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DEVELOPMENT OF A WRIST-HAND ORTHOSIS FOR CHILDREN WITH NEUROLOGICAL AND MOTOR DISABILITIES: CONCEPTUAL DESIGN AND MOCK-UP

Paula Midori Kaneko
Adriel Magalhães Souza
Daniel Takanori Kemmoku
Franco Henrique Moro
Gabriel Bellomi Schiavon
Lucas Ferrari Gerez
Luiz Arthur Piedade Nascimento
Zilda de Castro Silveira
University of São Paulo, São Carlos School of Engineering, São Carlos, SP, Brazil. Av. Trabalhador São-Carlense, 400 – Parque Schmidt, São Carlos. Postal Code: 13566-590
paula.kaneko@usp.br; adrielmagalhaes@usp.br; daniel.kemmoku@gmail.com; moro.franco@gmail.com; ga.br@hotmail.com; lucasfgerez@gmail.com; luiz.arthur.nascimento@gmail.com; silveira@sc.usp.br

Abstract. *This paper aims to develop the conceptual design for a feeding and writing auxiliary orthosis. Assistive Technology (AT) is a multidisciplinary area of knowledge, which prescribes equipment and strategies, assisting the rehabilitation of people with different difficulties. The development of AT projects includes the collaboration between engineering, healthcare professionals and patients, obtaining feasible solutions that satisfy the users' needs and support the mechanical requests. The informational design is the first step to obtain a degree of innovation and it delivers a report, which describes commercial products, patents, technical solutions, and aspects that must feature the solutions. The second step, the conceptual design, includes the conception of ideas from technical and functional inspirations and from creativity tools. Thus, the feasibility design was developed for a hand-wrist orthosis for children with motor difficulties, using design methodology tools as the Quality Function Deployment (QFD); Material-Energy-Signal flow (MEI); functional diagram; morphological diagram; Computer Aided Design (CAD); and a 3D printed mock-up. The usage of these techniques has allowed a better communication between the technical team and the users, enhancing the chances of meeting their needs. The preliminary results indicate the potential usage by occupational therapists, healthcare professionals, besides a number of benefits as physical, mental and wellness improvements. The mock-up must be tested and validated in future studies, applying the Single Case methodology.*

Keywords: *orthosis, assistive technology, QFD, multidisciplinary design, 3D printing*

1. INTRODUCTION

Providing conditions to the development and learning of all children is important for the whole society and social inclusion must be encouraged. In addition, every child should receive appropriate support and attention based on his/her potential and limitations. Besides, difficulties of grip and hand/wrist control affect the accomplishment of several daily activities like feeding, writing, personal hygiene, among other activities.

Movement difficulties may have several causes, among them: muscular atrophy, cerebral palsy, stroke sequelae, congenital or acquired neurological problems (Magalhães *et al*., 2004). The incidence of cerebral palsy is one of the highest, as it is the most common disease related to motor impairment, with an incidence of 2 to 3 per 1000 live births in Europe (Cans, 2007).

Occupational Therapists are the professionals that work in sense to return to patients or users the skills to perform daily activities. Thus, these professionals prescribe devices and exercises to enable the independence and to support the social insertion of children with motor and neurological impairments (Sabiá, 2014).

The development of personalized devices for people with special needs is extremely important, and because of this, Assistive Technology (AT) assists the process of searching for customized products that meet individual physical and psychological needs that may improve the self-esteem of disabled people, associating high added value to that type of device, since the loss of ability to perform basics functions affects severely the victims and their relatives (Cipriani, 2011).

The purpose of this paper is to present the development of a wrist and hand orthosis mock-up with degree of innovation, focused on children with Cerebral Palsy. The conceptualizing process explored the possibilities of its use at handwriting and eating activities, in order to improve the motor and cognitive abilities. The theories of Design Methodology and co-design were applied in order to reach a feasible design that satisfies the users' needs and expectation.

The orthosis designed was manufactured by additive manufacturing and, in the next steps, must be tested and evaluated by patients and secondary users applying Single Case Methodology to acquire data and assess the improvement using the orthosis.

2. CASE STUDY

The design methodology applied on this study was based on Rozenfeld *et al* (2006) and Pahl *et al* (2007), and the flowchart represented in Fig. 1 describes the informational and conceptual design development process for the orthosis. During these tasks and phases, there was composed a multidisciplinary team with professionals from health area (Occupational Therapists) and mechanical engineers.

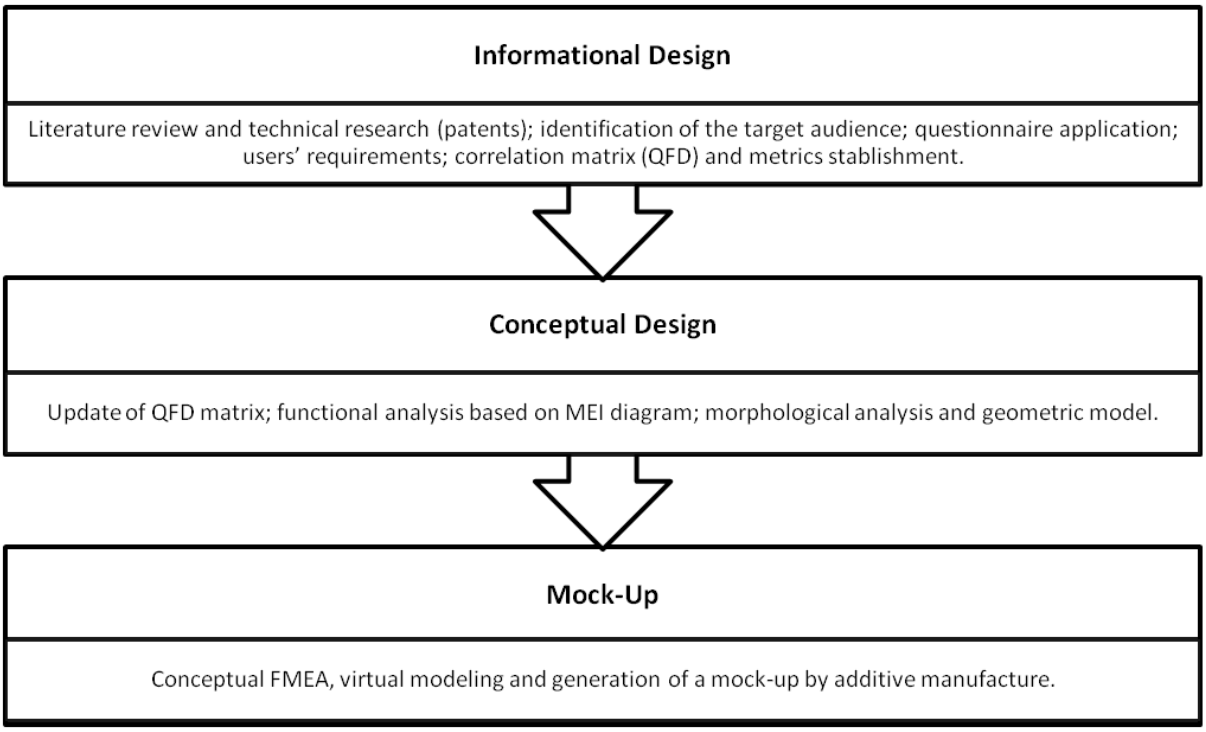


Figure 1. Flowchart and tasks for mock-up generation of a mock-up based on DfAM concepts

2.1 Informational Design

The main purpose of the Informational Design phase is to obtain information from the stakeholders (final and intermediate users, technical team, health area team and potential suppliers) to formulate a set of Users' Requirements (UR) to guide the Conceptual Design phase. In this way, a preliminary list of the UR was obtained with several attributes that satisfy the users' need and expectations about the orthosis. The list was refined applying questionnaires on occupational therapists, students from health area, parents and patients, when possible (Ethics Commission). This process that includes the users' opinion during the product's design phase is called co-design, or user-centred-design (UCD), and may be related to the success of the final product (Harris, 2017), as the user interferes directly with opinions, suggestions and needs that help the engineering team to satisfy them. The Figure 2 shows the UR, and the main features identified were: do not cause injury, be comfortable, allow the use of cutlery and pencil and have adjustable size.

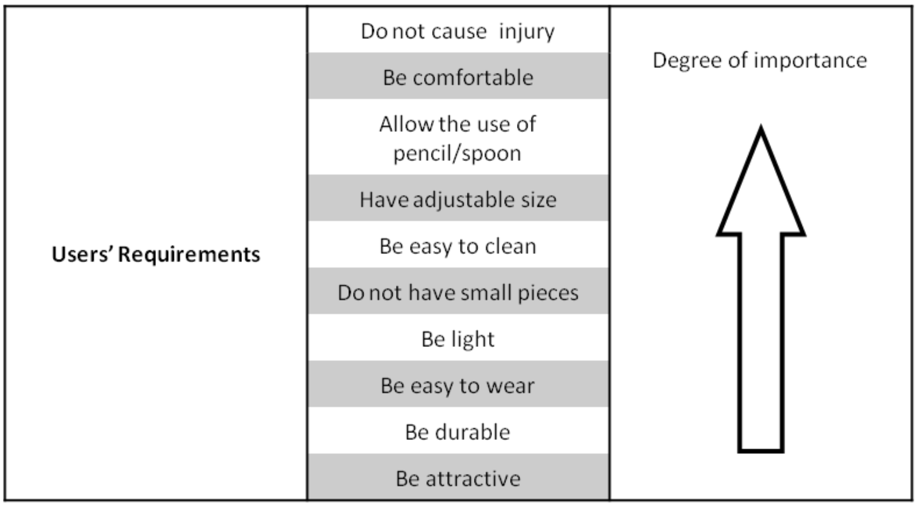


Figure 2. Users' Requirement

2.2 Conceptual Design

During Conceptual Design phase, initiated after Informational Design phase, the UR were converted into technical characteristics (TC), also known as engineer parameters; these functions were explored by concepts and technical solutions based on the following design methodology techniques: QFD (House of Quality), functional structural analysis, Material-Energy-Information (MEI) diagram; and morphological analysis, as detailed below.

The QFD technique, described by Pahl *et al* (2007) as a methodology for planning and quality design assurance, was also chosen and applied to establish the interface between health and engineering teams, in order to obtain the best understating of users' terms and needs. The Figure 3 shows the Correlation Matrix, the main matrix of the QFD technique; it represents the correlation between the UR (shown on the left of Fig. 3) and TC (shown on the top of Fig. 3), classified as weak, medium or strong relations. It also allows the visualization of the independence between the TC, represented by the diagonalization tendency of the strong relations, which means that each requirement may be satisfied individually.

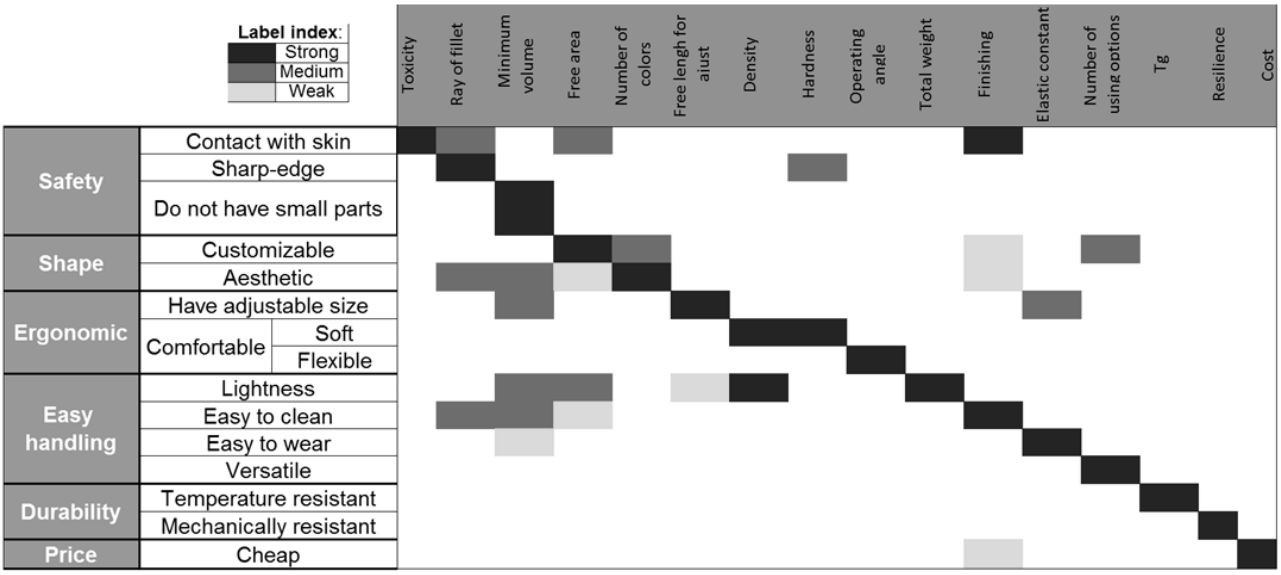


Figure 3. Correlation Matrix

The functional structure analysis, shown on Fig. 4, is the method in the Conceptual Phase that searches for specific solutions to the global problem by dividing it into objective problems (subproblems or subfunctions), and looking for appropriate operating principles that meet the associated functions and requirements. The functional structure analysis organizes the problem and helps the engineers' team visualizing each subfunction and so associate physical effects and working principles to them.

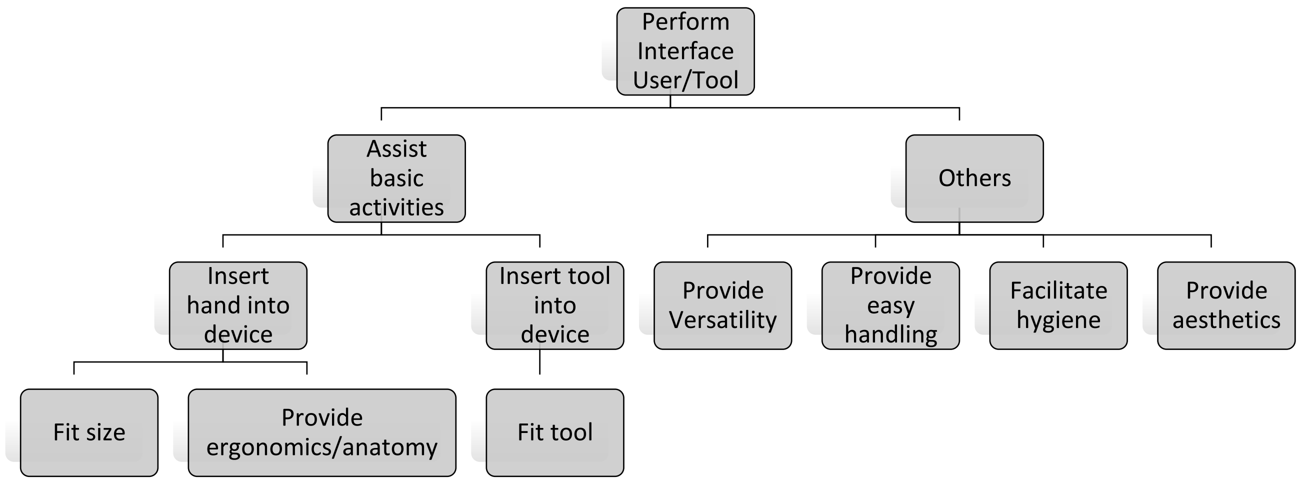


Figure 4. Functional analysis

In addition to the functional analysis, another technique applied was the MEI diagram, which organizes in chronological order the events and activities related to the use of the device. The main objective of the MEI diagram, elaborated after the QFD, is to deepen the dissociation of the global problem, through functional analysis cited above, into subsystems or small arrangements and, therefore, allow the logical visualization of the problem (Ogut, 2004), which makes the searching for feasible solutions easier. In Figure 5 is presented the MEI diagram, where the indicators 1, 2 and 3 are of the sensory type, such as tactile and visual.

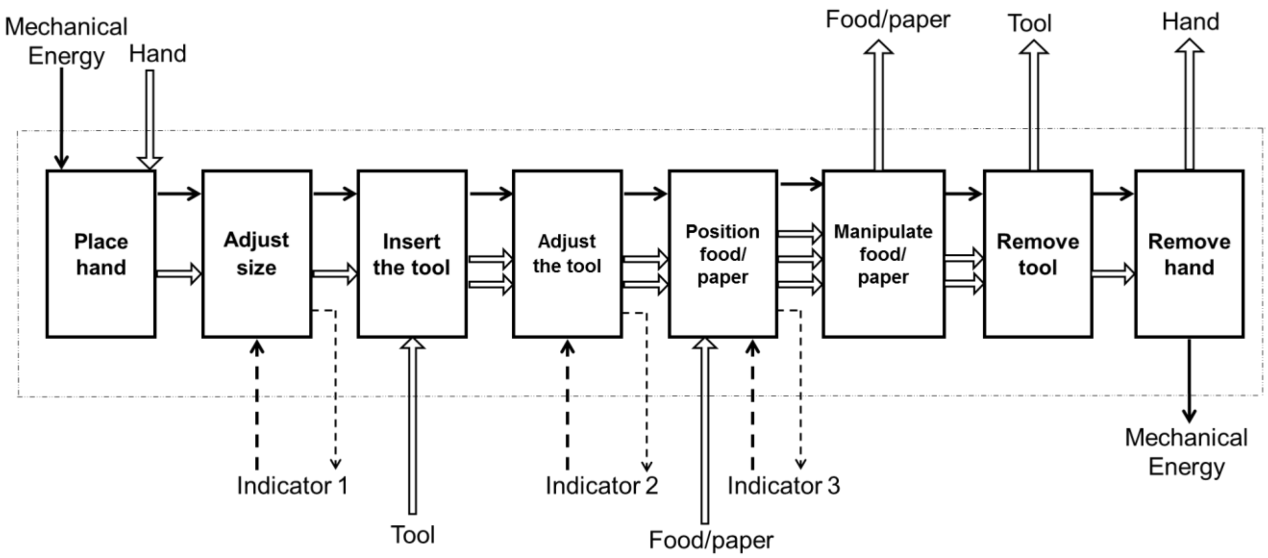


Figure 5. M-E-I diagram

The major function "perform interface between user/tool" was dissociated into the sequence of functions presented in the dashed box above, and the first activity fulfilled is to insert and place hand into the device, then the device must be adjusted to hold the hand. Afterwards, the same sequence is done to the tool, it means that there must be an accessory to fix the pencil/spoon (for example) as well as to fix and adjust the hand. Each of those characteristics became a parameter on the morphological analysis, explained bellow.

After the application of MEI diagram on the orthosis problem, a morphological analysis was elaborated to generate different combinations of creative solutions considering functional and/or technical approaches, and the final set was chosen based on the options' advantages and disadvantages, and the compatibility with the orthosis design. The possible solutions with the respective sub problem are shown on Fig. 6, as well as the final set chosen from the options listed.

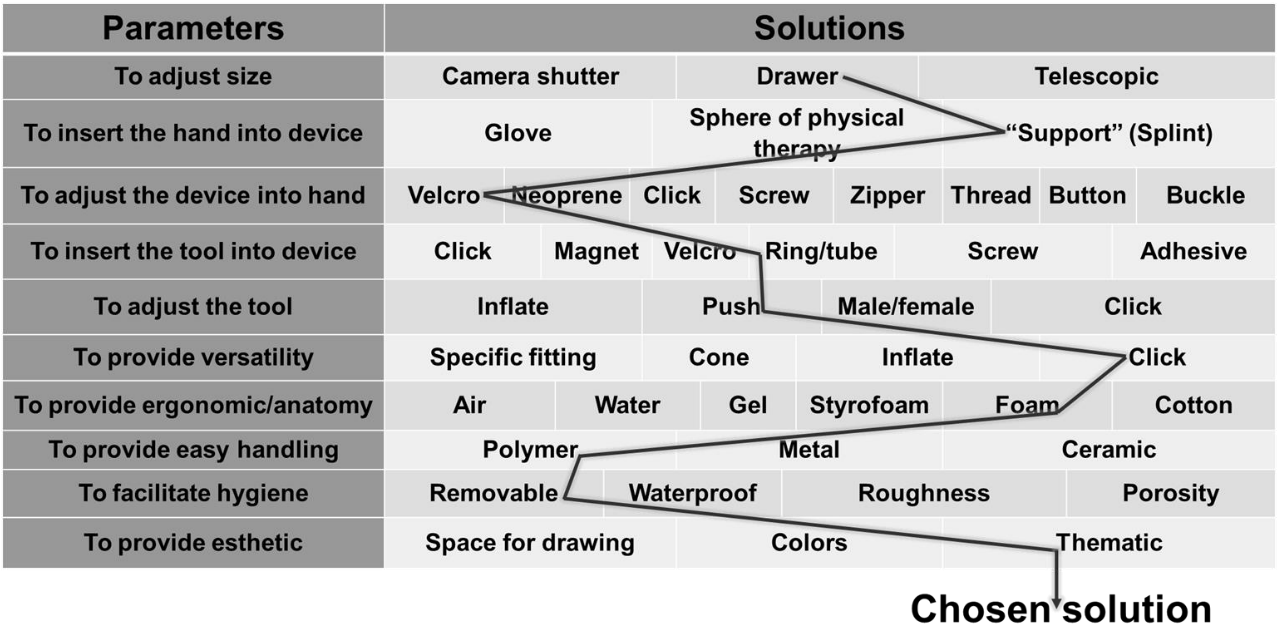


Figure 6. Morphological analysis of the orthosis

With respect to the chosen solution, the options of each parameter were compared in order to choose the option that best fits in the orthosis context. The drawer option was chosen as a solution to 'adjust size' because it is functional, compatible with the design and easily modeled. With respect to 'introducing the hand in the device', considering that the target audience are children with motor difficulties, the splint option offers more support. And 'adjusting the device into hand', with regard to the other options, the Velcro^{TM} is the easiest one to be used; besides it presents the facility of replacement, and advantages about cost and security. To 'insert the tool into device': the ring / tube option was chosen because it fixes better the objects, providing the versatility and also presents good durability. And 'to adjust the tool': the adjustment option pushing the tool is linked to the previous choice of the tool insertion form, because it adjusts better to the insertion of the tool in the ring/tube. 'Providing versatility': the click option was chosen because it has more advantages over the other options: with regard to the option of specific tools, the click option do not restrict the use of devices made specifically for the orthosis; with respect to the cone option, the click option offers more firmness and widens the possibilities of tool types; finally, the inflatable option may leak and is more difficult for the patient to use. 'To provide ergonomics/anatomy': the choice of foam has also been chosen by eliminating other options, considering the risk of leakage if a tear or hole occurs, air, water, gel and styrofoam options were eliminated; regarding the cotton option, the remaining option, the foam presents advantages such as availability and ease of conformation/ moldability. 'To provide easy handling': the polymer option was made due to good cost-benefit and stiffness-mass ratios. In addition, it presents high availability in the market, having the option of inert materials, a very important characteristic, since this was one of the main requirements of the users. 'Facilitating hygiene': the major advantage of being dismountable relative to the other options is the cost, in addition, being removable facilitates more cleaning than the other features, in case the need to wash or partially clean the orthosis. Finally, 'proving esthetic': considering children with motor difficulties, providing space for drawing is not as adequate as providing options for choosing characters or themes which patients can identify with.

2.3 Visual prototype: mock-up

After choosing the best set of solution, the following methodological design tools used were: Failure Mode and Effects Analysis (FMEA), Computer Aided Design (CAD) and conception of the mock-up.

The FMEA is technique that analyses the mode, effect and cause of possible failures that can become catastrophic, in which severity, occurrence and difficulty of detection are classified (Rozenfeld *et al*., 2006). The items with the highest associated marks deserve greater attention during the design, production and development phases, since they may represent some danger to the user or compromise the quality of the product.

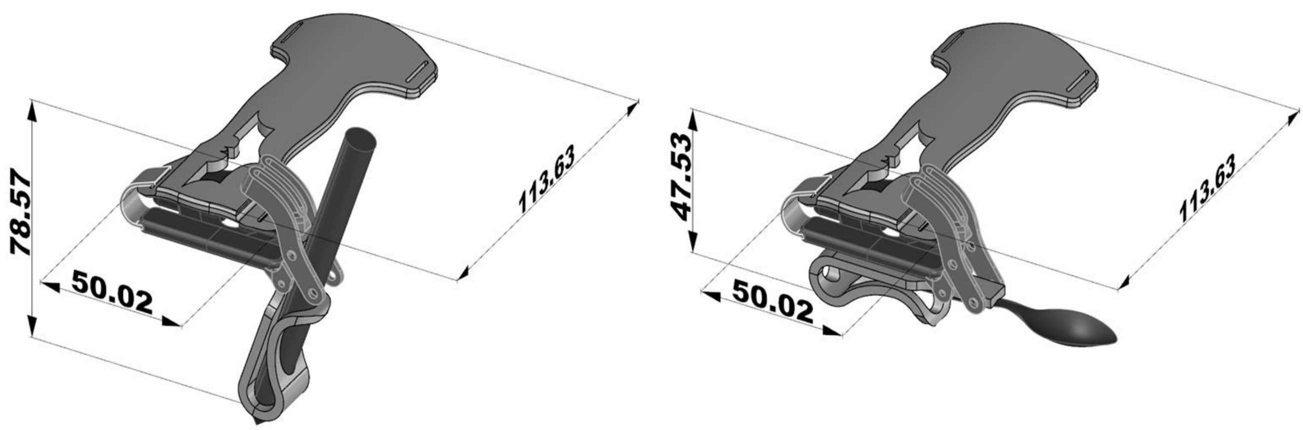
The FMEA for the solution is presented in Fig. 7, where the Risk Priority Number (RPN) is calculated for each failure mode by giving a value between 1 – low risk or probability of failure – and 10 – high risk or probability of failure – for the level of severity of the failure, occurrence of the failure and difficulty of detection of that failure mode. Those values are then multiplied, giving a RPN a value between 1 and 1000.

The highest risk was related to 'to adjust the tool in the hand', followed by 'to facilitate hygiene' and 'to provide easy handing'. The tool's adjustment has proved to be the item that most deserves attention in the project, because if the tool is not well fixed, it will not be possible to successfully meet the main objective which the orthosis was designed for. In addition, this failure may occur with a moderate frequency, and this fault will be detected, but not quickly. In order to achieve a good hygiene of the orthosis, it is necessary to pay attention to the humidity control, since the high humidity can cause the degradation of the material. Given the difficulty of detecting the problem, it is necessary to pay close attention to this item. At the end, as the target audience are children, the lightweight of the orthosis is very important to facilitate the satisfactory use of the instrument. It is not such a simple item to detect because muscle fatigue can be felt by the child only after a certain time of use.

Function and process requirements	Mode	Effect	Cause	RPN
To adjust size	Plastic deformation	Loose or tight orthosis	Geometry/Wrong sizing	48
To insert the hand into device	Rupture/Insufficient strengh	Inability to use	Geometry/Wrong sizing	120
To adjust the device into hand	Plastic deformation	Loose or tight orthosis	Loss of adhesion	48
To insert the tool into device	Plastic deformation	Inability to use	Geometry	48
To adjust the tool	Incorrect adjust/Insufficient strengh	Loose or tight orthosis	Loss of elasticity/Misuse	210
To provide versatility	Wear	Not working	Geometry/Material	75
To provide ergonomic/anatomy	Overheating/High humidity	Thermal discomfort	Geometry/Material	48
	Roughness	Lesion	Sizing	72
To provide easy handling	Weight	Muscle fatigue	Material	150
To facilitate hygiene	Roughness	Dirty	Material/Misuse	96
	High humidity	Deteriorate material	Material/Misuse	192
To provide esthetic	Unattractive	User dissatisfaction	Finishing	24

Figure 7. FMEA for the solution

After FMEA, the geometric model was elaborated, as well as the CAD model made in software Rhinoceros 5.0®, and then, printed by additive manufacturing using Fused Deposition Modeling (FDM) technique. The CAD is illustrated on Fig. 8, in writing position (A) and in feeding position (B) - in millimeters; and mock up made from poly lactic acid (PLA) material is shown on Fig. 9.



(A) (B)

Figure 8. Orthosis' CAD: (A) Writing position, using a pen and (B) Feeding position, using a spoon

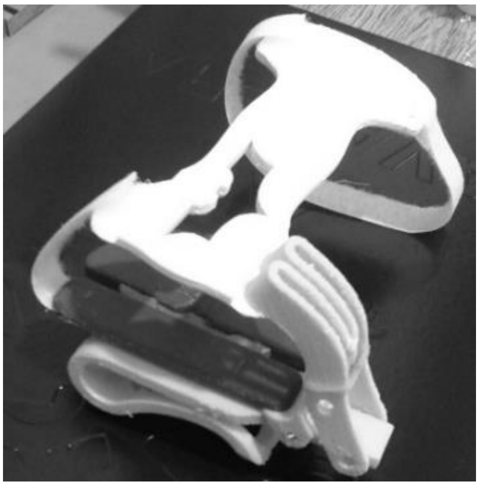


Figure 9. Orthosis´ mock-up (generated by FDM technique)

One of the main objectives of this orthosis' design is to use a mechanism that allows the monitoring of the child's growth so that the support may be given continuously. Thus, it was made a model with a central base size, then using scales, there were made a smaller size model for children with smaller hands, and a larger size for children with larger hands.

The orthosis' mock-up will be tested on further studies by patients and occupational therapists at a Rehabilitation Centre, thus the functionality and comfort will be analyzed and evaluated. If there is any need of changes or improvement, the design team returns to previous steps to adjust the orthosis' design.

The method that will be used to evaluate the orthosis is the Single Case, also known as Single User or Intensive Designs, and it is applied in studies at schools, hospitals, and many others activities (Kazdin, 2011). Although the method assesses a few samples (people) or even a single person, the Single Case methodology is able to evaluate individually the data acquired from the patients and use them to improve the interventions. Those data is obtained at different occasions, several times a week or daily, for example, until the results get stable, and the purpose of this method is comparing the effects of the intervention, in this case, the use of the orthosis for daily activities as painting or eating. Therefore, the child's ability must be assessed before the use and after the intervention, and the assess is visually made, searching for signs, symptoms or attitudes that may be related with the behaviour or performance studied.

3. CONCLUSIONS

The development of a personalized design, mainly when applied to health area is a difficult design process, since it involves many areas of study, professionals, different kind of users and potential suppliers. There are different technical and informal languages that must be converted in order to generate a feasible solution to the problem, a product or an apparatus to support the rehabilitation exercises.

In this way, the design methodology can support the design phases using different techniques to establish an interface between the design team, the health area team and the users. The methodology also defines a procedure of searching for creative, functional and feasible solutions, with degree of innovation.

The design methodology tools used in the device creation steps played an important role in the outcome of the orthosis, mainly during the Informational Design phase, where the users' needs are translated into technical requirements. Such tools that helped in the creative process of the project development do not replace the creative capacity, but are used as a way to guide the engineering team to innovative and elaborate functional solutions.

This paper presented a mock-up generation of a wrist-hand orthosis for children with motors or neurological impairments, applying design methodology techniques. The next phases will allow a more precise evaluation about de orthosis design and functionality, besides its need for improvement from the users' point of view. The tests may also show a progress related to the children's ability to perform basics activities.

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