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DESIGN AND PRODUCTION OF THE SPLINT USING REVERSE ENGINEERING AND ADDITIVE MANUFACTURING

Summary

Limbs that have suffered a fracture are usually immobilized with heavy and non-breathable plaster casts. Such immobilization limits the patient's movement, makes showering difficult, and results in excessive itching, sweating, skin rash, and infection. Such conditions also encourage bacterial growth. In addition, any prolonged wearing of a cast can lead to joint and ligament injuries. Such problems can be overcome by using custom-made splints that are becoming more feasible due to additive manufacturing. The advantage of such splints is their lightness and customized and attractive design. The aim of this study is to show how additive manufacturing (AM) technology can be used in medicine, more precisely, in the conservative treatment of forearm fractures. Forearm fractures have been chosen because they are the most frequent injuries. The study focuses on the process of making a splint from idea to realization, i.e., on the design and printing of the splint. Thus, a procedure for a customized production of 3D printed splints is proposed. First, the geometry of the hand was obtained using a 3D optical scanner. With the process of reverse engineering, the obtained CAD model was modified and prepared for 3D printing. Despite all the advantages of these splints, the main disadvantage of such a process that includes 3D modelling and AM is that the process is still time-consuming and expensive.

Key words: *3D digitizing; fused deposition modelling (FDM); hand splint; optical 3D scanning; reverse engineering; stereolithography (SLA)*

1. Introduction

AM technology is increasingly popular, and it is applied in all manufacturing areas having become one of the most rapidly growing technologies in the last few years. AM technology has become an integral part of our lives and improved the quality of life. Some things we dreamt about not so long ago are now possible due to AM techniques which can be used to manufacture parts with complex geometries that would be impossible to fabricate by conventional manufacturing methods. The most common additive manufacturing processes for fabricating polymer products are stereolithography (SLA), selective laser sintering (SLS), fused deposition modelling (FDM), laminated object manufacturing (LOM), 3D printing (3DP), and polyjet printing. FDM is one of the most widespread additive manufacturing processes for making customized plastic parts directly from digital data [1-6].

Closely related to AM is the process of reverse engineering which refers to techniques that create CAD models from physical parts by using the data digitization method [5]. The obtained computer digital model can be then applied in compliance with specific purposes of engineering, design, simulations, finite element analysis, etc. [7].

The field of medicine has also recognized the importance of incorporating new technologies to improve existing practices and achieve the best possible treatment and recovery outcomes. The advantages provided by AM technology in medicine are extremely useful in facial, jaw, and mouth surgery due to the complex anatomy of these areas [7]. Also, some scientists have tried to use AM technology for printing human skin, organs, and bones. In total, about 15% - 20% of AM applications are used in the medical field.

Unfortunately, bone fractures are very common today because humans are constantly on the move due to the fast-paced lifestyle, both in traffic and in sports. In the conservative treatment of bone fractures customized splints made of heavy and non-breathable materials are most commonly used. The main materials used in this traditional process of creating splints, which has remained practically unchanged since the beginning of its use at the end of the 18th century, are fabric, plaster, wire, elastomers, and low-temperature thermoplastics [8, 10]. The use of such splints can be uncomfortable for the patient causing skin problems such as rash, itching, or infection [9]. Fortunately, over the past few years, the application of additive manufacturing has spread in the field of medicine and enabled the fabrication of customized splints [11]. The design and production of the splints using AM bring numerous benefits to the patient. The lightness of the splint produced using AM is mostly achieved due to the lattice structure of the splint. Also, a lattice design contributes to the breathability and hygiene of the splint [12, 13]. The comfort for the patient is achieved by such well-designed splints produced with AM because they are in line with the geometry of the segments of the human body [14]. Despite all these benefits, the process of fabrication of a customised 3D printed splint is still very costly and time-consuming. For example, a standard traditional plaster splint tends to take about half an hour to fit it to a patient, whereas a 3D printing process of a wrist splint takes about three hours [9]. Besides, it is necessary to consider the time spent on 3D scanning, data processing, creating a 3D model, and preparing it for printing [6].

The typical procedure for fabricating splints produced using AM is the following: 1) obtaining the geometry of a body segment using a 3D scanner, 2) creating a 3D CAD model of the splint based on the geometry of the body segment, and 3) producing the splint by employing SLA and FDM processes [8].

The Cortex splint was one of the first splints fabricated using the AM technique [15]. In this method, a lattice design was used with the purpose of immobilizing the fracture with improved air circulation. Lately, Palousek et al. [16] investigated a general methodology to create a low-cost printed splint for a wrist hand orthosis. In this approach, a 3D splint model is created based on a 3D scanned geometry of the wrist, which is subsequently used for 3D printing of a splint using FDM technology. It should be noted that the lattice structure of the splint was not used in this approach. Following a similar approach, ActivArmor uses AM technology to create fully customized casts and splints with a lattice design, which is one of the first commercial 3D printed orthoses available in the United States [8, 17].

In this study, a splint model produced using the additive manufacturing technology has been proposed. The device used for 3D digitizing is a 3D optical scanner. This study proposes a method of combining reverse engineering and AM technology to improve the comfort and efficiency of customized splint production.

2. Experimental investigation

One of the fundamental requirements of the AM splinting approach was to deliver a custom-fit splint to the patient, as this is a standard requirement in traditional custom-made splinting.

In the first phase, before modelling, it was necessary to obtain a digital model of the hand to model the splint. Due to the complex appearance and the movement of the hand, it is quite difficult to measure and draw the hand to match its exact dimensions. For this reason, several available scanning tools were used to obtain the best results. The most widely used and free 3D scanning tool is Autodesk ReCap Photo, which allows the user to upload 100 photos of an object in a free version and turn it into a 3D model. The first attempt at scanning was made by placing the hand in a box, and it was photographed from all sides, after which the photos were uploaded to the above specified program. The program was processing the model for three hours, however, the processing result was quite bad. A flat model of the hand was obtained on which only the fingers could be read. The second attempt at photography was made by attaching the camera to the background, the hand was rotated around the camera, and enough photos were taken from all sides. Unfortunately, the result was equally bad. In the third attempt, the arm was placed calmly on a chair and the camera was photographing around the arm. This time, a model with several external objects was obtained, and the model of the arm was distorted. In the fourth attempt, an environment was created around the arm in which the surrounding objects could not be seen. Once again, as in the first attempt, a flat model of the arm was obtained. After manual scanning, it was concluded that the hand is quite a difficult model to scan, especially with photos, because although good lighting conditions were created, the hand probably moved when pictures were taken, which is invisible to the human eye, but the program cannot create the same grip points and cannot distinguish depth from images, creating crooked models. After unsuccessful attempts to obtain a model using photographs, a 3D optical scanner was used to obtain a three-dimensional model of the forearm.

3D scanning provides a set of coordinates of the scanned surface, called the cloud of points. Connecting these points into triangles can be done via polygonization, which results in a polygonal mesh. In this study, the point cloud data of the physical model were collected by a 3D scanner GOM ATOS 5 12M. This is an industrial scanner and its use for these purposes is a bit out of its bounds.

The ATOS 3D optical scanner uses the process of triangulation through a stereo camera setup that is integrated with a projection unit into the sensor head. During scanning, fringe projection with a blue light equalizer for the highest data quality is used. The sensor projects different fringe patterns onto the scanned surface of the object. These patterns are recorded with two 12-megapixel resolution cameras (left and right). Multiple phase shifts in a heterodyne principle are used by the ATOS scanner to achieve the highest sub-pixel accuracy. In this study, the measuring volume of 320 x 240 mm^2 was used. For the selected measuring volume reference points with a diameter of Φ1.5 mm were used. The reference point markers were glued to the hand (Fig. 1, left). These points enable tracking of the scanned object in the measuring space of the scanner, correct orientation of this object, and joining of each 2D image to the resulting 3D form. It is important that the scanner has always at least three dots in its focus during the scanning process. Since it is an industrial scanner, it is important that the scanning objects are fixed. For this purpose, the hand was fixed to the table with plasticine in the elbow area and it was placed on the spray packaging to move as little as possible (Fig. 1, right). Since the absolute rest of the hand is difficult to achieve, i.e., almost impossible because the fingers are constantly moving, several measurements were repeated. Another function of the handstand was to allow the lower arm to be scanned. During the scan, the thumb moved the most, so it was additionally fixed with plasticine. The scans were taken from different positions. The scanner moved around the arm model. Additional scans were made at different angles to the model to capture the lower arm.

Fig. 1 3D optical scanning of the arm

ATOS Professional software was used to operate the sensor head, process the 3D point cloud, and to edit and post-process the data. To obtain a design of the splint model, the 3D CAD software (Solidworks) and Autodesk Inventor 2020 were used. In order to compare the quality of produced items and the production itself, FDM and SLA were chosen as technologies for making the splint.

In the first case, the splint was produced employing the FDM technology using a 3D printer for polymers BCN3D Sigma D25 with a build volume of 420 mm × 320 mm × 200 mm (L×W×H). Polylactide (PLA) filament of 2.85 mm in diameter was used. The production parameters were: infill density 25%, layer thickness 0.2 mm, printing speed 50 mm/s, processing temperature 220 °C, and temperature of the working platform 65 °C.

In the second case, to improve the surface quality of the splint, SLA technology was used. For this purpose, additive manufacturing of the splint was performed on a printer for polymers Formlabs Form 3 with a build volume of 335 mm x 200 mm x 300 mm (L×W×H) using the Draft Resin material. The production parameters were: type of material from which the splint was made – Draft Resin, layer thickness 0.2 mm, temperature 35 °C, laser power 250 mW, laser spot size 85 μm. The product underwent additional curing in a Form Cure UV chamber for five minutes under 60 °C.

3. Results and discussion

The polygonization of the obtained point cloud data resulted in a 3D model of the arm. Because the fingers were constantly moving, that part of the hand model was deformed. But that part was not needed for the splint design, so it was simply cut off. The obtained model of the arm is shown in Fig. 2. The output was an STL format file of the model, which was used for further design. Afterwards, the STL file was converted into a CAD model in Autodesk Inventor 2020. In this program, the arm model was aligned so that the lower part of the model was visible on the top view, as shown in Fig. 3. As mentioned in [18], today, commercial 3D digitizing devices, with or without modifications, are used in the field of medicine to scan body parts. By resolving specific problems, such as the need for rapid acquisitions, a possible large imaging area, the movement of the object (body part), a traumatized patient, etc., it is possible to implement the scanning process quickly and easily with reasonable accuracy [18]. Also, the results of the scanning process are in a form that can be easily imported into any CAD program.

Fig. 2 3D geometrical model of the arm

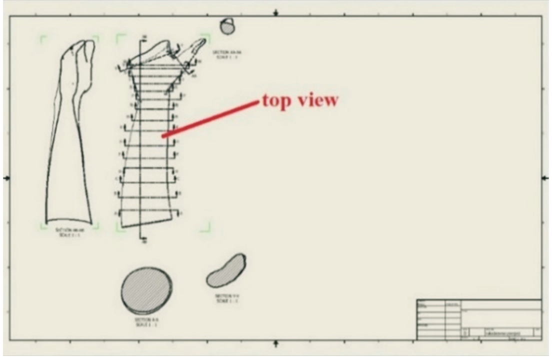

Fig. 3 Cross-section of the geometrical arm model

In this program, the arm model was aligned so that the lower part of the model was visible on the top view, as shown in Fig. 3. By aligning the arm model, full-length cross-sections were made. All arm-length sections were saved in a DWG file. Then, in the program AutoCAD, all unnecessary visible edges were deleted, and each section was converted to a closed loop (Fig. 4, left). Each contour was enlarged by 6 mm: 3 mm for the splint wall thickness and 3 mm for the breathability and safety factor due to splint tapering during printing. After the preparation and enlargement, each section was saved in a DWG file that can be opened by Solidworks. In AutoCAD, the distances between individual sections were measured because reference planes needed to be created in Solidworks. For each individual section, an equal starting point was defined to obtain the correct arm width. Therefore, two reference lines were defined: one for measuring from the left edge of the hand and the other for measuring the centre from the lower edge of the hand (Fig. 4, right).

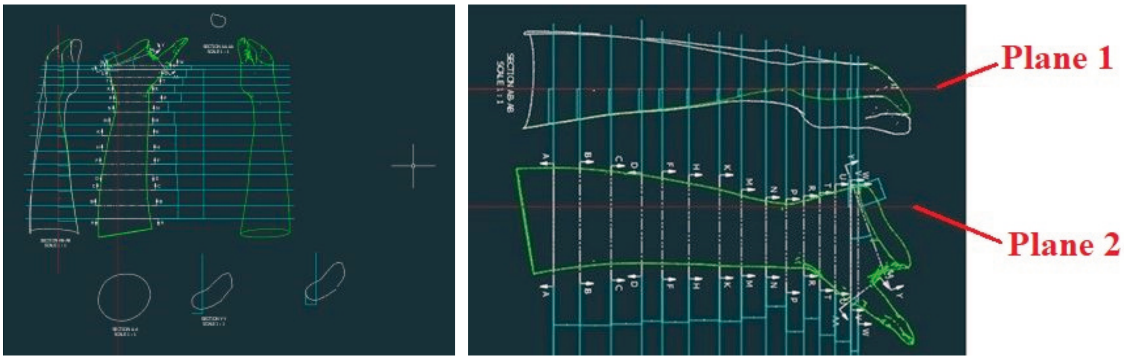

Fig. 4 Creation of individual sections of the arm model (left). Definition of reference lines (right)

In Solidworks, each section was opened separately from the DWG file, and by adding the reference planes at the intervals of these sections, the contour of the future splint was created. In addition to straight cross-sections, an angular cross-section was created because it was necessary to bypass the thumb, Fig. 5.

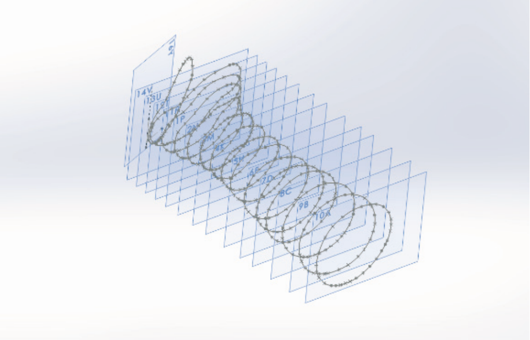

Fig. 5 Straight and angular cross-sections of the CAD model

The hand model was created using the LOFT command, which increased the cross sections of the hand by 6 mm in relation to the scan of the hand. The wall thickness of the splint was 3 mm, which ensured the required strength of the splint, and it was made using the Shell command.

The model around the hand was made using a curved cross-section with the Boundary Base command, and the wall thickness was defined using the Shell command. An opening for the thumb was cut using a cross-section previously defined in a plane perpendicular to the side of the hand. By cutting the opening for the thumb, a digital model of the splint was obtained, Fig. 6. After the final inspection of the splint dimensions against the initial hand scan, the design of the splint was started.

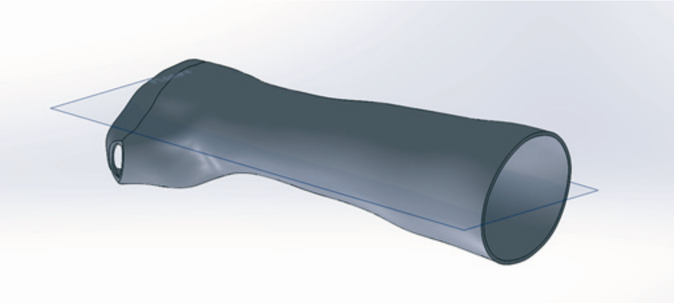

Fig. 6 A model of the splint with an opening for the thumb

The design of the splint was made in such a way that the user can place the splint on his/her hand as easily as possible, without big movements of the hand. For this reason, the splint was made of two parts. The first part covered most of the fist and thumb to secure the splint firmly to the arm, and the second part covered the rest of the hand.

Connecting the splint might pose a problem because the splint must be connected in the simplest but strongest possible way so that it does not move on the arm. At the very beginning, it was decided that screw connections and connections with metallic or magnetic elements were not to be used. Rubber elements, more precisely O-ring rubbers, seemed to be the best choice because they are strong enough to connect the two parts of the splint [19], and they make removing the splint from the hand when needed easy, Fig. 7.

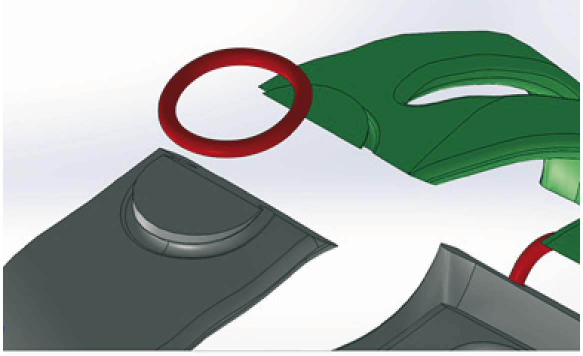

Fig. 7 Connecting two parts of the splint using O-rings

During the design of the splint, an ergonomic grip of the rubber bands was made, which contributes to the design and strength of the splint itself.

When designing, it is important to consider the weight of the splint as well as the fact that the user must wear it during hot summer days, which causes sweating of the hand. Therefore, the design of the splint was created with various holes that contribute both to less weight of the splint and breathability, Fig. 8.

The holes were made in such a way that the splint looks aesthetically pleasing, still leaving enough material so that the splint does not lose its strength, which is in accordance with the results presented in [20, 21].

The final design of the splint was cut in two, according to the section plane as shown in Fig. 6. In Solidworks, these two parts were interconnected by means of rubber O-rings measuring ϕ14 mm × 2 mm, which enable a firm connection, Fig. 8.

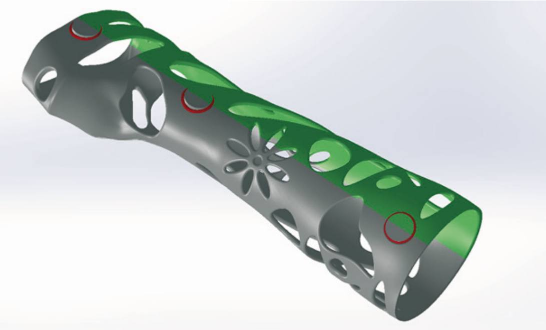

Fig. 8 3D designed splint model assembled with O-rings

The Cura BCN3D software was used to process and prepare the designed splint model for fabrication using a 3D printer BCN3D Sigma D25, Fig. 9. Considering the shape of the splint, it was important to choose an adequate position of the splint to obtain a quality model with as little support material as possible for easier post-processing.

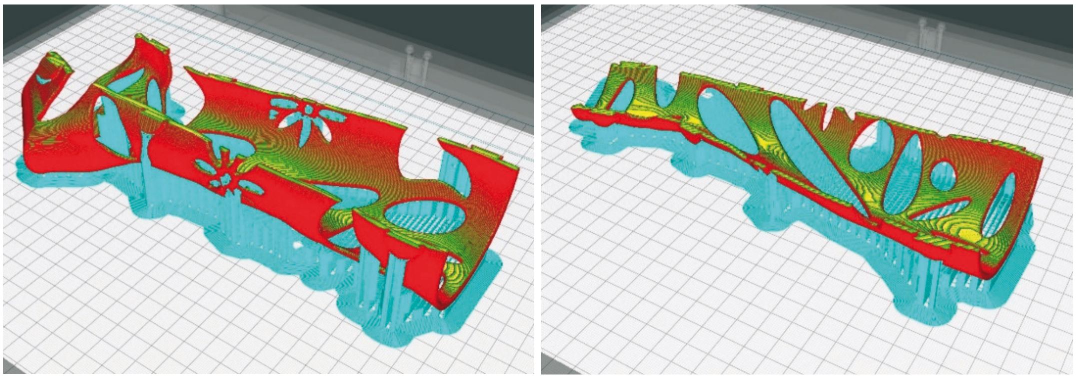

Fig. 9 Preparation of the splint model for 3D printing

The print orientation was selected so that the outer part of the splint was placed on the build platform and the inner part was facing up, toward the printer extruder, Fig. 9. With this orientation of the model, a higher quality and more comfortable surface of the inner part of the splint, which is placed directly on the user's hand, was achieved. In this way, a surface without rough parts (support marks) was obtained, because the printer prints the final layer on the inside. It took 10 hours and 41 minutes to print the lower part of the splint. Due to its size and shape, the lower part has supports all over it, but also in the inner part around the thumb (Fig. 10, left). The print of the upper part took 5 hours and 35 minutes. The support of this part is located only on the outside of the model, as shown in Fig. 10, right. The model and support were printed from the same PLA material, and after printing the support was mechanically removed.

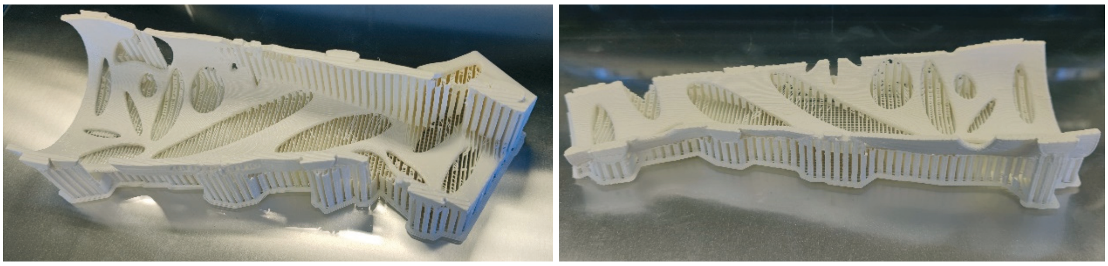

Fig. 10 Printed splint model: upper part (left) and lower part (right)

Using O-ring rubber bands, the upper and lower parts of the splint were connected and fastened to the arm, Fig. 11.

Fig. 11 Splint fastened to the arm

To improve the quality of the splint surface, SLA technology was used. The dimensions of the splint were larger than the working space of the printer, so it was necessary to cut each part of the model into two parts within the software. The printed models are shown in Fig. 12. After the physical printing was completed, the model was post-processed, which included removing supports and splicing parts. Mechanical removal of the support from the models printed in SLA technology was much easier because they were printed in a different position, thus using less support, unlike the models printed in FDM technology using PLA material. After removing the support, parts of the model were glued with quick-drying glue and were fastened to the arm with O-rings. The resulting model was smoother and more comfortable on the outside and inside compared to the PLA models, Fig. 13. The described procedure of designing and additive manufacturing of the splint is in line with the results presented in [22].

Fig. 12 3D printed SLA models with support

Fig. 13 SLA-printed splint

4. Conclusion

This study presented the advantages of and ideas for the design of splints produced with AM technology but also tried to point out the disadvantages of this approach that needs to be further improved to make the process of designing and producing splints with additive manufacturing as efficient as possible. Splints fabricated by using AM are quite different in appearance and have different features from traditional splints.

The procedure of AM production of a customized splint is a time-consuming and costly process and requires a large number of programs and tools to obtain the final product - an arm splint. First, it takes a lot of work to select appropriate software for the manipulation of the scanning data and to translate them into an STL 3D digital geometric model. Also, the designing of a customized arm splint requires the usage of appropriate software tools that can produce CAD data from digital data and, once again, lots of work and time. Finally, the STL preparation for additive manufacturing and 3D printer settings are very important in order to have good-quality physical models. It is very important to choose the right printing material and parameters to reduce post-processing and to make the quality of the splint as good as possible.

When AM technologies are used for production, quite complex geometries can be created, so these splints usually have refined features that save weight, improve strength, and are, in general, better designed products - splints are consistent with the geometry of a segment of the human body and thus provide comfort to patients.

Future research should focus on the optimization of the process parameters so as to achieve even better results.

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