A Semi-Automatic CAD Procedure to Design Custom-made Surgical Cutting Guides

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Abstract. The present paper presents the development of a novel procedure for the modeling of Surgical Cutting Guides (SCGs) exploiting an implicit modeling approach. As discussed in the text, this approach allows for a streamlined and efficient design of this type of medical device. A procedural approach based on the application of a series of a priori-known implicit modeling function allows the generation of personalized surgical guides starting from the i) patient's anatomy and ii) clinical decisions made by the medical staff. The CAD procedure is detailed in the text; achieved results are discussed and compared with a traditional CAD modeling approach on three case studies.

Keywords: Personalized Medical Device, Patient-Specific Instrument, Implicit Modelling, CAD.
DOI: https://doi.org/10.14733/cadaps.2022.733-740

1 INTRODUCTION

The rapid evolution of personalized medical treatments has highlighted the difficulty for physicians and their staff to personalize treatments with the best response and highest quality of care delivered in a suitably short time span. Whenever this type of approach involves the use of personalized medical devices, such as surgical cutting guides (SCGs), significant efforts must be spent in the design and fabrication phases. Accordingly, the evolution of personalized medicine has caused an increased need for CAD designers with a very specific skill set. Considering SCGs, which are used to guide precise resections, the design process starts with the retrieval of the patient's anatomy thanks to diagnostic imaging data (e.g., CTs, MRIs, etc.). Such data is interpreted to identify all the anatomical structures of interest. Subsequently, the surgeon plans the surgery by defining cutting planes, anchor points, and producing additional constraints that can influence the overall design of the instrument. This data is used by a CAD designer to generate a 3D model of the device: this operation is performed in a CAD environment exploiting the reconstructed anatomical data of the patient as reference. As previously mentioned, this operation can be onerous even for an expert designer. Once that the final 3D model of the SCG is generated and validated by the surgeon, the device must be fabricated; usually, additive manufacturing techniques are exploited at this stage due to their propension to the fabrication of small lots and unique parts. In order to increase the applicability of personalized medical treatments, a great effort has been spent in researching solutions to make this whole process easier and faster. Software solutions have been developed to speed up the most time-consuming and cumbersome phase, i.e., the design phase. Scientific literature presents significant examples of methods pursuing a more efficient approach to design patient-specific medical devices [4-7]. With specific reference to surgical guides, i.e., the focus point of the present work, few works dealing with the development of semi-automatic CAD tools supporting the design phase of such devices have been carried out. The main goals pursued by these studies are, essentially, the standardization of the design procedure and the achievement of an effective process. The first goal can be attained by defining a procedure that, although personalized on the anatomy and specific need of each patient, relies on a series of fixed rules and principles that can be used as guidelines for the treatment and the design of personalized medical devices. Evidently, the higher reliability of such a standardized procedure, and the resulting reduced risks for the patients, are fundamental. A significant example of a semi-automatic method to design SCGs for sternotomies in the case of Pectus Arcuatum is presented in [8]. The authors propose a semi-automatic procedure developed with Rhinoceros®, a surface modeler, together with its parametric modeling plugin Grasshopper®. The procedure relies on a set of rigorous geometric rules based on the anatomy of the sternum to produce an SCG tailored to correct the defect of the original bone. The results presented by the authors highlight the speed of the method compared with traditional processes and the benefit of offering a new tool to make clinicians more independent. As previously mentioned, one of the aspects that need to be dealt with in studying automatic design methods is the analysis of reliability and repeatability of the procedure. This usually comes down to the definition of a set of rules and operations, which can be repeated blindly, and a list of checkpoints where the intervention of a human user cannot be avoided to not compromise the effectiveness of the whole method. On this aspect, [3] discusses a study on the automatic recognition of clinical landmarks in knee surgery devoted to the automatization of the generation of cutting guides. The study proves the usefulness of statistical and geometrical analyses to extract useful information for automatic processes from the anatomical data.

In this work, a new semi-automatic CAD procedure to design SCGs for bone resections, able to fulfill all the constraints imposed by the surgeon, is presented. The aim is to provide a handy but robust tool, capable of producing a ready-to-print file of the desired SCG. Moreover, the reduction of the overall time-to-surgery, a critical aspect especially in oncology, is a global goal of this research. From a practical perspective, the procedure makes use of simple inputs (resection planes, accessible bone surface, SCG fixation characteristics - i.e., diameter and position of the fixation pins, manufacturing material, thickness of the blade used to perform the cuts). The presented procedure has been developed using nTopology® [9], a CAD software-driven by implicit modeling: this delivers significant advantages compared to the traditional CAD representation based on B-Reps, because, as it will be later better explained, the mathematical operations between implicit functions do not encounter the most common issues typical of CAD packages.

2 THE PROPOSED SEMI-AUTOMATIC PROCEDURE

SCGs design process must consider strict constraints imposed by the manufacturing technology, surgical equipment available in the theatre, and planned surgery. The manufacturing technology, and thus the material, affects both geometry and sterilization methods. SCGs are typically manufactured with metals or polymers: in the case of metal devices, the overall dimensions and thicknesses can be sensibly lower compared to polymeric SCGs due to the higher mechanical and thermal resistance. The surgical equipment plays a pivotal role to define the geometry of the

SCGs: saw thickness, type of the power tool, pins diameter, and length must be considered to guarantee a stable fixation and avoid excessive vibrations and debris produced by the saw's oscillation. Finally, the design process must also strictly follow the inputs provided by the surgeon based on the planned surgery, namely the resection path, the accessible bony surface for SCG fixation and position, as well as the number, of the fixators (Figure 1) [2]. While the manufacturing technology and surgical equipment lead to quantitative well-defined constraints, surgeons usually provide only coarse indications that must be later interpreted to be used as design inputs. Recently, efforts have been spent to promote effective ways of communication between surgeons and engineers through dedicated software for concurrent design; this way, surgeons can easily define the surgical constraints without specific 3D modeling knowledge [1]. It is then required the interpretation and refinement of such information, in order to obtain the external contour of the device: this step is performed by an expert CAD user and it represents the sole manual interaction before starting the automatic procedure presented below. The design approach implemented in this work considers the SCG composed of three regions (Figure 1):

- Blade slot: it is formed by an extrusion that includes the slot to guide the blade. The slot can be closed or open, at the surgeon's discretion (see Figure 1). The slot must follow the path defined by the surgeon: this path is always reducible to a series of incident segments. The thickness of the slot's walls depends on the material: usually, for SCG made of polymeric material, the thickness could be between 5 and 10mm.
- The model and dimension of the blade affect both the height and the thickness of the slot. The height must guarantee a sufficient stroke without interfering with the power tool, while the thickness of the opening must be equal to the thickness of the blade plus clearance to avoid wear phenomena.
- Base, necessary to maximize the stability of the device and give a reliable reference regarding its correct positioning (see Figure 1): Base must perfectly fit the bony surface to retrieve the planned resection planes on the very patient. The thickness of the Base must ensure good resistance and rigidity while minimizing mass and material. For polymeric SCG, 5mm is usually a good tradeoff value.
- Pins' holes, to fix the device. The pin diameter depends on the specific application. It is important that the axes of the pins are not parallel to each other to ensure stability. According to the authors' experience, a height of 10 mm for the Pins' holes represents a good value for most applications.

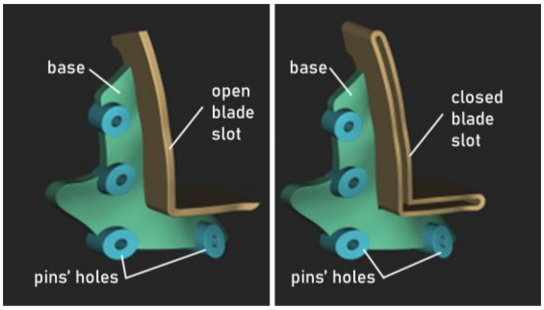

Figure 1: Main components of an SCG: green - base; cyan - pins' holes; yellow - blade slot. (a) open slot; (b) closed slot.

Typically, the design of an SCG is carried out by an expert CAD expert starting from the polygonal mesh of the target bone (obtained from the diagnostic imaging) and following the constraints provided by the surgeon. During the design process (Figure 2), all the sketches are drawn on the base plane, whose normal is the cutting direction provided by the surgeon. If there are multiple cutting directions, different base planes must be considered. In this case, for each Base Plane, an SCG can be created separately and merged at the end. The design workflow firstly requires retrieving the contact surface between the bone and the SCG. This surface will be used in subsequent steps to shape the SCG base to ensure its correct positioning and stability on the bone. The second step involves the definition of the blade slot: firstly, each segment drawn on the bone surface by the surgeon is refined to obtain a line (formed by one or more incident straight segments) that is then extruded according to the cutting direction. The extrusion is performed both through the bone as well as in the opposite direction at least as far as the chosen height of the SCG. This surface represents the osteotomy in three dimensions. The surface is then thickened, as explained above, by the value of the thickness of the blade plus the desired clearance. After that, the external profile of the blade slot must be sketched. This step is usually strictly related to the user experience and the result can change accordingly. The sketched profile is extruded from the bone surface up to the chosen height. The Blade slot is obtained by performing a Boolean operation (subtraction) between this extrusion and the thickened surface representing the osteotomy. Once the blade slot is completely designed, the SCG's base must be defined: to do that, it is first necessary to consider the position of the Pins' holes. This is because the base profile must include such elements since the fixation is a fundamental aspect to consider along with positioning and stability, guaranteed by the base. Consequently, usually, the designer firstly draws all the circles centered in the Pins' axes; the diameter of each circle is equal to the sum of the chosen pins' diameter plus the minimum thickness sufficient to ensure stable fixation. This way, by including these circles within the sketch of the base profile, the right fixation can be ensured without subsequent adjustments. As for the Blade slot, the shape of the SCG's Base is strictly dependent on the user. Both for the Blade Slot and the Base, it is important to respect the design area as indicated by the surgeon. According to the design specifications, the cylinders serving as Pins' housing can be extruded separately starting from the sketched circles, to create a thinner base and save material. The upper part of each region (Blade slot, Base, and Pins' holes) can be modeled to follow the bone's surface, to provide more reference during the positioning phase. To do that, it is sufficient to do an offset of the bone surface retrieved in the early stage and using it to cut the related region of the SCG. For each region, the value of the offset follows the design specifications. In the end, the three regions can be merged. Some refining operations, mainly represented by filleting and chamfering, are necessary to obtain the final model of the SCG.

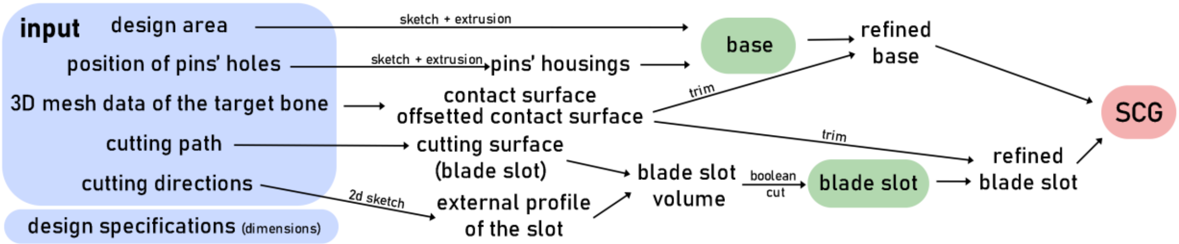

Figure 2: Typical workflow for the SCG CAD-based design.

The automation of such a procedure is complex because relies on operations as Booleans, offsetting, shelling, and filleting, which are often critical in traditional CAD packages, especially facing complex geometry with a wide variability between each case. To overcome these drawbacks, the presented workflow exploits the benefits of implicit modeling to capture the repetitive operations required to design an SCG, given the main constraints, and automatically generate the ready-to-print file. Operatively, the inputs for the proposed procedure required are i) cutting surfaces, obtained by extruding the cutting path along the cutting direction provided by the surgeon; ii) Base contour, projected on a plane perpendicular to the cutting direction; iii) surgical pins axes delivered as a couple of points; iv) triangular mesh of the target bone, extracted from diagnostic imaging. The user can specify, according to the design constraints and exploiting the GUI devised by the authors visible in Figure 3, the desired values regarding i) pin diameter; ii) blade thickness; iii) blade slot height; iv) base thickness; v) blade-SCG clearance. In order to minimize the input parameters, the pin's holes height is fixed and imposed equal to 10mm.

The presented framework, implemented in nTopology® [9], a CAD software based upon implicit modeling [10] [11], consists of a series of simple Boolean operations, which, as said, would be highly prone to failure with traditional CAD packages, as well as time consuming. nTopology® offers a procedural environment where operations are represented by blocks that can be conveniently combined to create personalized workflows and automate repetitive operations. To the author's knowledge, nTopology is the most advanced engineering implicit CAD modeling software currently available. In the following, the developed CAD procedure, implemented in the nTopology environment, will be discussed in detail; such workflow exploits the strength of implicit modeling and could be reproduced in any implicit modeling software. First, the cutting surface (composed of a series of incident planes) is thickened to create the blade slot's volume, then the Base profile is extruded parallel to the cutting direction and the pins' axes are used to create cylinders of the desired diameter. The second step is to perform a Boolean intersection of each part, namely Blade slot, Base, and Pins' holes, with an offset of the target bone; the offset distance corresponds to the final thickness of each part (Figure 4).

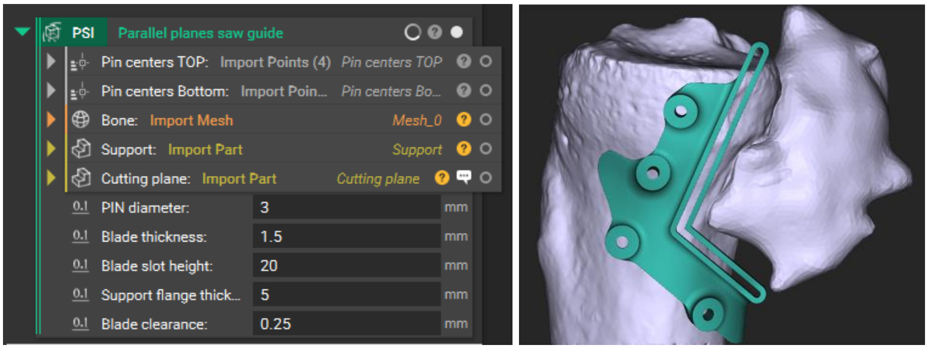

Figure 3: (a) nTopology® SCG modeling GUI: inputs required to the user in terms of geometrical data and numerical parameters; (b) final result produced by the method (i.e. SCG 3D model), continuously updated as the inputs provided in the GUI change.

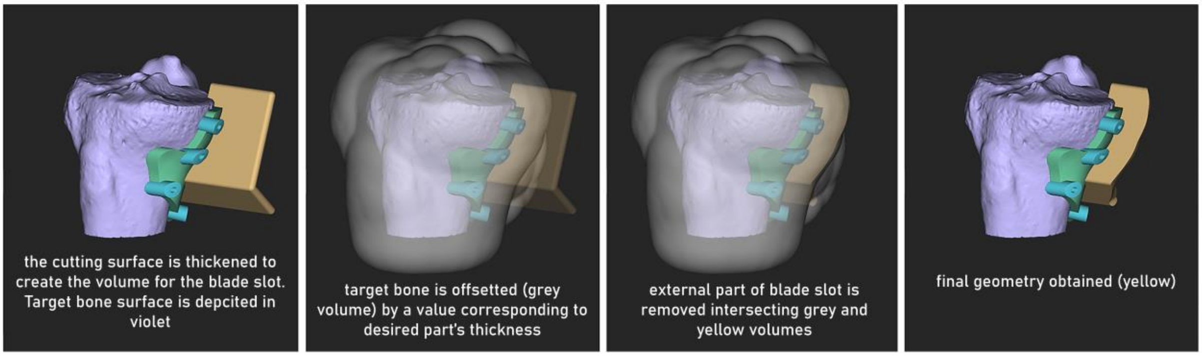

Figure 4: SCG Boolean intersection of the Blade Slot: the volume is created by thickening the cutting surface (a), then the target bone is offset by a value corresponding to the desired part's thickness (b); eventually these volumes are intersected (c) and the final geometry is obtained (d).

Once each part has been generated with the desired thickness, they are merged with a Boolean union. Within nTopology®, users can impose a blend radius for Booleans, which automatically creates fillets between each interface; as no edges are involved in implicit modeling, filleting always succeeds even with a significant variation of the solid shapes. Finally, the bone's surface, the blade's and pins' volumes are subtracted, which completes the process (Figure 3(b)).

3 MODEL VALIDATION

To assess the dimensional accuracy of the surgical guides generated using the presented process, a deviation analysis confronting the shape of the coupling surfaces on a series of surgical guides has been performed. Such analysis has taken into consideration the supporting surface of the surgical guide and the corresponding portion of the bone to be cut (i.e., the surfaces that will be matched together in the final application). Point-to-point distances have been computed using the "mesh deviation" tool within the 3D modeling software Geomagic Design X by 3D Systems. The analysis aimed at identifying significant errors introduced by the process and at validating the shape of the final 3D CAD models of the surgical tools. Moreover, the investigation has also attained a direct comparison between the results produced by the procedure developed in the context of this work and the 3D models obtained performing a traditional design within Geomagic Design X, using the common CAD model design workflow described in the previous section. Three different cases have been selected to validate the procedure on various anatomies, using different source data in each case. The bones to be resected are a tibia, a femur, and a pelvis. Therefore, deviation analyses have been performed on six surgical guides (Figure 5).

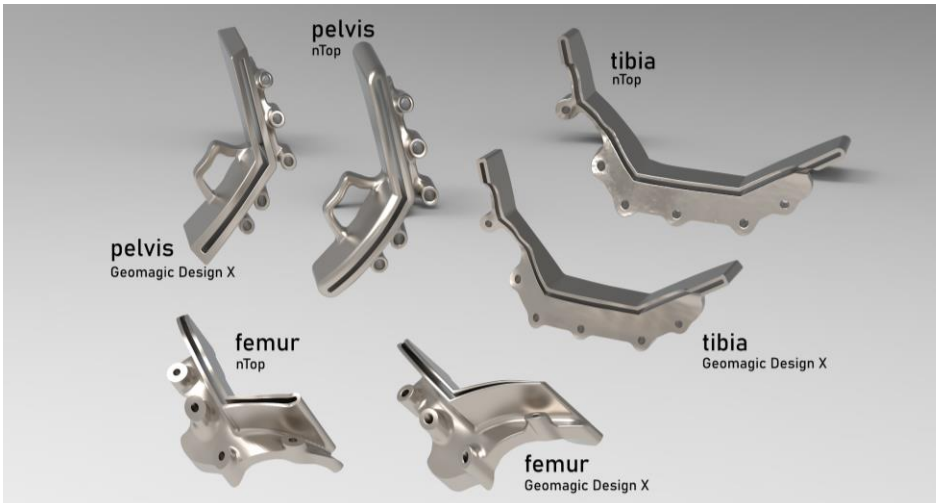

Figure 5: CAD models of the SCGs generated for this study.

The results obtained with the deviation analysis are shown in Figure 6. In each case, the surgical guide produced using nTop software follows the original bone surface with a higher degree of accuracy. The dimensional errors observed comparing the two surfaces are always in the range of –0.01/+0.01 mm. Conversely, the models generated using a traditional step-by-step CAD modeling procedure are affected by higher errors, in the range of -0,4/+0.4 mm. Such significant errors observed in the models obtained with the traditional approach are attributable to post-processing steps that are sometimes required to improve the quality of the 3D data used as a reference for the anatomy. While the implicit modeling approach can make use of any type of mesh as starting data for the process carried out in nTopology, surface fitting tools of Geomagic Design X may require a polished mesh surface to be executed. The accuracy that both procedures shown in the modeling process is compatible with the final application of the whole technology, which should also account for manufacturing errors. Nonetheless, the models generated using the developed procedure are evidently characterized by a supporting surface of the surgical guide that is almost identical to the surface of the reconstructed bone. Interestingly, observing the results of the analysis, it is clear that the three models generated using the nTop procedure show similar results, while the differences between the CAD models modeled with a traditional approach are more pronounced. Hence, the procedure developed in this work is also more robust, as the results obtained with the nTop approach are repeatable on different anatomies; on the other hand, for the traditional approach both design time and accuracy are strictly related to the user's experience and cannot be quantified objectively. The mean processing time required for the presented procedure implemented in nTop, run on a machine with a GTX 1050Ti and an Intel i7, is of 3.4 minutes for the three cases presented. Such a result is impressive if compared with the time required for the execution of the traditional approach for the attainment of this type of medical device. The design time with the traditional approach for the three case studies presented, which were performed by an expert user, required 1.15, 2.20, and 1.30 hours respectively for the femur, pelvis, and tibia SCGs.

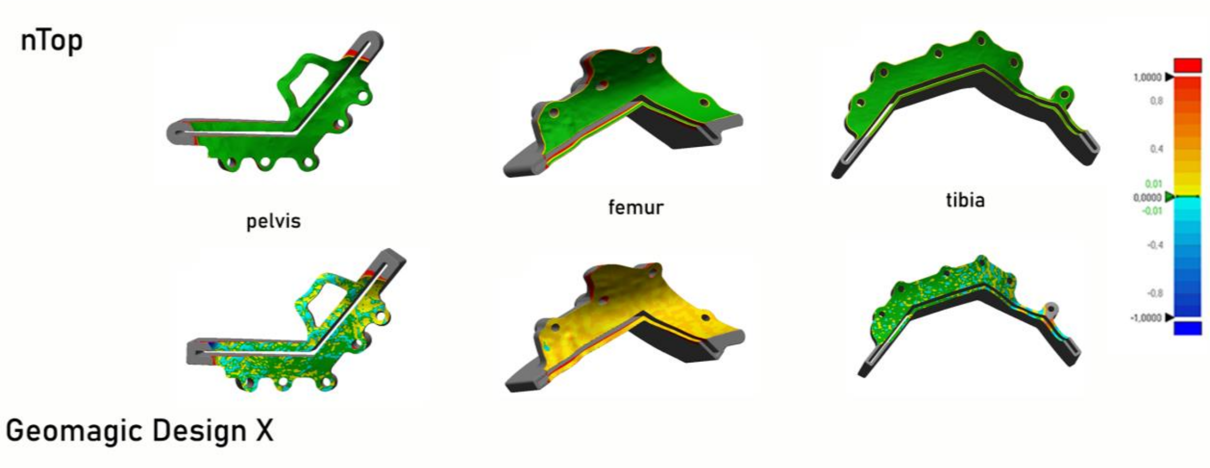

Figure 6: Deviation analysis results. The color map shows the distance of each support region of the SCGs from the respective bony surface.

4 CONCLUSIONS AND FURTHER REMARKS

The present work introduces a semi-automatic procedure for the design of SCGs based on implicit modeling. Such an approach is robust and requires minimal effort to produce the required inputs. One of the main advantages to deal with implicit representations, based on signed-distance functions, is there are no error-prone operations. So, operations like Booleans, filleting, and shelling are all instantaneous and fully reliable despite the complexity and variability of the geometry. Accordingly, the automation procedure was implemented in nTopology®, an implicit modeling-based CAD software; it provides a user-friendly interface, which allows to easily create personalized workflows according to the specific needs. The user interaction is limited to the definition of the inputs to be imposed before running the automatic procedure. As a semi-automatic tool, its main advantage is to dramatically reduce the design time compared to a manual CAD process; the required inputs can be obtained with little effort and basic knowledge of CAD modeling. An automatic design procedure delivers significant advantages in terms of product standardization, safety, and performance because limits human interaction and thus the risk of errors. Future studies will address the full automation of the design of SCGs: the idea is to develop software dedicated to surgical planning where surgeons can autonomously place resection planes, pins and highlight the accessible bony surface. Then, the necessary input can be automatically retrieved by the software to drive the proposed procedure. Skilled CAD users would no longer be involved, and ideally, each surgeon would be able to produce, within the span of a few hours, effective and personalized surgical devices, with a dramatic decrease of costs and thus delivering a huge impact in health care quality.

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