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DESIGNING AND MANUFACTURING OF AN ANKLE ORTHOSIS USING 3D PRINTING TECHNOLOGY

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Abstract: *Manufacturing of medical orthoses is one of the most spectacular applications of 3D printing methods. Forces acting on the orthosis and on the patient's foot and the biomechanical system of the foot are important to be considered when designing of an ankle orthosis is intended. The forces are important to be considered also in close correlation with the materials' characteristics from which the part will be 3D printed. PLA material has been successfully used for realizing one orthosis part by 3D printing, due to its reliable mechanical behavior proved by the results reached by finite element analysis that has been performed in the research.*

Key words: *3D printing, ankle, foot orthosis, PLA*

1. INTRODUCTION

3D printing is the method of generating three-dimensional solid objects from a computer file. An object is made in an additive method by laying down successive layers of material until the object is finalized [1]. The materials used in 3D printing are as varied as the items that are created are needed to be printed [2]. 3D printing methods are able to make customized foot orthoses and wrist splints with adequate fit and enough strength in limited clinical tests [3]. 3D printing can be used to improve the aesthetics and complexity of realized components, overcoming clinical barriers to improve efficacy and delivery time. However, as the 3D printing industry and technology advance, the cost of 3D printing equipment items is predicted to decrease as the rate of material deposition increases [4]. As a result of the use of 3D printing processes, better design can be produced. Even though most of studies on the 3D printing of the orthoses have been completed in the science laboratory, there is a need for long-term test to investigate the strength and durability which can be obtained using this 3D printing method [5-7].

2. 3D DESIGNING OF THE ANKLE ORTHOSIS

An ankle-foot orthosis is mostly used to treat musculoskeletal diseases of the ankle or joints, though it may also be recommended to manage the knee's stance phase. An ankle foot orthosis must apply suitable forces to the lower leg in a way that does not cause local tissue injury or discomfort in order to work successfully. The leg will also exert forces on the orthosis, which must be able to resist without breaking or losing function. When orthotic aid is required to compensate for plantar flexor insufficiency in the late stance phase, the forces are shown to be the highest. In the absence of dorsiflexion power during the swing phase, however, the forces are relatively minor when supplementary devices are utilized to support the foot. The force level is essential for the ankle foot orthosis's design, especially in terms of material selection and application. In order to create a personalized ankle orthosis, the most accurate measurements of the patient's foot are needed. In order to obtain the dimensions, a mold was created after the patient's foot as presented in Figure 1.

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Fig. 1. The mold required for designing of foot orthosis

In order to obtain the virtual 3D model of the mold, a scanning process took place in several stages, as following:

-the molding was photographed with a professional camera: Sony Alpha A6100

-each part / position of the mold was photographed at least 3 times

-the photos were introduced in the ReCap Pro 3D software. This software is able to repurpose the actual world as a digital asset. The images were imported into ReCap Pro 3D, which have been processed as a point cloud or mesh.

-The data from ReCap Pro 3D software was further processed in Fusion 360 program (see Figure 2) and MeshMixer to obtain a solid body like shown in Figure 3.

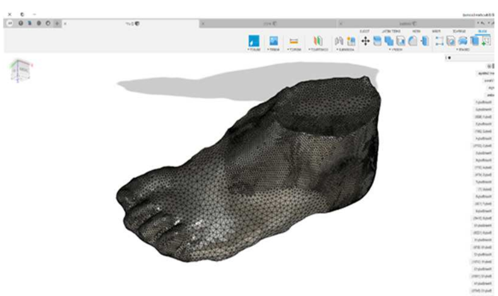

Fig. 2. Connecting of the images in order to create a part using Fusion 360 software

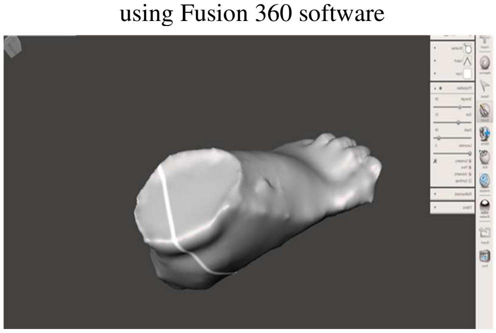

Fig. 3. Alignment of the mesh surfaces and converting of the file to a solid body using Meshmixer software

Its shape was improved in Solidworks as shown in Figure 4. The resistance system (bones), the connection system (joints), the muscular system (muscles, tendons, ligaments), the circulatory system (veins, arteries, capillaries), and the control system (nerves) make up the leg, which is a complicated anatomical structure. Applying forces to three separate places of the limb is important to be considered. Excessive pronation and valgus angles were considered with the use of a three-point pressure system. Rotations around the axes can be controlled and joint stabilizations can be ensured since this method restricts motion around the joint axis. The orthosis must be made to withstand these forces while also appropriately immobilizing the ankle joints.

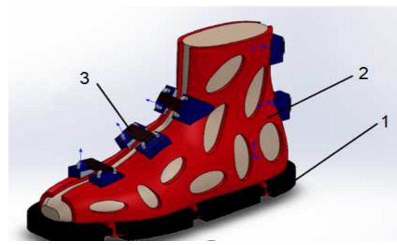

Fig. 4. Ankle foot orthosis designed using SolidWorks

In Figure 4 with 1 is marked the sole (which provides support), 2 is the part that wraps the ankle and the foot having the role of keeping it in a fixed position and 3 emphasize the closing and adjusting mechanism- elastic mechanism with Velcro. The circular flange represents an extension from the fixed part of the orthosis, fixed in the hollow of the sole, and that cylinder which is a common body with the sole has the role of keeping it in that stable position and stiffening the joint of detachable components of the orthosis. The headboard is provided with a notch that imitates the footprint. The orthosis closes with the help of hedgehogs that allow a controlled tightening of the part.

3. FINITE ELEMENT ANALYSIS TO DETERMINE THE MECHANICAL BEHAVIOR OF THE ORTHOSIS

PLA material has been considered proper for this type of application since this type of material is the most researched and widely used biodegradable and renewable aliphatic polyester. PLA is a thermoplastic material with high-strength. PLA material is a high-modulus polymer that may be considered proper from renewable resources every year to produce a variety of components to be used in the industry or for realizing of different medical parts (e.g. orthoses). Kinematical constraints were imposed as shown in Figure 5.

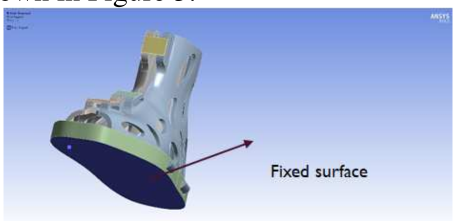

Fig. 5. Kinematical constraint

The next important step of the analysis consisted in the establishment of the technological constraints. The first important load was considered the force with which the patient presses the sole of the orthosis (see Figure 6).

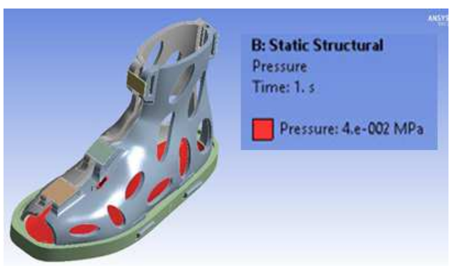

Fig.6. The force with which the patient presses the sole

The second load has been considered as being the force on the orthosis from twisting the wrist. This setting was in concordance with the clamping force of the closing mechanism as shown in Figure 7.

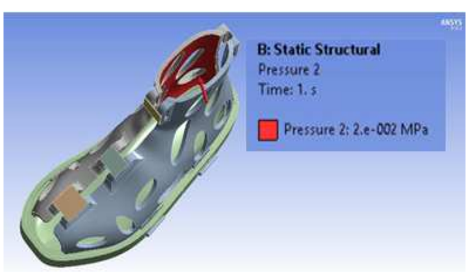

Fig.7. The force on the orthosis from twisting the wrist

After generating the mesh and running the analysis, the von Mises stress and total deformation have been determined. As one may notice in Figure 8 and 9, the maximum value of the total deformation to which the orthosis resists is 2.573mm. The maximum value of the equivalent stress to which the orthosis resists is 44,14 MPa.

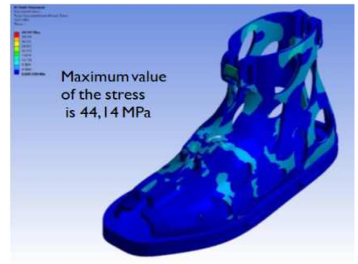

Fig.8. von Mises stress

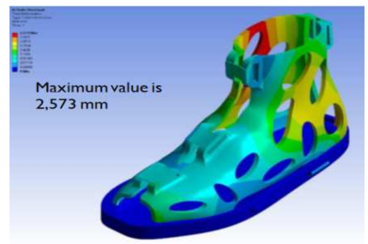

Fig.9. Total deformation

4. 3D PRINTING OF THE ANKLE ORTHOSIS

Anycubic Chiron printer was used for printing the part. This type of equipment has been chosen considering that the price-quality-functionality ratio of average value, the manufacturing costs on this equipment being considered reasonable in this variant. The software used by the Anycubic Chiron printer is Ultimaker Cura. This software has the ability to generate the G code that controls the movements of the printer and slices the 3d model into layers. Regarding the printing parameters, the extruding temperature was set to 205°C, while bed temperature was set to 55°C. Layer thickness of 0.15 mm and part was printed out with one speed up to 50 mm/s. One infilling rate of 40 % has been selected for the 3D printing process and supports were generated as presented in Figure 10.

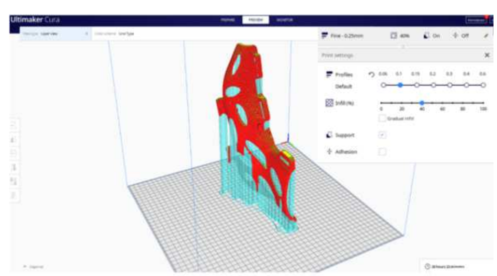

Fig.10. Preparing the file for printing using Ultimaker Cura software

In Figure 11 is presented the part before removing of the supports, while in Figure 13 is presented the final part that has been realized by using the Anycubic Chiron printer.

Fig.11. Realized part before and after support removal

5. CONCLUSIONS

Starting from a CAD model that has been designed according to the dimensions of the patients' foot, one functional orthosis which fulfills its function of supporting and immobilizing the foot subjected to a trauma was made by 3D printing. By using the finite element analysis method it was possible to obtain a customized ankle orthosis that was made in accordance with the 3D model of the patients' leg resulting from the scan. PLA material has been considered for being easy to print and because it has fairly good mechanical properties. This type of material has proved to be reliable in realizing the orthosis made by 3D printing technology as shown in Figure 11.

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Proiectarea si fabricarea unei orteze de picior folosind tehnologia de printare 3D

Rezumat: Fabricația ortezelor medicale este una din cele mai spectaculoase aplicatii ale tehnologiilor de fabricare prin printare 3D. Fortele ce actioneaza asupra ortezelor si piciorului pacientilor, precum si intregul sistem bio-mecanic al piciorului uman sunt elemente importante ce trebuie luate in calcul in etapa de proiectare a unei orteze particularizate pentru piciorul uman. Aceste forte trebuie sa fie determinate si in functie de caracteristicile materialului din care orteza va fi realizata in final prin printare 3D. Materialul de tip PLA a fost utilizat cu succes pentru realizarea unei orteze de picior prin printare 3D, analiza cu elemente finite realizata in cadrul acestei cercetari evidentiind comportamentul mecanic adecvat al acestui tip de material utilizat in vederea realizarii acestei orteze.

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