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Does fluoroscopy improve baseplate position compared to conventional technique in reverse shoulder arthroplasty? A preliminary study

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Abstract

Background: Accurate placement of glenoid component in reverse shoulder arthroplasty remains a challenge for surgeons of all levels of expertise; however, no studies have evaluated the utility of fluoroscopy as a surgical assistance method.
Methods: Prospective comparative study of 33 patients undergoing primary reverse shoulder arthroplasty during a 12-month period. Fifteen patients had a baseplate placed using the conventional "free hand" technique (control group), and 18 patients using intraoperative fluoroscopy assistance group, in a case–control design. Postoperative glenoid position was evaluated on postoperative Computed Tomography (CT) scan.
Results: The mean deviation of version and inclination for fluoroscopy assistance vs. control group was 1.75° (0.675–3.125) vs. 4.2° (1.975–10.45) ($p = .015$), and 3.85° (0–7.225) vs. 10.35° (4.35–18.75) ($p = .009$). The distance from the central peg midpoint to the inferior glenoid rim (fluoroscopy assistance 14.61 mm/control 4.75 mm, $p = .581$) and the surgical time (fluoroscopy assistance 1.93 ± 0.57/control 2.18 ± 0.44 h, $p = .400$) showed no differences, with an average radiation dose of 0.45 mGy and fluoroscopy time of 14 s.
Conclusions: Accurate axial and coronal scapular plane positioning of glenoid component is improved with intraoperative fluoroscopy at the cost of a greater radiation dose and without differences in surgical time. Comparative studies are needed to determine whether their use in relation to more expensive surgical assistance systems result in similar effectiveness.
Level of evidence: Level III, therapeutic study.

Keywords

Shoulder replacement arthroplasty, orthopaedic procedures, fluoroscopy, glenoid component, reverse shoulder arthroplasty

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Introduction

Malposition of the glenoid component (GC) during its implantation is one of the main causes of reverse shoulder arthroplasty (RSA) failure[1] and is associated with higher dislocation rates, range of motion limitations due to impingement, polyethylene wear, and revision rates. Accurate placement of the GC remains a challenge for surgeons of all levels of expertise because certain situations may condition a special difficulty for the optimal placement of this component: the complex and

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variable geometry of the glenoid, the absence of anatomical references, a limited surgical exposure of the shoulder or the presence of bone defects. Additionally, smaller bone defects are relatively frequent in primary surgeries: 10%–15% of patients with primary glenohumeral arthritis and 40% of cases with rotator cuff tear arthropathy have sufficient posterior or superior erosion that complicate correct implantation of the prosthesis.[2,3] Placement of baseplate too superior or in excessive anteversion or retroversion can predispose to implant loosening.[4]

The incidence of these complications can be diminished by placing the baseplate in the "ideal position" previously described by other authors.[5,6] Different surgical assistance systems have been developed such as navigated or computer-assisted surgery (CAS) or patient-specific instruments (PSI) based on presurgical CT scan. Several studies have shown that they provide greater accuracy in the implantation of the GC compared to the use of conventional instrumentation.[5,7–14] However, it is unclear whether they provide better results than the conventional technique, despite increasing surgical time, costs, and having a long learning curve, which at present limits their widespread use.[15]

Intraoperative standard fluoroscopy has been widely used to improve component position during total hip arthroplasty (THA).[16,17] However, despite being a less expensive instrument than PSI or CAS, to our knowledge, there are no published studies in the current literature related to its employment for baseplate positioning in RSA.

We hypothesized that intraoperative fluoroscopy could improve the version and inclination of the baseplate compared to the conventional "free hand" technique.

Materials and methods

Study design

The present series consisted of 33 patients undergoing primary RSA during a 12-month period. The first 15 patients had the baseplate placed using the conventional "free hand" technique (control group), and the following 18 patients had the baseplate placed using intraoperative fluoroscopy assistance (FA group), in a case–control design study. All the patients gave written consent to participate in this institutional review board-approved clinical study (C.I. 19/008-E_TFG). Patients with rotator cuff tear arthropathy, osteoarthritis with massive irreparable rotator cuff tear, and four-part Neer proximal humeral fractures were included. The exclusion criteria were also established: revision surgery, glenoid morphology requiring a special implant (augmented/custom-made baseplate) or bone graft, glenoid fracture, and absent of written consent. Among the 33 patients initially included in the study, one patient was excluded for not giving consent for the postoperative CT, so 32 patients were finally included in the study: 18 patients with fluoroscopic assistance vs. 15 patients in the control group.

Surgery

Patients underwent RSA implantation using one of the two implants employed in our Department: Delta Xtend (DePuy Synthes, Warsaw, Indiana) and the Lima SMR system (SMR Modular Shoulder System. Systema Multiplana Randelli; Lima-LTO, San Daniele del Friuli, Italy). All the patients had at least two preoperative orthogonal radiographs and a CT scan. Surgical planning was carried out using raw CT-scan images, without specific planning software. Each surgical procedure was performed by at least two of the three senior shoulder surgeons (FM, CG-F, YL) under general anesthesia plus an inter scalene block and in a beach-chair position at 45° through a deltopectoral approach.

Fluoroscopy-assisted group (FA group). The fluoroscopic assistance procedure includes the acquisition of two fluoroscopic views: true anteroposterior scapular plane view and axial view (Figure 1). The anteroposterior view helped us place the guide as low as possible to allow a secure fixation of the inferior screws in the solid bone of the scapula pillar, checking under fluoroscopy that was within the inferior margin of the glenoid bone. Additionally, the inferior tilt of the guide pin respect to the glenoid surface could be evaluated. The axial view allowed us to position the guide wire as centered as possible within the glenoid bone pyramid, according to the standard centerline (sCL)[18,19] (Figure 2). The direction and length of the superior/inferior screw and the anterior/posterior screw (only in Delta implant) were also verified in the FA group (Figure 3).

Control group: "Free hand" technique. The control group uses the glenoid surface as orientation and the scapular reference points: the base of the coracoid process and the inferior part of the glenoid neck, also aiming to position the baseplate as inferior as possible.

For both groups, the goal was to implant the GC in the "ideal position" already described by other authors[20–24]: centered in the horizontal axis and slightly lower on the vertical axis of the glenoid, with 0° version with respect to the major axis of the scapula or neutral version and with a lower inclination target between 0° and 10° for all the patients, since they are primary surgeries, without large bone defects.

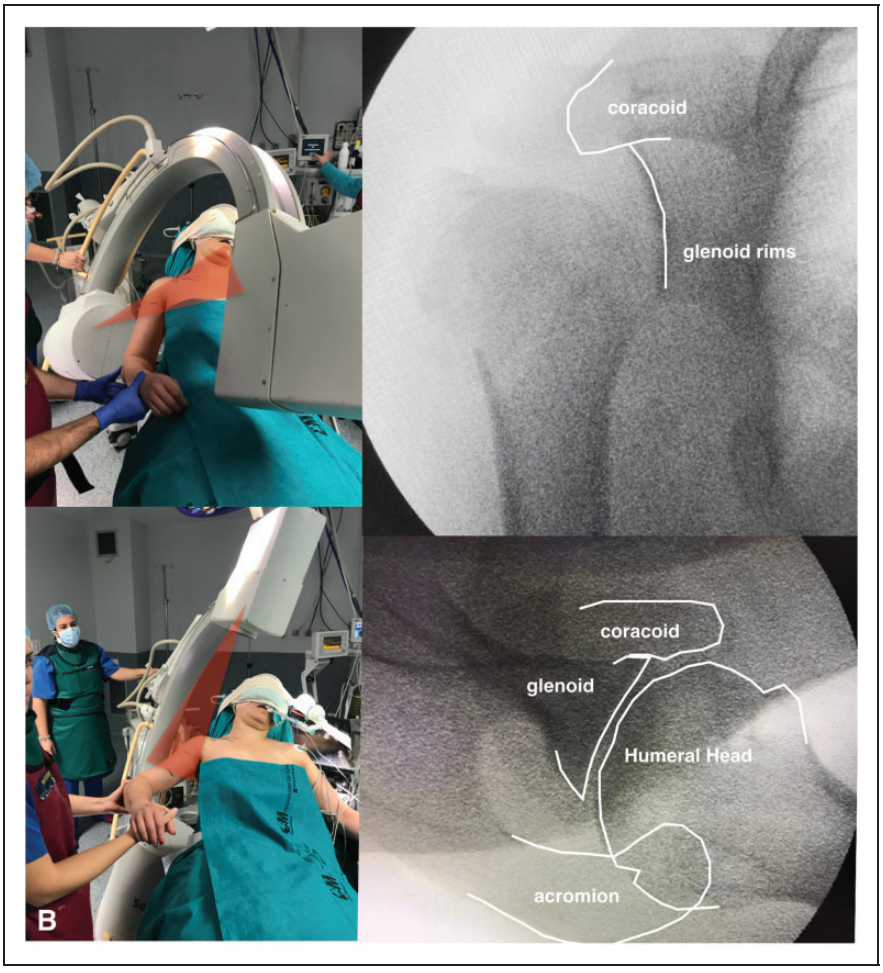

Figure 1. Fluoroscopy positioning. The device is brought into the surgical field from posterolateral to anteromedial and the C-arm is inverted so that the X-ray tube is placed at the top and the image intensifier at the bottom. (a) True anteroposterior scapular view: there should be no overlap between the glenoid fossa and the humeral head, the anterior and posterior glenoid rims are superimposed, and the coracoid process overlaps the glenohumeral joint. (b) Axial view: the joint space between the glenoid fossa and the humeral head must be clearly visualized, with the superior and inferior edges of the glenoid fossa superimposed and the lateral margin of the coracoid base aligned with the glenoid fossa.

Postoperative measurement of implant location

Each patient in both groups underwent postoperative CT scanning with 0.625 mm multiplanar layer reconstructions based on a standardized protocol provided by the investigators to measure baseplate positioning. A 64-row multidetector CT scanner (Optima CT 660 SE, GE Healthcare®) was employed. The DICOM data generated were imported into the AGFA Impax 6, Windows-based PC software (Agfa-Gevaert N.V®) reconstructing three planes,[25,26] coronal, axial, and sagittal. Metal suppression was applied to minimize implant artifacts and variations of the display of the window contrast were of help to optimize the measurements. The parameters measured were (Figure 4): version (α) as described by Friedman et al.,[27] inclination (β),[7] height, and (γ) screw/central peg positioning. All measurements were performed by two independent and blinded investigators not involved in the surgical procedures (MG-O, GC).

Results were considered as excellent if version and inclination deviation of the baseplate or both were within 5° of the ideal parameters, and satisfactory if they were within 10°.[28]

Statistical analysis

Based on previous studies that employed standard instrumentation compared to a different technology,[28] estimating a 15% loss of patients for various reasons, the initial calculated sample size was 30 patients (15 patients in each group), that would be sufficient to provide 80% power with a risk level of 0.05.

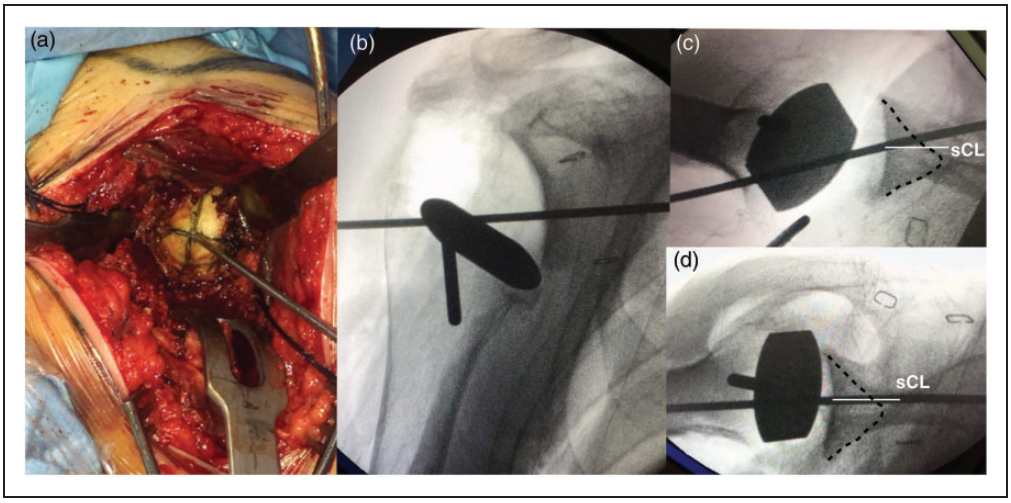

Figure 2. Baseplate guide wire positioning. (a) Wire position during the surgery. (b) Fluoroscopic true anteroposterior view. (c) Fluoroscopic axial view with the guide wire in an anterior position. (d) Correction of the direction of the guide wire. sCL: standard center (white line), glenoid vault has been marked with black dotted line.

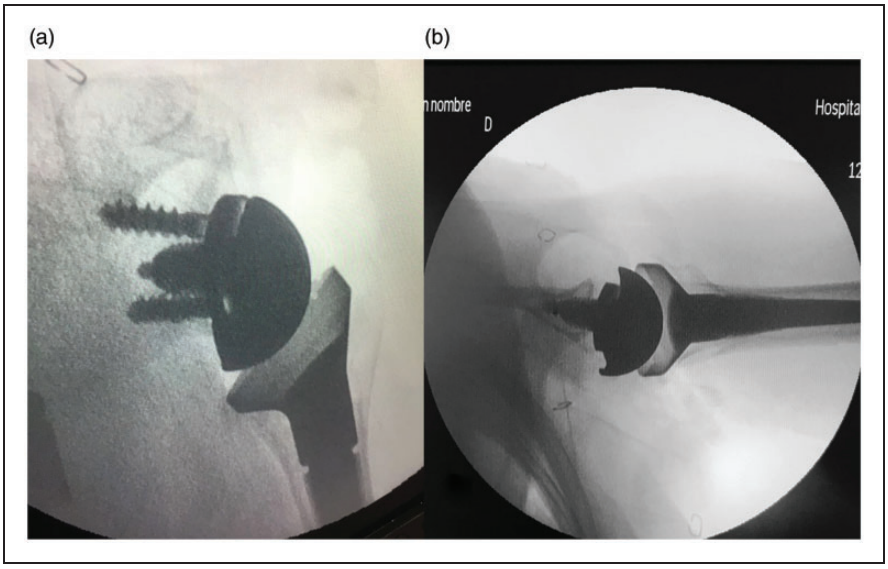

Figure 3. Baseplate positioning. (a) Fluoroscopic anteroposterior view. (b) Fluoroscopic axial view.

Data were statistically analyzed using SPSS® version 23 software (SPSS Inc., Chicago, Illinois, USA). For descriptive analysis, means and standard deviation were utilized for normal distribution variables and median and inter-quartile range for non-normal variables. The comparative analysis between the FA group and the control group was carried out with different tests according to the type of variables: the comparison between continuous variables (age, exposure to radiation, and operative time) was made through the t-Student test, and categorical and nominal data (sex, side, etiology) with the Fisher's exact test or Chi2.

To calculate the deviation of the final position of the baseplate over the initial placement objective, the following formulas were applied:

- Version deviation from the neutral version axis: $|x|$.
- Inclination deviation from the ideal inclination range of (-10° to 0°): If $x > 0 = x$; If $-10 < x < 0 = 0$; If $x < -10 = |x| - 10$.

Subsequently, the median of the deviations from each measurement was calculated.

The comparative analysis between the FA group and the control group of the deviation from the ideal

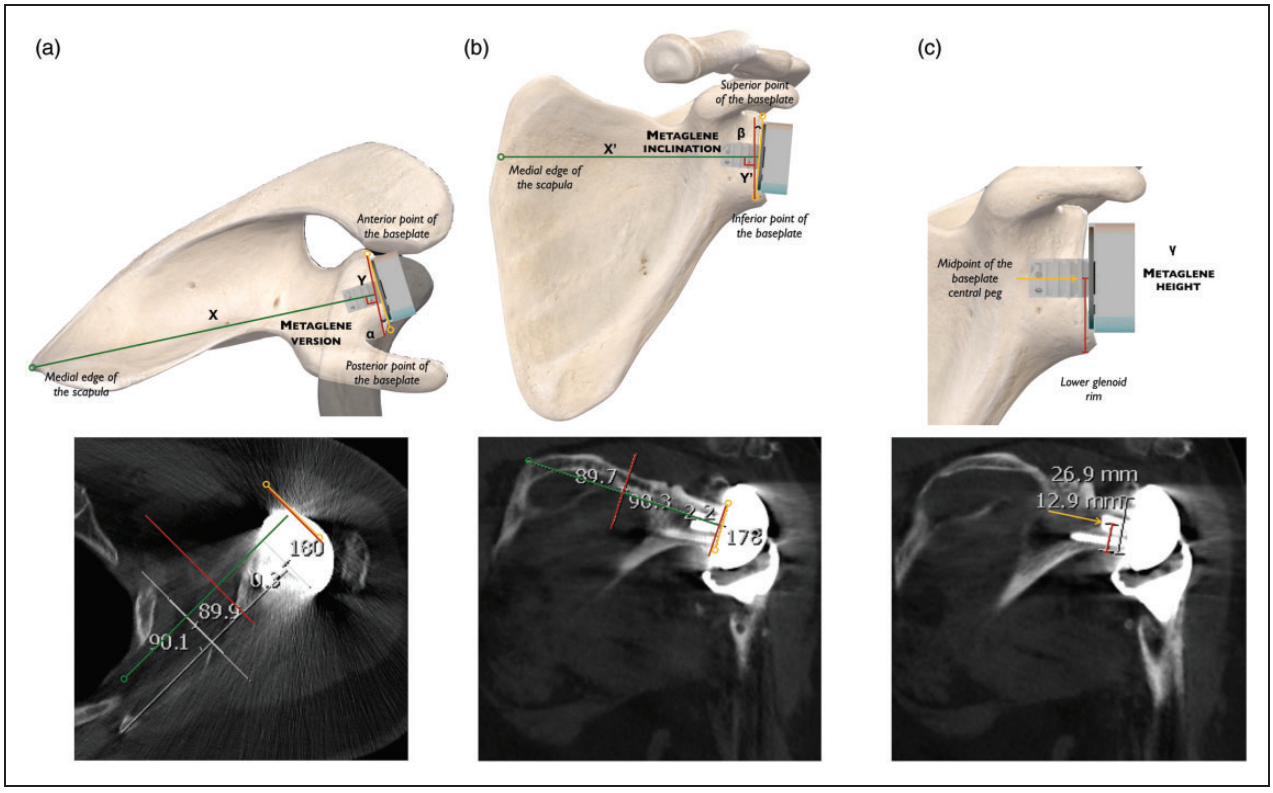

Figure 4. (a) Axial plane: baseplate version angle (α) between the line perpendicular to the long axis of the scapula (X) and the line that joins the anterior and posterior point of the baseplate (Y); anteversion was assigned as a positive value and retroversion as a negative one. A neutral glenoid component was defined as implanted in the central axis of the scapular body. (b) Coronal plane: baseplate inclination angle (β) between the line perpendicular to the transverse axis of the scapula (X′) and the line that joins the upper and lower edge of the baseplate (Y′); the superior inclination was represented as a positive value and inferior inclination as negative. (c) Coronal plane: height of the baseplate (γ) distance in millimeters from the lower edge of the glenoid bone to the midpoint of the baseplate central peg.

position for version and from the ideal range for inclination was conducted using the Mann–Whitney U for independent quantitative samples. $p < 0.05$ was considered as statistically significant.

Results

Epidemiological results

The mean age for the FA group was 78.83 vs. 76.78 for the control group ($p = .313$). All the patients were women in the FA group and 85.7% in the control group ($p = .183$) (Table 1).

Implant position

The mean postoperative glenoid version deviation for the FA group was 1.75° (range 0.675–3.125) and for the control group 4.2° (range 1.975–10.45), being the deviation smaller and less variable in the FA group ($p = .015$). The mean postoperative deviation of glenoid inclination with respect to the ideal positioning range in the coronal plane was 3.85° (range 0–7.225) of superior tilt in the FA group vs. 10.35° (range 4.35–18.75) in the control group ($p = .009$). The mean distance from the midpoint central peg to the inferior rim of the glenoid showed no statistical differences between the two groups: FA group 14.56 mm vs. control group 14.73 mm ($p = .581$). The results of version, inclination, and height are summarized in Figure 5.

Based on the measurement categorization regarding GC inclination and version according to Iannotti et al.,[28] 10 cases showed a satisfactory result and 7 an excellent one for both parameters in the FA group, while in the control group, 3 patients had a satisfactory and 2 an excellent result for both parameters. Figure 6 displays the above-mentioned results.

There were 5 misplaced screws in the fluoroscopy group (3 superior and 2 posterior) and 10 screws in the control group (5 superior, 2 inferior, 3 posterior), without statistically significant differences between groups ($p = .082$). The median screw length was not

statistically different between the two groups for the anterior, posterior, or inferior screw ($p = .058$, $p = .058$, $p = .09$), but showed statistical significance for the superior one, which was longer in the fluoroscopy group ($p < .01$), but was not related to poor positioning, instead to better intraosseous purchase. No significant differences between the groups were observed in relation to malposition of the central peg. In two patients, the central peg perforated the glenoid pyramid cortex in the control group and none in the FA group.

Table 1. Epidemiological results.

	Fluoroscopy-assisted group	Control group	p-Value
N	18	15	
Age	78.83	76.78	.313
Sex (% female)	100%	85.7%	.183
Side (Right/left)	9/9	4/11	.098
Etiology (%)			.917
Fracture	55.6%	50%	
Osteoarthritis with MICT	22.2%	21.4%	
RCTA	22.2%	28.6%	
Implant (Lima/Delta)	13/5	6/9	.036

RCTA: rotator cuff tear arthropathy; MICT: massive irreparable cuff tear.

Other parameters: Surgical time, radiation dose, fluoroscopy time

The mean operative time in the FA group was 1.93 ± 0.57 h and in the control group 2.18 ± 0.44 h ($p = .400$). The mean radiation dose in the fluoroscopy group was $.4479 \pm .2612$ mGy, and the mean fluoroscopy time 14.19 ± 6.59 s.

Discussion

The clinical success of RSA is highly dependent on the correct positioning of each of the prosthetic components.[29,30] In Scandinavian, Australian, and New Zealand national registries, the two main reasons for revision surgery following RSA are prosthetic instability and glenoid loosening.[31] Appropriate placement of the glenoid baseplate and secure fixation in adequate bone stock is important for RSA success. The need to improve this accuracy and precision of components positioning has led to the development of techniques such as CAS and PSI. Recent studies have compared the results of conventional shoulder surgery vs. assisted surgery with the previously mentioned systems[32,33] (Table 2). All the referred studies agree that the use of any computer- or instrument-assisted technique improves the positioning of the GC compared to the conventional "free hand" technique.

Even though these systems are an accurate tool to position the GC within the targets, some questions still remain concerning the relevance of these targets in relation to their clinical implications and the cost-effectiveness of using these advanced assistance systems, since they have a long learning curve and increase the operating time. This aspect has been widely studied in other orthopaedic fields that are ahead of shoulder surgery, such as hip or knee replacement surgery. In THA, prospective studies comparing clinical

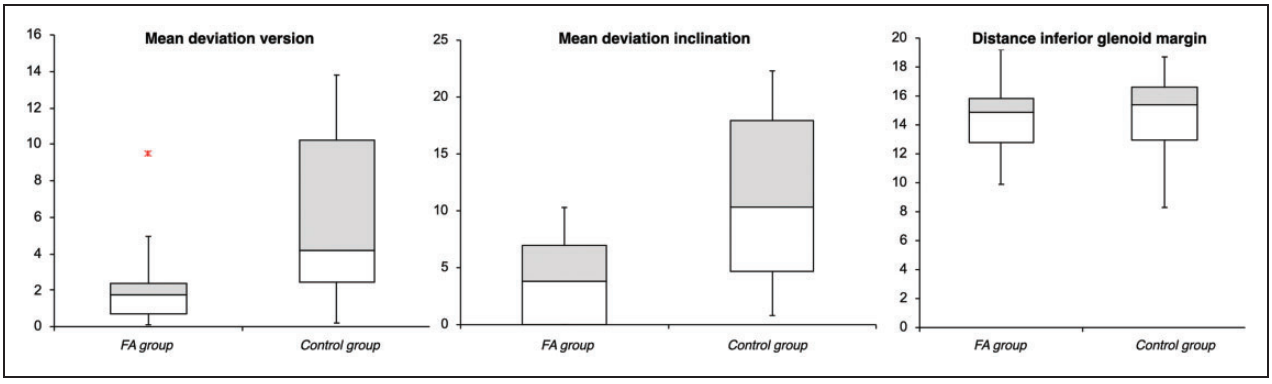

Figure 5. Box-plot fluoroscopy group vs. conventional technique group. (a) Version deviation. (b) Inclination deviation. (c) Baseplate height.

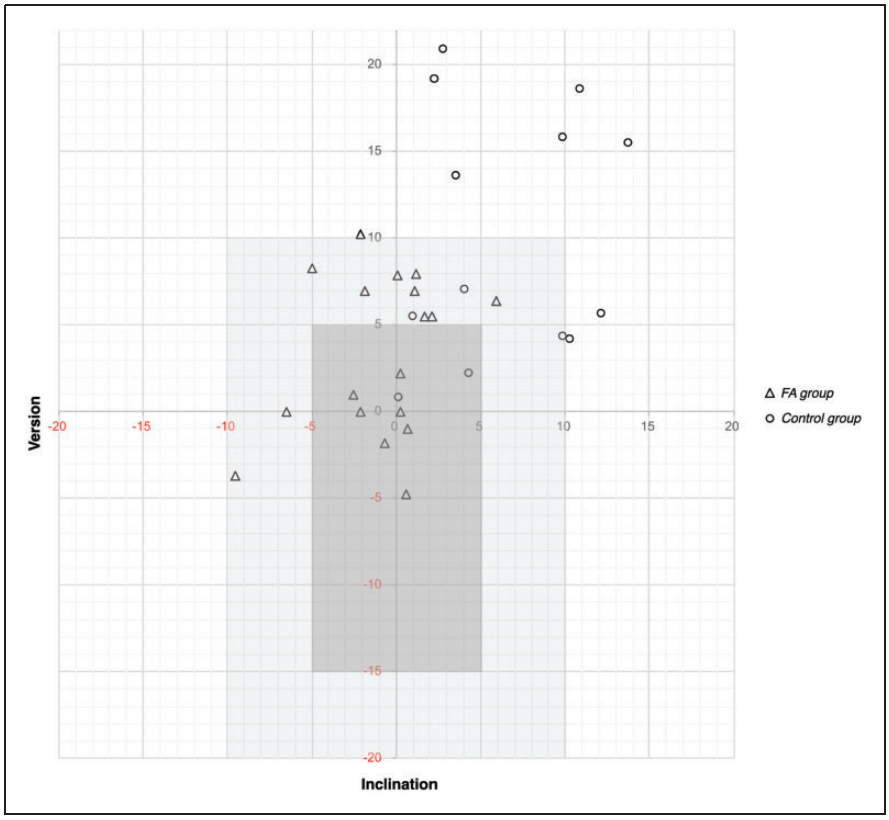

Figure 6. Scatter-plot measures results by group: Version (X axis) and inclination (Y axis). Fluoroscopy group (triangle) and conventional technique group (circle). Dark gray delimits "excellent" results (5° of variation) and light gray satisfactory results (10° of variation) in both planes.

outcomes,[40] radiological results, and also the survivorship of CAS cup placement vs. manual positioning concluded that CAS used for cup placement does not confer any substantial advantage in functionality, wear rate, or survivorship at 10 years after THA and justify the need for future studies due to the additional cost and surgical time associated with the CAS method. Furthermore, in total knee arthroplasty (TKA), the usefulness of navigation has been questioned[41] because several randomized clinical trials found no significant differences in clinical or radiological outcomes between CAS navigation and conventional TKA, whereas some others have demonstrated benefits when using CAS for lower extremity replacement,[42] especially when using robotic-assisted surgery.[43]

Although intraoperative fluoroscopy has been widely used to improve component position during THA,[16,17] we found no study that compared the use of intraoperative fluoroscopy with the conventional technique for the improvement of baseplate positioning in RSA. Fluoroscopy appears to be a more attractive option than robotic-assisted surgery or computer navigation owing to its decreased cost and accessibility. On the other hand, the application of patient-specific-instruments requires variable preparation time, which conditions an unacceptable delay in cases of trauma surgery. In an era of increased health care costs, more cost-effective solutions should be explored.

To improve the GC's position, consideration should be given to the definition of the optimal position for the GC. This has been a source of controversy since the early days of shoulder arthroplasty. Various aspects of GC positioning in RSA should be addressed: containment, version, inclination, and height.

- Containment implies the presence of support over 90% of the implant surface and complete central peg bone contention, with the sCL regarded as a referential assessment method previously defined by Bicos et al.[18] as a line perpendicular to the articular surface and exiting at the anterior scapular neck, since it represents optimal containment of the glenoid central peg within the vault. Accurate positioning of the C-arm during surgery is important to properly view the sCL in the axial view. Previous studies[44] analyzed the correlation between the center of the glenoid vault (at 15 mm of depth) and the glenoid face and found an absence of correlation between the center of the glenoid vault and the center of the glenoid face, which highlights the

Table 2. Summary of comparative studies and RCTs on the different surgical assistance systems in shoulder arthroplasty.

Reference	Assistance system	Type of study	n	Implant	Subject	Evaluated measures	Conclusions
Hendel et al.[34]	PSI	RCT	15 PSI vs. 16 CG	TSA	Human	Version, inclination, and offset.	Optimal implant preoperative plan execution with PSI
Throckmorton et al.[13]	PSI	RCT	35 PSI vs. 35 CG	TSA and RSA	Cadaver	Version and inclination	PSI is more accurate in version and inclination than CG
Heylen et al.[35]	PSI	Comparative	18 PSI vs. 18 CG	TSA and RSA	Human	Inclination	PSI reduces variability in GC inclination
Cabarcas et al.[19]	PSI	RCT	10 PSI vs. 10 CG	TSA	Cadaver	Version, inclination, pin entry point, and pin exit point	PSI improved accuracy of glenoid pin placement compared with CG
Mulligan et al.[36]	GTG	Comparative	29 GTG vs. 21 CG	Revision TSA and RSA	Human	Version	GG mayor precisión en versión que CC
Kircher et al.[8]	CAS	RCT	10 CAS vs. 10 CG	TSA	Human	Version and surgical time	Improved accuracy in glenoid positioning in the transverse plane using CAS
Nguyen et al.[37]	CAS	RCT	8 CAS vs. 8 CG	TSA	Cadaver	Version	CAS results in a more accurate GC placement relative to CG
Verborgt et al.[9]	CAS	Comparative	7 CAS vs. 7 CG	RSA	Cadaver	Version, inclination, height, screws o central peg perforation	CAS was more accurate and more precise than CT in GC placement in RSA
Nashikkar et al.[38]	CAS	Comparative	33 CAS vs. 27 CG	ATH	Human	Version and inclination	CAS may reduce the risk of GC placement outside of a neutral position in TSA compared with CG
Stübig et al.[10]	3D FA	Comparative	15 3D FA vs. 12 CG	RSA	Cadaver	Version, inclination, and height	3D FA improves GC positioning in the axial plane but not in the coronal and height
Theopold et al.[14]	3D FA	Comparative	17 3D FA vs. 17 CG	GC	Animal	Standard, alternative and glenoid vault centerline	3D FA is more accurate and precise than metaglene standard K-wire placement
Briem et al.[39]	3D FA	Comparative	5 3D FA vs. 5 CG	TSA	Cadaver	Version and OT	Version deviation from preoperative planning was significantly reduced in 3D FA, thus, OT is increased
Present study	St FA	Comparative	18 St FA vs. 15 CG	RSA	Human	Version, inclination, height, screw perforation, and OT	St FA results in more accurate GC version and inclination, without differences in height and OT

RTC: randomized controlled trial; GTG: generic targeting guides; CAS: computer-assisted surgery; PSI: patient-specific instruments; CG: Conventional "Free Hand" Technique Group; 3D FA: 3D fluoroscopy-assisted; St FA: standard fluoroscopy-assisted; GC: glenoid component; TSA: total shoulder arthroplasty; RSA: reverse shoulder arthroplasty; OT: operative time.

difficulty for an optimal placement in the glenoid vault when only anatomical references are used. Other authors analyzed the GC position with respect to this line by navigation with a three-dimensional-image intensifier system.[14] The relationship between the k-wire and the sCL in the axial view provides relevant two-dimensional information for the surgeon, and although it does not reflect the true complexity of the glenoid vault's three-dimensional anatomy, the authors considered this approach to be a valuable and cost-effective tool for improving baseplate positioning.

- The other aspects of glenoid positioning to be considered, version, inclination, and height, have been previously described[20–24] for RSA: centered in the glenoid horizontal axis and slightly inferior in the vertical axis of the glenoid, with a neutral version (0° in relation to the major axis of the scapula), and with an inferior tilt between 0° and 10°. Small variations, even of 5 mm with respect to the optimal position could influence the range of motion, and an increase in retroversion is related to prosthetic stability.[45] Similarly, a superior tilt of the GC increases tensile forces which leads to early aseptic loosening.[4]

Although in our preliminary study we did not find significant differences between the two groups in terms of the inferior positioning of the baseplate in the glenoid vertical axis, probably due to adequately glenoid exposure, the authors believe that the anteroposterior view provides important information to improve the accuracy of the baseplate placement in the lowest possible position, since the presence of inferior osteophytes can predispose to poor GC positioning and this can be verifies with fluoroscopy. A significant difference in glenoid inclination between groups was found in favor of the FA group, having an inclination closer to that established for the ideal position (3.85° vs. 10.35°). Previous studies that used computer navigation techniques[24] did not find a significant improvement in the inferior tilt of the GC that justified this outcome because of the absence of a coronal view. With the fluoroscopy-assisted method, the surgeon can estimate the inclination of the guide wire in the coronal plane.

Within the thorough evaluation of GC position performed by CT in the present study and the strict limits considered in the measurements, which were 5° for an excellent result and 10° for a satisfactory result, by fluoroscopic guidance, the accuracy of GC placement was superior to the conventional technique in the hands of shoulder surgeons (94% satisfactory or excellent CT positional results in the FA group compared to 36% in the control group). Considering that and despite rates of shoulder arthroplasty have increased over the past decade, there is still a low average volume per surgeon and hospital.[46] Therefore, low-volume institutions would benefit significantly from the use of an accessible and not particularly expensive method to improve baseplate positioning in RSA. Of course, as for other surgical assistance systems, further investigations regarding long-term clinical outcomes would be necessary.

Appropriate screw placement and orientation is an important factor in RSA fixation and should be oriented within the glenoid vault of the scapula. Also, the correct length of the screws is important as excessively long screws have been related to suprascapular nerve and artery injury[47] or even scapular spine fractures.[48] The number of screws wrongly positioned was inferior in the fluoroscopy group (5 vs. 10) and although the results were not statistically significant, the authors believe that the use of intraoperative fluoroscopy view is an effective tool to control the screw length and to optimize the position of the screws and the central peg, to achieve a completely inside the glenoid vault insertion and avoid bone perforation.

Interestingly, the fluoroscopy-assisted procedure did not result in a longer surgical time compared to the conventional "free hand" surgical technique, this fact having been previously reported in similar studies on the hip in which fluoroscopy is used to position the acetabular cup.[16] However, the additional time required to position and drape the fluoroscopic device was not counted, and although this is irrelevant for implant positioning, it can be taken into account for a future cost-study, with an estimated time employed of between 5 and 10 min. The absence of an increased "real" surgical time (from skin incision to wound closure) in the FA group compared to the control group may be related to familiarity and routine use during treatment of proximal humeral fractures, although the fluoroscopic techniques necessary to optimize GC placement are more rigorous than those for reduction and fixation of fractures.

Naturally, there is a greater exposure to ionizing radiation in the FA group, with an average dose of 0.45 mGy, equivalent to approximately eight weeks of uniform exposure to natural background radiation. We believe that the benefits obtained from a more accurate positioning outweigh its potential risks, although the long-term effects of low-dose radiation are unknown.

The present preliminary study has some limitations. First, we are aware that the method presented in this study for GC positioning has not been previously validated; however, the preliminary results presented in this paper are encouraging. Another important limitation of the study is the absence of randomization and long-term follow-up to assess the impact of the use of fluoroscopy as a surgical assistance technique on clinical outcomes. The small number of patients/groups could

also lead to bias due to three different pathologies and two different implants, although both implants have been extensively used by surgeons since the introduction of RSA, and glenoid morphology requiring a special implant (augmented/custom-made baseplate), or bone grafting has been excluded. The main strength of the study is that it is the first to report the use of this technique to improve glenoid positioning in RSA. Future studies should try to establish a correlation between the observed radiographic endpoints with the clinical endpoints, including patient-reported outcomes and complications. There is also a need for comparison with more expensive and sophisticated surgical assistance systems.

Conclusions

To the best of our knowledge, this is the first study that compares baseplate positioning with fluoroscopic guidance against the conventional ''free hand'' technique in RSA. These preliminary results suggest that the use of fluoroscopy can improve the accuracy of baseplate placement for surgeons performing primary RSA compared to the conventional technique, without increasing surgical time. The main advantages with the fluoroscopy-assisted procedure are a better GC placement regarding version and inclination, not height. Prospective randomized comparative studies are necessary to determine the cost-effectiveness of intraoperative fluoroscopy compared to more expensive surgical assistance systems.

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Declaration of Conflicting Interests

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Ethical Review and Patient Consent

Institutional Review Board (IRB) ''Ethics Committee for Clinical Research'' (CEIC) from Clínico San Carlos Hospital (Madrid, Spain) approved the present study (19/008-E_TFG). Written informed consent was obtained from the patients for their anonymized information to be included in this study.

Contributorship

All authors made substantial contributions to: Conception or design of the work; or the acquisition, analysis, or interpretation of data for the work. Drafting the work or revising it critically for important intellectual content. Final approval of the version to be published. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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