

The Use of 3D Printing in Preoperative Planning of Scoliotic Pathology

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Abstract

Introduction and Objective

Idiopathic scoliosis represents a complex spinal pathology with an unknown etiology which is regarded as a three dimensional spinal deformity. The imagistic planning is a key step in elaborating the therapeutic strategy. Establishing the spine's structure, especially in the case of scoliotic pathology, is extremely important for a correct diagnosis and for a performant preoperative care. It's becoming obvious that more and more orthopedic surgeons started introducing elements of 3D printing in modern medical practice. In our clinic, we are developing a study about the benefits of 3D printing in scoliotic pathology.

Purposes of the study: giving meaning to a tactile 3D preoperative planning for the scoliotic pathology; evaluating the utility of 3D printing intraoperatively, printed 3D model in the patient doctor relationship.

Materials and Methods

The printing of the 3D models are obtained by using the CT scan: it's one of the most modern technique used for evaluating scoliotic pathology. The technique is composed of a few stages of analyzing and transposing DICOM information and the printing process. This process involves a multidisciplinary team (orthopaedic surgeon, radiologist, IT technician)

Results

We assembled a strict work protocol to guide us in these projects and future ones, with precise parameters selected after various tests were performed. The 7 surgeons, pertaining to our medical team, subjected to this questionnaire found the 3D models to be very useful for surgical planning with an overall level of satisfaction that exceeded our expectations, all of them stating that they would further recommend this experience to other colleagues.

Conclusions

3D printing is a very useful modern technique used in preoperative planning of the spinal pathology. Surgeons find 3D printing models to be extremely helpful medical tools used to improve therapeutical outcomes and doctor-patient relationship

Keywords

Doctor-Patient Communication, Medical 3D Printing, Preoperative Planning, Personalized Treatment, Spine Pathology.

1 INTRODUCTION

Idiopathic Scoliosis is a complex pathology, of unknown etiology, which consists in a tri-dimensional deformity of the spine, involving the existence of abnormal curvatures of the spine in the frontal and sagittal plane, various rotations of the vertebrae in the longitudinal axis, as well as structural anomalies of the vertebrae. The planning based on the analysis and interpretation of the radiological findings represents a key step in assembling the therapeutic scheme. Discovering the spine's anatomical design for each patient is extremely relevant, not only for a precise diagnosis, but also for a better preoperative evaluation of the patient's condition. An elaborate evaluation opens the possibility of planning surgical steps and optimal approaches and also selecting and preparing a set of suitable surgical instruments and fixation devices "[1]". These are the premises of a well adjusted therapeutic plan, which may predict a better outcome.

In order to accomplish this preoperative evaluation, the orthopaedic surgeon has at his disposal various means. The

Roentgen examination is the most common and widely used in preoperative planning for spinal pathology, yet these acquisitions provide inaccurate information regarding the precise extent of the bone deformation.

There are more advanced methods used to upgrade the preoperative plan and also to reduce surgical risks, such as: using CT scans to make 3D virtual reconstructions, benefitting from a C-arm X-Ray machine, or exploring with the NeuroNavigation System. Although the quality of these acquisitions and the technological progress that they bring are indisputable, we have to consider the increased radiation impact upon the patient and the prolonged intraoperative time. The continuous development in the radiology department creates new possibilities to thoroughly evaluate orthopedic pathologies. Adolescent idiopathic scoliosis is one of those pathologies, characterised by a complex deformity of the spine that requires an elaborate treatment involving rigorously preparation and a challenging surgical procedure.

In the surgical correction of a scoliotic spine, pedicle screws are a popular option to correct coronal and frontal deformity, due to their biomechanical properties and superior results regarding the major curve correction. The rotation in the transverse plan of the affected vertebrae leads to a high risk of surgical errors, one of them being screw misplacement, with an incidence of 20% to 30% and neurovascular complications reported at some of these patients, facing severe consequences "[2]".

In order to reduce screw misplacement rate, several techniques have been approached, such as 3D CT reconstruction combined with experienced surgeons and multidisciplinary teams, but with limited results.

The 3D Printing Technology applied to grafical models obtained through CT scans, remains a cutting-edge technology, that with a modern and efficient approach sets new standards in the evaluation and treatment of the scoliotic pathology. This revolutionary technique requires multiple steps and a interdisciplinary team.

Data aquisition represents the first step of the process, consisting in performing the CT exam and save the data set as a DICOM file (Digital Imaging and Communications in Medicine). This is where the radiologist plays a crucial role, considering that both the aquisition and the reconstruction of the anatomical segment must be completed at certain parameters that will further allow this data set to undergo a biomodelling process. The next action will be to select the geometrical area designating the bone structure in question, by using the 3D Slicer 4.2.6. Software, an open source software "[3]". The purpose of this step is to simplify the complex CT data obtained previously, leaving a comprehensive representation of the segment of interest, in the shape of a volumetric dataset calculated from the DICOM data available "[1],[4]".

The obtained 3D virtual model will undergo different processing stages, depending on several criteria such as: the complex geometry of the model, the type of printer and material used, or the model's purpose.

Following this, a virtual 3D representation of the previously aquired 2D layers will be achieved, along with a subsequent image segmentation, through the help of a software. The image segmentation demands to be performed by a user with significant knowledge upon the human anatomy, having to do with dividing the image in individual anatomical parts "[4]". The processed dataset will be exported as an .stl file, a format that is supported by any 3D printer. In our study we used the Fused Deposition Modelling Technique (FDM). This choice of printing technique entails an additional step before sending it for print, called slicing, which involves cutting the virtual model into thin layers, equal in thickness.

Along with a fast developement of this technology, the implementation of 3D Printing in the medical field grew exponentially, bringing multiple and uncontested advantages in understanding the patient's anatomical particularities and developing a more adequate preoperative plan. The 3D printed models, based on CT scans data, are precise, from the morphological point of view "[5],[6]". Multiple studies revealed that these models,

obtained through this method, may have an error below 1 mm "[6],[7],[8]". This fact extends to any 3D printing technique, none of them being able to be more significant than others in this matter "[9],[10]". Due to the discovery of biocompatible materials that can be subjected to sterilization, this technology plays a significant part in designing and manufacturing surgical personalized tools and guides "[1],[11],[12]".

2 Objectives

1. Establishing a work protocol to guide the multidisciplinary team engaged in implementing 3D Printing in medical practice
2. Evaluate the length measurement agreement between the 3D printed model and the patient's CT
3. Evaluating the true use and efficiency of a tactile preoperative planning in scoliotic pathology
4. Evaluating the surgeons' feedback after simulating surgical gestures upon the printed models
5. Evaluating the benefits of using the 3D model as a tactile and visual support intraoperatory
6. Assessing the 3D printing implementation's impact in surgical resident education.

3 Materials and Methods

The NGP - Spine Study took place in the departement of pediatric orthopaedics of „Grigore Alexandrescu" Emergency Hospital for Children, from April 2017 to April 2019. During this period, the scoliotic patients undergoing medical investigations and treatment at this facility, were assessed by validating them as subjects on NGP- Spine The New Generation of Preoperative Planning in Scoliotic Pathology. The study was authorised by the ethical comitee pertaining to „Grigore Alexandrescu" Hospital.

The inclusion criteria for participation in the study covered the following: age under 18 years old, suffering from cyphotic and scoliotic deformities, congenital or neurological, that agreed to participate. The exclusion criteria refers to patients that don't require surgical intervention and patients that suffer from scoliosis caused by traumatic, tumoral or other factors besides the two previously mentioned. Also, patients with radiological investigations that don't match the parameters required in our study are not included as participants. The patients selected to follow our program benefitted from creating a 3D printed model based on CT scan data obtained priveously.

3.1 Imaging acquisition

In order to gather a dataset of CT images the patient must undergo a CT examination of the anatomical segment in

question. We used CT scan obtained through a device called Siemens Somatom Emotion , Excel Edition 2013. Contrary to what some may think, a CT scan suitable for 3D Printing doesn't require a wider body segment to be scanned, but it does entail a series of specific parameters in order to obtain better results in the 3D project one engages in.

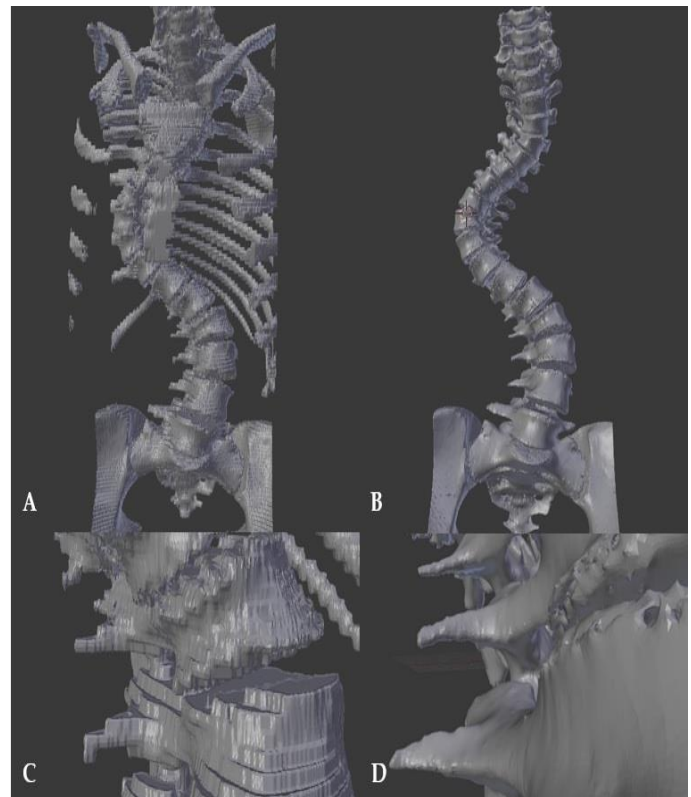
CT- scan examination requirements

A. Data Acquisition Instructions

1. The CT scan must include the whole body segment to be printed
2. The CT scan of the body segment in question must be performed during one session alone. CT- slices obtained through distinctive examinations are not accepted.
3. If the patient presents metallic implants placed in the anatomical region to be scanned, the CT parameters of this acquisition will be adjusted in order to diminish the artefact occurrence and the noise caused by the presence of these implants.
4. The CT scan examination will be performed with the patient lying in supine position, to avoid obtaining artifacted images. Otherwise, in prone position, the acquisition is subjected to artifacts, due to respiratory movement, that occur specially in the cervical and thorax regions.
5. The DICOM images obtained following a CT scan are available for transfer in the original format and dimensions, without any size alterations, such as compression.

B. Parameters

1. **Location:** It is important that the whole body region to be analysed is found in the same acquisition, so that the 3D reconstruction can be as precise and complete as possible and that no bone segments could be omitted during the cropping step of the post processing.
2. **The Acquisition:** One single, continuous and axial acquisition of the body region of interest must be performed (ROI).
3. **The scanning mode:** This can be spiral or helicoidal. The 3D printing process does not depend on the scanning mode, both spiral and helicoidal types are suitable for accomplishing valid 3D printed models. Considering that the NGP- Spine „New Generation of preoperative planning in Scoliotic Pathology” was performed on pediatric patients, the CT scan were executed using the spiral scanning mode and therefore reducing the exposure time and artefacted images occurrence due to voluntary or involuntary patient's movements.
4. **Slice Thickness:** This measurement should not exceed 1 mm. The Slice Thickness is a very important parameter for the whole printing process. The numerical value of this parameter is inversely proportional with the quality and image resolution of the 3D graphic model and of the final 3D printed



model. For the first patient subjected to our study, we used a CT scan with a slice thickness of 3 mm (Case 1). After processing the DICOM images and assembling the 3D virtual reconstruction in .stl format, we came to the conclusion that the graphic model's resolution was ineligible for further steps so we decided to stop at that point the printing process. For our next patient we chose to perform the CT scan with a slice thickness of 1.75 mm (Case 2), with significant but insufficient improvement upon the quality of our data. We then decided to use values of 1mm (Case 3) and 0.5 mm (Case 4) for the slice thickness on our next patients. The image quality we achieved in Case 3 was superior, with excellent representation of anatomical details and the surface of the 3D printed model obtained in this case was far smoother in comparison to the models of Case 1 (3mm) (Fig 1) and of Case 2 (1.75mm). Regarding Case 4, the results' quality was better than the one in Case 3 and far better than what we obtained in Cases 1 and 2. However, if we are to compare the resolutions between Case 3 and Case 4, a significant difference will not be noticeable, both models being perfectly able to faithfully embody the anatomical model and to express in a precise manner anatomical details. In both cases the models' surface was more than adequate without bumps or pixelated aspect. The time needed to process the DICOM images in Case 4 (0.5 mm) was longer by approximately 35-40% than the time required to process the model with a slice thickness of 1mm. Due to these aspects, we believe that for creating precise 3D models, of excellent resolution, the CT scan should be performed with a slice thickness set at maximum 1mm.

5. **Slice spacing / Increment** - or the distance between the images scanned by the CT- must not be wider than the slice thickness. If the Increment value does not exceed the slice thickness, the obtained images will be arranged after a certain

degree of overlapping, so that the Partial Volume Effect is decreased and a superior quality of both the 2D and 3D model is achieved.

6. **Kernel** - The Kernel function affects the reconstructive manner in which the images are done. This function controls how smooth or how sharp the resulted models are. In the beginning of our study we used Kernel B90S- sharp, for our CT

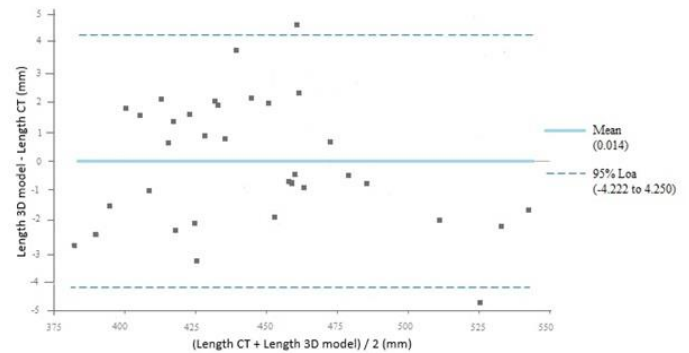
Fig. 1 Virtual 3D reconstructions of the same CT with different values of slice thickness (whole segment versus in detail)- A and C stand for a slice thickness of 3 mm; B and D stand for a slice thickness of 1 mm.

scans. This choice proved to be challenging because of the „noisy” images we managed to obtain, full of artefacts, due to the multitude of voxels with similar intensities as the ones where the bone has spread in the muscular layers. In the procedure of processing the DICOM images, it’s necessary to obtain a 3D reconstruction of the region of interest, based on bone structure selection on consecutive slices.

The bone selection process is a semiautomized task that also requires a manual correction (cleaning the DICOM images) of the bone geometry applied slice by slice. If the image contains multiple artifacts, the time of processing the image increases significantly. The importance of this step lies in the fact that if not performed in the first step of the processing procedure, then the graphical reconstruction will be filled with vertex units (a measurement unit specific to 3D graphic softwares), thus complicating the next step, where the cleaning process should be able to be performed automatically. Under these circumstances, we believe that Kernel B40S is the best fit for our needs. Not only does it highlight the bone structure with a medium satisfactory intensity but it has the great advantage of toning down the „noise” present in structures represented by muscles and soft tissue and therefore ease the next steps in operating DICOM data. If using a Kernel that is too smooth, one may risk fading the edges and limits of the bone area to be selected for printing and leading to an alteration of the original true shape or size of the bone. Processing the DICOM images was achieved using the Slicer 3D free license software.

3.2 The first 3D printed model of our study used for preoperative planning

For the first 3D printed model of our study to be used as preoperative planning tool, we used the following CT examination parameters: slice thickness of 1 mm and to rebuild the bone structure we used Kernel B40S (ultra sharp). After completing these tasks, the obtained data was imported in DICOM format (Digital Imaging Communications in Medicine) and uploaded in the 3D Slicer 4.6.2. for the selection and then reconstruction of the bone to be printed. Studies show that the existence of a strong and harmonious multidisciplinary collaboration, engaging the orthopedic surgeon, the radiologist and the IT ingeneer, is fundamental “[9],[13]”. However, in our case, the multidisciplinary team, responsible for printing the 3D



model, was assembled by the radiologist and the orthopaedic surgeons. Processing the imagistic data and creating the virtual 3D reconstruction came to be accomplished by an orthopaedic surgeon trained also in operating with these softwares. This proved to be a real benefit for our team, having to reduce in a significant manner the time and procedure of processing data. A professional trained not only in orthopaedic surgery, but also in operating with 3D processing softwares is capable to perform these tasks in a faster and more precise manner, due to his knowledge upon anatomy and also clinical, functional and pathological aspects.

The obtained data was saved as stl. format and uploaded to the WanhaoMaker Software. Following the completion of the processed virtual 3D graphic model comes the actual 3D printing step at a 1:1 scale. The size measurements of our printed models went up to 79.06mmX80.33mmX399.79mm and weighing the fact that our printer allowed printing objects with an upper limit size of 305mmX205mmX175mm, some of our models suffered a segmentation procedure and were assembled postprinting. Depending on how complex the anatomical deformity was, we chose to divide the model into 3-4 distinctive segments, this way decreasing the production duration and the quantity of material needed. A Bland-Altman analysis was used to evaluate the length measurement agreement between the 3D printed model and the patient’s CT (Fig 2). For the objects we printed during this study we used PLA (polylactic acid - (C3H4O2)n) and the printing settings were the following: Layer Height 0,25 mm, Wall Thickness 0,80 mm, Fill density 18%, Speed Print 50 mm/sec, Speed Travel 150 mm/sec, Speed Infill 85 mm/sec. The orthopaedic surgeon that accomplished the virtual 3D model was also in charge with the printing process surveillance and assembling the pieces into their final form, consisting in a 3D printed replica in a 1:1 scale, of great quality, suitable and ready to be used in preoperative planning, intraoperative activity and for doctor-patient discussions (Fig 3).

Fig 2 Bland-Altman analysis showing the relationship between measurements of 3D printed models in comparison with those of computer tomography images (mean difference 0.014, 95% LoA -4.222 to 4.250).

Preoperative planning practiced on a 3D palpable model comes with the following benefits:

1. The orthopaedic surgeon has at his disposal a life-sized



Fig. 3 Photographs of a 3D printed model of a congenital scoliotic spine.

Using the 3D printed model for doctor-patient discussions

The 3D printed model was at our disposal when engaging to the discussions held between doctor, patient and the patient's tutors. Explaining the patient's pathology on a 3D printed model, that embodied the exact specifics of the patient's spine and the deformities it suffered, but also explaining the surgical approach and steps that the patient will undergo, were far more accessible than we have encountered in our experience. Not only that the doctor's speech was considerably facilitated but the level of understanding and documentation pertaining to the patient's carers gave us the certainty of truly informing the patient and carers of the disease. Therefore, a better understanding of the pathology in question and acknowledgement of the severity of their disease led to a more realistic postoperative prognosis due to the patient's gained knowledge regarding the surgical limitations determined by a severe spine deformities.

4 RESULTS

Here are some guiding coordinates we should follow in our work protocol when using 3D printing for preoperative planning:

1. The biomodeling technique along with 3D printing offer personalized 1:1 replicas, that faithfully represent the patient's anatomical particularities, that may be further used to assemble an elaborate preoperative planning with the chance to practice the surgical maneuvers that are to be performed upon the patient. In the O.R. the 3D printed model finds its purpose in detecting vertebral important marks and establishing the pedicular screws' trajectory. These considerable advantages bring us closer to a complete understanding of the studied pathology and lead us to superior therapeutical decisions.
2. Concerning the first model printed in our study the amount of time spent on graphical processing was considerable, having to do not only with the extremely complex deformity, but also with the set of parameters we used in our CT acquisition (Kerner B90s ultra sharp, reconstruction at 3 mm). This way, for our next models, in collaboration with the radiologist, we upgraded the parameters to adequate standards (Kerner B40s sharp, reconstruction at 0.75 mm) and managed to obtain a decrease in the postprocessing time and an increase regarding the models' quality.
3. The selected area to be analyzed and printed was too

model, tangible and containing all of the patient's anatomical particularities

2. A better understanding of the anatomical or pathological particularities of the body segment in question with the help of a tridimensional representation of the bone defect.

3. The Bland-Altman analysis proved an accurate concurrence between the dimensions of the medical images and the ones of the 3D-models, allowing the doctor to perform exact measurements (length, girth, angles, diameters) upon the 3D model

4. Enabling a detailed study of the bone deformities secondary to scoliotic pathology, on the long term.

5. Establishing vertebra's particularities encountered in scoliotic pathology (counting vertebrae, identifying vertebral malformations: hemivertebrae, block vertebra).

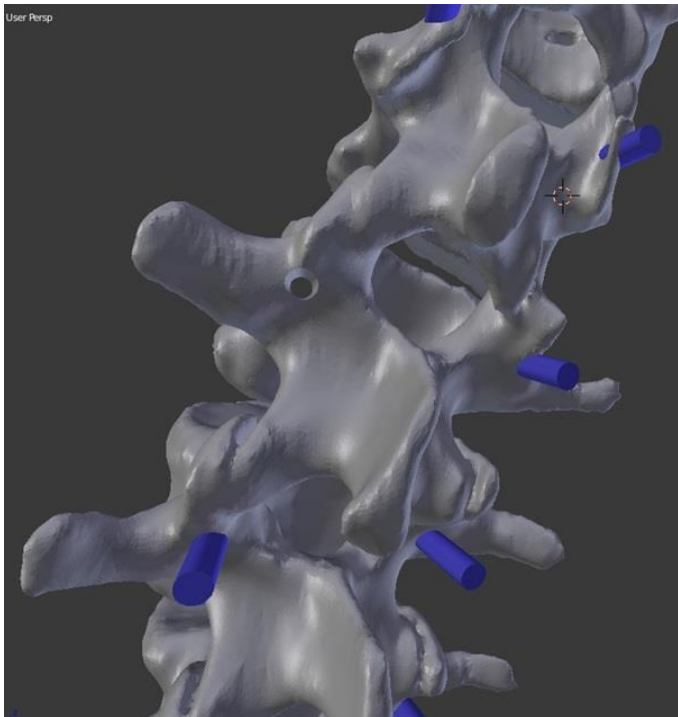
6. Setting the anatomical levels for the instrumentation system, entrypoints, and pedicular screws trajectories

7. Facilitating the intraoperative orientation in scoliotic pathology.

3.3 Intraoperative use

The first 3D prototype was used two times in the O.R., during the surgical intervention. The first time occurred when trying to identify the thoracic vertebra number 12 (T12) and the second time it was used intraoperative when inserting the pedicular screw through a highly deformed vertebra (T9).

The 7 surgeons subjected to this questionnaire found the 3D models to be very useful for surgical planning with an overall level of satisfaction that exceeded our expectations, all of them stating that they would further recommend this experience to other colleagues.



small, therefore we opted for a 3D model that would embody the whole thoracic and lumbar spine (T1-L5), along with the sacrum and iliac crests

4. For the rest of the printed models pertaining to our study, the CT acquisition parameters were set after the following coordinates: Kerner B40s sharp, reconstruction at 0.75mm. The selected area was expanded, thus including sacrum, for models No2 and No3, sacrum and iliac crests for the rest of our study's models. Other parameters remained unchanged since the original work protocol, previously mentioned. The enlargement of the targeted anatomical region brought new bone marks to serve as reference points and facilitate the detection of vertebral rotation in relation to the pelvic bones and the patient's position on the table.

Starting with printed model No 2, the solicitation rate during surgery exponentially grew, the model being requested for assessing pedicular screw's trajectory. This task is crucial for the surgical intervention's results. Having this in mind and observing how needed is such a tool during intervention, starting with our third model we incorporated in our process the virtual simulation of introducing the pedicular screws. Consequently, we brought in a new element to our work with biomodeling software, the virtual pedicular screw, that helped us select the optimal trajectories through the vertebral pedicles, for each screw in particular. In order to transfigure this information to our printed models, we extracted the pins (correspondents for screws) and left a tunnel-like hole in the pedicles that will represent the screws' trajectories. Intraoperative, Kirschner wires were inserted through these „tunnels“ for a better exposure. This practice led to an accelerated use of the printed model during surgical intervention and lowered the rate of using the X-Ray machine intraoperative (Fig 4)

5. The results we obtained applying this questionnaire to 7 surgeons, all of them involved in our study representing the surgical team responsible for treating the patients in our

study. Surgeons agreed that using 3D printed models in

Fig. 4 A detailed image of the CAD model depicting the ideal placement and trajectory of pedicular screws

assessing the spinal deformity was an undisputable improvement (7 out of 7). When asked about using 3D printed models for practicing surgical maneuvers against previous cases that didn't benefit from this technology, 7 out of 7 surgeons concluded that it was much better experiencing 3D printing as an adjuvant tool in medical practice. Concerning the level of presurgical preparation 6 surgeons considered that it was much better and one only better than not using 3D printed models. 5 surgeons believe that this is a much better alternative to avoid possible surgical complications. Also, 5 members of the surgical team agreed that using a 3D printed model in a case of scoliotic pathology reduces intraoperative time and decreases the intraoperative dose of X-Rays. One considered to be a better way to reduce these parameters and only one surgeon found no difference between the two instances, regarding this matter. In what concerns the doctor-patient relationship, 7 surgeons out of 7 decided that this experience was a much better way to conduct these discussions with the patients and their carriers and all of them also stated that they would further recommend this experience to other colleagues.

5 CONCLUSIONS

3D-printed models accurately replicate the patient's anatomy and are extremely helpful for planning surgery in complex diseases marked by severe deformities. They may potentially reduce operative time, surgical complications and morbidity.

During our study we found that, in order to obtain accurate and complete results, a work protocol is required, but also a harmonious collaboration between interdisciplinary members of the team is essential.

After receiving such a positive feedback from our medical team we are pleased to discover that surgeons find 3D printing models to be extremely helpful medical tools used to improve therapeutic outcomes and doctor-patient relationship.

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