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## Chapter 1

# Child Prosthetics

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Research into myoelectric upper-limb prosthetics has focussed on algorithmic approaches to decoding muscle signals. A cursory search of PubMed indicates that the ratio of upper-limb myoelectric papers focussed on prosthesis control to those which mention children is approximately twenty to one. Of those papers which mention children, only a subset focus on paediatric upper-limb prostheses. A similar ratio exists between control algorithms publications and research on myoelectric upper-limb sockets. These disparities are likely to reflect differences in the barriers to entry for various types of research, and the overall time commitments necessary to obtain and validate sufficient data for publication.

The majority of information surrounding myoelectric upper-limb prosthetics for children is anecdotal. This reflects the fact that active upper-limb prosthetics is a relatively small field, both clinically and academically, of which paediatrics is an even smaller section. As the overall area is small, technical research, whether performed in academia, commercial enterprises or by non-profits, very rarely reaches or involves the clinical teams necessary to validate developments and evidence efficacy.

This chapter summarises conversations between researchers working in health-care and academia linked through membership of the Starworks network, a UK National Institute for Health Research initiative to accelerate the translation of child prosthetics research into daily use. Specifically, it aims to unpack challenges identified by the network and critically analyse the current ‘state of the art’ in relevant upper limb myoelectric prostheses areas, informed by multiple perspectives. Each section outlines an area of emerging influence over the past decade which is likely to remain influential over the next. It begins with a brief introduction to the Starworks Network and concludes with recommendations from the authors.

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## **Starworks**

The Starworks Network was established in 2016 as a response to ‘market failure’ within child prosthetics. Traditional market forces cannot drive innovation in a field characterised by low patient numbers and the highly individualised and rapidly changing needs of children with the result that this group are under-represented in upper-limb prosthesis design. In the early stages of the network, a focus was to bring together key stakeholders from across the UK comprising children and families, academics, healthcare professionals and industry experts to better understand the real, day-to-day challenges of children who use prosthetics. A co-design approach was taken to facilitate reflection and mutual learning between these different stakeholders, as well as early ideation and concept development.

Discussion and activities within the Starworks Network considered lived experiences of children, their daily routines and their wider life context including school, home life, impact on siblings, socialising and hobbies. This was complemented by experiences from healthcare professionals concerning the life course of the child as they grow, and what is needed from the prosthesis technically as well as insights from industry and academia, as to what would be technically possible. This work helped to highlight previously unmet needs, as well as give a more rounded, child-focussed, ‘real life’ understanding of existing research priorities such as socket fit, adapting to the rapid growth rates of children, personalisation, individualisation, regulation and, crucially, the unique needs of upper limb prosthesis users.

### **1.1 Co-design**

Co-design, or ‘the creativity of designers and people not trained in design working together in the design development process’ [1], has become somewhat of a buzzword in recent years, but in fact has a rich heritage, emerging from the field of Participatory Design with roots in the civil rights movements of the 1960s and 1970s [2]. As it has moved into more complex contexts such as healthcare and involved a wider range of potentially vulnerable stakeholder groups such as children, the field has matured and demonstrated several strengths that made it particularly relevant to initiatives developing child prosthetics. These include:

- principles that give equal value to the contributions of different stakeholders, positioning each as ‘virtuosos of their own experience,’ [3].
- a vast catalogue of tools and methods to create a ‘common language’ between disparate stakeholder groups, with a focus on flattening hierarchies and addressing potentially stifling power dynamics [4], for example, between children and adults, or between managers and front line healthcare staff, and
- skills and activities to elicit hard to reach knowledge, such as tacit, experiential, institutional, etc [5]. This is particularly important with embodied technology such as prosthetics, and complex contexts such as prosthetics services. Considering these different types of knowledge from a range of stakeholders is key to

getting to the crux of the problem quicker, to inform the design of new products and technologies, and to anticipate barriers to implementation.

A co-design approach was utilised and promoted throughout the Starworks Network [6]. Limbitless Solutions also employ a modified Participatory Design approach when creating a prosthesis which they term ‘Cooperative Expression’ [7]. While co-design aligns well with rapid pace enterprise-based innovation, achieving similar iterative progress in academia can be challenging. Emergent properties of co-design make the process inherently unpredictable. Although academics and funding bodies will often affirm that the public should play an active role in health research, they usually do so within environments that favour the traditional progression of a lead investigator’s pre-existing ideas by promoting detailed project planning and linear progression with fixed milestones.

## 1.2 Additive Manufacturing

The last decade saw an explosion of interest in using additive manufacturing, commonly referred to as 3D printing, to produce upper-limb prosthetics for children. Proponents of 3D printed child prosthetics often cite open-source designs, individualisation and low manufacturing costs as core advantages over traditional methods.

The origins of this approach largely lie in the distributed, open-source community e-NABLE [8]. e-NABLE open-sourced a design for the first 3D printed child prosthetic in January 2013. In March 2013 Joel Gibbard started the open-source ‘Open Hand Project’ initiative [9]. Two of the most influential organisations in 3D printed child prosthetics, Limbitless Solutions [10] and Open Bionics [11] were both founded in 2014. Limbitless Solutions, a non-profit organisation founded by Albert Manero, focusses on child prosthetics. Open Bionics is a private 3D-printed prosthetics company founded by Joel Gibbard and Samantha Payne. The original team at Limbitless Solutions were e-NABLE volunteers while Open Bionics is the commercial continuation of the Open Hand Project.

### 1.2.1 Open Source

While open-source design enabled widely dispersed individuals in the e-NABLE community to produce highly influential prosthetics, the approach is largely incompatible with existing medical device frameworks. A 2016 review of 3D printed hand prostheses identified 58 distinct designs, of which the majority were intended for children [12]. These designs are often free and regularly updated, however they are unregulated and untested and are therefore unlikely to be monitored by health-care professionals [13].

### 1.2.2 Cost

The cost advantages of 3D printing prosthetics are difficult to establish. Researchers report low manufacturing costs for small print runs as a central advantage of 3D printing [14]. When production is low scale and parts are highly customisable, it

is probable that costs can be reduced significantly relative to traditional techniques [15]. However, in more general cases injection moulding is often cheaper than 3D printing [12]. The majority of 3D designs require significant manual labour, and additional customisation incurs time, the commercial viability of large scale production is therefore questionable [15]. It is likely that the cost benefits of 3D printing low quantities of customized components will be integrated into existing fabrication pipelines.

### *1.2.3 Bespoke fitting*

Many of the advantages of 3D printing child prosthetics relate to bespoke fitting. Paediatric upper-limb prosthetics require regular adjustment because children's residual limbs are still growing. Poor socket comfort is a regular reason for prosthesis rejection [16] and poor fit is increasingly recognised as limiting myoelectric control [17]. Additive manufacturing is highly complementary to scanning and allows bespoke parts to be produced rapidly. Various companies now 3D scan residual limbs. For example, Glaze Prosthetics produce 3D printed sockets and paediatric prosthetics based on this technology [18]. However, there is little evidence to suggest artisan components such as children's transradial myoelectric sockets can be produced to current standards, particularly without the involvement of specialist clinicians.

### *1.2.4 Individualisation*

Printed prosthesis may be scaled in size and also offer aesthetic individualisation in terms of colour and overall appearance [12], allowing for designs tailored toward children [13]. Limbitless Solutions provide an artistic customisation service for children based on participatory design. By involving children in the prosthesis design the system is intended to increase engagement and promote a greater sense of ownership of the new device [7].

### *1.2.5 Regulation*

Many misconceptions surrounding 3D printed prosthetics relate to regulatory conformity. The often reported notion of devices being an 'order of magnitude' cheaper is based on the faulty reasoning that component costs drive prostheses' prices. In reality, price reflects multiple sunk costs, not least of which is securing regulatory conformity, along with prospective costs and enterprise overheads. Similarly, lightweight materials are a moot point without evidence of functionality, durability and safety. Prolonged skin contact also requires materials meet ISO standards for biocompatibility, a non-trivial factor which often appears to be misinterpreted or ignored.

In summary, a disparity exists between public perception of 3D printed child prosthetics and any available scientific evidence. This may be attributable to the leaps made by international teams of innovators using rapid participatory design methods and publishing their research as internet posts and design files, rather than traditional

literature. In parallel, a number of projects have moved to meet the demands of regulating 3D printed prosthetics and these groups have little incentive to publish the evidence generated.

Public perception of 3D printed child prosthetics is, like the adult market, largely driven by quotes, adverts and media pieces rather than data. Again, akin to the adult market, media reporting on child prosthetics is typically shallow. Of note reporters usually appear to be naive to the role ‘professional’ prosthesis users play in marketing devices and of the increasing involvement of multinational companies in driving positive child prosthetics narratives. Should 3D printing proponents validate that commercial demand exists for low cost upper-limb prosthetics for children, they will also invite competition. However, efficient, automated machining centres and advances in computer-aided design and computer-aided manufacturing mean cheaper, faster and more reliable methods of production may be used to make the next generation of child focussed devices.

### 1.3 Socket Fit

The fundamental design of sockets for children with upper-limb loss are the same as those built for adults. Fluctuation of residual limb volume is a recognised problem in adult amputees [19, 20]. Adults who experience lower-limb loss are physiologically unlikely to remain fit and as a result, the residual limb volume is often unstable. A typical solution is to wear differing numbers of liners depending on the time of day. Adult upper-limb amputees, irrespective of the nature of the loss, are usually otherwise physiologically fit. Therefore, the residual limb is, relatively speaking, volume stable.

Limb growth in children is continual and the consequences of this must be mitigated in order for the prosthesis to remain functional. Children at the most common transradial level of congenital limb absence are usually provided with a hybrid self-suspending socket, that enables a satisfactory range of motion at the elbow, with some degree of comfort, and effective suspension of the prosthesis. Often, the clinician will allow some growing room within the socket, to mitigate against the need for frequent re-socketing and visits to the clinic. However, this means electrodes in myoelectric devices are often looser immediately following socket delivery, which can affect levels of control and prosthesis functionality. This is one reason why functionality and comfort [21, 22], two properties commonly associated with paediatric prosthesis rejection, [23, 24, 16], are often intrinsically linked.

#### 1.3.1 Digital manufacturing

Digital socket manufacturing, or manufacturing based on a digital work flow, often refers to 3D sockets informed by 3D residual limb scans. As mentioned earlier, this type of technology is already used by a number of enterprises, many of whom work in child prosthetics [18, 25]. Digital socket manufacturing is based on the premise that automation can produce sockets more cheaply than current techniques [26]. Relative to traditional casting, digitally scanning residual limbs offers numer-

ous benefits, many of which relieve pressure on the prosthesis user [27]. As socket fitment is an irregular occurrence in adults, and because current casting techniques can be time consuming and arduous, this technology may be considered particularly salient to child prosthetics.

Digital scanning of residual limbs can be performed using mechanical, optical or electromagnetic methods [28] and upper-limb sockets have been successfully produced using computer tomography scans [29], optical scanners [26] and traditional casting followed by optical scanning [30]. A key advantage of digitisation is that patient data can be easily retained, meaning subsequent socket modifications do not require additional cast moulds. It is important to note that digital scanning is not an entirely automatic process. In order to create a comfortable and functional well fitting socket, practical information about soft tissue areas and bony prominences must be collected, in addition to any areas of skin sensitivity [26]. Anecdotal evidence suggests that early claims that scanning could readily supplant casting have not held true, and that this is widely recognised, both in start-up and commercial funding arenas as well as within academia.

### *1.3.2 Adaptable sockets*

The alternative to multiple low-cost sockets are single sockets which adapt to changes in shape over time. The past decade has seen a number of novel innovations in socket design. These innovations do not target children, rather they are applicable to any user for whom changes in residual limb volume are to be expected.

Many adaptive socket designs derive in some way from compression/release stabilised (CRS) sockets [31, 32]. Compression/release stabilised sockets use longitudinal depressions to compress tissue in the residual limb. Compression displaces tissue which would usually sit between the bone and the socket. The effect of this displacement is a reduction in ‘lost motion’ between bone and socket movement. Relative to traditional sockets, the CRS design is easy to adapt, because only the longitudinal sections need change.

The general idea of pressure adjustable sockets is to control the pressure at the interface of the residual limb. Two such systems were introduced in 2014. Razak et al. developed an air splint socket system for transhumeral users [33] which utilised built-in sensors to allow the wearer to adjust pressure via a microcontroller. A transradial socket based on pressure adjustable chambers and a vacuum pump was developed by Sang et al. [34]. The socket introduced a novel design concept whereby compression would be increased during prosthesis use and decreased during rest; aiming to enhance both functionality and comfort simultaneously.

### *1.3.3 Johns Hopkins University*

Recent adaptive upper-limb socket research has come from Johns Hopkins University. This team developed the first adaptive socket based on automatic closed-loop feedback from region specific pressures [35]. The Johns Hopkins socket controls four pneumatically actuated independent air bladders, with embedded textile sensors measuring pressure between the socket and the residual limb and an accelerometer

providing information about position. Preliminary experiments demonstrate that by continuously monitoring contact pressure, limb position and operating load, dynamic adjustments can be made to ensure reliable attachment across various activities [36].

### 1.3.4 Salford University

Research at Salford University proposes a more user-friendly alternative to the standard method of simply inserting myoelectric electrodes into fixed housings within the socket walls. Unlike the standard method, where the electrode contacts are intrinsically tied to the mechanics and fit of the entire socket, the contact pressure and alignment of control electrodes in Salford's design can be adjusted independently [37, 22]. The child focussed version of this system is being developed as part of the Starworks project. This approach would enable prosthetists to continue fitting sockets which accommodate growth and provide an adjustable electrode housing to allow electrode alignment and contact pressure to be tuned over time. The overall goal of this project is to develop a housing which can physically decouple the electrode from the socket, thereby reducing the impact of motion artefacts on myoelectric prosthesis control, and also enabling socket comfort and fit to be enhanced without adversely affecting electrode contact.

## 1.4 Game-based training

Myoelectric control is not perfect. As a consequence participants typically have to learn to produce patterns of muscle activity which can be readily distinguished by the myoelectric device [38]. In a rehabilitation context it is widely recognised that patients usually fail to meet the number of movement repetitions required to induce the adaptation necessary for behavioural improvement. Rehabilitation-relevant muscle activities in the context of game-play offer an alternative motivational and engaging method to increase the number of repetitions performed [39]. Games are promising in this context because they can provide challenging, intensive, task-specific conditions necessary to promote the adaptation of behaviour [40]. As with adaptive upper-limb sockets, while game-based systems do not target children per se, their potential application in younger adults is clear. There are currently a number of research groups using game-based training systems for myoelectric control.

### 1.4.1 University of New Brunswick

Game-based training systems for training of myoelectric upper-limb prostheses was pioneered at the University of New Brunswick. In highly prescient research, Lovely *et al.* described many of the concepts and challenges of game-based rehabilitation in the late 1980s [41, 42]. In more recent times, the team at New Brunswick have used user-centred design involving patients and prosthesis experts to develop a 2D platform-style game based on low-cost hardware [43] and a virtual reality system for training pattern recognition control of upper-limb prostheses [44].

### 1.4.2 *Medical University of Vienna*

Researchers led by a team at the Medical University of Vienna developed a game-based rehabilitation protocol which used various muscle contract types to control pre-existing games. The game-based protocol was found to improve muscle separability and fine muscle control while being more enjoyable than standard training [45, 46]. Following from this, the Vienna team went on to validate a custom game-based home training system designed around rhythm and music [47].

### 1.4.3 *Limbitless Solutions*

Limbitless Solutions have developed game-based rehabilitation solutions designed for children. Unlike many other projects, these games are specifically designed to teach proficiency with Limbitless prostheses. In these conditions, the prosthesis can effectively *be* the game controller, blurring the boundary between prosthesis training and prosthesis use. Game design research from Limbitless stresses the importance of training aligned to real world use [48, 49] and initial tests show enhanced performance with relatively short training sessions [50].

### 1.4.4 *Newcastle University*

A game-based system for teaching children prosthesis control in the home is being developed at Newcastle University as part of the Starworks project. The game uses a first person perspective and children control the position of a virtual arm mapped to their residual limb and a virtual prosthesis controlled by muscle activity [51]. The game mechanics involve picking up and manipulating objects in a scene and levels are themed around specific aspects of prosthesis control. The most recent version of the game uses a microcontroller to detect arm movement and muscle activity [52].

### 1.4.5 *University of Groningen*

Researchers based at the University of Groningen use a systematic experimental approach to investigate whether skills learned in games actually improve prosthesis use [53, 54, 55, 56]. Groningen research suggests myoelectric control is task-specific, and the nature of training is pivotal to whether abilities learned transfer to prosthesis control [53, 54]. While game-based systems can train people to produce desirable EMG activity, this does not appear to directly translate to significant improvements in prosthesis control [56]. The Groningen group propose that to improve prosthesis control the coupling of action and perception within a game must match reality, and more abstract forms of training are unlikely to work [55].

Leveraging motivation and engagement is a fundamental of game-based rehabilitation. However this idea is not trivial to implement and the majority of game-based training systems for upper-limb rehabilitation suffer from recognised recurring issues, which have been acknowledged for a long time [42, 57]. In addition, recent research suggests the efficacy of game-based rehabilitation will differ depending on



design [53, 54, 48, 49] with simulation of reach and grasp tasks becoming a common proposal [48, 49, 55]. To achieve traction, these design requirements will have to be addressed along with those of the clinical upper-limb rehabilitation community [58].

## 1.5 Recommendations

The following recommendations arise from the topics raised above.

### 1.5.1 *Co-design*

The meaningful involvement of users and stakeholders (in this case, children, families and prosthetists, alongside academics and industry) is crucial to understanding the crux and complexity of real-world issues more quickly, as well as to develop comprehensive solutions that encourage uptake - all of which are necessary to positively impact upon this previously under-served area of research. The co-design process enables fast-paced innovation within industry and non-profits. Facilitating the same effectiveness within academia requires adaptation. It is important to note that co-design is rarely linear, and the traditional research paths and project plans used by academics and funding bodies often fail to accommodate this.

### 1.5.2 *Additive Manufacturing*

There is an academic need for evidence supporting a range of claims made about 3D printed upper-limb prosthetics. Materials must be validated for durability during prosthesis use and for safety in the case of breakages. A need exists to determine whether 3D printed child prosthetics designs provide sufficient grip strength [15]. Academia should provide more robust critique to ensure that unfounded arguments surrounding printed child prosthetics are moderated in the media. Frequent promises of low-cost access to state-of-the-art technology contributes to public misunderstanding and, in the case of child prosthetics, are sometimes questionable.

### 1.5.3 *Socket Fit*

It is essential to recognise that socket fit is fundamental to upper-limb child prosthetics, particularly for myoelectric devices. As fit is a determinant of both comfort and functionality it is a key predictor of prosthesis rejection in children [16]. Of the transradial amputees referred for prosthesis treatment in the UK, when discounting those where cause of limb-loss is unrecorded, the majority are congenital [59]. Despite these statistics, knowledge of why prostheses are rejected [24, 16] and data supporting the importance of early intervention [60], relatively little research and development has been focussed on socket design. There is a need to develop sockets which can adapt to a child's growth while ensuring sensor contact for control.

### 1.5.4 *Game-based training*

Evidence is required to show that skills developed during game-based training transfer to real-world prosthesis use. It is probable that the nature and degree of skill transfer will relate to game mechanics. Given the limited resources available within prosthetics, future development should focus on game styles confirmed to transfer skills. For bespoke training systems, engagement must be addressed; how to design games such that users will be motivated to play in the medium to long-term. It is unlikely that a single solution can address these challenges for all children. This raises a broader question: how best to enable scaling, such that research can move from smaller projects with limited longevity toward more viable solutions.

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