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The Role of 3D Printing in the Positioning of the Glenoidal Component in Total Shoulder Arthroplasty. An Experimental Study

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Abbreviations:

ATPBI: Automatic Thresholding Based on Pixel Intensities; AP: Anteroposterior; CT: Computer tomography; DICOM: Digital Image communication in Medicine; FDM: Fused deposition mode; PLA: Polilatic Acid; Rx: X-Ray; PSI: Patient specific instrumentation; STL: Standard tessellation language; 3D: Tridimensional

1. Abstract

The total shoulder arthroplasty is the surgical treatment when the non-surgical treatment fails. The key point of this procedure is the correct implantation of the glenoidal component to avoid the loosening and to promote long term survival of the implant. Despite of the use of medical images resources in pre-operative planning, this procedure continues to be challenging due to difficulties in the correct spatial positioning of the components. The 3D print brought the possibility to reproduce the anatomy of the patient being helpful in the pre-operative planning, due to the real tridimensional characteristics. The objective of this study is to evaluate the positioning of the glenoidal component in total shoulder arthroplasty comparing the use of TC scans and anatomic 3D print models, from patients with shoulder osteoarthritis, in the pre-implantation planning.

From nine consecutive patients submitted to a total shoulder arthroplasty were generated 54 3D print scapula models, used for implant polyethylene glenoid component, hiding the anatomic parameters like in a real surgery, done by three intervenors in a randomized way, using in the pre-operative planning the correspondent CT scans or the anatomic 3D printing scapula. The angular positioning in anteroposterior view and axillary view related to the scapula body, was evaluated with X-Ray, and measured by tree independent evaluators.

It was no significant difference when comparing the measures of angulation of the implantation of glenoidal components in osteoarthritis scapula models, when comparing the use of the TC scans or the 3D print scapula models in pre-implantation planning, with exception founded in one intervenor, in anteroposterior view, in favor of 3D printing model.

When comparing the use of 3D printed scapula and TC scans for planning the implantation of glenoidal component in total shoulder arthroplasty, both methods proved to be equivalent.

2. Introduction

The shoulder osteoarthritis is a common condition among a variety of age groups, mainly after the 60's, causing pain and functional impairment of the upper limb [1,2]. This clinical condition is due to a primary osteoarthritis or due to inflammatory diseases as rheumatoid arthritis, or shoulder instability among other conditions. When the non-surgical treatment fails, the shoulder arthroplasty can be indicated to relief pain and restore the movements of this joint with good results. Those implants are generally divided in anatomic, this one restores the anatomy of the joint, can be total or partial, resurfacing or not the glenoid cavity with a polyethylene implant. The other group is the reverse shoulder implants, manly used when there is a mechanical disbalance of the shoulder, like in shoulder arthropathy, malunions among other clinical conditions [3].

In the last two decades, there is an increasing indication of shoulder arthroplasty for the surgical treatment of osteoarthritis. In the USA, between the years of 2000 and 2008, there was a rise in the use of shoulder arthroplasties from 5,000 to 25,000 annually. Other studies projected an increase of 192 to 332% from 2007 to 2015 [4,5].

The major complication of total shoulder arthroplasty is the glenoidal component loosening, leading some surgeons to avoid the use of this component in younger patients or indicate reverse implants. Some studies point out variations between 26 to 44% in loosening of the glenoid component in long term follow-up, and it is well known that the surgical technique such as glenoid reaming and correction of the deformity for the proper positioning of glenoidal component, may influence in glenoid failure rates. Excess glenoid retroversion with formation of posterior neoglenoid , classified by Walch as B2 glenoid, has increasing been recognized as a risk factor for glenoid loosening [6-8] .

The correction of the osteoarthritis deformities in the glenoid side, is crucial to the survivor of the glenoidal implant. Differently of the other joints, the glenoid side is difficult to approach and to establish proper landmarks for correction of the deformities, and to do a perfect implantation of the components. The ideal angular positioning of the glenoid component in transversal plane, must be near to normal glenoid retroversion, around zero to minus five degrees of in relation to scapula body like in native glenoid [9] .

To guide this positioning, different image resources are being used for pre-operative planning, from CT scans, MRI to special software, to guide the correction of the deformities and the positioning of the glenoidal component. Despite the use of these resources there are still great difficulties in doing this procedure, mainly in cases that there is a great deformity in the glenoid side [10,11]. With the goal to overcome this difficulty, the 3D printing from the anatomy of the patients is being used in many fields of medicine, helping the surgeons in planning surgical procedures, bringing the anatomy of the patient to the hands of the surgeon [12,13].

The purpose of this study is based on the hypothesis that the use of the 3D anatomic printing of the scapula of arthritic shoulder, would be more effective in guiding the positioning of the glenoid component, during anatomic total shoulder arthroplasty, when compared to CT scans images, in pre-implantation planning.

3. Methods

This project was developed in the Hand and Upper Limb Surgery Discipline of the Universidade Federal de São Paulo (UNIFESP) / Escola Paulista de Medicina - Brazil, with the collaboration of Department of Mining and Petroleum Engineering of University of São Paulo – USP - Brazil, approved by Institutional Review Board UNIFESP under the number 66570717.6.0000.5505. There were selected CT scans DICOM files (Digital Image and Communications in Medicine) of nine sequential patients with shoulder osteoarthritis from UNIFESP University Hospital's database. These data were fully anonymized before accessed and selected by a person not directed related to the study and the informed consent was waived by ethics committee. From these files, 81 3D scapulas were printed, that were used as model to implant a polyethylene glenoid component, from a conventional total shoulder arthroplasty. It was evaluated the accuracy of the positioning of the glenoidal component using the TC scans versus the matching print scapula scapular in the pre-implantation planning.

4. Production of the Prints

It was used Mimics/3-matic software (Materialise, Leuven-BEL), to generate the STL (Standard Tessellation Language) files from each selected scapula. Each DICOM (Digital Images and Communication in Medicine) file was segmented by 1- ATPBI (Automatic Thresholding Based on Pixel Intensities); 2- Edition of the masks producing precise limits; 3- Mask interposition and smoothing of the limits. This workflow and the dimensions of the printings are already validated by other studies [14,15]. Heterotopic bone formations were not suppressed from the images and impressions. For filling the holes in generated images, it was used the completely filling tool besides the surface smoothing tool. Then, it was generated STL files and submitted to Simplify Software providing the sets to be printed. The models were printed in polylactic acid (PLA) using a FDM (Fused Depositing Modeling) GTmax3D printer (Americana–BRA), using the follow settings: 1-5mm extruder nozzle, 2- Temperature 190° Celsius, 3- Extrusion speed 40mm/s, 4- honeycomb pattern with 10% infill. This pattern was used after many resistance and abrasion tests to simulate the glenoidal arthritic bone. It was printed 81 pieces corresponding to nine copies of each of sequential patient after quality control of each print.

5. Implantation Procedure

Three orthopedic surgeons (intervenors), not directly related to the study, with more than five years of experience in shoulder arthroplasty, made the implantation of the glenoidal component, in different moments in a randomized way. In each clinical case, using the 3D-print correspondent scapula, or correspondent CT scans, for planning the desirable implantation positioning, zero to minus five degrees, related to the scapular body in transversal plan. From those 81 scapulae printed, 27 were used in the pre-implantation planning, corresponding to each scapula model used for implantation. The other 54 3D print scapula were prepared reproducing the exposition of the glenoid side, like in the real surgical field surrounding by a tissue, hidden the anatomic parameters (Figure 1). The implant used was a polyethylene pegged implant (Exactech Co. Gainsville-USA), using the correspondent set of instruments for the implantation. During the procedure, it was not allowed to access the CT scans or the correspondent print of the scapula.(Figure 1)

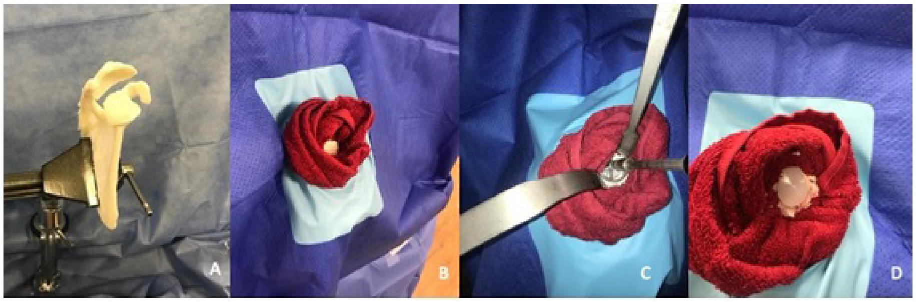

Figure 1: Preparation for implantation of glenoidal component. A – 3D print scapula. B- The scapula was prepared in all cases to hide the anatomic parameters like in a real surgery. C -Exposition of the glenoid side and correction of the version of the glenoid with a reamer. D- Final implantation of glenoidal component.

6. Evaluation of the Positioning of the Glenoid Components

All 54 3D print scapulae submitted to implantation of the glenoidal components, were evaluated by orthogonal X-Rays (Ysio Max Siemens Healthcare® - Munich-GER), using the criteria defined by por Nyffeler et al, for the positioning [16]. All digital X-Ray images were measured using the software Geogebra® (Linz-AUT) in the antero-posterior and axillar scapula views, by three orthopedic surgeons (assessors) not directly linked to the study. It was considered ideal the positioning when, in the axillary view, the angle of glenoidal component get closer to the transversal axis of the scapula, varying from zero to minus five degree of retroversion, as defined by Freidman method, and in anteroposterior view to the angle described by Meurer, taking as a reference the supraspinal fossa. [17,18]. In the AP view the measures were made between the axis of glenoidal component and the line of supraspinal fossa. In the axillary view was considered the transversal axis of scapula from medial border crossing the glenoid (F-G line) in relation of the line crossing the anterior e posterior margin of the glenoidal component (C-D line) and the central axis of the implant (E-H line), the resulting angle (E-K-I) (Figure 2).

In the anteroposterior view were considered the line crossing the supraspinatus fossa from distal (B) to proximal (A), related to the central axis of the implant (D-C), the resulting angle in AP view (D-A-E)(Figure 3).

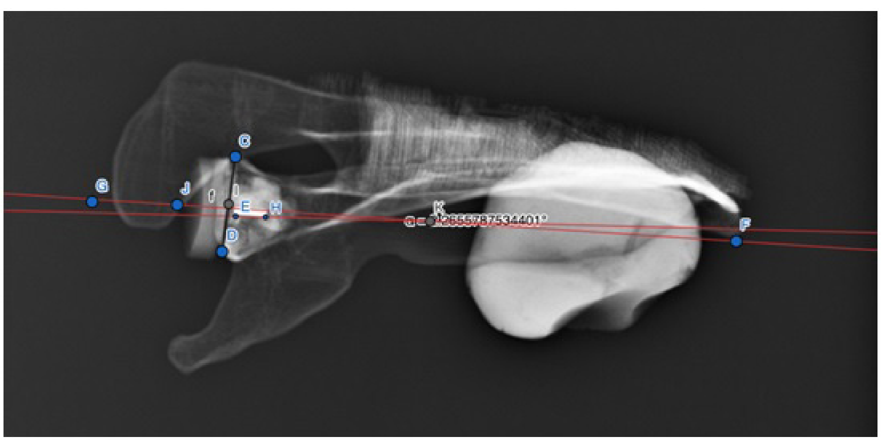

Figure 2: X-ray in axillary view of the model showing the lines and angle measures of the positioning of glenoidal component

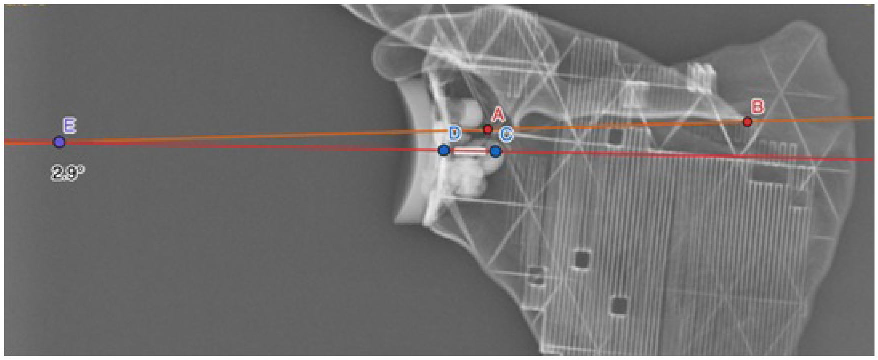

Figure 3: X-ray in anteroposterior view of the model showing the lines and measurement of the angle.

7. Results

There were compared the angular values in AP and axillary X-Ray view, from each group (3D guided group or TC guided group). The data was pared and analyzed using Wilcoxson test meaning the angular values. We concluded that were statistic difference between 3D and CT when analyzed the interveners (E), when the angular measure was 7.54 in the 3D Group against 10.56 in CT group (p value 0.049) (Table 1). There were no statistic differences when other interveners were analyzed separately or in group, comparing CT or 3D group in AP view (Table 2). When evaluating the angular measures in axillary view between CT and 3D group there were no statistic difference, related to each intervener or considering all the measures. In relation to the angle evaluators, the data were pared and used the Friedman Test and there were no statistical differences between them (Table 3).

Table 1: Comparison of 3D and CT in AP view.

	Group	Mean	SD	N	CI	p-value
Interv. A						
	3D	7.06	7.18	27	2.71	0.361
	CT	8.41	6.81	27	2.57	
Interv. B						
	3D	7.23	8.03	27	3.03	0.456
	CT	6.18	5.77	27	2.18	
Interv. E						
	3D	7.54	6.9	27	2.6	0.049
	CT	10.56	7.57	27	2.85	
Overall						
	3D	7.28	7.3	81	1.59	0.168
	CT	8.38	6.91	81	1.5	

SD: standard deviation; N: number of analysis; CI: confidence interval

Table 2: Comparison of 3D and CT in P view.

	Group	Mean	SD	N	CI	p-value
Interv. A						
	3D	6.34	3.94	27	1.49	0.302
	CT	5.53	4.89	27	1.84	
Interv. B						
	3D	8.22	5.31	27	2	0.203
	CT	7.89	6.35	27	2.4	
Interv. E						
	3D	9.92	7.82	26	3.01	0.869
	CT	10.1	7.27	26	2.79	
Overall						
	3D	8.14	5.99	80	1.31	0.375
	CT	7.81	6.43	80	1.41	

SD: standard deviation; N: number of analysis; CI: confidence interval

Table 3: Comparison of assessors.

	Assessor	Mean	SD	N	CI	p-value
3D AP						
	1	6.07	7.15	27	2.7	0.197
	2	8.28	7.91	27	2.98	
	3	7.49	6.89	27	2.6	
3D P						
	1	9.06	6.02	27	2.27	0.553
	2	7.73	7.14	27	2.69	
	3	7.59	4.54	27	1.71	
CT AP						
	1	8.73	7.02	27	2.65	0.355
	2	8.38	7.55	27	2.85	
	3	8.04	6.36	27	2.4	
CT P						
	1	7.16	6.86	26	2.64	0.764
	2	7.22	5.98	26	2.3	
	3	8.08	5.83	26	2.24	

SD: standard deviation; N: number of analyses; CI: confidence interval

8. Discussion

The pre operatory planning is crucial for the success of any orthopedic , and most of them are based on medical images. In shoulder arthroplasty CT scans have been used to indicate and plan shoulder arthroplasty, the clinical decision making thus, depends on accurate version measurement of the glenoid. When a CT image is obtained, the radiology technician orients the axes of the scanner to produce axial, sagittal and coronal slices from 3-dimensional raw voxel data, these slices are typically oriented 20 – 30 degrees of anteversion in relation to coronal body plan, not considering the patient anatomy leading to low reproducibility of the measures of glenoid inclination. Some authors propose the correction of orientation of slices for more precise measures, showing that the variation on the measures of a glenoid inclination can vary as 27 degrees, justifying the search for other methods to overcome this difficulty [19].

The 3D printing has been showing its importance in medical field in the last decade, this technology allowed the render process developed physical objects from TC Scans or MRI, images transforming bidimensional images into tridimensional realistic volumes [20-22]. This kind of method brings the anatomy of the patient to the hands of the surgeon, and it has been used in pre-operatory planning or even in medical education . In orthopedic surgery, mainly in shoulder arthroplasty, due to anatomic peculiarities, the space orientation given by an anatomic print model is useful for the positioning of the components, with superiority to 3D images generated by conventional medical images, placed in a screen, and with the possibility to be use in the surgical field. Our brain is get used to understand even the 3D reconstruct TC images, as a two dimensional images placed on the screen, and in terms of orientation de 3D printed volume show the superiority because it is really a 3D physical object Wang et al, evaluated the 3D printing anatomic models from shoulder osteoarthritis, and concluded that is an excellent method for pre-operatory evaluation for a shoulder arthroplasty, due to show morphologic alteration presented in the glenoid side [23]. Prachi et al, used the 3D print model from patients with hip osteoarthritis suggesting that meticulous preoperative planning is necessary in front of a great aberration of the joint, due to absence of normal anatomical landmarks, CT scan is mandatory, and 3-D reconstruction with solid model is useful [24]. Searching in the literature there were no articles related to use of the patient anatomic 3D printing models to help in the positioning of the glenoidal component in shoulder arthroplasty, in this way our research is unique. Tack et al, in a systematic review of the literature concerning the use of 3D print technology in the orthopedic field, pointed the use of 3D printed specify guides in 60% of the publications, and 37,85% of the articles referring to 3D anatomic prints for surgical planning. In relation to these studies in 48% the surgical time decreased using the printed anatomic models, showing their great utility. [25].

As point in the literature (PSI) 3D printed guides associated to 3D anatomic models, have been using, to guide positioning in many orthopedic procedures, despite being costly and a demanding process. In relation to 3D printed specific guides, authors as Vilette and Walter et al, pointed that despite the improvement in positioning orthopedic implants, more studies are needed to state the clinical and cost benefit of the use, mainly in shoulder arthroplasty [26,27]. Another resource that is been used nowadays are the software that produces 3D images in the screen, form TC scans, simulating a series of implant positioning in shoulder arthroplasty being used in the preoperative planning, the disadvantage is the lack of full access for all surgeons, and they can be used only for a type of implant. Olaya et al, in a systematic review of the use of these specific software, stated that the use increases the accuracy in shoulder arthroplasty implant positioning when comparing to use of 2D images in the preoperative planning, but questioned themselves about the benefits in relation to clinical outcomes [28] . These data motivated this study in order to validate a simple and easy method to optimize the positioning of the glenoidal component in shoulder arthroplasty, using an patient anatomic 3D printed model, that can easily done by the surgeon with low cost not limited to any kind of implant. Another advantage is the possibility to use this anatomic model to simulate a surgical procedure, avoiding and anticipating difficulties in correcting bone loss and the positioning of implanting components in a safe way, moreover it also can be used in training different procedures or surgical strategies .The strengths of our study is to propose a method to simulate a real implantation of a glenoidal component in a 3D printed osteoarthritic anatomic models, in a safe way avoiding risk to the patient, using realistic anatomic models. We evaluate the accuracy of use of the anatomic 3D print model of the correspondent scapula in guiding the positioning of the implant compared to the current method used by the surgeons, the TC scans. One of the weaknesses of our study was the selection bias of the cases, since the shoulder with osteoarthritis were selected in a sequential way, selecting patients with concentric shoulder osteoarthritis, without significant bone loss or deformity, this factor showed a major influence in the results, due to the lack of necessity of eccentric reaming to correct the glenoid version. Another bias was the experience of the surgeons involved in the study, all of them with great experience in shoulder arthroplasty, maybe the results could be different if were involved surgeons with another level of experience in shoulder arthroplasty. In our opinion the results could be also different when selecting only type B2 or C glenoid, these notably represent a challenge for the surgeon. Another point was not to evaluate the elapsed time for implantation in each group, it could be different between the groups, showing the advantage of one method in relation to another. Our results showed no differences in 54 glenoid implants when comparing the group using the anatomic model or TC scans, despite the difference founded favor to 3D group among one of the intervenors in AP measures. We believe that the use of correspondent model guiding the implantation of glenoidal component in shoulder anatomic arthroplasty, is useful in many cases that required angular correction or in great deformities in the glenoid side, when there is necessity of bone graft to make the proper correction with the possibility to do the procedure previously to the surgery. Despite our result we still believe that the anatomic model of the scapula is useful, and the continuity of our research is to separate deformities in specific groups of glenoid deformities , searching for efficiency in procedures allowing the universal use independent of the specific implant [29]. In relation to precision in the positioning of the components PSI guides, despite the lack of evidence in clinical benefits, maybe will be another solution for this issue, but the ideal will be the development of a universal software, with an easy workflow, allowing the accesses to most of the surgeons . Maybe soon, the development of other orientation tools, like virtual reality in the operation room could play a major role in the results of all kinds of arthroplasty.

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