

A CASE STUDY OF USING POIGO PLATFORM FOR COLLABORATIVE DESIGN OF CUSTOMIZED SURGICAL GUIDES

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ABSTRACT:

DESIGN OF CUSTOMIZED SURGICAL GUIDES INVOLVES STRONG COOPERATION AND COMMUNICATION BETWEEN SURGEON AND ENGINEER DURING ALL THE PROCESS STEPS. HOWEVER, THIS IS NOT AN EASY TASK TO ACCOMPLISH DUE TO DIFFERENT REASONS RELATED MAINLY TO SPECIFIC PROFESSIONAL LANGUAGE, DIVERSE APPROACHES TO PROBLEMS SOLVING AND ASSESSING OUTCOMES, DIFFERENT WORKING TIME SCHEDULES OR GEOGRAPHICAL LOCATIONS. THEREFORE, AN ONLINE INTELLIGENT PLATFORM WAS DEVELOPED FOR IMPROVING SURGEON-ENGINEER COLLABORATION, FOR SIMPLIFYING THE PATIENT-SPECIFIC SURGICAL GUIDES' DESIGN PROCESS AND FOR AUTOMATIZING SOME OF ITS STEPS. THE PLATFORM IS BASED ON STRUCTURED QUESTIONNAIRES USED FOR AUTOMATICALLY TRANSPOSING MEDICAL INFORMATION AND REQUIREMENTS INTO DESIGN SPECIFICATIONS IN THE FORM OF TECHNICAL REPORTS. THE CURRENT PAPER PRESENTS A CASE STUDY FOR ILLUSTRATING THE APPROACH IMPLEMENTED IN THE PLATFORM. BASED ON A SCENARIO, SEVENTEEN ENGINEERS TESTED THE PLATFORM AND ANSWERED A QUESTIONNAIRE FOR GATHERING DATA REGARDING THE COMPLETENESS OF INFORMATION AND TOOLS PROVIDED BY PLATFORM FOR DESIGNING GUIDES. FURTHER RESEARCH WILL INVOLVE PERFORMING TESTS WITH A LARGER GROUP OF USERS, BOTH DESIGNERS AND SURGEONS, IN ORDER TO DEPLOY AN IMPROVED VERSION OF THE PLATFORM.

KEY WORDS: PATIENT SPECIFIC SURGICAL GUIDES, 3D PRINTING, COLLABORATIVE DESIGN, ONLINE PLATFORM

1. INTRODUCTION

The development and implementation of POIGO platform – dedicated to the collaborative design of personalized guides for orthopedic surgery⁵ – was dictated by the

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need to improve surgeon-engineer communication during the design phase of these medical instrumentations, as well to the necessity to automatize some steps of this process for simplifying both surgeons and engineers work. Hopefully, the platform will determine an increase in the use of these surgical aids during surgery.

A customized surgical guide is a medical device which transposes the cutting or drilling trajectories set by surgeons in the planning phase of the surgery, being based on patient Computer Tomography (CT) scanning data⁶. Therefore, surgical guides are unique for each patient, anatomical zone in which they are used (arm/shoulder, spine, forearm/wrist, thigh/tibia/foot), surgical approach and diagnostic (degenerative deformity, post-traumatic deformity, malformative deformity), intervention type (fusion, osteotomy). However, these surgical guides include some common features, namely hollow cylinders (for accommodating drills) and slots (for accommodating saw blades), placed in different positions and at different orientations as indicated by surgeons⁷. These are attached to the guide body, which usually is designed as negative of the supporting bone structure, using connection structures (arches, ribs, etc.).

The advantages of patient-specific guides: decrease in the surgical time and x-ray exposure for patient and surgeons, easier alignment/placement of bone fragments in the correct position for plates and screws fixation, makes them valuable during surgery⁸. However, the design process for these guides is complicated, requires expertise and specific skills, as well as a good cooperation between surgeon and engineer for correctly transferring preplanned tools trajectories into surgery.

In this context, POIGO platform implements several tools such as: structured questionnaires dedicated to the aforementioned anatomical zones and to several pathologies, automatic technical report generation based of questionnaires' answers, contextual information which can be used by surgeons while answering the questionnaire, collaborative design tools, dicom and images archives loading tools, online communication tools.

2. POIGO PLATFORM

POIGO platform can be used by surgeons for: 1. building an anatomical model based on dicom (CT) data of a patient, 2. building a surgical guides also based on dicom (CT) data of a patient. Figure 1 illustrates the work flow for each case.

⁵ Popescu, D., et al., Workflow for Additive Manufacturing of an Individualized surgical template, Journal of Proceedings in Manufacturing Systems, vol.10, issue3, pp.131-140, 2015

⁶ Gibson, I., et al., Medical Applications for Additive Manufacturing, Springer, 2010; Iacoviello, D., Andraeus, U. (eds), Biomedical Imaging and Computational Modeling in Biomechanics (Lecture Notes in Computational Vision and Biomechanics), 2012, Springer

⁷ Popescu, D., Laptoiu, D., Rapid prototyping for patient-specific surgical orthopaedics guides: A systematic literature review, Proc Inst Mech Eng H., 230(6):495-515, 2016

⁸ Bibb R., et al., Rapid manufacture of custom-fitting surgical guides, Rapid Prototyping Journal, Vol.15, No. 5, pp.346-354, 2009; Tack, P., et al. 3D-printing techniques in a medical setting: a systematic literature review, Biomed Eng. Online, 15(1):115-136, 2016

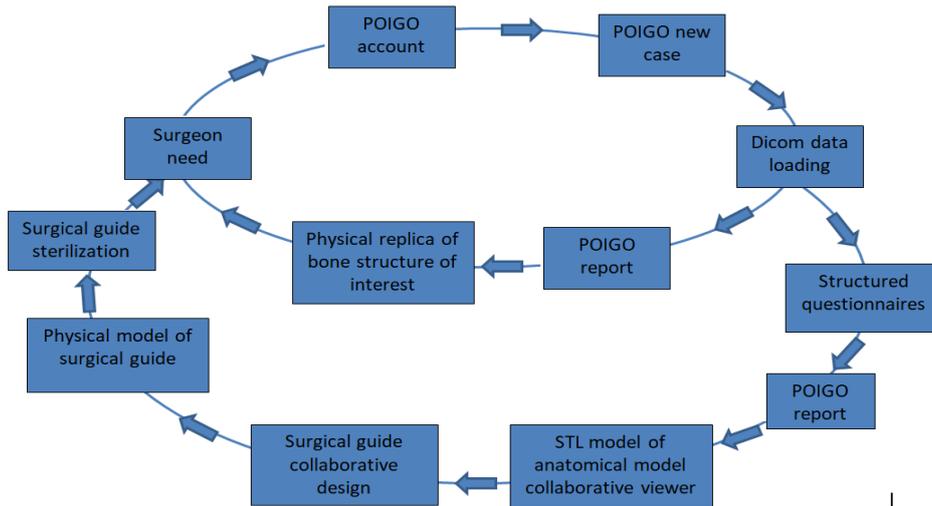


Figure 1. Work flows in POIGO platform

As example, some of the working steps in POIGO platform are presented in figures 2-5 for the case of designing an osteotomy guide.

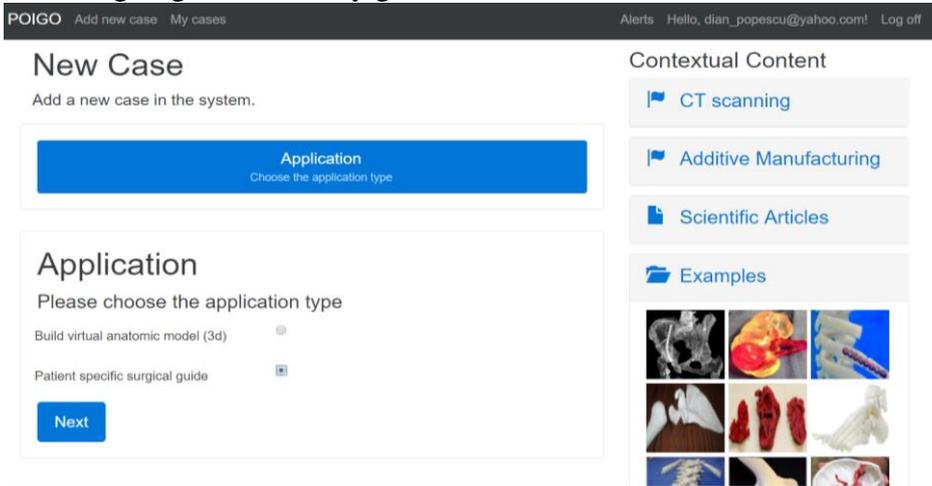


Figure 2. Starting a new case and choosing between anatomical model and surgical guide

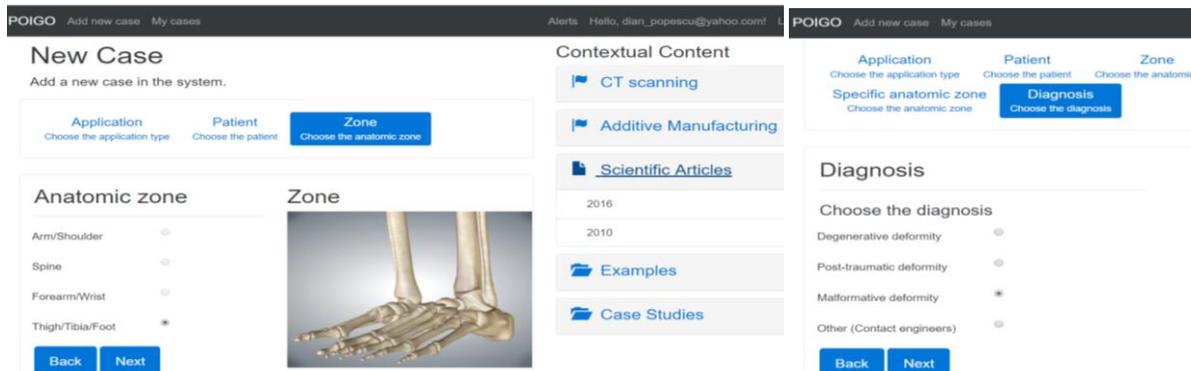


Figure 3. Filling in the questionnaire for building a guide for tibia/knee anatomical area and choosing diagnostic

The figure shows two sequential screenshots of the POIGO 'New Case' form. The top navigation bar includes 'POIGO Add new case My cases'. The main heading is 'New Case' with the instruction 'Add a new case in the system.' Below this, there are three columns for selection: 'Application' (Choose the application type), 'Patient' (Choose the patient), and 'Zone' (Choose the anatomic zone). The left screenshot shows the 'Intervention' step with options for 'Specific anatomic zone', 'Diagnosis', and 'Intervention' (highlighted in blue). Under 'Intervention', 'Osteotomy' is selected with a checked checkbox, and 'Fusion' is unselected. 'Back' and 'Next' buttons are at the bottom. The right screenshot shows the 'Upload data' step with 'DICOM Upload CT data' and 'Choose File' buttons for '6_-_45deg_...p_File.zip' and 'Charcot_foot.rar'. 'Back' and 'Next' buttons are also present.

Figure 4. Selecting the type of osteotomy guide and uploading dicom and pre-planning images archives

The figure shows two sequential screenshots of the POIGO 'Guides type' and 'Fixation' steps. The top navigation bar includes 'POIGO Add new case My cases'. The left screenshot shows the 'Guides type' step with options for 'Specific anatomic zone', 'Diagnosis', and 'Intervention'. Under 'Intervention', 'Guides type' is highlighted in blue. Below it, 'A set of two guides (pre-reduction and post-reduction/repositioning)' is selected with a checked checkbox, and 'One combined guide (pre-reduction + post-reduction/repositioning)' is unselected. 'Back' and 'Next' buttons are at the bottom. The right screenshot shows the 'Fixation' step with options for 'Application', 'Patient', and 'Zone'. Under 'Zone', 'Fixation' is highlighted in blue. Below it, 'Screws', 'K-wires', and 'Fixation plates' are listed. 'K-wires' is selected with a checked checkbox. 'Back' and 'Next' buttons are at the bottom.

Figure 5. Choosing the type of guide and the fixation type for a pre-reduction guide

3. DESIGN OF AN OSTEOTOMY GUIDE FOR FOOT SURGERY

3.1. Case study description

Male patient with foot deformity (Charcot osteoarthropathy) caused by diabetes complications requires removing osseous prominences, multi-planar realignment osteotomy and bones' repositioning and fixation with screws. The goal of the surgery is to re-establish a plantigrade – (stable, realigned) foot during stance.

This information is sent to the designer using POIGO platform along archives containing dicom files and two images with the pre-planning osteotomy trajectories (fig.7).

The other information necessary for obtaining the 3D virtual model of the guide are generated by the platform based on the answers given by surgeons to the structured questionnaire. Thus, the engineer receives an email with data for a new case (as technical report), generates the STL model anatomical zone and selects (on the anatomical model) the supporting surfaces and the cutting trajectories based on dicom files and images. Then, using online collaboration and visualization tools, she/he presents these data to the surgeon. Together they establish on the 3D virtual model, the K-wires and screws insertion points, these being the final details needed for designing the guide.



Figure 7. Pre-planning trajectories annotated by surgeons

3.2.Surgical guide design and manufacturing

The surgical guide for the wedge osteotomy was designed to be the negative of the bone structures on which is placed. Also, it includes three hollow cylinders (interior diameter of 2 mm) for accommodating K-wires which fix the guide on bone, as well as two slots (2.5 mm width) for accommodating saw blades (fig.8). Guide overall dimensions are 50mm x 56mm x 53mm.

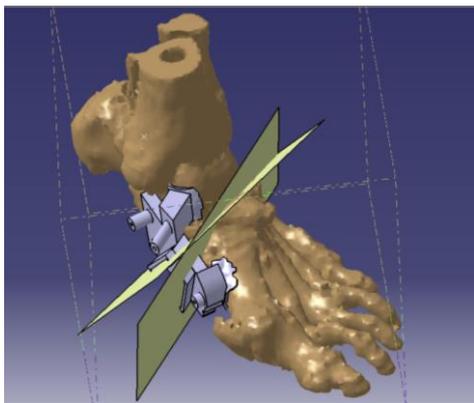


Figure 8. Virtual foot and surgical guide



Figure 9. Foot and surgical guide physical models

The guide was 3D printed using Mojo 3D printer (Stratasys Inc., USA) from ABS (Acrylonitrile Butadiene Styrene). The total 3D printing process was approximately 8h, other 6h being required for eliminating support structures. During manufacturing, the guide was oriented so that its surfaces coming in contact with the bone are not built with support structure, even if this orientation was not optimal from time and cost points of view.

3.3.Testing POIGO platform – engineers perspective

Based on this case study, a group of seventeen engineers with 3D CAD modeling background tested the platform and answered a Likert-based questionnaire for gathering information on the completeness of information and tools provided by POIGO for supporting the design process.

At the evaluation have participated ten experienced designers/engineers and seven young designers/engineers. Three participants were women.

Four experienced participants (P3, P4, P6 and P7) and three young participants (P11, P13, P15) were not informed about the working flow in POIGO platform and no previous presentations of the structured questionnaires (surgeons' perspective) were shown to them.

In the first stage, demographic data were gathered from engineers (age, gender, number of 3D CAD software used, general experience in design field). Then, a hands-on

session for using the platform was organized by simulating a scenario. The respondents received and evaluated the report generated by the platform. Finally, the following questions were asked:

- Q1. Is information provided in POIGO' report enough for starting the design process of a surgical guide?
- Q2. Is information from the report clearly presented?
- Q3. Is information regarding medical producers (screws, K-wires, plates, etc.) necessary?
- Q4. Is information received on producers enough for the design process of a surgical guide?
- Q5. Are the communication tools well implemented in the platform?
- Q6. Are the design collaboration tools well implemented in the platform?
- Q7. What other information do you consider useful for guides' design process?

The questions were rated: 1 (completely disagree) to 5 (completely agree).

4. RESULTS AND CONCLUSIONS

Figures 10-12 shows some of the evaluation results based on average values.

In general, experienced designers rated better the platform to all investigated aspects (fig.10). Young designers were slightly more convinced about the usefulness of receiving information about medical instruments producers (question Q3) in comparison to experienced designers.

Participants who did not received complete information and did not see the demonstration about the platform workflows, evaluated less well the data provided by platform as technical report (questions Q1, Q2, Q4, Q5 and Q6). Therefore, visual tutorials and platform users' documentation are needed for facilitating a steeper learning curve.

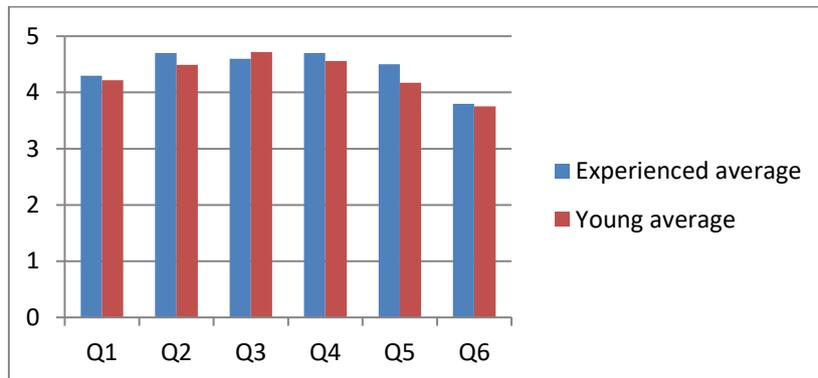


Figure 10. POIGO platform evaluation results based on average values

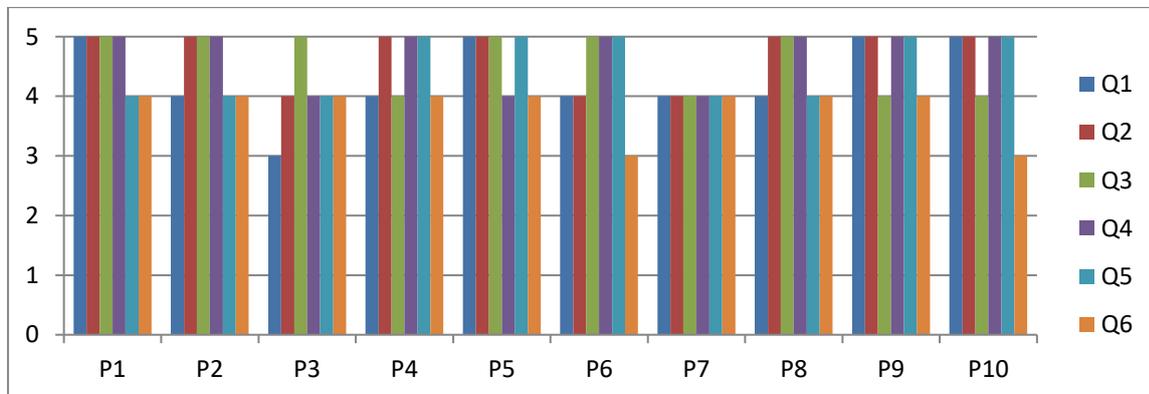


Figure 11. Experienced designers (average age of 40.6, average number of years of experience: 13.6)

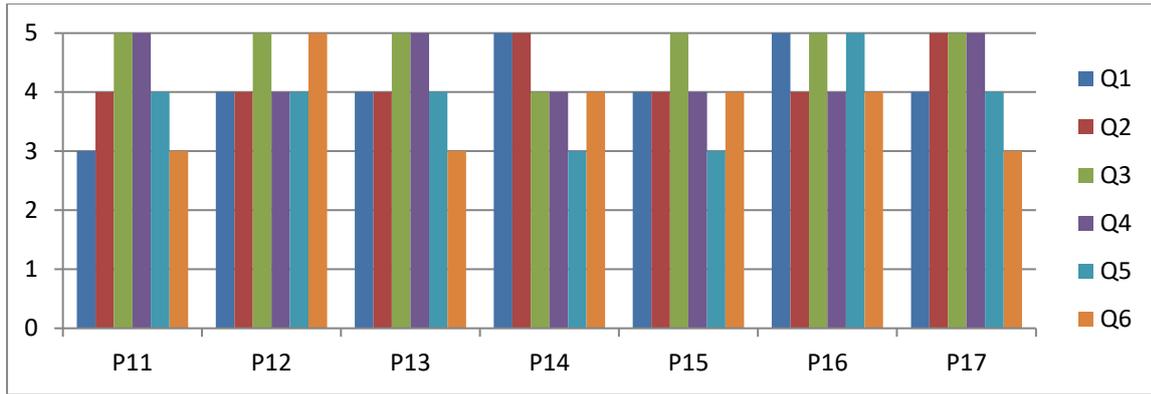


Figure 12. Young designers (average age of 23.8, average number of years of experience: 1.5)

In case of experienced designers, no direct correlation could be established between the number of years of experience and the evaluation results. Also, despite a significant difference in years of design experience, the average scores to Q1-Q6 were almost the same for both groups of respondents (fig.10-12).

Participants' comments (Q7) referred mainly to the design collaboration instruments, suggesting the development of dedicated tools/software which, in the first place, should be easily to use by surgeons when indicating pre-planned cutting or drilling trajectories.

Further research will suppose performing tests with a larger group of users, both designers and surgeons, in order to deploy an improved beta version of the platform.

ACKNOWLEDGEMENT

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