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Entre
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e
INGENIERIA
3

Armando Dias Duarte
(Organizador)

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Entre

CIENCIA e INGENIERIA

3

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A coleção de trabalhos intitulada “*Entre Ciencia e Ingenieria 3*” é uma obra que tem como foco principal a discussão científica por intermédio de diversos trabalhos que compõem seus capítulos. O volume abordará de forma categorizada e interdisciplinar, pesquisas cujos resultados possam auxiliar na tomada de decisão, tanto no campo acadêmico, quanto no profissional.

Nos capítulos apresentados, são encontrados estudos de grande valia nas áreas da simulação computacional, materias, gestão energética, aspectos industriais, estudos ambientais, na área da educação e otimização.

A composição dos temas buscou a proposta de fundamentar o conhecimento de acadêmicos (as), mestres (as) e todos (as) aqueles (as) que de alguma forma se interessam pela área da Engenharia, através de temáticas atuais com resoluções inovadoras, descritas nos capítulos da coleção. Sendo assim, a divulgação científica é apresentada com grande importância para o desenvolvimento de toda uma nação, portanto, fica evidenciada a responsabilidade de transmissão dos saberes através de plataformas consolidadas e confiáveis, como a Atena Editora, capaz de oferecer uma maior segurança para os novos pesquisadores e os que já atuam nas diferentes áreas de pesquisa, exporem e divulgarem seus resultados.

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DESIGN, MANUFACTURE AND VALIDATION OF CUSTOMIZED SURGICAL GUIDES FOR TOTAL KNEE REPLACEMENT

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ABSTRACT: This project focuses on the development of customized cutting guides for arthroplasty. Surgical guides are designed and manufactured using AM (Additive Manufacturing) technologies to establish the characteristics of the tibial cut and femoral cut for replacement by a surgical prosthesis. The design process of the guides is detailed, which starts with the reconstruction of the patient's anatomy by a CT (Computed Tomography) scan and is subsequently used for the decision of measures

and angulations of the guides, using specific 3D design software. Subsequently, the realization of the personalized surgical planning and the choice of the specific material and method for the surgical guides are explained. Finally, the guides and the knee reconstruction model are 3D printed.

1 | INTRODUCTION

Orthopedic surgery is a branch of medicine that specializes in the locomotor system; bones, muscles, ligaments, etc. Within this branch is prosthetic surgery; the key surgery that is used for the replacement of a joint when the repair of this by other means is impossible. Arthroplasty is the name of the surgery for the replacement of a joint. The most frequently replaced joint is the knee joint; currently, the number of arthroplasties performed annually is around 65,000 interventions in Spain, according to data collected by the Organization for Economic Cooperation and Development [1]. The conventional surgical procedure for knee arthroplasty consists of replacing the joint with a knee prosthesis by making cuts in the bones of the joint [2]. With the aid of standard instruments, three cuts are made in the femur and one in the tibia where the prosthesis will later be placed. Some of these surgeries present certain difficulties such as the rare anatomy of the patient or vision problems of the doctor, among others. The difficulty of these surgeries can result in more time in the operating room or

greater risk for the patient, so the best option would be to avoid these cases.

Manufacturing surgical guides can be an option in order to deal with the typical problems of an operation. These guides ease the surgeon so as to work more freely. In this way, the likelihood of suffering a setback is reduced.

Then, regarding the manufacture of prostheses, the most common method used so far is using certain specific sizes that surgeons have available for the operation. However, even though these prostheses have impacted in a great manner in patients' lives by improving their quality life, individually-customised 3D-printed prostheses are the future. This is a fact since the personalization in medicine is a reality. Using AM technologies can lead to the development of surgical guides, among other 3D printed parts, since they used the information acquired from medical images, known as DICOM (Digital Imaging Communication on Medicine). According to ISO/ASTM 52900 Standard [3], there are seven categories: binder jetting, direct energy deposition, material extrusion, material jetting, powder bed fusion, sheet lamination and vat photopolimerisation. Amongst these options, each one has its own advantages and disadvantages as well as a range of materials able to be used.

Manufacturing surgical guides has already been studied in different areas of the medical field. For example, Beom et al. [4] 3D-printed surgical guides using the material jetting technology for breast cancer patients who received neoadjuvant chemotherapy. Also, Wang et al. [5] 3D printed surgical guides in resection and reconstruction of malignant bone tumour around the knee joint. The efficacy of the surgical guides was compared with surgeries carried out without any surgical guide. All in all, results showed that there was no significant difference in the operation time between the two groups ($p>0.05$). Nevertheless, the blood loss, resection length and complication rate were found significantly lower in the group with surgical guides than in the group without surgical guides. This shows the efficacy of the use of surgical guides.

Given the above, the present work studies the customization of arthroplasty surgery for a 77-year-old male patient in need of this intervention. The design and manufacture of personalized surgical guides using 3D printing technologies that fit perfectly to the patient's bone and that, together with standard instruments, indicate to the medical team where to make the cuts that have been previously studied digitally, is carried out.

2 | MATERIALS AND METHODS

2.1 Software

The following software has been used for the complete realization of the work. Materialise Mimics is a software created for medical image data processing in the area of engineering and research. It has been used to segment the patient's anatomy from the images obtained by a CT scan and to create a 3D biomodel of the knee joint. Unigraphics

NX software, an advanced high-end CAD/CAM program, was used for the creation of references and the subsequent design of customized surgical guides.

CES Edupak, software that allows the study of existing materials and manufacturing processes has been used to determine the material and manufacturing method used according to the specified requirements. Finally, the Magics program prepared the biomodel and surgical guides for immediate fabrication.

2.2 Design and manufacture process

The process of creating customized arthroplasty guides begins with the physician's communication about the need to operate on a patient and ends with the use of the customized surgical guides in surgery (Figure 1).

After the need to operate on the patient, medical images of the anatomy of the knee, ankle, and hip are collected; this process is performed employing a CT scan. These images are processed and segmented for the creation of a 3D biomodel of the knee, ankle and hip, Materialize Mimics software reads DICOM files obtained from the TAC and identifies all the layers of the in three planes different, the axial plane, the sagittal plane and the coronal plane. In these three planes. You can see layer by layer the anatomy of the patient's joint, where it is can distinguish bone from soft tissue by the level of absorption of the radiation. Once at this point, you have to select the area in which you are interested, to create a 3D of this. For the 3D to be correct, only the areas of interest of each layer and plane. In this case, it is intended to recreate the joint of the knee, so the areas that correspond to the bones have to be selected participants of this joint, which tend towards the target since the bone absorbs a large amount of radiation. (Figure 1a)

The next step is the generation of the axes and cutting planes (where the cut will be made in the intervention) that serve as a reference to create the customized guides with the correct size and shape. As it has been possible to assume to obtain these axes, it is necessary both the tibiofibular joint and the femorocoxal joint. For this, it could be done a CT scan of the whole leg, but in order to avoid excessive and unnecessary radiation, a CT scan is obtained only of the knee joint (as seen in the obtaining the biomodel), the ankle joint and the hip joint. As already mentioned in the section corresponding to obtaining the TAC, with all three joints is enough. Next, the process explained above is repeated to obtain of the biomodel of the knee joint with the other two CTs. The areas of interest correspond to the proximal femur and the distal tibia. With these three biomodels (Figure 1b), the creation of the axes is carried out in which the mechanical axes of the bones are taken as a reference. The mechanical axis of the femur bone corresponds to the straight line drawn from the centre of the femoral head to the intercondylar fossa. For the tibia axes, a line is drawn from the midpoint of the tibial spine to the centre of the tibioperoneoneotragal joint (Figure 1c). The guides are then created in 3D and manufacture (Figure 1d and e).

Finally, the material and manufacturing method are studied and determined, and

finally prepared for printing.

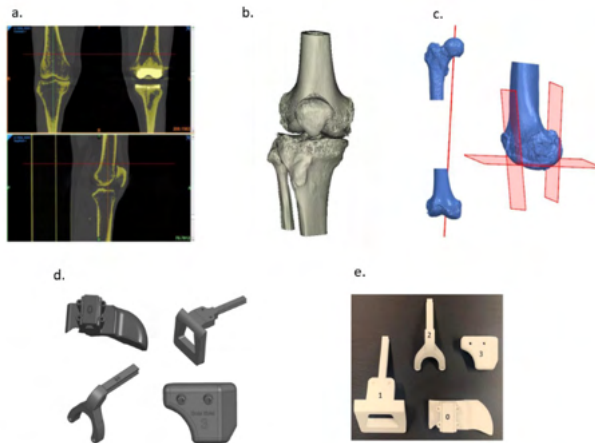


Figure 1. a. CT images processing. b. Creation of biomodels. C. Generation of axes and cutting planes. d. Design of customized surgical guides. e. Manufactured customized surgical guides.

2.3 Design of surgical guides

The customization procedure developed includes the design of four guides called guide 0, guide 1, guide 2 and guide 3.

Guide 0 (Figure 2a) is placed in the anterior cortex of the bone and is perfectly coupled to the bone. It has a rail recess and 4 fixation holes. Guide 1 (Figure 2b) has a rail with the same shape as the hole of guide 0 through which guide 1 is introduced during the operation until it collides with the medial condyle of the femur. It also has some holes that will be used by conventional instruments to perform the femoral cut. Guide 2 (Figure 1c) has a similar shape to guide 1 since it also has a rail that is introduced through guide 0, until it rests on the femoral cut already made and to be able to make the two remaining femoral cuts. Guide 3 (Figure 2d), is perfectly coupled to the tibia and has two holes that will be used to perform the tibial cut using the corresponding instruments.

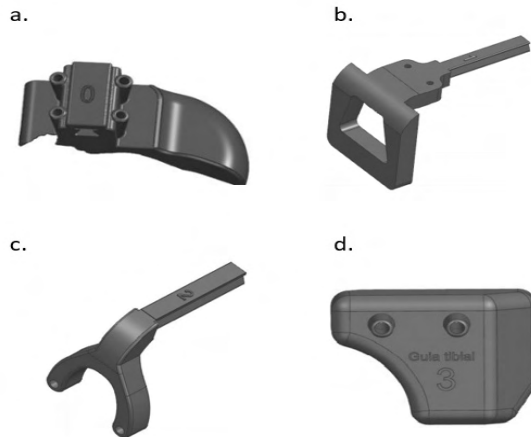


Figure 2. Surgical guides. a. Guide 0. b. Guide 1. c. Guide 2. d. Guide 3.

2.4 Material and manufacture method

Given the complexity and geometric difficulty of the product, the material and manufacturing method must meet certain requirements. The material must be (1) biocompatible, (2) non-toxic, (3) fracture-resistant and (4) sterilizable. The fabrication method must be (1) valid for creating complex 3D geometries and (2) economically cost-effective for the production of customized products.

The study of these requirements and the materials and fabrication methods has been carried out with the CES Edupak software and database, filtering the data bases of materials and manufacturing methods by the given characteristics and requirements.

The study resulted in the use of Polyamide (PA) 12 as the material and selective laser sintering technology (SLS) as the fabrication method.

3 | RESULTS

3.1 Biomodel

Figure 3 shows the result of the fabrication of the knee biomodel. This biomodel serves as the starting point for preparing the surgery, obtaining the exact anatomy of the patient before the incision on the leg, to know on beforehand what the doctors are going to find. It is important to highlight that the use of 3D models started many years, but most of the 3D printed biomodels (those with soft tissues) have been manufactured used material jetting technologies.



Figure 3. 3D knee biomodel.

3.2 Customized surgical guides

Figure 4 shows the result of the manufacturing of the customized surgical guides. The surgical guides help the surgeon to accomplish the surgery in a great manner and improve the outcome of the surgery.



Figure 4. Customized surgical guides.

3.3 Customized procedure

The customization of the guidewires results in avoiding some steps of conventional surgery and avoiding risks.

During the operation, after the approach and exposure of the joint bones, guide 0 is placed on the anterior femoral area and fixed with the pins corresponding to this guide (Figure 5a). Guide 1 is then introduced through the hole in guide 0 until guide 1 is resting against the medial condyle (Figure 5b). Holes are drilled in the holes provided in guide 1. After this step, the rail of guide 1 is broken with the aid of a chisel and the pieces are removed. The next step is to make the distal cut. For this, the distal cutting guide, a commercial guide of the corresponding brand that has been studied, is inserted into the holes made with the help of guide 1. Once fixed, the cut is made with a saw, as in conventional surgery, except that the placement of the guide has already been studied. The femur now has the distal cut. The guide rail 2 is then inserted through the corresponding hole in guide 0 (Figure 5c). Guide 2 is placed on the distal section, and holes are drilled again in the areas indicated for this purpose. Next, the 4:1 cutting guide, also a commercial guide, is placed and the anterior cut and the posterior cut are made based on the location of the holes provided by guide 2. Finally, the tibial cut is performed. To do this, guide 3 is first placed on the tibia (Figure 5d), and following the same steps as for guides 1 and 2, holes are drilled in the prepared locations. Finally, the commercial tibial cutting guide is placed in these holes and the bone is cut with a saw.

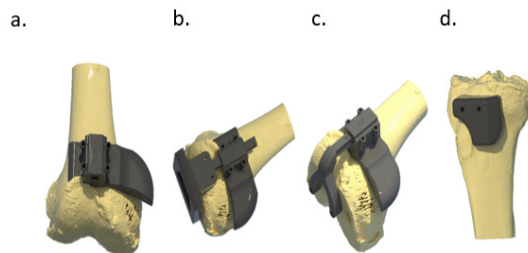


Figure 5. Placement of the surgical guides. a. Placement of guide 0. b. Placement of guide 1. c. Placement of guide 2. d. Placement of guide 3.

The final result after the digital cuts is shown in Figure 6.

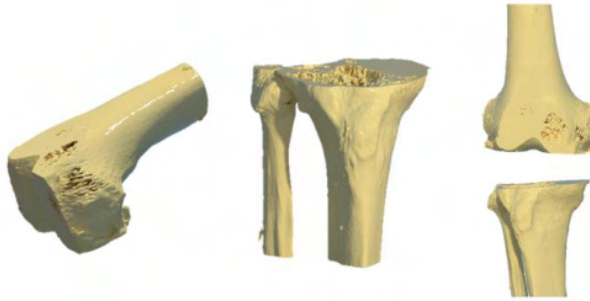


Figure 6. The result after cutting the bones.

3.4 Validation

Within MIZAR HEALTH SL, a post-validation of the 3D printed parts is done in which several aspects are taken into consideration, mainly by the doctor. Most of the important points are covered with the design carried out within the scope of the present work.

It is true that a clinical investigation in which many and varied opinions about the design and manufacture of the guides would be the correct way to confirm the validity of the surgical guidelines. In this way, the procedure and product would be approved by the medical sector apart from the regulatory agencies for medical devices. However, this research does not validate the entire product, but offers factors whereby it can be improved, as it is a product still under development, so that after several tests and improvements it could become a marketed product

4 | CONCLUSIONS

The advantages of using this personalized procedure are many, especially when it comes to people's health. With this procedure, alignments and measurements during the operation are avoided, since they are done digitally, which reduces bleeding, minimizes the possibility of error and the operative time; which translates into less risk for the person being operated on. This method also makes it possible to perform these surgeries in patients with anatomical problems or diseases; and allows anticipating the outcome of possible complications to find a solution before they arise, as well as the final result of the surgery.

In terms of design, several details remain to be specified that gain importance in the field of health, where achieving perfect accuracy is paramount. It should also be kept in mind that many of the design aspects are quite subjective and bone-dependent.

In summary, given the advantages, it is clear that it is a procedure that would offer solutions to the most complicated cases and would improve the field of health. It therefore why a very precise procedure must be created and adapted to each patient for the

development of this product.

For this reason a full clinical investigation has to be the next step to follow, in order to complete the validation of the product, making it totally useful and marketable following the European Regulation for this kind of product.

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