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Research Article

PROTOTYPING OF INDIVIDUAL ANKLE ORTHOSIS USING ADDITIVE MANUFACTURING TECHNOLOGIES

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ABSTRACT
The paper presents design and manufacturing process of an individualized ankle orthosis using additive manufacturing technologies and reverse engineering. Conventional processes of manufacturing of orthoses are expensive and time consuming Thus, an alternative method was proposed. The patient's leg was 3D scanned and the orthosis was designed using a CAD system. It was then manufactured using the Fused Deposition Modelling technology, assembled and fully tested. Positive results were obtained.

Keywords: ankle orthosis, additive manufacturing, reverse engineering.

INTRODUCTION

Modern prosthetic and orthotic devices are designed in such a way to ensure that several types of dimensions are suitable for as broadest group of patients as possible, meaning no full individual comfort and functionality [2]. Only recently, thanks to popularization of reverse engineering and rapid prototyping, it has become possible to adjust orthopedic products to a particular patient and type of injury. Modern computer-based technologies of manufacturing orthoses for individual patients can ensure appropriate use comfort, as well as allow adjustment of geometry for each patient according to their needs [2].

Ankle sprain is one of the most common orthopedic injuries of lower limbs. The ankle joint joins shankbones (tibia and fibula) with foot bones through the ankle bone. This joint must be stiff, as it bears the weight of the body. Its stabilization is ensured by ligaments located around the joint, which support the ankle and allow free movement at the same time. The ankle sprain usually occurs while participating in sport activities, through standing on a foot in a wrong position. Such a sprain can cause various damage to the joint [18].

More complex injuries require a visit in a specialized clinic and stabilizing the joint. The ankle foot orthoses are a comfortable and effective alternative to a plaster cast, because of lower weight and better use comfort [8]. There are also other possible causes of needing such an orthosis, such as movement problems caused by cerebral palsy, as well as inborn or acquired instability of ankle joint.

The paper presents a project aimed at using reverse engineering and additive manufacturing technologies (3D printing) in prosthetics and orthotics [19]. A classic design of the ankle foot orthosis (AFO) was improved by enriching its shape with individual features of a patient. A process of 3D scanning of a limb was used along with CAD systems to create a digital model of the orthosis. The shape was optimized for the human body and character of the ankle injury. It was also adjusted to be possible to manufacture it using 3D printing technologies, which was realized in the further stage. The orthosis and its features were then verified in practice by the person for whom it was built.

THEORETICAL INFORMATION

Anklesprain – causes and treatment

There are three degrees of sprain of the ankle joint. They differ mostly with size of the damage and limitation of the movement. The first degree is the least dangerous and the most common. The two other degrees of ankle sprain are related to more serious damage of joint structure. The second degree consists in partial breaking of ligaments and joint capsule, while in the third degree, they are completely torn apart. The second and third degree require intervention of an orthopedist, as improper treatment may be a cause of a chronic ankle instability [18]. Ligaments in the ankle joint can be stretched or broken as a result of foot twist or without any external forces. The way of treatment is dependent on the cause and intensification of the instability. The treatment is usually conservative and does not involve surgery. The dominant form is physiotherapy and use of an appropriately selected stabilizing orthosis. Wrong fitting of the orthosis may lead to occurrence of other problems with the motor organs [17].

Additive Manufacturing Technologies and Reverse Engineering in orthotics

Additive manufacturing (widely known as 3D printing) and rapid prototyping have found many applications in industry (e.g. in foundry [20]), as well as in medicine [15]. They are in use everywhere there is a need of an individualized solution, as they allow fast obtainment of a demanded shape with no tooling [1]. Examples of medical use include treatment of injuries of ankles or wrists [11] or arch supports [14].

Among many methods of additive manufacturing, the Fused Deposition Modelling technology (FDM) is one of the most widespread technologies, it is available to a very wide group of recipients [6]. It is due to low cost of purchase and maintenance of FDM machines, as well as a simple and environmentally friendly manufacturing process. The thermoplastic materials in a form of filaments are used, among which the ABS (Acrylonitrile-butadiene-styrene) and PLA (Polylacticacid) are the most popular, but the range of available materials keeps expanding [12]. Material strength and dimensional accuracy are also advantages for which there are so many possibilities of application of the FDM products [3, 4].

The use of additive manufacturing and reverse engineering in production of prosthetic and orthopedic supplies allows adjustment to an individual patient and character of his injury [10]. There are many cases described in literature, regarding manufacturing of elements or whole products for the prosthetic and orthopedic applications, such as a prosthetic socket made out of nylon in FDM technology for an individual patient [7] or strong and light AFOs made out of ABS using Selective Laser Sintering (SLS) technologies [8].

As a basis for the additive manufacturing processes in production of orthopedic supplies, parts of human body shape must be digitized beforehand. That is where reverse engineering comes in handy, for quick creation of a digital version of a physically existing object – for example, using a photogrammetric process [5]. There are many other widely available technologies of reverse engineering, such as 3D optical scanning or laser scanning. Thanks to the use of optical scanning, patient's limb can be digitized in mere minutes. That has a very large influence on orthotics, where effectiveness of treatment is affected, among other things, by thorough knowledge of anatomy of a specific patient, use of precise models and necessity of application of individualized (personalized) tools [16].

PRACTICAL STUDIES

A prototype of an ankle foot orthosis was made for a 22-year old female patient with acquired chronic ankle joint instability. After planned endoscopic strengthening of ligaments of the ankle joint, the patient requires long-time immobilization of foot and ankle joint in treatment after an orthopedic procedure. The treatment is aimed at periodic prevention of contractures and protection from mechanical damage.

Project of the orthosis was inspired by typical AFOs, made for children by students of Gonzaga University. They have been made out of materials such as PLA or PETG using the FDM technology. Traditional process of building individual orthoses is labor and time consuming. The first stage is taking a measure from the patient through manufacturing of a plaster cast and then making gypsum positives of foot and shank [13]. If additive manufacturing is planned for use, modern measurement techniques can be used for direct 3D scanning of the whole lower limb, which allows obtaining its model in much

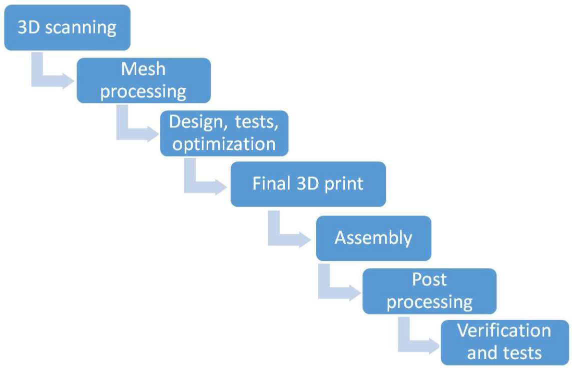

Fig. 1. Scheme of design and production of the orthosis

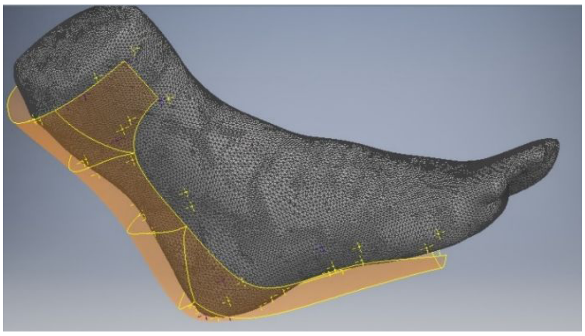

Fig. 2. Three-dimensional scan of patient's foot and freeform surface of the orthosis in the initial design stages

shorter time, thus accelerating the whole manufacturing process. This approach is constantly developed, to make it possible to reduce both time and costs of material [9].

The first stage of the project was 3D scanning of lower part of the patient's leg, using an optical 3D scanner. The obtained result was a 3D model in form of a triangular mesh, saved to an STL (Standard Triangulation Language) file. The obtained mesh was appropriately prepared and then it was placed in a 3D CAD system for preparation of design of the orthosis. On the basis of the created solid model, the FDM process was planned and realized. After the 3D printing out of the ABS material, the orthosis was assembled and post-processed. Finally, it was verified and tested by both in the laboratory and real life conditions.

Schematic course of the process is presented in Figure 1.

The scanning was performed in laboratory conditions, using a non-contact structured white light 3D scanner ATOS I by GOM company. Large measurement area of 500 mm was applied, as it significantly accelerated the data gathering process – the whole scanning operation took 15 minutes. Preparation of the patient consisted in proper positioning of the lower limb by maintaining proper bend of ankle, at an angle of approx. 90°.

Preparation of the STL mesh (removing discontinuities and defects, smoothing, closing holes) was performed in the GOM Inspect V8 software. Then, the created model was implemented in the Autodesk Inventor Professional 2016 CAD system using a dedicated plugin Mesh Enabler. On the basis of the STL mesh, a surface model of the orthosis was created by a method of freeform modelling, adjusting it to the shape of patient's foot and ankle (Fig. 2). After obtaining appropriate shape of the surface, thickness of 6 mm was added.

a. b.

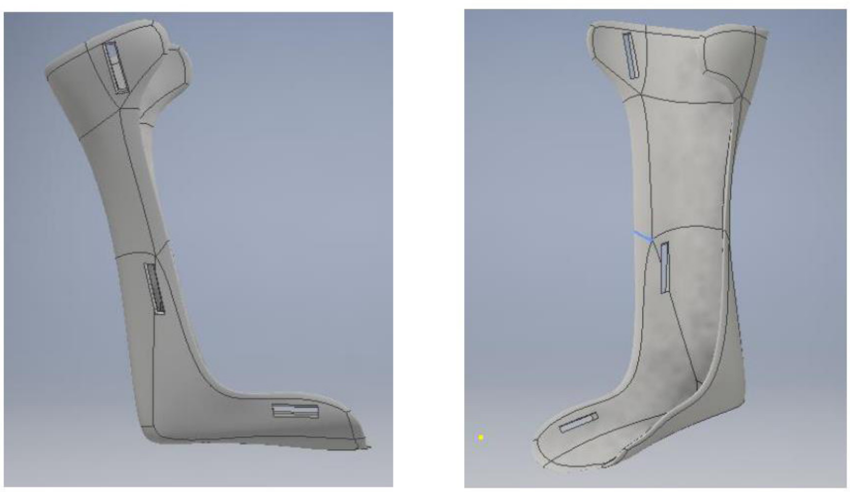

Fig. 3. Final design of the orthosis in the Autodesk Inventor software

Fig. 4. Final prototype of the orthosis

In the next stages, the solid model was adjusted and corrected. Slots were added for appropriate mounting on patient's leg. The final design is presented in Fig. 3.

Because of a limited print volume of the MakerBot Replicator 2X device (selected for manufacturing of the orthosis), the model was divided into three parts in a way enabling its easy and durable connection by gluing – a shape-based connection system was planned consisting in complementary overlays, for proper mutual positioning and area for glue deposition. Each part was manufactured out of ABS material, with layer thickness of 0,2 mm and 90% infill. High Impact Polystyrene (HIPS) material was used as a support material. Total time of manufacturing of all the elements was approximately 16 hours.

Fig. 5. Testing the orthosis – use with regular shoes

After finishing the layer deposition process, the post-processing was performed, consisting in mutual fitting of elements and connecting them using a cyanoacrylate glue. The connected elements were additionally smoothed by sanding and covered with paint.

The manufactured orthosis was laid out with polyurethane foam of several millimeter thickness, to ensure comfort of use. The last step was assembling straps and belts for mounting the orthosis on patient's leg. Both the foam and the straps were permanently glued to the main frame of the orthosis. The final product is presented in Fig. 4.

RESULTS DISCUSSION

The AFO was manufactured according to the initial assumptions, using FDM technology with additional manual post-processing. The patient verified the orthosis as comfortable and adjusted but rigid and fully stabilizing the joint. The orthosis could be used with regular shoes (Fig. 5).

Additional practical tests were performed to further verify comfort of use, strength and functionality of orthosis. The first test consisted in walking on a walkway over a distance of approximately one kilometer. The test ended with success, no bruises or irritations occurred on patient's skin. Additionally, the foot maintained its position before and after the test, what confirms stabilizing function of the orthosis.

Another functional tests included walking upside and downside the stairs and riding a bike. It was all possible, although with certain problems related to immobility of patient's ankle. However, it was not possible to drive a car in the orthosis.

Additionally, the level of individuality of the orthosis was tested by attempting to use the orthosis by another female patient of similar age on both legs, as well as on the left leg of the original patient. In both cases the orthosis was not fitting, thus making it impossible to use. It confirmed a high level of personalization of the product.

Total cost of manufacturing was calculated and presented in Table 1 and 2 (working hours and materials, respectively).

Total cost of manufacturing of the product was 1333,94 PLN. Cost of the materials is very small, only about 132 PLN – the main cost of building this type of products is work by human operator and machine.

Table 1. Costs of working hours on all stages of manufacturing of the orthosis

Processstage	Workinghours	Cost
Data processing	45 min	30 PLN
Design	7 hours	280 PLN
3D printing	16 hours 18 min *	492 PLN
Assembly	2 hours	80 PLN
Post processing	4 hours	320 PLN
Total	30 hours 3 min.	1202 PLN

* Real time, estimation byMakerBotDesktop software: 12 hours 41 min.

Table 2. Costs of materials used for manufacturing the orthosis

Material	Amount	Cost
ABSfilament (build)	192,8g*	68,45 PLN
HIPS filament (support)	63,94g**	28,49 PLN
Additional materials ***	-	15 PLN
Polyurethanefoam	210mm x 350mm	10 PLN
Straps and belts	2m	10 PLN
Total	-	131,94 PLN

* Amount estimated by MakerBotDesktop software, price – 355 PLN/kg.

** Amount estimated by MakerBotDesktop software – 602 PLN/kg.

*** Constant cost of additional materials for 3D printing: kapton tape, acetone, adhesives, resins, paint.

CONCLUSIONS

Persons after endoscopic strengthening of ligaments in ankle joint often do not invest in an individual orthosis, which could help in treatment after orthopedic procedures. That is due to high costs of production and long manufacturing time. Production using additive manufacturing and reverse engineering allows reduction of both costs and time, although it requires higher engineering qualifications to complete all the tasks than in the traditional manufacturing process.

All the design assumptions were realized with success. Light and strong orthosis of the ankle joint was manufactured using a 3D printing process (FDM), ensuring proper joint stabilization. The orthosis can be worn together with regular shoes and is perfectly fit for the patient.

After consulting a specialist from the Stanley company, it was found that traditional AFO device for this injury would be a cost of 2000 PLN. In case of the orthosis manufactured during the presented studies, the total cost was approx. 1334 PLN, where only 12% is the material used. Assuming a certain reduction of working hours (this project was an experimental one, as there are no ready methodologies of designing and manufacturing such orthoses using 3D printing), this might be a potentially much more economically justified approach. Total time of manufacturing was approximately 30 hours, which is less than 4 working days. The time of manufacturing of the traditional orthosis is a little bit longer, but is incomparably more labor consuming, as all the operations require manual work. Therefore, the presented method was proven to be both more effective and cost efficient.

Certain problems occurred during the 3D printing processes. The MakerBot Desktop software underestimated the printing times by almost 4 hours total (the estimated time was 12 hours 41 minutes with the real time of 16 hours 18 minutes). The model had to be divided in three parts, which were later glued – it was a labor consuming task, with high possibility of making errors. This could be omitted if having a 3D printer with a larger working area. Another problem was the low shape accuracy of the 3D printed parts. The raw parts did not fit each other, although certain clearances were planned in the 3D model. It was due to known problems – the staircase effect and general low accuracy of the low-cost 3D printers. This inaccuracy resulted in a need of manual sanding of all three parts in the connection area, which again was very labor consuming.

The tests were performed by a volunteer patient after partially cured instability of the ankle joint. It must be emphasized, that part of the tests (bicycle ride, for example) could not be repeated by a patient right after the orthopedic procedure, as it is very important in the healing process not to load the limb excessively.

To sum up, it can be stated that the CAD 3D, reverse engineering and additive manufacturing technologies have a considerable potential in manufacturing medical products, individualized for the particular patients and injuries, in short time and at reduced price. In the near future, the authors can imagine a situation where the doctor or even the patient himself manufactures an orthosis on a 3D printer – the design process can be partially or fully automated, which will be a future work of the authors.

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