WORKFLOW FOR ADDITIVE MANUFACTURING OF AN INDIVIDUALIZED SURGICAL TEMPLATE

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Abstract: Individualized surgical templates are becoming increasingly used in the medicinal field due to their advantages, ensuring better orientation during intervention, decrease of the surgery time and costs, risks of infections and X-ray exposure during surgery. Moreover, their use enrolls in the modern approach of personalized medicine, which envisions tailoring interventions and instruments according to patient’ characteristics and needs. This article presents the workflow for design and manufacturing orthopedics guides using additive technology. A customized osteotomy template for hand is presented as case study, exemplifying the integration between different applications (for medical modeling, .stl files correction, 3D CAD guide modeling, virtual model viewer and annotation, etc.) and serving to the deployment of an intelligent online platform which can support guides’ design and manufacturing process automation. Moreover, this platform contributes to a better communication between surgeon and engineer, thus helping bridging the gap between two fields which have specific professional languages, evaluation criteria, etc.

Key words: design, additive manufacturing, computer tomography, individualized template, osteotomy.

1. INTRODUCTION

The advent of Additive Manufacturing (AM) and its later developments in terms of materials, manufactured objects’ mechanical properties, manufacturing accuracy, working space, slicing optimization etc., make possible the use of this group of technologies for obtaining objects with complex geometry (freeform shapes) which satisfy the requirements of many applications. These AM processes are particularly suitable for the medical field, being possible to build objects directly starting from the patient-specific data available by Computer Tomography (CT) or Magnetic Resonance Imaging (MRI). Thus, scaffolds, surgical guides or instruments, prosthesis, casts, etc., can be nowadays customized and obtained by AM.

The need of patient-specific surgical devices or instruments can arise from routine activities or it can be dictated by new and complicated procedures, for surgical situations not encountered before. In orthopedic applications, patient-specific guides (PSGs) match the patients’ bone structures and materialize the pre-planned paths for drilling or cutting. Therefore, their use contributes to improving the accuracy of different procedure (e.g. for trauma surgery as inserting pedicle screws in vertebrae, knee or hip, for inserting plates for osteotomies around the knee or applying guides for different steps in arthroplasty, etc.), helping the surgeons to better orient during intervention, to decrease the surgery time, costs and risks of infections and to reduce X-ray radiation exposure during surgery for patients and surgeons.

In this context, the current paper is focused on presenting the workflow for the design and manufacturing of AM surgical orthopedic guides, with a practical perspective on cutting guides design. This workflow has been implemented in POIGO – a collaborative intelligent online platform integrating the specific tools and knowledge needed for supporting the translation of surgeons’ requirements into design, material and manufacturing specifications of customized surgical guides. By using this platform, the exchange of medical and technical information will be facilitated, and a high degree of automation will be ensured to a procedure which otherwise has to be resumed for each patient/clinical case.

2. WORKFLOW FOR DESIGN AND MANUFACTURING OF PATIENT-SPECIFIC GUIDES

A typical workflow for generating PSGs [1–3] is depicted in Fig. 1. It is based on a Reverse Engineering (RE) approach in which patient’ CT scan data are transferred between different specific software packages for generating 3D virtual models of the anatomical zones of interest, and then for modeling the guides. The 3D anatomical models are used for determining the geometry of the surgical guides, along with specific information pro-
vided by surgeon like number and positions of supporting areas, anatomical landmarks/points, types of design (templates with V-shaped edges, templates with clamps or templates modeled as negative of anatomical surfaces of interest, templates with slots for accommodating cutting tools, etc.) and material. Thus, the geometry of PSGs should contain features that depend on the type of surgical procedure (positioning, drilling, tapping or cutting), such as: hollow or full angled cylinders, slots/slits, support or connection structures, arches or trusses, blocks and bars, handles, etc. All these geometrical elements contribute to the transfer of the planned tools’ trajectories from computer-aided planning to surgery, i.e. from the virtual environment into the operation room, and to an efficient use during surgery.

A literature survey showed that there are more than 60 studies focused on orthopedic surgical indications, in the period 2004–2014. Among these, 14 studies are presenting clinical cases in which osteotomy guides manufactured using AM processes were used (Table 1). Among AM processes, Stereolithography (SL) and Selective Laser Sintering (SLS) are preferred due to their ability to manufactured accurate objects, from materials which can be sterilized.

Further in this section, the studies of Murase et al. [2], Zhang et al. [4] and Tricot et al. [5] are presented, detailing several approaches used in the design process of patient-specific cutting guides. This information serves for developing and implementing protocols dedicated to each general type of intervention, as required by POIGO platform functionality.

In [2] individualized osteotomy guides for long-bone deformity of the upper extremity are designed based on patient CT data. Using these data, 3D models of the bones were virtually reconstructed and superposed on the goal model (a mirror model of the patient normal bone). Cutting planes were set on the virtual model of the interest bone. These were used for materializing the cutting trajectories. The modeled cutting guide had a shape that fits the bone surface and contained two slots for accommodating the cutting tool and two holes for inserting K-wires. A transparent surgical guide was printed from medical resin using SL process.

In [4] the design and manufacturing of a template for use in a cubitus varus deformity was reported. CT data of the affected zone and of the patient normal elbow were obtained. Mimics software was used for reconstructing the anatomical models based on these data, while Imageware application was used for defining the carrying, tilting and osteotomy angles. In this pre-operative phase, surgeons also defined the range of wedge osteotomy that was employed in designing the template. The particularity of this guide is its ‘collar’ shape and the absence of K-wires holes for positioning on the bone. The physical model of the template was built using SL, from SOMOS acrylate resin. The authors stress the importance of being aware of the errors introduced by the segmentation and manufacturing process, as well as the importance of placing the guide close to the bone surfaces during surgery.

Another clinical study focused on individualized osteotomy guide is presented in [5] for posttraumatic distal humeral deformity. Based on the 3D reconstructed model of the humerus, the wedge osteotomy was virtually planned. The customized guide consisted of two parts assembled together. These were placed on the bone and modeled as negative of the anatomical zones of interest. One of them is removed after the first cut and the other after the second cut. No K-wires guides were used during this surgery. The guide’s geometry contained no slots, but only features that allowed assembling its components.

The design and manufacturing stages described above mandatory involve the collaboration between surgeon and engineer, problems usually appearing in the exact understanding of the medical requirements and, from here, in transferring them on the virtual and then physical guide. Usually, the surgeons set the requirements for CT scanning, while the 3D reconstruction of the anatomical areas of interest is made by an engineer using dedicated software: Mimics, 3D-Doctor, OsiriX, InVesalius, etc., based on .dicom files. During the surgical pre-planning stage, the surgeon and the designer should collaborate in order to establish, and then to transfer onto the virtual model of the anatomic models and surgical guides, the cutting planes or angles or drilling directions.

In this context, there is a need for a knowledge-based support software solution, able to assist the surgeon and the engineer in: establishing the surgical guide design by analyzing and processing CT images, obtaining the 3D digital model of the working area/areas, setting the minimal number and the placement of anatomical landmarks necessary for a correct, unique and stable positioning.

![Fig. 1. Workflow for the design and additive manufacturing (AM) of patient-specific surgical guides.](image)
by offering different design options. The proposed online
protocol, facilitating the cooperation surgeon-designer and
same time it allows automating the process of quantifica-
specifications.

The screws will be inserted, the anatomical landmarks
already available devices models), the vertebra in which
selecting the intervention area (cervical, lumbar or tho-
the chosen type of intervention (Fig. 2). For instance, if
surgeon requires a drilling guide for inserting a screw
which can be used, the type of screws (link to different
catalogues or web sites of producers, comparative studies,
different images or presentation movies etc.). While
filling in the questionnaire, the surgeon can access rele-
vant information or case studies presented in literature.
In the same time it allows automating the process of quantification
of surgeons needs and their translation into design
specifications.

3. POIGO PLATFORM

Any project on POIGO platform starts with the need
of a surgeon to use a PSG for a certain orthopedic surgical
procedure, either a more complex procedure, either a
less experienced surgeon. The surgeon creates and ac-
cesses an account from the online support platform and fills
in a questionnaire containing questions specific to the
chosen type of intervention (Fig. 2). For instance, if
the surgeon requires a drilling guide for inserting a screw
in a vertebral pedicle, the options/questions will consider
selecting the intervention area (cervical, lumbar or tho-
aracic area, for each of them with information regarding
already available devices models), the vertebra in which
the screws will be inserted, the anatomical landmarks

<table>
<thead>
<tr>
<th>Study</th>
<th>Indication</th>
<th>Area/atomic zone</th>
<th>Software</th>
<th>AM process/material</th>
<th>Surgical guide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bellanova, 2013</td>
<td>Tumor</td>
<td>Tibial</td>
<td>ITK Snap, Blender 2</td>
<td>SLS, polyamide</td>
<td>Guides with positioning wires and cutting guides for bone resection and allograft reconstruction</td>
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<td>[6] – 4 patients</td>
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<tr>
<td>Chai, 2013</td>
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<td>Femur</td>
<td>Mimics 10, Imageware 12</td>
<td>SL, polyamide</td>
<td>Cutting guide for wedge osteotomy</td>
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<td>Kunz, 2013</td>
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<td>Radius</td>
<td>Mimics</td>
<td>SL, acrylate resin, Dimension SST Stratays printer</td>
<td>Osteotomy guide modeled as negative of bone surface</td>
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<td>[8] – 9 patients</td>
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<tr>
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<td>Malunion</td>
<td>Radius</td>
<td>Mimics</td>
<td>SLS, polyamide PA-12</td>
<td>Osteotomy guide modeled as negative of bone surface</td>
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<td>[9] – 6 patients</td>
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<td>Tricot, 2012</td>
<td>Deformity</td>
<td>Humerus</td>
<td>Mimics</td>
<td>SL, acrylate resin</td>
<td>Osteotomy guide (assembled from two parts) modeled as negative of bone surface</td>
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<td>[5] – 3 patients</td>
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<tr>
<td>Zhang, 2011</td>
<td>Malunion</td>
<td>Humerus</td>
<td>Mimics 10, Imageware</td>
<td>SL, acrylate resin</td>
<td>Simple osteotomy guide modeled as negative of bone surface</td>
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<tr>
<td>[4] – 18 patients</td>
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<tr>
<td>Murase, 2008</td>
<td>Malunion/ fractures</td>
<td>Upper extremity</td>
<td>Magics RP, Visualization Toolkit</td>
<td>SL, medical grade resin, Eden 250 &amp; Viper si2</td>
<td>Complex reduction guide and osteotomy template</td>
</tr>
<tr>
<td>Mahaisavary, 2005</td>
<td>Malunion</td>
<td>Cubitus</td>
<td>Mimics, Magics RP</td>
<td>3DP, polyamide, Z Corp printer</td>
<td>Guide for osteotomy, modeled as negative of bone surface</td>
</tr>
<tr>
<td>[10] – 2 patients</td>
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<tr>
<td>Imai, 2013</td>
<td>Congenital Madelung</td>
<td>Radius</td>
<td>Visualization Toolkit, Bone Simulator, Magics RP</td>
<td>SL, medical grade resin, Eden 250 or Viper si2</td>
<td>customized osteotomy template and reduction guide</td>
</tr>
<tr>
<td>Oka, 2012</td>
<td>Malunited fractures</td>
<td>Radius</td>
<td>Bone Viewer, Bone Simulator, Magics RP</td>
<td>SL, transparent resin, Viper Si2 and Eden 250</td>
<td>Guide for osteotomy, modeled as negative of bone surface</td>
</tr>
<tr>
<td>[12] – 2 patients</td>
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<tr>
<td>Omori, 2014</td>
<td>Varus deformity</td>
<td>Cubitus</td>
<td>Bone Viewer, Bone Simulator</td>
<td>SL, medical grade resin</td>
<td>Guides for osteotomy guide, reduction guide, and real-sized bone model</td>
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<tr>
<td>[13] – 17 patients</td>
<td>malunion</td>
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<td></td>
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<tr>
<td>[14] – 9 patients</td>
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</tr>
</tbody>
</table>

Study Indication Area/ deformity

Synthetic data from studies on RP-PSGs guides used in general orthopedic surgery applications

- Study: Bellanova, 2013
- Indication: Tumor
- Area/atomic zone: Tibial
- Software: ITK Snap, Blender 2
- AM process/material: SLS, polyamide
- Surgical guide: Guides with positioning wires and cutting guides for bone resection and allograft reconstruction

Moreover, such a support system should support sur-
geons and engineers in taking the best design decisions by offering different design options. The proposed online
platform implements the above mentioned working pro-
tocol, facilitating the cooperation surgeon-designer and
helps developing a common communication language
based on contextual suggestive 3D models/images. In the
same time it allows automating the process of quantification
of surgeons needs and their translation into design
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the surgeon requires a drilling guide for inserting a screw
in a vertebral pedicle, the options/questions will consider
selecting the intervention area (cervical, lumbar or tho-
aracic area, for each of them with information regarding
already available devices models), the vertebra in which
the screws will be inserted, the anatomical landmarks
which can be used, the type of screws (link to different
catalogues or web sites of producers, comparative studies,
different images or presentation movies etc.). While
filling in the questionnaire, the surgeon can access rele-
vant information or case studies presented in literature.
Moreover, each device designed using the platform can
be added to the examples’ database available through the
platform, and accessed by other surgeons/designers.

In the next stage, the surgeon uploads the CT data of
the patient in the platform. These data are processed by a
designer using dedicated medical modeling software to generate a model of the interest area/s, model which will be
afterwards processed using 3D modeling software.
Based on the information from the surgeon and on the
3D model of the interest area/areas, a minimal number of supporting points necessary for correctly positioning the
guide is set, as well as the tools trajectories for drilling and/or cutting. Also, the surgical guide main geometrical
characteristics (features), dimensions and tolerances are
established in this phase.

The surgical guide, personalized for each patient,
must be designed so that the positioning and orientation
during surgery to ensure stability, uniqueness and preci-
sion, easy placement and use, offering as well possibili-
ties for checking position (e.g. transparency). Also, the
surgical guide must be manufactured from a biocompati-
ble material, to be sterilized and to have a small manufacturing price. The digital model of the guide is loaded on the platform and it can be visualized simultaneously by surgeon and designer using a 3D viewer, serving as a communication base and for making modifications and annotations. The design and material specifications are the fundamentals on which the manufacturing process is chosen.

Thus, the design and manufacture of PSGs using POIGO platform, in terms surgeon and engineer tasks, can be summarized as follows (Fig. 3):

**Surgeon:**
1) chooses the anatomical zones and type of surgical intervention from the lists implemented on the platform;
2) fills in the step-by-step questionnaire displayed on the platform;
3) loads on the platform the CT patient data;
4) collaborates with the engineer in designing the custom guide using 3D viewer and other communication tools.

In parallel, the application implemented in the platform:
5) displays that questionnaire which correspond to the choose anatomical zone and type of intervention;
6) generates the list of technical specifications for PSG;
7) sends the engineer the CT data and the PSG specifications.

The tasks executed by the engineer/designer, in relation with those above mentioned, are:
8) reconstruction of the anatomical model of the interest zones based on the received CT data;
9) design of one or more 3D variants/models of the PSG;
10) editing of the PSG design based on surgeon online collaborative feedback/input;
11) choice of the manufacturing process and material.

The next stages are performed outside the POIGO platform, after the PSG model is sent to the AM machine:
12) PSG manufacturing;
13) PSG sterilization;
14) PSG shipping to the surgeon/hospital;
15) intra-operative PSG use.

3.1. POIGO technical specifications

- Platform access:
  - Guest user – general access;
  - Surgeon user – user’s account and password;
  - Engineer user – user’s account and password.
- **Application, info & databases access:**
  - Guest user: general information on POIGO project, PSG advantages, tutorials, databases with case studies presented in literature, AM processes, material, forum, etc.;
  - Surgeon user: project launching, choosing collaborator – engineer, questionnaires, CT data loading, 3D viewer and other communication tools;
  - Engineer user: technical specifications list, CT data, applications, 3D viewer and other communication tools.
- **Databases management system:**
  - Microsoft SQL Server.
- **Administration tools:**
  - Users’ accounts administration;
  - Heterogeneous databases management;
  - Messages save management;
  - Reports generation (number of launched projects, number of registered users, number of PSG designed, etc.);
  - Online monitoring of design and/or manufacturing process.
- **Communication tools:**
  - Real-time communication using written messages;
  - Other web communication tools (emails, alerts, forums, etc.);
  - 3D model annotation.
- **Graphical Users Interface (GUI):**
  - Uses data input and selection options like: dialog boxes, selection windows, contextual menus;
  - Uses as many standardized icons and buttons, as possible;
  - Uses significant graphical images for supporting users’ selection tasks;
  - Includes options for interactively selecting points or annotating the 3D models displayed by the viewer.

Further are listed the general specifications for POIGO platform, that ensure that the required functionalities are fulfilled:

![Fig. 2. Selecting the anatomical zone of interest.](image)
3.2. POIGO functional architecture

From a functional point of view, POIGO contains the following modules and sub-modules:

- **Data acquisition module:**
  - Sub-modules:
    - Data acquisition based on questionnaires;
    - Patient CT data loading.

- **Knowledge capture module:**
  - Sub-modules:
    - CT data segmentation;
    - 3D reconstruction of anatomical zones.

- **Knowledge inference module:**
  - Sub-modules:
    - Engine for rules correspondence;
    - Engine for neural network generation and training.

- **Collaborative design module:**
  - Sub-modules:
    - 3D CAD models collaborative visualization;
    - 3D CAD model annotation;

- **Knowledge databases;**
- **Administration tools.**

As can be seen, POIGO platform integrates several applications for medical modeling, .stl file correction, 3D guide modeling, viewer, etc. Therefore, it is important to manage these applications import-export files formats for ensuring a flawless integration (Table 2). Currently, the platform is in the second stage of implementation which consists in finalizing the interface design and creating the platform content.

In order to test the whole process described in Fig. 1, and thus to gather valuable practical information (knowledge) on all the design steps: modeling, data transfer, technical specifications, collaborations modalities, etc., a case study was performed, which is presented in the next section of the paper.

Regarding the applications used by the designer to reconstruct the virtual 3D model of the interest zones and to model the guide, several software packages were tested. Based on information from literature and from the tests performed, for 3D anatomical reconstruction Mimics software is used, for the PSGs modeling CATIA V5 (CV5) software can be a solution, while for checking .stl file the free versions of Netfabb [15] or Meshlab [16] applications can provide the required functionalities.

Attention was paid to the different errors that can occur during the whole process. These errors are caused by the data acquisition and medical modeling processes (already well documented in the literature [17]), by the information transfer between different software packages (documented by the tests performed by authors and also by the literature presented as references of this study) and by the manufacturing process (documented in studies such as [18]).

4. CASE STUDY

Fractures of the wrist are some of the most common seen in the emergency room (18 to 25%) [19]. They occur frequently after 50 years of age and are related to low energy trauma accidents as found in household falls. A 72 years old woman that addressed Colentina Clinical Hospital with pain and deformation, several weeks after the initial cast was removed. Clinical and radiological examination confirmed the malunion of the radius with excessive tilt, loss of palmar flexion and grip strength. A CT investigation was performed for treatment decision using a SIEMENS CT scanner with 1 mm slices, at 0° tilt, performing sagittal, coronal and lateral imaging series. Thus accurate information was gathered regarding not only if the fracture has healed, but also about inclinations of fragments, slope and position of carpal bones.
Table 2

<table>
<thead>
<tr>
<th>Tasks</th>
<th>Tasks details</th>
<th>Input files format</th>
<th>Output files format</th>
<th>Who sends the files</th>
<th>Who receives the files</th>
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<tr>
<td>Anatomical modeling</td>
<td>Processing CT scan data for generating the 3D anatomical model of the interest zones</td>
<td>dicom</td>
<td>Igs, stp, stl, point cloud (.txt)</td>
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<td>Designer</td>
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<td>PSG modeling based on 3D anatomical model and surgeon technical specifications list</td>
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<td>Surgeon, Designer</td>
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<tr>
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<td>stp, igs, stl</td>
<td>stp, igs, stl</td>
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</tbody>
</table>

Fig. 4. Hand model reconstruction in Mimics.

The complex 3D profile of the osteotomy needed to correct the deformity imposed performing an opening wedge dorsal and radial with a sliding component. Fluoroscopic X-ray control is mandatory during this type of surgery. The difficulty of the procedure was not only to get the best efficient bone cuts, but also to reduce operative time by preparing the necessary steps – as the guide wires for temporary fixation of the fragments and the direction for drilling of the screws.

The 3D reconstructed model from CT data was available to the surgeons using Osirix, but a software application with dedicated planning tools, as well as a physical model for the patient’s anatomy a surgical guide to help performing the cutting would have been an advantage.

This is a typical case study, which was solved in a traditional manner. In the same time this is also a typical case in which the use of a PSG could reduce the X-ray exposure of both the patient and the surgeon and could improve the surgical procedures and outcomes.

Corrective osteotomy is usually performed using a dorsal approach to the distal radius, with the patient in supine position and under general anesthesia [20]. Fluoroscopic X-ray control is mandatory and the use of a dedicated guide could potentially reduce the exposure of both the patients and the surgeons.

Figure 5 shows an intraoperative imaging profile of the wrist with the laminar spreaders holding the osteotomy site. Usually only lateral and antero-posterior incidences are performed, thus the correction control is possible only in these two planes. After required correction is obtained, fragments are held in place with K wires and bone grafting is performed.
Definitive fixation requires one or two LCP (locking compression plate) anatomical plates with 2.4 mm locking screws (Fig. 6). Plates are required to support the construct and be stable during joint assessment for forearm rotation, to make certain there is no anatomical block. Aftercare requires 10 to 14 days of immobilization before starting wrist and forearm motion. Plates are removed only in case of local tendon irritation and not earlier than twelve months.

This particular case data and the practical experience gathered during surgeries of this type were used for establishing a workflow for implementation in POIGO platform.

An individualized osteotomy guide was modeled based on patient CT data and manufactured using Fused Deposition Modeling (FDM) process. The first step was to reconstruct the 3D model of the hand, for this Mimics software being used (Fig. 4) for importing .dicom data and generating the anatomical model. The Binary file of the reconstructed 3D model was then saved and imported in Netfabb for checking and repair (Fig. 7). This file was send to the AM machine for building the prototypes of the hand for visualization and guides’ fit checking.

The 3D hand model was also imported in CV5 and processed using Digital Shape Editor and Quick Surface Reconstruction workbenches, as two separated parts because it contains two distinct meshes.

In the next stage, the cutting planes were set on the 3D anatomical model, the cuts were virtually performed and the bones were brought into the correct positions. Using a standard plate and locking screws, the final positions for screws’ holes were established. These are used for designing the first drilling guide which is placed on the bones before the cutting guide and help pre-drilling the screw holes. Moreover, this guide materializes also the trajectories for K-wires which are used for correctly placing the cutting guide.

Thus, two guides should be used during surgery:

- A drilling guide which contains hollow cylinders for screws and 2 hole for K-wires (2mm diameter). The holes will be used after osteotomy, for fixing the plate.
- A cutting guide which materializes two osteotomies planes and therefore contains two slits and 2 hole/cylinders for K-wires for ensuring the correct placement in position. After cutting the bone, the guide is removed, and the radius is brought in the correct position relative to the other bones and to the level of the joint. Then, the plate is placed using K-wires and screws are inserted in the holes prepared using the drill guide.

4.1. Questionnaire

For this case study, the medical information was gathered by direct conversation between surgeon and designer. In this sense, the following questions (Q) were asked by designer, answers (A) being given verbally by surgeon or by pointing, rotating and setting points and directions on the 3D anatomical model in CV5:

Q1. How the intervention takes place in a traditional manner, i.e. without using a PSG?
A1. (verbally) – The intervention requires precise positioning and correction of several angles in the malunion site of the radius – one of the forearm bones. The first steps require placement of several guide wires – because the osteotomy cut must be parallel to the joint line, with stabilization of the cutting blade within the calculated correction angles. Normal distal radius surface is radial inclined around 20° with a palmar slope around 10°. The blade used is from an oscillating saw, with a 0.5 mm thickness and a cut depth from 10 to 25 mm. Laminar spreaders hold the osteotomy and correction is usually approximated on true lateral radiographs. After required correction is obtained, fragments are held in place with K wires and bone grafting is performed. Definitive fixation requires one or two LCP anatomical plates with 2.4 mm locking screws. Plates are required to support the construct and be stable during joint assessment for forearm rotation, to make certain there is no anatomical block.

Q2. Which is the anatomical zone of interest?
A2. (selection) – Selections of different surfaces of the 3D model anatomical model

Q3. Which is the type of guide? Drilling, cutting, drilling and cutting, other?
A3. (verbally) – Double cutting guide with guide with 1 mm slots for accommodating the cutting tool – 25 mm long, 0.5 mm thickness 7 to 9 mm cutting edge oscillating saw blades – if deeper cuts are needed, blades up to 60 mm are available in 0.5 mm thickness but larger (16.5mm) cutting edges. Q4. Which are the cutting directions?
Fig. 7. Checking and repair STL model of the hand using Netfabb Basic software.

Fig. 8. Surface model of the anatomical zones of interest and cutting planes in CV5 Generative Surface Design workbench.

Fig. 9. Annotation of the cutting trajectory, set by the surgeon on two plane views (front and lateral).

A4. (selection) – Selections or indications of points for setting the directions

Q5. How the cutting guide will be placed and held during surgery?

A5. (verbally) – Dorsal positioning on the metaphyseal area of the radius; two guide wires used for fixation.

Q6. Which are the supporting points for the guide?

A6. (selection) – Selections of supporting points.

Figure 8 presents a screen capture of the reconstructed anatomical model imported in CV5 and with the cutting directions. In the absence of an interactive tool to set the cutting trajectories (as is intended for implementation in POIGO’s viewer), this information was presented by the surgeon as in Fig. 9, and then transferred on the 3D CAD model by the engineer.
Figure 10 presents two designs of guides presented to the surgeon and which were manufactured using FDM process. Finally, another more robust design was chosen.

Figure 11 presents an image from the building process on an Ultimaker 2 machine which uses molten filaments for obtaining each layer of material. The material used was PLA (Polylactic Acid), the filament diameter is 2.85 mm and filament diameter after extrusion is 0.4 – 0.3 mm [21].

In Fig. 12 the prototype for the hand and the final guide are shown.
5. CONCLUSIONS AND FURTHER WORK

Establishing and applying the workflow for the design and manufacture of customized surgical guides from CT patient data, as described in the current paper, allowed gathering important knowledge for POIGO platform’s implementation and piloting. More precisely it will be used in establishing:

- The CT scanning protocols – for obtaining an accurate 3D anatomical model;
- The types of information exchanged between surgeon and engineer – for developing specific tools for the platform’s viewer;
- The software packages to be used in the design process – for ensuring the input/output formats compatibility;
- The type of data necessary for the design and manufacturing process – for setting the questionnaires framework.

Regarding the manufacturing process using Ultimaker 2, the accuracy provided was enough for building different models of guides and thus visualizing the design concepts. However, for building guides for use during surgery, a professional AM system should be taken into account.

Further work considers designing the POIGO platform interface and developing the inference engine that supports the automatic generation of the list of specifications for the engineer/designer from the surgeon questionnaire’s answers. Also, collaborative tools such as the 3D viewer and online communication means for ensuring the collaborative approach, the development of and the questionnaires for different type of surgical orthopedic intervention will be developed and implemented in the next stages of the project.

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