Original article

Shoulder patient-specific guide: First experience in 10 patients indicates room for improvement

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A B S T R A C T

Background: Implantation of the glenoid component of a total shoulder prosthesis can be facilitated by using a patient-specific guide (PSG) designed to ensure replication of the preoperatively planned position. The objective of this study was to assess the reliability and accuracy of a PSG in replicating the planned glenoid component position during total shoulder arthroplasty (TSA).

Hypothesis: Additional criteria should be used for 3D preoperative planning and PSG design to further improve the accuracy of glenoid component positioning.

Material and methods: We studied 10 patients who underwent TSA with use of a PSG to position the glenoid component after preoperative 3D planning. Postoperative glenoid version and tilt were measured and compared to the planned values. We also used new criteria to assess implant rotation and global 3D position, as well as accuracy of the 3D pilot hole for the glenoid guide-pin.

Results: Mean errors in glenoid position were −1.7° ± 4.4° for version, −0.4° ± 4.9° for tilt, and 6.0° ± 13.5° for rotation. Mean difference in global orientation of the glenoid implant versus the planned value was 4.9° ± 2.5°. Mean 3D discrepancy in glenoid pilot hole position was 2.9° ± 0.5 mm; the discrepancy was greater in the mediolateral direction (1.9° ± 0.9 mm) than in the supero-inferior (1.1° ± 1.2 mm) and antero-posterior (0.8° ± 1.2 mm) directions.

Discussion: The poor performance of the PSG in controlling rotation and reaming may explain the difference in global glenoid position compared to the planned value. Improvements in PSG design to incorporate these two parameters deserve consideration.


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1. Introduction

Accurate glenoid component positioning is a key factor in the functional outcome and long-term survival of total shoulder arthroplasty (TSA). Glenoid loosening is the main source of TSA failure, leading to a 15-year survival rate of only 34% [1]. According to recommendations for glenoid preparation and positioning, retroversion should be less than 10°, tilt less than 10°, seating more than 80%, and reaming as limited as possible [2–5]. To achieve these objectives, a 3D approach to the implantation technique is needed. Free-hand placement by an experienced surgeon has about 7° and 11° accuracy for glenoid version and tilt, respectively, which are the two standard parameters used to assess glenoid position [6–10]. The largest errors occur during drilling and reaming, as no reliable intraoperative landmarks exist to position the glenoid guide-pin. Patient-specific guides (PSGs) have been developed to improve the accuracy of glenoid implant positioning. The PSG is created based on preoperative 3D planning using computed tomography (CT) of the shoulder.

PSGs are useful only if sufficiently reliable and accurate to replicate the values determined by preoperative planning. An in vitro study of 18 cadaver scapulas used a PSG to direct the guide-pin into the glenoid [11]. Mean differences between achieved and planned values were 1.42° ± 1.37° for tilt, 1.64° ± 1.01° for version, and 2.39° ± 1.16° for overall 3D guide-pin orientation. Glenoid implant position after guide-pin placement was not assessed directly. Similar findings were obtained subsequently in vivo, in 17 patients [12], with mean error rates versus the planned values of 3.4° ± 1.1°
for version and $1.8^\circ \pm 5.3^\circ$ for tilt. Errors in guide-pin pilot hole position were $0.1 \pm 1.4$ mm in the horizontal plane and $0.8 \pm 1.3$ mm in the vertical plane [12].

Both studies [11,12] were carried out by the groups that designed and sponsored the PSGs used and their preoperative planning systems. Thus, the surgeons had an unusually high level of expertise in using the PSGs. This point may explain the very accurate glenoid positioning in both studies. In addition, errors in glenoid tilt and version versus the planned values were assessed in only two planes, i.e., the horizontal and vertical planes.

The objective of this study was to assess the accuracy of glenoid positioning achieved when a PSG was used in everyday practice by surgeons who had no role in designing or marketing the preoperative planning software or PSG. In addition to glenoid version and tilt, other postoperative parameters were assessed. Thus, accuracy in the sagittal plane was evaluated based on glenoid rotation, a parameter determined in part by the location of the guide-pin pilot hole in the antero–posterior and supero–inferior directions. Accuracy of mediolateral pilot hole position in the coronal plane was also determined. The goal of the PSG is to accurately replicate the values determined by a rigorous and accurate preoperative 3D planning procedure. Therefore, we also assessed the error in global 3D orientation of the glenoid, which reflects errors in the axial, sagittal, and coronal planes. The working hypothesis was that additional criteria should be used for 3D preoperative planning and PSG design to further improve the accuracy of glenoid implant positioning.

2. Material and methods

This study was approved by our institutional review board (13B-T-Shoulder-RM). Written informed consent was obtained from each patient before study inclusion.

2.1. Material

2.1.1. Patients and surgeon

This prospective, single-centre, single-surgeon study was conducted between 1st July and 31st December 2014 in the first 10 patients with primary concentric gleno-humeral osteoarthritis managed with PSG-assisted TSA in our department. There were nine females and one male with a mean age of 71.2 years (range: 44–88 years) and a mean body mass index of 28.7 kg/m$^2$ (range: 24.7–32.1 kg/m$^2$).

All 10 procedures were performed by the same senior surgeon (LF), who had considerable experience with shoulder arthroplasty. He had not participated in designing or promoting the preoperative planning software and PSG system used for the study (BluePrintTM 3D Planning) and had no ties to the company marketing this system (Wright Medical France, Monbonnot-Saint-Martin, France).

2.1.2. BluePrintTM software and patient-specific guide

BluePrintTM 3D Planning applies a validated method [13,14] to automatically segment and reconstruct the preoperative CT images then to obtain accurate measurements in a 3D planning of the standard parameters used to characterise the glenoid (version and tilt) and humerus (posterior subluxation of the humeral head). These measurements describe the abnormal morphology that must be corrected by implanting the glenoid component of the total shoulder prosthesis (Fig. 1, Table 1).

BluePrintTM 3D Planning allows selection of the glenoid component of the chosen type of prosthesis and provides detailed information on optimal positioning of this component based on the preoperative measurements of glenoid version and tilt. The PSG is then designed and produced, using a resin 3D printer, as the mould of the abnormal glenoid cavity. The PSG fits into the glenoid cavity where it is attached by four fasteners. It then serves to position

the guide-pin around which the glenoid is prepared as appropriate to obtain the desired changes in version and tilt determined preoperatively (Fig. 2).

2.1.3. Total shoulder prosthesis

In all 10 patients, the prosthesis was the Aequalis™ PerFORM glenoid component and Ascend Flex humeral component (both from Wright Medical) (Fig. 3).

2.2. Method

The steps of the study protocol are described below.

2.2.1. Preoperative computed tomography (CT)

CT of the shoulder was performed before surgery in all 10 patients according to a detailed and validated acquisition protocol allowing use of the images stored in digital imaging communication in medicine (DICOM) format for the preoperative planning stage. The protocol involved bony windowing, image resolution (X, Y) of less than 0.5 mm/pixel, slice thickness (Z) less than 1 mm, an acquisition field of view of up to 300 mm ensuring visualisation of the entire scapula, a 512 × 512 matrix, tube voltage set at 140 kV, and tube current-time product set at 200–300 mAs.

2.2.2. Preoperative planning and design of the patient-specific guide (PSG)

The surgeon who performed the TSAs used BluePrint™ 3D Planning software to plan the procedure (Fig. 1). He first checked that the 3D measurements of glenoid version, glenoid tilt, and humeral head subluxation obtained by the software were consistent with the 2D CT slices available in each of the three planes separately. He then positioned the glenoid component in compliance with current recommendations [2–5,15], i.e., in less than 10° of retroversion and less than 10° of tilt, with at least 80% seating, and with minimal reaming to preserve the subchondral bone. If the preoperative planning results supported the appropriateness of TSA, the PSG was produced. Otherwise, the procedure was stopped and a more appropriate type of prosthesis chosen.

2.2.3. Guided surgery

The same standardised surgical technique was followed in all 10 patients. The patient was in the beach chair position with the arm on a mobile armrest. The delto-pectoral approach was used. Osteotomy or elevation of a small fragment of the lesser tuberosity was performed to allow management of the sub-scapularis. The anterior capsule was released. The tendon of the long head of the biceps was severed and sutured to the tendon of the pectoralis major. The humerus was then prepared, allowing optimal
Table 1
Preoperative and postoperative data for each of the 10 patients managed using a patient-specific guide.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Side</th>
<th>Preoperative retroversion,</th>
<th>Preoperative tilt,</th>
<th>Glenoid type, Walch</th>
<th>Pilot hole, 3D offset (mm)</th>
<th>Pilot hole, lateral offset (mm)</th>
<th>Pilot hole, anterior offset (mm)</th>
<th>Pilot hole, superior offset (mm)</th>
<th>Global 3D orientation error (°)</th>
<th>Version error (Â)</th>
<th>Inclination error (Â)</th>
<th>Rotation error (Â)</th>
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</table>

SD: Standard Deviation
exposure of the glenoid via the appropriate positioning of retractors and placement of a temporary protector over the cut humeral neck surface. The glenoid labrum was trimmed but the peripheral osteophytes were left intact, as they served as readily identifiable landmarks for ensuring the stable fixation of the four PSG fasteners. The glenoid preparation guide-pin was aimed at the glenoid through the PSG. Light reaming was then performed around the guide-pin, which was in theory ideally positioned. During reaming, care was taken not to breach the subchondral bone, as no depth guidance was available. The receiver site for the glenoid component keel was then prepared, with close attention to achieving optimal rotation, another parameter not guided by the PSG. After cancellous bone impaction, the glenoid component was permanently fixed using high-viscosity fast-setting cement. The cement was applied only to the keel receiver site, taking care to avoid leakage onto the rest of the prepared glenoid surface. Finally, the humeral head was press-fit into the intramedullary canal, after sutures were threaded through the humeral cut to allow repair of the sub-scapularis. The lesser tuberosity osteotomy, if performed, was repaired by screw fixation combined with tendon suturing.

2.2.4. Postoperative computed tomography (CT) and matching

To compare the position of the glenoid component achieved using the PSG to the goals set during preoperative planning, the 10 patients underwent CT of the shoulder at our department 3 to 12 months after the TSA. The CT protocol was the same as that used preoperatively. Given the presence of the prosthesis, a validated protocol was followed using Mimics® software (Materialise, Leuven, Belgium) to suppress artefacts and to perform manual segmentation of the scapula and metal markers in the glenoid component [16] (Fig. 4). Finally, the reconstructed image of the implanted scapula was overlain on the image of the scapula used for preoperative planning (Fig. 5) and each surface on the postoperative image was matched to the corresponding surface on the preoperative image. This step required the creation of a new set of 3D coordinates shared by the preoperative and postoperative images. The guide-pin pilot hole was located 2 mm lateral to the midpoint between the lateral ends of the two marking wires, and guide-pin orientation was along the main axis of the wires (Fig. 6). It was thus possible to compare the markers in the preoperative mould and implanted glenoid component (Fig. 7).

2.2.5. Parameters used to assess glenoid implant position

Glenoid implant position achieved in each of the 10 patients was compared to the goals set during preoperative planning based on the following four parameters: position (mm) of the glenoid guide-pin pilot hole in a 3D coordinate system (X, Y, Z), version (°), tilt (°), and rotation (°). For each parameter, the error defined as the difference between the actual and the planned values was reported as the absolute value. For guide-pin pilot hole position, the error was assessed separately in the antero-posterior direction in the horizontal plane (ΔX), supero-inferior direction in the sagittal plane (ΔY), and mediolateral direction in the coronal plane (ΔZ). The global 3D error in guide-pin pilot hole position was computed using the distance formula for 3D space as √(ΔX)² + (ΔY)² + (ΔZ)². The same formula was applied to compute the global 3D glenoid implant positioning error combining the errors for version, tilt, and rotation.

2.3. Statistical analysis

The preoperative and postoperative data were quantitative variables that were compared by applying Student’s t-test. Values of p ≤ 0.05 were considered significant. The statistical tests were done using StatView software (SAS Institute, Cary, NC, USA).
3. Results

The preoperative glenoid deformity in the horizontal plane was type A1 in 3 patients, A2 in 5 patients, B1 in 1 patient, and B2 in 1 patient (Table 1). In the 10 patients, mean preoperative version and tilt measured by the planning software were 6.6° ± 18.4° and 9.5° ± 8.4°, respectively. Mean posterior subluxation of the humeral head was 65.5% ± 13.0% (Table 1).

Mean version and tilt validated by the surgeon as the desired goals based on the preoperative planning and used to produce the PSGs were 9.0° ± 5.1° and 4.8° ± 4.4°, respectively. For the glenoid implant seating goal, the mean value was 83.4% ± 10.1%, corresponding to a mean reaming thickness of 1.1 ± 0.3 mm.

After guided surgery, mean glenoid implant position error was 3.5° ± 2.9° for version, 2.5° ± 1.7° for tilt, and 8.2° ± 4.7° for rotation. Mean error in global glenoid implant position was 4.9° ± 2.5°. Mean error in 3D guide-pin pilot hole position was 2.9 ± 0.5 mm, with a greater error in the mediolateral direction (1.9 ± 0.9 mm) than in the supero-inferior (1.1 ± 1.2 mm) and antero-posterior (1.2 ± 0.7 mm) directions (Table 1).

After guided surgery, mean glenoid implant position error was −1.7° ± 4.4° for version, −0.4° ± 4.9° for tilt, and 6.0° ± 13.5° for rotation. Mean error in global glenoid implant position was 4.9° ± 2.5°. Mean error in 3D guide-pin pilot hole position was 2.9 ± 0.5 mm, with a greater error in the mediolateral direction (1.9 ± 0.9 mm) than in the supero-inferior (1.1 ± 1.2 mm) and antero-posterior (1.2 ± 0.7 mm) directions (Table 1).
4. Discussion

The accuracy with which the preoperative planning goals were achieved by using the PSG compared favourably to that reported in earlier work [6,8,12]. Mean error was 3.5° for version and 2.5° for tilt. The standard deviations for each of these parameters were smaller than reported previously. Nevertheless, an about 5° error occurred in overall glenoid implant position. This amount of error may diminish any benefits expected from using a PSG, as mean accuracy of free-hand positioning is about 7° to 11° [7–10]. In addition, the error seen with the PSG may jeopardise the likelihood of achieving residual retroversion of less than 10°, a value above which the risk of glenoid implant loosening may be increased [15].

The error in overall 3D glenoid implant position may be ascribable to insufficient rotation. Rotation was measured post-operatively in our study, in addition to the standard parameters. The error in implant rotation compared to the planned value was 8.2°, with a fairly large standard deviation of nearly 5°. Rotation has not been reported previously as a criterion for glenoid implant positioning but deserves to be incorporated into the preoperative planning strategy and taken into consideration to produce and use the PSG. The PSG used in our study had four fasteners that attached to the abnormal glenoid cavity. The surgeon reported no adverse events related to use of the PSG in the 10 patients. Nevertheless, inadequate fit between the PSG and glenoid cavity may produce errors in version or tilt of the implant. The four fasteners may fail to firmly secure the PSG and to replicate the planned values for these two parameters, in the horizontal and vertical planes, respectively. More specifically, the fasteners must be sufficiently rigid and resistant to deformation when under stress, applied for instance during difficult exposure of a glenoid cavity exhibiting major deformities. However, achieving the desired amount of rotation in the sagittal plane is not facilitated by using a PSG. Indeed, the PSG does not assist in preparing the glenoid implant keel, whose position can influence the final rotation of the implant. This finding from our study suggests that incorporating implant rotation into the planning strategy may hold promise for improving PSG design.

Inaccuracy also occurred in the 3D position of the glenoid guide-pin pilot hole. The error was about 3 mm with, however, a small standard deviation. Most of this inaccuracy was related to mal-position in the mediolateral direction, where the error was twice as large as in the supero-inferior and antero-posterior directions.

Mediolateral pilot hole position governs the depth of reaming. The PSG failed to assist with this crucial step of the procedure that ultimately determines the quality of glenoid implant fixation. Adding information on reaming depth during preoperative planning may further improve PSG design. Thus, implant seating can be planned preoperatively but cannot be guided intraoperatively when using the PSG and reaming the glenoid cavity. A reasonable assumption is that optimal reaming may play a key role in producing the target version and tilt values, since the guide-pin, although properly positioned, may be placed under stress during this step.

Limitations of our study include the small sample size of 10 patients. Furthermore, in some patients, the amount of retroversion was small and within the range that is easy to correct in practice with or without a PSG. Nevertheless, these were the first 10 patients managed with this new surgical guiding system, and the surgeon had neither contributed to design the PSG system not used it before the study. In addition, the accuracy achieved in these 10 patients is encouraging. Extending the use of the PSG to a larger patient population would be expected to increase the expertise of the surgeon, thus decreasing the errors in glenoid position. Any glenoid position errors would then be ascribable to the design of the PSG rather than to insufficient surgeon experience with the PSG. This point is among the sources of bias in our study.

Comparing our group of patients managed using a PSG to a group managed conventionally or with 3D preoperative planning would have provided useful information. The superiority of 3D preoperative planning over conventional surgery based only on 2D CT slices has been reported previously [17]. The use of a PSG has also been found superior over 3D preoperative planning alone [8,18–20]. However, the rotation and global 3D orientation criteria used in our study to assess implant position were not measured in these earlier studies. Glenoid guide-pin pilot hole position was evaluated in a single in vivo study conducted by Gauci et al. in 17 patients [12]. This parameter was described previously by Walch et al. in a study of cadaver scapulas [11]. Both these studies [11,12] were done by the designers of the PSG.

Our study has the major advantage of providing further evidence of a persistent disparity between 3D preoperative planning and production of a PSG. Both the accuracy and the execution of 3D planning have improved considerably. The current PSG technology, however, fails to transfer the full range of information obtained by 3D planning to the execution of the surgical procedure. Thus,
reaming, preparation of the keel (on which the degree of rotation depends), and cementing are not considered in the PSG design procedure, although, taken together, these factors can produce errors in glenoid implant position [6].

5. Conclusion

This study reports the first data on the use in surgical practice of a commercially available PSG based on a validated 3D preoperative planning procedure. The results indicate room for improving the current PSG design and production method. Glenoid implant rotation and 3D global position are assessed during 3D planning and deserve consideration as additional PSG design criteria. Improvements are needed in the system that fastens the PSG to the native glenoid, as well as in reaming control. Thus, the present study can serve as a preliminary to designing an improved second-generation PSG.

Disclosure of interest

Luc Favard: consultant for Tornier-Wright*. The other authors declare that they have no competing interest.

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