UNIVERSITY OF MEDICINE AND PHARMACY BUCHAREST
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DISCIPLINE OF ORTHOPEDICS AND TRAUMATOLOGY

ACETABULARY DEFECT MANAGEMENT THROUGH THREE-DIMENSIONAL PRINTING AND RECONSTRUCTION WITH A CUSTOMIZABLE IMPLANT

PHD THESIS SUMMARY

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CONTENT

In the last two decades, access to hip prostheses has been much easier financially and in terms of existing numbers, which is why many surgeries have been performed on patients requiring hip arthroplasty for various reasons (primary or secondary degenerative). Thus, we expect the number of hip revisions to increase in the coming years, which forces us to find new ways to resolve the defects that occur as accurately as possible.

The main observation from which this paper started is the difficulty of revising the acetabular component of the hip prostheses, especially in the conditions of a deficient pre-operative planning. In this regard, the main objective of the study is to obtain a high-performance imaging method for the management of acetabular defects in hip revision cases, by using 3D reconstruction and 3D printing based on CT images of the pelvis, and by designing a milling guide and implantation of the customized cup with an "ideal" position, design of the customized defect at the level of the cup and design of an external guide for milling and positioning augment with commercial trabecular metal type implant. The purpose of obtaining this high-performance imaging method is to allow the surgeon to make an accurate diagnosis of the acetabular defect and to make the best treatment decisions for its surgical resolution.

Difficulties with acetabular bone deficiency are among the most important challenges encountered in hip surgery. Acetabular reconstruction in total hip revision arthroplasty can be successfully achieved by using hemispherical components with a porous surface and several screws for minor acetabular defects. The choice of acetabular components is largely based on the size of the bone defect present. In the presence of combined cavitary and segmental defects, reconstruction using an acetabular allograft protected by a cage is the preferred option among surgical options. However, many complications of this intervention have been described, including weakening of the acetabular component, infection, dislocation and implant wear.

3D printing is used in the medical industry for multiple purposes, from making prototypes for teaching purposes to studying and practicing various complicated surgeries, to producing certain medical instruments. [1] [2] The process of 3D printing has been studied for a long time, and it is based on obtaining three-dimensional objects of digital models by depositing layer by layer a very small amount of material, there are several technological methods used today. [3] [4] Among the most important branches using 3D technology are the medical and dental industries, along with the industrial, electronic and automotive industries. Numerous data from the current literature support the idea that 3D printing in the medical industry is constantly growing and emphasizes that multidimensional printing offers many advantages over conventional methods, facilitating the production of complex surfaces and geometric shapes that can be individualized to the patient in our case.

Table 1. Materials used in 3D printing for medical devices

material	*features*
ABS-M30, ABSplus	versatile, durable
ABS-ESD 7	resistance to electrostatic discharge
ABS- ABS-ESD M30i	biocompatible
ABSi	translucent
ASA	UV stable
PC	resistant (to tension)
PC-ABS	impact resistant
PC-ISO	biocompatible
resin ULTEM 9085	flexible
resin ULTEM 1010	biocompatible, high temperature resistant
PPSF	heat and chemical resistant
Nylon 12	stress resistant

Of course, one of the medical branches that benefits directly and in a significant percentage, is represented by orthopedics, a field in which it has been observed that 3D printing can lead to a high degree of success of surgeries, to increase surgical accuracy, to increase patient confidence, as well as the growing desire to explore new sources of innovation in both preoperative planning and surgical methods. In conclusion, one of the most interesting applications of 3D printing is the creation of realistic models that serve as surgical guides in the planning of complex surgeries. Surgeons can create and practice models of parts of the body to be operated on. In very complicated cases where a multidisciplinary team is needed, the ability to determine the best approach, especially when it comes to teams from different specialties (cardiovascular, orthopedics, neurosurgery) for the same patient, is extremely important. Anatomical models thus allow surgeons to practice various scenarios to approach surgery. 3D printing in the medical industry can be seen as a new way of doing old things. It can be a new way to model new products or new categories of products that could not be made by conventional, older technologies. [1] [2]

An important part of 3D reconstruction is represented by CT images. Without this CT image base, 3D reconstruction cannot be performed. This doctoral dissertation describes in detail the CT protocol, how the images are acquired and how they will be processed in order to obtain 3D reconstruction. [5] [6] [7] An important chapter is devoted to the methods of attenuating metal artifacts in orthopedic implants. With the use of CT, many methods have been proposed to suppress the given metal artifacts, the most complex of these and widely used worldwide being the O-MAR method, which is a commercial product developed by a well-known company. [8] [9]

The O-MAR principle consists in the existence of an iterative loop through which the corrected output image is subtracted from the initial input image. The resulting image will later become the new input image at which the process will be repeated. The first step is to create an image of the metal from the original input image. This image will be used to identify metal projections. If large groups of metal pixels are not viewed, the process will not continue. Therefore, O-MAR has no impact on metal-free images. The O-MAR algorithm is able to reduce the effect of metal on CT images to improve diagnostic quality, despite the fact that it cannot completely remove metal artifacts. In current practice, due to the increase in life expectancy, CT is a common imaging method used in patients with hip prostheses. These are large metal objects that can lead to important artifacts on CT images.

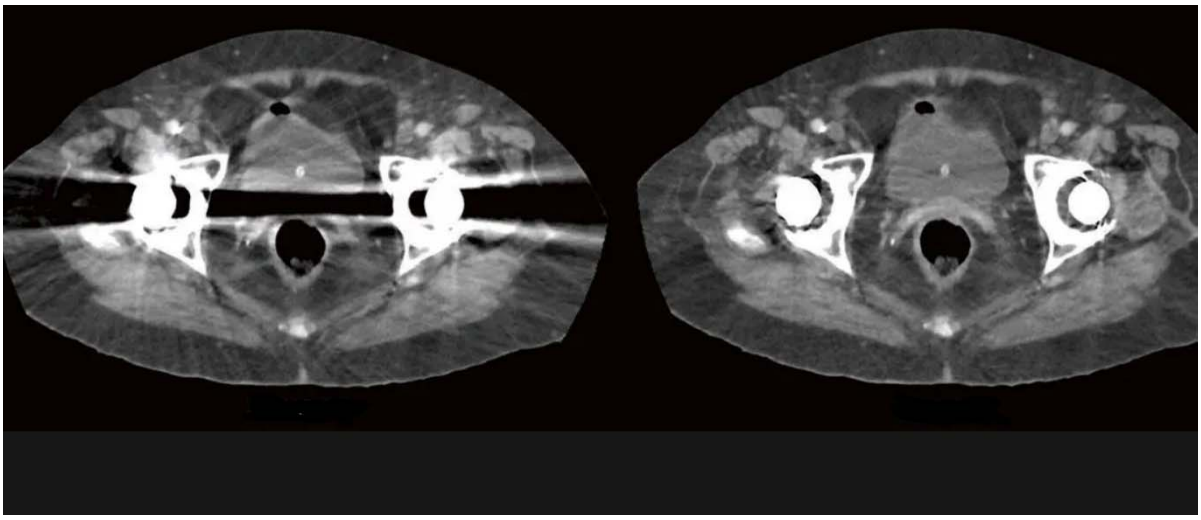


Fig.1 Before and after using the O-MAR function

A particular case is that of a patient with both prosthetic hips. This will lead to the appearance of a large area of black pixels in the central area of the patient's anatomy, which means that it is impossible to make a diagnosis based on these CT images. In this particular situation, the O-MAR algorithm has a definite indication. Metal artifacts have an impact not only on two-dimensional images, but also on 3D images.[5] [6] [9]

Fig.2 CT image with attenuation of metal function

Going further, as mentioned above, after obtaining the CT images, the 3D design was done. For this, the 3D Slicer software version 4.11.20210226 was used. [10] [11] [12] Some essential elements are used in the 3D printing process, including the 3D model and the 3D printer, the link between which is established by the printing software which acts as an intermediary. For those who are not programming specialists, the easiest explanation is that a 3D printing slicer is used, which prepares the selected model for the 3D printer, then a G code is generated, which is a numerically controlled programming language widely used. There are a large number of printing software, many of which are free. 3D Slicer is a free software package widely used for medical and biomedical research. This software is designed to solve advanced imaging challenges, especially for clinical and biomedical applications. The major advantage of this program is also a large community of users and developers working together to improve the end result. The development of 3D Slicer, including its many extensions, problem reports and suggestions are made possible by users, developers, collaborators around the world. This paper will describe step by step all the steps taken to obtain 3D reconstruction in the part dedicated to it.[10] [11] [12]

After the software has roughly performed the reconstruction, the result is processed manually at the level of the defective areas given by the metal aberrations. By selecting it, the software is able to synchronize by exact positioning in the CT cross sections, then improve the reconstructed areas. The effect on the work area, after manual processing by selecting the incorrectly marked segments, is represented by the disappearance of the wrongly selected area by the software and thus the 3D reconstruction's specifity improves.[11]

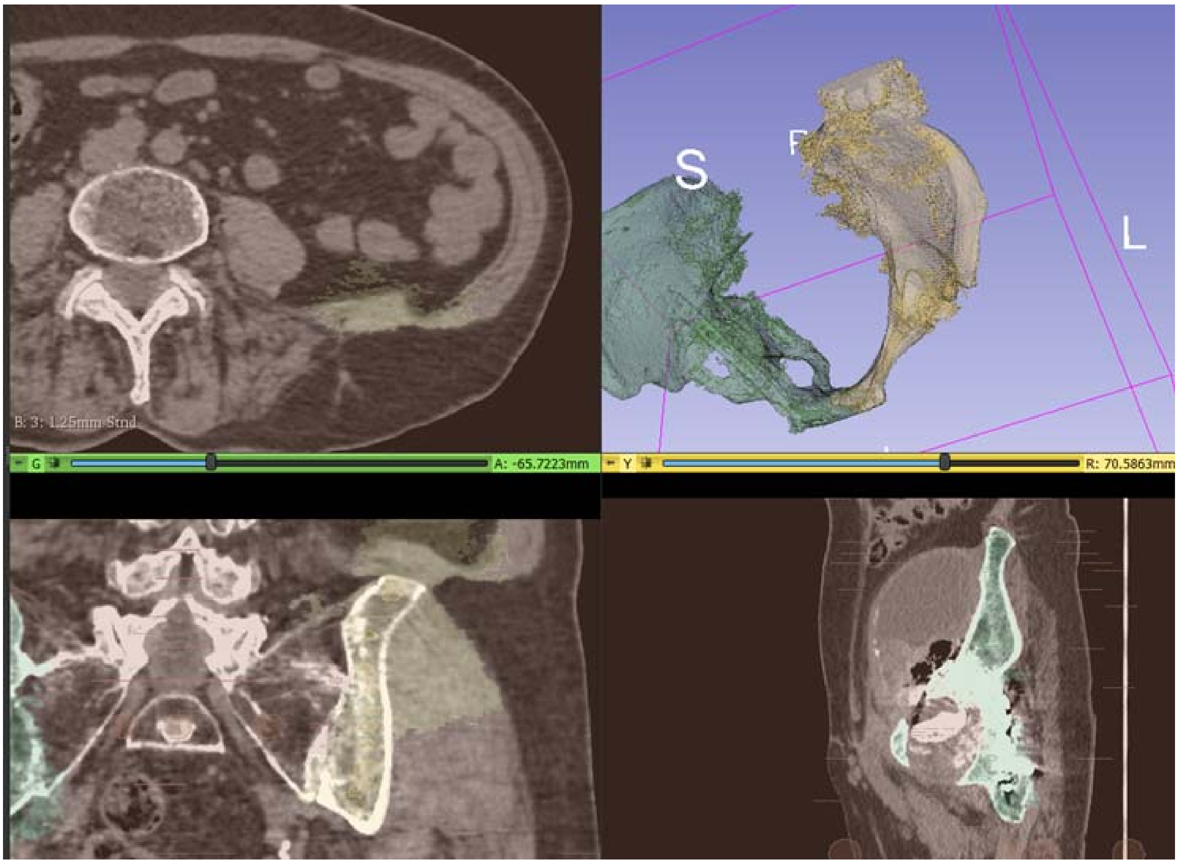


Fig. 3 Three-dimensional reconstruction of the pelvis based on CT images

In the second stage of creating the 3D model, the Autodesk Meshmixer software will be used for the geometric processing of the model surface, helping to simplify it. Using the "import" function, import the previously saved "STL", select "open". After importing the work file, the items of interest are double-clicked. Use the "modify" and "invert" functions to change the area of interest. Unselected geometry will be deleted by pressing the "delete" key (sections that remain outside the selected area and are not connected to the selected area will disappear).[11]

To achieve the objectives of this paper, 2 studies were performed, one comparing the influence of three-dimensional reconstruction on the decision of diagnosis and surgical treatment versus radiography and CT and one evaluating the influence of three-dimensional reconstruction exclusively on the decision of diagnosis and surgical treatment. versus radiography, CT and 3D reconstruction.

In the two studies, 10 patients with acetabular defects from our clinic were introduced, who required hip revision surgery. All patients underwent preoperative radiography as well as CT with metal attenuation. With the help of CT images, the 3D reconstruction of the pelvis was performed, in order to better understand the acetabular defect and for a more accurate pre-operative planning. Radiographic, CT, and 3D reconstruction images were viewed by 10 orthopedic surgeons who completed a table for the 10 patients placed in the study based on a standardized questionnaire. Thus, for each patient, taking into account that both two-incidence radiographs and CT with metal attenuation were performed, the volume of images obtained was considerable. We started from the idea that the large volume of data or images as well as the pandemic situation COVID-19 will be difficult to manage by the 10 orthopedic surgeons, which is why two films were created which were later sent electronically to doctors who have participated and who conducted hip revision surgeries.

The questionnaire includes a number of 10 questions that refer to both the diagnosis and the treatment and management of the acetabular defect, and to simplify the centralization of answers and to perform the statistical study, the answers to all 10 questions are yes or no. For the diagnosis of acetabular defect we chose the Paprosky classification.

Regarding the statistical methods used to obtain the results to be presented, several types of variables were used (qualitative, continuous), and all statistical tests were performed using IBM SPSS Statistics software, version 25.0 for Windows (Armonk, NY , IBM Corp.).

The initial orthopedic intervention was the installation of a hip prosthesis in 7 patients (70%) and the osteosynthesis of the acetabulum in 3 patients (30%), respectively. Of the 7 hip prostheses, 5 were uncemented (71.4%) and 2 were cemented (28.6%). The revised orthopedic interventions (hip prostheses and osteosyntheses) had a median age of 10.5 (0-

22) years, given that all three cotyledon osteosyntheses were revised in the month in which they were fitted.

The causes of the revision of the initial orthopedic interventions were, in descending order of frequency: acetabular loosening (present in 6 patients - 60%), acetabular fracture (present in 3 patients - 30%, all of whom had originally had osteosynthesis of the in 2 patients - 20%), prosthesis infection and pseudo-osteoarthritis of the acetabulum (present respectively in one patient - 10%). The initial orthopedic interventions were reviewed in 7 patients for one reason only, while in 3 patients the decision of the review was motivated by a combination of two reasons (acetabular loosening and pseudo-arthrosis of the acetabulum, acetabular loosening and dislocation, respectively infection and recurrent dislocation).

All revisions were performed by postero-lateral surgical approach, and in the case of two patients a previous approach was also performed. The revision involved cups of all 7 initial hip prostheses, while the stem revision was performed in only 4 patients (57.1%).

Of the total revisions of the initial orthopedic interventions, 5 (50%) involved a commercial trabecular metal implant (revision cup, including in the case of a patient who had originally had osteosynthesis of the acetabulum), 2 (40%) of which also required augmentation, on when in the other 5 patients (40%) the revisions required various solutions: prosthesis and spacer ablation, cup and augment, Burch-Schneider box and revision cup, Kerboull type box and revision cup, respectively cemented cup. All 10 respondents agreed that by including the 3D reconstruction a more precise surgical planning can be performed ($p = 0,002$).

In the first study, in terms of the results obtained, evaluating each patient, initially with data from conventional radiology and CT, then using data from conventional radiology, CT and three-dimensional reconstruction, the responding physicians significantly changed their answers to question 1 related to the Paprosky classification in half of the evaluated patients ($p = 0.005$), which means that the influence of 3D reconstruction is significant and is an important component that can be considered in the future an essential method in the preoperative planning of these patients. Regarding the surgical approach, it was not significantly influenced by the exposure to the three-dimensional reconstruction information, the variations of the answers not being statistically significant, as most doctors preferred and maintained their preference for the postero-lateral approach.

Unlike the first study, the second one aimed to evaluate three-dimensional reconstruction in the absence of classical imaging. As expected, the responses did not vary significantly, in other words, the impact of radiology and CT is minimal in the surgeon's decision and there are no major differences between the two decisions.

In many countries, as in our country, the number of hip revisions is increasing. [13] [14] This is the main reason why orthopedic surgeons must make the right treatment decision, in terms of the type of prosthesis chosen and the planning of surgery, especially given that revision is required due to acetabular defects such as several times complicated or by the existence of acetabular loosening. Thus, pre-surgical evaluation is paramount in assessing acetabular defect. [15] To date, most surgeons have performed this preoperative assessment using classical imaging methods, namely conventional radiography and CT imaging. We can assume that, if only conventional radiography were used, the surgeon should be very well trained in performing this type of surgery and with a great deal of surgical experience. It is generally accepted that preoperative acetabular defect assessment is the most important part of surgery, after which it should be classified according to accepted classifications. There are usually two types of classifications accepted in the literature for acetabular defects, namely, the Paprosky classification, also used in this paper, and the AAOS classification. [16] [17] [18] [19] In view of the usual use of the two classifications, in addition to their validation in many specialist papers, their limitations have also been presented. For example, Yu and Campbell state that the use of these classifications is subjective and that another standardized, objective method for validating the acetabular defect as accurately as possible should be considered. [17] [18] [20]

Currently, CT imaging is commonly used to perform preoperative planning, which provides a detailed perspective on acetabular defects, and measurements of angles or bone thickness or density can be made. [21] [22] Thus, three-dimensional CT imaging is an objective method of diagnosis and treatment, but it also requires the orthopedist to be experienced and does not offer the possibility of making custom implants.

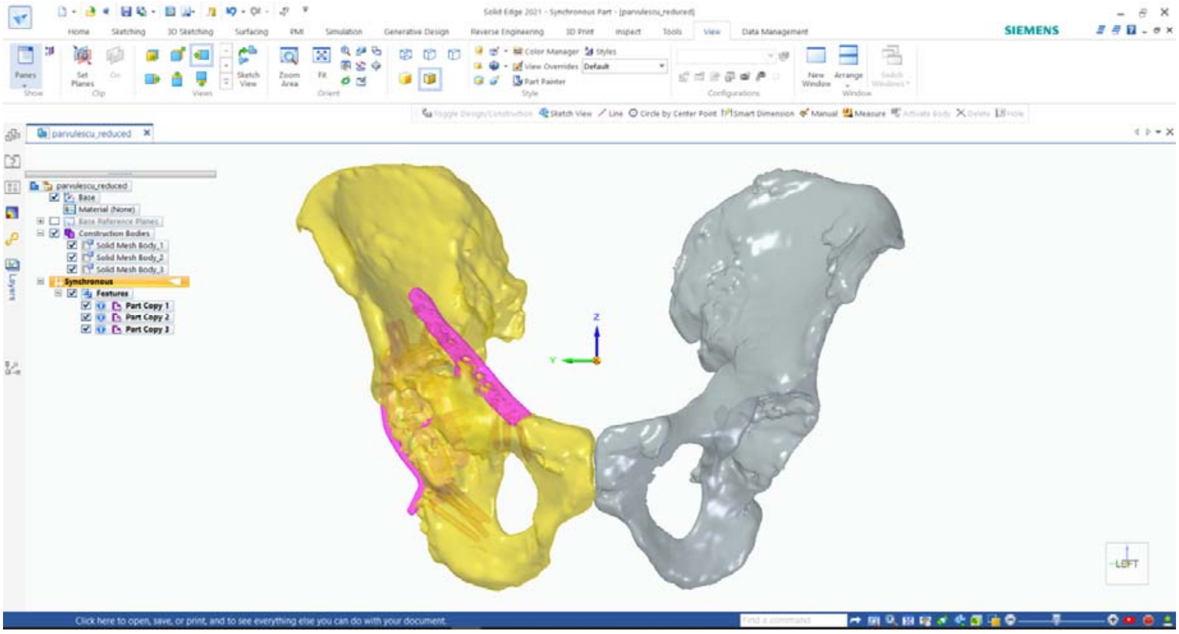


Fig.4A

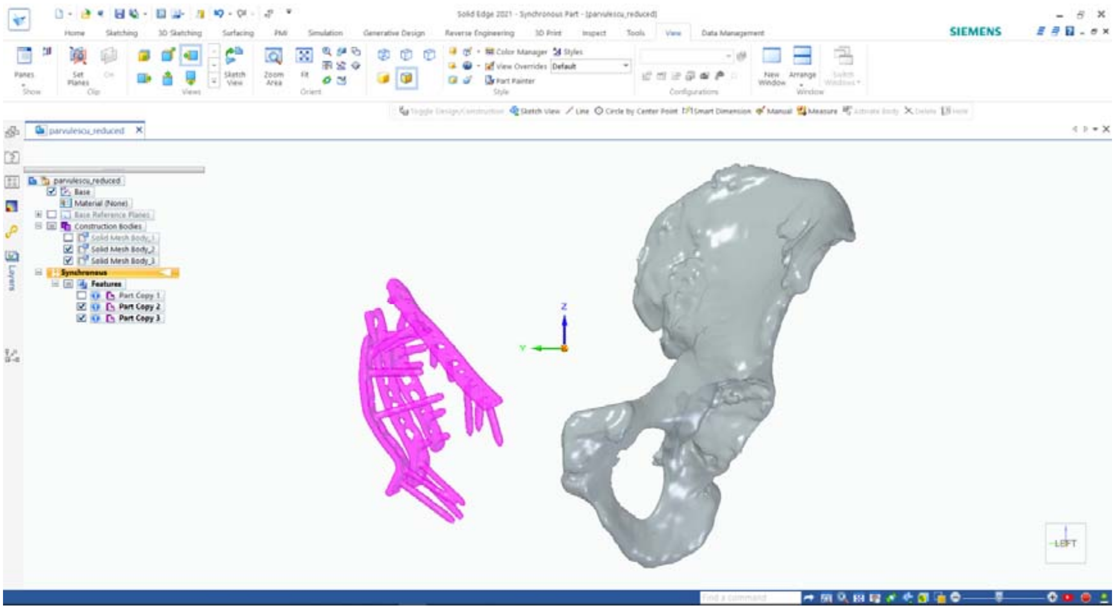


Fig. 4B Presence of osteosynthesis material on the right side, secondary to the acetabular fracture by fixation of the anterior and posterior columns after 3D reconstruction

Practical example for the "mirroring" function to transpose, for example, the center of the healthy hip to the affected one is an ideal benchmark for correctly identifying the future position of the center of rotation of the cup

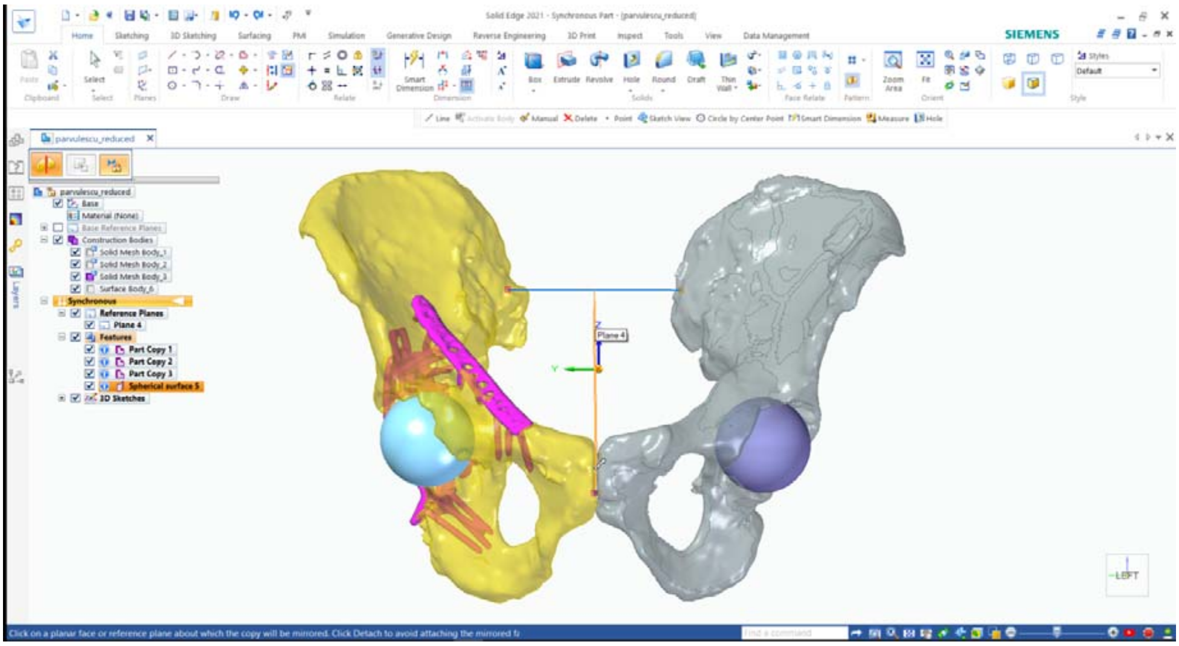


Fig. 5 Transposition of the center of rotation from the unaffected hip to the one of interest

Thus, for the reasons presented above and to avoid misdiagnosis of complex acetabular defects, in many studies, but also in many orthopedic medical institutions that perform the hip revision intervention, the 3D reconstruction of the acetabular defect was accepted and used. With a real three-dimensional model of the acetabular defect in mind, the orthopedic surgeon can correctly visualize the local anatomy and can at the same time, through collaboration with specialized engineers, make a customized implant. At the same time, simulations of surgery can be performed on a three-dimensional model printed with a 3D printer, which means a significant improvement in efficiency and safety. This paper, as mentioned in the literature, has shown that 3D technology makes significant improvements in the accuracy of assessing acetabular defects compared to usual imaging (radiography and CT), but there is little work in the literature to prove its value. in performing hip revision surgery. However, it was observed that the existence of a 3D model that allowed surgeons to visualize the acetabular defect in a preoperative manner, led to a decrease in operating time, as well as a reduction in the need for blood transfusions. [23] [24]

CT based 3D printing also has limitations, and one of them is that cartilage or soft tissue cannot be represented. [25] [26] In this regard, this paper also emphasizes the need for better collaboration with engineers specializing in 3D printing technology, who, as it is used as much as possible, will accumulate more experience and value of 3D printing will increase exponentially in the future. It is also very important to mention the material used in 3D printing, which must have mechanical properties as close as possible to those of the bone to avoid diagnostic and treatment errors. Another limitation of 3D printing may be the high cost, which can be a problem when you want to use it as widely as possible. [27] In addition, it should be borne in mind that 3D printing requires a longer examination time than usual imaging.

At present, as mentioned above, the materials used for 3D printing are not equivalent to bone tissue, and grayscale models in general cannot represent the complete rigidity of structures. An attempt is made to solve this problem, and in this sense polychrome materials or the combination of several types of materials with different mechanical rigidity that could represent the state of the acetabulum are considered. Both bone density and the quality of existing bone are taken into account. Thus, imaging data must be obtained that will be analyzed by the computer in such a way that a model with a calculated rigidity can be created. Future studies are needed to obtain these materials.

Unlike primary hip arthroplasty, hip revision surgery is much more complex and many obstacles can be encountered during it. Some of these obstacles are represented by: periprosthetic fracture, malposition of the implant that can lead to difficulties in removing it, poor quality of the remaining bone. [28] [29] [30] [31] All of these together lead to many challenges for the orthopedic surgeon during hip replacement surgery.

The two classifications used are Paprosky and AAOS, being the most common, they are mainly focused on the acetabular defect, but less on the iliac wing or other areas of the pelvis more distant from the acetabulum. Many studies, as well as clinical practice, have shown that these areas, even if they do not come into direct contact with the femoral head, can negatively influence their condition and the biomechanical properties of the hip. This leads to the conclusion that the commonly used classifications, as we used in the present study, do not fully cover all bone defects that may exist in the event of a need for hip revision. Note that the two classifications are based in principle on classical methods of hip revision, such as conventional prostheses, cages, bone grafts and others. Thus, as we improve our revision methods, a method of improving the classification of bone defects will also be required. From our point of view, the obvious improvement brought to the revision method consists in the realization of the 3D model of the acetabular defect which leads to a well-defined preoperative planning and which gives the surgeon the real image of the bone defect, leading to correct diagnosis and appropriate treatment.

The development of the 3D model based on the CT images obtained leads to the possibility of avoiding the use of allografts, which further prevents the risk of fracture, leads to decreased intraoperative time, as well as reduced use of other osteosynthesis materials which implicitly leads to smaller traumatic risk.[32] [33] [34] There are few studies that have evaluated the use of individualized prostheses by 3D printing based on the 3D model made using CT images. These studies have shown that individualized prostheses depending on the patient by 3D printing, can adapt to the local anatomy influenced by complex bone defects of the patient, which makes it easier to mount and immediately achieve hip stability. The precise, individualized shape of these prostheses, as well as their structure, help to avoid excessive reaming to place the implant, which means that the stability of the hip is increased in the long run and much of the existing bone mass is preserved, especially in the case of in which further revision will be required. [35] [36] Of course, these studies also have some limitations. One of these is the need to make a 3D model, which involves performing a CT scan, the model being made based on the images obtained, rather than using only conventional radiography which is insufficient, although it is cheaper and less irradiating. Three-dimensional reconstruction plays a key role in preoperative planning and prosthesis design, in addition it greatly increases the complexity of the diagnostic process, but at the same time increases the cost.

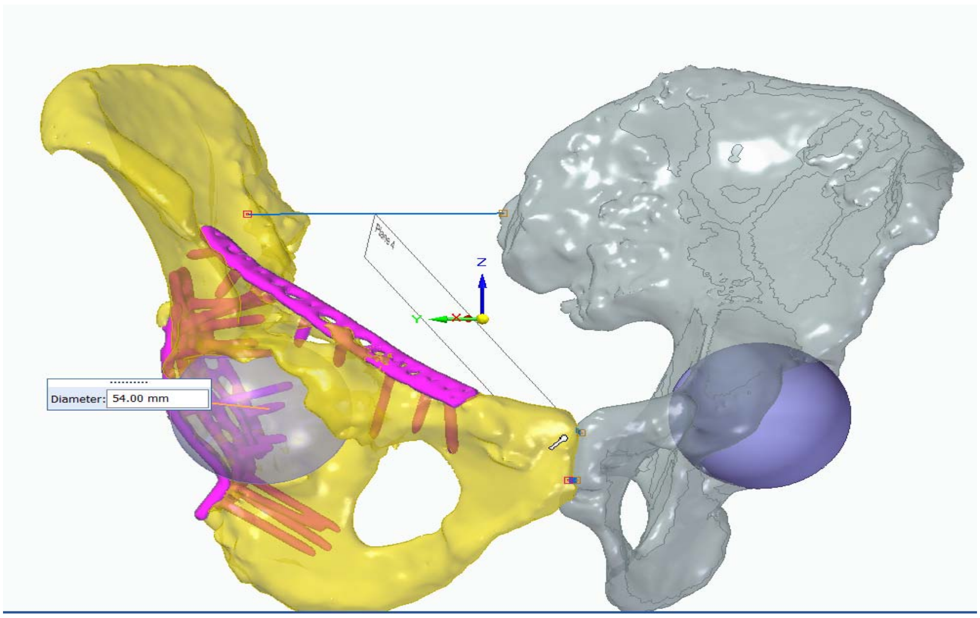


Fig. 6 The final aspect after processing, in which the intimate relationship is visualized and the maximum size that can be reached in order not to come into contact with the osteosynthesis material.

CONCLUSIONS

- We obtained the three-dimensional image of the pelvis with the metal implant to give the orthopedic surgeon a better view of the acetabular defect in order to make an accurate diagnosis of it and to make the best surgical decisions.
- By three-dimensional printing based on CT images of the pelvis, we obtained a high-performance imaging method for preoperative planning, its standardization in the management of acetabular defects in cases of revision of hip prostheses.
- Through three-dimensional reconstruction starting from CT images, we were able to visualize and analyze the bone defect very well, we were able to predetermine the steps that will be followed during the surgery, as well as methods of bone defect management.
- I made a guide for milling and implanting the bucket with an ideal position, according to the preoperative planning and local bone defects. With its help we were able to establish an ideal positioning of the final cup, when the bone defect is massive and the classic parts cannot be used.

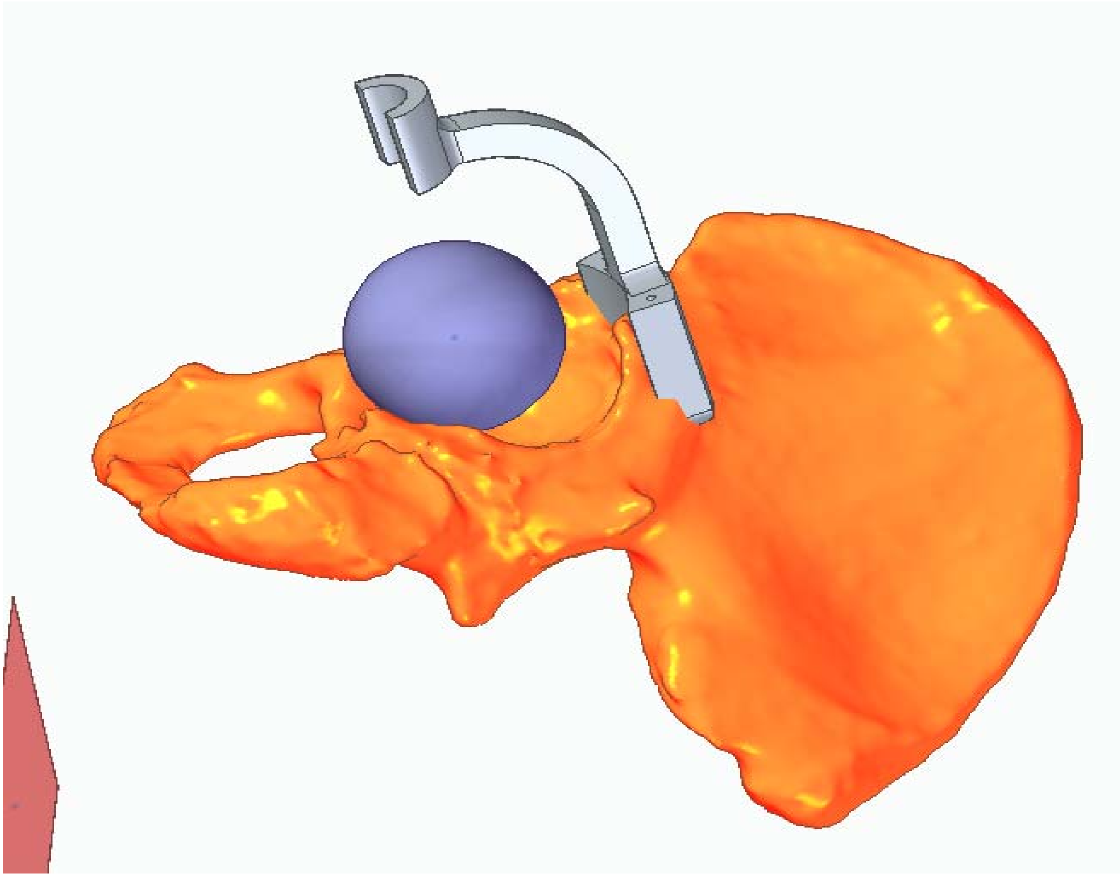
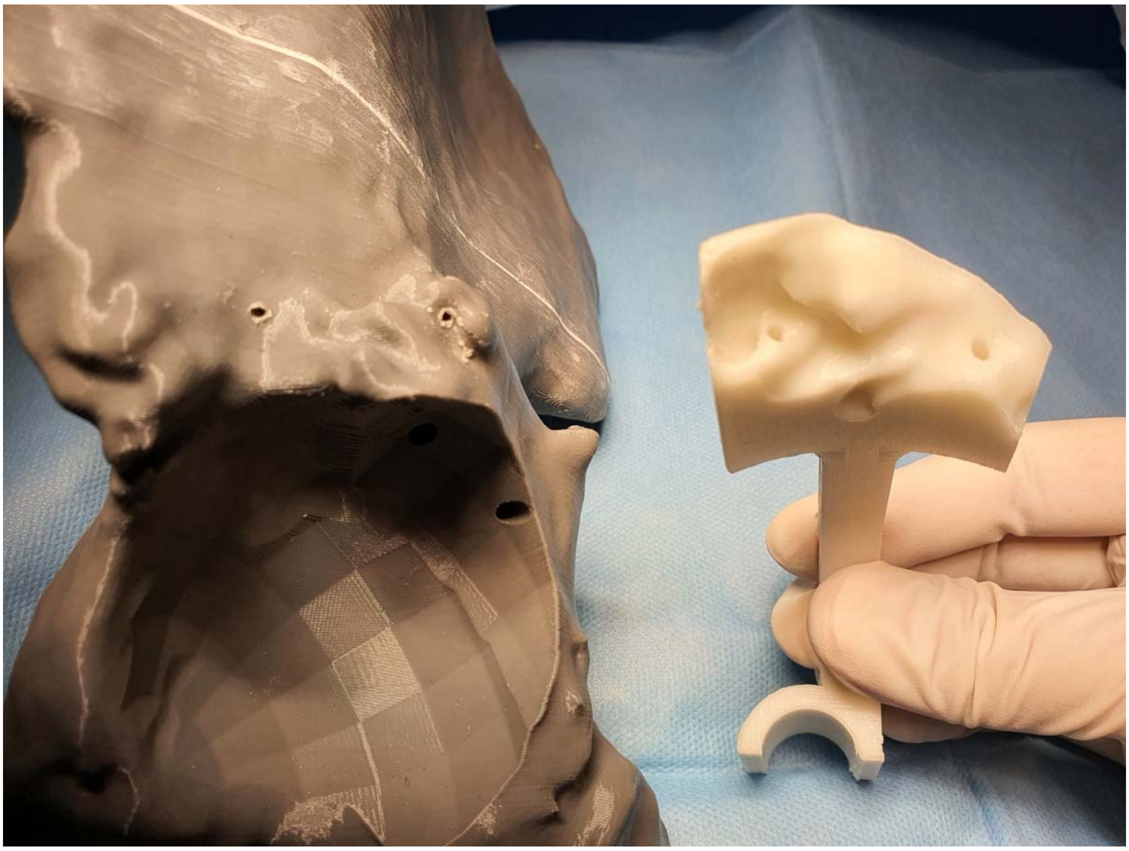
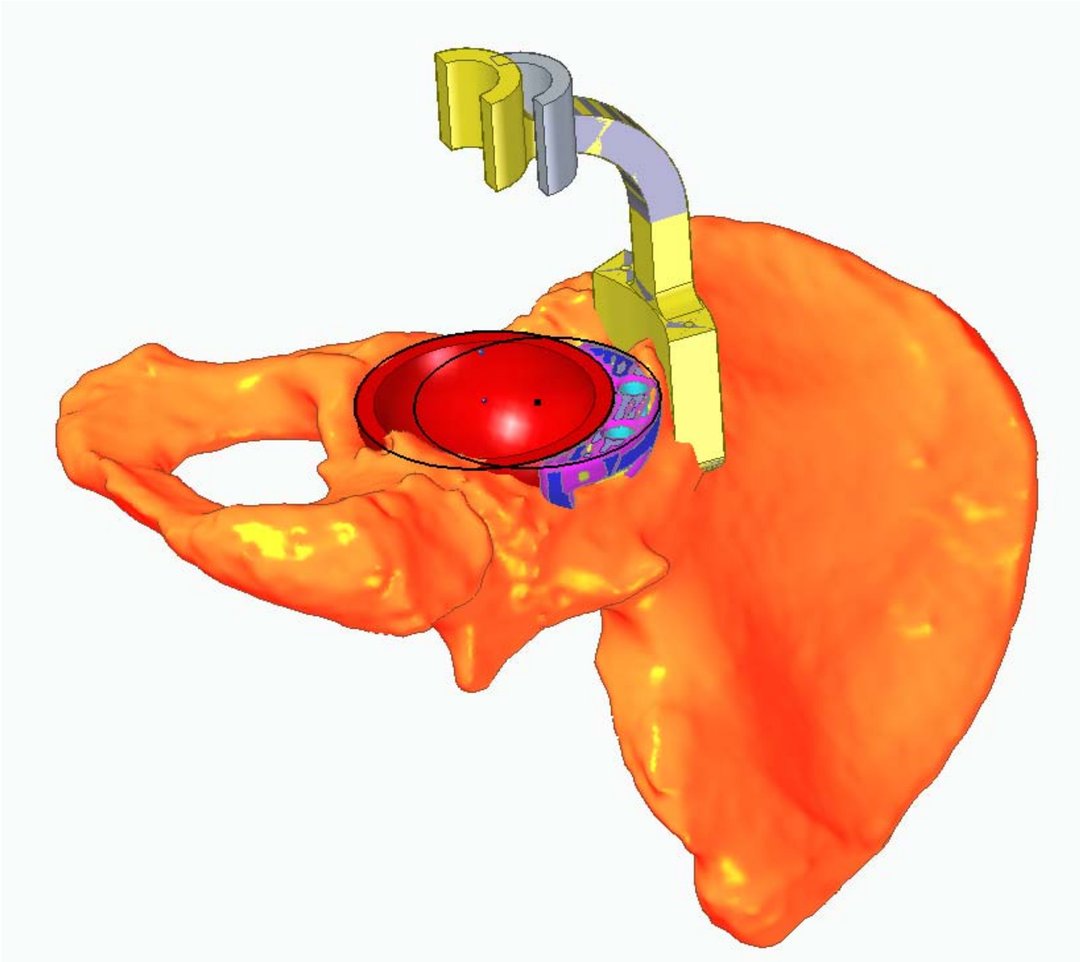


Fig. 7 Exemplification of the design of the external milling guide at the level of the acetabulum

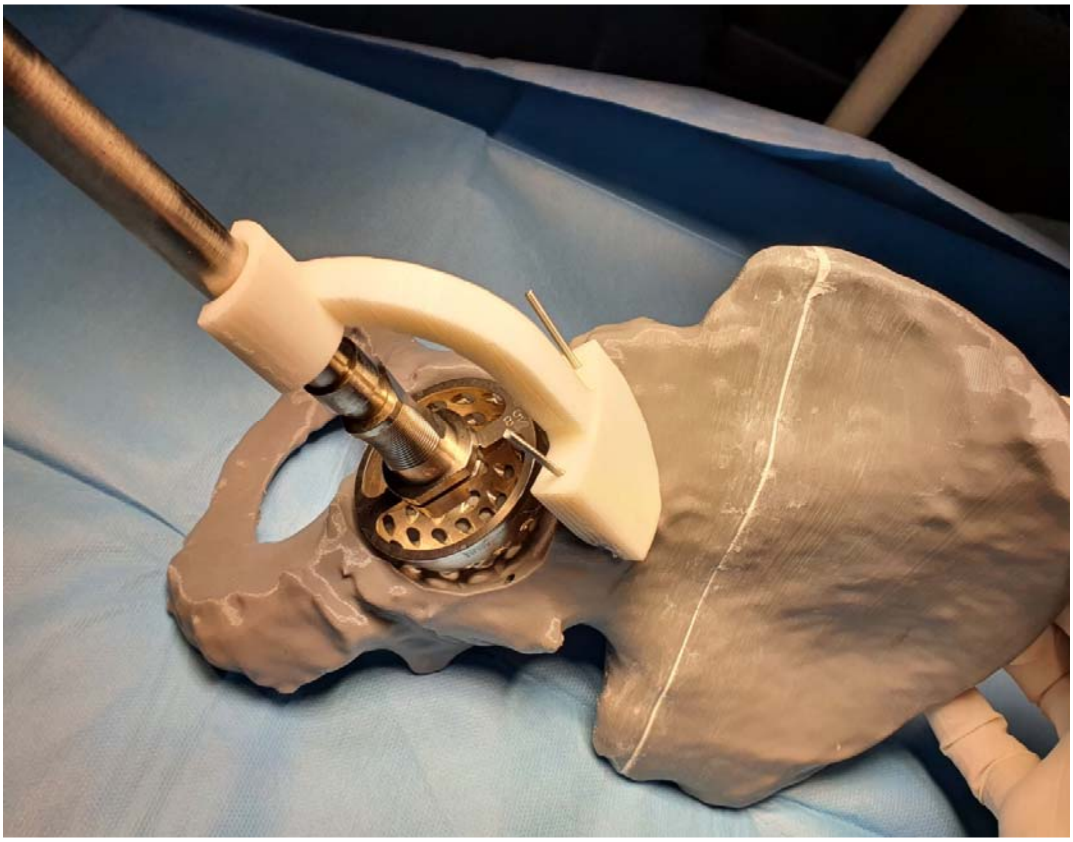
Exemplification of the design of the external milling guide at the level of the acetabulum with 2 cylindrical holes at a convergent angle through which 2 brooches of the desired diameter are inserted to fix it.



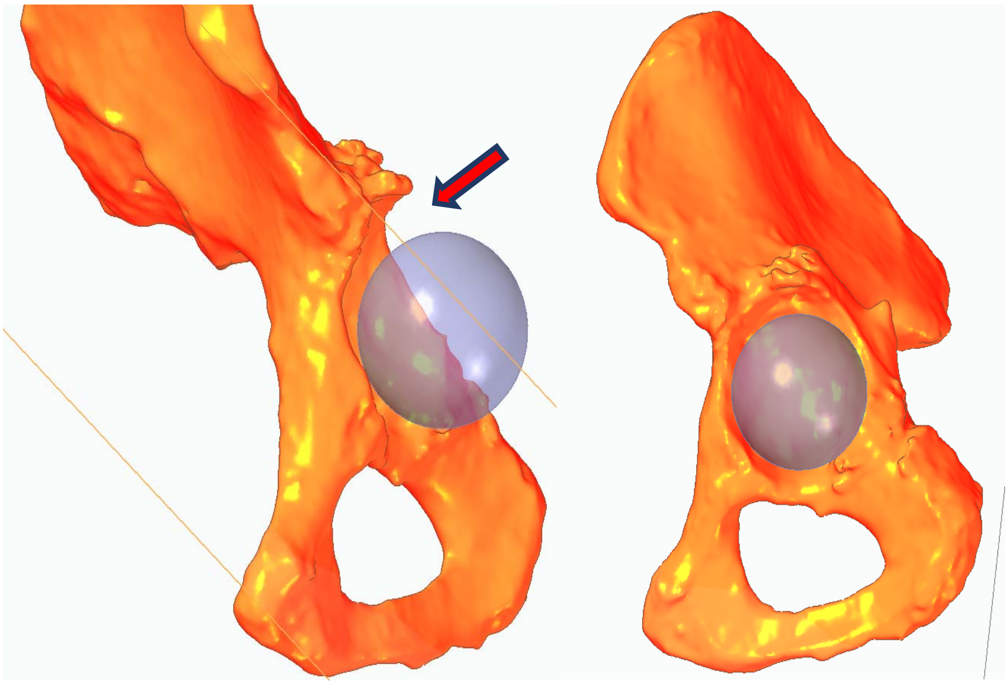
- ❖ Reconstruction of acetabular defects with prefabricated 3D augmentations and orientation and simulation of acetabular reconstruction are important steps in the evolution of management and surgery. The development of customized three-dimensional acetabular milling guides, as well as custom implants with 3D printing, as well as the development of guides for positioning the screws for fixing tantalum cups and augments were the main steps we followed throughout the study, and these were successfully completed and led to significant results.



- We obtained the possibility to simulate, within the software, the surgery with the minimum sacrifice of the remaining bone stock at the level of the acetabulum.
- The use of the computer tomograph without metal attenuation and the specific settings in the software is useless as long as the acetabular defect cannot be appreciated due to the metal artifacts, in order to correspond as much as possible with reality.
- One of the main objectives was to obtain an optimal orientation for the cup when the local anatomy is significantly modified. What we managed to achieve after the research is the execution of an external guide for milling and positioning the cup in the ideal position, which can not be misplaced even if the patient is obese, wrong sitting on the operating table or despite the heavily modified local anatomy and significant local bone defects.



❖ One of the great advantages of three-dimensional design is the possibility of reporting to the healthy hip when it does not have an implant present or is not dysplastic to restore an ideal center of rotation that does not affect both limb length and thus muscles.



- The method we have managed to describe can also be used by less experienced surgeons in terms of hip prosthesis revision. Through three-dimensional reconstruction, each stage of the surgery can be methodically planned, any complications that may occur during the surgery, so that they can be avoided or if they cannot be avoided, the solution will already be known.
- A thorough pre-operative planning done can lead to a significant shortening of the duration of the surgery by decreasing all the adjacent risks (infection, bleeding, mortality) and at the same time obtaining an effective result of the surgery.
- Following the studies performed in this paper, we obtained the fact that, after analyzing radiographic images and CT surgeons, the classification of the acetabular defect in the Paprosky classification is different, increasing the degree after viewing the three-dimensional reconstruction.
- The proposed method can be used in the training for the qualification of young surgeons, especially by the effective printing of the pelvis comprising the entire bone defect, then milling can be performed and simulate all operating steps.
- All of the above involve the need for collaboration and training with a technician in order to obtain the three-dimensional reconstruction and the external guide, and the disadvantage comes from the fact that it can mean additional costs. From our point of view, a profitable investment in the future for surgeons who want to perform complex surgeries that require special training, is in their training in terms of existing and accessible program and software, training that is done by a specialized technician.

Study perspectives

In the future we will be able to discuss the possibility of standardizing surgery, but without losing an important word that is part of the title of this paper, namely, customizable. We will be able to continue the research until the direct printing of the acetabular defect from a biocompatible material, which satisfies all the necessary conditions (osteo-inductive, mechanical resistance, stability in time, etc.), which can be fixed directly, without other adjustments and in a position that could be decided in advance.

3D printing is a technology that allows the creation of new medical devices, which means that the future is open for new models or inventions to permanently improve the surgical technique.

List of published scientific papers

Articles published in specialized magazines:

- Journal title: Romanian Journal of Military Medicine, vol. CXXV, nr. 1/2022, pp. 152-157, 2021. Titlul lucrării: “3D Reconstruction protocol in complex acetabular defects”
  Authors: **Dinache G.**, Avram G., Hantascu A., Paraschiv R. și Tillieci L.

www.revistamedicinamilitara.ro

http://www.revistamedicinamilitara.ro/wp-content/uploads/2022/02/3D-reconstruction-protocol-in-complex-acetabular-defects.pdf

- *Journal title: Revista de Chimie Bucuresti - Romania,* Vol. 1 din 269; ISSN 0034-7752, nr. 12, pp. 3664-3668, 2018. ISI cotată, Factor de impact pe anul 2017: 1.412 Titlul lucrării: “Theoretical aspects, modern treatment options and practical case presentations in hip and knee tumoral and revision bone defect reconstruction surgery”
  Authors: **Dinache G.**, Drignei M., Ganatsios S., Jovenet E. și Costea R.,

www.revistadechimie.ro

https://www.academia.edu/55662652/Theoretical_Aspects_Modern_Treatment_Options_and_Practical_Case_Presentations_in_Hip_and_Knee_Tumoral_and_Revision_Bone_Defect_Reconstruction_Surgery

- *Journal title: Revista de Chimie Bucuresti - Romania,* Vol. 69 Issue12, 3669-3674, pp. 3669-3674, 2018. ISI cotată, Factor de impact pe anul 2019: 1.755; Titlul lucrării: “The Role of Osteosynthesys Materials in the Etiopathology of Bone Malignant Tumors and Reconstruction Possibilities” Case report
  Authors: Cezar Ionut Calin, Marinel Drignei, Stergios Ganatsios, Eric Jovenet, **George Dinache**, Florin Savulescu, Dumitru Ferechide
  https://revistadechimie.ro/Articles.asp?ID=6816

Co-author: “Note de curs” **Prof. A.Barbilian;** Cod produs: 302659; Editura: Anamarol; anul:2015; Nr. Pagini: 255 pagini; ISBN: 9786066401326

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