

Towards a Product Service System Framework for Lower Limb Prosthetic Devices

N. Patiniott ¹, J. C. Borg ¹, E. Francalanza ¹, A. Gatt ¹, P. Vella ¹, J. Zammit ¹ and K. Paetzold ²

¹ University of Malta, Malta, ² Technische Universität Dresden, Germany

✉ nicholas.patiniott@um.edu.mt

Abstract

Amputees face challenges with prosthesis such as cost, long delivery periods, as well as social discomfort. Simultaneously, the prosthetists and manufacturers have a difficulty to handle such diverse issues. We thus contribute a Prosthetic Life-Cycle Service System (ProLiSS) Framework, prescribed to involve amputees in different life phases. From an evaluation of ProLiSS, we conclude that it influences how prosthetics need to be designed and that it is beneficial to perform further research to provide manufacturers with a systematic, amputee-centered development and servicing framework.

Keywords: user-centred design, design for x (DfX), co-design, product-service systems (PSS), medical devices

1. Introduction

In spite of advances made in science and technology, lower limb (*LL*) amputees still face a number of challenges when acquiring and using a prosthetic device, especially when one considers that their needs and aspirations evolve and change over time. One major issue amputees face is the time it takes for their prosthesis to be custom designed, developed and delivered. Repeating this process every time they need to make improvements to cater for their evolving needs and aspirations, coupled with the time it takes to regularly get it serviced, amplifies this problem as well as costs.

Some research work to improve how *LL* prosthesis are designed has been performed but this focuses on current rather than evolving amputee needs (G. Colombo et al 2010). The research reported in this paper aims to precisely address the question on how a cost-effective Product-Service System (*PSS*) can be designed to cater for both the current and evolving needs of amputees, whilst concurrently considering (Borg, J.C. et al 2000) the input and needs of the other stakeholders involved i.e. Podiatrists/Prosthetists as well as Prosthesis part manufacturers/suppliers, that may change over time. As the rest of this paper will disclose, the research methodology we adopted is one based on that by Blessing et al (Blessing, L et al 1995), in that we first generated a descriptive model of the prosthesis product development process as a basis by which to establish details of current problems and challenges. Based on this detailed understanding, our research work then led to the design and evaluation of a prescriptive *PSS* framework called ProLiSS.

1.1. Key problems of prosthesis development stakeholders

To understand the issues involved in the development of prosthesis our research team has performed an empirical analysis to establish and model the current phases through which the design and development of *LL* prosthetic devices go through. Figure 1 extracted from one of our internal research

reports, based on survey data collected from a sample of amputees, prosthetists and suppliers, illustrates a descriptive model with the key steps, sequence and stakeholders involved in each phase of prosthesis product development.

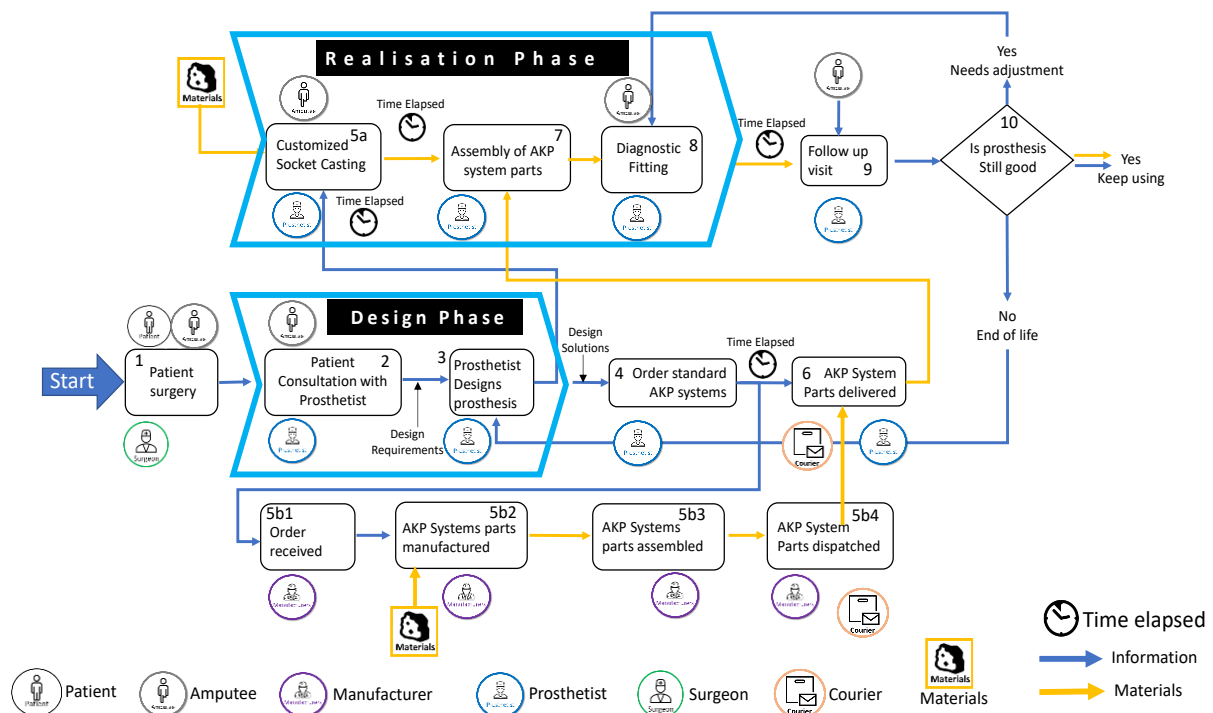


Figure 1. Prosthetic Device Product Development Descriptive Model

Through this survey analysis, coupled with a relevant literature review, a number of problematic patterns have emerged, will be discussed next for each of the main stakeholders involved.

1.1.1. Amputee Problems

One of the major issues that LL amputees face is that the cost of a LL prosthesis can range anywhere from \$5,000 to \$50,000 and upwards (Ronda Turner 2020). The difference is related to the degrees of freedom, functionality and mobility that the prosthetic device can offer. Therefore, a low end, low priced prosthetic device would offer limited functionality, degrees of freedom and mobility when compared to a device at the high end which would offer significantly more degrees of freedom, functionality and mobility (Ronda Turner 2020). Another issue that amputees face is that the prosthetic device would have to be normally replaced several times during the amputee's lifetime either because of amputee growth, change in daily needs or because device performance deteriorates. Additionally, throughout the device's lifetime, the device would have to undergo several adjustments and services, once again increasing the cost. The incorporation of smart features drastically affects the cost of the prosthetic device (W. Carlos de Silva et al 2015). Another issue that amputees encounter is the time that they must wait from being measured to obtaining and being fitted with a functional prosthesis. This delay can range from a few days to around 39 weeks (A. B. Wanamaker et al 2017). The final issue is the amputee's emotional acceptance towards the prosthesis. The loss of a lower limb has a significant impact on the psyche as the loss of a limb is akin to part of their identity being lost. If the prosthesis is not accepted, the result is social discomfort and body image anxiety which can lead to activity restriction and depression. It is therefore important that the prosthesis generates positive emotions for the amputee such that the prosthesis will be accepted (O. Horgan et al 2004).

1.1.2. Prosthetist Problems

In terms of LL prosthetics, there is a significant emphasis on the *interface* between the device and the amputee's residual limb, termed the *socket* (G. Colombo 2010) and its customisation, since

each limb is unique in size and shape. Therefore, each socket must be carefully designed and crafted to fit a specific patient. This process is referred to as *anatomic customisation*, (*Georgia Prosthetics, Types & Options of pain-free Prosthetic Sockets*). It is then up to the prosthetist to prescribe the best prosthesis for the amputee, and this is usually done by selecting pre-fabricated prosthesis sub-systems from established suppliers. Little to no customisation of mechanical *Above the Knee Prosthesis (AKP)* system parts is done ([M. Buzzi et al 2012](#); [G. Colombo et al 2010](#)).

There are two other factors that must be considered, making the socket, and waiting for the AKP system parts to arrive. The making of the socket is a difficult and time-consuming process that is highly dependent on the skills and experience of the prosthetist. The first step in making a socket is to make a cast of the residual limb. This is referred to as the negative mould. This cast is then used to create the life size and anatomically correct model of the stump. This is known as the positive mould. A thermoplastic sheet is then heated until it forms a large bubble, at which point it is pulled over the positive mould. Vacuum equipment is then used to create a negative pressure inside the bubble, forcing the thermoplastic to shrink and wrap itself around the positive mould. It is then left to cool, and once cooled the shape of the socket will be formed. The related time-consuming process is waiting for the AKP system parts to be delivered once they have been ordered. This process could take around 4 weeks to several months, depending on where the order originated from *Fairview Patient Education, What to expect: The Months After Amputation Surgery*.

1.1.3. Prosthetic Manufacturer/Supplier Problems

The AKP manufacturers are involved in both designing and making their products. Designing the functionality of the prosthetic device has been the main concern of the manufacturers for many years. However, recent studies have shown that it is just as important for the amputee to accept the prosthesis ([S. Sansoni et al 2015](#); [R. Hartson et al 2019](#); [S. Triberti et al 2017](#); [A. Walter 2011](#)). This means that the prosthesis must be designed and manufactured to be emotionally pleasing to help generate positive emotions. It is important to note that emotions are something intangible and at times can be difficult to predict as they vary from person to person. Therefore, to make a prosthesis emotionally appealing, the manufacturers must increasingly become familiar with and exploit concepts of *design for emotions* ([Desmet 2003](#)).

Additionally, in some of today's societies and cultures, having a prosthesis is still considered to be a stigma, this resulting in the prosthesis not being accepted and therefore impacting the sales manufacturers can make. The reasons for this lack of acceptance varies from social backgrounds to upbringing, to lack of knowledge about the device or the prosthetic device generates negative emotions. This is shown in a study where part of their subject group rejected the prosthetic devices due to social and cultural implications, while another part of their subject group rejected the prosthetic device due to aesthetic reasons. Manufacturers must therefore take into consideration the aesthetic, emotional and social expectations of the amputees besides functionality and design the prosthetic devices accordingly as emotion dominates decision making ([T. Van Gorp et al 2012](#)).

1.1.4. Overall stakeholder issues and concerns

To summarize, the stakeholders considered encounter issues and concerns outlined in Table 1. Our research thus concluded that one way of how to cater for these different issues, some of which can be conflicting (e.g. low cost yet emotionally pleasing) is to develop a LL product service system approach that allow the needs of the different stakeholders to be systematically considered. To explain how this has been achieved, the paper will proceed by a review of PSS to understand better how interactions with the different stakeholders take place during different life phases, the ultimate aim being of prescribing a Product Service System Framework that will improve an amputee's experience during different "Prosthesis Life Phases".

Table 1. Summary of prosthesis stakeholder problems

Problem	Amputee	Prosthetist	Manufacturer
1	Cost of prosthesis is too high, forcing patients to go for less expensive, low-end devices	Lack of customization for AKP system parts	They are unable to develop high quality yet low-cost LL prosthesis resulting in less sales
2	The time that the amputee has to wait before receiving the fully assembled prosthesis	Socket casting and manufacturing is a long and labour intensive process	Prosthetic devices are not accepted in all cultures, reducing the reach of their prosthetic devices
3	Prosthetic devices tend not to appropriately cater for the emotional needs of the amputee	Long waiting time for standard AKP system parts (e.g.. knee) to be delivered	Designers do not interact with specific amputee, thus not being able to fully understand their specific needs
4	The LL prosthesis would have to be replaced several times throughout the amputee's lifetime		Prosthetic devices not <i>Designed for multi Xs</i> but tend to focus for functionality; thus, serviceability and disposability tend not to be catered for.

2. Prosthesis User Interactions During Different Life Phases

To help develop a PSS for prosthetic devices, this research embarked on understanding the interactions taking place during the different life-phases of a prosthesis. At the same time, these have been compared with interactions taking place within different life-phases for other products such as cars and photocopiers.

2.1. Concept of a PSS Approach

Consider a company whose sole focus is on the value of the product. In such a case, the company is considered to operate with a *Pure Product* scope. On the other hand, a company whose focus is on the value of their service content, this would be based on a *Pure Service* scope. However, a PSS approach is based on the amalgamation of the two, which involves aspects that are made up of varying aspects of pure product and pure service. These are the Product Oriented, Use Oriented and Result Oriented schemes (A. Tukker 2004). Consider for instance a photocopier which can be either purchased or leased. Table 2 which illustrates the difference between a *Product Purchasing System (PPS)* for purchasing a photocopier machine versus a *Product Service System (PSS)* approach for acquiring photocopying services. In a traditional PPS approach of acquiring a photocopier, the customer not only purchases the product (the photocopier), but also the consumables needed to run the product during its life. The customers must also monitor the performance of their device and arrange for servicing to be done when they consider it necessary. This means that the customer takes full responsibility for the product. Here, the manufacturer essentially develops the relevant product/technology and sells it in the form of a photocopier to the customer.

Conversely, in a PSS approach, the ownership of the photocopier is not transferred to the customer but rather remains with the product supplier. The product supplier would now provide a *Document Management Solution*, which consists of providing the correct device for the customer's needs and any other equipment and necessary. In addition to this, the product supplier would also monitor the performance of the photocopier and carry out any servicing necessary. During this period, a temporary replacement photocopier may be also given until the original device is being serviced.

Table 2. Difference between a Product Purchasing System vs a Product Service System

	Selection	Purchase / Lease	Product Ownership	Cost of Consumables	Responsibility	Product Performance Monitoring	Service
Traditional	End User	Purchase	End User	End User	End User	End User	Product Supplier
PSS	Product Supplier	Lease	Product Supplier	End User	Product Supplier	Product Supplier	Product Supplier

Of relevance to a PSS approach is that a number of stakeholders interact with a product, this giving rise to what is termed as an *interaction map* (N. Morelli 2006). An interaction map is indicative of the different stakeholders that need to be considered during the design of both a product and its PSS. Morelli argues that there is no set of standard tools and methods designed to help develop a PSS. However, it was indicated that narrative tools tend to be preferred during the definition phase of a PSS while more technical tools are preferred when defining the structure of the PSS

2.2. Typical PSS application sectors and life-phases considered

The main sectors where a PSS approach is typically used, are in customer products and services (A. Tukker 2004; A. M. Hein et al 2018; F. Ceschin et al 2014; A. R. Tan et al 2006). No explicit literature has been encountered concerning a private PSS approach that is in use when it comes to the manufacture, distribution, ownership and use of LL prosthesis. Consultation with amputees does however indicate that public health sectors do provide a partial service to amputees to help cover the costs of procurement and servicing of prosthesis intended for daily activities such as walking in normal living environments, using stairs and ramps. However, extending the service to other activities such as dedicated sport or work environments will require changes to the LL prosthesis that are not currently entertained. In any case these types of public services limit the involvement of amputees to the extent that there is no real user-centred design approach – rather amputees are given with a take it or leave it prosthesis, this many times not addressing issues outlined above such as emotional needs or life-long serviceability.

In the case of traditional products such as domestic appliances, manufacturers and suppliers adopting a PPS approach, tend to focus on the *use phase*. However, manufacturers and suppliers adopting a PSS approach, other phases tend to be considered (A. Tukker 2004; A. M. Hein et al 2018; F. Ceschin et al 2014; A. R. Tan et al 2006). However, the user is *rarely* directly involved and consulted during the different phases, something which due to the requirements of developing custom LL prosthesis is not sufficient. Additionally, the feedback from the service to the designer has so far been provided by chance. Thus, in the case of prescribing a healthcare PSS for LL prosthesis, such service needs to consider the interactions and emotions of amputees during the different phases. That is, the servicing issues need to be made explicitly known to the designers such that improved designs can be generated. This is precisely one of the advantages of ProLiSS.

2.3. Key Differences

Based on the previous arguments, it is evident that when acquiring traditional products such as a photocopier, through either purchasing or a PSS approach (Figure 2a), the user *only* interacts with the product during the use phase. However, in the case of acquiring a prosthesis, the amputee has some form of interaction/input with the product (i.e. the prosthetic device) *during the different life phases* as outlined in Figure 2b. Since the prosthesis needs to be customisable, the amputee's input during different phases is vital to providing the correct prosthetic solution that would suit their needs. For instance, during the prosthesis design phase (Figure 2 b), the amputee is involved with the prosthetist such that they collectively come up with the design requirements of the prosthesis. During this interview, the prosthetist, together with the amputee, explore alternative design solutions to the amputee's mobility problems. The amputee is once again involved during the realisation phase as s/he is needed for the socket casting, such that an accurate mould may be achieved. This once again not only requires the amputee to be physically present such that measurement may be taken, but also requires the verbal input of the amputee, as various methods and options are available for the casting. The amputee is then involved in the use phase, as they will be using the prosthetic device to walk. Similarly, during servicing, the amputee is typically involved to provide feedback on any adjustments being made to the device. As in the case of a prosthesis, the user interacts with the evolving prosthesis design, the amputee experiences emotions *during* different phases. For example, an amputee might feel that the socket casting process is taking too long or it may be uncomfortable when being fitted. Thus, emotional aspects during different phases have to be also considered.

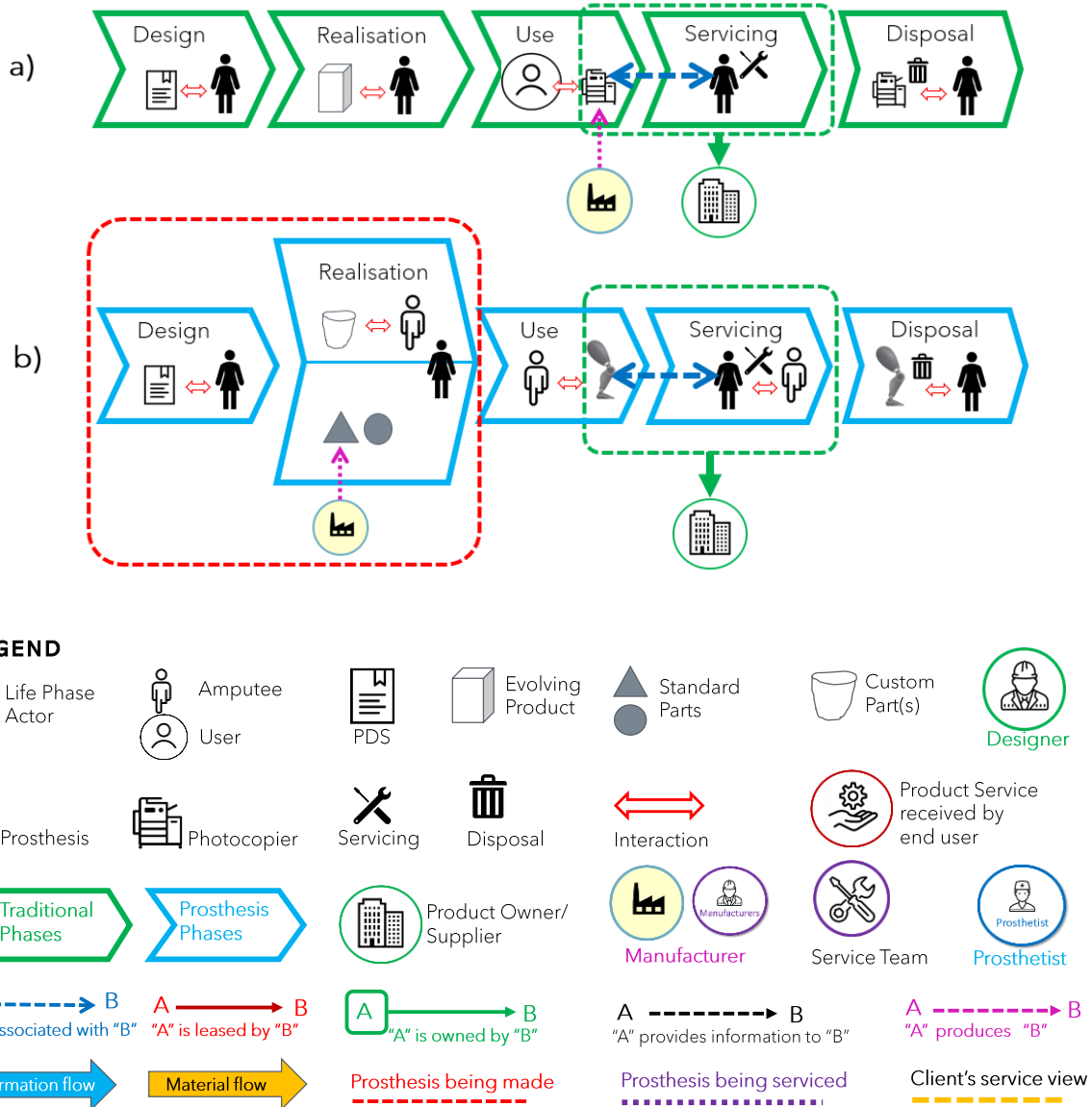


Figure 2. User-Product Interactions during different life phases, a comparison between (a) a traditional product that makes use of a PSS and (b) the traditional health care service by which an amputee receive their prosthesis

3. ProLiSS: A prescribed PSS framework for prosthetic devices

Our research work has thus prescribed an amputee-centred PSS model explicitly aimed towards addressing the needs of the stakeholders involved in the life (see Figure 1) of a LL prosthesis. This model has been termed the *Prosthetic Life-Cycle Service System (ProLiSS) Framework* (Figure 3). The intent of *ProLiSS* is to enable amputees to be provided with a relevant service throughout the different phases of their prosthesis' life to help improve the overall healthcare service they obtain. By adopting the ProLiSS Framework, healthcare systems will be able to provide a range of relevant services to amputees (See Table 3).

(legend as in Figure 2)

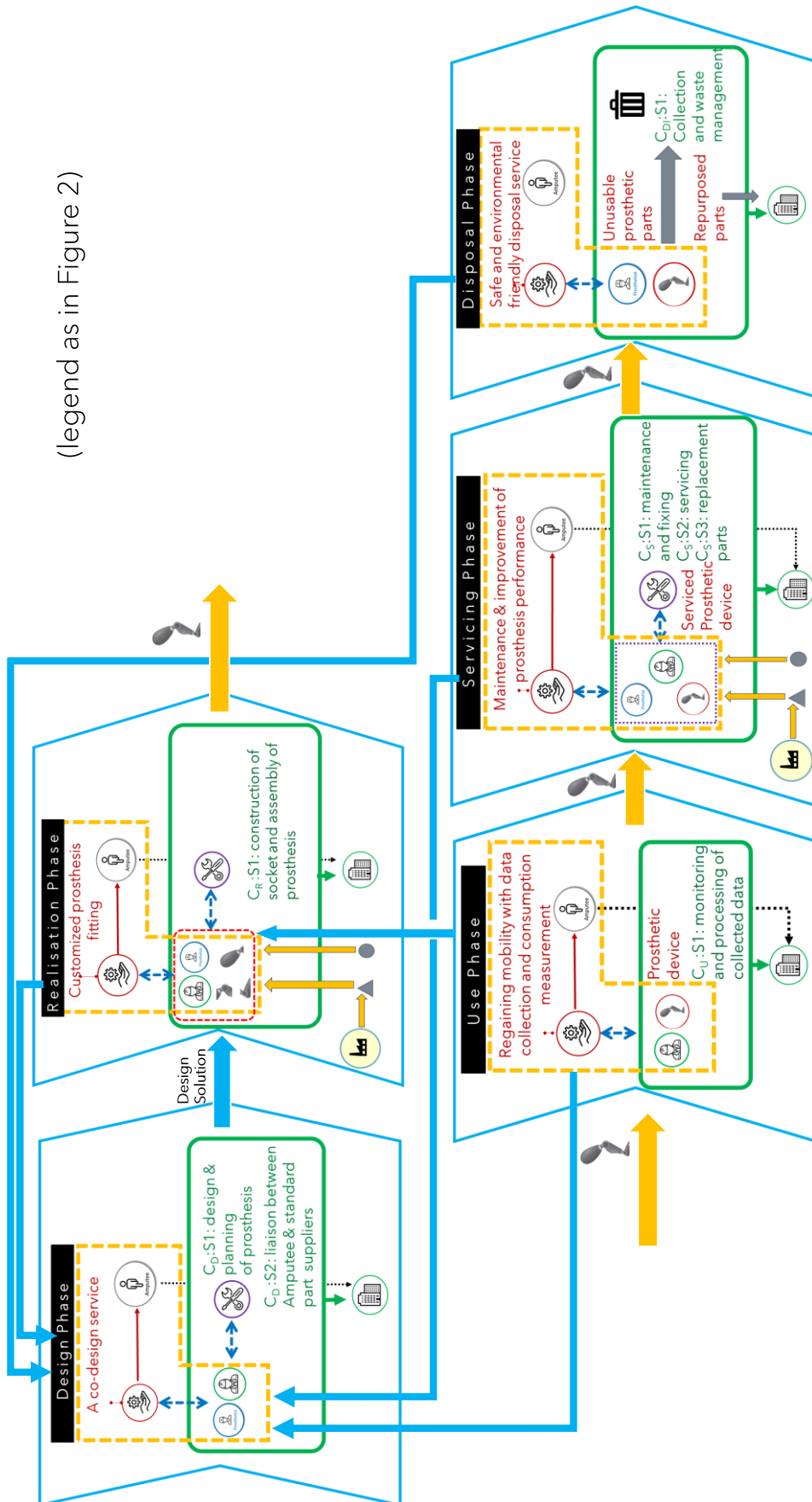


Figure 3. The Prosthetic Life-Cycle Service System (ProLiSS) Prescriptive Framework

Table 3. Prescribed ProLiSS Framework Services

Life Phase	Service Being Provided to Amputees
Design	The amputee is provided with a co-design service as he/she will work closely with the Prosthetist and the technical designer to arrive at a solution satisfying their requirements yet able to be produced from a range of standard parts (e.g. knees, ankle systems). This service consist of C _D :S1 which is a user-centred design and planning approach as well as C _D :S2 which consists of liaison between the amputee's needs and the standard part suppliers. The prosthetist and the technical designer can now design for multi-X and cater for the amputee's emotions as well as their needs.
Realisation	During this phase the amputee is provided with a customised prosthesis development and fitting service, which is suited towards his/her physical and emotional needs. The prosthetist and his/her technical service team will develop the custom parts (e.g. limb socket) to fit the amputee's residual limb and assemble this together with other standard parts (e.g. knee system) acquired from manufacturers, as dictated by C _R :S1. The amputee is also serviced with fitting refinements to the overall solution to ensure a perfect fit.
Use	In this phase, the amputee makes use of the customised prosthesis that was developed in the Realisation phase. This prosthesis will enable the amputee to regain their mobility and allow the amputee to perform daily tasks, in addition to catering to their emotional needs. This service consists of C _U :S1 where the data collected from the prosthetic device, while being used, is monitored and processed such that further improvements in the next iteration of prosthesis can be made.
Service	During this phase, the prosthesis is serviced and maintained keeping its proper level of quality and performance. The services provided to the amputee are C _S :S1 which consists of maintenance and fixing of the prosthesis, C _S :S2 where the device is being serviced and C _S :S3 where worn out or damaged parts are replaced. The servicing could also include adjustments to the existing device to improve its performance.
Disposal	During this phase the amputee is supported through an environmentally friendly and safe disposal service of the prosthesis, besides being provided with a replacement prosthesis. As part of service C _{DI} :S1, the discarded prosthesis elements are separated into unusable parts which are disposed of, and parts that can be repurposed and reused.

4. ProLiSS Framework evaluation

Before embarking on implementing changes to a healthcare service, one needs to evaluate and validate the ProLiSS framework. Since at this stage it is a prescriptive model, the ProLiSS Framework has been peer reviewed by three established product development researchers, one established healthcare researcher, and one practicing prosthetist.

Table 4. ProLiSS Framework Strengths and weaknesses

Strengths	Weaknesses
User-centred design enables both the needs and emotions of amputees to be catered for.	ProLiSS capital expenses will be higher as different service team members are required in different phases
The potential to collect feedback from the different life phases, provides valuable information to designers, manufacturers and technical servicing teams, improving the overall service.	Initial complex framework which could lead to resistance by practitioners and thus a prolonged transition period from a traditional system to a ProLiSS approach.
The involvement of amputees, prosthetists and feedback from manufacturers in the design phase results in a <i>Design for multi-X</i> approach.	Design of prosthesis may take longer due to involvement of amputee who may challenge emerging solutions proposed by Prosthetist.
The useful life of a prosthesis can be extended by timely maintaining it in proper working condition	

These evaluators were given an overview during individual face to face interviews of the steps involved in the ProLiSS approach framework to the development of a prosthesis and clarifications they required answered. Through their multi-disciplinary background, the strengths and weaknesses of ProLiSS were established as shown in Table 4. As one anticipated, there were both strengths and

weaknesses identified, but collectively the Framework was considered a step forward to how prosthesis should be developed, thus meriting that further research work and further evaluation be carried out.

Conclusion

This paper has contributed a PSS framework for prosthetic devices termed *ProLiSS*. The ProLiSS framework has been prescribed to cater for the involvement of the amputee in different life phases, to ensure that the LL prosthesis is customised for the amputee's needs that change and evolve over his or her life. The amputee will be able to provide valuable insight in terms of both his/her current and foreseeable functional needs as well as the emotions that the prosthetic device elicits. To ensure valuable feedback provided by amputees is captured and appropriately re-used by designers, each and every servicing team in the different life phases includes a prosthesis designer. The ProLiSS framework also outlines the information flow including feedback information involved in the different phases.

This fact in itself impacts the design of *LL prosthesis* intended to be used in such a ProLiSS framework, such as for instance providing the prosthesis with smart features to automatically capture and share relevant performance data to appropriate stakeholders. The availability of such life-phase data will enable a customised and rapid service to be provided, this helping in the useful life and performance of prosthesis to be prolonged and improved. Thus, the ProLiSS framework itself impacts the design requirements of LL prosthesis as well as the design approach to be an amputee centred one and total life oriented. These characteristics of ProLiSS combined with the framework's overall positive evaluation feedback obtained from multi-disciplinary peer reviewers indicates that it is indeed beneficial to engage in further research to make it a useful healthcare service framework for the benefit of amputees as well as to contribute prosthesis manufacturers with a systematic, amputee-centred development and servicing framework.

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