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METHODOLOGICAL DEVELOPMENT OF PERSONALIZED ORTHOPEDIC SPLINTS THROUGH LOW-COST ADDITIVE MANUFACTURING

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1. INTRODUCTION

Orthopedic splints made of rigid material remain the most common devices to treat fractures or even severe dislocations. These elements allow immobilization of the injured area, ensuring healing, tissue recovery, or the proper correction of bone structures to progressively regain mobility. Additionally, they are useful for treating joint conditions such as arthritis, muscular injuries, paralysis, etc. [1].

The general classification of splints is divided into three main types: immobilizing splints, mobilizing splints, and restrictive splints [2,3]. The former is the most used orthopedic tool, the simplest to manufacture and place in various medical treatments, with the aim of preventing movement of the joints in the affected area or completely stabilizing the structure, depending on whether the immobilizing splint is articulated or not [4]. The other types of splints aim to achieve movement or prevent joint movement in some direction by providing joint stability [5].

The materials used for splint manufacturing vary widely, being made from polymers, metals, plaster, or fiberglass, among others. Additionally, depending on their application or the type of injury being addressed, it's possible to use prefabricated splints of different sizes or they can be custom-molded. However, the most common material for making immobilizing splints is plaster [6,7]. This type of immobilization, widely adopted due to its low cost and ease of obtaining the material, has numerous drawbacks that directly affect the patient. These include limited water resistance, minimal breathability, considerable weight, limited access to the immobilized area, difficulty in cleaning, and potential for skin damage due to friction or contact, among others [8,9].

On the other hand, additive manufacturing (AM) has opened a wide range of possibilities in the fabrication of parts and components in any field, by allowing the creation of physical models through the successive addition of layers of material from a 3D model [10]. AM is enabling the production of very complex, customized, and economically competitive geometries, issues that were previously unfeasible [11,12]. There are many examples of advancements in the medical field, such as the creation of personalized prostheses [13], biomodels for assisted surgical preparation [14], bioprinting for cell cultures, scaffolds, or tissue fabrication [15], manufacturing of surgical instruments [16], or models for training for students and professionals [17,18].

Another application of AM in the creation of personalized medical models is the manufacturing of splints. Various studies have analyzed the use of conventional plaster splints and prefabricated ones. Boutis *et al.* [19] found the same medical efficacy in both methods in a study on children aged 5-12, but with a

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significant preference for the use of the prefabricated splint due to satisfaction and comfort compared to the conventional plaster splint. Other authors, like Paterson *et al*. [20], have developed proposals for specific CAD software for the design of splints and their production using 3D printing. However, despite observing benefits in this development, significant limitations derived from the software were noted. Jianyou Li *et al*. [21], also developed a programmable modeling tool for the semi-automatic design of splint models, enabling doctors with little CAD knowledge to carry out the design process efficiently. However, the use of paid commercial software is required. Additionally, Cazon *et al*. [22] mechanically analyzed traditional prefabricated splints, like those used by Boutis *et al*. [19], with the designs obtained by the method developed by Paterson *et al.* [20]. Comparing the deformations and stresses generated showed that the splint obtained through additive manufacturing matched or even surpassed the traditional ones, thus validating additive manufacturing as a feasible method. Yan *et al.* [23] also proposed a method for obtaining splints from optimized design using finite element computational methods and additive manufacturing, maintaining maximum displacements of less than 2.5 mm, a medical immobilization requirement established by some authors.

Despite all this, most of the work carried out to date focuses on the development of splints in a partial way, without considering all the necessary aspects from a complete medical perspective, nor in an environment of low economic resources as proposed in the present work. Blaya *et al.* [24] and Sponchiado *et al.* [25], for example, analyzed the general design phase of a splint through the use of different paid software, without considering the necessary mechanical needs of the splint, and requiring advanced knowledge of use of design software. Similarly, Jianyou Li *et a*l. [26] did not analyze any type of mechanical behavior or deformation and also used commercial software. In any case, and despite the absence in many of these studies of the resistant or immobilization analysis of the splints obtained, some clinical studies have validated the suitability of printed splints in patients with real fractures, with satisfactory results [27] or the studies by Chen *et al.* [28] where in addition to validation, different high load situations were analyzed with finite element methods along with the detailed analysis of the interaction of said forces with the bones of the inside of the arm.

Therefore, the use of CAD technologies and additive manufacturing allows to produce immobilizing splints with better features than conventional ones, such as high breathability (through surface holes), material waterproofing, maximum customization, low manufacturing cost, greater patient satisfaction, possibility of visual control and access to superficial pathologies, or even the ability to place electrodes in the fracture area for personalized rehabilitation [29,30]. However, the existing methodologies for the development of these splints are mainly limited by the use of non-free commercial software and the need for high-cost scanning systems. These two factors, combined with the lack of a clear systematic methodology, significantly restrict access to splint development through AM, especially in areas with greater limitations in digital technology and financial resources.

In this study, a systematic methodology is proposed for the design and manufacturing of immobilizing orthopedic splints using free access or low-cost software and technologies, so that it is accessible even in areas or communities with limited financial resources. The process covers everything from the scanning and digitization phase of the limb to be immobilized to the realization of the splint through AM.

2. MATERIALS AND METHODS

2.1. Scanning method

The scanning application Ethan Makes 3D Scanner (EM3D, developed by Brawny Lads Software, LLC.) was chosen among various low-cost scanning options due to its reasonable scanning quality, ease of use, and low cost (€7.99 for scanning and exporting the STL model option. Price as of 2023). This application is designed for iPhone mobile devices (Apple, Inc) equipped with a TrueDepth camera (version 11 models or higher).

2.2. 3D printing material

Filament made of polylactic acid (PLA) from Smart Materials 3D was used, with a diameter of 1.75 mm. The choice of this material is justified by the many advantages it offers such as its biocompatibility, low cost, suitable hardness, impact resistance, rigidity, and torsional strength.

The actual mechanical properties of the PLA used in the manufacturing of the splints were obtained through flexural tests in accordance with the UNE-EN ISO 178:2019 standard using a LY-1065 test machine (Dongguan Liyi Test Equipment Co. Ltd., Dongguan, China). For this purpose, 5 test specimens were produced using 3D printing. They were tested with a support distance of 64 mm and a loading speed of 10 mm/min until breaking.

The average results of the elasticity modulus and stress at the elastic limit for the five PLA test specimens tested in flexure were 2,744 MPa and 83.72 MPa, respectively. These values were used as material data in the mechanical simulations. Regarding the Poisson's ratio, a value of 0.36 was set based on references from other studies [31].

2.3. Additive manufacturing method

For the additive manufacturing method, 3D printing equipment using material extrusion technology was chosen. Two low-cost printing technologies were used to reduce development times of the methodology and to carry out different necessary print tests. An Anycubic i3 Mega S (Hongkong Anycubic Technology Co., Ltd.) machine and an Atom 3D printer (Taiwan, Dayi Innovation Co., Ltd.) were utilized.

The main printing parameters used were a nozzle diameter of 0.6 mm, a layer height of 0.2 mm, a bed temperature of 60 °C, a print temperature of 210 °C, a 100% rectilinear fill and a printing speed of 50 mm/s.

2.4. General splint modelling methodology

For splint modeling, using the scanned file, the mesh processing software Autodesk Meshmixer (2017 Autodesk Inc., version 3.5) was employed. The choice of software is justified as it is free, has a quick learning curve, processes mesh operations excellently, and has all the necessary options to achieve a satisfactory result without high computational requirements. These factors support the development of a simple, effective, and economically accessible methodology.

The general splint design methodology begins with the importation of the STL file into the software after scanning the limb (Figure 1a). The area to be immobilized with the splint design is selected (Figure 1b), and an "extraction" operation of 1 mm is performed to provide a minimal clearance to the splint.

Next, the selected work area is obtained (Figure 1b, orange-colored area) as a new object within the file, along with the mesh obtained from scanning (Figure 1b, dark gray area). A partition plane is then generated using the "primitives-add plane" operation as a reference for subsequent operations (Figure 1c).

Subsequently, the surface remeshing operation "remesh" (0% density) is performed on the splint area to improve its quality and prevent future mesh errors. On this new mesh, the desired surface lightening pattern is designed (Figure 1d) according to the considerations established by this methodology, which determines areas of greater or lesser lightening, among other factors. Modeling continues with the "extrusion" operation outward from the generated surface (already lightened) to the desired thickness (Figure 1e). After adding any desired fastening elements, the splint is divided into two parts using the "plane cut" operation (options slice both and remesh fill) (Figure 1f). Finally, the mesh is converted into a

solid element (Figure 1g), and the two parts are exported as STL format files for subsequent manufacturing.

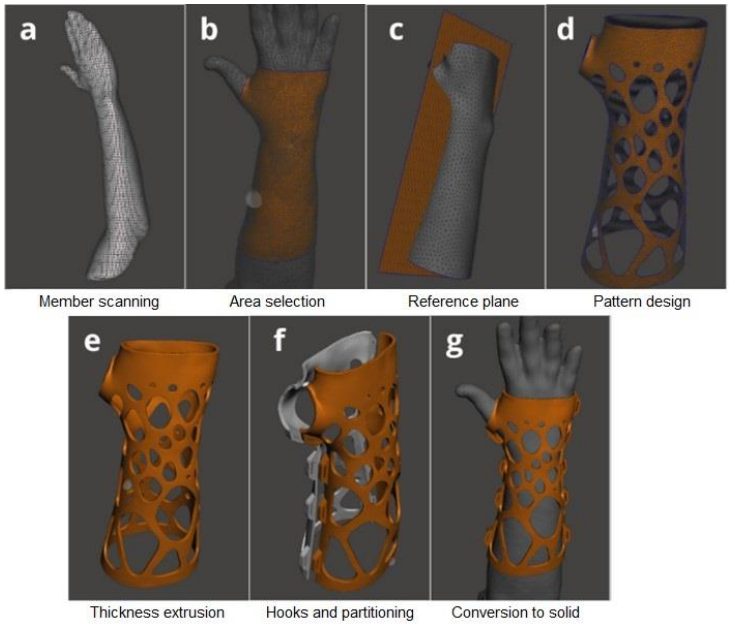

Figure 1: Splint design process in Meshmixer: a) limb scanning, b) selection of the working area, c) reference plane, d) lightening pattern, e) thickness extrusion, f) model partition, and g) solid conversion.

2.1. Mechanical analysis of the splints

In order to establish design criteria that ensure the therapeutic functionality of the splint, its mechanical behavior has been analyzed based on the two most relevant geometric variables: the overall thickness of the splint and the lightening pattern of its surfaces.

Regarding thickness, high values guarantee mechanical performance, but increase manufacturing times and costs, as well as the weight and volume of the splint. In contrast, reduced thicknesses can compromise the mechanical rigidity of the splints and, therefore, their medical functionality. To establish a general criterion for appropriate thickness, two analysis stages were carried out. In the first phase, splints of different uniform thicknesses were manufactured in PLA, with 50% interior fillings (infill) (to reduce manufacturing times and costs) and without surface lightening. The tests consisted of the actual fixation and use of the manufactured splint reproducing the different hand movements and everyday situations of its use. These preliminary tests allowed for a qualitative analysis, showing clearly deficient mechanical behavior in thicknesses less than 3 mm (breakages and deformations under light loads) and high rigidity when thicknesses exceeded 5 mm (no breakages or deformations under high loads).

In a second stage, based on the results obtained in the qualitative preliminary tests, mechanical simulations were carried out using finite element methods for splints of 3 and 5 mm using the SolidWorks 2016 software (Dassault Systèmes SolidWorks Corporation). The splints were designed with solid and uniform thicknesses throughout their geometry and without surface lightening patterns. This analysis provides the fundamental stress profile to design surface lightening patterns.

The mechanical simulations were modeled based on the main movements of the wrist joint that are desired to be restricted in a clinical immobilization case (Figure 2). Radial deviation corresponds to wrist movement towards the thumb, while ulnar/cubital deviation moves in the opposite direction, from the wrist towards the pinky finger. The other two main movements correspond to flexion and extension, where the wrist rotates inward and outward of the forearm, respectively. Performing these movements can generate different types and ranges of force that, in any case, must be restricted by immobilizing splints. Table 1 collects the force values generated in each movement obtained as average force values calculated in the studies by Cazon *et al.* [22] and Yan *et al.* [23].

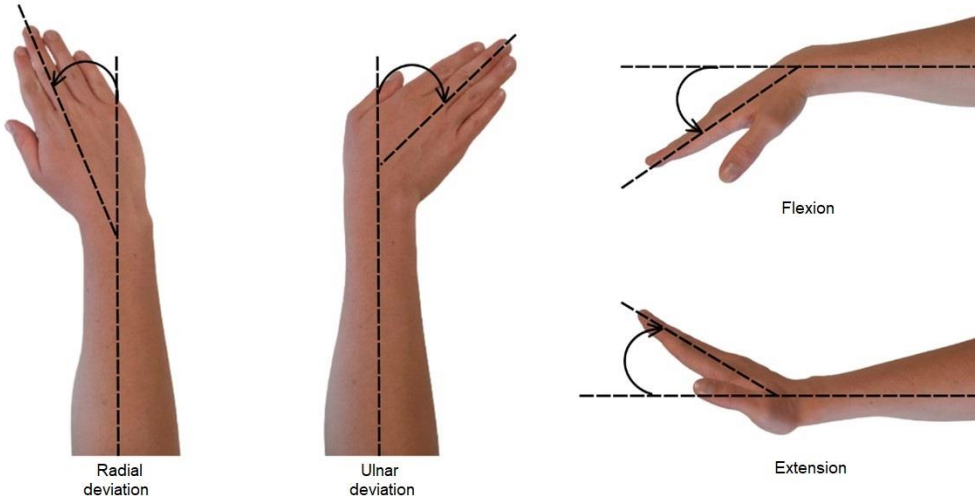

Figure 2: Main movements of the wrist joint.

Table 1: Forces exerted according to the wrist joint movement.

Movement	Force (N)
Radial deviation	62.36
Ulnar/Cubital deviation	48.54
Flexion	73.75
Extension	38.08

To model the surfaces on which the forces are applied, real immobilization tests were carried out with the preliminary splints manufactured, and the contact points between the different parts of the wrist and forearm with the splint were determined. Figure 3 shows the location of the loads (arrows in violet), according to Table 1, and the support zones where movement has been restricted due to the presence of the splint (arrows in green).

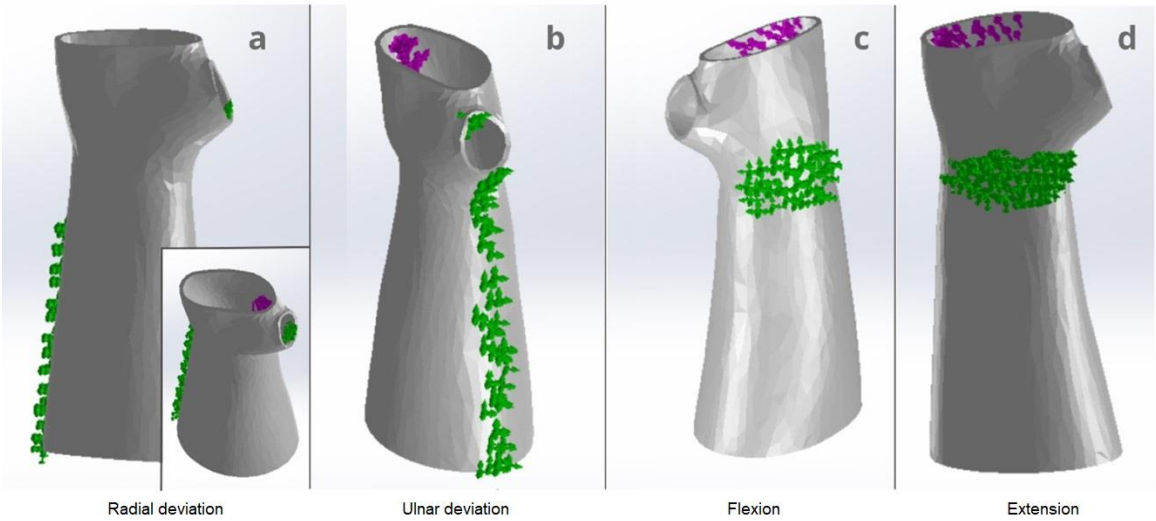

Figure 3: Conditions of the loads (arrows in violet) and constraints (arrows in green) established in the mechanical simulations for each basic movement.

Based on the distribution of stresses on the splint, areas susceptible to lightening were identified. In this way, it is possible to establish lightening criteria considering the areas with the highest stresses, where lightening is not considered because they require the greatest possible rigidity, as well as the areas of minimum stress, with minimal contribution to the mechanical rigidity. The lightened designs resulting from

the established methodology were again evaluated mechanically through simulations with the same conditions set in the first stage.

2. RESULTS AND DISCUSSIONS

2.1. Stress and displacement analysis in preliminary splint without lightening

Table 2 displays the Von Mises stresses, unit deformations, and maximum displacements obtained in the simulations of the splints for each main wrist movement and for the cases of solid splint without surface lightening pattern of 3 mm and 5 mm thickness.

Table 2: Results of the mechanical analysis of a solid splint without surface lightening.

	3 mm thickness			5 mm thickness		
Movement	**Maximum stress (MPa)**	**Maximum unit deformation**	**Maximum displacement (mm)**	**Maximum stress (MPa)**	**Maximum unit deformation**	**Maximum displacement (mm)**
Radial deviation	6.81	0.002	0.31	4.59	0.001	0.10
Ulnar/Cubital deviation	4.39	0.001	0.28	1.06	~ 0.000	0.05
Flexion	11.66	0.004	1.07	4.54	0.010	0.31
Extension	2.93	0.001	0.41	1.44	~ 0.000	0.12

The obtained results show Von Mises stresses much lower than the elastic limit tension of the material (83 MPa) in both thicknesses and for all the main wrist movement hypotheses. Hence, the 3 mm thick model has sufficient rigidity to withstand the stresses the splint will be subjected to under typical usage conditions. Likewise, it's observed that the unit deformations and displacements (Figure 4) at the most unfavorable points are very reduced, with displacements practically less than 1 mm in all cases, which is entirely compatible with medical immobilization requirements [23]. On the other hand, it's noteworthy that the highest stresses and displacements are produced by the flexion movement due to the application of greater force and the lower rigidity provided by the geometry of the splint in that direction. As expected, the results obtained in the 5 mm thick splint design are more favorable although in both cases the rigidity of the ferrule far exceeds the forces applied under normal conditions of use.

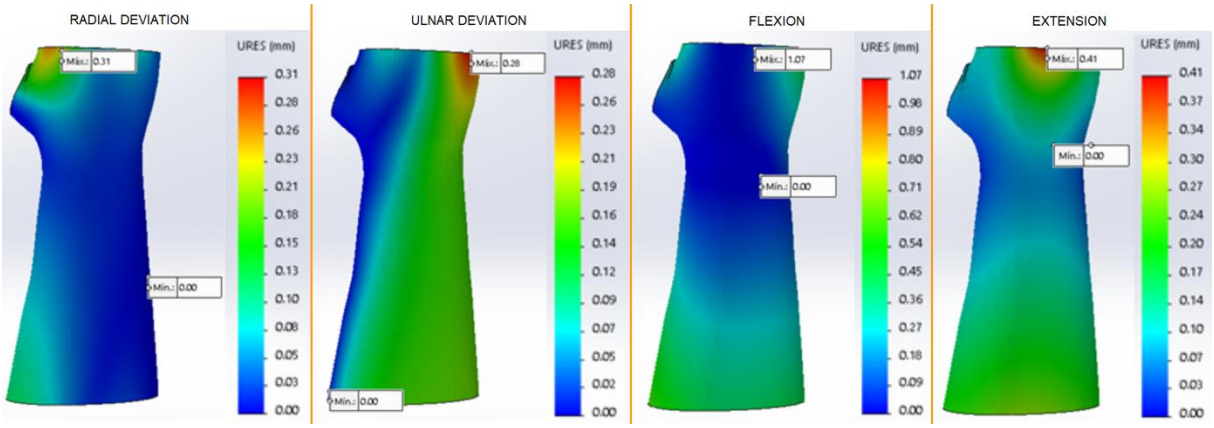

Figure 4: Displacements of the non-lightened splint with a thickness of 3 mm for each wrist movement.

Regarding displacements, the results show a high rigidity of the solid splint of 3 mm, producing negligible unit deformations, which cause maximum displacements fully compatible with the immobilization process. These deformations, as expected, correlate with areas of maximum tension.

2.2. Lightening patterns

For the development of lightening patterns, the areas of the lower peripheral ring of the splint, upper peripheral ring, and the peripheral support ring of the thumb were excluded as the greatest possible rigidity was required. On the other hand, areas with minimal stresses and deformations are established as areas for maximum lightening, which contribute to enhancing the advantages introduced using additive manufacturing. These advantages include the creation of patterns that provide breathability, accessibility, or weight reduction, among others. These areas mainly correspond to the inner forearm and the posterior forearm areas. Finally, there are intermediate areas where low stresses are found in one or several of the wrist movements, in the palm and back of the hand areas. Therefore, within the framework of this design methodology, recommendations for the size and areas of the lightening pattern are established (Table 3), based on the diameter that can be circumscribed in each lightening hole.

Table 3: General design criterion for the lightened splint.

Splint area	Lightening	Geometry type	Design recommendation
Upper peripheral ring	No	Solid perimeter	> 20 mm height
Palm area	Yes	Lightened pattern	Ø circumscribed < 15 mm
Dorsal area	Yes	Lightened pattern	Ø circumscribed < 10 mm
Thumb ring	No	Solid perimeter	10 y 15 mm height
Inner forearm	Yes	Lightened pattern	Ø circumscribed < 35 mm
Posterior forearm	Yes	Lightened pattern	Ø circumscribed < 40 mm
Lower peripheral ring	No	Solid perimeter	> 15 mm height

2.2. Stress and displacement analysis in the lightened model

The verification of the splint's lightening design is carried out using finite element analysis with a lightened splint model according to the conditions established in the previous section, with a global solid thickness of 3 mm and under the same conditions as those set out in section 2.5.

The results of the maximum tensions achieved (Figure 5) show how the established methodology allows obtaining a functional splint, where the highest tensions continue to occur in the flexion movement, still with values below 50% of the PLA's elastic limit (implying a high safety factor against breakage). The other movements produce minimal tensions, of 6.42, 4.02, and 19.43 MPa for radial deviation, ulnar/cubital deviation, and extension, respectively.

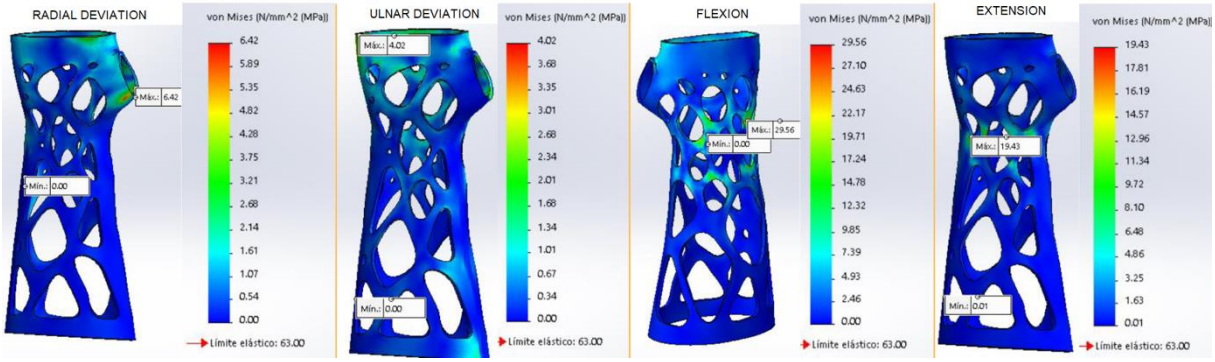

Figure 5: Von Mises stresses in the lightened splint with a 3 mm thickness for each wrist movement.

Regarding displacements, the highest values are observed in flexion and extension movements (direction of least stiffness), with a maximum displacement value of 3.15 mm in the lower peripheral ring and values close to 3 mm in the upper peripheral ring. The other movements (radial and ulnar) continue to have displacement values that do not compromise wrist immobilization (less than 2.5 mm). However, it is important to note that the displacements in the area of immobilization (wrist of the hand) values are much lower than 2.5 mm.

2.3. Qualitative results of fabrication of lightened splint

Splints with different lightening patterns, printed in both vertical and horizontal configurations, were obtained with satisfactory rigidity in all cases, observing minimal displacements and a great immobilization capacity for all wrist movements (figure 6). The splints designed using the methodology described here allow for the omission of supports during manufacturing when oriented vertically (even in thumb ring areas). In addition to saving material, manufacturing time (print times varied between 8 and 14 hours depending on model and orientation), and post-processing of the piece, this produces an adequate surface finish on the inner side of the splint (parts in contact with the limb). Splints manufactured in a horizontal alignment also yield satisfactory results, although they produce supports that need post-processing.

Figure 6: Example of splint parts' fixation system.

3. CONCLUSIONS

This study presents a methodology for designing and manufacturing low-cost splints (economical materials and technologies) using freely accessible software and accessible scanning and manufacturing technologies for any environment or geographical area, even in low-resource areas.

With the case study analyzed using this methodology, corresponding to the immobilization of a human wrist, it can be concluded that a 3 mm thick splint, made of PLA with 100% infill, allows a fully functional immobilization for the usual wrist movements. This splint provides satisfactory mechanical stiffness, deformations compatible with the required immobilization, and a broad lightening pattern. All these factors potentially enhance the medical use experience by having less weight, greater breathability, accessibility to the inside of the immobilization, sanitation, among many other advantages, compared to conventional plaster immobilizing splints.

It is worth noting that this methodology recommends the design and generation of splints according to the criteria established in sections 2.4 and 3.2 for manufacturing, preferably in a vertical configuration. Each designer must incorporate a system for joining and fixing the parts of the splint as they see fit.

On the other hand, it is essential to note that obtaining splints through additive manufacturing requires significantly longer times than manufacturing traditional plaster splints. Therefore, its use would not be justified for minor or short-duration immobilizations. Thus, its use should be oriented to special uses, long-duration immobilizations, or after scheduled surgical interventions where there is sufficient foresight for its generation.

Regarding dimensional tolerances, complementary studies are needed to determine more accurately the dimensional quality of the digital models obtained in the scanning system. These dimensional studies can be extended to manufactured parts and the most suitable dimensional adjustments depending on the type of immobilization required.

Finally, the proposed methodology can be applied to the immobilization of other body limbs by analyzing the immobilization loads that are required or obtaining similar medical devices where additive manufacturing can offer improvements over conventional technologies.

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SUPPLEMENTARY MATERIAL

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