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RESEARCH ARTICLE

Innovation in Ulnar Deviation Orthosis using Parametric Design and Additive Manufacturing

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ABSTRACT

Background: Technologies of additive manufacturing (AM) enable the creation of parts with suitable finish and resistance, including those with complex geometries, which allows custom design and rapid manufacturing solutions at reliable cost, thus making possible its application to orthotic and therapeutic devices in rehabilitation practice.

Objective: To introduce the development of computer-designed orthotic tools through parametrization for manufacturing of custom dynamic orthoses for ulnar deviation.

Methods: The methodology consisted of two stages, with the first involving the development of parametric design methodology and the second involving the project evolution from the evaluation with 23 participants.

Results: The final design had six components with 10 reference measurements from the hand to the arm, whose data were entered into an electronic spreadsheet (MS Excel) so that the CAD software could automatically redraw the parts in a few seconds. The parts were manufactured by using FDM (Fused Deposition Modeling) in about 10 hours, including 15 minutes for assembly and adjustments.

Discussion: The choice of this new methodology came from the need to have a tool that could be easy to handle by therapists in any clinic setting, and also enable the therapist to use her/his skills to evaluate and provide functional training of the kinetic orthosis, without the need to have specific skills or materials to manufacture the device.

Conclusion: The parametric orthosis project was successful at different levels of deformity, providing ulnar deviation correction and enabling full wrist and finger flexion/extension without causing any disturbance during daily activities. Although the initial project was costly in relation to the reference version due to the high demand for therapists and the industrial designer, the parametric versions become economic as the cost impact is focused only on the digital manufacturing.

Keywords: Rehabilitation; Orthotic devices; Rheumatoid arthritis; Self-help device; 3D Printing.

Introduction

Rheumatoid arthritis (RA) is a chronic and systemic disease characterized by involvement of peripheral joints, especially of the feet and hands, which affects the individual as a whole as RA leads to joint pain and deformities that cause major impact on functional abilities[1–3]. Affected hand joints can cause subluxations and deformities at the metacarpophalangeal joints (MPs), interphalangeal joints (IPs) and wrist. The joint synovium becomes inflamed and thickened, forming an altered synovial membrane named pannus, resulting in the erosion of cartilage and underlying bone. RA has a prevalence three times higher in women, increasing between 35 and 55 years of age[4]. Although there is no consensus about the etiology of RA, it is observed that the combination of inflammation and synovial hypertrophy can lead to cartilage and bone destruction, joint damage and instability[5], affecting predominantly the wrist, metacarpophalangeal (MP) and proximal interphalangeal (PIP) joints. Such factors are related to the pathomechanics of the deformities[1].

The finger ulnar deviation (FUD), a common deformity in RA, is a result of joint damage[6]. This deformity has gradual progression, favored by external and internal pressures that interfere with the grasp capacity and by a lack of MP extension[3,7].

Orthotic rehabilitation promotes balance through the application of external forces and diminishes pain and inflammation through joint alignment, with improvement of both function and ability to perform activities of daily living[8-10].

As the evolution of the disease and its related deformities are individualized, the orthosis design should be very specific regarding loads distribution and stress concentrations. In this sense, the project design and customized manufacturing must be qualified for the orthotic fabrication process, which was recently highlighted by researchers who reported on the alternative use of 3D scanner and additive manufacturing[11-13].

Additive manufacturing (AM) is known as the fabrication process by using additive layers, direct manufacturing or rapid prototyping (RP). This comprises a number of technologies that allow the production of specific parts directly from a model generated through computer aided design (CAD) by sequentially joining individual layers of the object[14]. Strictly, the evolution of the so-called rapid prototyping (as initially and widely known) for additive manufacturing means that the parts are actually the end products, since advancement and improvement of AM technologies offer components with suitable finish and mechanical resistance[11,12]. In addition to the ability to produce complex geometries, which allows for rapid custom design and manufacturing solutions at a reliable cost, the use of AM for orthoses and therapeutic devices has been highlighted[14].

Medical reverse engineering (MRE) is an emerging technology that generates 3D models from physical anatomical structures. It can be applied as a system to analyze and investigate how to redesign a model or model-based accessories that permit changes to meet exactly the needs of each patient[15,16].

There are two main methods of customized reverse engineering/rapid prototyping for hand orthosis by using 3D printing technologies: mechanical and digital ones. The mechanical method is based on direct contacts and measurements, which can be done with a coordinate-measuring machine or manually. For the transcription of the measurements to generate the model, it is necessary an integration with CAD software, which can incorporate a certain degree of automation[17].

Baronio et al.[18] point out that the digital method involves three main phases: acquisition of 3D geometry of the anatomy by using 3D scanner; processing of the acquired data through software (3D CAD); and production of the orthosis by using a 3D printer. The authors discuss the difficulty in scanning the hand, especially the fingers, due to the small movements that occur while making the acquisition, which was also described by Paterson et al.[19]. Moreover, the 3D CAD modeling process requires certain specificities, thus being the most complex phase in the conversion of the triangular mesh into a mathematical surface[19].

To customize the parts, the parametric design is one tool that can aid in the mechanical method. During the design process, the designer can manually set dimensional and geometric constraints, namely constructive approach. The geometric control of the model is achieved by applying constraints or dependencies to the model's dimensions. These restrictions are made for the main dimensions and parameters of calls related to the input variables (reference measurements), which are responsible for the final geometry of the model. Thus, by modifying these variables, it is possible to vary any geometry of the model, resulting in a pre-set behavior[17,20].

In this innovative work, we report on the development of a customization process applied to hand orthosis by using parametric computer design tools and additive manufacturing. Secondly, in order to demonstrate the process and results, as well as to verify the potential challenges and benefits of its implementation in rehabilitation practice, it is described the development of kinetic orthoses for ulnar deviation by means of the presented process, and an assessment carried out with users and therapists.

This new methodology of orthosis fabrication is innovative as there is a multi-professional integration seeking to facilitate the prescription and dispensation, in a short time, of a complex orthosis.

Material and Methods

This project was approved by the research ethics committee of the Medical Faculty of Ribeirao Preto Clinics Hospital, University of Sao Paulo, according to process number 15857/2014. The pattern model starts with the concept of the auto-articulated long ulnar deviation orthosis (OLADU)[3,21] (Figure 1a). The design evolution[3] (pattern model) was based on the anatomical parts of a standard hand-arm by using CAD construction design (editing; drawing sketches; dimensioning and features) and Solid Edge CAD software ST9 (Figure 1b).

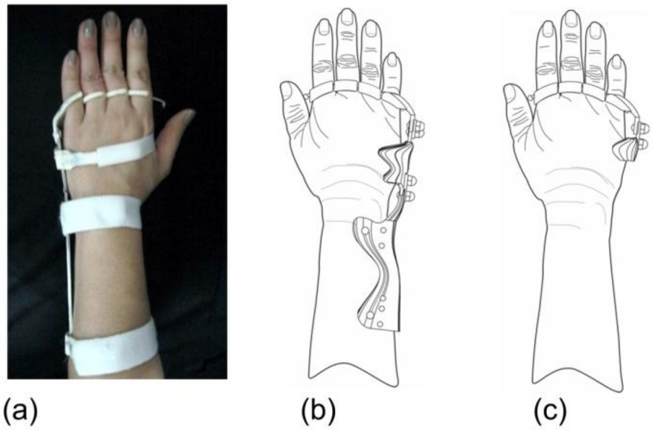

Figure 1. Kinetic hand orthosis prototype (a): OLADU concept, (b) CAD design OLADU; (c) CAD design OCADU (short version).

To convert the pattern model into a customized orthosis, reference measurements representing input variables of the parametric design (Figure 2) are used for either long (OLADU) or short (OCADU) version. The parametrization is a mathematical process that links and binds variables with coordinates, primitives and geometric operands of the digital model, which allows automatic reproduction of the model after each variable modification by maintaining proportionality and shape of the object[22,23].

For application of the parametric design, reference measurements (Figure 2) based on input variables and control variables were recorded into an electronic spreadsheet (MS Excel) for evaluation, which was performed by a therapist in the clinic setting who also filled out an evaluation form consisting of demographic and clinical data, including 10 measurements made with a caliper. Those measurements are related to the orthosis parts design: (a) is related to the rings angles; (b,c h) with the forearm; (d) the rings and (e,f and g) the palmar part.

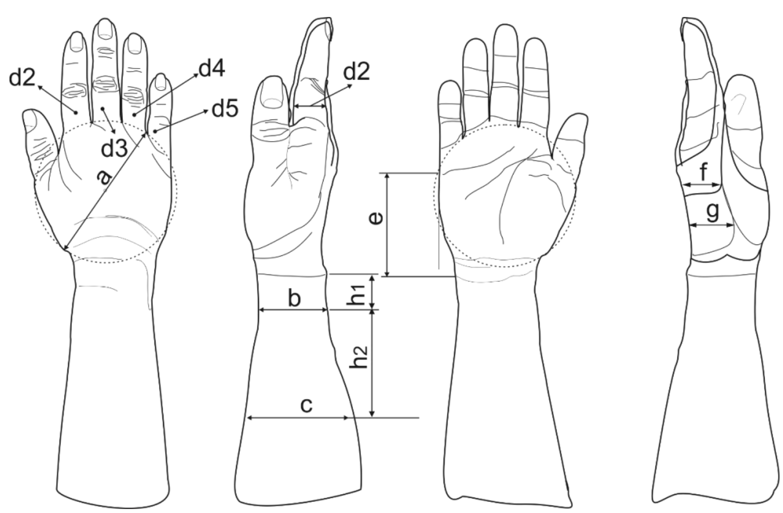

Figure 2. OLADU pattern model: Reference measurements, (a) base of 5th finger to the trapeziometacarpal joint, (b) forearm (h_1) 50 mm distal to the ulna head, (c) proximal forearm (h_2) 80 mm from (b), (d) finger heights (D2- 2nd D3- 3rd, D4- 4th, D5- 5th), (e) distal palmar crease to the proximal wrist crease, (f) distal hypothenar height (5th MP joint), (g) proximal hypothenar height (30 mm bellow the distal palmar crease).

Due to the parametric design, each orthotic component/part has a wide measurement range (Table 1), encompassing a large variation of adult hand sizes.

Table 1 - Dimension range for parameterization of components.

Orthosis Component	Measurement	Standard value (mm)	Minimum value (mm)	Maximum value (mm)
Forearm	"e"	43	35	59
	"f"	58	40	86
Palmar	"i"	63	45	80
Locking ring (5th finger)	"d5"	15	11	20
Ring 4 (4th finger)	"d4"	18	13	25
Ring 3 (3rd finger)	"d3"	19	13	25
Ring 2 (2nd finger)	"d2"	19	13	25

With these measurements, the therapist or practitioner in the prototyping office insert them into an electronic spreadsheet (Excel, MS), and the system automatically makes the customized design of the parts by using Solid Edge, with the resulting STL files being saved and sent to the machine, printed in Fused Deposition Model (FDM) and processed in a solid mode (AM *Dimension Elite* - Stratasys®), using ABS material.

The orthotic components were initially tested on a standard hand and submitted to 19 changes in design and angles involving different parts so that better force distribution and comfort could be achieved, as well as regular use of the hand during daily activities. A pre-test was performed for 6 hours during 3 days to assess the function safety. The validation of the customized orthosis was performed in two phases.

The first phase consisted of using the OLADU model in seven patients presenting ulnar deviation due to RA for a period of 30 minutes in the therapeutic setting, followed by an evaluation of the patient's opinion regarding comfort, deformity correction and hand function. Analysis of the orthosis biomechanics and patient's opinions led to design changes that were then performed, with the model being repeatedly tested until the patient reported no complaint.

In the second phase, 23 patients with ulnar deviation due to AR, used at least one orthosis (OLADU and/or OCADU), which was randomly chosen to be worn, for a minimum of 4 hours during daytime for a period of 30 days. Measurements of ulnar deviation (goniometry) and pain level (Visual Analog Scale) were taken before and after the orthosis use, and a satisfaction questionnaire was applied using a 1-10 rating score (1 = bad/difficult to 10 = good/easy) for the following items: ease of Donning/Doffing putting on/taking off; cleaning; comfort;

deformity correction; pain; moving the hand; grasping objects after the use of each orthosis.

Results

Two designs were developed for the orthosis, namely, a long (OLADU) and a short (OCADU) version (Figure 3). The long orthosis has six manufactured components (forearm; palmar; locking ring; and three rings), whereas the short version has five. The designs for the forearm, short palmar and palmar parts are bilaterally, and the locking ring and rings have left and right parts, totalizing 11 parameterized designs. OLADU has two articulations (wrist and MP joints), with the locking ring and rings being attached to a curved metal rod with an end lock, including a stainless shaft and push nut for fastening the hinges.

The orthosis provides deformity correction (from 60 to 100% correction) while allows free flexion/extension of the wrist and fingers during daily activities.

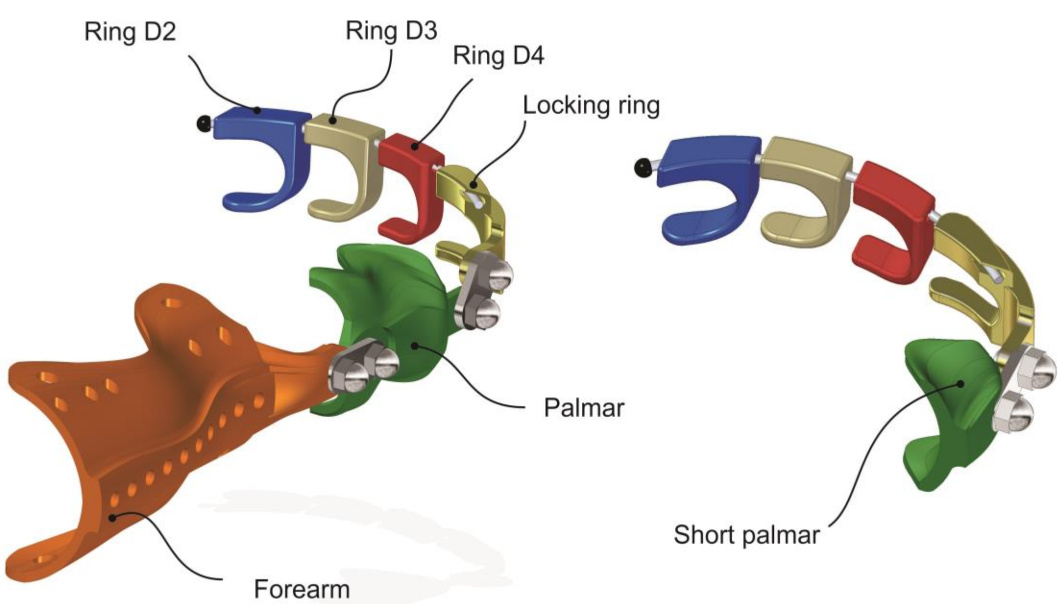

Figure 3. CAD Design for OLADU and OCADU models, showing parametric parts.

A full piece with the locking ring and rings is available and dismiss the use of the rod (figure 4)

Figure 4. One-piece ring.

To achieve the results, the designs were developed and modifications performed by designer and therapist, who used the patient's opinion as a reference. The developed orthosis was customized through a parameterization process, making its prescription quite easy and allowing prototyping offices to manufacture it.

In order to verify the practicality of the procedure, five therapists linked to hand therapy clinics received written instructions on hand measurements and evaluation forms, with 60% reporting that it was easy and 20% reporting that it was very easy.

After the tool is structured, the manufacturing of the orthosis parts is automatic and fast, being easy to put the parts together (i.e. assembly). The material and design allow small adjustments to be made by the therapist in the therapeutic setting (e.g. trimming). Both orthoses (OLADU and OCADU) can be used on both sides and by patients with different degrees of hand deformity.

In the phase 1, a group of seven patients (six females) with mean age of 61 years old (58 and 75) who had different levels of deformities (finger ulnar deviation between 10° and 70°, with and without MP extension) and hand measurements close to the referenced, used OLADU from 10 to 30 minutes, during appointment.

The researchers observed the orthosis fit and functioning with special aim to deformity correction and hand movement. The team analyzed the changes needed in each part, with the orthosis being tested again after any modification during the weekly follow-up in the rehabilitation service.

It was observed that some changes were needed regarding the orthosis. Thus, the versions were also tested for the parametric design, in this way, meaning a customization. This procedure was repeated and there were over 10 changes in the parametric design of the parts (mainly the locking ring, palmar and articulated parts). The aspects that lead to corrections were: partial correction of the deformities; pinching of the base of the 5th finger when grasping small objects, and feeling that the rings were moving distally.

In general, with modifications made, the patients reported improved comfort with the use of the orthosis. In an immediate hold/release test with objects, such as writing with a pencil, grasping a pair-of-scissor or a glass to drink, they reported that the orthosis did not interfere with holding them and, thus, they believed that they could use them at home with no problems.

In the phase 2, there were 23 patients (16 females), including those from the 1st phase, who had one or both orthoses personalized for their use.

Although in phase 1 the patients were well-adapted to the orthosis as they used it for a long period of time, there was the need to make other design modifications. The patient's opinions justifying some modifications are illustrated in Table 2.

Table 2. Correlation between patient's opinion and modifications in the mechanical orthosis design.

Patient's opinion	Modification in the orthosis parts
Finger pain; pinching the fingers	Modification in the angles and design of rings and locking ring
Pain/pressure on the dorsum of the MP when grasping objects, as if the rings were escaping distally from the right place, leading to grasping difficulties.	Modification in design and angles of the parts. Changes in the articulation system at the wrist and MP joints.
Poor deformity correction.	Different designs for the locking ring
Loosen attachment.	Application of anaerobic glue to the parts, resulting in one-piece rings.

Due to the required modifications, we ended up having five versions of OLADU and four versions of OCADU. Figure 5 shows the flowchart of patients using the last three versions of OLADU and two versions of OCADU, and some of them had worn what we denominate the conventional orthosis (i.e. thermoplastic hand based and elastic traction).

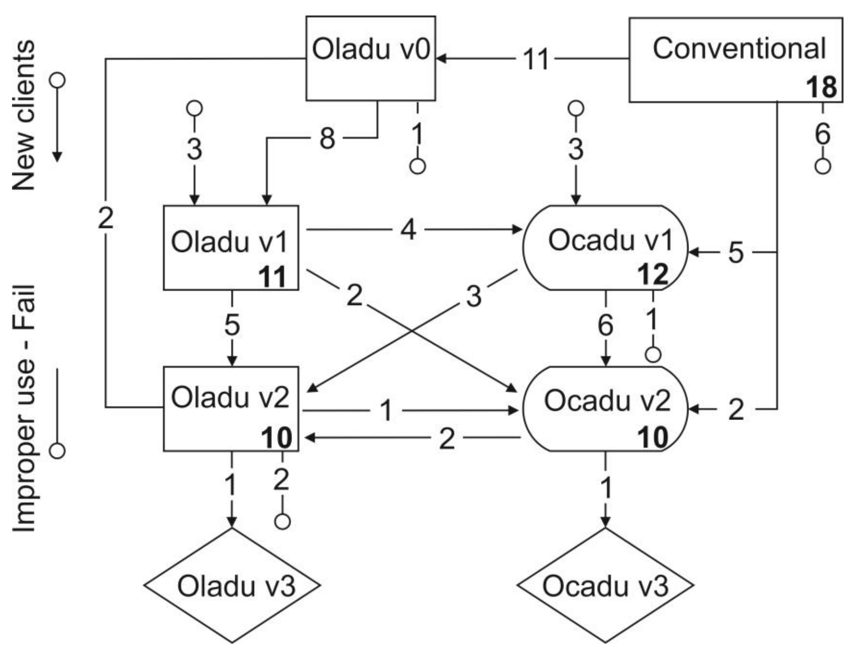

Figure 5. Flowchart of the trying-on of the orthoses by the patients.

The 12 patients who used both orthoses (OLADU and OCADU) answered a satisfaction questionnaire, with rating score ranging from 0 (bad) to 10 (good), independently of the deformity degree, as shown in Figure 6.

Figure 6. Orthosis rating.

Descriptive analysis showed that some patients (n=10) were wearing the orthosis they choose (3 OLADU; 7 OCADU) for more than 4 months, with 90.8% reporting less pain or no pain, 40% having 10 to 90% of ulnar deviation corrected, and 30% gaining 10 to 20% of MP active extension. Also, 20% of the patients reported that they felt their fingers more properly aligned and with more movement, even when they were not using the orthosis.

Discussion

Although the literature regarding the manufacturing of customized orthosis emphasizes the digital acquisition of anatomy data through 3D scanner and use of image software[16,19,24] the availability of such a device is still far from our clinical reality.

Also, the current literature is focused on the acquisition of better images and how to work with them in the manufacturing of customized orthoses, but without considering the opinion of the patients who use them on a regular basis[12,16].

The choice of this methodology came from the need to have a tool that could be easy to handle by therapists in any clinic setting. Another aspect is to enable the therapist to use her/his skills to evaluate and provide functional training of the kinetic orthosis, without the need to have specific skills or materials to manufacture the device.

The non-usage and the abandonment of assistive devices are important issues that can impact the rehabilitation process and limit users' functionality and independence[25]. The study of Sugawara et al. found that upper limb orthoses are amongst the assistive devices with higher levels of abandonment[26]. From an anatomical and biomechanical perspective, the extent to which the device is properly fit to the user's limb is crucial for the success in the rehabilitation outcomes, as well as for the user's comfort and functionality while using the orthosis and performing daily activities[2]. A device designed from high-resolution anatomical data results in a more stable coupling with proper orientation of the joints and parts, thus contributing to a less uncomfortable and more effective device. These are advantages that may, ultimately, benefit users' acceptance and satisfaction with the device[26].

As for the methodology used in our clinical routine, we have used reference measurements which were manually acquired for (pattern model) orthosis design. The kinetic orthosis design was initially costly due to the large demand of therapists with experience in product design. But in a parametric design, as proposed in this work, this reference version becomes economic and very easy and practical for reproduction, meaning that the focus should be now only on specific measurements.

The therapist assesses the need and uses the plug to insert the measurements made with the aid of a caliper, then he or she can either manufacture the component by saving it in STL (for additive manufacturing) or send it to a prototyping office that will prepare and assemble the orthosis and return it by mail.

By using this methodology, 3D printing brings this possibility to reality by making it available to the population, that is, the concept of a business model elaborated to be implemented in a specialized company (Figure 7).

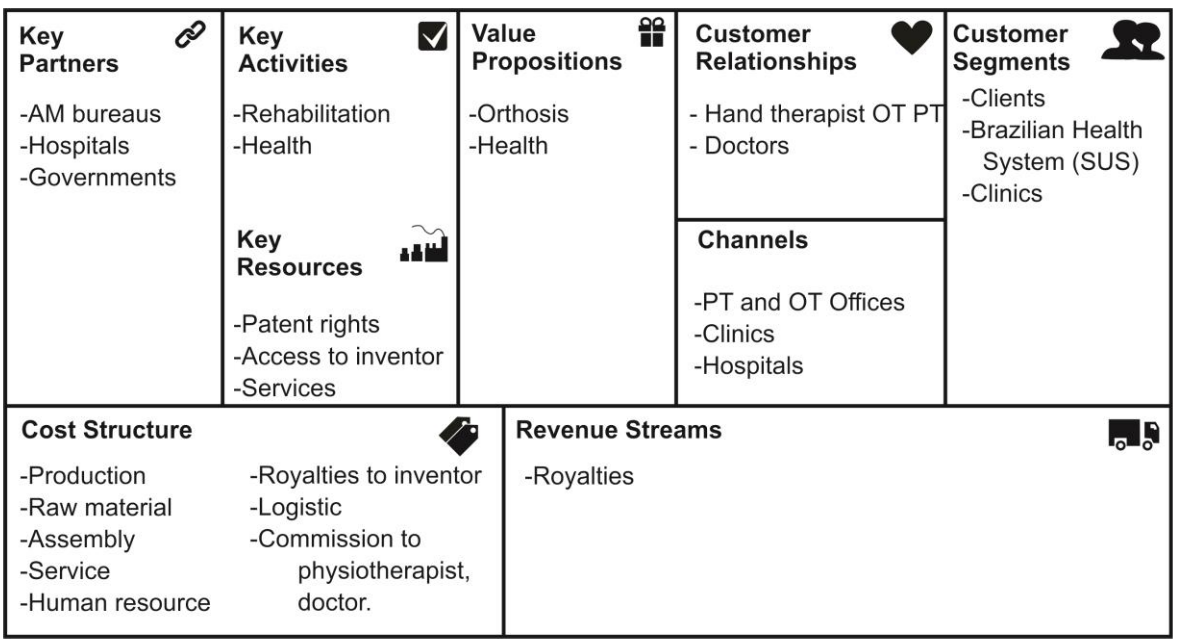

Figure 7 – The Business Model Canvas for implementing the manufacturing of orthoses for the community. Adapted from Osterwalder & Pigneur[27].

The results of the methodology were satisfactory, and the patient's opinion was very important for obtaining the most recent version of the customized orthosis through additive manufacturing. However, this study has limitations such as little number of patients who used the last version of both orthoses and for longer time. Studies are being conducted to verify pressure over the fingers by means of sensors, including reliability analysis of the hand measurements by using caliper and usability for both orthoses.

Although the initial project is costly regarding the reference version due to the high demand for therapists with industrial design expertise, it ends up becoming economic in the parametric versions, where the cost is focused only on the digital manufacturing.

Conclusion

This type of methodology has made it possible to manufacture a kinetic orthosis by means of additive manufacturing, which is now a reality and an option for orthotic fabrication[21].

The project of parametric orthosis was successful for different levels of deformity, since it holds the ulnar deviation correction and allows full flexion/extension of wrist and fingers without any disturbance during daily activities.

We have presented a methodology that requires expertise of the designer and a close relationship between hand therapist and patients, but the final result is a tool that is easy to use by the health professional.

Conflict of Interest:

None

Funding:

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