CAD-Aided Preoperative Simulation in Complex Orthopaedic Surgery

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Abstract

This work aims to present the application of mechanical modeling software in three dimensions in the medical field, analyzing the procedures used by the engineer to support the orthopedic surgeon in preoperative planning.
The first step of the procedure involves CT examinations in patients selected for surgery: DICOM images are managed in post-processing to obtain multiplanar reconstructions of the bone lesion to be treated.
The files are then optimized, made shareable and imported into CREO's work platform; this is part of a family of CAD software products for mechanical design, developed by PTC, and is the fundamental application dedicated to parametric modeling. The result will be a faithful representation of the anatomical part both before and after surgical procedure, screening all the intermediate phases.
The doctor will assess different lines of action according to the results, than he will communicate them to the engineer who, consequently, will correct and regenerate the model.
The method finds its power in the dialogue between engineer and doctor: in complex cases closer collaboration is needed while, for the evaluation of less demanding injuries, the exam could be assigned as a remote project which, once completed, is returned to the medical facility of competence.

Keywords
3D modeling, surgical simulation, computer aided, preoperative planning, parametric software.

1. Introduction
Due to changes occurring in healthcare systems around the world, there has been an increasing demand for efficient orthopedic surgical simulation systems, preoperative planning has therefore evolved over time following technological progress and taking advantage of the latest discoveries.
Moreover, increasing emphasis on patient safety has considerably limited the timing in the operating room and the possibility of testing new methodologies involving real patients. (Badash et al. 2016)
In this paper we want to illustrate the next step by guaranteeing specialists not only the visualization of the three-dimensional reconstruction of the anatomical parts, but also their modeling, dissecting and altering them according to the purpose, thanks to the application of a 3D CAD software.
Computer-aided surgical simulation (CASS) is becoming an increasingly important means of improving skills acquisition, optimizing clinical outcomes and promoting patient safety in orthopaedics and traumatology but, while

there have been great strides in other fields of surgery, CASS is in its relative infancy within paediatric orthopaedics (PO). (Sariali et al. 2016)
This work is the outcome of a partnership between the Department of Industrial Engineering of the University of Bologna and the Rizzoli Orthopedic Institute of Bologna, whose staff has allowed us to access the complex clinical cases that are the foundation of the study presented here. The aim of this collaboration is to present an in-house low-cost CASS process in paediatric orthopaedic surgery with the specific use of CREO Parametric, a mechanical modelling program, for the development of the simulation of surgery.

1.1 Objectives

Here is presented an in-house low-cost method that can provide a file that faithfully represents an examined anatomical component. The 3D model will be edited at will to ensure an effective analysis by the surgeon and a correct diagnosis of the pathology. Moreover, it will be possible to simulate through the use of the CREO Parametric software the phases of the corrective surgery, keeping all the subsequent steps adopted saved, as well as the final model with the outcome of the operation.
With the tools listed above, the doctor is able to estimate the extent of the injury or pathology and then decide how to solve them, immediately appreciating the results, minimizing the risks to the patient and evaluating more solutions thanks to the simulations
The patient himself also finds obvious advantages: in addition to seeing the impact of the operation on his body limited to a minimum, he can become aware of all the phases of the treatment that will be carried out with perfect transparency as the doctor will be able to explain, in much more detail, the characteristics of the disorder and the methods of intervention.

2. Literature Review

In the last decade, literature has shown that medical research is based on simulation-based medical education. The points that are treated by the researchers include: feedback, skills acquisition, simulation fidelity and timing. (Mediouni and Volosnikov 2015)
There is an increasing expectation of improved performance, patient safety, and fiscal responsibility that can only be satisfied with a technological development in methods for the analysis and solution of pathologies. (Bae 2015)
In the field of maxillofacial treatments, the use of 3D technologies is already widespread and several proposals can be found for efficient simulation methods. The complexity of the anatomy has made it necessary to use advanced tools since the acquisition of data as in Clinical Feasibility of Computer-Aided Surgical Simulation (CASS) in the Treatment of Complex Cranio-Maxillofacial Deformities (Gateno et al. 2007), 3D planning in orthognathic surgery: CAD/CAM surgical splints and prediction of the soft and hard tissues results (Aboul-Hosn Centenero and Hernández-Alfaro 2012) and Accuracy of a computer-aided surgical simulation protocol for orthognathic surgery (Hsu et al. 2013), all searches starting from CT scanning flanked by jig models, digital viewers and laser scanners. In addition to the analysis tools, interesting simulation methods of osteotomies have been developed in maxillo-mandibular surgeries, in A novel method of computer aided orthognathic surgery using individual CAD/CAM templates (Li et al. 2013) is shown the effectiveness of the use of parametric software (Unigraphics NX 7.5) in creating orthognathic templates while in Three-dimensional surgical simulation (Cevidanes et al. 2010) the dedicated PROPLAN CMF™ software, specific for cranio-maxillofacial surgery applications, is used.
In the orthopedic field, on the other hand, research is less developed and the difficulty in devising an effective methodology without causing an increase in timing and costs has led many to question the usefulness of aided CAD methods as explained in the script To simulate or not to simulate (Dutta 2006). Although the use of 3D technologies proves to be expensive for simple pathologies, orthopedic surgeons have shown a lot of interest in their application in complex articular bone fractures (e.g., foot, wrist, hand, knee). To date, various paths have been designed for the reconstruction of a virtual model of anatomical parts but the next step in creating a method to fully simulate surgical operations in detail is missing. A valid option is to use dedicated medical software: in Accuracy of the preoperative planning for cementless total hip arthroplasty (Sariali et al. 2012) make use of the Hip-PlanTM software (Symbios, Yverdon, Switzerland), which deals only with hip arthroplasty planning while in Integration of CAD/CAM planning into computer assisted orthopaedic surgery (Wong et al. 2010) the model is transformed into three dimensions and create customized bone prostheses for the patient via MIMICS software. In Application of computer simulation in the treatment of traumatic cubitus varus deformity in children (Jiang, Li, and Wu 2019) MIMICS is used for the simulation of osteotomy. With the work “Double Level Osteotomy Assisted by 3D Printing Technology in a Patient with Blount Disease: A Case Report” (Gómez-Palomo et al. 2020) have developed a methodology to solve a Blount disease through a Tibial osteotomy with the specific cutting guide designed on the computer and customized on the

patient. Another interesting research is the one presented in Patient-specific 3-dimensional printing titanium implant biomechanical evaluation for complex distal femoral open fracture reconstruction with segmental large bone defect: A nonlinear finite element analysis (Wong et al. 2020) where a novel titanium 3D printing patient-specific implant, starting from a model made with parametric software, is presented. In Patient-specific three-dimensional printing for pre-surgical planning in hepatocellular carcinoma treatment (Perica and Sun 2017) the possibility of applying research to soft tissues is also addressed, but for the used technologies it is ineffective. Some studies of the same character have been carried out on cadavers to test methods of simulation and realization of customized three-dimensional jigs: tow examples are Improving the accuracy of wide resection of bone tumors and enhancing implant fit: A cadaveric study (Helguero et al. 2015) and Use of a patient-specific CAD/CAM surgical jig in extremity bone tumor resection and custom prosthetic reconstruction (Wong et al. 2012)
It is also important to mention the works of which this study is the development: specifically, in New Methodology for Diagnosis of Orthopedic Diseases through Additive Manufacturing Models (Frizziero, Liverani, et al. 2019), it is shown a fast implementations of an additive manufactured bone model, converted from CAT data, through the use of free open-source software. This research has been supported using his method in two other studies, Description of the CAD-AM Process for 3D Bone Printing: The Case Study of a Femur (Frizziero, Donnici, et al. 2020) and Description of the CAD-AM Process for 3D Bone Printing: The Case Study of a Flat Foot (Napolitano et al. 2020).

2.1 Summary Paragraph:
Regardless of the different level of progress in the various fields of surgery, the large number of texts dealing with computed aided simulation testifies the interest and effectiveness of these techniques in solving complex traumas and pathologies. It commonly emerges that a balance must be struck between the accuracy of the simulation and the computational time required to analyze the model in order not to cause an increase in costs or a decrease in the accuracy of the treatment. (O'Toole et al. 1995)

3. Methods
The present study is a report of an ongoing prospective research aimed at developing, refining, and implementing in clinical practice specific CASS tools and processes, in pediatric orthopaedics and traumatology surgery with the specific use of a parametric mechanical software. (Frizziero, Liverani, et al. 2019)
The CASS process was accomplished according to the surgeons' preferences and experiences, thus, the study was not randomized and patients were not consecutive. Parents and carers gave consent for the study.
Two complex clinical cases were taken, in order to test the software abilities and the effectiveness of the method.

3.1 From CT to 3D Digital Model
The first step concerns the conversion of tomographic images into a three-dimensional model.
The program used is InVesalius, a free medical software able to generate virtual reconstructions of structures of the human body based on CT scans. The first operation to be performed in InVesalius is importing a DICOM (Digital Imaging and Communications in Medicine) format file, Figure 1, then there is the segmentation of the image using colored mask, gray threshold level, comparable to a certain tissue density, Figure 2.
The use of InVesalius generate 3D surfaces in standard triangulation language (STL), Figure 3, but the model is too heavy, computationally speaking, and is characterized by a thick structure that must be optimized, thus reducing the inner material. Moreover, the structure obtained have holes, cavities and, in general, imperfections that have to be resolved.
For shape optimization, we used MeshLab: it is essential to remove the material inside the object by deleting vertices and faces included in the inner cavity of the model, Figure 4. This can be accomplished using the "Ambient Occlusion" filter, which is a shading technique used to calculate how exposed each point in a scene is to ambient lighting.
The last step to obtain the finished surface is the processing in another free 3D modeling software called Meshmixer, Figure 5.
Compared to the method previously proposed in the research, the use of Blender, a computationally heavy software and not fundamental for the elaboration of the model, has been exceeded.(Frizziero, Santi, et al. 2020)
The model in output from MeshMixer is imported into the mechanical modeling CAD Creo Parametric, Figure 6.

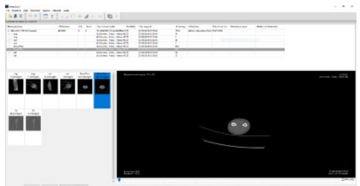

Figure 1. Tomographic image

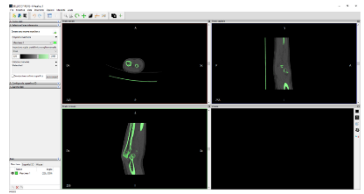

Figure 2. InVesalius mask

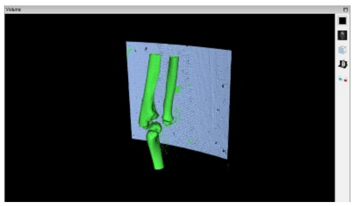

Figure 3. Virtual surface from InVesalius

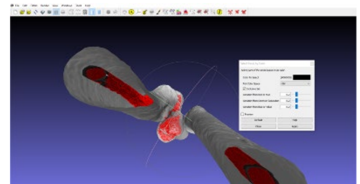

Figure 4. Ambient Occlusion in MeshLab

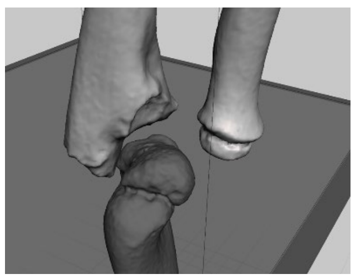

Figure 5. Finished surface in MeshMixer

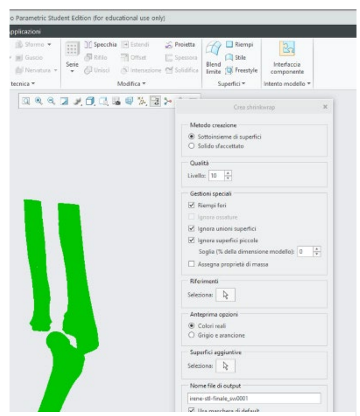

Figure 6. Import into CREO with Shrinkwrap

3.2 The Simulation

Simply importing the outgoing STL file from MeshMixer is not enough to be able to machine the anatomical components on CREO. This format, in fact, represents an object whose surface has been discretized into triangles and, although it is very easy to generate and process, is not recognized as a solid real workable by 3D modeling programs. To solve this problem is then used a conversion of the file to type "Shrinkwrap". It may happen that, depending on the complexity of the imported geometry, the obtained object presents surface’s defects that must be corrected before starting the simulation of the actual intervention.

We then proceed by identifying on the surface the remarkable points and plans necessary to give basic constraints, since, by importing a model outside the program, this assigns it only the three main planes automatically and it would not be possible a controlled handling of components.

The final elaboration of the model consists in the choice, depending on the pathology, of the bone segments to be divided and the parts that you want to obtain through the tools present in the dedicated areas of the program. After the subtraction, all the parts were available to create the assembly, set the right constraints, and simulate the intervention. A reference system was implemented to enable accurate assembly, maintaining the correct relationship among the bony segments: this elaboration have been performed entirely in the CREO’s ambient “assembly”, Figure 7.

On the side of the screen, you can see the machining tree where you can review and modify all the steps taken. The assembly model that represents the template for the operation can be saved as a single file and exported in various formats, Figure 8.

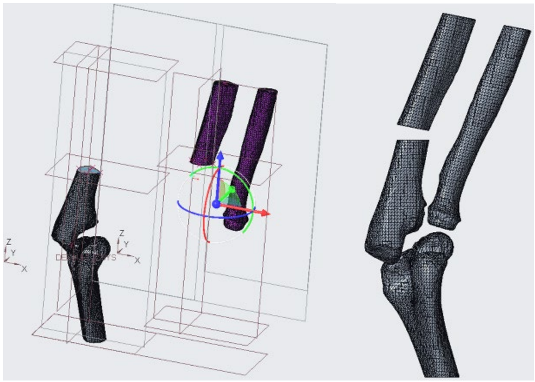

Figure 7. Simulation in CREO's ambient "assembly" for a right forearm

Figure 8. Finished and operated template for the femur.

4. Data Collection

Acquiring information for the reconstruction of the three-dimensional model starts from the computed tomography examination on whose accuracy depends the fidelity of the anatomical reproduction that we are going to realize.
At this stage it is necessary to pay close attention to the density range that you want to export as this affects the accuracy of the three-dimensional surface.
Further processing with 3D modeling software should be applied without excessively exporting or altering the obtained surface. It is very important to set the right level in the quality section of the Shrinkwrap function in order not to alter the geometry of the studied component (the maximum level is recommended: 10). Table 1 associates the respective data acquisition methods to the various programs, used in the bone model reconstruction process.

Table 1. Data Acquisition

Acquisition system	CT	InVesalius	MeshLab	MeshMixer	CREO Parametric
Yardstick of accuracy for data selection	Number of sections selected during the exam	Density range set for the mask	Filter for selecting unnecessary geometries for simulation	"Strength" of the brushes for surface modification	Quality level in the Shrinkwrap function

5. Results and Discussion

5.1 Numerical Results

Taking as an example two complex cases where accurate preoperative planning is necessary, it is possible to show the advantages provided by the use of 3D technologies in the orthopedic field. At the end of the process a three-dimensional model, clean and ready for any 3D prints or for the accurate diagnosis of the pathology, a .asm file on CREO Parametric, containing all the phases of the simulated operation and a three-dimensional representation of the anatomical component operated, shareable in various formats, were made.
We have focused on obtaining a method that can facilitate the surgeon's work without causing an increase in cost times and, to do this, all free and easy-to-find software have been specially chosen, except for CREO.

In complex injuries or malformations, the method finds its power in the collaboration between engineer and doctor, two figures who must collaborate closely to best solve each phase of surgery and to reduce the time of organization.
Meanwhile, in the case of simple pathologies the exam could be assigned as a real project, with its specifications, which once completed is returned to the health facility of competence. (Xia et al. 2006)
To show the processing of several bones at the same time a forearm bone group was chosen, Figure 9, while, in the study of the femur we have shown the advantage of CREO's modeling function in making the various tools necessary for the operation, such as fixing screws or electromagnetic mold, Figure 10. The data of the models realized are easily measurable through the "measure" function in the analysis section of CREO with high precision. For the case of study on the radioulnar group, a comparison was made with the operation already performed, verifying the size of wedge to put and the relative positions between the various bones. The orthopaedic surgeons found to support of the CASS method very valuable, so much that they proposed to continue the research by testing the simulation procedure on a patient afflicted with a femur disease. In this case it was also possible to create the tools necessary for the insertion and securing of the electromagnetic pivot; the sizing was carried out through the use of specific catalogs (NuVasive 2020).

Figure 9. File obtained with CREO after simulation (above) and forearm operated after insertion of the wedge (below)

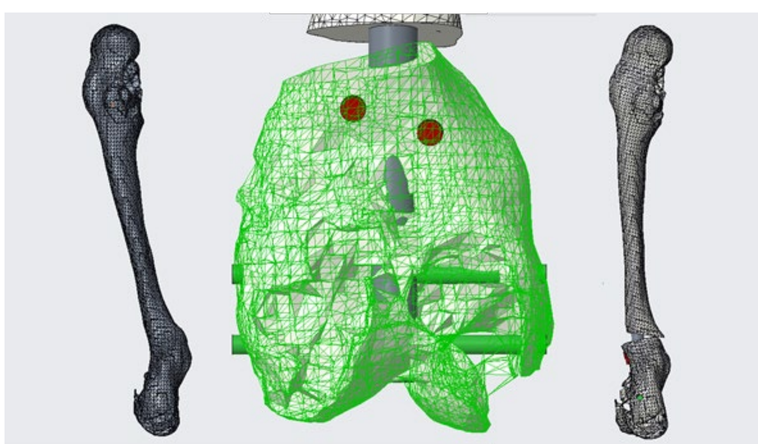

Figure 10. Correction of femur dysmorphism by inserting an electromagnetic value following osteotomy. Two screws (red) are also represented to guide the insertion of the pivot and two (green) for its fixing with the lower epiphysis

5.2 Graphical Results

Particular attention was paid to the timing of the implementation for the intermediate phases (the considerations given here involve individual work):

- The STL file from InVesalius is obtained very quickly, it takes a few minutes only for the selection of the components you want to maintain and for the choice of the density threshold.
- The time to make the three-dimensional model, clean and optimized in postprocessing, varies dependently of the complexity and extent of the component.
- For the two simulations presented here we used 1h for the and 40min for femur disease. Carrying out all the stages of the surgery on CREO takes longer but, approximately, the time needed is one day including the meeting with the surgeon for the choice of operations.

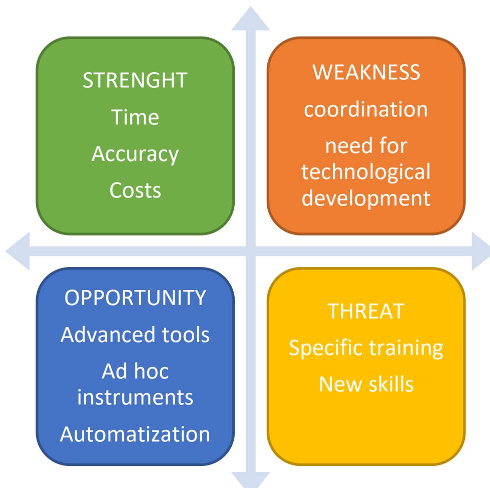

Figure 11. Issues of the method

A SWOT analysis was carried out to highlight the main aspects of the methodology, Figure 11.
The improved quality of the procedure has a strong impact on both the patient and the doctor. The former sees a reduction in the number of visits, achieves greater awareness of their surgery, and has lesser exposure to X-rays. The latter tests the procedure on the prototype and clearly defines the surgical plan, thus improving surgical outcomes.
Coordination between the doctor and the mechanical engineer can be a weak point. Proper collaboration is, thus, needed for the success of the prototype and to avoid inconsistencies in the actual anatomy of the reproduced bone. An optimal solution would be to entrust the realization of the model to professionals that are well-versed in both the medical and engineering fields.
Surgeons, radiologists, and engineers must develop new skills and assume new roles. Without specific training on specific software and hardware, there is the risk of incorrect implementation, subsequently leading to higher costs and stretched timelines. (Frizziero, Santi, et al. 2019)

5.3 Proposed Improvements

- Augmented Reality
  Using three-dimensional reconstructions as a basis, the phases of surgery could be replicated in augmented reality with the use of visor systems.
- Orthopaedic Training
  CAD files, which preserve pathologies and related interventional solutions, can also be listed and ordered to be reused as educational tools for doctors and medical students; it is clear that this process makes easier, especially for surgeons, practical learning by providing them with extensive documentation for both preparation and control.

6. Conclusion

The traditional methodology has certain limitations. The first is inaccuracy of the techniques used for diagnosis. This has prompted a desire to provide surgeons with tools that allow better understanding of the difficulties related to the anatomy of each individual case. Our study describes the application of a safe, effective, user-friendly, and low-cost CASS process to achieve a detailed and realistic representation of the anatomical region of interest, producing a high-customized copy of the patient bone.

The surgeons expressed their appreciation, providing positive feedback on the advantages that this technology can bring, particularly in the preoperative diagnosis phase. However, it is important to keep in mind that this type of research nowadays focuses on a very small number of patients and the applications of the method performed are still few. A recommendation for further future research could be to carry out a similar study expanding the number of patients involved in order to obtain a quantitative and not only qualitative assessment of the satisfaction of medical personnel. (Frizziero, Donnici, et al. 2019), (Liverani et al. 2019), (Francia et al. 2018).

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Biography

Leonardo Frizziero is a Senior Assistant Professor of the Department of Industrial Engineering, at Alma Mater Studiorum University of Bologna. He promotes the scientific issues related to the Mechanical Design and Industrial Design Methods (CAD 2D, 3D, Advanced Design, QFD, TRIZ, DFSS, DFD, DFA, ecc.). In 2005, he was recruited by Ferrari Spa, as project manager of new Ferrari cars projects. In 2009 he came back to University, obtained the Ph.D. degree and started collaborating with the Design and Methods Research Group of Industrial Engineering becoming Junior Assistant Professor in February 2013 at DIN of AMS University of Bologna. He teaches and follows researches in the design fields, participating at various competitive regional, national and international research projects. Since 2018 he has been a Senior Assistant Professor. Since 2017 he is qualified Associate Professor of Design and Methods of Industrial Engineering (ING-IND/15). Prior to the role of university professor, he held relevant positions for some industrial companies.

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Alfredo Liverani is a Full Professor and Chief of Mechanical Engineering Degree Course at the Department of Industrial Engineering of Alma Mater Studiorum University of Bologna. Prof. Alfredo Liverani is a member of CbEM (Computer-based Engineering Methodologies) research group and he is involved in several activities related to Computer Aided Design (CAD), Computer Graphics, Virtual and Augmented Reality. In detail he focuses on realtime visualization and interaction with particular attention to mechanical, aeronautical applications and also Industrial Design. Surface modelling, reverse engineering, mesh generation (FEM) and manipulation, virtual prototyping and live simulations are fields investigated in the several publications available at http://diem1.ing.unibo.it/personale/liverani.

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Stefano Stilli: Chief Surgeon of the Department of Pediatric Orthopaedic and Traumatology of the Rizzoli Orthopaedic Institute in Bologna.

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Paola Zarantonello, Stefano Stallone: Senior Resident at the Department of Pediatric Orthopaedic and Traumatology of the Rizzoli Orthopaedic Institute in Bologna.

The team is specialized on the orthopaedical disorders of the pediatric population, focused on the clinical and research activity about congenital, developmental and post-traumatic disorders of upper and lower limb, with particular interest about considerable deformities and rare diseases.