PRODUCT DESIGN AND DEVELOPMENT OF A FUNCTIONAL PROTOTYPE FOR A WRIST ORTHOSIS

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ABSTRACT: The aim of this research is to create a functional prototype for the wrist orthosis previously studied in the papers "Cercetări privind dezvoltarea și fabricarea unei orteze personalizate pentru încheietura mâinii" and "Research regarding the anatomical modelling of a wrist orthosis for 3D printing application". The progress made consists in designing, manufacturing, and testing three different methods of closing the orthosis. The conclusion of this paper is that one out of the three concepts is not acceptable while the other two are functional but can be improved by changing some dimensions. However, future research is needed to obtain a final product. Among the most important future directions of research there can be listed: choosing an adequate lining, determine the suitable pattern, testing the possibility to generate a parametric model, creating a generative model, and studying the possibility to include different sensors on the orthosis.

KEY WORDS: wrist orthosis, FDM technology, snap-fit joint, Autodesk Fusion 360, closing system.

1. Introduction

The product development process refers to all the steps implicated in changing an idea or a concept into a market released product. One of the stages of developing a new product is to create a prototype to test it and validate it [1]. Sometimes, this step can become iterative. One solution for rapid prototyping is using additive manufacturing technology. It involves relatively low costs, reduced working time and it can manufacture complex geometries [2].

A functional static orthosis must sustain, support, protect and restrict the movement of the wrist joint [3]. A significant property of the wrist orthosis is that it should be easily put on and taken off, without causing any harm to the skin or worsen the patient's condition. So that, one important step in the development of the orthosis is to find the most suitable closing method that will accomplish the condition stated above.

Taking into consideration all this, this paper will focus on the development of a closing system. This research is based on the conclusions and the anatomical model design obtain as results of previous research [4, 5].

2. Current stage

Previous research [4] have demonstrated that it is not necessary to use long and time-consuming methods of molding to create a custom-made splint. That long molding process can be replaced by using a 3D scanner that scans the patient's arm and generates an exact 3D image of the body part (fig. 1 A). This image can be converted into an **.obj* or **.stl* file. Using software such as Meshmixer, it is possible to create various patterns onto the surface of the orthosis (fig. 1 B). The files created with Meshmixer can be used as applications for 3D printing (fig. 1 C). The problem was that neither the scan file nor the pattern generated by Meshmixer are editable, therefore there was not possible to bring many changes to it. To solve this problem [5], there was used Autodesk Fusion 360 software, that allows T-splines modelling. The **.obj* file was imported in Autodesk

Fusion 360 and it was used as reference to generate a T-spline that copies as accurate as possible the geometry of the wrist joint (fig. 1 D). Then, the T-spline was converted into a surface and the surface was converted into a volume. There was applied a Voronoi pattern by using the command Voronoi Sketch Generator (fig. 1 E). Despite the notable progress, we cannot yet speak about a final product. A very important aspect that needs to be considered further is the closing system: the patient should be able to easily put on an off the orthosis.

In the first research, we were able to create a monobloc orthosis, where the closing system was basically inexistent. Moreover, it was difficult to put on and off the orthosis and there was a high chance of hurting the skin in the process. In the second research, we came back to this issue and tried to design a functional system. It was obvious, even from the designing stage, that the closing system was not an optimal choice. This paper aims to solve the closing system problem - the methodology used for this will be presented in detail in the following chapters.

Fig. 1 Transformation stages of the orthosis
A. 3D scanned file; B. Design of the optimal product obtained in the first research [4]; C. 3D printed products obtined in the first reasearch [4]; D. Creating a CAD file using the 3D scan; E. Model obtained in the second research [5]

3. Design and development of the product

3.1. Designing the closing system

The wearing schedule of a wrist orthosis is different for each patient, depending on the type of condition he/she suffers from and on its severity. Often, patients should go to periodic physical examinations or perform therapeutic exercises and they must take off the orthosis. Also, the splint must be periodically cleaned. [6] Keeping that in mind, we can all agree that an orthosis should be easy to put on and take off, without causing any pain or scratches on the skin surface.

To find the best solution for a closing system that would ease the patient's life there were designed 3 concepts. All 3 concepts are based on the snap-fit joints features. There are different types of snap-fit joints but all off them work on the same principle: a protruding part of one component is deflected briefly during the joining operation and catches in a depression in the mating component. After the joining operation, the snap-fit features should return to a stress-free condition.[7]

To design the closing system there was chosen *Autodesk Fusion 360* software – student edition and there was used the anatomical CAD model obtained in a previous research [4]. The first step was to remove the existing closing system (that was not an optimal choice) and the existing pattern because this could affect the resistance structure of the product (fig. 2). It was decided that it is more appropriate for the generation of the pattern to be the last step performed in the process of designing the orthosis.

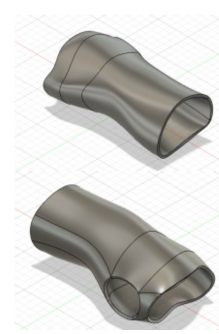

Fig. 2 Model before designing the closing system

First concept. For the first concept it was decided to split the orthosis in 2 parts, one that will cover the forearm and the other one that will cover the hand. In this way, the closing system would be designed on the lateral of the hand (fig. 3). To do that, there was created an offset plane from the XY plane and after that there was used Split Body tool from the Modify menu to divide the existing body by the plane that was earlier created.

On the exterior part, there was designed something similar with an annular snap-joint with sphere shape (fig. 4 A, B). This kind of joints offers the orthosis a certain possibility to rotate, adds mobility to the assembly, and it is suitable in the situations when you need to take the parts out often. [8]

On the inferior part of the orthosis (the one that covers the forearm), there were designed 6 little spheres along its edge (fig. 4 C). On the superior part, there were designed 6 negative shape of the sphere; sockets where the spheres must be inserted when the orthosis is correctly assembled (fig. 4 D).

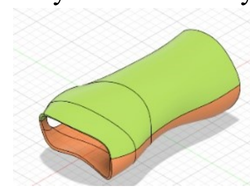

Fig. 3 Splitting the orthosis

On the interior part of the hand (the side with the thumb), there was designed a different type of joint. The lower part's edge was extended and narrowed. The same operation was mirrored on the upper part so that the two parts can perfectly align. To do that, and at the same time keep the geometry, there were duplicated the existing bodies, they were split (operation similar with the one performed earlier); there was used *Offset face* command from the *Modify* tab menu and *Combine* command from the same menu to create just 2 bodies. The unnecessary bodies left after splitting were deleted. Because of the complex geometry of the model, using a mirror command was not an applicable solution so that the same exact steps were performed to create the upper part.

A. B. C. D.

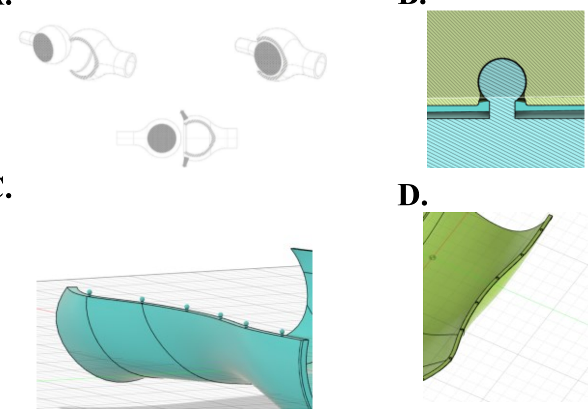

Fig. 4 A. Snap fit joints [8]; B. Snap fit design for the orthosis; C. Lower part of the orthosis; D. Upper part of the orthosis

After that, in the upper part, on the narrower sector that we have just created, there were made 4 rectangular cuts. To do that, there was created a plane (offset from the XZ plane) on which there were sketched the rectangles. The sketches were cut into the orthosis by using *Extrude* command from the *Create* menu (in the contextual menu of the command, there was chosen *Cut* option) (fig. 5 A). On the inferior part, there were created pins that would go through the cutouts and lock the orthosis on the hand. Between the 2 pins there is a gap, so that they can be deformed and forced to enter the cutouts. Also, they are thinner at the base and thicker at the top so that the orthosis does not unlock by itself while the patient in wearing it (fig. 5 B).

The last step was to add fillets and chamfers to make the margins as smooth as possible to avoid accidentally hurting the skin of the patient (fig. 5 C).

A. B. C.

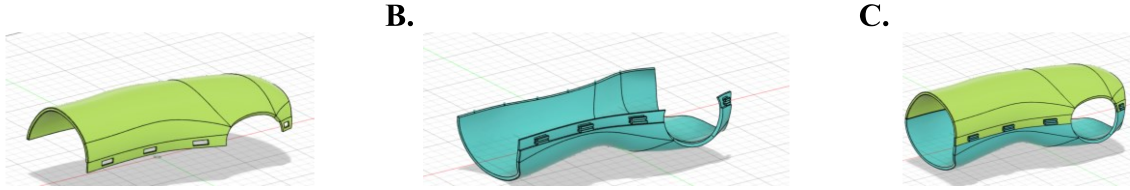

Fig. 5 A. Upper part of the first concept of the orthosis; B. Lower part of the first concept of the orthosis; C. First concept of the orthosis (assembled)

Second concept. For the second closing system a different approach was tried. The orthosis is also split into 2 parts, but this time the cut was made on the dorsal side of the hand. Another difference from the previous concept is that now there was used the same closing system on both sides. For splitting the main body and for adding the narrower edges there were used the same techniques described above. In this model, the superior part was made even more narrow so that there will not be a big height difference between the pins and the rest of the orthosis. A big height difference can become a problem, making it easy for the patient to cling to various objects.

On the left side, there were designed 2 tangent holes, one of them with a bigger diameter, and the other one with a smaller diameter (fig. 6 A). On the right side there were designed cylinders and on top of each of them, another cylinder with bigger diameter (fig. 6 B). There are 3 of this holes and pins on the upper side and 4 of them on the lower side (fig. 6 C).

A. **B.** **C.**

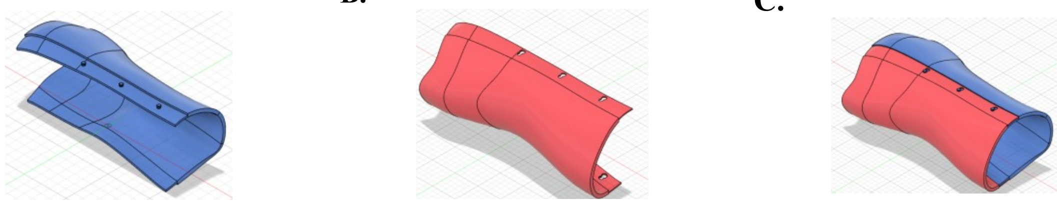

Fig. 6 A. Right part of the second concept of the orthosis; B. Left part of the second concept of the orthosis; C. Second concept of the orthosis (assembled)

The working principle is simple: it consists in sliding one side towards the other: the cylindrical pins are inserted into the bigger hole, then the right half is pushed to left; the thinner cylinders will enter in the smaller holes, where they will be locked. When the patient wants to take off the orthosis, he will pull the right side and the two parts of the orthosis can be removed.

Third concept. For the third concept there was used a model similar to the first one: the closing system is again positioned on the lateral part of the hand. Again, there were created the narrower edges by using the same methods. In this case there was adapted and designed a cantilever snap fit (fig. 7). This type of snap fit consists of a protrusion on one part that is inserted in a specific cut-out [8]. In our case, the lower part has some protrusions (fig 8 A) that are introduced into the upper part (fig. 8 C).

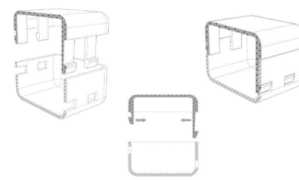

Fig. 7 Cantilever snap fit [8]

Because of the complex geometry of the model, the protrusions could not be created from sketches. There was necessary to duplicate the existing bodies, split them, offset, and extrude them until there was obtained an adequate shape. On the superior part, there were created cut-outs in which the protrusions must enter (fig. 8 B). The used method was the same as in the first concept.

A. **B.** **C.**

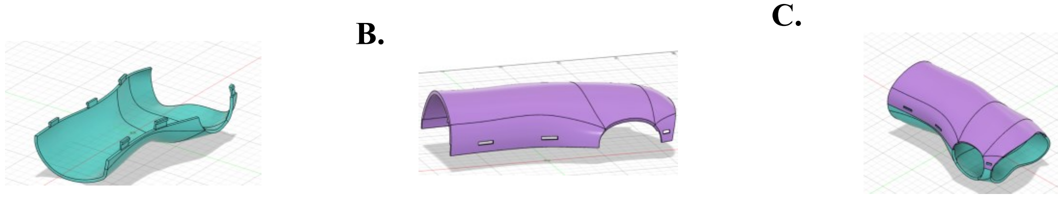

Fig. 8 A. Upper part of the first concept of the orthosis; B. Lower part of the first concept of the orthosis; C. First concept of the orthosis (assembled)

3.2. 3D Printing

To test the functionality and the properties of the previously designed closing systems, they were manufactured by using FDM 3D printing technology. For reasons of material and time economy, there was not printed the entire splint. If the designed closure system is not effective for the printed piece, then it would not have been effective to support the entire orthosis. The entire prototype of the orthosis will be 3D printed once identified the optimal closing system. Each of the 3 concepts were sectioned and were exported from *Autodesk Fusion 360* as **.stl* files.

For printing, there was used a Zortrax M300 Plus printer. The **.stl* files were imported in Z-Suite software, the specific device for Zortrax devices. This program prepares models for 3D printing by saving projects in the **.zcode/*.zodex* format. Also, in Z-Suite you can adjust the printing parameters, such as layer thickness, type of infill and the quantity of support structures [9]. After importing the **.stl*, there were set the parameters (table 1). After setting the parameters, the *Preview* command will slice the model and will generate a final report. The report resumes all previous selected parameters and estimates the printing time (in this case 15h 54 mins) and the material usage (in this case 112 g).

According to its technical data sheet, Z-HIPS material is an adaptable thermoplastic suitable for 3D printing prototypes that can be used for tests before the production process. Also, apart from removing the support structures, printing with Z-HIPS does not require post-processing. [10] These properties make Z-HIPS material appropriate for manufacturing the orthosis prototype.

After printing, it was necessary to deburr the parts; this step was easily done by breaking the support structures that were meant to support the material during printing.

Table 1. Printing parameters

Material	Z-HIPS
Support type	Automatic
Support angle	30°
Nozzle diameter	0.4 mm
Layer thickness	0.14 mm
Quality	Normal
Infill	50%
Fan speed	Auto
Surface layers Top	5
Surface layers Bottom	5
Raft enabled	Yes
Raft layers	7

4. Discussion

After deburring, the parts could be assembled. It was noted that the following changes should be made:

- The distance between the forearm and the orthosis is too big; the gap between the hand and the orthosis should be considerable smaller. In connection with this aspect, it is proposed to decrease the Offset value;
- The first concept is not acceptable. Because of the complex geometry, the sphere and the socket can not be assembled. In addition, the pins cannot deform enough to go through the hole. Even with different tolerances, a patient would not be able to deform enough the pins so that those can enter through the cut outs, taking into account that he/she will be able to use only one hand;
- The second concept needs a series of improvements to become acceptable. There are proposed the following changes: the edges that we have created need to be thicker: those are too fragile and may break while putting on and taking off the orthosis. Either the shape or the tolerances of the holes need to be modified. With the current thickness of the edges and with the current cut-outs the orthosis will break. It has been suggested to test a new geometry, illustrated in the fig. 9 A;
- The third concept is considered the most suitable solution. Even though, there are some changes that should be made to make it optimum: the edges are too thin to resist to frequent closings and openings, so that they should be thicker; the difference of the dimension between the cut-out and the pin should be bigger – because of the quality of the printing it is difficult to make the pins fit into the cutouts (fig. 9 B).

A. **B.**

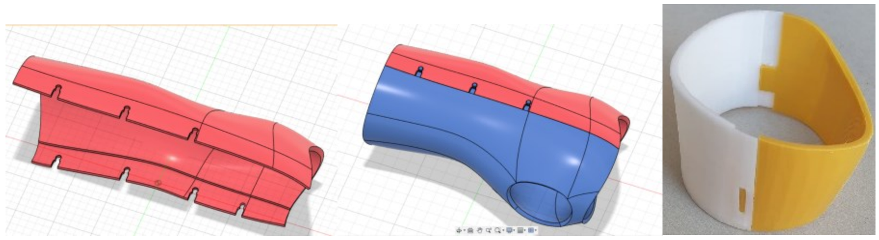

Fig. 9 A. Optimization of the second concept; B. Prototype of the third concept

5. Conclusion

To sum up, there were designed 3 concepts of closing system for the orthosis by using an existing anatomical model and the software *Autodesk Fusion 360*. There were 3D printed samples to test the applicability of the proposed solutions and to identify the optimum one. After printing, deburring and assembly it was noted that the first concept is not an acceptable solution, the second one could become acceptable and the third one is the most suitable one, but can suffer a series of improvements, stated in the previous chapter of this paper.

This paper contributed to the progress of the product development – customized wrist orthosis by elaborating the following aspects:

- Exploring the possibility to use snap-fit joints as a closing method for the orthosis;
- Examine the feasibility of positioning the closing system both on the upper and lower part, respectively, on the lateral one;
- Testing the functionality of 3 different concepts and observing that 2 out of 3 are acceptable solutions;

Additional research is required to develop a quality functional product. Future research directions include:

- Modifying the second and third concepts (as indicated in chapter 4) and repeating the printing process;
- Generating the suitable pattern for the orthosis, that will accomplish both functional and aesthetic role;
- Choosing an adequate lining that will be barrier between the skin's surface and the orthosis' material. This lining should be soft enough to offer comfort to the patient and, at the same time, resistant enough to be worn for medium or long time periods;
- Analyzing the possibility to incorporate different type of sensors (such as pressure sensors, temperature sensors etc.) on the orthosis that will be able to generate data about the healing process;
- Evaluate the possibility to create a parametrical model that will make possible the series production of the orthosis;
    - Create a generative model of the wrist orthosis.

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