Design and Development of an Upper Limb Prosthesis

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Thesis to obtain the Master of Science Degree in Biomedical Engineering
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Abstract - *The Limb Deficiency Disorders (LDD) is a group of congenital anomalies with significant hypoplasia or aplasia of one or more bones of the limb* [1] *that occur in 1 in 1300 to 2000 births* [2]*. Initial upper limb prosthetic fitting is recommended according to the psicomotor development of the child, namely when the child is able to sit independently. This procedure is intended to stimulate bimanual activities and body symmetry, as well as to improve the acceptability of more complex prosthetic hand devices in the future. However, there is a need in personalized prosthetic hands for children of such a young age.*

The objective of this work is to design and develop a cosmetic prosthesis device for a two-year-old child with a congenital malformation of the right upper limb. This task is performed with computer-integrated design approach. The selected technologies are Tridimensional Scanning (3D SCAN), Computed tomography (CT), Computer aided design (CAD) and Addictive Manufacturing (AM).

Furthermore, a novel methodology was established to apply to the design of prosthetics to children with this kind of disabilities. In this way, the approach achieved throughout this case study may also be applied to people of other ages. Last objective of this work is to sum up the state of the art of body-powered hand prostheses, fabricated through additive manufacturing. After this, a draft of a body-powered solution was suggested to the child of this case study.

Keywords — Cosmetic Prosthesis, 3D Anatomic Geometries Acquisition, Computed Aided Design, Computer Aided Manufacturing, Orthopaedic Devices.

1. INTRODUCTION

1.1. Motivation

Human hand is a powerful anatomical structure that allows the interaction with the surrounding. It is important for perceiving and operating in the environment, namely to perform actions of sensing textures, heat and humidity, grabbing heavy or delicate objects, and so forth [2]. It performs an important role in social interaction, giving emphasis to the expression of movements and gestures [2,3].

Therefore, any malformation of this exposed structure of the body affects psychologically the wellbeing even if it does not reflect on a corporeal interaction [3].The Limb Deficiency Disorders (LDD) is a group of congenital anomalies with significant hypoplasia or aplasia of one or more bones of the limbs [1] that occur in 1 in 1300 to 2000 births [4]. Initial upper limb prosthetic fitting is recommended according to the psicomotor development of the child, namely when the child is able to sit independently [5–8].This procedure is intended to stimulate bimanual activities and body symmetry [3], as well as to improve the acceptability of more complex prosthetic hand devices in the future [3,9].

However, there is a need in personalized prosthetic hands for children of such a young age. Prosthetic hands construction requires some customization steps [2] and there is a lack of methodologies to perform these devices for this children. Available technologies of tridimensional scanning (3D SCAN), computed tomography (CT) and additive manufacturing (AM) offer the possibility of achieving a personalized solution [10,11] with a reduction of production costs, time and intermediary steps [12].

1.2. State of the Art

Prosthetic prescription for upper limbs should be tailored to help meet each patient's functional goals, which often includes a terminal device, wrist, socket and a suspension system [11].

Regarding the sockets, advances in both upper and lower limb prosthetic socket have been accomplished due to progresses in materials field [11]. Socket customization is often performed with the usage of Plaster of Paris [13]. However, several authors pointed the potential of using Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM) in socket fabrication [13].

3D SCAN is a common method to acquire stump external geometry [14]. On the other hand, CT offers the possibility of generating both 3D and 4D images, which is particularly beneficial for patients who are unable to sustain the same position [10]. MRI can also be used to establish computational models of stumps [14].

Methods of CAD/CAM for prosthetics have been available since the 1980s [15]. In 1985, it was outlined the possibilities of creating and fitting a socket in matter of hours [16]. There are even some CAD/CAM prosthetic systems available in the market [17].

Several authors have investigated rapid prototyping (RP) technologies applications in the medical devices field, namely sockets and remaining prosthetic elements as well as hand orthosis [15,18].

However, there are no records of a 3D printed cosmetic hand prosthesis in the scientific area. For this, there is a need of small and basic hand prosthetic devices suitable for young children.

1.3. Objectives and main contributions

The objective of this work is to design and develop a cosmetic prosthesis device for a two-year-old child with a congenital malformation of the right upper limb. This task is going to be performed with computer-integrated project basis. The selected technologies are 3D SCAN, AM, CAD and CT. Furthermore, it is aimed to establish a novel methodology to perform among children with this kind of disabilities, which may also be applied to people of other ages.

The developed methodology comprises three main computational tasks: acquisition of amputated upper limb geometry, acquisition of opposite upper limb geometry and an alignment of the obtained anatomical geometries. For this purpose, the required technologies are SCAN 3D, CT and a few CAD softwares.

The next step is then to fabricate the prosthesis prototype through additive manufacturing. The chosen material to produce the device is *NinjaFlex®* from *NinjaTek®*, a truly flexible and high-strength material. Properties associated to *NinjaFlex®* will give high wear resistance and flexibility features to the prosthesis.

The last objective of this work is to sum up the state of the art of body-powered hand prostheses fabricated through AM, suggesting after a draft of a body-powered solution.

The main contribution of this thesis is the development of a customization methodology comprised by geometry acquisition, CAD manipulation and CAM. Besides that, the process of acquiring a two years-old hand geometry played an important role in order to allow a reuse of the geometry in future cases of fitting an upper limb prosthetic device for a disabled child. This process culminated in an innovative 3D printed device, with modern 3D printing technology and printable materials.

2. UPPER LIMB DISORDERS

2.1 The problem

2.1.1 Etiology

Upper limb deficiencies differ greatly in their anatomy and etiology [4], presenting two possible origins. A congenital upper limb deficiency is defined as “the absence or hypoplasia of a long bone, metacarpal, metatarsal, or phalanx of one or more limbs, which was significant enough in appearance to be detected by an examining physician within the first 5 days of life” [4]. While, an acquired upper limb deficiency (or an acquired amputation) is defined as “as any surgical amputation after birth as a result of trauma or disease” [19].Congenital limb deficiencies are more common in children than the acquired ones, resulting of an error related to the formation of limb bud [20]. On the other hand, the vast majority of acquired amputations cases occur due to trauma and disease [21,22].

2.1.2 Upper limb disorders classification

Upper limb disorders are split into two categories, the transverse and the longitudinal ones. A transverse disorder denotes absence of elements beyond a particular level [1,4]. A longitudinal disorder denotes a reduction or absence of one or more skeletal elements within the long axis of the limb. However, there may be normal skeletal elements in the distal portion of the affected bone or bones [6].

2.2 Clinical procedures

A congenital limb deficiency is identified on a fetus mostly during the first trimester, a critical pregnancy phase for limb formation [21,23] . When a congenital limb deficiency is identified, it is important to perform a thorough evaluation to look for other anomalies. Overall management depends on the disability diagnosis[1]. A 3-generation pedigree shall also be performed. Regarding the pregnancy, a record of drug use, medications and relevant aspects shall be done [1,24].

Acquired upper limb amputations require a different set of clinical procedures. Treatment evolution record is an important task to perform. A proper surgical technique is fundamental to the success in treating an acquired limb disorder [11]. Decision making among professionals regarding limb salvage versus amputation remains complex [11,25]. In this way, patients shall be informed about the consequences of each procedure [25,26]. Treatment evolution record is an important task to perform. The physical components of this evaluation include bilateral manual muscle testing, range of motion on the affected and unaffected sides, limb volume measurement, scar evaluation and sensitivity of the residual and non-residual limb [27].

Transverse congenital limb deficiencies and acquired limb deficiencies are suitable to be introduced to a prosthetic device [28]. Longitudinal congenital limb deficiencies are a challenge in the orthopedics field in that they may be entirely unsuitable for standard prosthesis[29]. This first introduced device is usually a passive one, regardless of the type of defect [28]. Several studies reported that delaying the first fitting procedure to a prosthesis increases the risk of abandonment of the device [9,30]. If the passive prosthesis is accepted by the child, a more complex device may be introduced, namely a body-powered or a myoelectric one [28].

Weight and socket adjustment are critical aspects to improve any prosthetic fitting [31]. An upper limb prosthesis must be lighter than the limb it replaces. The lack of an intimate connection between patient and limb replacement means that the prosthetic device is felt as an external load [31], while a well-adjust socket avoids prosthesis displacement, which could cause friction between device and limb. Due to this discomfort, patients may reduce the daily duration for which they use the prosthesis and even reject the prosthesis [13,32].

3. CONCEPT DEVELOPMENT

3.1 Clinical case

This work is based on a clinical case of a 2 years old child with a congenital malformation of the upper limb, which is transversal, at the forearm level, in the upper third. The child already uses a rudimentary device since its first year of life, which is comprised by a hand of a doll and a cup customized by a technician.

3.2 The concept

The developed methodology to conceive the cosmetic device comprises five main computational tasks. At first, amputated upper limb and opposite upper limb geometries were acquired. After this, its computational processing and fabrication with RP techniques for each limb geometry was done. Once the geometries were obtained, some tests were performed with the child.

After this, upper limb geometry files were joined to define the cosmetic prosthesis. The last step of the methodology was prosthesis fabrication by the means of RP. This procedure was performed with a 3D printer with a dual extrusion technology.

Figure *1* sums up the developed and implemented methodology.

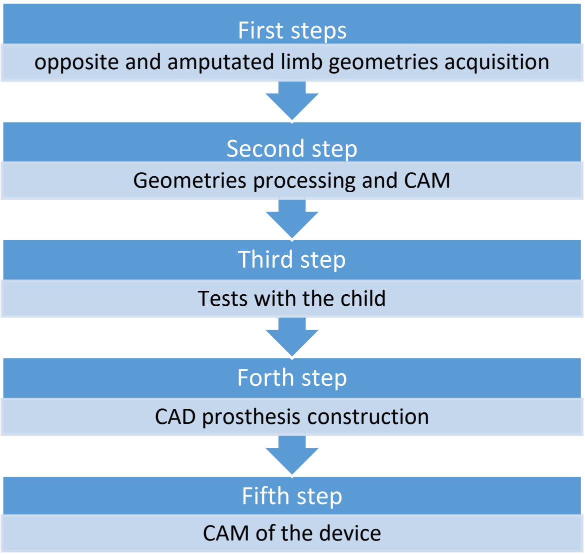

Figure 1: Scheme of the main tasks of the developed methodology

3.3 The methodology

3.3.1 Anatomical geometry acquisition

Anatomical data capture is essential for the manufacture of customized prosthetic devices [10]. In this way, 3D SCAN and CT were the chosen technologies to capture geometrical surfaces of child upper limbs.

3.3.1.1 Amputated limb geometry acquisition

3D SCAN was used to capture residual limb geometry. To acquire anatomical surface with this technology remains a challenge, due to the risk of involuntary movement. A single movement may void all data [10,33], which is even more common when it comes to infants. To reduce these artifacts, a reference tridimensional scenario was set. The scenario was randomly filled in with the reflective dots. The infant placed his right forearm inside the referential and the scan was moved towards the limb. During this procedure, neither the limb nor the referential should move or vibrate.

3.3.1.2 Opposite limb geometry acquisition

3D SCAN shows some handicaps, namely the inability to capture wanted internal structures and intricate surfaces [10]. Due to this hurdle and the lack of data bases with human hand geometries, it was decided to perform a CT.

3.3.2 Geometry processing

3.3.2.1 Amputee limb geometry processing

Acquired data suffered some manipulations performed with the *add-in ScanTo3D* tool from *SolidWorks*. These manipulations allowed the definition of a socket. Once the socket defined, the geometry suffered two different pathways. One of them was conducted to lately define a physical structure to test with the child. On the other hand, additional modifications were executed in order to adapt the socket to the prosthesis.

Figure 2 presents the final stump geometry obtained in Solidwor*ks*.

Figure 2:Final stump geometry.

3.3.2.1.1 Socket modifications-The *Voronoi* Mesh

Due to the need of testing the socket geometry with the child, a *Voronoi* mesh [34] was draft. This step was undertaken on a *MeshLab* environment, with *Voronoi Vertex Coloring* tool.

3.3.2.1.2 Socket modifications-the socket as a prosthetic element

During scanning procedure, distal portion of the forearm wasn't capture. This was due to its intricate geometry and displacements occurred during the acquisition. However, prosthetic socket geometry needed to be closed in this portion to assure a proper fitting. For that, stump collected measurements referred in section 3.3.3 were taken into account and the geometry shown in Figure 2 was edited in *SolidWorks*.

3.3.2.2 Opposite limb geometry processing

The following proceeding aims to convert CT data into an editable point cloud. Such procedure allows CT data to be manipulated in CAD softwares and integrated on the remainder of project framework.

Limb geometry was processed according the pipeline suggested by Lopes[35]. Figure 3 sums up the procedures performed to process CT data into the final STL file.

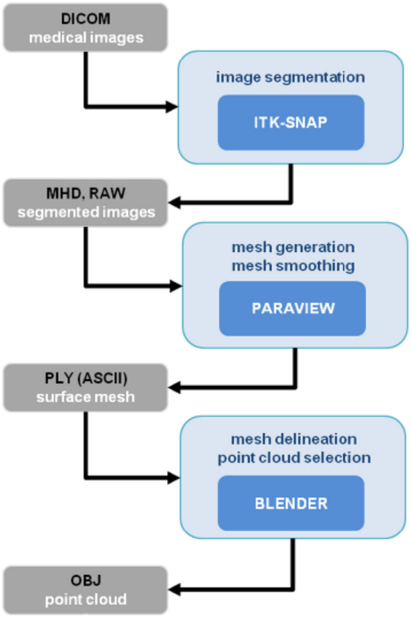

Figure 3: Pipeline for the CT data processing

3.3.3 Tests with the child

To test the geometry of the amputee forearm and the size of the hand and forearm collected from CT data, the referred geometries were produced in AM. Results of the referred prints are shown in Figure 4.

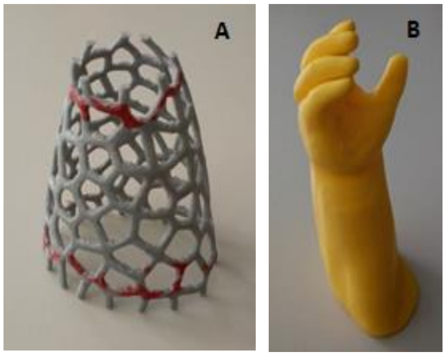

Figure 4: 3D printing results: A: Voronoi Mesh amputee forearm geometry; B: Hand and left forearm.

Such tests revealed a good adjustment of *Voronoi* mesh and proximal limits for the socket were defined. Measurements of the distal portion of the stump were also are collected in order to finish socket geometry.

However, there was a need to scale up hand mesh due to child growth. For that, some measures of his hand and wrist where taken. Both limbs of the child were simultaneously photographed, bearing in mind the need of defining the alignment between socket and prosthetic hand.

3.3.4 CAD Prosthesis definition

3.3.4.1 Geometries alignment

Once the tests performed, the next task is to align socket and hand geometries. This step is the beginning of the definition of the cosmetic prosthesis shape. Geometries alignment procedure was undertaken with the aid of *Blender* and *MeshLab* tools.

3.3.4.2 Geometries adjustment

Once geometries aligned, hand and forearm mesh is ready to be adjusted to socket, in order to obtain a smooth transition between meshed and then to improve cosmesis. A lack of tools to perform this process automatically was noted. For this, a set of manual sculpt procedures was taken. A final mesh correction was also conducted with *Materialize MiniMagics 3.0* software tools. Afterwards, forearm and hand mesh was joined with socket mesh (Figure 5). In this way, cosmetic prosthesis file is ready to be produced in AM

Figure 5: final cosmetic prosthesis geometry

3.3.5 Final tests with the child

Once achieved the cosmetic prosthesis geometry, the device was produced with RP techniques. Detailed information about fabrication process is included on Chapter 4.

The child was then fitted to the device. At first, the child was fitted to the PLA device. Lately, one of the NinjaFlex® print results was fitted to the child as well. It was added to both devices an elastic socket, as well as a structure composed of strings and Velcro to sustain the prosthesis into the limb. Figure 6 shows the child with the cosmetic prosthesis.

Figure 6: A and B: User with the cosmetic prosthesis in different activities.

4. COMPUTER AIDED MANUFACTURING (CAM) OF THE DEVICE

4.1 Additive Manufacturing and its applicability in prosthetics

AM is the name that describes the technology of building 3D objects by adding layer-upon-layer of material [36]. AM presents a number of compelling advantages over traditional manufacturing techniques [37].

The RP technique used in this thesis was FDM, a technology developed and patented by S. Scott Crump in 1988 [38].

Some printers have the ability of printing two different materials during the same print, which is called dual extrusion. This technique is useful to print objects with more than one color or material. It is also used to print a certain object and its support structures in different materials.

4.2 NinjaFlex® and its suitability to hybrid printing technique

The material chosen to use for prosthesis fabrication was *NinjaFlex*® from *NinjaTek*®. This material is a thermoplastic polyurethane with an easy-to-feed texture, presenting great flexibility and longevity compared to non-polyurethane materials, as well as a higher abrasion resistance. *NinjaFlex*® can suffer 660% elongation without wear or cracking. Its polyurethane composition allows for excellent vibration reduction.

4.3 Print specifications

At first, cosmetic prosthesis geometry was produced in white PLA where the supports were removed with the aid of a paper knife. After that, the object suffered some polish with grindstones and sandpaper. The final result is presented on

Figure 7.

Figure 7: Final result after support removal and polish.

Once *NinjaFlex*® and *FlexyDually* Tool Head available, efforts were concentrated on obtaining prostheses prototypes produced in this material. At first, *NinjaFlex*® was used together with ABS due to its ability to bind to this material [39]. ABS was used to build support structures. Several prints were performed with these materials and with different features. However, all prints showed some incrustations of ABS between *NinjaFlex*® layers, as well as some other problems, as shown in Figure 8.

Figure 8: Final print result of NinjaFlex®-ABS print.

Due to that, PVA was used in the following prints instead of ABS. Once the object printed, ooze shield was manually removed and support structures were dissolved in water. Incrustations problem was solved with the use of PVA. However, some layers were printed with some displacements and support structures damaged the surface of the object. Furthermore, after support dissolution, *NinjaFlex*® layers presented some modifications, which affected the overall object appearance and structure, as shown in Figure 9.

Figure 9: Final print result of NinjaFlex®-PVA print.

4.4 Production Costs

PLA prosthesis print wasted 75 grams of material, the average print cost of the device is US$0.468. *NinjaFlex*®-ABS prints wasted 127 grams of *NinjaFlex*® and 39 grams of ABS. For this, *NinjaFlex*® wasted portion costed US$11.00 and ABS portion costed US$1.68. Final print cost of the device is US$12.68, if printed with these two materials. On the other hand, *NinjaFlex*®-PVA print wasted 136 grams of *NinjaFlex*® and 109 grams of PVA. *NinjaFlex*® wasted portion costed US$11.78 and PVA portion costed US$7.62. Final print cost of the device is US$19.40, if printed with these two materials.

Regarding the computational work required to build the device from the limb geometries acquisition until the CAD definition, it is expected that a professional with experience in the field will need near to 20 hours of work to perform all the tasks suggested in the methodology. In the end, the overall procedure to define a cosmetic prosthesis will this methodology takes at least 37 hours. Cost-wise, considering that the hand-labour is payed at €20/hour, prosthesis labor costs €740.

For that, the final price of the device would be around €750. Additional costs related to features as suspension system weren't considered. However, these low costs present an advantage regarding current prosthetic solutions available in the market.

5. CONCEPT GENERATION FOR BODY POWERED PROSTHESES

5.1 State of the art of 3D printable body powered upper limb devices

A body-powered prosthesis is a device in which the person uses his or her own muscular power to operate it. Open and closing the device can be done at different anatomical levels, usually depending on the type of disability

When talking about 3D printable body powered upper limb devices, Enabling The Future has the main role. Enabling The Future is a global network of volunteers that use 3D printing to provide upper limb devices for disabled people. The association has several upper limb 3D printed device designs, which are divided into two categories: wrist actuated and elbow actuated. Enabling the future doesn't offer 3D printable devices for an above elbow limb disorder [40].

Regarding wrist actuated devices, Enabling the Future offers seven main printable devices. Some of them are dedicated for young children and sports, for example. On the other hand, the association owns two main designs for elbow actuated devices.

Still regarding body powered devices, prehensor system exhibits an important prosthetic feature, for the reason that one of the main causes of body-powered prosthesis abandonment is its limited function. In this way, body-powered devices can present a voluntary closing (VC) and voluntary opening (VO) system. In a VC device, the user actively closes the device and a passive element (for example, a spring) returns the prehensor to the default open state. On the other hand, a VO device is actively open by the user and a passive spring returns the device to the default closed state [41]. VO and VC devices present different advantages and disadvantages, which makes them suitable for different disabled people.

5.2 Suggestion of 3D a printable body-powered upper limb devices

Once collected all the information about 3D printable devices, as well as the advantages and disadvantages regarding VO and VC devices, now is time to define a future body-powered solution for the child of this case study.

Regarding all the information collected and shown in section 5.1, a hybrid of *Odysseus hand* and *Team Unlimbited arm* with a VC system is suggested as the first body-powered device for the child of this case study. A draft of the suggested solution is shown in Figure 10.

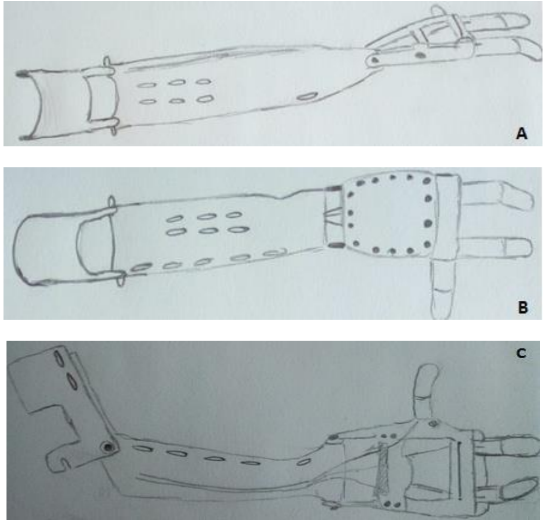

Figure 10: Draft of the suggested body-powered solution: A: side view; B: bottom view; C: top view.

6. CONCLUSIONS AND FUTURE WORK.

6.1 Conclusions

In this work, an upper limb cosmetic prosthesis is conceived and developed for a case study of a two years old child.

In order to frame upper limb prosthetic devices, a chapter of upper limb disabilities, as well as a section about the historic evolution of limb prostheses, were drafted.

A methodology was designed to conceive this type of devices. For that, innovative technologies were used. 3D SCAN was used to acquire stump geometry and the traditional method of application of plaster of Paris was avoided.

Opposite limb geometry was also acquired to conceive the prosthetic hand with CT technology, which will help to give a natural appearance to the cosmetic device. However, the decision of performing a CT was taken by medical doctors. This procedure allowed the storage a digital geometry of a child's hand for future cosmetic devices. This way, when such geometry is available, it is possible to skip opposite limb geometry acquisition step.

A set of CAD softwares were used to process data and to define the geometry of the device. A detailed workflow with the purpose of each software was also defined. During this process, CT geometry data was sculpted to fit to stump geometry, which took more time than expected due to the deformation of the forearm captured in the CT. In this way, when performing a CT, it shall be assured that the anatomical region to acquire is placed in the desired final shape. Once this deformation avoided, some alignment algorithms (such as volume minimization algorithms[42]) can be applied to align stump and opposite limb geometries

The device was fabricated with RP techniques. At first, the prototype was printed in PLA and later produced in *NinjaFlex®*. The first solution was polished and then fitted to the child. Some months after, the second solution was fitted to the user as well. Both devices were well accepted by the user, as the child wears the device every day and for more than 8 hours a day. This aspect means that stump acquisition, socket design and geometries alignment were well performed. Furthermore, the child integrates both new devices (the PLA and *NinjaFlex®* ones) as a preponderant aid in several tasks. This is possibly linked to the flexed hand shape. Besides that, parents noticed that these devices are lighter than the previous one, meeting one of their concerns. It is possible to conclude that, with a proper polish finish, PLA shows to be an alternative solution to rudimentary solutions. Regarding *NinjaFlex®* solution, it is also feasible to conclude that this material is suitable to manufacture prosthetic devices.

A dual extrusion printing technology was used to produce the prototype. At first, *NinjaFlex®* and ABS were used to print the device and its support structures, respectively. However, prototypes printed with these two materials presented some pieces of ABS in the middle of *NinjaFlex®* layers. For that, it was possible to conclude that, when the final aspect plays a role in *NinjaFlex®* objects, ABS isn’t suitable to print its support structures. Later, ABS was replaced by PVA to print supports. Its water solubility promoted an easy support removal. However, *NinjaFlex®* properties suffered some modifications after water contact, which affected the overall object.

RP techniques proved its suitability for prostheses field. However, dual extrusion techniques still present some challenges. Default print parameters showed to be inappropriate to all objects. It is expected that, for each geometry and printer, print parameters may need some adjustments.

It is also possible to conclude that the proposed methodology is suitable to produce upper limb cosmetic prostheses. There are no records of such a methodology for an upper limb cosmetic device entirely produced with RP techniques. Furthermore, the process of acquiring opposite limb geometry to use as prosthetic hand represents an innovation in contrast to the literature. This methodology gives a high personalization level to the device.

6.2 Future work

The areas for future work remain into 4 categories: CAD softwares, RP improvements, prosthetic suspension system and body-powered solutions.

Opposite limb geometry acquisition was only performed due to the inexistence of digital geometries of child hands. There is a need for digital data bases where this kind of geometries are available in standard formats and ready to use in several CAD environments.

During CAD modifications, there were several switches between softwares due to its limitations. It would have been very helpful if some software allowed to do all the modifications, that is, in an integrated way. Regarding the production of the device with AM, it is important to find which print parameters improve cosmetic prosthesis appearance. Different printers may be used, for instance. Other elastic printable polymers can also be tested to produce these devices. Support structures material choice needs to be redefined. Both ABS and PVA revealed to be unsuitable to perform this task with an object printed in *NinjaFlex®* with an intricate geometry.

Furthermore, the work related to the suggested body-powered solution needs to be continued. It is important to confirm if *Odysseus hand* and *Unlimbited arm v2.0* are able to be adapted or to check if there is another suitable body-powered solution for this child.

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