ELEMENTS OF A PRESCRIPTIVE AND ADAPTIVE PROSTHESIS DEVELOPMENT SERVICE FRAMEWORK

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ABSTRACT

Amputees face a number of challenges when acquiring and using a prosthesis, with major issues being the cost of the device, the time it takes for their custom prosthesis to be developed and delivered, as well as the challenges they face to get it regularly serviced and maintained. The other stakeholders involved, including the prosthetists and standard systems manufacturers, have a difficulty to collectively handle so many issues that occur to the different amputees. To address these challenges, our research reported in this paper contributes an approach to how these can be handled, through a Prescriptive approach entitled Adaptive Prosthetic Life-Cycle Service System (adProLiSS) Framework. Unlike other product service systems, adProLiSS is designed to explicitly involve and serve the amputee and their evolving needs during different phases throughout the amputee's life. This impacts how a prosthetic device needs to be designed to ensure a smoother interaction between the amputee and the device. The adProLiSS preliminary evaluation shows an improvement by which amputees can be efficiently provided with a prosthesis that evolves with their changing needs and aspirations, this fostering a longer term 'patient-centred care' service.

Keywords: Product-Service Systems (PSS), User centred design, Collaborative design, Smart Prosthesis, Patient-Centred Design

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1 INTRODUCTION

In spite of advances made in science and technology, upper (UL) and lower limb (LL) amputees still face a number of challenges when acquiring and using prosthetic devices, especially when one considers that their mobility, emotional needs and aspirations evolve and change over time (Young M et al, 2019), a fact that current patient centred prosthesis services tend to ignore. One example of such a challenge is the considerable time it takes for their prosthesis to be custom designed, personalised parts fabricated and standard system parts to be delivered, all to be later assembled together. As the needs and aspirations of the amputee's evolve with time, alterations and improvements must be made to their prosthesis. These alterations take significant time, effort, resources and increase costs.
The development of a prosthesis is a complex set of activities and processes that require the input of many stakeholders such as prosthetists and manufacturers. Each of these stakeholders have constraints and needs that can evolve with time. All these activities and processes need to be simultaneously coordinated and performed in a friendly way to ensure both long term customer satisfaction as well as a sound and sustainable prosthesis service operation. There has been some research work (G. Colombo et al 2010; Sansoni et al 2015) carried out to precisely address how the design and development of prosthesis can be improved, but this tends to focus on only the current rather than the evolving amputee needs. The research reported in this paper aims to precisely address the question on how a cost-effective Prosthesis Development Service (PDS) Framework can be prescribed to cater for both the current and evolving needs of amputees whilst concurrently considering (Borg, J.C. et all 2000) the co-evolving needs of the other stakeholders such as prosthetists and standard system part manufacturers. To achieve this goal, the research reported in this paper has been based on first generating a descriptive model (Blessing, L et al 1995) of the prosthesis product development process as a basis by which to establish details of current problems and challenges. Based on this detailed understanding, an improved and thus prescriptive and adaptive PDS framework called adProLiSS has been developed and evaluated taking LL prosthesis as a case-study.

2 DESCRIPTIVE PROSTHESIS LIFE CYCLE MODEL

To understand the issues that the current stakeholders are having, it is important to understand the processes involved in the development of the prosthesis. Focusing on an above knee LL prosthesis system in our research, as illustrated in Figure 1, this consists of different sub-systems, some of which are custom made to fit an individual amputee, while other systems are standard.

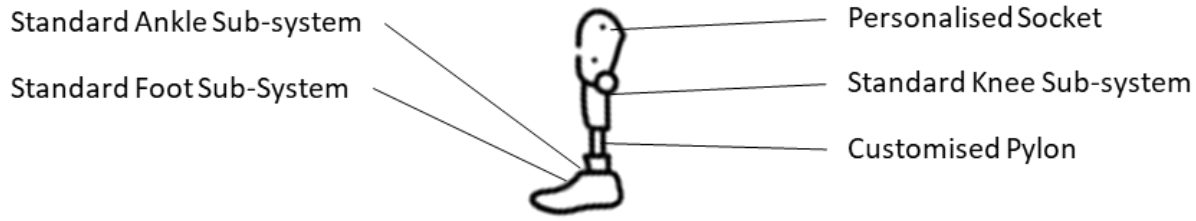

Figure 1. A Prosthesis consisting of personalised, customised and standard systems

An empirical analysis was carried out to establish and model the current phases through which the design and development of a LL prosthetic device goes through was conducted. Figure 2 is extracted from one of our internal research report (Patiniott, N and Borg, J.C. 2022 PREMIER Project M2.1 Detailed Problem Analysis, Department of Industrial & Manufacturing Engineering, University of Malta, 19th Sep 2022) discloses a descriptive model outlining the key steps, sequences and stakeholders involved in each phase of the prosthesis product development. Data in this report is based on a mix of literature reviews and survey data collected through structured interviews with a sample of amputees, prosthetists and suppliers. Through the analysis disclosed in the internal report, several problematic patterns have emerged, these summarised in Section 2.1 below.

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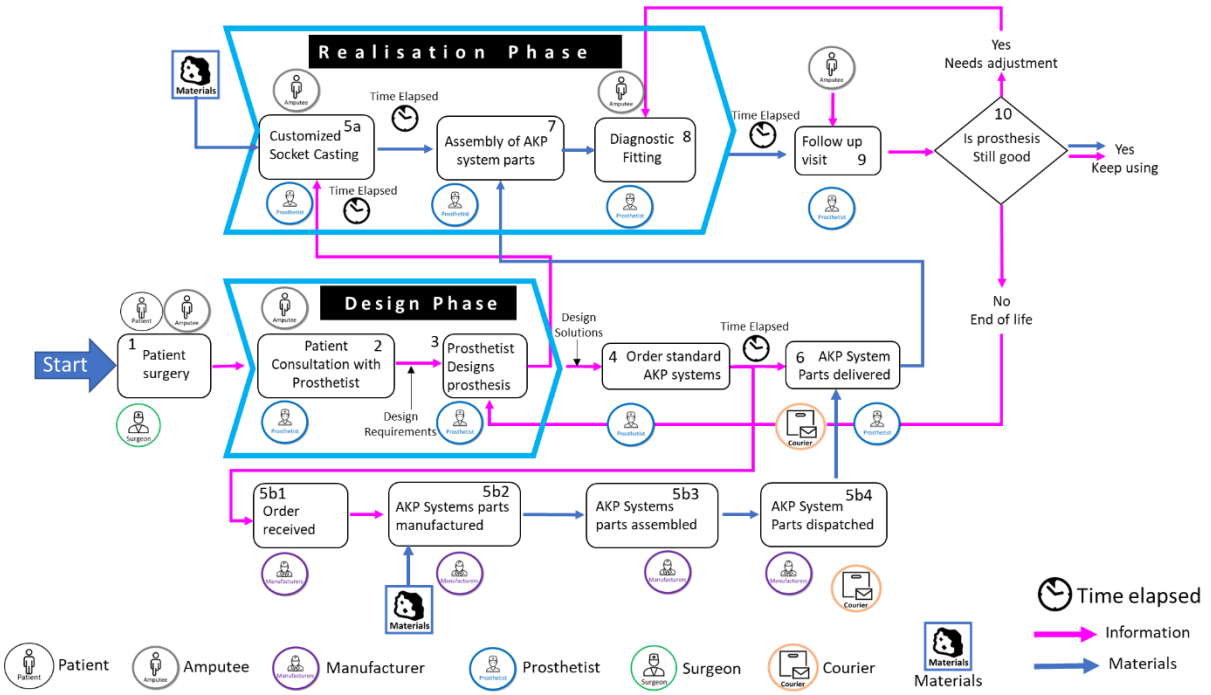

Figure 2. Prosthetic device product development descriptive model

2.1 Key stakeholder issues and concerns

The key stakeholders involved i.e. the amputee (A), the prosthetist (P) and standard system manufacturers (M), encounter issues and concerns. Generalising, the current issues involved in the development of a prosthesis can from a high level be classified into two (a) technical constraints (Table 1) and (b) financial limitations (see Table 2).

Table 1. Summary of prosthesis stakeholder problems

	Amputee (A)	Prosthetist (P)	Manufacturer (M) [1]
1	Prosthesis fabrication is a specialised process that requires a long period of time, increasing the waiting time for the amputee before they can actually use their prosthesis.	Prosthetist are constrained to a finite set of AKP sub-systems available on the market, this limiting the amount of customisation they can offer to the amputee.	Designers do not interact with individual amputees; thus, the manufacturers are not able to fully understand their specific needs.
2	The amputee requires time to adequately bond (emotionally) with the prosthesis.	Socket casting and manufacturing is a long, labour-intensive process, consuming large portions of the prosthetist's time.	Prosthetic devices are not Designed for multi-X (D. A. Gatenby & G. Foo, 1990) but tend to focus on functionality only.
3	The LL prosthesis must be replaced several times throughout the amputee's lifetime due to wear and tear	Prosthetists dependent on standard system parts (e.g. knee), many times resulting in long delivery periods.	
4	Prosthesis misalignment will cause the amputee significant discomfort, resulting in the amputee feeling less stable while using the prosthesis.		

[1] By Manufacturer, it is hereby assumed in this paper to be the organisation producing the standard parts and thus will involve designers, fabricators and others.

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With regards to the technical aspect, the main issue is of how rapidly a prosthesis can be designed, produced and delivered in such a manner that the prosthesis is of high quality, comfortable and safe. When it comes to the financing, there are multiple hurdles that must be faced, these are how to fund the materials as well as the professionals and suppliers involved in the development of a customised prosthesis. Table 1 shows that there are sometimes conflicting issues e.g. a low cost yet emotionally pleasing prosthesis. To cater for such conflicting and evolving issues, our research proceeded by developing a LL product service system (PSS) approach that allows the needs of the different stakeholders to be systematically considered, with the aim of prescribing a PSS Framework that will improve an amputee's experience during different "Prosthesis Life Phases".

Table 2. Summary of prosthesis stakeholder financial issues

1	Cost of prosthesis is too high, forcing amputees to go for less expensive, low-end devices.	In some countries, funding for the prosthesis can be an issue, forcing the prosthetist to select the cheaper and less beneficial option.	Prosthetic devices are not accepted in all cultures, reducing the sales market size of their prosthetic devices.
2			The drive for high profit means that manufacturers are not motivated to develop low-cost, high quality cost LL prosthesis.

2.2 Requirements of an improved prosthesis development model

Developing a customised LL prosthesis requires achieving a LL device that is both acceptable to the amputee but also one that is relatively easy to produce and also maintain. An improved prosthesis development model must hence cater for a set of LL design specifications as well as the prosthesis manufacturing and prosthesis service business needs. Hence considering that design, manufacturing and business aspects have to be concurrently considered, the model of our novel Framework has been founded upon the Integrated Product Development (IPD) approach by Andreasen and Hein (Andreasen et al, 2000). Thus, based on an analysis of the different stakeholder's problems as well as feedback obtained on the initial concept of the framework (Patiniott et al, 2022), a set of requirements for an appropriate product service system framework were gradually established, these outlined below:

must support the prosthetist in efficiently configuring the design of a LL prosthesis personalised for the needs of an amputee from a range of optional sub-systems readily available;
result in the delivery of a personalised prosthesis that is of high quality, that is comfortable and considered to be safe from a stability perspective;
enable customised prosthesis to be manufactured cost effectively and efficiently;
very importantly cater for the evolving needs and aspiration of amputees that change over time, even after a LL prosthesis has been delivered;
result in an overall reduction in the time it takes to deliver a customised LL prosthesis.

3 ADPROLISS: A PRESCRIPTIVE AND ADAPTIVE PROSTHESIS DEVELOPMENT SERVICE FRAMEWORK

To address the issues outlined in Section 2, the research reported in this paper has resulted in a novel prescriptive and adaptive prosthesis development service framework that takes into consideration both the customisation and personalisation of an amputee's prosthesis. This Framework (Figure 3) is divided into three Frames, with each Frame being sub-divided to show the different process that take place. The Frames, in order of sequence are:
Standard Systems Development Frame
Custom Prosthesis Development Frame
Prosthesis Adaptation Frame

Manufacturing (including Assembly) of the prosthesis is represented by the arrows denoted with M; the Design Pillar shown by the arrows denoted with D; and the Healthcare Service Business shown by

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the arrows denoted with B. As outlined, in this framework there is an underlying inter and intra frame information flow highway that is intended to enhance the flow of information between all stakeholders involved. The three Frames and their sub-sections will be explained in Sections 3.1 to 3.3.

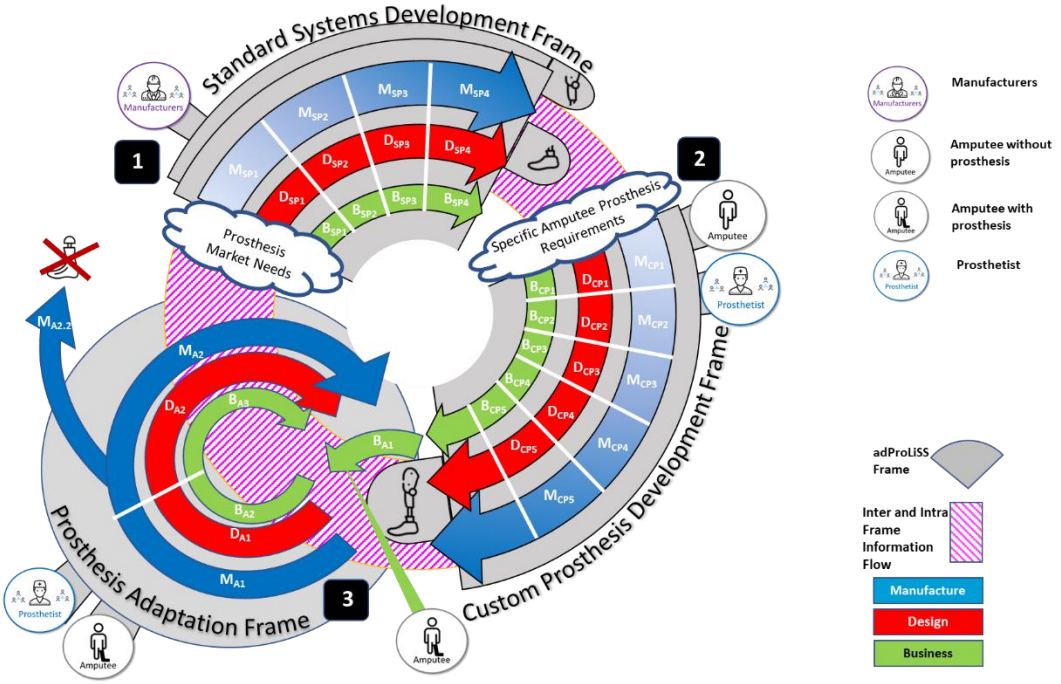

Figure 3. The adProLiSS prosthetic development service framework

3.1 The standard systems development frame

The Standard Systems Development Frame (step #1) represents the processes used by the established standard system manufacturers (see Figure 3). Each of the three Pillars are divided into four sections and are outline by Table 3. Note that this Frame is an accumulation of multiple Frames, where the output of each Frame is a different standard system (e.g. ankle system or knee system). Through the Business Service Pillar, the manufacturing company commences by determining the prosthesis market needs. The manufacturing company can then move on to investigate the market, prepare for sales within the targeted market and finally advertise and sell their products. These activities are represented by BSP1 to BSP4. In the Product Design Pillar, the manufacturing company must determine the type of product that they wish to produce, they must come up with a preliminary design of the product, they must ensure that they are able to manufacture and produce their product and must cater for any foreseeable adaptation that may come. These activities are represented by DSP1 to DSP4. In the Standard Systems Manufacturing Pillar, the manufacturing company will begin the process of manufacturing the product by considering the process type, determining the production principles, prepare for production and finally begin the production of their product. These activities are represented by MSP1 to MSP4.

Table 3. Standard system development frame sub-sections

Business Service		Product Design		Standard Systems Manufacture	
BSP 1	Determining the basic prosthetic needs	DSP 1	Determining the type of product	MSP 1	Consideration of process type
BSP 2	Market Investigation	DSP 2	Preliminary product design	MSP 2	Determining production principles
BSP 3	Preparation for sales	DSP 3	Modification for manufacture	MSP 3	Preparation for production
BSP 4	Sales	DSP 4	Product adaption	MSP 4	Production

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3.2 The custom prosthesis development frame

The Custom Prosthesis Development Frame (step #2) is where the personalised socket and the chosen standard system parts are assembled to form the complete prosthesis. This process is one based on a co-design (Robert. G et al, 2021) approach involving the prosthetist and amputee working closely together. It starts off by the prosthetist working with amputees to understand their needs and then selecting a set of standard system parts that best suit the amputee's goals. The prosthetist will then go on to measure the residual limb and proceed to make the personalised socket. The prosthetist will then assemble the standard system parts together with the socket to form the complete prosthesis. The different process that are used in this Frame are shown in Figure 4 and each step is detailed in Table 4.

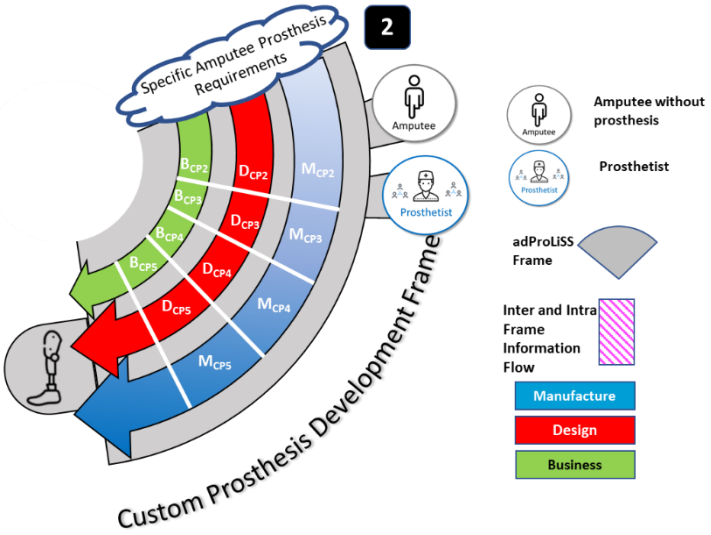

Figure 4. The custom prosthesis development frame

The Healthcare Service Business represents the business aspect of an entity such as a private hospital that offers a service and a product to a population of amputees while at the same time making a profit. The first step that this entity must go through is to determine the needs of the amputee, only then can the prosthesis preparation and assembly take place. Once the prosthesis has been fully assembled, it must then go through an evaluation process to determine if it meets the amputee's needs. These steps are shown through BCP1 to BCP5. Through the Configuration Design Pillar, an investigation of the standard systems available from established manufacturers must be conducted such that the appropriate standard systems may be selected for the amputee. These standard systems are then ordered from an established manufacturing company. These steps are shown through DCP1 to DCP5. The Custom Parts and Standard Systems Assembly Pillar is where the prosthetist takes the anatomical measurements of the patient's residual limb and uses these measurements to fabricate the socket. These steps are shown through MCP1 to MCP3. The standard systems are them assembled and attached to the socket. Once assembled, a trial run of the prosthesis is carried out followed by an evaluation (steps MCP4 to MCP5).

Table 4. Custom parts development frame sub-sections

Health Business Service		Configuration Design		Custom & Standard Parts Assembly	
BCP 1	Amputee Basic Need	DC P1	Investigation of standard parts	MCP 1	Dimensions taken for cast
BCP 2	Product Preparation	DC P2	Evaluation of standard parts	MCP 2	Selection of materials for cast
BCP 3	Product Assembly	DC P3	Configuration design of standard parts	MCP 3	Socket casting
BCP 4	Full Prosthesis Assembly	DC P4	Evaluation of configuration design	MCP 4	Socket and standard parts assembly
BCP 5	Prosthesis Evaluation	DC P5	Standard parts evaluation	MCP 5	Full prosthesis evaluation

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3.3 The prosthesis adaptation frame

The Prosthesis Adaptation Frame (step #3) focuses on maintaining the health of the amputee and their prosthesis by closely monitoring them even after the LL prosthesis has been delivered. This would be made possible by collecting up-to-date information (e.g. socket pressure, temperature and humidity) both automatically through sensors and manual feedback. This information will enable the prosthetist to remotely address any issues that may arise, determine what parts need to be maintained or disposed of and what can be repurposed. To achieve this, the Prosthesis Adaption Frame has been split into three stages, shown in Figure 5 and detailed in Table 5.

The information collected is a key factor within this Frame and it will be used by the prosthetist to maintain and improve the amputee's experience of the prosthesis. This information can also be anonymised and sold to different manufacturing companies. This would allow the Healthcare Service Business to generate income, whilst also providing the manufacturing companies with relevant information that they could use to further improve their products.

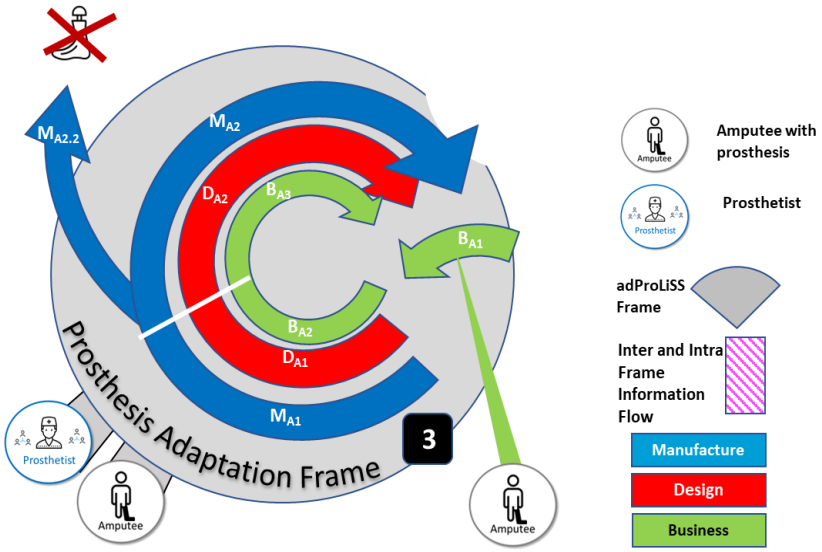

Figure 5. The prosthesis adaptation frame

Table 5. Prosthesis adaptation frame sub-sections

Health Business Service		Configuration Design		Custom Parts and Standard Systems Assembly	
BA 1	Prosthesis and Patient Health Management	DA 1	Diagnostic and analysis of data	MA1	Prosthesis servicing, Maintenance and Adaptation
BA 2	Prosthesis and Patient Adaptation	DA 2	Redesigning, adaptation and disposal design	MA1.2	Repurposing of standard system parts that are in good condition but no longer fit the amputee's needs
BA 3	Prosthesis end of Life Management			MA2	Prosthesis Disassembly
				MA2.2	Disposal of worn out parts

The main aim of the Healthcare Service Business is to provide a service that will cater for the changing needs of the amputee while the amputee is using the prosthesis. This will encompass a monitoring service that will constantly monitor the amputee and the prosthesis health. This is achievable by having real-time data being collected and transmitted automatically to the relevant stakeholders (BA1). The collected data will then be processed, and the information will be used in later stages. The Prosthesis and Patient Adaptation stage (BA2), is where a service is provided to

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realise changes that need to be made to the prosthesis based on the information obtained during BA1. The last stage in the Health Service Business is to provide an end-of-life management service for the prosthesis (BA3). The Configuration Design (Darr, T. et al, 1998) Pillar concerns itself with the selection, adaptation and redesigning of the custom parts and standard systems based (DA1 and DA2) off the information collected. The first stage in the Configuration Design Pillar (DA1) is to analyse the information collected, then diagnose and solve any problems that would have risen. DA1 is then followed by step DA2 where the redesigning and adaptation of the prosthesis takes place.

The Custom Parts and Standard Systems Assembly Pillar is where the physical assembly, maintenance and disposal of the prosthesis occurs. This process starts with MA1, where the servicing, maintenance and adaptation of the prosthesis is carried out based on the designs obtained during DA2. At this stage, the standard systems that are in good condition but no longer suit the needs of the current amputee, are selected and set aside to be repurposed such that they may be later used by another amputee. The process then continues with MA2, where further physical adaptation and alterations are made to the prosthesis. However, at this stage, the parts that are removed are selected for disposal as they would no longer be in good working order (MA2.2). These parts are then broken down and their raw materials are reused.

4 PRELIMINARY EVALUATION OF ADPROLISS

Before the adProLiSS development Framework can be introduced in LL prosthesis healthcare service systems, it needs to of course be evaluated. At this stage of our on-going research, the adProLiSS Framework has been thus peer reviewed by two established product development researchers who took the perspective of manufacturers (M), one experienced podiatrist who took on the perspective of a prosthetist (P), one practicing prosthetist (P) and one amputee (A). During each interview, a case-study was demonstrated highlighting how the adProLiSS Framework could be applied and exploited by the different stakeholders. Through their combined feedback, the strengths and weaknesses of the adProLiSS Framework were established as outlined in Table 6.

Table 6. adProLiSS framework strengths and weaknesses

	Strengths	Weaknesses
A	User-centred that design that enables the needs and emotions of the amputee to be catered for; during the realisation of the prosthesis and especially during the maintenance and adaptation stages.	Design of a prosthesis may take longer due to the heavy involvement of the amputee who may challenge emerging solutions proposed by the prosthetist.
P	The ability to collect information throughout the customisation and adaptation frames. Due to the active monitoring of the patient and prosthesis health, certain issues and problems may be avoided as. appropriate pre-emptive actions may be taken The useful life of a prosthesis can be extended by timely management and maintaining it in proper working conditions thanks to the heavily involved Prosthesis Adaptation Frame.	The initial complex adProLiSS Framework could lead to resistance by practitioners and thus a prolonged transition period
M	The information exchange arising from the close involvement of the amputees and the prosthetists allows for regular feedback to reach the manufacturers through the underlying information highway, this enabling them to engage in a Design for multi-X approach.	The capital expenses required to enact adProLiSS will be higher as more stakeholders will be involved at any given stage in the frames.

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5 CONCLUSIONS

Through the regular involvement of the amputee and the exchange of useful information with the prosthetist and manufacturer, the adProLiSS Framework ensures that the ever-changing needs of the amputees are catered for throughout the life-time of their prosthesis. The information will be collected though automated means that is being highly emphasised during the Prosthesis Adaptation Frame. This in itself implies that prosthesis should be designed in such a way as to smartly collect information relevant to prosthetist to help them monitor both amputee and prosthesis device performance. Not only would this enable a personalised and rapid service to be provided, it would also make it possible for the concept of digital twins (Batty, M., 2018) to be exploited during the development of LL prosthesis. The regular information captured would enable the relevant stakeholders to have an up-to-date virtual digital model of the patient's prosthesis. This will allow better amputee and LL prosthesis system monitoring, making it possible for issues to be noticed and rectified before the situation deteriorates. The resulting personalised and rapid service would significantly improve and extend the life of the prosthesis by catering for the ever-changing needs of the amputee. For example, the continuous monitoring of the socket pressure would be of significant importance to both the amputee and the prosthetist. This information would be useful to the prosthetist as they would be able to detect pressure points within the socket, allow them to take preventive action and thus avoid potential sores. This would allow the amputee to continue to safely use the prosthesis with less discomfort and paint, as well as reduce the amount of time that the amputee does not use the prosthesis.

The current work performed has so far been only applied to the activities and stakeholders involved in lower limb prosthesis. It would indeed be interesting to explore if the same framework can be applied to upper limb prosthesis, but this would require further research to explicitly understand if the type and number of steps involved in the different frames would need to change. Nevertheless, we can at this stage conclude, that the preliminary evaluation of adProLiSS Framework indicates that it contributes an approach that collectively improves how a LL prosthesis is developed and maintained. In particular, two main elements established for this prescriptive framework are the 'Prosthesis Adaptation Frame' and the 'inter/intra information highway', that collectively help cater for the evolving LL amputee requirements throughout their lifetime, this fostering a longer term 'patient-centred care' service.

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