Development of new products for Rehabilitation Medicine using Additive Manufacturing:

Customized Design of a knee Positioning Orthosis

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Abstract

Off-the-shelf orthoses used in rehabilitation medicine present challenges in the individualized comfort they offer and in the support of the different motor conditions of the affected individuals. Although custom-made orthoses address these issues, their current fabrication method consists of a laborious, time-consuming and material-wasteful manual process performed by skilled orthotists. Additive manufacturing offers a more efficient and flexible alternative method for the design and fabrication of new customized solutions.

While combining 3D scanning, 3D modelling and additive manufacturing, this thesis proposes and tests a method for the fabrication of custom-made products for rehabilitation medicine. In collaboration with Centro de Medicina de Reabilitação do Alcoitão, the method is applied in the design and development of a customized knee positioning orthosis for a patient with cerebral palsy. In this process, the individual needs of the patient were identified and used as input for a common product development model applied in the design of the orthosis.

This project aimed to be an exploratory work on the capabilities of the use of additive manufacturing in mass customization of orthoses. Having developed, prototyped and tested four different concepts with the patient, from which one was successfully accepted, it is possible to demonstrate the potential of industrialization of these technologies.

As future work, the development of new material and technology selection methodologies is proposed, as well as studies on the economic viability of the developed concepts.

Keywords: Additive Manufacturing, Rehabilitation Medicine, Product Design and Development

1 Introduction

Rehabilitation medicine covers the diagnosis and treatment procedures with the objective of optimizing physical and psychological functions of people with disabling medical conditions, usually neurological or musculoskeletal impairments. Orthoses and several other medical devices often play an important role on the success of the rehabilitation strategy. An orthosis is a medical device that is applied externally to the human body with the purpose of aligning, assisting, restricting, controlling or supporting movement for specific body segments, aiding in rehabilitation from fractures or surgical operations, and correcting shape deformities, to extend functional capabilities and/or reduce pain.

One key requirement for the clinical efficacy of the orthosis is its correct fitting and alignment to the patient's anatomy, in order to improve comfort and performance. Traditional methods for fabrication of customized orthoses are laborious and time-consuming, as well as limited in the ability to incorporate innovative features in its design.

As 3D scanning and medical imaging techniques emerge as alternatives to traditional cast moulding, Computer-Aided Design/Modelling (CAD/CAM) technologies can be used to assist the manufacture of custom-made orthotic devices. These include the parametric modelling of the orthosis and its fabrication using additive manufacturing. The goal of this study was to explore the feasibility of an integrated protocol combining these technologies. The proposed framework for mass customization of new products for rehabilitation medicine is based on three phases as described in Figure 1.

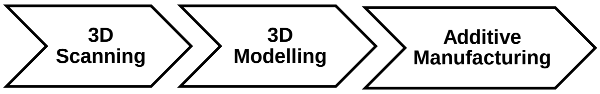

Figure 1 Protocol for the production of a customized orthosis.

The process starts with 3D scanning the surface of the body segment of interest. This data acquisition technique intends to replace the creation of casts and moulds that take up a large amount of time and that usually can only be used once. Next, the acquired data is processed, by means of appropriate software and the design of the orthosis is made around the obtained 3D surface. Finally, the orthosis is fabricated using additive manufacturing technologies.

The potential of this approach was demonstrated by exploring how a new orthotic design challenge, proposed by the CMRA, could benefit from it. In this work, the development of prototype orthoses for knee positioning during bedtime, for a patient with cerebral palsy, is presented. For this, a product design and development method was employed. Several concepts explored the design freedom of AM, while focusing on customer needs and requirements.

2 Background

2.1 Cerebral Palsy

Cerebral palsy (CP) is a collection of disorders of movement and posture that result from a lesion in the immature brain. Although the cerebral lesion is non-progressive, the musculoskeletal disorders are permanent and not unchanging [1]. In addition to motor disorders, CP is often accompanied by disturbances of sensation, perception, cognition, communication and behaviour [2]. According to the lesion site and extension, CP can be classified into three main types [3] in which the change in muscle tone leads to different kinds of impairments and motor patterns. In spastic CP, which represents 70% to 80% of CP cases, there is an increase in muscle tone, i.e., due to an imbalance of excitatory and inhibitory inputs, there is an increase in the physiological resistance of muscle to passive motion, a condition known as spasticity. According to the amount of body involvement, spastic CP can be further classified mainly as hemiplegia (one side of the body is more involved than the other), diplegia (the lower extremities are more involved than the upper extremities) and quadriplegia (total body involvement). Spasticity is the main origin of difficulty in movement, abnormal postures and gait patterns, and also contractures that further lead to deformities. Therefore, it restricts joint motion and limits mobility. The other less common types of CP are dyskinetic, characterized by changing muscle tone and involuntary movements, and ataxic, in which there is a decrease in muscle tone and lack of coordination.

2.1.1 The use of night static orthoses

When spasticity is present, the muscles are weak and there is muscle shortening, which leads to unusual bony torsion due to abnormal muscle forces, resulting in joint instability and degeneration. This leads to loss of functional range of motion. Contractures can be avoided if the muscles are maintained at a stretched position [4]. Although there is a collection of studies with mixed results regarding the night time use of stretch orthoses, practitioners claim they get positive results by keeping the muscles in a lengthened position during sleep. With that further muscle shortening can be avoided.

2.2 Additive Manufacturing

Additive Manufacturing (AM) refers to a group of technologies that allow the creation of products through the addition of materials, layer by layer [5]. A typical process of AM (Figure 2) starts with the creation of the 3D model using CAD software, which is then saved as an .STL file that represents the model in a triangulated mesh. The AM equipment software then slices the data file into several layers. Following, the AM system reads this file and the object is created, by joining layers of material, one on top of another. Depending on the material and the complexity of the intended product, some post-processing might be necessary.

There are several AM processes that make use of different technologies. The main approaches are stereolithography (SLA), fused deposition modelling (FDM) and selective laser sintering (SLS).

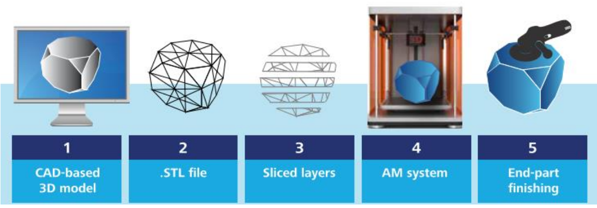

Figure 2 Additive manufacturing process flow [5].

2.2.1 AM in Rehabilitation Medicine

The main advantages that AM can present in the field of medical technology, particularly in the production of orthoses and prostheses are [5,6]:

Customization: AM may represent not a replacement for mass production, but a way to mass customization, since there is no need for complex tooling, allowing to combine the low costs of mass production with the flexibility of individual product customization. In any orthotic device, forces created from improper alignment will be transmitted to the user, decreasing comfort and increasing shear forces on the skin. These can limit the function and the effective life time of the device [7].

No need for moulds: a 3D scan of a patient's anatomical region of interest is enough to design and fabricate a perfect fitting medical device.

Design complexity: AM delivers freedom to explore new shapes, and therefore the design of medical devices can be done by function instead of by form, delivering specific functionality.

Speed to market: AM allows the product to be produced when and where it is needed. This aligns well with the need of mass customization of orthoses, while reducing warehouse and distribution costs. Furthermore, the time it takes for a customer to receive a customized orthosis can be decreased.

To conclude, AM offers the opportunity to explore novel orthotic features and designs, while keeping patient-specific needs in mind.

3 Production Protocol for Customized Orthosis

This chapter describes the steps and technical aspects which were used to support the design and the fabrication of the prototypes for the orthosis. Furthermore, it can be seen as a general guideline for the application of such process in the design of other orthosis.

3.1 3D Anatomical Image Acquisition

The acquisition of the 3D image of the patient's lower extremities was made using a portable 3D scanner, ZScanner™ 700 by Z Corporation® (Figure 3 a)), during his stay at CMRA – Figure 3 b) c). A thin black layer of fabric with reflective markers was enclosed around both limbs, to facilitate the acquisition. Each scan took about 10 minutes to perform.

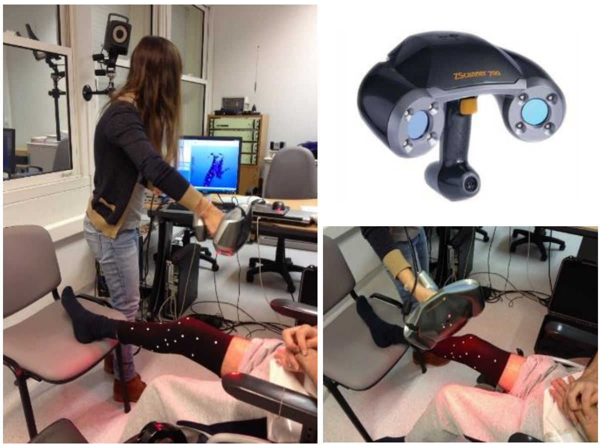
Figure 3 Anatomical Image Acquisition. **a)** ZScanner™ 700 [8]. **b)** 3D scanning of the lower extremities at CMRA.

This phase was intended to be fast and easily manageable in the clinical environment.

3.2 3D Anatomical Image Processing

After the acquisition, the surface image needed to be cleaned and prepared for the design of the orthosis by converting it into a CAD editable file. The scanned surface in .STL format, contained unwanted artefacts, such as extraneous facets captured from nearby objects, missing facets or surface irregularities due to the layer of fabric – Figure 4 a). The image was first processed as a mesh with Solidworks® software (version SP0.0, 2014), using automatic tools that allowed mesh orientation, noise removal, extraneous data removal, mesh simplification and smoothing and hole filling. The mesh was then converted into a surface, where faces containing errors were removed and manually refilled. The necessary cuts were made to delimitate the surface.

Next, to fully prepare the acquired data for orthosis design, a small offset was performed in the entire surface. The resulting surface from the last steps had too many faces which led to errors in the offset – Figure 4b. To successfully offset it, the surface had to be further smoothed and simplified, using MeshMixer® software. To the resulting surface (Figure 4c) it was possible to perform a 3 mm offset. From this new surface, an appropriated thickness can be applied, according to the design concept.

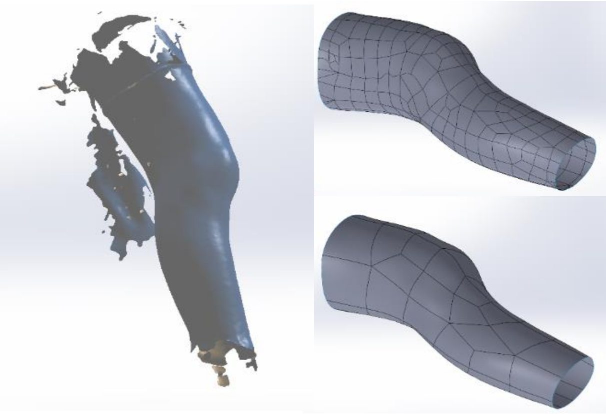

Figure 4 a) Acquired 3D image of the right lower limb b) Cleaned surface before simplification. c) Cleaned surface after simplification, ready for orthosis modelling.

3.3 Additive Manufacturing Equipment

After modelling the orthosis, the CAD model is then reconverted into a .STL file to be read by the AM equipment. Different parameters must be taken into account while preparing the model to be fabricated, which will influence the printing time, material usage and mechanical properties of the resulting object. The main parameters are layer height, infill percentage, building orientation, support material usage and building velocity.

For the additive manufacture of the designed concepts, two FDM based AM machines were available. For rigid components, *Dimension SST 768* by Stratasys® was used. This system fabricates models with ABS plastic (ABS-P400^{TM}) and uses soluble support technology (P400SR^{TM}). The support material is soluble in a sodium hydroxide mixture. For flexible material components, the MakerBot® Replicator 2 desktop printer was used with Ninjaflex® filament (TPU). Since it was originally optimized for the fabrication of models with less flexible materials, the use of this material in this printer was a challenge that required some iterations of parameter optimization before a correct print was made.

4 Design and Development of a Customized Knee Night-Time Positioning Orthosis

The knee immobilization orthosis used for the demonstration of the proposed protocol was developed using a product design and development model based on the one proposed by Karl Ulrich and Steven Eppinger [9]. This work focused on and implemented the product planning and concept development phases of this model - Figure 6. A graphical technique called *House of Quality* (HoQ) [10] is used to guide the concept generation, selection and prototyping cycle, by relating the identified needs and established specifications for the product, as well as by integrating a competitive analysis. The HoQ is constructed in steps, which are described throughout the following sections.

4.1 Opportunity Identification

Opportunity identification for the development of a new product was done at CMRA, starting with understanding the patient's condition and the problems with the existing solutions.

The patient to whom the orthoses were design for suffers from spastic cerebral palsy, presenting a “crouch” and “scissoring” gait pattern, characterized by contractures of excessive knee flexion and valgus deformity – Figure 5. In order to improve gait, the patient was submitted to a muscle lengthening surgery. However, the benefits of the surgery can only be maintained if the muscles are stretched daily, which can be done by using a night-time orthosis that keeps the knee in an extended position. In addition, this orthosis should also prevent the valgus deformity from worsening.

Figure 5 Knee contractures observed in the patient. **a)** Knee flexion contracture [11]. **b)** Valgus/Adduction knee contracture [12].

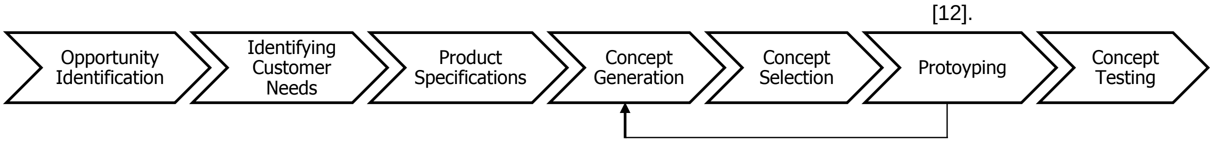

Figure 6 Adopted product design and development process phases.

The patient was observed in the ward, during bed time, where the currently used positioning solution was accessed. It is a large and bulky foam splint fastened around the lower extremity with elastic straps. According to the patient, this solution had several problems:

- He could not put it on and off by himself;
- It caused discomfort due to heat accumulation;
- It restricted freedom of movements during sleep.

Further literature review led to conclude that the current positioning solutions for the knee are often big, bulky, heavy and uncomfortable. Current off-the-shelf night orthosis are not well accepted since they are not a custom fit and do not properly align with anatomical landmarks [4]. Consequently, there is an opportunity to improve patient's comfort, ease of use and overall performance of the orthosis, summarized in Table 1.

Table 1 Mission statement.

Mission Statement	
Product Description	Customized night-time knee positioning orthosis.
Benefit Proposition	Better fitting and faster production.
Key Product Features	Easy and independent use. Innovative. Fast and cheap production.
Primary Market	Adult cerebral palsy patients (with limited mobility and knee contractures).
Secondary Market	People in need of knee positioning (children with cerebral palsy and adults with sequels of perturbations in muscle tone).
Assumptions and Constraints	Designed from digital 3D scanned image of the limb. Additive manufactured. Limited materials.
Stakeholders	Consumers (patients and healthcare professionals). Manufacturers.

4.2 Identifying Customer Needs

To guide the design and generation of concepts for the new product, the qualitative assessment and understanding of the needs of the individual was made. Customer data was first gathered during informal interviews with the healthcare professionals involved in the rehabilitation of the patient. Then, the patient was observed while using an existing solution. The collected information was interpreted and the needs were sorted into four main sets: usability, comfort, performance and other needs.

The list of identified needs was used to start the construction of the HoQ, where these are placed in rows – Figure 7. Each need was assigned a relative importance (from 1 to 5), so that the most important are the ones that allow the desired clinical effect to be achieved (customized, prevent knee flexion and adduction), and that interfere with the acceptance of the orthosis by the user (being easy to put on and off, low weight, fresh and light).

4.3 Product Specifications

Product specifications are the product characteristics that define quantitatively what the product has to do. From the identified needs, the specifications that could best reflect how the product may satisfy the customer needs were chosen. These were divided into technical details and production specifications and placed in columns, in the following step of the construction of the HoQ – Figure 7. Next to each specification, a positive or negative sign designates if it is its increase or reduction, what is first expected to contribute to the satisfaction of the customer needs.

Following, the HoQ's relationship matrix is constructed, indicating how much each specification affects each customer attribute. A positive sign represents a positive contribution on the satisfaction of a need, and a negative sign represents the opposite.

Before the analysis of this matrix, information from competitive products was added to the HoQ. Four different products were evaluated according to the customer perception of how each need is satisfied. Products A and B are direct competitors, being the two most used night positioning solutions for the knee. Products C and D are indirect competitors, since they are indicated for post-surgery rehabilitation, but can be used for the same purpose. This evaluation allowed to validate the observations made by the users during opportunity and need identification, stating that current existing solutions are difficult to don on and off, not fresh, bulky, heavy, not customized, do not efficiently prevent knee adduction, and are not very resistant nor attractive. It should be noted that the performance requirement of preventing knee flexion is already fully met by

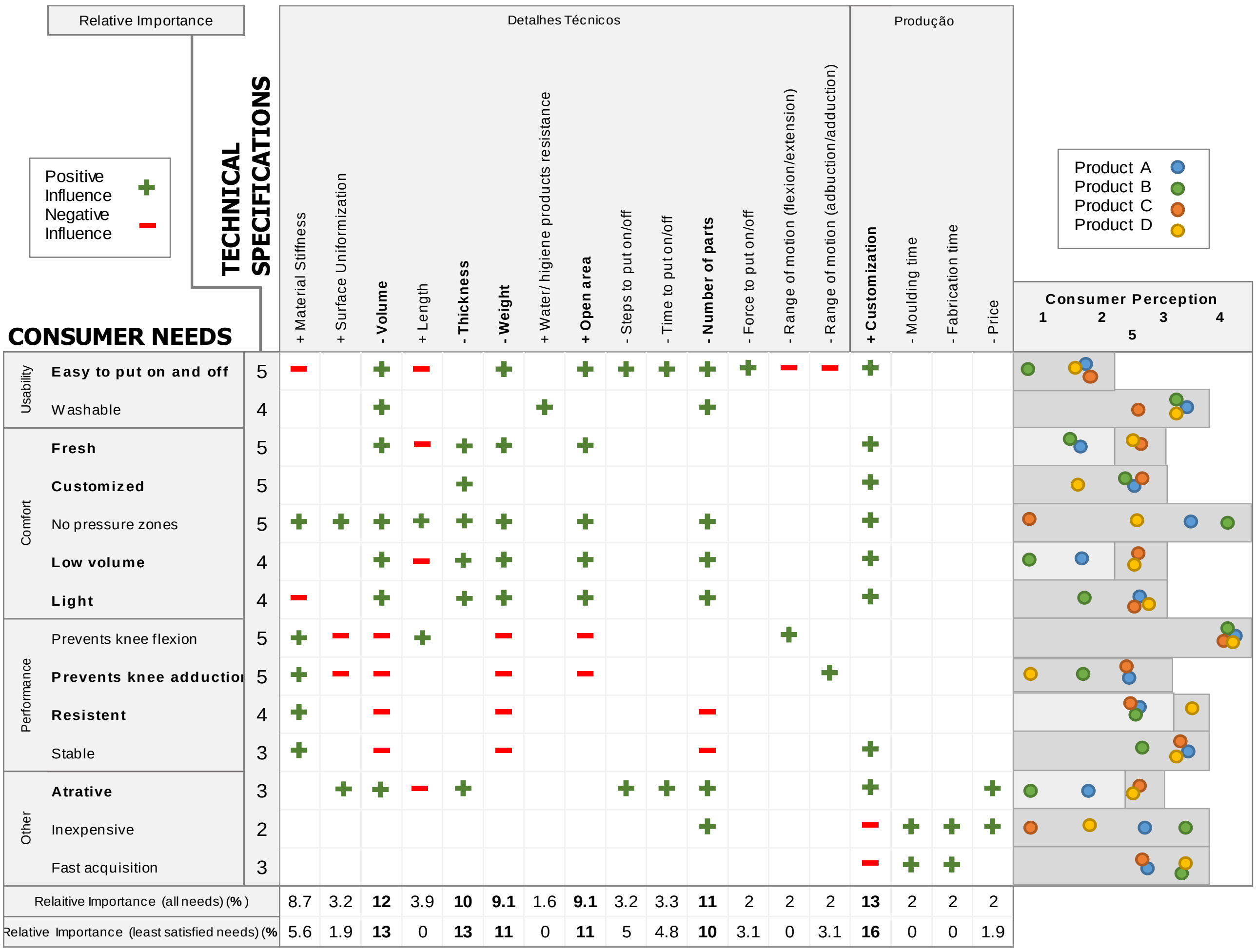

Figure 7 House of Quality.

competitors. While keeping this need satisfied, new product features should focus on improving the way an orthosis satisfies the needs that are not currently met.

To understand how each specification might help satisfy customer needs, its relative importance was calculated by the sum of positive contributions, weighted by the relative importance of each need. This was done twice, considering all needs, and considering only the ones least satisfied by the competitors, as shown at the bottom of Figure 7. In both cases, the group of specifications that may lead to the best overall need satisfaction was the same. Consequently, the concept generation phase should rely on keeping:

- Low volume
- Low thickness
- Low weight
- High open area
- Low number of parts
- High customization

4.4 Concept Development

The first concept generation, selection and prototyping cycle started with a choice of direction, guided by the knowledge acquired from the previous phases. In total, 5 different concepts were developed in an iterative process, where each concept gives a set of learning points used in the generation of new concepts. Figure 8 illustrates these learning points. These learning points are considered with the previous analysis of needs and specifications in mind, so that a new design direction is pursued.

4.4. 1 Concept 1

The design focus for the first concept was making the orthosis easy do put on and off. To this end it was thought that the orthosis should be articulated with a locking mechanism so that the patient could lock it when already comfortable in bed and unlock it to easily move or step out of bed. From the different generated concepts, concept 1 was chosen. Its 3D model was designed for the right lower limb and is pictured in Figure 9a. It presents two rigid cylindrical parts that envelop on the

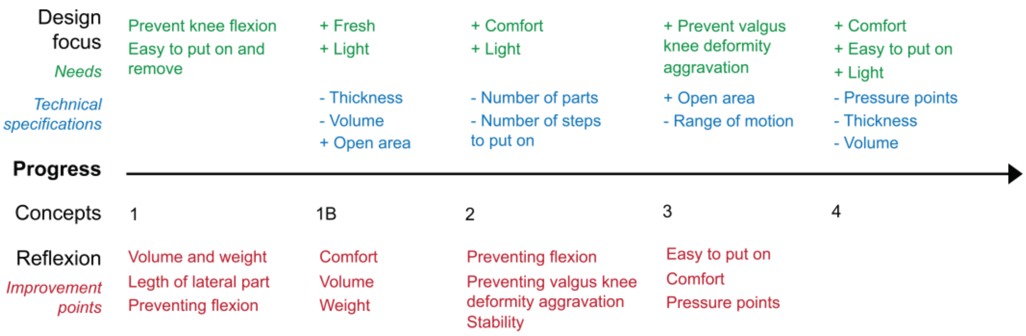

Figure 8 Concept development process.

upper and lower leg, with each part articulated in its lower portion by flexible material. These parts are enclosed on the limb by an "L" shaped lock and are joint by flexible material around the knee. The locking mechanism of the orthosis consists on a lateral piece that articulates with the lower part and is fixed on the upper part with a piece of flexible material. This concept was prototyped using AM for the fabrication of the rigid parts. Due to the unavailability of the flexible material at this point, the flexible components were made with alternative materials – Figure 9b. This prototyped revealed that the chosen thickness was too large, making the whole structure two voluminous and heavy. In addition, the locking mechanism was not effective due to the over length of the flexible piece.

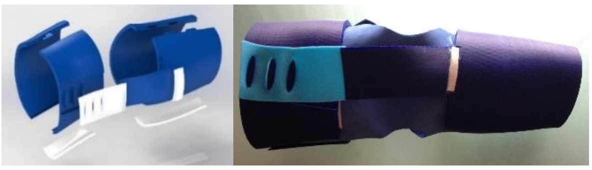

Figure 9 Concept 1. **a)** 3D Model. **b)** Prototype.

4.4.2 Concept 1B

From the identified flaws, the first concept was redesigned by focusing on the specifications that were considered the most important. Thickness reduction and a perforated structure led to lower volume and weight, as well as an higher open area of the orthosis – Figure 10a. The locking lateral part was articulated in a lower portion of the structure and the fixation to the upper part became almost completely rigid. Due to the reduction of the thickness, the "L" shaped lock of the cylindrical parts had to be replaced with Velcro straps placed over them. For this prototype (Figure 10b), the flexible material components were successfully fabricated with AM. Although much lighter and open, this concept was still too bulky and due to the overall rigidity, comfort was thought to be compromised.

Figure 10 Concept 1B. **a)** 3D Model. **b)** Prototype.

4.4.3 Concept 2

Maintaining the focus on the facilitation of putting the orthosis on and off, new concepts were generated in order to reduce weight, volume, and the number of parts. Concept 2 was selected from these new concepts and was also designed for the right lower limb (Figure 11a). It is mainly flexible, with a lateral piece that can be inserted and removed in a lateral compartment. This concept still allows the main body of the orthosis to be worn while the knee is flexed and the positioning to be made afterwards. The prototype for this concept (Figure 11b) was not successfully built since the flexible structure was not possible to fabricate with AM and the alternative material used (neoprene) was much more elastic than intended. Also, due to the small dimensions of the lateral part, the prototype proved to be both unstable, and able to bend in the frontal plane of the orthosis, not being able to prevent knee adduction.

Figure 11 Concept 2. **a)** 3D Model. **b)** Prototype.

4.4.4 Concept 3

The previous concepts did not allow for a correct prevention of the aggravation of the valgus knee contracture. Plus, due to the instability observed in concept 2, a new concept was developed in which the knee flexion is restricted in the posterior area of the lower limb – Figure 12a. This concept was designed for the left lower limb, presenting a medial support on the knee, thus facilitating the correct alignment in the valgus/varus axis. The prototype (Figure 12b) was fabricated with AM for the posterior part, with a neoprene strap over the knee, fixed laterally with Velcro bands. The main disadvantage observed in this concept were the pressure areas that appear due to the mainly rigid structure being placed posteriorly.

Figure 12 Concept 3. **a)** 3D Model. **b)** Prototype.

4.4.5 Concept 4

The last developed concept tried to incorporate the different learning points taken from the previous designs. To improve pressure distribution, concept 4 presents a one-part rigid structure that is fitted on the anterior portion of the upper leg and the posterior portion of the lower leg. The same structure has a medial support for the valgus knee contracture. The 3D model was also designed for the left lower leg and is shown in Figure 13a. The model represents the rigid part only, which was fabricated with AM – Figure 13b. To fix the orthosis to the limb, two neoprene straps with Velcro were incorporated. This concept presents a low weight, low volume and open solution. The simple structure and perfect fitting to the patient's limb allows a good clinical efficacy as well as an easy putting on and off.

Figure 13 Concept 4 **a)** 3D Model. **b)** Prototype.

4.5 Concept Testing

Prototypes 1B, 2, 3 and 4 were tested with the patient according to their fitting and usability. The patient's and healthcare professionals' opinions led to the confirmation of the main hypothesis raised about usability, comfort and performance issues during each concept development. The overall evaluation of the concepts according to the main need categories is presented in Table 2.

Table 2 Prototype evaluations.

	Usability	Comfort	Performance
1B	+	+	++
2	+	++	+
3	++	++	+++
4	+++	+++	+++

4.6 Cost Estimation

Since the last concept was the most accepted by the patient and healthcare professionals, the costs associated with the additive fabrication of this orthosis were investigated. According to where the orthosis could be fabricated, significant cost differences were identified.

The prototyped fabricated with the FDM equipment available at Instituto Superior Técnico had a total manufacturing cost of €112.18, including material (€63.9), equipment (€48.24) and labour (€25) costs. Applying a profit margin, the orthosis could present a sale price of €228.23+IVA. When asked for a price, Centimfe [13] presented a price of €320+IVA for the fabrication of the same part using an SLS machine in polyamide. Although the total costs involved are not known, it was informed that material costs are approximately €90/Kg, which would make this part cost €12.05 in material. Shapeways® [14], one of the several companies that offer AM services online, presents the following prices for fabrication by SLS in polyamide: €33.50 for material, €42.91 for equipment and €1.35 by part, which makes a total of €77.75. If one considers the available desktop printers, usually with FDM technology, material filament can be bought for €25/Kg, which would mean this same part would cost about €3.62 in material.

5 Discussion

Figure 14 depicts the application of the proposed protocol on the development of a customized knee positioning orthosis for a cerebral palsy patient. The developed work allowed to explore and validate each one of the phases of this protocol, which were implemented with success. However, in each phase there were some limitations that redirected its implementation.

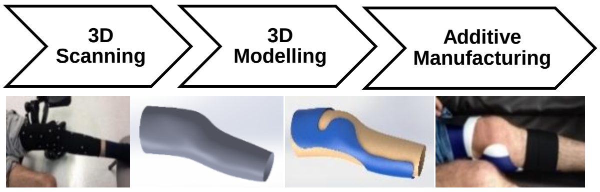

Figure 14 Production protocol applied to the development of the 4th concept.

The 3D scanning phase could be improved with the use of scanners that facilitate the acquisition for patients with reduced mobility, so that they don't have to keep the limb in the same position for a long time. 3D scan data conversion and the orthosis design should make use of software dedicated for that purpose, since the filters and tools that were used led to a loss in anatomical detail. The short range of AM equipment and materials available for testing limited the concept exploration phase in the development of the new orthosis. FDM fabricated models have lower geometric accuracy and weaker mechanical properties than those fabricated using SLS for example. Due to the type of process and materials that are available, SLS allows the fabrication of stronger and more elastic models, facilitating the incorporation of geometric details and the use of smaller thicknesses. The reduced dimensions of the build platforms of the used equipment resulted in the splitting of the different parts that had to be glued back together, compromising the mechanical behaviour of the prototypes. The low availability of materials also led to a negligence in the finishing features of the orthoses. The internal coating that is in contact with the skin, is an important requirement in any orthosis, allowing the reduction of pressure points and avoiding skin lesions. One of the main problems in the traditional fabrication of orthoses is that coatings are often glued, breaking away easily. The exploration of multimaterial AM technologies may offer a good solution for this issue.

The product design and development method that was used allowed the generation of concepts that reflect the patient's needs. This process was limited by the lack of access to competitor's products and data, which only allowed a qualitative analysis of its characteristics and problems.

The iterative cycle for the generation of the different concepts, in which different design focuses were developed, allowed to demonstrate the versatility of AM in the production of customized orthosis. This versatility is shown by the ability to produce different customized prototypes without the need of making new moulds or acquisitions of the patient's anatomical segment. This process, in which each concept/prototype was used as a learning step towards the next one, culminated in the development of an orthosis that was well accepted by the patient and healthcare professionals. This last design included features not commonly included in the solutions used for night positioning of the knee:

1. It is completely designed to fit precisely the anatomy of the patient, considering bony prominences and abnormal alignments;
2. It is light, of low volume and easy to put on and off. Quick application time and easy adjustment features allow an independent use of the orthosis;
3. It allows the prevention of the valgus knee deformity aggravation;
4. It is of easy and quick customization and production.

Although these pre-clinical test results showed acceptance of a new product by the patient, the orthosis performance and usability requirements should be tested in the intended use conditions, i.e., during the night.

It is important to mention that, in each prototype, the parts should be modified to correctly include the necessary attachment points of the remaining components, such as Velcro straps.

The different cost estimations that were made cannot be directly compared, since they correspond to different AM technologies and materials, besides not having the discrimination of all involved costs. However, it is possible to observe a tendency for the reduction of costs associated with AM. The same model is presented a price of €320 when produced by a company that integrates different services, and €77 when produced by a company that is dedicated exclusively to the production of AM objects. The industrialization of the proposed protocol is expected to lead to a further decrease in costs. To understand how this industrialization could be advantageous in the production of customized orthosis, a detailed business plan should be elaborated, integrating the 3D scanning and 3D modelling services that accompany this new type of orthotic design and fabrication.

6 Conclusions

With the present work, a knee positioning orthosis was successfully developed using 3D anatomical image acquisition, 3D modelling and additive manufacturing technologies. This customized orthosis was well accepted by the patient and chosen from a set of four developed, prototyped and tested concepts. The development of the several concepts was supported by product development tools, such as the House of Quality, which aided the translation of the patient's needs into technical specifications. This enabled the creation of a new product in a structured and documented way. Specifically, it allowed the presented orthosis to stand out from existing solutions, answering to consumer needs not currently satisfied, such as the ease of putting it on, the lightness and the prevention of the valgus knee deformity aggravation.

Furthermore, the several steps involved in the production of the orthosis were completed in less than 2 days, with the 3D anatomical image being acquired in 10 minutes, the 3D modelling executed in 1 to 2 hours and the additive manufacture lasting about 12 hours. This presents an advantage in the light of customized orthotic production, as the current production times observed in traditional fabrication methods tend to be much higher.

With this, it was possible to demonstrate the versatility that the used protocol and respective technologies can offer to the production of new products for rehabilitation medicine. It is considered that the ease of customization and adaptability of these new products meets the necessity of adequately answering the dynamic evolution of pathologies and respective manifestations.

Exploring the application of these new technologies enabled the interactive discussion with the patient and healthcare professionals. The interaction with CMRA was positive, allowing a multidisciplinary approach in the use of new technologies in the improvement of healthcare.

With the acceptance of the here presented orthosis solution by the patient, it becomes interesting to conduct more user research with the goal of understanding the possibility of creating a final product and business model around it.

The achieved results demonstrate the potential of design freedom offered by additive manufacturing, suggesting that new customized orthoses can be produced outside the current state of art. With the current progresses in technology, material availability and cost reduction, it is concluded that additive manufacturing presents an interesting and viable exploration field in a near future, which will increase the number of prescription options available for orthoses that adapt to each patient's needs.

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