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Original article

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

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ABSTRACT

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 $-1.7^\circ \pm 4.4^\circ$ for version, $-0.4^\circ \pm 4.9^\circ$ for tilt, and $6.0^\circ \pm 13.5^\circ$ for rotation. Mean difference in global orientation of the glenoid implant versus the planned value was $4.9^\circ \pm 2.5^\circ$. 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.
Level of evidence: II, prospective cohort study.

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 $1.42^\circ \pm 1.37^\circ$ for tilt, $1.64^\circ \pm 1.01^\circ$ for version, and $2.39^\circ \pm 1.16^\circ$ 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 position errors versus the planned values of $3.4^\circ \pm 5.1^\circ$

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for version and 1.8° ± 5.3° for tilt. Errors in guide-pin pilot hole position were 0.1 ± 1.4 mm in the horizontal plane and 0.8 ± 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 (BluePrint™ 3D Planning) and had no ties to the company marketing this system (Wright Medical France, Monbonnot-Saint-Martin, France).

2.1.2. BluePrint™ software and patient-specific guide

BluePrint™ 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 system 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).

BluePrint™ 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).

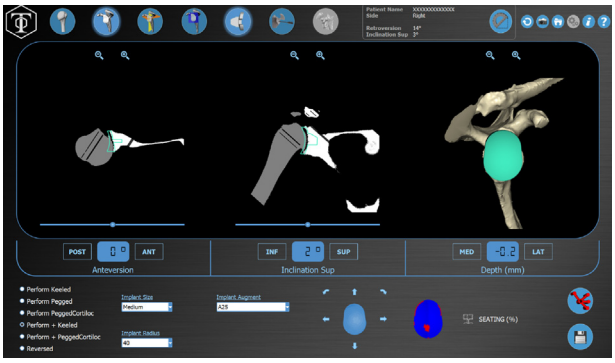

Fig. 1. Screenshot of the 3D preoperative planning data obtained by the surgeon for each patient using BluePrint™ 3D Planning Software (Wright, Montbonnot-Saint-Martin, France).

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

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