Inrterdisciplinary-based Development of User-Friendly Customized 3D Printed Upper Limb Prosthesis

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Abstract. This study reports on the development of a customized transradial mechanical prosthesis for an infant patient with bilateral transradial amputation, with a design process based on an interdisciplinary project combining the areas of product design, rehabilitation, rapid prototyping and ergonomics. The design process started with the clinical assessment of the patient characteristics, functional abilities and needs, as well as interviews for exploring patient's preferences and interests. Next, a first version of the 3D prosthesis was designed and prototyped and later tested with the patient. From this first test, a second design process was started, aiming to solve the problems and improve the prosthesis hand function. A second test was then carried out with the user, revealing that the second prototype provided a more appropriate and comfortable coupling with the limb, an easy activation of the hand prehension by flexing the elbow and, finally, met the child's preferences and expectations. It was possible to manufacture tailor-made, customized and personalized parts according to the users' preferences, in a faster and more precise way than the conventional method, making them more suitable for the development of prostheses for each patient, which must be custom fabricated.

Keywords: Design · Prosthesis · Assistive Technologies · 3D Printing

1 Introduction

Global data show that more than one billion people in the world experience deficiencies of different types and degrees (WHO, 2011). In low-income and developing countries, many people do not have access to assistive devices and, therefore, have limited independence and social participation. Assistive Technologies (AT) have the potential to promote social inclusion and dignified life.

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While lower limb prostheses work satisfactorily for most of the users, substituting the complexity of hand function remains a difficult challenge. Most upper limb prostheses are heavy, difficult to operate and do not allow for efficient and satisfactory functioning in daily activities. As a result, many people with unilateral upper limb amputation tend to adapt to perform daily tasks with one hand. The upper limb prosthesis, in many cases, are not used and, finally, abandoned.

Usability problems related to upper limb mechanical prosthesis have been reported (REFs). Also, studies have addressed the stigma associated to the design of assistive technologies, highlighting the need of customizable design not limited to practical concerns, but also focusing on best meet the user's preferences, thus benefiting acceptance and satisfaction (REFs).

3D Printing and Rapid Prototyping (RP) are technologies that started to be applied to the field of prosthetics and can enhance the fabrication process by enabling tailored (unique and customized) parts to be produced faster, more accurately, and more sustainably compared to the conventional modeling and prototyping process, making them more suitable for the development of prostheses.

This paper describes the interdisciplinary collaborative development of a customized transradial mechanical prosthesis for an infant patient with bilateral upper limb amputation (forearm level), combining knowledge and approaches of areas of product design, rehabilitation, rapid prototyping and ergonomics.

2 Development

Thus paper reports on the development of a customized low cost upper limb prosthesis based on interdisciplinarity approach between Product Design and Rehabilitation. Specific knowledge and practices of both areas were applied to a linear development process, as shown by Fig. 1.

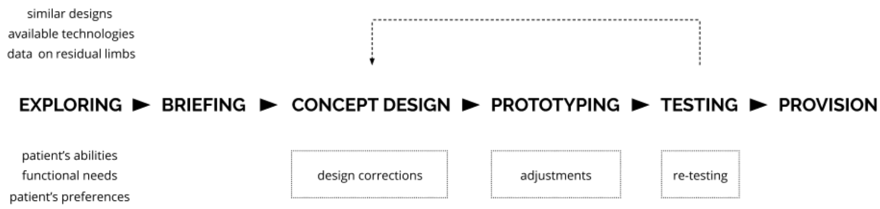

Fig. 1. Design Process of the upper limb prosthesis development.

2.1 Exploring

This case involved a patient who, with a year and a month, had her upper and lower limbs amputated, due to the occurrence of meningococcemia, an infection caused by the bacterium Neisseria meningitidis (meningococcus), the same type of bacteria that can cause meningitis. The disease has caused sequelae in the patient, bilateral transtibial amputation in the upper third of the leg (calf area, tibia and fibula are cut) and bilateral transradial amputation (bony section between the elbow and wrist joint. It may be proximal, middle or distal). SORRI Bauru began follow-up treatment in 2009, the year that the amputations occurred. The patient had prosthesis on both of her lower limbs but still did not have the upper limbs protected.

First, an interview was conducted to learn about the patient's needs and expectations. The patient had some complaints about her inability to perform daily activities alone such as conducting her personal hygiene, using the toilet, changing clothes, using zippers, closing buttons, brushing her hair, to mention a few. In addition, she complained about perspiring too much when she writes, since she uses both stumps to hold the pencil, which is distracting and taxes her energy. The patient takes athletic classes, loves to play with her dolls, watch cartoons, and is extremely active despite her condition.

The patient had an unsuccessful previous experience with a standard mechanical prosthesis similar to the one presented in Fig. 2.

Fig. 2. Standard mechanical prosthesis provided by the Public Health System.

Mechanical prostheses are the most suitable for children because of their adaptive characteristics.

2.2 Briefing

Due to the needs of both the patient and the available technologies, we focused on the design of an upper limb prosthesis that could activate hand grasp by the movement of elbow flexion and extension (mechanical prosthesis). In this case, it is better to work with a mechanical prosthesis because the patient needed a functional prosthesis that went beyond simply having a stump (aesthetic / passive prosthesis), since the patient still has the natural movement of the elbow.

To support proper decisions during the design process, the main aspects of the prosthesis design were separated into three categories: technical, ergonomic and aesthetic aspects (Table 1). From the technical perspective, it was important that the prosthesis met the following requirements: easy maintenance; resistant material; low cost; simple manufacturing elements - printed parts should be as simple as possible.

From an ergonomic point of view, the prosthesis should be as light and easy to activate as possible. Also, it should comfortably fit the left limb, as the stump is longer than the right side, thus facilitating the elbow flexion (which is the movement that activates the hand grasping). Simple hygiene, easy attachment / placement and increased friction on fingers and palm to facilitate the user to hold objects are other important ergonomic features to be presented in the prosthesis design. Finally, the aesthetic aspects were crucial for the acceptance and satisfaction of the user, specially for a child. In this context, the prosthesis should look playful, so that the child could see it as a "toy" that could help her in her daily activities. The prosthesis design should therefore consider the preferences of the child, such as colors and cartoon characters.

Table 1. Briefing results.

Technical	Ergonomic	Aesthetics
Easy maintenance	Right stump	Playful (“toy”)
Resistant material	Lightweight	Customizable according to user
Low cost	Simple hygiene	
Simple manufacturing elements	Comfortable	
Durable	Easy Attachment	
Open Source, reproducible	Finger tips coated for better grip	
Efficient		

2.3 Concept Design and Prototyping

A test was performed to better analyze the Unlimbited Arm model, which after research was the best option among the transradial open-source prostheses available. For the construction of the prosthesis, the instructions available on the prosthesis page on Thingiverse was followed, a website dedicated to the sharing of digital files created by its users.

Some user measures were required for the creation of the prosthesis, such as biceps circumference, forearm length, and hand length. This data was applied in Customizer, a Thingiverse application that allows files to be modified. First, it must be chosen to which side (left or right) the prosthesis will be made, then place the measurements (all in mm).

The prosthesis consists of a total of 34 pieces, divided into: fingers (5), phalanges (5), palm (1), forearm (1), long pins (13), circular pins (4), template, clamp (1) and tensioning pins (3).

The printing was done at CADEP – the Center for Advanced Product Development at UNESP Bauru using the CubeX Duo 3D Printer and at Fab Lab Livre SP, Cidade Tiradentes unit, using a Sethi3D AiP 3D Printer. Both machines used the same material, namely white and blue PLA (Polyactic Acid) plastic filament.

To perform the assembly, it was followed the instructions presented online.

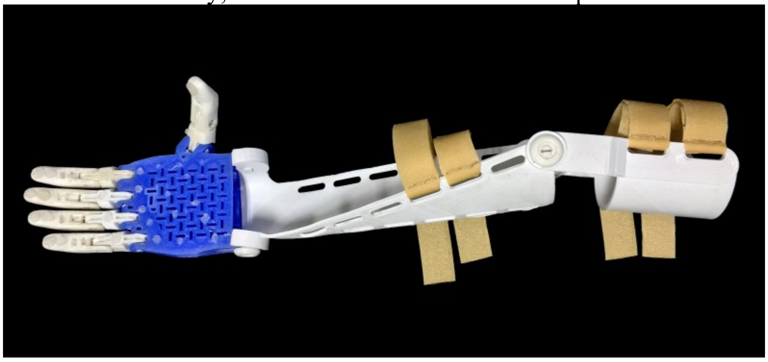

Fig. 3. Unlimbited Arm assembled.

2.4 Testing

For user testing, some objects that are easy to pick up was chosen so as not to generate frustration, such as Lego blocks, a glass, a jar, and a textured cylinder.

The prosthesis was worn by the patient, who soon began to open and close her hand, even before explaining how to perform the movement.

It was noticed that the prosthesis could be better fixed by simply applying one more Velcro to the proximal part of the forearm, so that the user did not have to apply so much force to generate the movement of the fingers. It was also sanded the proximal part of the forearm because it was limiting the movement of the user. These procedures facilitated biceps flexion.

The test was also done in the left stump, where we had a better result, being able to close the fingers more easily.

Fig. 4. User test.

2.5 Final Concept Design and Prototyping

After testing with the user, we concluded on how the final prosthesis should be. It must be made for the left stump; the proximal forearm should be reduced approximately 4 cm in length; the distal clamp should be curved for added comfort during use; the palm of the hand and fingers should have more grip / larger contact surface. For this final prosthesis, the holes for the Velcro inserts can be removed because rivets can be used; the thumb should be rotated approximately 10 ° upwards, so that it becomes more natural and improves the grip; edges must be smoothed; modification of the fingers, by adding another phalange (joint); the mechanism will be the same as it works perfectly well. To improve the forearm and armband, a cast of the user's stump was made. We would scan three-dimensionally and apply these parameters obtained to adapt the geometry of the forearm to perfectly fit the patient.

For the prosthesis to meet the aspects of the briefing, it must have few parts; simple form; construction, mechanisms, assembly and simple accessories; have less material (reducing thickness and dimensions); the material used should be plastic (easy to clean) and be lightweight; to be comfortable. In addition, it needs to be aesthetically attractive according to the user, allowing customization for user needs and specifications.

The aim was to redesign the prosthesis, with greater playfulness, to refer more to a toy than to a prosthesis, consequently becoming more attractive to children.

Stump Mold Making. For the dimensions of the stump of the user in a more precise way, the user stump mold was made in SORRI - Bauru. By obtaining the positive mold, it is possible to mold the forearm and the armband in it and consequently the fixation on your stump and arm will be perfected. Thus, the user will be able to open and close the prosthesis more easily.

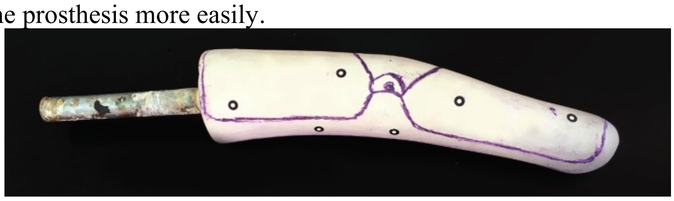

Fig. 5. Positive mold with reference points for scanning.

Mold Scanning. The mold was digitalized at CADEP, to obtain a digital polygon mesh. For this process, the 3D mobile optical scanning system, GOM, model ATOS I 2M was used, which obtains three-dimensional data of an object quickly and accurately due to the high resolution. An outlet points of this equipment can get up to two million points, and each individual outlet is added to the set of previous measurements, resulting in a dense cloud of points. The parameters obtained will be used to adapt the geometry of the prosthesis to fit perfectly to the stump of the patient.

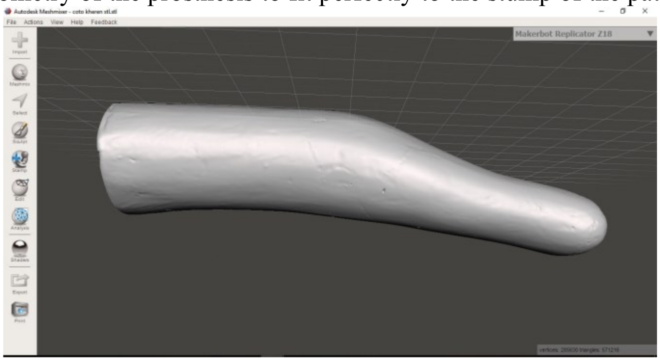

Fig. 6. Virtual mold after scanning.

Redesign of the prosthesis. For the editing of the pieces, the software Rhinoceros and Meshmixer were used. The only files that did not require any modification were the pins and the template. In all the pieces the edges and the mesh of triangles were softened.

On the fingers the cat paws were applied to increase the grip and the contact surface. In the phalanges the paws in the center of the lower part, however, a cavity was made where the paws should stay, to print them in a material different from the phalanges. In the palm, the vector of a drawing of the "Marie kitten" was applied and the general geometry was modified, as the inner canals, which were reduced for passage of the nylon threads, besides removing the mesh from the palm, and creating an internal mesh, giving flexibility to the piece. In the forearm, it was used as the basis for the modification of geometry the scanning of the forearm mold. It was reduced 3 cm in length, and a mesh of kitten paws was applied to reduce material and transmit playfulness to the prosthesis. A U-shaped cut was made at the proximal and distal but softer end. The channel of the nylon wires was reduced. Only three cavities were retained for the passage of Velcro. In the clamp, a "U" cut was made from the distal end of the piece and applied the user's name and project logo.

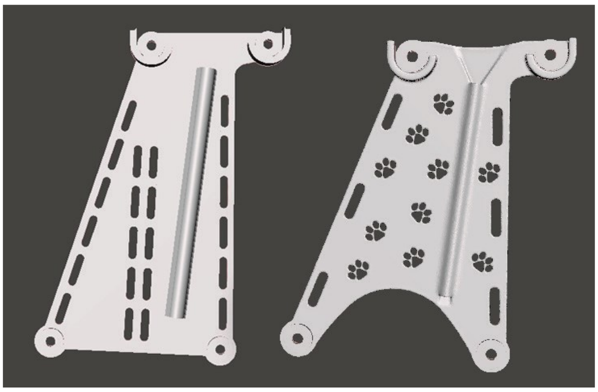

Fig. 6. Forearm. On the left, before the redesign; on the right, after.

3D Printing. The Sethi S3 3D Printer was used for the printing of the pieces and for the preparation of the pieces for the printing were used the software Repetier and Cura 2.6.2. The files were imported into the software, positioned on the 3D printer table. Support was only used in the clamp because it does not have self-support. The settings for printing were adjusted, such as layer thickness, print speed, among others, and then the pieces were sliced by the software in 2D layers, finally ready for printing.

The use of PLA was preferred as it is biodegradable and non-toxic, as well as having a lower molding temperature compared to ABS (Acrylonitrile Butadiene Styrene) filament. Also, the TPU (Thermoplastic Polyurethane) filament was used to have flexibility in some of the pieces.

All parts were 3D printed, except for the template, which was reused from the first prototype.

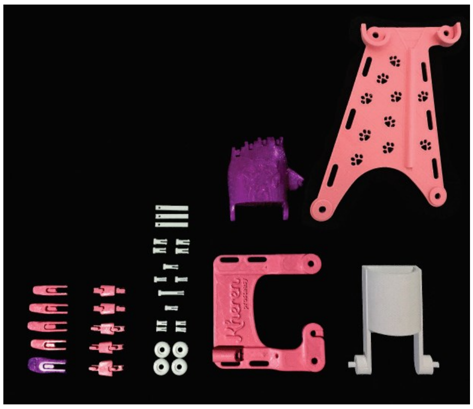

Fig. 7. Parts ready for the assembly of the prosthesis.

Assembly

First the pieces were sanded for better finishing. Only the molding of the forearm was different from the assembly of the similar prosthesis, since the plaster cast was used to shape the forearm and the armband. In addition, since the paws meant for application to the phalanges needed to be 3D printed separately, they had to be fixed together with Cyanoacrylate.

Fig. 8. Assembled prosthesis.

2.6 Provision

The final test was conducted at SORRI in the presence of a prosthetist and occupational therapist. The prosthesis was delivered to the patient, who was delighted with the result.

The user was asked to perform some tasks, such as picking up simple objects such as an eraser. Another task we asked the user to perform was writing. One of the main complaints was that when she wrote, she perspired a lot because she held the pencil with the two stumps. An adapter was placed in the pencil and the user was able to write without difficulty. Also using an adapter, the user was able to close zippers and buttons, another complaint from her.

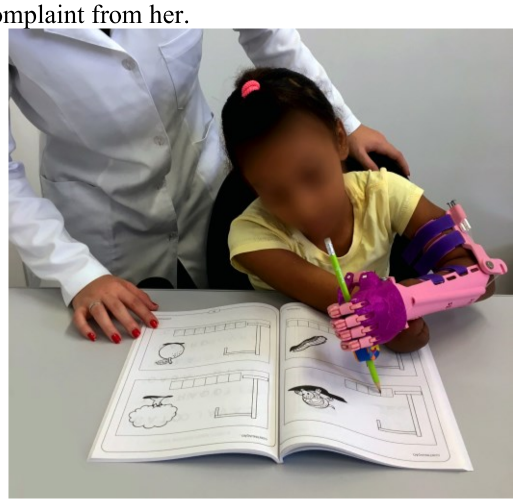

Fig. 9. User writing with the prosthesis.

3 Conclusion

The manufacture of the prosthesis was simple, all executed by 3D printers, while only the assembly was done by hand. The durability is greater because the Velcro can be regulated for the fixation of the prosthesis on the user. The prosthesis is extremely efficient as it does not require much effort from the user to perform the movement of opening and closing the fingers (hold) compared to the prosthesis made by SORRI. Another aspect elaborated upon was the lightness, compared to the conventional prosthesis.

The cat paw was applied on the fingertips and phalanges to create a texture that facilitated the grip of objects, because during the test prosthesis the fingers were smooth, causing objects to slip out of the hand. The handle of the prosthesis was much improved compared to the Unlimbited Arm, due to the increased contact surface using the flexible plastic filament (TPU) in the palm of the hand. It was used the character and the colors requested by the wearer, making it playful, making it feel like more like a toy than a prosthesis. Another great differential between the final prosthesis and the Unlimbited Arm was the use of the user's stump mold to mold the forearm, making the part the exact shape for the wearer's stump. According to the wearer, the prosthesis is comfortable, and the placement of the prosthesis is as simple as just adjusting the Velcro. A great result was obtained, the user was satisfied with the prosthesis in every aspect.

Simple maintenance of the prosthesis can be easily performed by the wearer's parents, replacing the elastics and Velcro when necessary. Also, the prosthesis can be sanitized with water at room temperature and soap.

We conclude that 3D Printing and Rapid Prototyping can contribute greatly to the manufacturing process of assistive technologies, mainly prostheses, as we demonstrated in this work, streamlining development processes, and reducing product costs.

In addition, 3D Printing and RP technologies have contributed to the execution of tailor-made and user-tailored parts which is much faster and more accurate compared to the conventional manual prosthetic process.

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