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EDUCATION & TRAINING

Design of an Orthopedic Product by Using Additive Manufacturing Technology: The Arm Splint

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Abstract

The traditional fabrication process of custom-made splints has hardly undergone any progress since the beginning of its use at the end of the eighteenth century. New manufacturing techniques and the new materials can help to modernize this treatment method of fractures. The use of Additive Manufacturing has been proposed in recent years as an alternative process for the manufacture of splints and there has been an increase in public awareness and exploration. For this reason, in this study a splint model printed in 3D, that replaces the deficiencies of the cast maintaining its virtues, has been proposed. The proposed methodology is based on three-dimensional digitalization techniques and 3D modeling with reverse engineering software. The work integrates different scientific disciplines to achieve its main goal: to improve life quality of the patient. In addition, the splint has been designed based on the principles of sustainable development. The design of splint is made of Polycarbonate by technique of Additive Manufacturing with fused deposition manufacturing, and conceived with organic shapes, customizing openings and closing buttons with rubber. In this preliminary study the final result is a prototype of the 3D printed arm splint in a reduced scale by using PLA as material.

Keywords Splint additive manufacturing · Reverse engineering · Three-dimensional digitization

This article is part of the Topical Collection on *Education & Training*

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Abbreviations

FEM	Finite element method
AM	Additive Manufacturing
PLA	Poly lactic acid
FDM	Fused Deposition Manufacturing
CAD	Computer-Aided Drafting
ABS	Acrylonitrile butadiene styrene

Introduction

The optimization of industrial processes has made it possible to improve the quality of products and services and the reduction of costs and production times offered by various industrial sectors [1]. This was also possible thanks to the use of Computer aided design (CAD) software in the design of the product or of the technological process [2]. The application of knowledge from the various branches of engineering in the medical field has made it possible to achieve the quality of life we enjoy today and a high average age. In recent years, in fact, bioengineering studies have made it possible to improve the

Table 1 Advantages of polycarbonate

Demonstrated adequacy to additive manufacturing
lightness
Impermeability
High mechanical resistance
Elasticity
Thermal isolation
Resistance to UV rays and fire
No interference with X-rays for diagnosis

quality and performance of materials used in the production of prosthetic implants [3–7], also through the simulation of the dynamic behaviour of human joints [8–10]. The application of engineering to medicine has also allowed improvements in the development and production of hospital equipment. This was also possible through the development of additive manufacturing processes such as 3D–printing [11]. The medical applications that use the 3D printing techniques are: facial reconstruction, orthodontics, exoskeletons, prosthesis, tumor detection, chirurgical optimization, biocompatible organ and tissue printing. In the medical field, the traditional manufacturing process of custom-made orthopedics splints depends on the operator skills. It requires a lot of production time and the splints themselves makes several problems respecting the patient compliance [12, 13]. For example, in the case of a conventional arm splint, its weight can lead to pain in the neck or back and loss of muscle mass in the arm. The difficulty of bathing and the lack of ventilation can cause induced sweating with consequent allergies and itching due to the poor hygiene of the device and the arm. Another negative aspect of traditional cast orthopedic implants is the difficulty of handling it in some daily activities by patients [14, 15]. In addition, the non-recyclability of the cast, causes a large amount of waste. In fact, according to the National Ambulatory Medical Care Survey & American Academy of Orthopedics, 2.4% of the population experiences some fracture [16] producing an average of 670,000 kg of waste per year [17]. Furthermore, traditional orthopedic casts do not allow the start of rehabilitation or visual control of the damaged limb during the immobilization period due to the closed surface of the device.

The above problems can be solved by using additive manufacturing (AM) technologies. For these reasons, the objective of this study is to improve, through the use of the proposed splints, the following factors that affect patients with immobilization after a fracture:

- Reduction of complications associated with the immobilization period due to lack of visual control over the affected area.
- Possibility of application of physiotherapeutic techniques during the immobilization period for the beginning of the rehabilitation of the patient and in order to accelerate its functional readjustment.
- Contribution to the improvement of the patient life quality in terms of personal hygiene and skin care.

To achieve this, a procedure methodology has been established:

- Design and manufacture of a product of the Biomedical Sector applied to orthopedics field.
- Application of three-dimensional scanning techniques and modeling by using reverse engineering software.
- Application of additive manufacturing techniques for printing a splint by using 3D printing.

The obtained result in this study for the proposed 3D printed arm splint have been compared to those found in scientific literature.

Materials and method

Materials

The choice of polycarbonate [18] for the splint is due to several factors. It is a biocompatible and recyclable material. This ensures that no skin reaction or irritation occurs. On the other

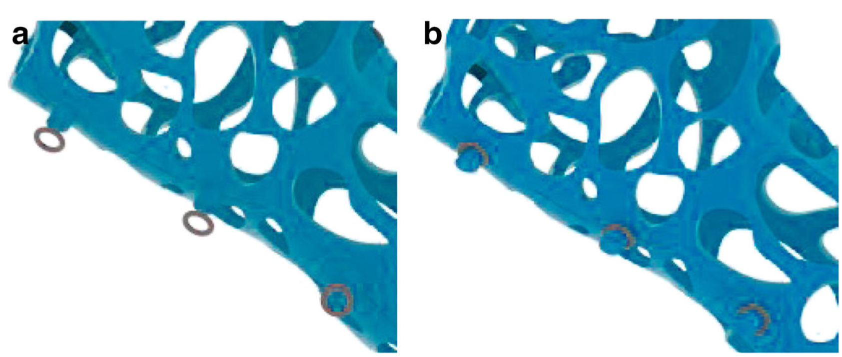


Fig. 1 How to use the button stop closure with rubber

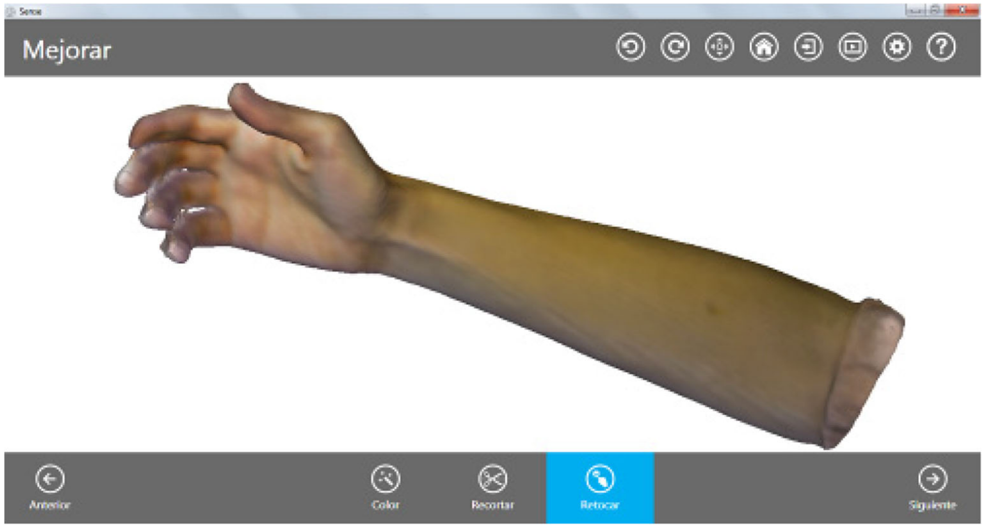


Fig. 2 The arm after the Sense digitalization

hand, a recyclable splint would suppose a great reduction of waste and of costs. The other advantages of Polycarbonate are shown in Table 1.

In this study, the material chosen for the prototype has been the PLA. It is due to the availability of the range of colors and the similarity in the manufacturing process with the material chosen for the final realization: polycarbonate.

Design

Three main characteristics have been considered in order to optimize the splint, in this study: the aesthetic and functional openings, its organic shape and rubber button as closure system.

Openings

The presence of the openings allows ventilation and gives the possibility of washing the affected area improving the recovery period of the patient to avoid sweating, allergic problems, skin changes and allow a visual control of the injured area favoring the diagnosis of the doctor in his periodic reviews. In addition, they reduce the risk of pressure syndromes such as Südeck's Algodistrophy [19] and in security issues, they contribute to the visibility of the limb avoiding the possibility of hiding weapons in the splint.

A splint with openings can help:

- venous return and lymphatic drainage by designing specific windows for access to lymphatic drainage points.
- The use of muscle electrostimulation, which prevents the loss of muscle mass in the affected limb and consequently reduces the period of functional rehabilitation.
- The application of physiotherapy techniques before removing the immobilization by using iontophoresis, sonotherapy, laser therapy, magnet therapy and hydrotherapy.

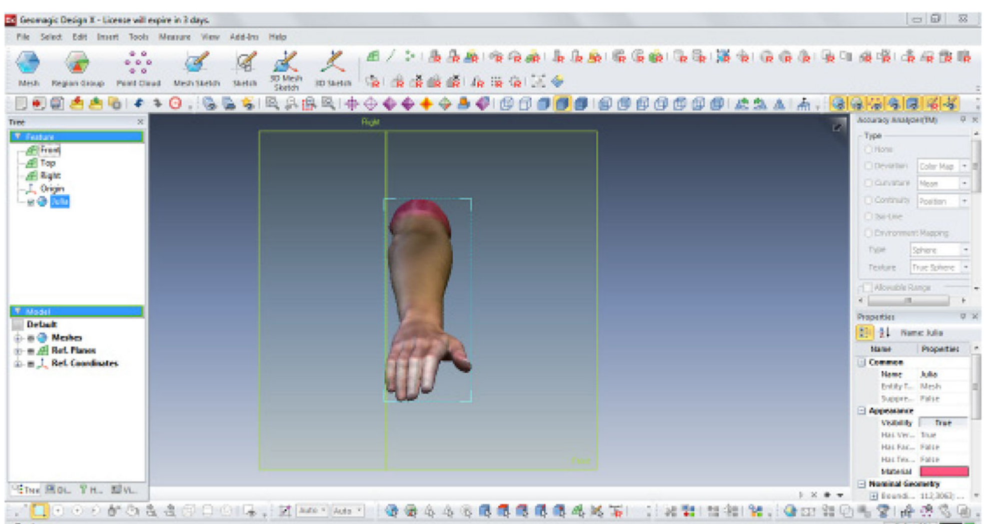


Fig. 3 The arm in Geomagic® DesingX

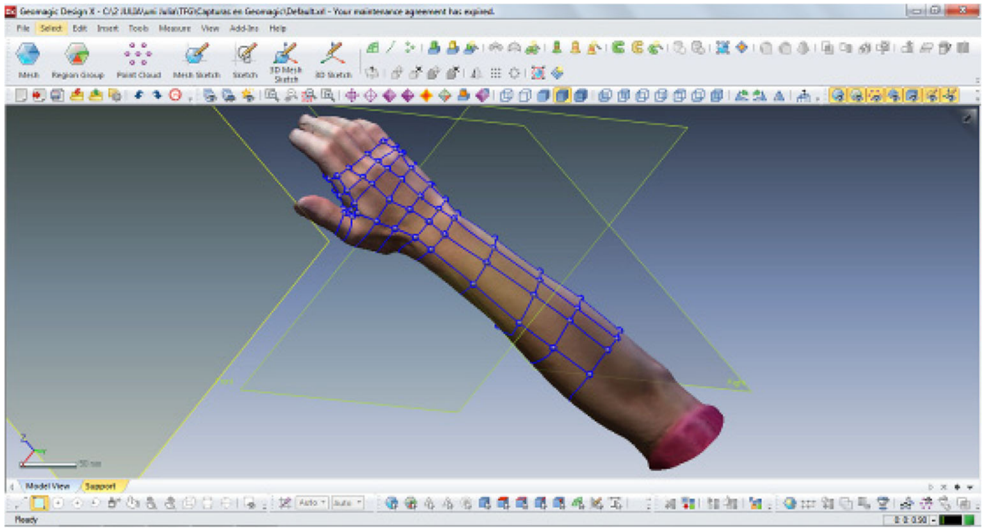


Fig. 4 Sketch by Splines

Organic shape

The organic shapes of the holes have been chosen in part for the resistance that they provide compared to the geometrical figures that promote breakage by accumulating tensions in their vertices. In addition, the organic form is more hygienic related to the ones designed with vertices. In fact, they avoid deposits, facilitate cleaning, provide simplicity and lightness, and allow personalization by giving a less hospitable appearance than the traditional orthopedic casts. The customization allows an attractive and personal aesthetic that identifies the splint with a non-orthopedic supplement and avoids the patient feeling less convalescent or sick.

Rubber button and closure system

This type of closure represents a cheap and discreet solution. Two pieces that make up the splint are held by the buttons with the rubbers. Rubber button and closure system are very efficient and very easy to use. The proposed closure system does not cause any cleaning problems, too. It also allows the detachable union of its parts and therefore the occasional removal of the splint in order to establish a visual control in the medical revisions (Fig. 1).

Manufacturing

The Manufacture with Fused Deposition Manufacturing (FDM) has been chosen in order to minimize the inconveniences, to reduce the initial investment for the implementation of the technology and minimizes the printing times. In fact, the FDM is cheap ad it allows the creation of complex geometries with high resistance and precision. Thanks to this, the splints can be perfectly adapted to the injured limb.

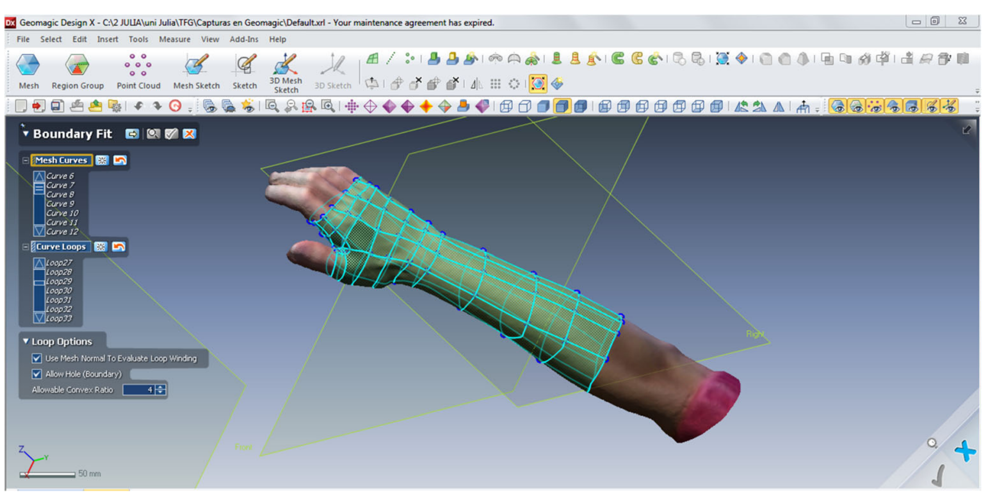


Fig. 5 Surface that appears with Bounday Fit tool

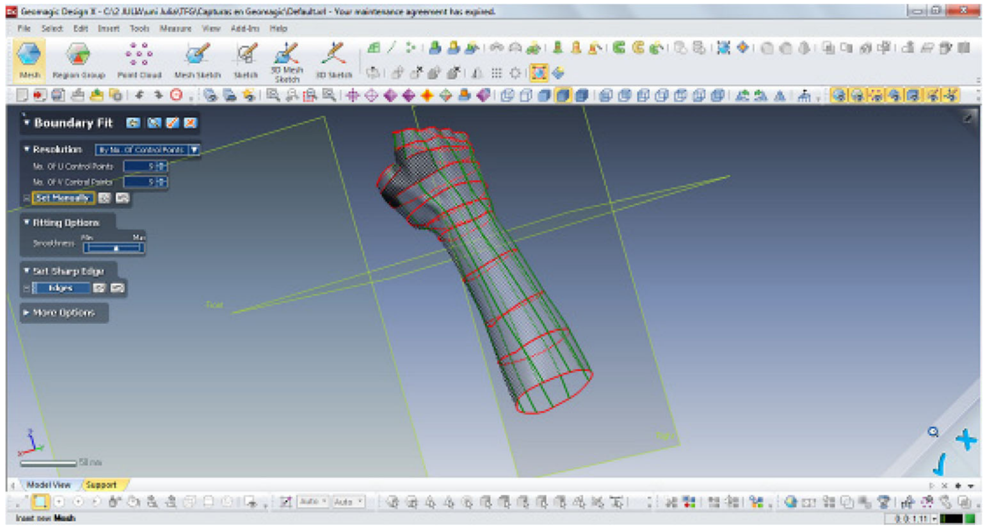


Fig. 6 Surface that appears in the second window of Boundary Fit tool

Methodology

The methodology to follow for the manufacture of the splint consists of three parts: three-dimensional digitalization, 3D modeling and additive manufacturing.

Three-dimensional digitalization

The first step has been the digitization of the member and needs the immobilization by using a 3D scan. In this study the forearm and right hand of a 20-year-old Caucasian woman with a weight of 55 kg were used as a model. The Sense scanner has been used. Its dimensions are 17.8 × 12.9 × 3.3 cm, with a scan volume: between 0.2 × 0.2 × 0.2 m^3 and 3x3x3m^3. Its operating range varies between 0.35 and 3 m, Horizontal field of view 45°, Vertical 57.5°, Diagonal: 69°, depth of image size 240(high)×320(width)px. Operating Temperature is between 10 °C to 40 °C. The option of *person scanning* has been selected in Sense software in order to generate the 3D model. A 360° horizontal rotation has been performed around the injured limb with the scanner (performing simultaneous vertical scans in order to capture all areas). This step, although fast, is of great importance. In fact, it speeds up the procedure and optimizes the product when it is customized. Once the model of the arm has been generated, post-processing has been carried out solidifying the model, cutting out the noise and limiting the remaining anatomy and smoothing the geometry of the fingers. In this way it has gone from a point cloud to a simpler mesh limiting the area of interest (Fig. 2).

3D modeling

For 3D modeling, the forearm file saved in *.ply format was exported to a CAD program: Geomagic®DesignX (Fig. 3).

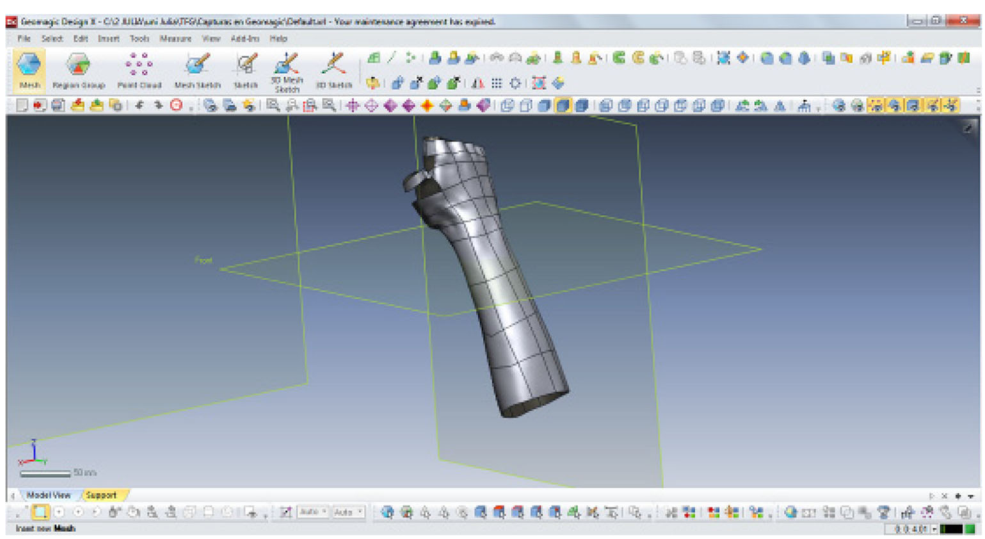


Fig. 7 Created surface

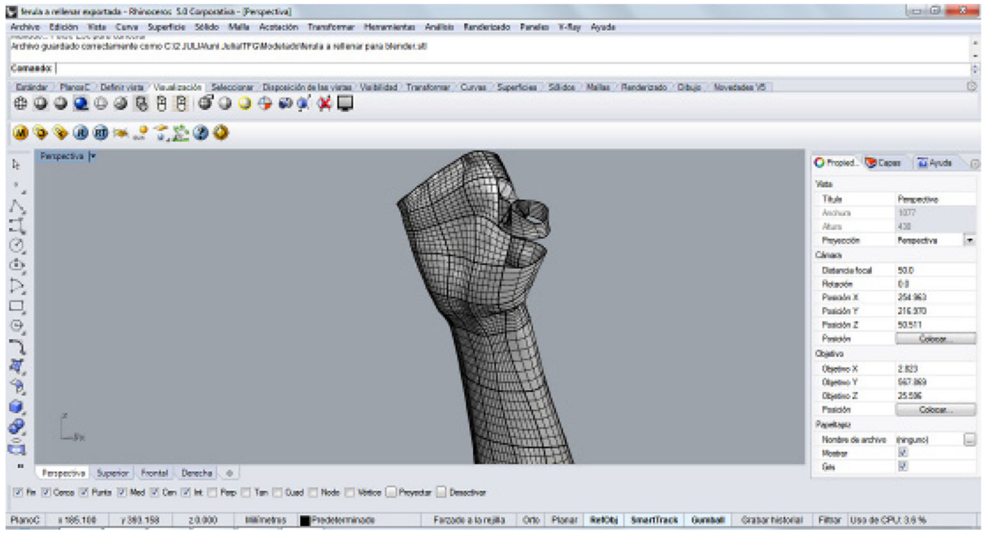


Fig. 8 Display of the splint in Rhinoceros® 5 as surfaces

In Geomagic®DesignX, a sketch of the mesh surface of the arm has been generated directly on the object by using the *3DMeshSketch* mode and by ensuring its adaptability. A grid has been made using splines. The detail is increased by creating more splines in more complex areas (Fig. 4).

Once the sketch is finished, the surface has been generated by the *Boundary fit* tool. This has allowed to insert a surface between the created splines (Fig. 5).

Once the device outer surfaces have been obtained, the forearm has been removed (Fig. 6).

The surface will appear superimposed on the mesh. Hiding the mesh, the result is shows in Fig. 7.

Once the surface has been created, it has been exported in format *.igs, to another CAD program, Rhinoceros®5, to fix the surfaces around the thumb, which is the most complex part (Fig. 8).

For that, a surface has been created from the lower and upper edge of the hole. The result is shown in Fig. 9.

Realization of 3D solid

The first step was the alignment of the splint with the reference axes of the program. Afterwards, a surface has been generated with an offset of 1 mm towards the outside to allow some slack and so that the splint is not too tight to the forearm. The surfaces are offset in the normal direction to the initial surfaces and in the direction indicated by the arrows (Fig. 10).

The result of offset surfaces is shown in Fig. 11.

Once the reference surface has been obtained, a 4 mm thick solid has been created (Fig. 12).

The next step has generated the surfaces that make up the holes of the splint, with their organic forms (Fig. 13).

Two ellipsoids have also been generated on the surface of the arm splint. It allows the possibility to create two holes in order to place the electrostimulation diodes. The curves have been extruded as solid as shown in Fig. 14.

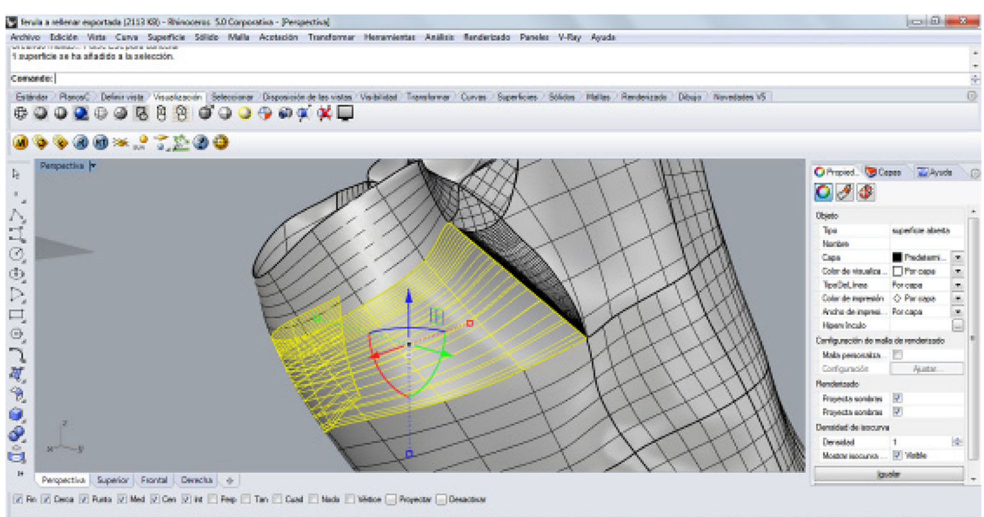


Fig. 9 Main hole with the final surface that adapts to the 4 edges

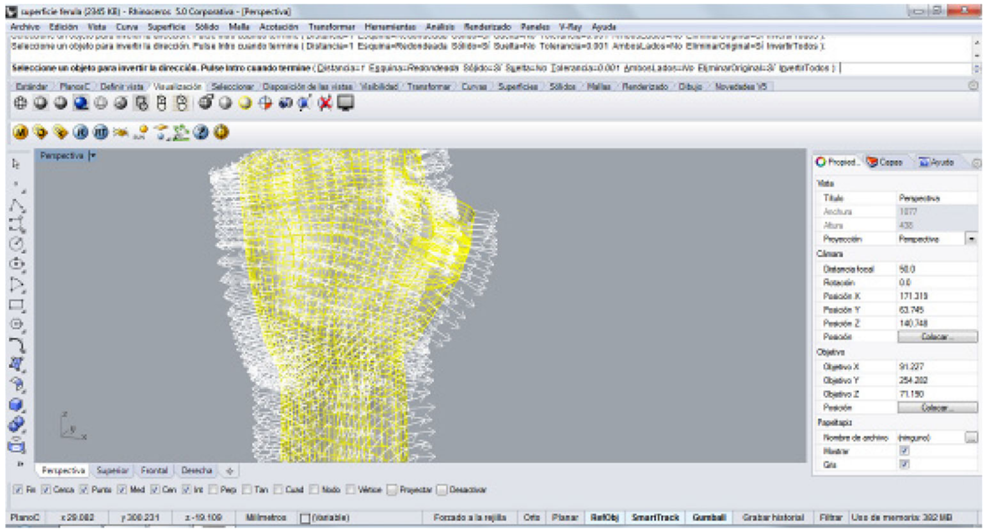


Fig. 10 Offset directions of the surface

The solid has been separated in the two pieces that will form the splint for the creation of the openings in the surface of the arm splint (Fig. 15).

Once the two parts of the arm splint have been obtained the solids for the creation of the openings can been placed. They are molded, copied and scaled on the shape of the arm as needed to complete the entire surface(Fig. 16).

Through a Boolean operation the material has been subtracted as shown in Fig. 17.

Once the openings have been obtained, the closing system has been placed. For the closure, 9 concentric solid cylinders have been made, placing them according to the inclination of the section in which they are going to be placed (Figs. 17 and 18).

Cutting planes have been generated on each button (Fig. 19) that has to be divided into two parts of the arm splint.

The result of the solid model of the created splint is shown in the Fig. 20.

Additive manufacturing

For the 3D printing of the prototype of the two parts of the splint, a Prusa3iBQ Hephestos printer has been used. The material chosen for the prototype has been PLA due to the availability of the range of colors and the similarity in the manufacturing process with the material chosen for the final realization: polycarbonate. In order to be able to make 3D printing, the printer has been prepared, a user profile has been chosen with the printing characteristics of the model and for filament PLA. The vertical printing position and the parameters such as the printing temperature and the density of the material were selected. The Cura program has been used in order to prepare the model and generate the file to print. Due to the printing volume of the printer ($215x210x180mm^3$) it has been necessary to scale the model of the prototype of the splint reducing its size of

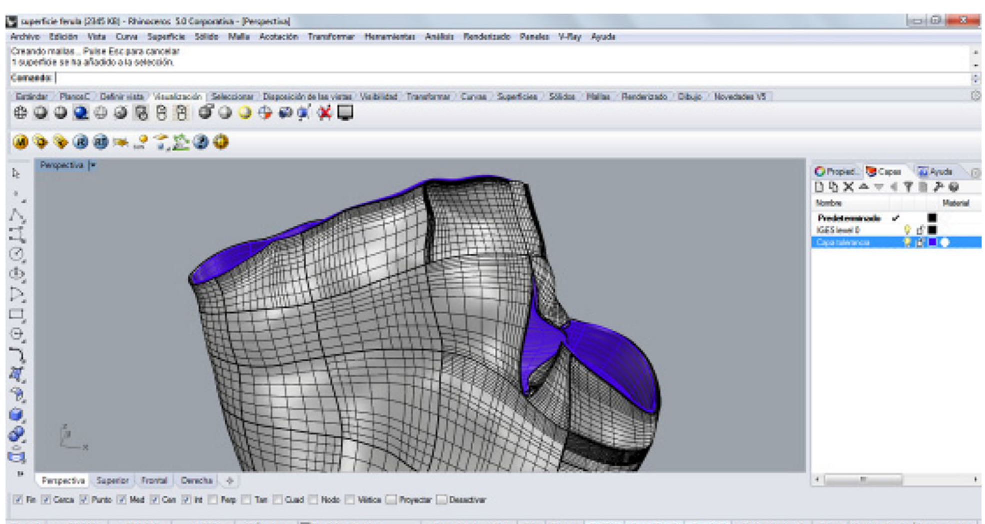
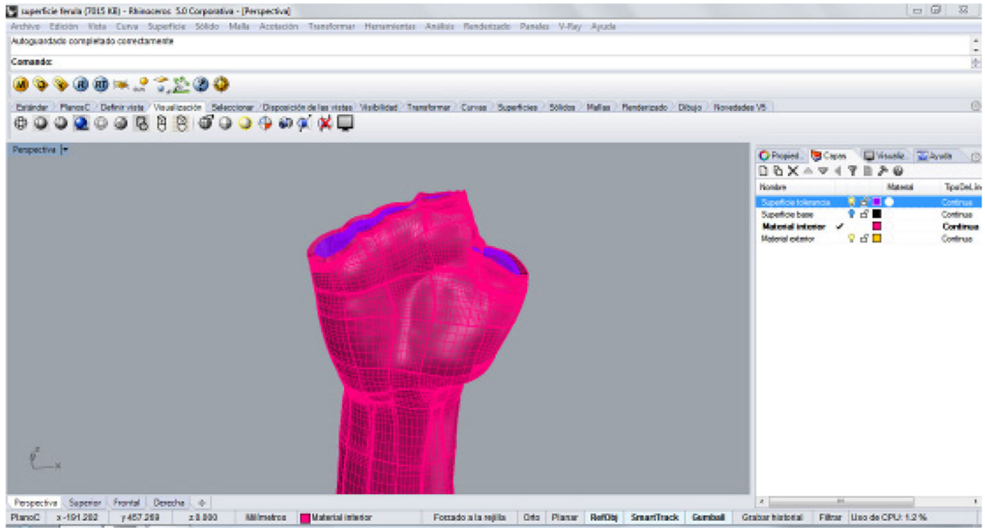


Fig. 11 Offset surface

Fig. 12 Solid surface



40% with respect to its real dimensions. The measures of width and length of the hand have been: 68,5 mm y 95,9 mm. Taking into account the thickness of the splint model (4 mm), this has also been reduced by 40%, reaching a real thickness of 2.4 mm. Once it has been verified that the splint fits in the printer, it is checked in which way it has more "overhang", which is the hanging space that will need support and that is more difficult to print (red part in Fig. 21) [20].

The characteristics of the printing profile are shown in Table 2:

In order to verify the correct adaptation of the splint to the arm, this has also been printed. Using the CAD program, Blender™ (Fig. 22), the lower part of the arm model is trimmed in order to make it flat and facilitate printing by using a *boolean difference*.

Results

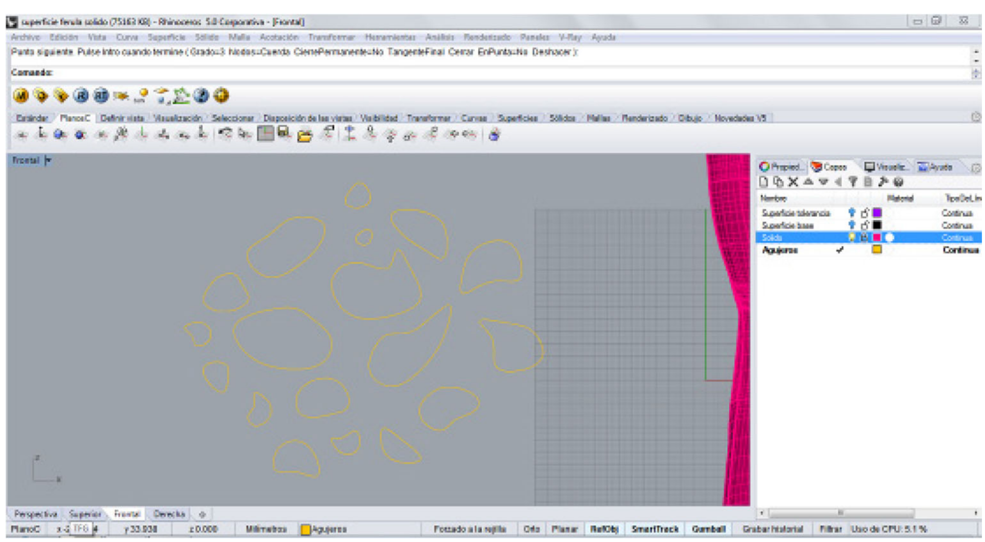
Table 3 and Fig. 23 show the results achieved for the arm splint prototype:

The prototype of the designed splint (Fig. 23) has been successfully printed for the sample of its optimal adaptation the arm (Fig. 24). Figure 25 shows the assembly of the prototype with the model of the arm printed in 3D.

Discussions

In recent years different forms of traditional immobilization of the wrist have been developed by using the AM technique, from patients like Bush [21] and Evill [22], going through new companies like Amphibian Skin [23], arriving at the drawing

Fig. 13 Curves for the holes



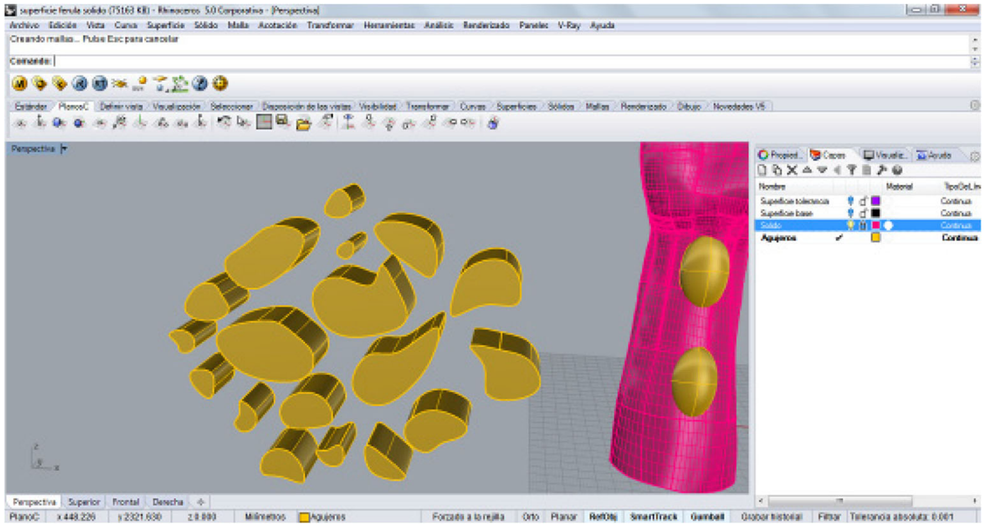


Fig. 14 Cut curves transformed into surfaces

for the research [24]. In 2013, students like Solakian, Nguyen and Buell have developed a splint prototype using the technique of Selective Laser Sintering (SLS) that requires a very high investment when using high power lasers [25]. In the same year, Jake Evil designed the first splint model 3Dprinted by using nylon and by proposing the AM technique of SLS. The drawbacks were: the expensive printing technique and the difficulty to work with nylon [22].

In 2014, Abby Paterson has developed a prototype software for printing splints in 3D by using the SLS technique. The prototype was more aesthetically attractive, comfortable and potentially cheaper than traditional splints. Osteoide [26] was the first splint, designed by Deniz Karashinen, to take into account rehabilitation by using the bone simulator system with low intensity rhythm ultrasound (LIPUS) [27, 28]. The technique used for its production was FDM. The material used was ABS, recyclable, although more expensive than others. It allows customization in both color and modeling depending on the type of injury. It has openings for rehabilitation that are also designed without neglecting the aesthetic. However, the use of ABS and the arrangement and quantity of the holes have caused it to require greater robustness and less lightness. In 2013, Exovite [29] proposed a splint model that needs 5 min for the scanning of the immobilizing part and for its own impression. The used material was biocompatible photosensitive resin that gives rise to splints of 350 g, 75% lighter. In addition, they have designed an electrostimulation system and have developed: Exopad, a mobile application that makes it possible to call the emergency service, the location of the clinic and to treat the patient, and Propad, a database for doctors, of the treatments, of the evolution and patient results in order to generate feedback. Regarding the technique used for

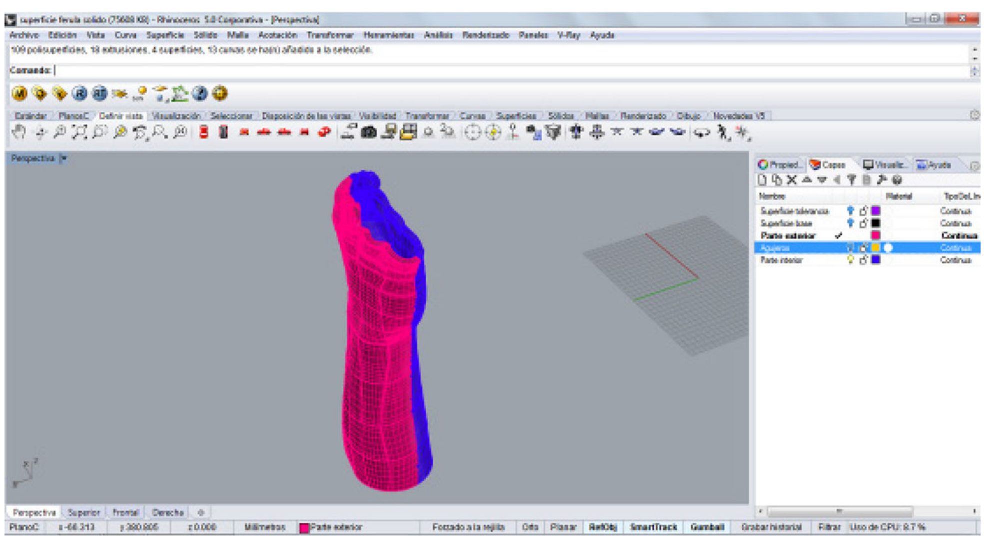


Fig. 15 The two differentiated solids

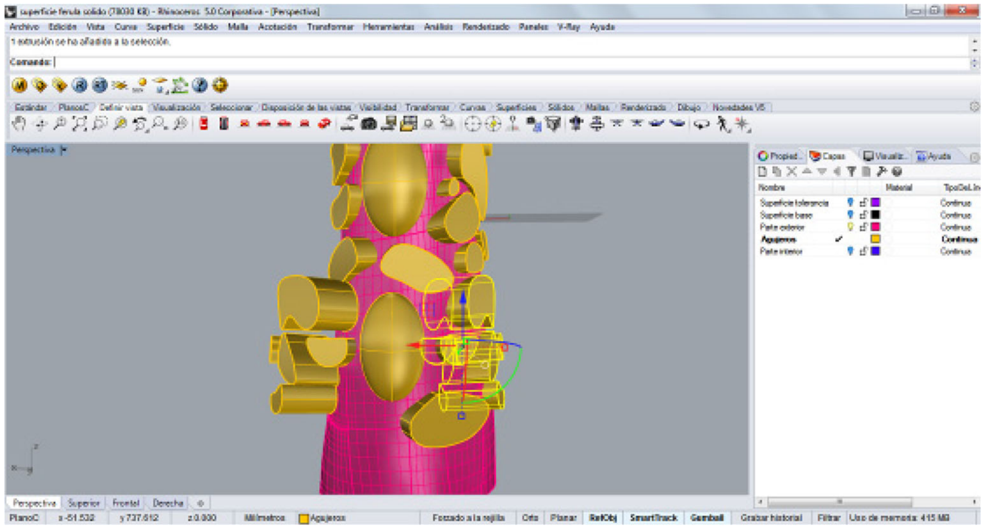


Fig. 16 Placement of the holes on one of the parts

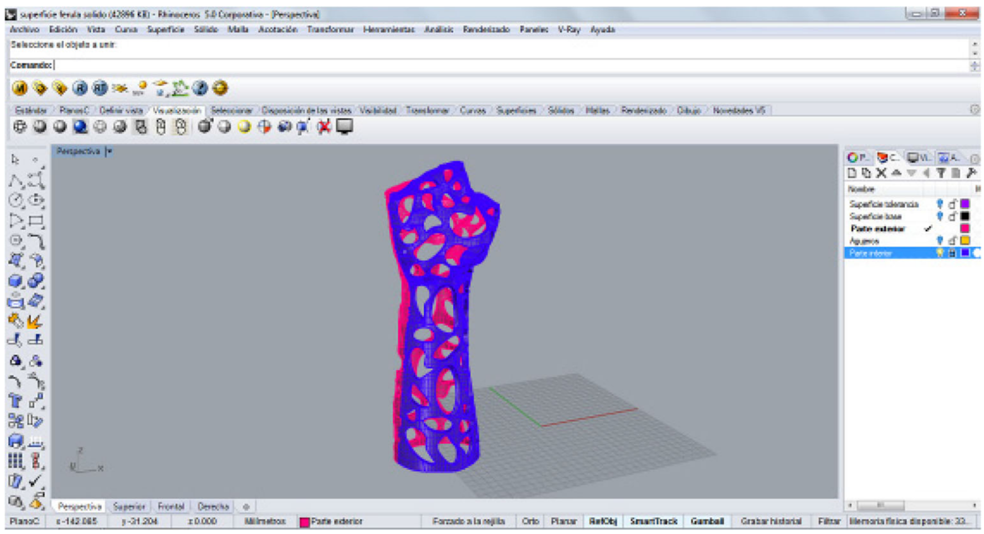


Fig. 17 Perspective of the two parts with all the holes

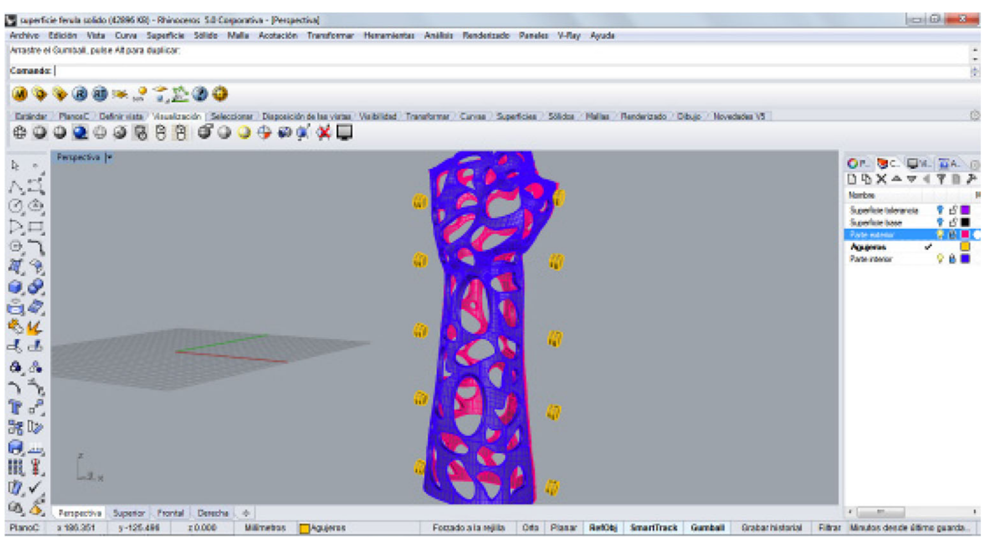


Fig. 18 All closing buttons created

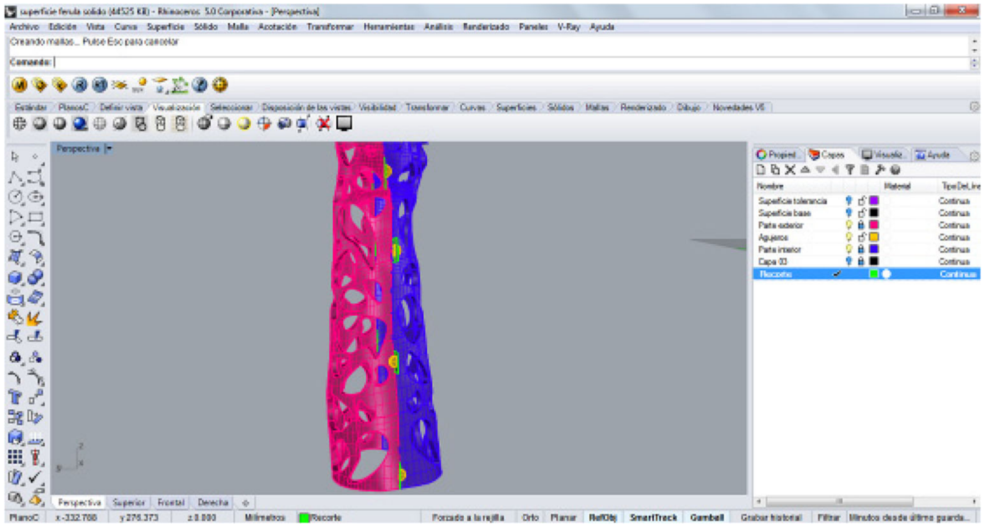


Fig. 19 Cut of the buttons

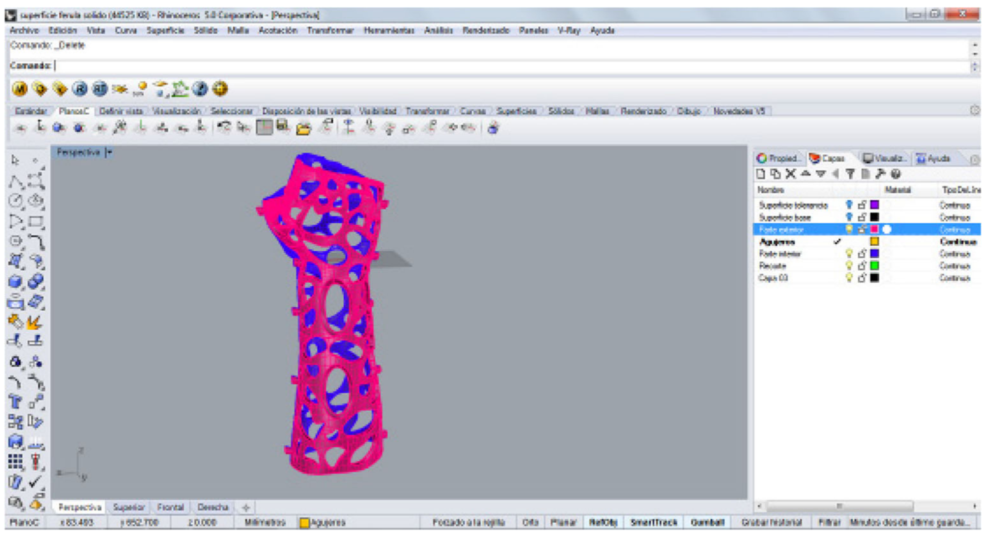


Fig. 20 Perspective of the finished splint

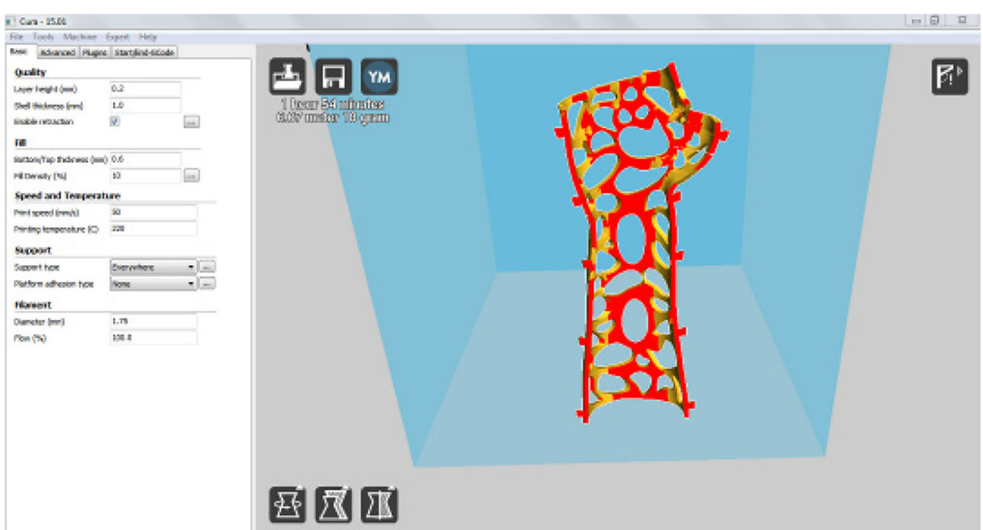


Fig. 21 “Overhang”

Table 2 Characteristics of the printing profile

Layer height [mm]	0.1
Extruder [mm]	0.4
Print density [%]	80
Thickness perimeter of closure of each layer [mm]	1.6
Thickness [mm]	2.4
Temperature [°C]	210
Print speed [mm/s]	60

manufacturing, Exovite uses FDM, SLS and Digital Light Processing (DLP). The DLP technique produces pieces of great precision. Its drawback is that it is for photopolymers, materials more fragile than other materials and that they need structures during printing and post-processing for hardening. 3DMedScan in 2014 has created the Amphibian Skin splint [10] using ABS as material for the FDM. Abby Taylor from the University of Bristol and Jonathan Rainers from Open Bionics [30] have created a 3D printed splint by using the FDM at the end of 2016. It is modeled following the Voronoi pattern and combining PLA with Ninja Flex. The solidity of the PLA was harmonized with the flexibility of the filament printed inside it. In addition, the Ninja Flex acts as a hinge allowing the patient to remove the splint easily. Paterson et al. [31] have developed a prototype splint with a hinge closure system, incorporated into the design, to facilitate the placement of the same splint. It was made by using the technique of Material Jetting, which allows to manufacture high precision parts and the production of parts by using different materials. Unfortunately, the poor long-term properties of the material have allowed only the creation of prototypes.

Table 3 Results

Material	Model	Manufacturing
Polylactic acid (PLA)	Openings Organic Shape Button closure with rubber	Fused Deposition Manufacturing (FDM)

There are still few products available, but the replacement of conventional orthopedic casts with 3D printed splints is a market that is beginning to develop [32]. It has been observed that the characteristics of the modeling and the processes are quite similar in the different models and that it is especially in the material where there is a greater diversity of solutions.

It can be concluded that the main complications to overcome are the printing times and the high initial investment. In this study, the biocompatibility and recyclability of the material have been prioritized. It is essential that the splint be biocompatible with the skin and that the material can be melted for reuse once its life cycle has finished. In this way, there is a considerable reduction in the waste generated in the biomedical sector and sustainable development is favored. The product has to facilitate the rehabilitation and rehabilitation of the patient. It has to be comfortable, reliable, effective, economical and with an attractive aesthetic, so that the benefits are mainly in the users.

Digitization by scanning allows the complete adaptation of the splint to the user, optimizes the product by personalizing it and streamlines the procedure. Thanks to the investigation of different paths to follow, the most favorable form has been reached and observed successes not found in the manufacturing process.

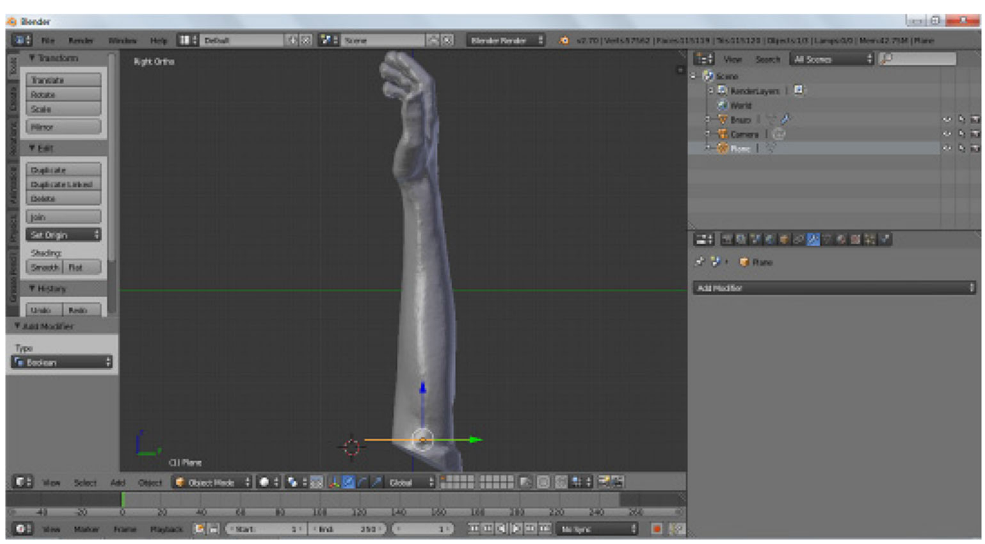


Fig. 22 Plane to trim the arm

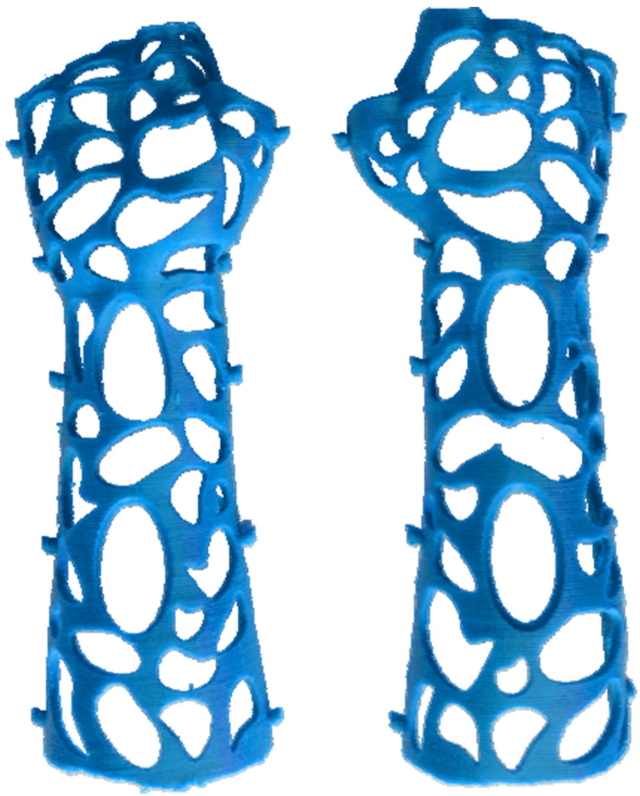


Fig. 23 PLA printed prototype

Fig. 24 PLA printed arm

Conclusions

The achievements in this work have been the study, design, prototyping and 3D printing with the technique of AM of an orthopedic arm immobilization product. This has allowed the improvement of some characteristics of traditional splints as:

- Water resistance that improves personal hygiene.
- Cost reduction due to the choice of used material.
- Recyclable product
- Lightness
- The pleasant and novel aesthetics
- An orthopedic product for immobilization that allows visual control of the skin and anticipation in the application of physiotherapeutic treatments during the immobilization period
- A biocompatible splint, that does not irritate the skin and that favors the ventilation of the skin.

The future lines that could be followed from this idea would be:

- Printing of the real splint by using Polycarbonate. A PLA prototype has been realized that serves to verify the solidity of the design and to be able to show it in a much closer and palpable way. Its good characteristics could be observed in practice by printing the splint with Polycarbonate, the material for which the splint has been created.
- Creation of a software that is responsible for carrying out the modeling process based on the design.

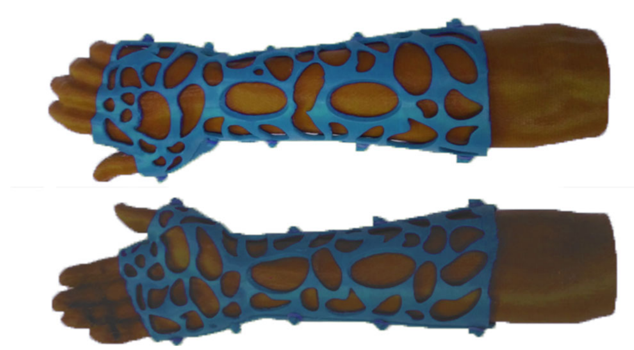


Fig. 25 Assembly of the prototype with the model of the arm

- Printing times reduction.
- Provision of 3D printers and software to hospitals.

It would also be viable the possibility of a comparison study with a traditional splint, by using patients with the same fracture and/or with the same orthopedic problem who need the immobilization of the arm in order to:

- avoid the appearance of skin-related problems by allowing visual control.
- Reduction of the immobilization time and the anticipation in the application of physiotherapeutic techniques.
- Reduction of patient's disability time and acceleration of the functional rehabilitation period.
- Contribution to the improvement of the quality of the patient life.

Compliance with Ethical Standards

Conflict of Interest Fernando Blaya declares that she has no conflict of interest. Pilar San Pedro declares that he has no conflict of interest. Julia López Silva declares that he has no conflict of interest. Roberto D'Amato declares that he has no conflict of interest. Enrique Soriano Heras declares that he has no conflict of interest. J. A. Juanes Méndez declares that he has no conflict of interest.

Ethical Approval This article does not contain any studies with human participants or animals performed by any of the authors.

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