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Reverse shoulder arthroplasty: methodology improvement through personalized modelling techniques and FDM technology

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Abstract

Reverse shoulder arthroplasty (RSA) is a surgical technique that relieves pain and functional incapacity in certain shoulder pathologies. Adequate sizing and positioning parameters are very sensitive to each individual patient's shoulder features, such as: degenerative stage and glenoid morphology among others. The interplay of different shoulder features is often nuanced, nontrivial, and highly nonlinear. Therefore, general guidelines can often fall short at delivering the best possible clinical outcomes. To overcome this, a new trend uses imaging techniques to manufacture bespoke mechanical guiding tools customized to each patient's shoulder features. The application of FDM technologies allows doctors to obtain physical models of the patient's bone geometry in anticipation of surgery and, consequently, the manufacturing of a patient-specific guide to be used to guarantee the correct position of the glenoid base plate during surgery. This paper focuses on the design and further manufacturing process developing a protocol that controls and minimizes the manufacturing deviations, in order to get to the optimal product design using the patient's Computed Tomography (CT) information. The modelling and parametrization of the customized guide is based on the study and optimization of the bone reconstruction as well as the variables of the manufacturing process. In this research both the CAD information analysis and the FDM process are focused on the application of new design techniques and the optimization of bones geometry analysis in order to obtain a specific surgery guiding tool to be manufactured by FDM with limited deviations.

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1. Background

RSA [1] is a surgical technique that is primary indicated in degenerative arthroplasty of the rotator cuff, in elderly patients with non-reconstructable proximal humerus fractures, in revision surgeries and in tumor pathologies [2]. These pathologies are expected to increase in coming years due to the demographic growth of the pluripathological elderly population. The biomechanics of RSA invert the component functions of the glenohumeral joint, and although the technique offers good outcomes for treating the conditions described above, it carries a risk of complications when the characteristics of the prosthesis are poorly matched to the patient's morphology [3].

In order to avoid the abovementioned issue, the use of a specific guide ensures the correct orientation of the prosthesis components (base plate, glenosphere, stem, ...) into the scapula and humerus volume [4]. The Additive Manufacturing (AM), and specially the FDM, is a suitable manufacturing technology to obtain physical models of the initial bone geometries [5, 6] and the customized surgery guide for each patient. Nevertheless, the proper 3D model reconstruction from the CT patient information (DICOM files), the further Stereolithography (STL) to CAD models processing, and the characterization and optimization of the FDM process parameters should be studied to delimit the uncertainty and tolerancing in the final product (physical bone models and guides).

Nomenclature

AM Additive Manufacturing
FDM Fused Deposition Modeling
RSA Reverse Shoulder Arthroplasty

CT Computed Tomography

DICOM Digital Imaging and Communication in Medicine

STL Stereolithography
CAD Computer Aided Design

2. Methodology and results

This study follows a structured sequence that has to be performed for each patient given that bones geometry is dependant on patient pathology. In this paper, a specific pathology of arthropathy casued by the rupture of the rotator cuff is shown, with a large displacement of the humerus head to the acromion (Fig. 1).

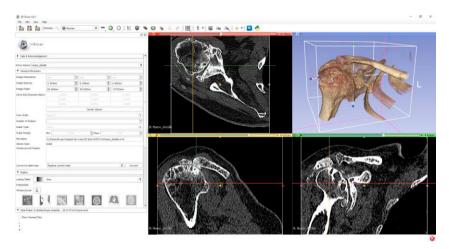


Fig. 1. Volume rendering of patient pathology from DICOM files.

2.1. DICOM files processing

The DICOM files from CT patient information have been processed with 3D Slicer v4.8.1 software, which is distributed under a BSD-style open source license.

The DICOM images resolution is 0.45 x 0.45 mm (512 x 512 pixels), with a slicing distance of 0.4 mm, which has not been interpolated in volume cropping to the region of interest (ROI).

The bones segmentation has been established in the Hounsfield range from 300 to max value, in order to consider the cortical tissue with acceptable mechanical properties to hold firmly the components of the prosthesis once they have been anchored (Fig. 2). The medullar tissue to be considered for bone growing around the prosthesis has been determined applying the Growing Seeds filtering within the Hounsfield range from -150 to 299 outside the cortical segments. This filter has to be intensified for this patient due to his osteoporosis, in order to achieve a more accurate result in critical areas (glenoid and humerus head). To avoid the very small details and noise voxels produced by isolated pixels, the Opening Filter (0.6 mm) and the Closing Filter (1.0 mm) have been applied to the bone segments.

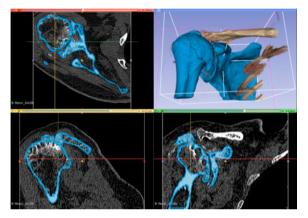


Fig. 2. Cortical tissue segmentation of scapula and humerus.

The area of interest that has been evaluated is the glenoid area, where the base plate of the prosthesis must be inserted. Due to the facet approximation model of 3D Slicer, the resulting STL models have an estimated maximum deviation shown in Eq. 1. This approximation is shown on the DICOM images at Fig. 3.

$$\Delta l_{STL} = \sqrt{\left(\frac{\Delta x_{slice}}{2}\right)^2 + \left(\frac{\Delta y_{slice}}{2}\right)^2 + \left(\frac{\Delta z_{slice}}{2}\right)^2} = 0.376 \text{ mm}$$
 (1)

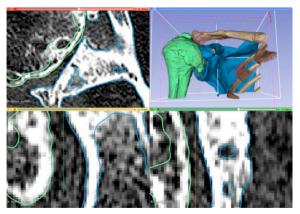


Fig. 3. STL model approximation in glenoid area.

2.2. STL files processing and CAD restyling

The STL models of cortical and medullar tissue of humerus and scapula need to be improved in order to obtain the corresponding CAD models. The STL files have been processed with Geomagic Studio 10 SR1[©] from Geomagic, Inc.

To improve the STL models, the Noise reduction and Relax filters have been applied with a maximum deviation of 0.15 mm, outside of the glenoid area (ROI) of the cortical and medullar scapula (Fig. 4). The deviation results from 3D Slicer models are shown in Table 1.

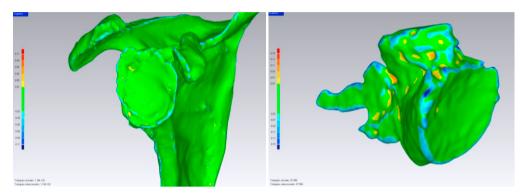


Fig. 4. Results of STL filtering of scapula models (cortical and medullar).

Table 1. Deviation results for improved scapula models.

Model	Mean distance (mm)	Maximum distance (mm)
Cortical Scapula	0.005	0.111
Medullar Scapula	0.033	0.392

The humerus models (medullar and cortical) have been simplified within the head medullar region in order to avoid unnecessary post-processing with small details that are going to be cut off in the prosthesis assembly (Fig. 5). The deviation results from 3D Slicer models are shown in Table 2.

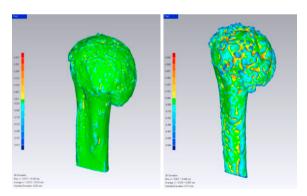


Fig. 5. Results of STL filtering of humerus models (cortical and medullar).

Table 2. Deviation results for improved humerus models.

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Model	Mean distance (mm)	Maximum distance (mm)	
Cortical Humerus	0.013	0.417	
Medullar Humerus	0.087	0.667	

The CAD restyling from STL models has been performed with an auto estimation in number of patches definition, a grid resolution of 20 with a relaxing tolerance of 0.05 mm, and an adaptive NURBS surface fitting with a maximum of 18 control points and a tolerance of 0.05 mm (Fig. 6, 7). The deviation results of CAD models from 3D Slicer models are shown in Table 3.

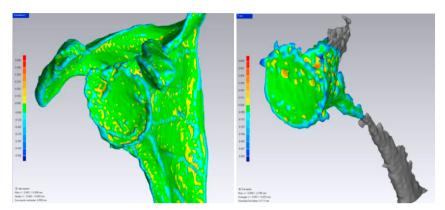


Fig. 6. Results of CAD restyling of Scapula STL models.

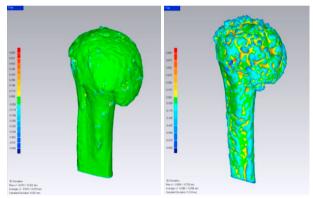


Fig. 7. Results of CAD restyling of Humerus STL models.

Model	Mean distance (mm)	Maximum distance (mm)	
Cortical Scapula	0.049	0.506	
Medullar Scapula	0.079	0.658	
Cortical Humerus	0.018	0.612	
Medullar Humerus	0.086	0.804	

Table 3. Deviation results for CAD models from 3D Slicer STL models.

2.3. Pre-surgical models manufacturing for surgery planning

Surgeons need to evaluate the geometric conditions of damaged joint bones in order to plan surgery and prevent entry directions that may be feasible for guide drills. Although this treatment in digital format is possible using the 3D Slicer software, surgeons prefer the manipulation of a physical model of the joint because it allows a better visualization of the areas affected by the surgical intervention (anatomical neck of the humerus; and glenoid main surface and glenoid neck of the scapula).

For this task, it is necessary to manufacture the cortical bone models by means of 3D printing, trying to ensure maximum reliability in the geometry. According to the mean geometric deviations evaluated in the models (Tables 1,

2) and the estimated deviation in initial STL models from Eq. 1, the use of the improved STL models offers an adequate level of bone details, together with a maximum deviation of 0.381 mm for the scapula model and 0.389 mm for humerus model.

FDM models processing have been carried out with Ultimaker Cura 3.6.0 from Ultimaker B.V., and FDM manufacturing has been carried out with a XYZPrinting Da Vinci 1.0 Pro printer and with Sakata ABS-E material (Fig. 8). The main FDM parameters are shown in Table 4.

	or							
Nozzle diameter (mm)	Layer height (mm)	Wall thickness (mm)	Print speed (mm/s)	Infill density (%)	Infill pattern	Printing temperature (°C)	Build plate temperature (°C)	Built Plate Adhesion Type
0.4	0.2	0.8	20	10	Gyroid	230	90	Raft
					1			

Table 4. FDM Manufacturing parameters of improved STL models.



Fig. 8. 3D printed models of scapula and humerus for pre-surgical analysis.

FDM manufacturing tolerance has been evaluated on pattern models with the abovementioned printing parameters and it has been established in the range [-0.2, +0.0] mm. So the deviation of the 3D printed models for surgery analysis can be estimated in 0.589 mm, within the range of [-0.395, +0.195] mm.

2.4. Prosthesis positioning and design of guiding tool for surgery.

The design of the guide for surgical planning requires a detailed restyling of the glenoid area. This restyling has been carried out using the PTC Creo 4.0° software from PTC Inc. The positioning of the guiding tool requires the establishment of the effective Friedman line based on the plane tangent to the glenoid surface (Fig. 9). The Friedman line is used as a reference to determine the version of the glenoid, and the vertical and horizontal tilt angles of the base plate axis must be established on it. The angles of vertical and horizontal tilt of the base plate axis must ensure that the hydroxyapatite core of the plate is surrounded by medullary bone, while the outer surface must rest on the maximum cortical bone to guarantee its anchorage during surgery (Fig. 10).

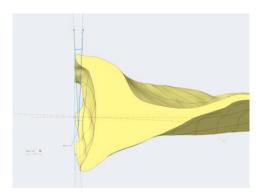


Fig. 9 Possitive glenoid version (anteversion) from Friedman line.

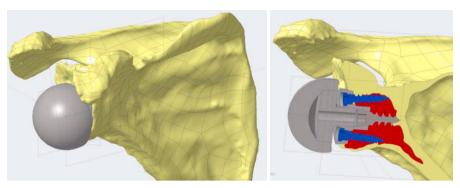


Fig. 10. Scapullar prosthesis positioning.

For this study, glenoid version has been determined in +5,37° (anteversion), while the base plate optimal positioning angles of are: -1.5° for horizontal tilt (retroversion), and -5.0° for vertical tilt (glenosphere elevation). This base plate positioning allows a minimum deltoid elongation of 29.1 mm, with an abduction mobility range of 70° without knocking.

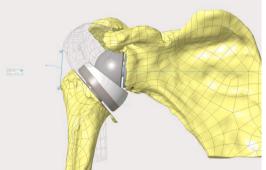


Fig. 11. Deltoid elongation after surgery due to optimal base plate positioning.

The base plate guiding tool design has been determined over the CAD glenoid surface and considering the screw axes for base plate anchoring (Fig. 12).

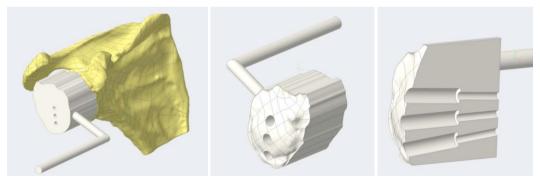


Fig. 12. Design of guiding tool for drilling assistance.

According to the mean geometric deviations evaluated in the CAD model of cortical scapula (Table 3) and the estimated deviation in initial STL models from Eq. 1, the theoretical model of guiding tool offers an adequate level of bone details, together with a maximum deviation of 0.425 mm.

FDM model processing of guiding tool have been carried out with Ultimaker Cura 3.6.0, and FDM manufacturing has been carried out with a XYZPrinting Da Vinci 1.0 Pro printer and with Sakata ABS-E material (Fig. 13). The main FDM parameters are shown in Table 5.

				• 1	-			
Nozzle diameter (mm)	Layer height (mm)	Wall thickness (mm)	Print speed (mm/s)	Infill density (%)	Infill pattern	Printing temperature (°C)	Build plate temperature (°C)	Built Plate Adhesion Type
0.4	0.1	0.8	10	10	Gyroid	230	90	Raft

Table 5. FDM Manufacturing parameters of improved guiding tool model.



Fig. 13. 3D printed model of guiding tool for pre-surgical analysis and surgical assistance.

FDM manufacturing tolerance has been evaluated on pattern models with the abovementioned printing parameters and it has been established in the range [-0.14, +0.0] mm. So the deviation of the 3D printed model of guiding tool for surgery assistance can be estimated in 0.565 mm, within the range of [-0.352, +0.213] mm.

3. Conclusions

As it can be seen, the developed methodology allows obtaining a STL model with 3DSlicer software from the CT information with a controlled accuracy of model restyling. These models can be easily processed as CAD models in order to design an appropriate and customized guiding tool for surgery, taking into account the patient's pathology and the prosthesis design.

The FDM technology is a suitable manufacturing technology to obtain the customized guiding tool for pre-surgical analysis and surgical assistance, so it helps surgeons to optimize the prosthesis positioning into the bone, according to the patient's medullar and cortical structure. The design of the guide based on the glenoid area and considering the particularities of the patient allows obtaining the best anchorage and mobility of prosthesis. In further studies, these results will be used to establish the geometric uncertainty of positioning of this guiding tool and its effect on the final prosthesis positioning.

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