THE UNIVERSITY OF MEDICINE AND PHARMACY

"CAROL DAVILA", BUCHAREST

DOCTORAL SCHOOL

THE FIELD OF MEDICINE

The Role Of 3D Printing In Scoliotic Pathology In The Pediatric Patient

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Content

1. The fundamental problem

This thesis presents a new approach regarding therapeutical, educational and diagnostical management of the scoliotic deformity of the spine in the pediatric patient. Starting from the desire to expand our knowledge in scoliotic pathology and guided by the search for new ways to improve treatment and diagnosis techniques we chose to explore the means of implementing a new tool in the medical approach of this pathology: 3D Printing Technology.

According to the chronological events, this paper is structured in two studies that express the two major objectives that this project is based on. In the first study we focused on using 3D printing in preoperative planning with virtual CAD model and a physical model (3D printed) of the affected spine. With the second study we explored the use of 3D printed personalized surgical guides.

2. Theory

In the light of latest studies and personal research in this new and exclusive medical sector we started this project based on the hypothesis that the use of 3D printing in current medical practice may revolutionize the therapeutical management od scoliotic pathology, having multiple benefits seen both in clinical and objective laboratory features and in the patients' and doctors' feedback, after beneficiating from this technology.

3. Objectives

The general objective for the first study was to analyze the impact of 3D printing being used in routine medical practice. We mention that the first study was conducted in real pediatric patients suffering from scoliosis and being treated in the Orthopedic ward of the Clinical Emergency Hospital for Children "Grigore Alexandrescu" from Bucharest.

First Study Objectives:

1. Assembling a Work Protocol
   a. The need to involve a multidisciplinary team (a radiologist, an IT Technician, an orthopedic surgeon) in the making of 3D printed anatomical models
   b. Establishing work guidelines in order to obtain high quality models suitable for preoperative planning use
2. Preoperative objectives
   a. Identifying structural alterations of the vertebrae
   b. Assessing the curve angle and severity
   c. Assessing the in situ rotation grade
   d. Accomplishing exact measurements
      i. Pedicle diameter
      ii. Pedicle length and vertebral body length
   e. Correct identification of entry-point
   f. Determining the future pedicle trajectories
   g. Selecting the proper vertebrae for surgical instrumentation
   h. Collecting intraoperative data based on the printed model in order to further compare with preoperative data
3. Intraoperative objectives
   a. Assistance in vertebral detection
   b. Assistance in choosing the entry-points
   c. Assistance in choosing the proper screw trajectories
   d. Allowing connections between superficial bone surfaces seen intraoperative with deeper bone structures connected to them visible on the 3D printed model

e. Collecting intraoperative data based on the printed model in order to further compare with preoperative data

4. Objectives in medical-patient relationship
    a. A better understanding of bone deformities encountered in this pathology and how they impact the prognosis
    b. A proper understanding of the surgical procedure and its implications
    c. Assembling a realistic therapeutical plan and understanding the therapeutical limitations in complex pathologies
    d. Increasing the level of patient compliance due to a better understanding of all the treatment steps
5. Educational objectives
    a. Using 3D printed models by doctors in order to achieve a better understanding of the patient's pathology and anatomical specific features
    b. Using 3D printed models by doctors in order to simulate surgical procedures on printed models
    c. Training young medical interns in complex pathology that require complex surgical procedures, difficult to comprehend
    d. Using 3D printed models as part of teaching protocol for medical students
6. Long term objectives
    a. Creating a large tridimensional database of pre- and post- operative information
    b. Analyzing the modifications visible right after surgery by comparing them to the 3D model that was previously printed
    c. Identifying potential loss in rotation in long term checkup

4. Materials and methods

The entire process around preoperative planning based on 3D models is a very complex process that requires a multidisciplinary team (an orthopedic surgeon, a radiologist, an IT technician and a computer programmer with CAD design training).

This 3D printing process enabling this type of preoperative planning, has the following steps **Fig 1**:

1. Obtaining DICOM data of the region of interest
2. Creating a CAD model representing the region of interest
3. The actual 3D printing of the model

It is necessary to involve a multidisciplinary team consisting of pediatric orthopedic surgeons and pediatric radiology as main components, therefore this project required a well established work protocol involving the radiology department at Emergency Hospital for Children "Grigore Alexandrescu". We use this opportunity to express our gratitude towards the team led by Stefan Bogdan Olteanu MD (Head of Radiology Department) for their excellent collaboration. The 3D graphic data processing of the DICOM images along with the entire printing process were accomplished the undersigned, Liciu Eduard MD (orthopedic surgeon) with special training in this field. The opportunity to assign these tasks to a single member of the team that possesses medical and surgical skills but also skills in 3D graphic design and printing proved to be a great advantage. As we said the doctor in charge with post processing DICOM images can achieve an accurate and precise selection of the anatomical section of interest and in a shorter period of time.

The work protocol has the following steps:

1. Obtaining DICOM images of the anatomical region of interest
2. Post processing DICOM data
3. Obtaining a CAD model of the region of interest
4. CAD model post processing
5. Export CAD model in stl format
6. Slicing process
7. Create Gcode and print the model
8. Analyzing the 3D printed model

   Integrate the model in medical practice)

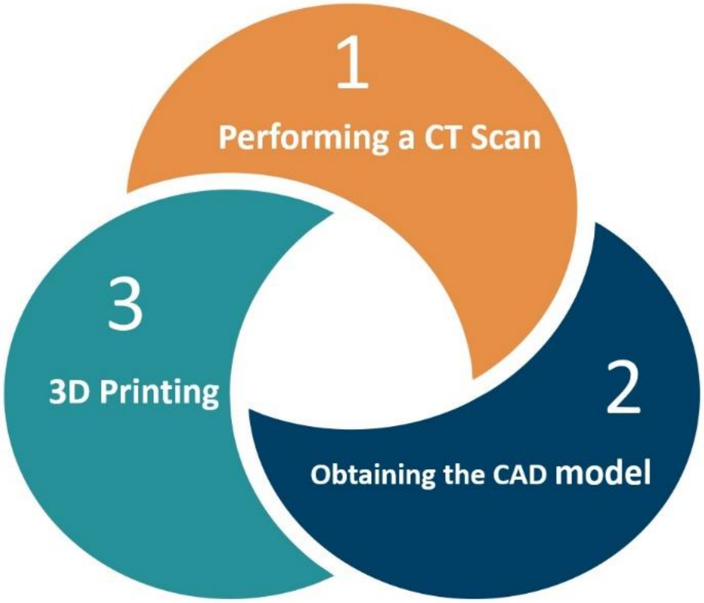

Fig 1 The process of 3D printing in medical field

5. General Part

Scoliosis is a spinal deformity that can affect segments of varying lengths of the spine and consists in the concomitant existence of lateral curves and vertebral rotation. This condition present in all three spatial planes (sagittal, frontal and transverse) is incompletely reducible. Treatment for this condition offers three major options: physical therapy, bracing (corset) and surgical treatment. Therapeutic goals are to prevent progression, correct existing curvature and maintain the correct position. The surgical indication in the treatment of scoliosis is considered in scoliosis with a Cobb angle greater than 40-45 °. The basic principle used in the surgical approach to scoliosis is intervertebral arthrodesis. The instrumentation used can remain incorporated in the patient for life without greatly disrupting the normal activities of the individual.

3D printing is a process of making a solid object, with any shape (geometry), a process that involves the successive deposition of layers that ultimately form the physical 3D model. The process starts from a graphic 3D model (volume) which is processed by a slicing process (slices on the Z defined axis), by assigning some printing parameters and which is executed layer by layer by a 3D printer in order to obtain the physical 3D printed model. The history of 3D printing in medicine began in the early 1980s with the first documented use of 3D printing technology in 1981. From the beginning, 3D printing technology is adopted and rapidly implemented in the field of medical research, where its benefits are recognized one by one. exponentially increasing the degree of use on different levels of research. 3D printing has registered a continuous development, a development that aimed both at the development of new and new 3D printing techniques, the improvement of the initial techniques by the continuous improvement of 3D printers and by the development and diversification of 3D printing materials. All these aspects have led to a decrease in the price of 3D printers, a decrease in the prices of 3D printing materials and consequently an exponential increase in the use of this technology in the medical field and beyond.

As mentioned above, this paper is structured in two studies that analyze and explore the usefulness of 3D printing in scoliotic pathology. In the first study we followed the use of 3D printing in the preoperative planning of vertebral deforming pathology, following the second study in which we decided to extend the study in a more practical direction by introducing virtual planning and 3D printing, but also 3D printed surgical guides.

II. Studiu I

Study I was conducted within the Pediatric Orthopedics Department of the Emergency Clinical Hospital for Children "Grigore Alexandrecu" Bucharest. During the study, patients with scoliotic pathology who underwent medical investigations and treatment in the Pediatric Orthopedics Department mentioned above, were analyzed for inclusion in the study. In order to include the patients in the study, a series of measures were taken to comply with the deontological norms of the research.

During the study, for the patients selected in the study, a number of 35 3D printed models involving segments of the spine or the entire spine (cervical-thoracic-lumbar and sacral) were made. The study included 33 patients, 24 girls and 9 boys, with scoliotic pathology: 4 patients with kyphosis (4 boys), 1 patient with neuromuscular scoliosis (1 girl) and 28 idiopathic scoliosis (5 boys and 23 girls). All patients included in the study benefited from 3D printed models in preoperative and surgical treatment.

Preoperative planning on a tactile 3D model brings the following advantages:

1. The orthopedic doctor has at his disposal a life-size model, palpable with the anatomical particularities of the patient for the preoperative planning.
2. Understanding the anatomical features of the evaluated region, three-dimensional highlighting of bone changes / malformations.
3. Making accurate measurements (length, diameter, angles) on the palpable 3D model.
4. The study of bone deformities following scoliotic pathology with long evolution.
5. Establishment of vertebral peculiarities in kypho-scoliotic pathology (counting vertebrae, identification of vertebral malformations: hemivertebrae, vertebral blocks).
6. Establishing the level of instrumentation, entry points and trajectories of pedicle screws in scoliotic pathology.
7. Facilitates intraoperative identification in kypho-scoliotic pathology.

The intraoperative use of 3D printed models facilitated the vertebral finding, the process of locating the entry points, the choice of optimal trajectories for the pedicle screws, as well as a better correlation between the bone planes exposed in the wound and the deep bone planes.

The use of 3D printing technology in the doctor-patient relationship

The printed 3D model allowed its use in communication with the patient and his relatives. The explanation on the 3D model of the scoliotic pathology, of the deformities appeared as well as of the surgical procedure were facilitated. A good understanding of the evolutionary stage of scoliotic pathology, allowed the realization of a realistic postoperative prognosis, the patient understanding the limitations of surgical correction due to severe deformities.

Conclusions for Study II

The need to use 3D FDM printers with higher 3D printing volume and more 3D FDM printers to reduce production time.

The need for comparative analysis between FDM technology and other types of 3D printing technology (eg SLA, MSLA, DLP) that can allow printing at a higher resolution of 3D printed models, as well as the use of biocompatible materials, resistant to sterilization chemical and thermal.

The need to use 3D printers whose 3D printing volume allows the printing of an integral column (cervico-thoraco-lumbosacral as well as the pelvis) integral or segmented in as few parts as possible.

The need to design, develop, implement customized guidance devices in order to choose the entry points of the pedicle screws in a way that is as precise as possible, less chronophagous and requiring as few uses of the intraoperative scope.

III. Study II

The second study was conducted at the Clinical Hospital for Children "Dr. Victor Gomoiu" during

The following period: January 2020- August 2021. This study was designed to apply the previous work protocol in the new Hospital, to follow a preoperative planning routine based on 3D printed models and to use 3D printed personalized surgical guides for patients with scoliotic pathology diagnosed at this hospital. During this study, the patients suffering from scoliosis were investigated and treated in this ward and selected after thorough examination to participate in the study.

Seeing how the pandemic overlapped with our ongoing study and the restrictions no longer allowed to treat chronic patients, the study continued to resume it's activity but abiding to the new restrictions. We followed a strict set of rules to comply with the deontological protocol of medical research. The patients as well as their tutors were informed and asked to sign a consent agreement before entering the study in order to make sure they fully understand their participation.

In study II, two female patients diagnosed with idiopathic scoliosis were registered, for whom 4 3D printed models of the integral spine plus pelvis were performed, models were performed based on imaging investigations (Computer Tomograph) performed pre and postoperatively, as well as the second set of 3 3D printed surgical guides for a number of 3 apical vertebrae for each patient. The guides allowed the easy identification of the entry-points of the bilateral pedicular screws, as well as of the drilling from the posterior to the anterior, on the ideal trajectory for the pedicular screws.

The process of designing a customized surgical device in Study II took place in two stages:

- Stage I creation of a personalized surgical guide model starting from the particularities of the target vertebra and the relationship with the rest of the anatomical structures
- Stage II modification of the design according to the analysis of the finite elements of the model I, in order to improve the mechanical performance of the model.

The models were made with LowForceSLA technology, using biocompatible resins and were used intraoperatively. Following the intraoperative use and the analysis performed, we formulated a series of advantages and disadvantages of using customized 3D printed surgical guides.

Second Study Objectives:

Considering how well the first part of the study underwent we decided to continue exploring the use of 3D printing in scoliosis management and in medicine in general. Therefore, in the second part of the study, besides the first study objectives previously mentioned we will also analyze the following:

a. The need of a larger number of FDM 3D printers in order to significantly decrease the printing time per model
b. Using FDM printers with a higher capacity to reduce the number of pieces assembling the final spine

c. Using other 3D printing technologies (SLA, MSLA, DLP, LowForceSLA) and comparing them to FDM
d. Using other printing materials (UV resin) for preoperative planning but more important using a special UV resin that can undergo a sterilization process to create surgical devices serving as intraoperative guides for proper screw placement and precise entry points
e. Analyzing complete elements of the surgical guide
f. Using 3D printing to facilitate the pedicular screw fixation
g. Due to several events occurring in my professional life (changing the place of work, pandemic context) certain objectives pertaining to the first part of the Study were readdressed in order to ensure the proper function and purpose of our study in the new accommodating hospital
    - The need to involve a multidisciplinary team (a radiologist, an IT Technician, an orthopedic surgeon) in the making of 3D printed anatomical models
    - Establishing work guidelines in order to obtain high quality models suitable for preoperative planning using the radiological equipment of the Clinical Hospital for Children "Dr. Victor Gomoiu" from Bucharest and following the appropriate parameters for using these models in preoperative planning.

a. .

Advantages of custom printed 3D surgical guides:

1. Use of a custom device to establish entry points for pedicle screws and drill transpedicular under the guidance of the device
2. Decreasing the time required to perform these surgical steps
3. Personalized device made on the basis of imaging investigations of the patient within the extended preoperative planning
4. Custom device made with LowForce SLA 3D printing technology, extremely precise technology
5. Personalized device made of biocompatible, sterilizable, radiolucent material.

6. The design of the model II is much more resistant, no changes in shape are observed when applying external forces

7. The design respects the local anatomical features

8. Unlike model I, it no longer rests on such a large area of the vertebra, which is why appropriate dimensions could be used to increase the strength of the model.

9. The reinforcing structures have improved their mechanical properties by providing better resistance to impact as well as to the forces discharged on the guide at the time of use,

10. The reinforcing structures facilitate the manipulation of the model, its positioning and support when inserting Kirschner pins through pedicles to the vertebral bodies.

11. The use of finite element analysis of the surgical guide before manufacture has led to the identification of the weaknesses of the model, the way in which the forces are dispersed (uniformly or unevenly) and the identification of regions where the model will be deformed during maneuvers.

12. Possibility to adapt the model according to the FEA results, without the need to print a model and expose the model to the simulation of surgical maneuvers in order to test the resistance

13. The use of 3D printed surgical guides is increasing

a) Safety by reducing the time of anesthesia, reducing intraoperative complications, reducing the time of exposure of the patient to intraoperative conditions of ischemia, radiation or bleeding.

b) Efficiency by reducing the duration of the intervention and complications intraoperatively and remotely

c) Improves results by increasing surgical accuracy, improving the doctor-patient relationship by increasing compliance with treatment and reducing the number of surgical reoperations.

Disadvantages of 3D printed surgical guide technology LowForce SLA:

1. The need to develop and implement a workflow adapted to virtual planning and 3D printing (printed planning and surgical guides)

2. The Multidisciplinary Team involved in the process of creating virtual planning, 3D printing and surgical guides

3. The need to include in the multidisciplinary team a specialist in 3D graphics and 3D printing

4. Additional time for 3D reconstructions, surgical guides

5. Additional time for creating a graphical model on which the analysis of finite elements can be performed
6. It is necessary to use a license for FEA dedicated software
7. Requires hardware devices with high-performance properties to support the finite element analysis process,
8. Expensive technology (both equipment and consumables are more expensive compared to FDM technology)
9. The need for a laborious post-processing process (Washing with isopropyl alcohol, finalizing the curing process by exposure to UV and heat - dirty technology that requires additional devices)
10. Biocompatible material, sterilizable but brittle (NOT shock resistant)
11. The material from which the guide is printed is semi-transparent which makes the guide difficult to identify in the intraoperative wound, difficult to assess the relationship with other anatomical structures
12. The introduction of reinforcement structures, to improve the mechanical properties, for a better resistance to impact and to the forces discharged on the guide at the time of use, led to the obstruction of the intraoperative field, being quite difficult to verify the position of the guide on the vertebra .

Another objective of the study was the implementation of 3D printing in the university field. In order to obtain this desideratum, we have held numerous presentations, workshops, conferences in international and national congresses as well as in student congresses. The interest of students in the field of 3D printing has been very high from the beginning and has grown steadily, leading them to actively participate in various events on 3D printing held within the Romanian Medical Association for 3D Biomodeling whose president and founder are . An important moment for achieving this goal was the inauguration of a 3D printing laboratory within the Innovation and eHealth Center within UMFCD, a laboratory that offers students the opportunity to learn 3D printing and use it in university projects.

IV. Published works

Articles

1. Liciu E, Frumuseanu B, Golumbeanu M, Sterian AG, Popescu MB, Tevanov I, Ulici A, The Use of 3D Printing in Preoperative Planning of Scoliotic Pathology, International Journal of Scientific & Engineering Research Volume 10, Issue 10, October-2019 ISSN 2229-5518, 1296-1302
2. Tevanov I, Liciu E, Chirila MO, Dusca A, Ulici A. "The use of 3D printing in improving patient-doctor relationship and malpractice prevention." Rom J Leg Med. 2017;25(3). doi:10.4323/rjlm.2017.279
3. Ulici A, Liciu E, Dima A, Frumuseanu B, Mihai MM, Murzac R, Ionescu S, 3D Printing - An Easy and Efficient Method to Fabricate High-Resolution 3D Printed Models for Medical and Educational Purposes, International Journal of Scientific & Engineering Research Volume 10, Issue 2, February-2019 774 ISSN 2229-5518, pag 774-778.
4. Liciu E, Mihai MM, Carp Ș, Popa L, Vreme C, Vlad C, "3D PRINTING IN PEDIATRIC ORTHOPEDICS – THE NEW GENERATION OF PREOPERATIVE PLANNING IN THE FIELD OF PEDIATRIC ORTHOPEDICS" *JSS*, vol. 7, no. 3, pp. 85-92, Dec. 2020.https://doi.org/10.33695/jss.v7i3.39.
https://journalofsurgicalsciences.com/index.php/jss/article/view/390

Presentation

1. The XVII National Congress of Orthopaedics and Traumatology 18-21 octombrie 2017 Timisoara – Speaker "Printare 3D in Medicina NGP - Spine"
2. 8 International Conference "Biomaterials, Tissue Engineering & Medical Devices" 27-29 September 2018, Cluj Napoca - Speaker "3D Printing - High-Resolution 3D Printed Models for Medical and EducationalPurpose"

3. WOFAPS 2018 Bucharest Annual Meeting "Integrated approach for better children' outcomes – avoiding disability - Speaker "THE USE OF 3D PRINTING IN SURGICAL PLANNING FOR CONGENITAL SCOLIOTIC PATHOLOGY". Certificate ID 140
4. CAMP 2018 - Organizația Tinerilor Medici Cluj - Napoca 26-28 octombrie 2018, organizator și speaker în cadrul Work-Shopu-ul: "Printarea 3D în Medicină" 27 octombrie 2018, Cluj- Napoca. Work-Shop realizat în parteneriat cu Organizația Tinerilor Medici - AMRB3D:"3D Printing Activity","Medical Imaging The Evolution: Shifting From 2D To 3D","3D Printing in Medicine"
5. Organizator si Lector in cadrul Conferintei "3D Printing in Medicine: The new age of Personalised Treatment Conference" desfasurat in cadrul The International Medical Student's Congress of Bucharest 05-09.12.2018 Serie IMSCB no. 10502 code 5017.
6. Organizator si Lector in cadrul Work-Shop-ului "3D Printing in Medicine" desfasurat in cadrul The International Medical Student's Congress of Bucharest 05-09.12.2018 Serie IMSCB no. 10502 code 5017.
7. Organizator si Lector in cadrul Work-Shop-ului: “3D printing: from CT scans to bones” 4 th edition of Medics – Medical International Conference for Students 11-14 aprilie 2019
8. Organizator si Lector in cadrul Work-Shop-ului: “3D printing in Medicine” 3 iunie 2019, Work-Shop organizat in cadrul Scientific Organisation of Medical Students – SOMS.
9. Lector și organizator în cadrul Work-Shop-ului "Printarea 3D parte a tratamentului personalizat" desfășurat în cadrul proiectului TransMed 10-16 noiembrie 2019.

Poster

103 Congresso Nazionale della Societa Italiana di Ortopedia e Traumatologia, Bari 9-12.11.2018

Prezentare tip poster abstract N°. 1011: "Stampa 3D in patologia scoliotica" deplasare realizata in cadrul proiectului FDI nr.0547/ 2018, Universitatea de Medicină și Farmacie „Carol Davila” din București funded by "National Council for Higher Education, Ministry National Education".

National and International Grants and Projects

1. „Educatie inovativa pentru studentii UMFCD prin dezvoltarea bazelor de practica in Printarea 3D, Simulare Medicala, Telesemiologie si Big Data – INNOV.STUD" – CNFIS-FDI-2021-0531 functie Coordonator Departament de Printare 3D CieH
2. " PRINTARE 3D – NOUA GENERAȚIE DE PLANNING ÎN CHIRURGIA SPINALA "(NGP SPINE), contract nr. 9288/04.04.2017, funcția: Membru în echipa de cercetare, grant finalizat conform Raportului final și notei informative 177/18.12.2019.