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

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Introduction:
The rapid evolution of personalized medicine treatments has produced a great increase in the time required to clinicians and their staff to tailor therapies with the best response and the highest quality of the care delivered. 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 intervention 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. The literature presents significant examples of methods pursuing a more efficient approach to design patient-specific medical devices ([3-5]). With specific reference to surgical guides, i.e. the focus point of the present work, fewer works 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 for the design of personalized medical devices.

A significant example of a semi-automatic method to design SCGs for sternotomies in case of Pectus Arcuatum is presented in [6]. The authors propose a semi-automatic procedure developed with Rhinoceros®, a surface modeler, together with its parametric modelling plugin Grasshopper®. 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, [2] 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® [7], a CAD software driven by implicit modelling: 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 CAD functions do not encounter the most common issues typical of CAD packages.

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 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 (Fig. 1). While the manufacturing technology and surgical equipment lead to quantitative well-defined constraints, usually surgeons only provide coarse indications that have to 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 (Fig. 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 Fig. 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 affects 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 a clearance to avoid wear phenomena.
- **Base**, necessary to maximize the stability of the device and give a reliable reference regarding its correct positioning (see Fig. 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 a 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.

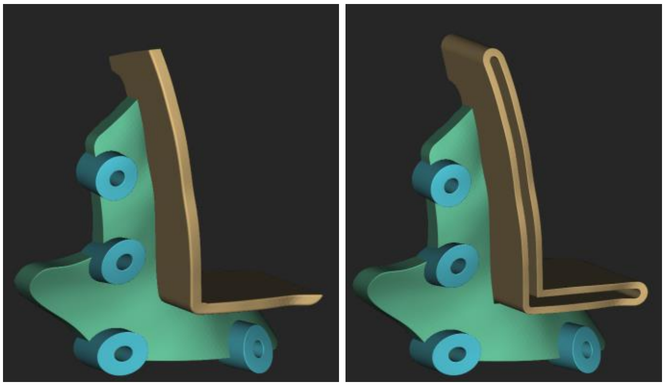

Fig. 1: Main components of a SCG: green - base; cyan - pins' holes; yellow - blade slot. (a) open slot; (b) closed slot.

Usually, a CAD software is used to manually design the SCG. The automation of the design procedure is complex because it 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 modelling to capture the repetitive operations required to design a 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 specification and exploiting the GUI devised by the authors visible in Fig. 2, 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® [7], a CAD software based upon implicit modeling, 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 combined to create personalized workflows and automate repetitive operations. In the following, the developed CAD procedure will be discussed in detail. First, the cutting surface (composed by a series of surfaces) 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 (Fig. 3).

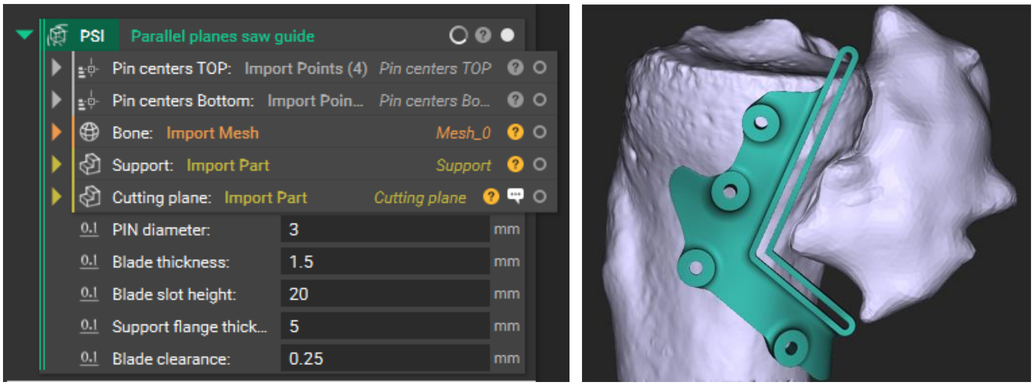

Fig. 2: (a) nTopology® SCG modelling GUI: inputs required to the user in terms of geometrical data and numerical parameters; (b) final result produced by the method (i.e., SCG 3D model), continuously updated as the inputs provided in the GUI change.

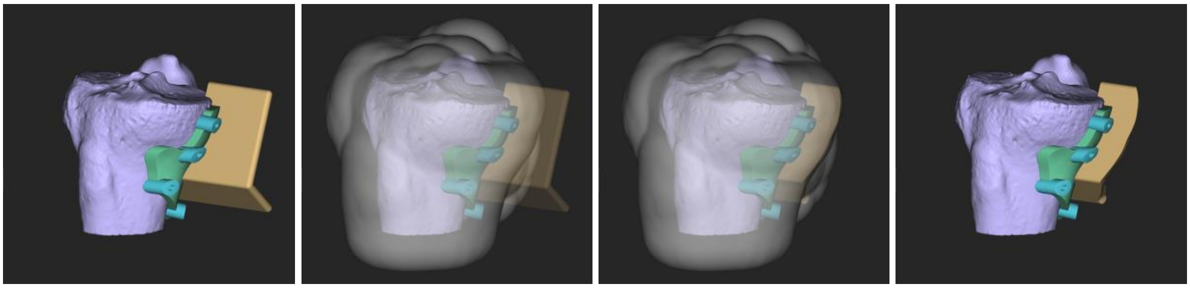

Fig. 3: SCG Boolean intersection process with the offset of the target bone (grey).

Once each part has been generated with the desired thickness, they are merged with a Boolean union. nTopology® imposes 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's shapes. Finally, the bone's surface, the blade's and pins' volumes are subtracted, which completes the process (Fig. 2(b)).

Conclusions and Further Remarks:

The present work introduces a semi-automatic procedure for the design of SCGs based on implicit modeling implemented in nTopology®. The procedure dramatically reduces the design time compared to a manual CAD process; the required inputs can be obtained with little effort and basic knowledge of CAD modeling.

In order to assess the dimensional accuracy of the surgical guides generated using the process developed in this paper, a deviation analysis confronting the shape of the coupling surfaces on a series of surgical guides has been performed. Point-to-point distances have been computed using the "mesh deviation" tool within the 3D modelling 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. The results obtained with the deviation analysis are shown in Fig. 4(b). In each case, the surgical guide produced using nTopology® follows the original bone surface with a higher degree of accuracy. The accuracy that both procedures showed in the modelling process is suitable for the final application. Nonetheless, the models generated using nTopology® clearly allow to minimize the errors of the design phase. Interestingly, observing the results of the analysis, it is clear that the three models generated using the nTopology® procedure show similar results, while the differences between the CAD models modelled with a traditional approach are more pronounced. Hence, the procedure developed in this work is also more robust, as the results are repeatable on different anatomies.

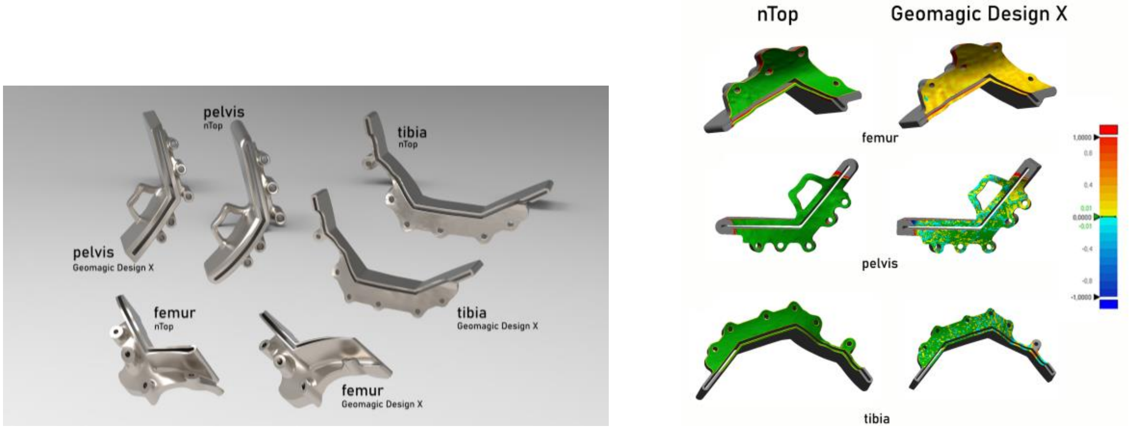

Fig. 1: (a) CAD models of the SCGs generated for this study. Three are generated using the nTop procedure, three using the reverse modelling tools provided by Geomagic Design X; (b) Deviation analyses results. The color map shows the distance of each support region of the SCGs from the respective bony surface.

Future studies will address the full automation of the design of SCGs; the idea is to develop a 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.

References:

[1] Buonamici, F.; Guariento, L.; Volpe, Y.: 3D Digital Surgical Planning: An Investigation of Low-Cost Software Tools for Concurrent Design, Lecture Notes in Mechanical Engineering, 2020, 765–775. https://doi.org/10.1007/978-3-030-31154-4_65

[2] Cerveri, P.; Manzotti, A.; Confalonieri, N.; Baroni, G.: Automating the design of resection guides specific to patient anatomy in knee replacement surgery by enhanced 3D curvature and surface modeling of distal femur shape models, Computerized Medical Imaging and Graphics, 38, 2014, 664–674. https://doi.org/10.1016/j.compmedimag.2014.09.001

[3] Furferi, R.; Guariento, L.; McGreevy, K. S.; Mussi, E.; Parri, N.; Uccheddu, F.; Volpe, Y.: 3d printing-based pediatric trainer for ultrasound-guided peripheral venous access, IFMBE Proceedings, 76, 2020, 735–745. https://doi.org/10.1007/978-3-030-31635-8_87

[4] Marzola, A.; Governi, L.; Genitori, L.; Mussa, F.; Volpe, Y.; Furferi, R.: A semi-automatic hybrid approach for defective skulls reconstruction, Computer-Aided Design and Applications, 17, 2020, 190–204. https://doi.org/10.14733/cadaps.2020.190-204

[5] Mussi, E.; Furferi, R.; Volpe, Y.; Facchini, F.; McGreevy, K.S.; Uccheddu, F.: Ear reconstruction simulation: From handcrafting to 3D printing, Bioengineering, 6, 2019. https://doi.org/10.3390/bioengineering6010014

[6] Servi, M.; Buonamici, F.; Carfagni, M.; Volpe, Y.; Facchini, F.; Ghionzoli, M.; Messineo, A.: CAD-based automatic modelling of customized cutting templates for Pectus Arcuatum surgical correction, Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society, EMBS, 2020-July, 2020, 6044–6048. https://doi.org/10.1109/EMBC44109.2020.9175824

[7] Next-Generation Design & Engineering Software | nTopology. https://ntopology.com/