b) Natural Tendency to Incline towards outer left side ; c) Volume reduction and steep slope (red), Toe break angle and position mark (blue)

On v3 therefore, the toe angle was increased by 13 degrees so it helps with the natural gait on toe-off position, and the foot was slimed at dorsalis pedis and lateral plantar to ease fit in the shoe. A wedge of 5mm on the bottom surface of the prosthetic foot was added to combat the left inclination. It was then printed in 1:1 with 80% infill mesh.

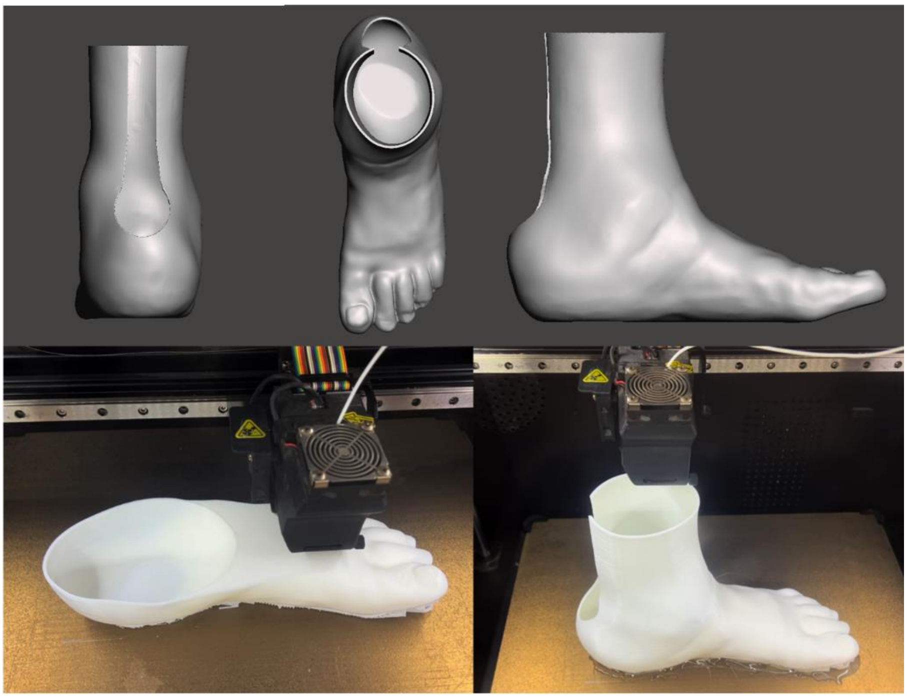

Figure 11: Digital design and printing of v3

After the application of 5mm thick EVA foam at the socket inner base foot was tested.

Figure 12. Fitting of v3 with Participant 1

Feedback and Outcomes on v3:

1. Participant 1 found it more comfortable than conventional one. Despite heavier in weight than the manual solution, he still felt it lighter in comparison
2. The addition of wedge removed the pain issue that Dhan felt at first, while wearing v2.
3. The addition of toe break angle made it easier to walk
4. The sleek design made easier to put it inside the shoe and remove off the shoe.
5. User liked the natural appearance of the foot balancing his looks in comparison to right foot.
6. Before putting it to long term use and testing the prosthetist suggested some slight modification better user experience and long-term adoption and to avoid any pains while using the prosthetic foot.

With these minor adjustments, the expectation is v4 will go into longer term testing, however this is on halt due to Dhan's worsening of wound, due to overuse of the manual solution. We await reports from the participant's surgeon and Diabetic Clinic, at which point our prosthetist will approve moving ahead.

Selected Testing Outcomes for Manual and Digital Solution v2

Occupational Performance Problems (OPP)	Importance	Performance T2	Satisfaction T2
Driving vehicles	10	8	10
Toileting	10	10	8
Pain while walking	10	10	10
Community management	8	8	10
Playing with grandkids	8	8	10
TOTAL SCORE (∑=1+2+3+4+5)	46	44	48
Average Score (∑/number of OPPs)	9.2	8.8	9.6

Figure 13: COPM Outcome Scores for Participant 1 following a month of use of the manual solution

These scores, seen in Figure 13 when compared to the initial COPM show dramatic improvement with provision of the manual solution, which can stand as the benchmark for the digital solution. Not described here for the sake of brevity is the weartime data collected for the manual solution that indicated to us that the participant was wearing the device for considerably longer than advised, against the graded approach to use which was advised in the rehabilitation plan. This describes the very high patient satisfaction with the prosthesis, however this resulted in the exacerbation of a known wound on the stump, and has delayed further testing for a period to allow healing.

For 2MWT, he walked 123.2 meter on the first day of fitting of manual solution and walked 149.72 meter after a month. The comfort score after a month was 9, he felt very mild discomfort in the first day and after a month the socket was the most comfortable and pain free.

Participant 1 found the digital solution to be lighter and initially more comfortable to wear, even though it was actually heavier than the manual solution. It is assumed this is due to it being attached to his feet more accurately/closely, increasing the surface area for better weight distribution. However, he reported minor pain due to the offset creating a rotation – this was fixed by adding a further 3mm to the wedge, which will be added to the digital design for a v4. Due to this (socket comfort score was 7) the 2MWT in digital solution was not performed on v3 as planned.

On the first day of fitting of the manual solution the Four Square step test score was 21.8 second which was improved to 10.81 after a month. The Score was 16.17 second on the first day fitting of digital solution.

TUG test score on first day was 11.60 sec in the manual solution and 11.16 sec in the digital solution. As expected, improving to 8.41 sec in after a month of fitting in the manual solution, and we are waiting to see the second score for the digital solution,

Case Study 2

Overview

The second case is a 26-year old young man who suffered a machine injury on his left hand, leading to a partial hand amputation. Our cocreation journey for Participant 2 covered a range of design approaches that could address his desires, with some potential design avenues needing to be tried in order to eventually decisively rule them out – these centred around body-powered actuation. On exposure in real life to what these designs would be like, they were no longer desirable. This led to design of a digitally fabricated device that focuses on amplification of his retained dexterity and cosmetic appearance, which once iterated upon and evaluated with the participant, has now produced a device that will be taken into long term testing.

Participant Profile

Participant 2 is a motivated 26 yr old young man who suffered a machine injury on his left hand around 3 years ago. He was taken to the hospital where remaining part of his crushed hand was saved leaving him with a partial left hand. In terms of physical activity, he does push-ups without any difficulty. Previously, he rode bicycles and took part in competitions too, post-amputation, applying brakes are a challenge for him.

His daily routine has not changed since amputation but his socialization has reduced drastically as his friends have discriminated against and perceived incompetent due to his injury. He now spends time with only a few of his close friends. Cosmesis has been observed as an area of concern for him.

With right hand as his dominant hand, his Activities of Daily Living (ADLs) are not significantly hindered except while applying creams, moisturisers, and to soap his back while showering. He uses a rubber band to secure his shaving brush.

While eating, he reports he can hold a spoon easily with his partially amputated hand but he cannot hold a glass with it. He helps his family in cooking and cutting vegetables is difficult for him since it required bimanual hand use and stabilising vegetables with the non-dominant hand.

Dressing himself is a challenge, and tasks like buttoning his shirt, pulling his shirt/pants zip, folding sleeves and tying shoe laces are difficult. He likes wearing shirts and thus wants to be able to wear shirts and fold sleeves independently. Using the toilet, combing hair or writing is not a challenge for him. He likes to play games on his smartphone and that is difficult too.

He reported sensory impairment in the stump area in the form of tingling sensation occurs every two or three weeks, or sometimes for a few hours, and when the stump hits any solid surface, a sharp sensation is felt. The occupational therapist suggested adaptive chopping boards, long handled shower sponge, adaptive clothing for his ADLs.

He drives vehicles, and expressed he wants to take up driving as his primary occupation and wants to move to India for the same since his father is not supportive of his driving. Obtaining a driving license is difficult due to his partial hand amputation. Changing gears is a major challenge due to loss of spherical grasp in his left hand.

He currently helps his father in his small bag repair shop which demands dexterity of hand to insert thread into the needle, use scissors, manipulate clothes/bags which is difficult for him. Tailoring is not his interest of work.

His expectations after wearing a prosthesis is to be able to drive easily using gears, obtain a driving license, dress easily and to reintegrate into his social group.

Participant 2 worked with the occupational therapist to identify his occupational performance problems and rated their importance, his performance and satisfaction. Three OPPs were identified and rated as following:

Occupational Performance Problems (OPP)	Importance	Performance T1	Satisfaction T1
Driving vehicles	10	5	5
Buttoning and folding shirt sleeve	10	5	7
Socialization with friends	10	3	1
TOTAL SCORE (∑=1+2+3+4+5)	30	13	13
Average Score (∑/number of OPPs)	10	4.3	4.3

Figure 14: COPM Outcome Scores for Participant 2 prior to provision

Solution Design and Fabrication

The journey to a final approach, that does mimic that for Participant 1 was more complex here, and not obvious to begin with. In initial sessions, it was clear from Participant 2 that there were two major desires for what a device could be – a fully articulating grip through some form of actuation, along with a highly cosmetic device that would make his injury less noticeable. It was recognised very quickly that these two things are very difficult to achieve together, even in the most advanced full hand prostheses on the market.

Figure 15: An adapted design for an actuating prosthesis based on an open source design[49]

Focusing on function first, we explored existing designs for body powered actuating prosthetic hands, of which there are many. The industry engineers then quickly pinpointed a possible design that could be altered to suit a partial amputation, adapted the design and printed a prototype. On testing with Participant 2 with the a printed design adapted to his specific anatomy, as seen in Figure 15, he quickly decided that this was not a desirable solution, due to aesthetics, cumbersome size. This matched the functional concerns of our prosthetists as well.

With this option ruled out, the focus was then re-directed to a cosmetic device. Discussion then quickly focused on the participant's retained functionality with his injured hand – if purely passive, a cosmetic device would reduce this functionality. Ideas on how to embed actuation in the fingers of a device were explored and some concepts were drawn up, for example those seen in Figure 16.

Figure 16: Concept designs for embedded actuation in a cosmetic device

Although these concepts are possible for future development, the team decided them unlikely to be realistically developable within this project or to be made durable enough. They would also require considerable manual construction, making their likelihood to be taken forward as a service offering unlikely, due to cost.

From here, design session discussion focused on designs that could, through stabilised enough passive structures, better amplify his existing grip, with a focus on the specific tasks he desired, seen in Figure 17 are an example of some early drawings of this. For holding a gear stick and buttoning a shirt – this is a rudimentary spherical grip and a pinch grip. We were conscious to re-examine existing approaches throughout these focus change periods for inspiration [50].

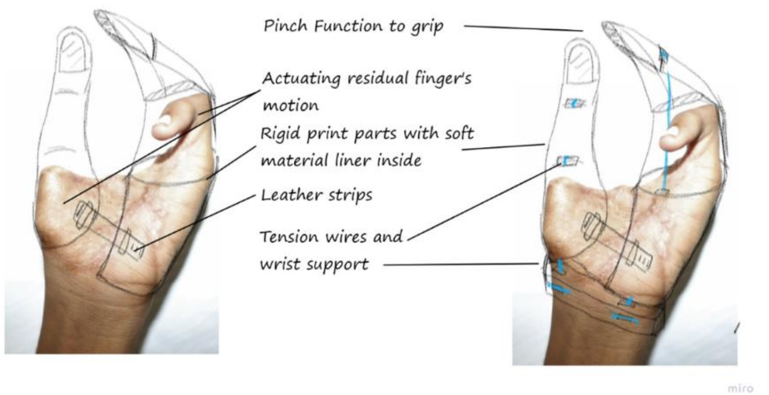

Figure 17: Concept for minimal designs to amplify the retained function in the residual hand

Methods for secure attachment of any component was a challenge here. This led us back to this approach of using scans of both the residual and opposing limb, to rapidly produce a new design.

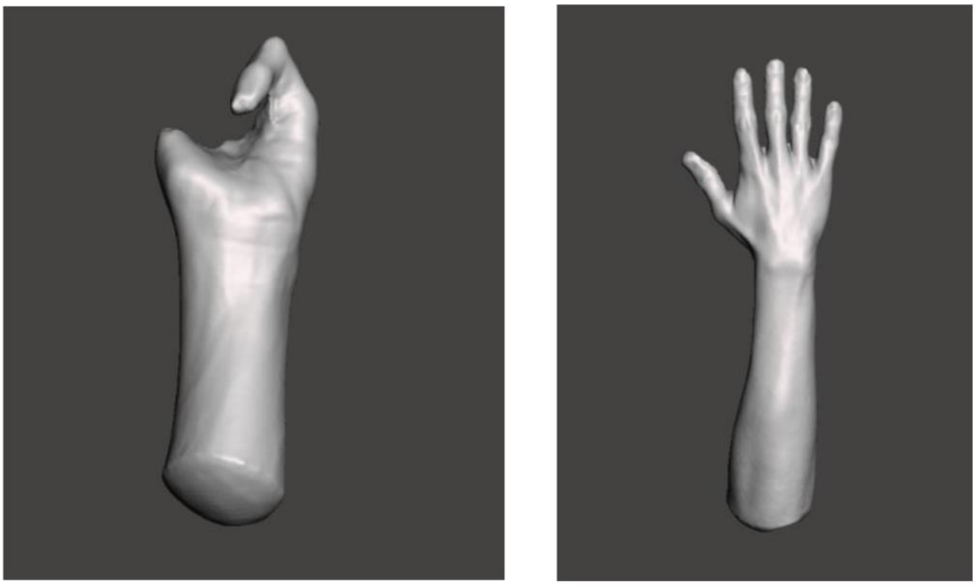

Figure 18: Scans of Participant 2's residual and opposing hands

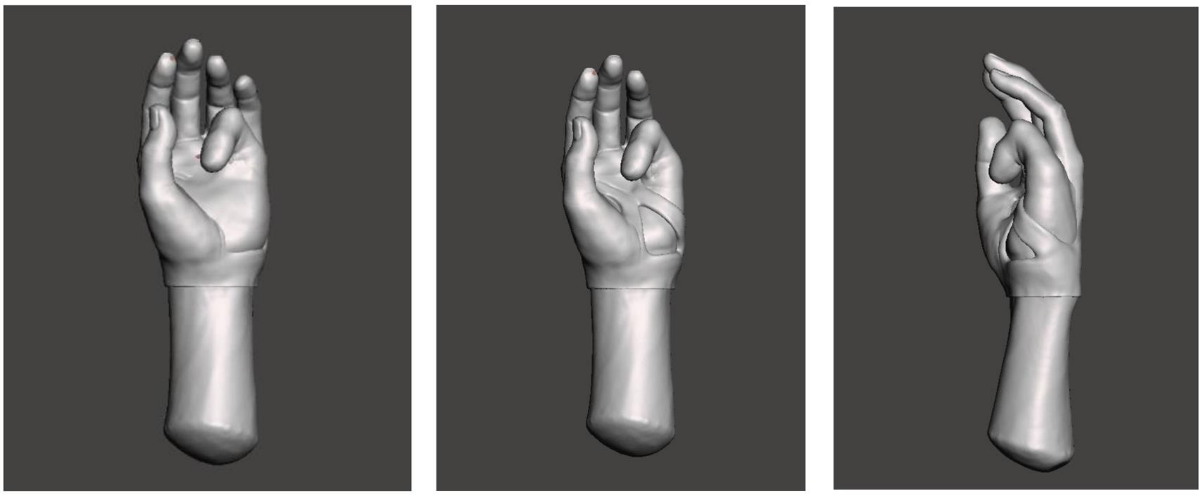

Figure 19: Moving from merged scans to printable designs: a) merged hands; b) &c) first designs of a device

In Figure 18 can be seen scans of the participant's limbs, and in Figure 19 can be seen the move to first prototype designs, which was printed and coloured, as seen in Figure 20.

Figure 20: Printing and user testing on v1

On physical testing, Participant 2 immediately felt more confident after wearing the hand, finding it comfortable and well sized, however the gaps between the fingers hindered function. The position and distance between fingers were adjusted, and the colour and skin tone needed to be more accurate to his normal right hand – this was done in v2 seen in Figure 21.

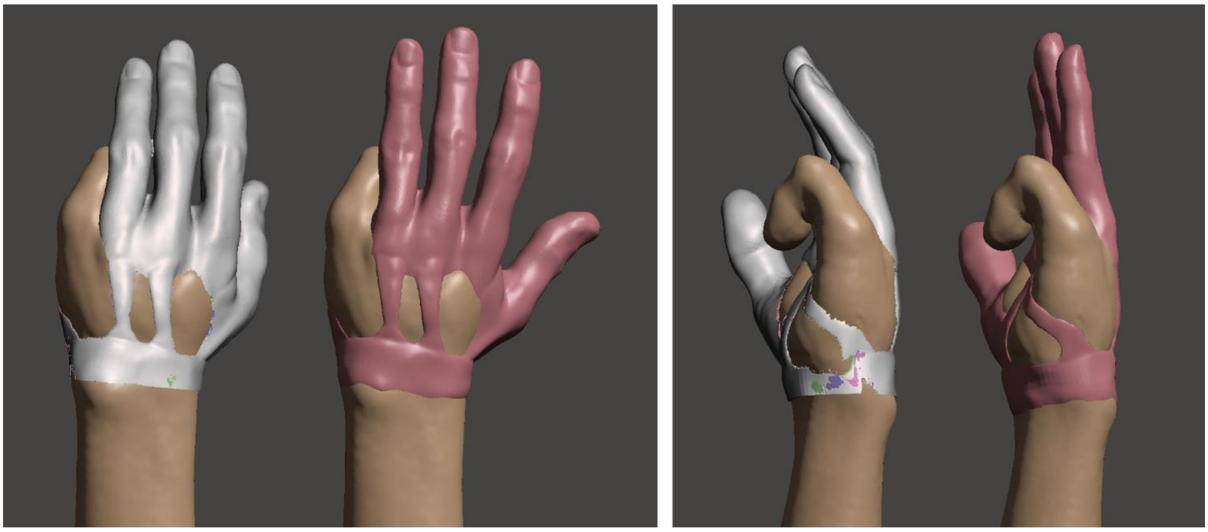

Figure 21. Comparison between v1 and v2 where highlighted grey is v2 and Pink is v1

The design for v2 was evaluated virtually and seen as more anatomically correct and functioned better for grip, with the participant preferring its look. The gaps between the fingers still needed to be reduced and the finger tips reducing. Also, the band needed to be extended proximally. Suggested by prosthetist, the open areas on palm and dorsal side could be better closed, understanding that the flexible filament would accommodate some extension - also the closed part could give a more natural aesthetic. The v2 was then revised into v3 without a printed version, which can be seen in Figure 22. The v3 was then printed for evaluation. The wall thickness of 2mm all around was maintained in the design.

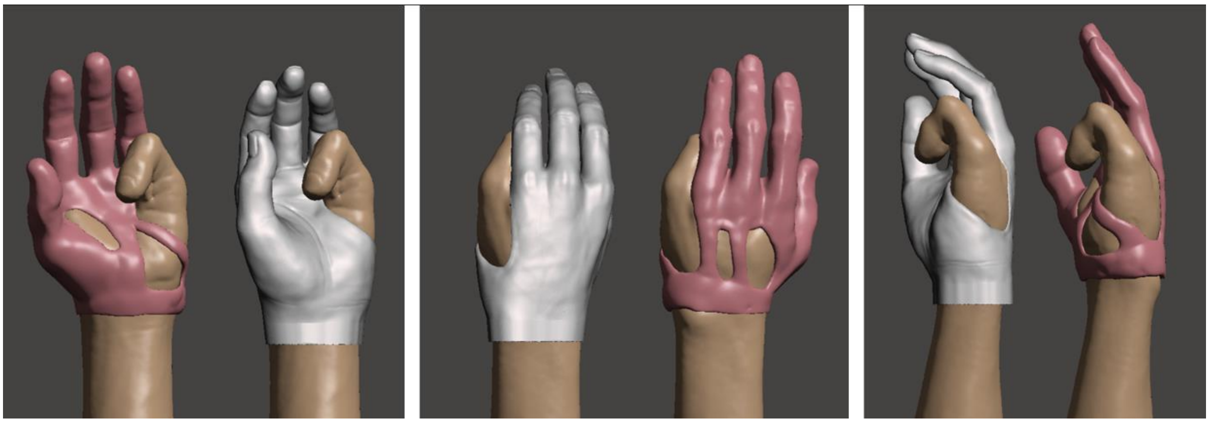

Figure 22. Comparison between v3 (grey) and v2 (pink).

Figure 23. Printing of v3 in TPU flexible filament

Figure 24. Hand v3 printed and colour works in progress.

In Figures 23 and 24 can be seen v3 post print and is now awaiting colour choice and testing with Participant 2 for clinical assessment with the prosthetist and occupational therapist.

Discussion

While still preliminary, we hope the opportunity for a fuller description of the iterative design stages and decision-making involved are of interest to the community, and highlight the importance of a cohesive inter-disciplinary innovation team. The product developments are soon to be moved into final stages of testing, where long term use will be evaluated. These pilot product developments are in no way complete service offerings yet - indeed the way a service approach would be implemented would have to be very different to the way we have innovated, as is expected. However, we have learned various lessons about how we would operate a next innovation phase of similar work.

We had the initial intention to conduct all sessions as full codesign sessions with the participant present. These began as in-person sessions in clinic, moving to a mixture of hybrid and online sessions using Miro boards as a basis for discussion. We found that fully inclusive codesign presents context specific challenges. As expected, language barriers across the team are a hurdle, as whereas all the Nepali members of the innovation team are fluent in English and Nepali, the non-Nepali members do not speak Nepali, and the participants do not speak English. We eventually decided to have the participants present at alternate sessions, so that we could have a balance between direct inclusion and not having dual-language conversations slow the process down too much. This enabled us to quickly have some sessions focused on manufacturing processes that affect design, and some sessions more purely focused on design and hypothesising use and outcomes, with the dominant language varying. Ultimately however, we are still ambivalent about what the best strategy is. More rigidly defined topics across the series of sessions may be needed to define what comes under 'design' and what doesn't. Clear was that communication in the team simply improves with practice and familiarity with each other, and there is no real shortcuts to this.

Although the breadth of team expertise has allowed the protocol development for both rehabilitation and research, it means that work takes longer. We particularly found that scheduling sessions was challenging across people's already busy working lives. This also meant momentum was occasionally lost. It was felt that in the future, more intense periods of work might better achieve our aims, and produce faster results for participants.

Digital design and fabrication is a skillset in itself, and currently quality outcomes are much more feasible with dedicated expertise. Excellent progress is being made to develop and implement models by which prosthetics clinical personnel– either prosthetists, or orthopaedic technicians can be trained in the required processes. Multiple commercial offering exist, and can work well for standard components, such as prosthetic sockets or ankle-foot orthoses that can be streamlined into user-friendly software. Although possible in the future, more complex needs cases currently require a higher level of CAD skill, bespoke hardware optimisation and maintenance, and that would be huge training burden for clinics. Expert design and fabrication facilities, paired with clinical experts, could unburden the existing clinical services, while retaining their professional oversight, however the implementation model for this is yet to be proven. We wish to note here also that, although obviously not a coincidence, we had not originally intended to use a similar process in both cases. From conducting these cases in the same period, we now more fully recognise the design advantage that the rapidly accessible opposing limb geometry for a digital scan-design-print formats gives. We are interested to take this forward to other applicable cases.

The question of how much of this design process would carry forward to a mature service offerings cannot be adequately assessed currently - this will have a major impact on feasibility, and could be investigated with a next small scale phase looking solely at delivery of the designed processes. We predict that service models such as these are likely only possible through flexible manufacturing capacities that can address multiple different complex needs – digital fabrication models combined with traditional machine and manual manufacturing allow this, however the training and expertise required are inevitably more complex. Companies such as Zener, that already have a stable market across a range of other products, are good potential sites for an AT specialist service, as their sustainability does not rest purely on AT.

Previous international work in LMICs, that create from scratch, new production capacities, have very often failed to survive – as soon as there is a gap in funding, a production site will close, and personnel will look for safer options for their livelihoods.

Reflecting now on our aim to develop an innovation ecosystem that is built with existing institutions and businesses in Kathmandu - a key point here is that although our activities so far are fledgling and exploratory, the institutions/businesses involved are already established and stable, and the members of the active team are already well-respected experts in their roles. The relationships and learning achieved will be retained, even if dormant periods arise due to funding gaps. For ecosystem development, these nodes of stability within a potential ecosystem are crucial to be identified, and nurtured, as these have the best chance of continued resilient development of innovation potential. Resource use and effort should be avoided for 'unstable nodes', ie. where value to the system is difficult to retain long term. An example of an 'unstable node', ie. specifically in terms of this Kathmandu Innovation Ecosystem, would be the developing skills of global partners, ie. the UK and Irish academics in the team, although we aim for this still. Unlike in many product developments, the innovation prowess that has been developed so far, is centred on local actors, rather than simply consulting or including them.

This has meant that as well as the other current workstreams mentioned above, and upcoming further AT2030 work, due to these prosthetic developments the local EFC innovation team has been able to lead and secure funding for a larger project with philanthropic funding through UNICEF Nepal - this has involved the additional connections of further local and global partners. This aims to produce over 50 devices, and train multiple prosthetic delivery sites in Kathmandu and Western Nepal. This expansion and strengthening of a fledgling global-local AT innovation ecosystem will be examined in later publications.

Key Suggestions of this Interim Report

- For AT innovation, the combined expert perspectives, including users as experts of their own life and needs, is highly advantageous throughout the innovation process -particularly for recognising and overcoming design faults at an early stage, and critically evaluating next steps, as designs are iterated through. It cannot be well predicted who is needed when.
- If codesigning with users, preformed expectations will initially drive design directions. This may result in dead ends and perceived wasted time and effort, however this could be the only way to ruling out some options, and ultimately lead to better, more appropriate final designs.
- The benefits of a large interdisciplinary innovation team must be weighed against the ability to progress quickly. Intensive periods of development may be more effective than regular, shorter work sessions.
- For global actors, the starting point of developing a locally-centred community for scoping and direction setting, creates joint ownership of projects, and could be key to driving the sustained growth of innovation potential.
- For the development of a fledgling AT innovation ecosystem, identifying important 'nodes of stability' might be key for continued resilient growth, ie. capacities and resources that are stable independent of the intervention being conducted.

Conclusion

The described product developments are leading to the provision of products to two persons in need of them, who otherwise would not be able to receive appropriate devices, while also building an evidenced, operational global-local innovation team centred on Kathmandu, that is able to attract further global funding routes to continue to develop a sustainable ecosystem of practice. As discussed, larger follow-on funding for digital fabrication of prosthetics has already been obtained by the EFC team as a direct result of the demonstrable pilot case studies. The intention is to continue to nurture this innovation ecosystem, continuing to identify synergistic directions for it to grow.

This project is part of AT2030, a programme funded by UK Aid and led by the Global Disability Innovation Hub. AT2030 will test 'what works' to improve access to AT and will invest £20m to support solutions to scale. With a focus on innovative products, new service models, and global capacity support, the programme will reach 9 million people directly and 6 million more indirectly to enable a lifetime of potential through life-changing assistive technology. More information at AT2030.org.

References

1. World Health Organization. Global Report on Assistive Devices. *Global Report on Assistive Devices*. 2022;1:1-11. Accessed October 13, 2023. https://www.who.int/publications/i/item/9789240049451

2. Priority Assistive Products List.

3. Holloway C, Morgado Ramirez DZ, Bhatnagar T, et al. A review of innovation strategies and processes to improve access to AT: Looking ahead to open innovation ecosystems. *Assistive Technology*. 2021;33(sup1):68-86. doi:10.1080/10400435.2021.1970653

4. PN prostheses | AT2030 Programme. Accessed April 17, 2024. https://at2030.org/pn-prostheses/

5. Oldfrey B, Barbareschi G, Morjaria P, et al. Could Assistive Technology Provision Models Help Pave the Way for More Environmentally Sustainable Models of Product Design, Manufacture and Service in a Post-COVID World? *Sustainability 2021, Vol 13, Page 10867*. 2021;13(19):10867. doi:10.3390/SU131910867

6. Borg J, Östergren PO. Users' perspectives on the provision of assistive technologies in Bangladesh: awareness, providers, costs and barriers. *Disabil Rehabil Assist Technol*. 2015;10(4):301-308. doi:10.3109/17483107.2014.974221

7. Gowran RJ, Goldberg M, Comanescu G, et al. Developing country-specific wheelchair service provision strategic plans for Romania and the Philippines. *Disabil Rehabil Assist Technol*. 2019;14(6):612-627. doi:10.1080/17483107.2018.1539131

8. Eide AH. Living conditions among people with disability in Nepal. *157*. Published online 2016. Accessed April 24, 2024. https://sintef.brage.unit.no/sintef-xmlui/handle/11250/2429857

9. Gupta S, Wong EG, Nepal S, et al. Injury prevalence and causality in developing nations: Results from a countrywide population-based survey in Nepal. *Surgery*. 2015;157(5):843-849. doi:10.1016/J.SURG.2014.12.020

10. Mytton JA, Bhatta S, Thorne M, Pant PR. Understanding the burden of injuries in Nepal: A systematic review of published studies. *Cogent Med*. 2019;6(1):1673654. doi:10.1080/2331205X.2019.1673654

11. Katz JS. What Is a Complex Innovation System? *PLoS One*. 2016;11(6):e0156150. doi:10.1371/JOURNAL.PONE.0156150

12. MacLachlan M, Scherer MJ. Systems thinking for assistive technology: a commentary on the GREAT summit. *Disabil Rehabil Assist Technol*. 2018;13(5):492-496. doi:10.1080/17483107.2018.1472306

13. World Health Organization. Global report on assistive technology. *Global report on assistive technology Summary*. Published online 2022:1-11. Accessed April 17, 2024. https://www.who.int/publications/i/item/9789240049451

14. Landry MD, Salvador EC, Sheppard PS, Raman SR. Rehabilitation following natural disasters: Three important lessons from the 2015 earthquake in Nepal. *Physiother Pract Res*. 2016;37(2):69-72. doi:10.3233/PPR-160075

15. Groves CC, Poudel MK, Baniya M, Rana C, House DR. Descriptive study of earthquake-related spinal cord injury in Nepal. *Spinal Cord 2017 55:7*. 2017;55(7):705-710. doi:10.1038/sc.2017.25

16. Landry MD, Sheppard PS, Leung K, Retis C, Salvador EC, Raman SR. The 2015 Nepal Earthquake(s): Lessons Learned From the Disability and Rehabilitation Sector's Preparation for, and Response to, Natural Disasters. *Phys Ther*. 2016;96(11):1714-1723. doi:10.2522/PTJ.20150677

17. Karki J, Rushton S, Bhattarai S, De Witte L. Access to assistive technology for persons with disabilities: a critical review from Nepal, India and Bangladesh. *Disabil Rehabil Assist Technol*. 2023;18(1):8-16. doi:10.1080/17483107.2021.1892843

18. Farrar M, Niraula YR, Pryor W. Improving access to prosthetic services in Western Nepal: a local stakeholder perspective. *Disabil Rehabil*. 2023;45(7):1229-1238. doi:10.1080/09638288.2022.2057599

19. Oldfrey B, Holloway C, Walker J, et al. Repair strategies for assistive technology in low resource settings. *Disabil Rehabil Assist Technol*. Published online 2023. doi:10.1080/17483107.2023.2236142

20. David PA. Path dependence: A foundational concept for historical social science. *Cliometrica (Berl)*. 2007;1(2):91-114. doi:10.1007/S11698-006-0005-X/METRICS

21. Kingston W. Innovation : the creative impulse in human progress : industry-art-science. *(No Title)*. Accessed April 17, 2024. https://cir.nii.ac.jp/crid/1130000797841510144

22. Uusitalo P, Lavikka R. Overcoming Path Dependency in an Industrialised House-Building Company through Entrepreneurial Orientation. *Buildings 2020, Vol 10, Page 45*. 2020;10(3):45. doi:10.3390/BUILDINGS10030045

23. Bevan G, Robinson R. The Interplay between Economic and Political Logics: Path Dependency in Health Care in England. *J Health Polit Policy Law*. 2005;30(1-2):53-78. doi:10.1215/03616878-30-1-2-53

24. Matt D. Trends towards Distributed Manufacturing Systems and Modern Forms for their Design. *Procedia CIRP*. Published online January 1, 2015. Accessed April 17, 2024. https://www.academia.edu/18442739/Trends_towards_Distributed_Manufacturing_Systems_and_Modern_Forms_for_their_Design

25. Routes to Resilience through Distributed Manufacturing and Circular Economy approaches.

26. Cervantes M, De Backer Koen, (OECD) O for EC operation and D. Open innovation in global networks. Accessed April 17, 2024. https://tind.wipo.int/record/24693

27. Chesbrough H, Kim S, Agogino A. Chez Panisse: Building an Open Innovation Ecosystem. *http://dx.doi.org/101525/cmr2014564144*. 2014;56(4):144-171. doi:10.1525/CMR.2014.56.4.144

28. Boger J, Jackson P, Mulvenna M, et al. Principles for fostering the transdisciplinary development of assistive technologies. *Disabil Rehabil Assist Technol*. 2017;12(5):480-490. doi:10.3109/17483107.2016.1151953

29. 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. *Prosthet Orthot Int*. Published online April 16, 2024. doi:10.1097/PXR.0000000000000351

30. Smith EM, Boger J. Better together: Promoting interdisciplinary research in assistive technology. *Assistive Technology*. 2022;34(1):1. doi:10.1080/10400435.2022.2047397

31. Thorsen R, Bortot F, Caracciolo A. From patient to maker - a case study of co-designing an assistive device using 3D printing. *Assistive Technology*. 2021;33(6):306-312. doi:10.1080/10400435.2019.1634660

32. Schmermbeck K, Ott O, Ralfs L, Weidner R. Fostering Inclusion: A Regional Initiative Uniting Communities to Co-Design Assistive Technologies. 2024;24. Accessed April 25, 2024. https://arxiv.org/abs/2403.12263v1

33. Aflatoony L, Jin susan Lee S. AT Makers: A Multidisciplinary Approach to Co-Designing Assistive Technologies by Co-Optimizing Expert Knowledge. *ACM International Conference Proceeding Series*. 2020;2:128-132. doi:10.1145/3384772.3385158

34. Aflatoony L, Lee SJ, Sanford J. Collective making: Co-designing 3D printed assistive technologies with occupational therapists, designers, and end-users. *Assistive Technology*. 2023;35(2):153-162. doi:10.1080/10400435.2021.1983070

35. Howard J, Tasker LH, Fisher Z, Tree J. Assessing the use of co-design to produce bespoke assistive technology solutions within a current healthcare service: a service evaluation. *Disabil Rehabil Assist Technol*. 2024;19(1):42-51. doi:10.1080/17483107.2022.2060355

36. Slegers K, Kouwenberg K, Loučova T, Daniels R. Makers in Healthcare: The Role of Occupational Therapists in the Design of DIY Assistive Technology. *Conference on Human Factors in Computing Systems - Proceedings*. Published online April 21, 2020. doi:10.1145/3313831.3376685

37. Jennings M, Guilfoyle A, Green J, Cleary Y, Gowran RJ. Octopus Watch Fosters Family Resilience by Enhancing Occupational Engagement for Children with Spina Bifida and/or Hydrocephalus: Pilot Study. *International Journal of Environmental Research and Public Health 2020, Vol 17, Page 8316*. 2020;17(22):8316. doi:10.3390/IJERPH17228316

38. Stokols D, Misra S, Moser RP, Hall KL, Taylor BK. The Ecology of Team Science: Understanding Contextual Influences on Transdisciplinary Collaboration. *Am J Prev Med*. 2008;35(2):S96-S115. doi:10.1016/J.AMEPRE.2008.05.003

39. Mâsse LC, Moser RP, Stokols D, et al. Measuring Collaboration and Transdisciplinary Integration in Team Science. *Am J Prev Med*. 2008;35(2):S151-S160. doi:10.1016/J.AMEPRE.2008.05.020

40. Hamidi F, Mbullo P, Onyango D, Hynie M, McGrath S, Baljko M. Parcipatory design of DIY digital assisve technology in Western Kenya. *ACM International Conference Proceeding Series*. 2018;18:78-88. doi:10.1145/3283458.3283478

41. Hook J, Verbaan S, Durrant A, Olivier P, Wright P. A study of the challenges related to DIY Assistive Technology in the context of children with disabilities. *Proceedings of the Conference on Designing Interactive Systems: Processes, Practices, Methods, and Techniques, DIS*. Published online 2014:597-606. doi:10.1145/2598510.2598530

42. Higgins E, Oliver Z, Hamidi F. Towards a Social Justice Aligned Makerspace: Co-designing Custom Assistive Technology within a University Ecosystem. *ASSETS 2023 - Proceedings of the 25th International ACM SIGACCESS Conference on Computers and Accessibility*. Published online October 22, 2023. doi:10.1145/3597638.3608393

43. Higgins E, Easley WB, Gordes KL, Hurst A, Hamidi F. Creating 3d printed assistive technology through design shortcuts: Leveraging digital fabrication services to incorporate 3d printing into the physical therapy classroom. *ASSETS 2022 - Proceedings of the 24th International ACM SIGACCESS Conference on Computers and Accessibility*. Published online October 22, 2022:16. doi:10.1145/3517428.3544816

44. Hofmann M, Burke J, Pearlman J, et al. Clinical and Maker Perspectives on the Design of Assistive Technology with Rapid Prototyping Technologies. *Proceedings of the 18th International ACM SIGACCESS Conference on Computers and Accessibility*. 2016;4(2). doi:10.33137/CPOJ.V4I2.36188

45. Mankoff J, Hofmann M, Chen X, Hudson SE, Hurst A, Kim J. Consumer-grade fabrication and its potential to revolutionize accessibility. *Commun ACM*. 2019;62(10):64-75. doi:10.1145/3339824

46. Costanza-Chock S. Design Sites: Hackerspaces, Fablabs, Hackathons, and DiscoTechs. Published online 2020:338. Accessed April 18, 2024. https://designjustice.mitpress.mit.edu/pub/yvwnnz7b/release/1

47. Local Production and Local Solutions – COVIDaction – Medium. Accessed April 23, 2024. https://medium.com/covidaction/local/home

48. Desmond D, Layton N, Bentley J, et al. Assistive technology and people: a position paper from the first global research, innovation and education on assistive technology (GREAT) summit. *Disabil Rehabil Assist Technol*. 2018;13(5):437-444. doi:10.1080/17483107.2018.1471169

49. Hand by BQEducacion - Thingiverse. Accessed May 3, 2024. https://www.thingiverse.com/thing:1095104

50. Graham EM, Hendrycks R, Baschuk CM, et al. Restoring Form and Function to the Partial Hand Amputee: Prosthetic Options from the Fingertip to the Palm. *Hand Clin*. 2021;37(1):167-187. doi:10.1016/J.HCL.2020.09.013