Title:
Design Automation of Lattice-based Customized Orthopedic for Load-bearing Implants

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Introduction:
Additive Manufacturing (AM) has emerged as a central factor in the transformation of the healthcare industry, as it has allowed the improvement of patient care in several clinical areas. In orthopedics, surgeons have reduced the invasiveness of surgical interventions, which can now be performed relying on customized tools specifically manufactured for the patient, and have improved the surgical outcome [1]. Patients' safety and satisfaction have consequently seen an increase in the last years [2]. More importantly, because AM allows for the rebuilding of severely damaged bones and the restoration of joint kinematics that would otherwise be untreatable, it is directly helping to the advancement of the medical field. In this scenario, the diffusion of custom orthopedic prostheses is hindered by the effort required to design such specific devices, whose shape and features are influenced by the patient's anatomy and anamnesis. Indeed, the design phase of such devices is cumbersome and time-consuming, as it involves different human skills (medical and engineering) and resources (medical imaging and 3D modeling software systems). This ultimately leads to a time-consuming process that implies significant costs.

The goal of the present work is to optimize and automate the design phase and 3D modeling of custom orthopedic implants, with the aim of making such devices more and more accessible, safer and with better performances compared to the state of the art. Specifically, regarding the automation of orthopedic implant design, an algorithm has been developed within nTopology [3] that is able to generate the 3D model of pelvic prosthesis in 2±0.15 minutes starting from simple CAD inputs. The goal is to develop a simple and effective tool within the reach of non-expert CAD users, reduce design time and the related costs.

Workflow:
The design process

The design process of custom implants can be resumed by the following Fig. 1, where the operations carried out by clinicians are represented in red, while those demanded to engineers and technicians are highlighted in blue.

The process begins with the generation of the required 3D anatomical models; these are identified and modelled, through a process called segmentation, from the diagnostic images of the patient; dedicated software is used to attain this result. Such models are used to plan the surgery and identify constraints that need to be enforced.

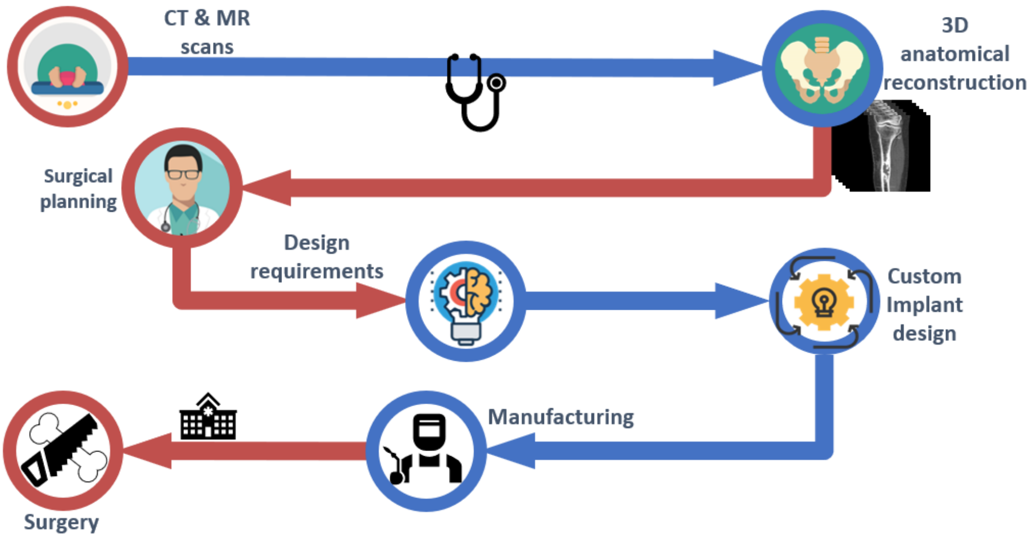

Fig. 1: Design workflow of custom devices.

Because various severe biomechanical and technological issues must be taken into account, this is by far the most time-consuming procedure. As a result, several iterations are often required before the final design is accomplished. A continuous confrontation between surgeons and engineers is typically required to design a product that is effective and well-built. When designing load-bearing implants that will face severe load conditions or will require an extreme optimization in terms of mass reduction, Finite Element (FE) Analysis can be performed to evaluate the interaction of the device with the surrounding tissues. However, this step is highly time-consuming and conflicts with the need to achieve the final design of the prosthesis as soon as possible, especially when dealing with oncological cases, which impose a narrow temporal window to counter cancer's advance. The final step of the process is, evidently, manufacturing; depending on the shape of the device and the technology, occasionally some modifications are required, even in this phase, to improve the quality of the product.

How to improve

The development of tools automatizing the design process could deliver significant advantages in terms of safety and reliability, as they could provide structure to a process that, nowadays, could be considered almost artisanal. Moreover, by reducing the time spent in the modelling phase, more resources could be spent of structural analyses, achieving a higher optimization of the design.

Ultimately, the goal is to make the design and production of custom orthopedic implants more efficient and accessible for patients. The design automation also delivers significant advantages in terms of product safety and reliability; in addition, by reducing the time associated with implant's modeling, more resources can be spent on FE analysis for a deeper biomechanical evaluation of the system and further optimize the design. This work focuses on pelvic implants to tackle the challenges introduced by the complex anatomical structure as well as the presence of numerous vital structures [8]. Nevertheless, the principles exposed in this work can be easily transferred to other anatomical districts.

In order to improve the current design strategy for orthopedic implants, where lattice structures are limited to a few millimeters at the bone-implant interface for osseointegration, in this work the devices are designed with an internal Gyroid-based lattice structure [4]–[6], which exhibits promising features for load bearing applications. The introduction of the lattice structure, besides mass and cost reduction, has the positive effect to match the global stiffness of the implant with that of the bone, thus mitigating bone remodeling effect due to stress-shielding [7]–[9], and providing a biomimetic environment which promotes osseointegration.

Design automation:

Several case studies, provided by the Department of Oncological Orthopedics of Careggi Hospital of Florence have been analyzed to get an insight of the design process of a custom pelvic implant and find the repetitive operations to be optimized and automated. 20 case studies have been considered, which included a wide variety of oncological cases as well as revision implants. The design process can be summarized as follows: i) Virtual anatomical reconstruction (acetabular parameters, mesh repair); ii) CAD modelling of the implant geometry; iii) Lattice infill design. Fig. 2 resumes these three phases.

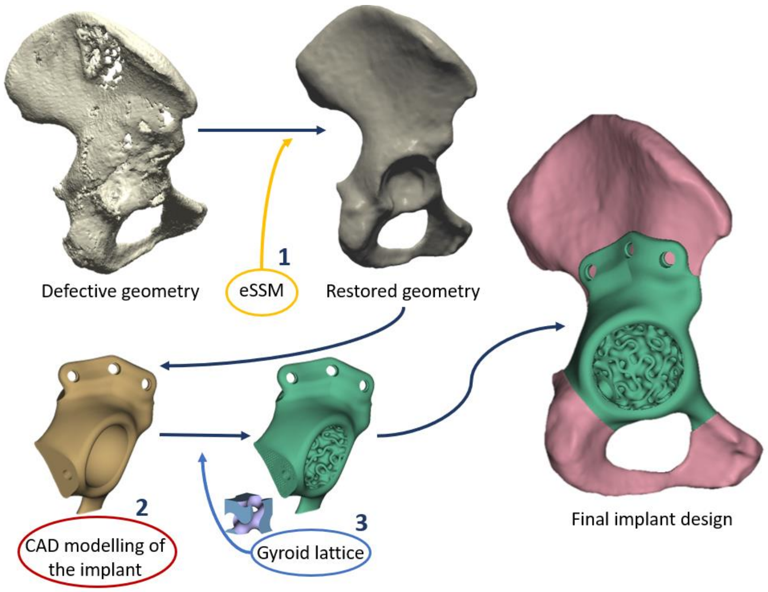

Fig. 2: Three steps for custom implant design.

Virtual anatomical reconstruction

To improve the virtual anatomical reconstruction phase, a dedicated tool based on Statistical Shape Analysis, named eSSM (enhanced Statistical Shape Model) [10], was developed. The tool exploits the knowledge acquired mapping several physiological anatomies to restore the shape of highly defective anatomies with no effort, with a great advantage in terms of time. The eSSM that was built in this application automatically evaluates anatomical inputs that are required to design an implant. Specifically, the eSSM presents to the user the position of the articular Center Of Rotation (COR) of the acetabulum and the acetabular orientation which can be exploited for the following CAD operations.

CAD Modelling

The second phase of the process, CAD modelling, is performed in a 3D implicit modelling software. The process automatization starts with the identification of the major variants of pelvic implants, which require a different series of modelling functions to be generated. Fig. 3 presents the three most common types of pelvic implants.

The first example depicted, Fig. 3 (a), represents a hemipelvic implant; among the cases considered, is the most invasive and, due to its typical large dimensions, the lattice infill is not easily applicable for manufacturing issues, mainly for the non-sintered powder removal. The second and third cases, Fig. 3 (b), Fig. 3 (c) can be manufactured with a lattice internal structure instead. The design of each type of implant is tackled with a specific modelling algorithm that is composed by a different series of functions and CAD operations.

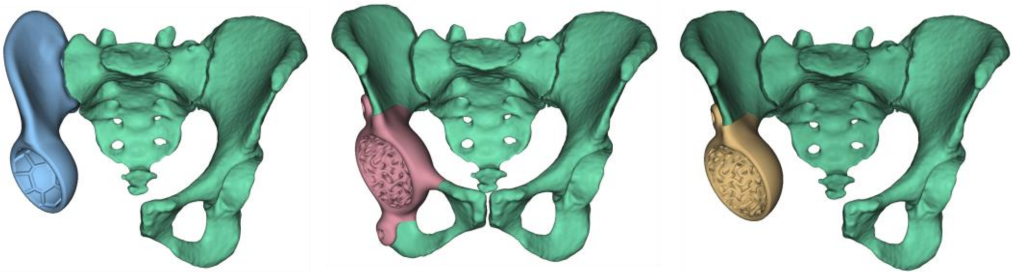

Fig. 3: (a) Hemipelvic implant, (b) acetabular implant, (c) acetabular implant with removal of pelvic ring.

Lattice Design

For this application, an algorithm has been developed within nTopology which encloses the repetitive CAD operations required, taking as inputs the polygonal mesh of the target bone, the resection planes, the acetabular parameters, namely articular Center of Rotation (COR) and acetabular orientation, a set of points corresponding to the location of the fixation screws and, whenever required, a set of CAD surfaces to trim undesired portions of the original bone. The user only has to set the desired values for the design variables, as flange height and thickness, dimensions of the acetabulum and lattice parameters, and the software delivers a ready-to-manufacture 3D model of the implant. Fig. 4 shows the implemented custom function in the nTopology environment.

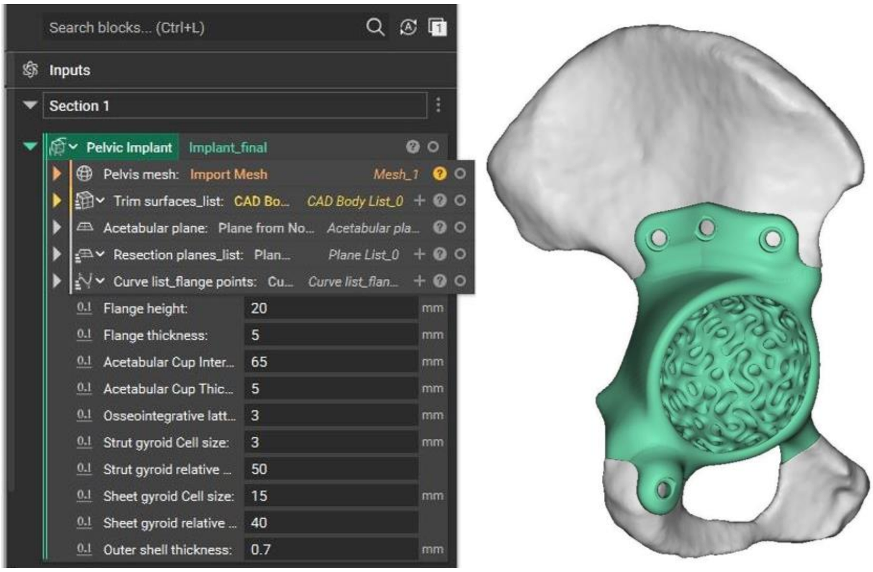

Fig. 4: Custom block in nTopology for acetabular implants.

Considering the third phase highlighted in Fig. 2, i.e., lattice infill design, nTopology offers advanced integrated functions for lattice creation which are integrated within the implemented automatic workflow. The implicit functions used by the software result convenient to handle the complex surfaces that characterize lattice structures in an efficient way.

Results

The automatic procedure has been tested over 20 cases studied which encompassed a broad variety of cases; the algorithm proved to be extremely robust since delivered the expected result in each case analyzed. The great advantage of this method is the processing time, which resulted in 2±0.15 minutes, compared to a manual process, which might take up to several hours. To the best of the authors' knowledge, there aren't other procedures at the state of the art capable of producing this type of result. Design automation also improves the product's safety by reducing the human interaction and allows non expert CAD users to perform the task. Due to the high design flexibility allowed by the implemented algorithms, it is possible to easily adapt the procedure to design implants in different anatomical regions with little effort.

To date metal implants are manufactured with fully dense material, with a lattice structure only at the bone-implant interface for osseointegration; the novelty of this work is to implement a gyroid based resistant and easily manufacturable lattice structure within the whole implant, with a great advantage in terms of weight reduction, stress shielding mitigation, cost and manufacturing time reduction.

References:

[1] Javaid, M.; Haleem, A.: Additive Manufacturing Applications in Orthopaedics: A review, Journal of Clinical Orthopaedics and Trauma, 9(3), 2018, 202-206. https://doi.org/10.1016/j.jcot.2018.04.008

[2] Javaid, M.; Haleem, A: Current Status and Challenges of Additive Manufacturing in orthopaedics: An overview, Journal of Clinical Orthopaedics and Trauma, 10(2), 2019, 380–386. https://doi.org/10.1016/j.jcot.2018.05.008

[3] nTopology, "nTop Platform." https://ntopology.com/ntop-platform/, New York, NY 10013, USA, 2020.

[4] Guariento, L.; Buonamici, F.; Marzola, A.; Volpe, Y.; Governi, L.: Graded Gyroid Structures for Load Bearing Orthopedic Implants, 2020, 02SAMA20-1-5. https://doi.org/10.1109/NAP51477.2020.9309692

[5] Yang, L.; Mertens, R.; Ferrucci, M.; Yan, C.; Shi, Y.; Yang, S.: Continuous graded Gyroid cellular structures fabricated by selective laser melting: Design, manufacturing and mechanical properties, Materials and Design, 162, 2019, 394–404. https://doi.org/10.1016/j.matdes.2018.12.007

[6] Li, D.; Liao, W.; Dai, N.; Xie, Y.: Comparison of Mechanical Properties and Energy Absorption of Sheet-based and Strut-based Gyroid Cellular Structures with Graded Densities, Materials, 12(13) 2019, 2183. https://doi.org/10.3390/ma12132183

[7] Arabnejad, S.; Johnston, B.; Tanzer, M.; Pasini, D.: Fully Porous 3D Printed Titanium Femoral Stem to Reduce Stress-shielding Following Total Hip Arthroplasty, Journal of Orthopaedic Research, 35(8), 2017, 1774-1783. https://doi.org/10.1002/jor.23445

[8] Ridzwan , M. I. Z.; Shuib, S.; Hassan, A.Y.; Shokri, A.A.; Ibrahim, M.N.M.: Optimization in Implant Topology to Reduce Stress Shielding Problem, Journal of Applied Sciences, 6(13), 2006, 2768-2773. https://doi.org/10.3923/jas.2006.2768.2773

[9] Haase, K.; Rouhi, G.: Prediction of Stress Shielding around an orthopedic screw: Using stress and Strain Energy Density as Mechanical Stimuli, Computers in Biology and Medicine, 43(11), 2013, 1748-57. https://doi.org/10.1016/j.compbiomed.2013.07.032

[10] Marzola, A.; Buonamici, F.; Guariento, L.; Governi, L.: Enhanced Statistical Shape Model: A Statistical-Based Tool to design Custom Orthopaedic Devices, 2022, 27–38. https://doi.org/10.1007/978-3-030-91234-5_3