Glenoid component positioning and guidance techniques in anatomic and reverse total shoulder arthroplasty: A systematic review and meta-analysis

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Abstract

Background: Positioning of the glenoid component is one of the most challenging steps in shoulder arthroplasty, and prosthesis longevity as well as functional outcomes is considered highly dependent on accurate positioning. This review considers the evidence supporting surgical navigation and patient-specific instruments for glenoid implant positioning in anatomic and reverse total shoulder arthroplasty.

Methods: A systematic literature search was performed for studies assessing glenoid implant positioning accuracy as measured by cross-sectional imaging on live subjects or cadaver models. Meta-analysis of controlled studies was performed to estimate the primary effects of navigation and patient-specific instruments on glenoid implant positioning error. Meta-analysis of absolute positioning outcomes was also performed for each group incorporating data from controlled and uncontrolled studies.

Results: Nine studies, four controlled and five uncontrolled, with 258 total subjects were included in the analysis. Meta-analysis of controlled studies supported that both navigation and patient-specific instruments had a moderate statistically significant effect on improving glenoid implant positioning outcomes. Meta-analysis of absolute positioning outcomes demonstrates glenoid implant positioning with standard instrumentation results in a high rate of malposition.

Discussion: Navigation and patient-specific instruments improve glenoid positioning outcomes. Whether the improvement in positioning outcomes achieved translate to better clinical outcomes is unknown.

Keywords

total shoulder arthroplasty, reverse total shoulder arthroplasty, glenoid, patient-specific instruments, surgical navigation, image-guided surgery

Date received: 29th June 2018; revised: 27th August 2018; accepted: 17th September 2018

Introduction

Glenoid component position is a critical factor for post-operative function and long-term implant survival in both anatomic and reverse total shoulder arthroplasty,¹ defining shoulder motion, impingement points, and stresses at the bone–prosthesis interface.² Glenoid component failure is one of the most common complications of total shoulder arthroplasty,^{3,4} and malposition of the glenoid component has been associated with instability, implant, loosening, early failure, and inferior clinical outcomes.⁵

Achieving adequate alignment and stable fixation of the glenoid component can be technically challenging³

owing to restricted visualization, limited bony landmarks, and the complex and variable scapular geometry. Abnormal glenoid morphology and bone loss is common in primary and revision procedures, which

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further complicates positioning the baseplate along the anatomic centerline and achieving stable fixation.⁶

Over the last decade, surgical navigation (NAV) and patient-specific instrument (PSI) techniques have been developed for improving glenoid implant positioning in total shoulder arthroplasty.⁷ The efficacy of these systems at improving radiographic outcomes has been investigated in a number of controlled and uncontrolled studies, with varying sample size, methodological quality, and results.^{7–30} Some studies have found significant improvement in glenoid positioning accuracy; however, glenoid positioning systems have not yet been widely adopted. There exist trade-offs between the potential benefits of these positioning systems and potential challenges relating to increased cost, increased operative time, system availability and reliability, operator training needs, and other barriers to adoption and implementation.⁷ A systematic review of the available literature and meta-analysis is necessary as a first step to quantitatively evaluate these trade-offs.

A meta-analysis of seven controlled glenoid NAV studies was conducted by Sadoghi et al.³¹ However, this previous review did not apply rigorous study-methodology selection criteria, include any PSI studies, or assess accuracy of the translational degrees of freedom in the glenoid implant position.

The purpose of this meta-analysis is to compare radiographic positioning outcomes obtained by standard instrumentation (SI), surgical NAV, and patient-specific instruments (PSI) for glenoid implant positioning in anatomic and reverse total shoulder arthroplasty. The null hypothesis is that radiographic outcomes are equivalent between positioning techniques.

Materials and methods

Eligibility criteria

This study was conducted and reported according to the PRISMA guidelines for systematic reviews and meta-analysis,³² and prospectively registered with PROSPERO (registration number: CRD42017080177).

Randomized controlled trials (RCTs), non-randomized controlled studies (NRSS), and cohort studies (retrospective and prospective) measuring glenoid implant positioning error with PSI, NAV, or SI and meeting the following eligibility criteria were included in this study: (1) the study was performed on human or human cadaver shoulders, (2) positioning error is measured using cross-sectional (CT or MRI) imaging, (3) mean positioning error magnitudes are reported.

Studies were excluded if (1) the procedure was performed on a sawbone or synthetic model; (2) the results were reported in terms of guide-pin position only; (3) multiple procedures were performed on the same

cadaver model; or (4) the glenoid was adulterated prior to arthroplasty, such as to create a glenoid defect model.

Search strategy and study selection

PubMed and MEDLINE were searched from inception to 6 October 2017. The search strings and parameters used are detailed in Appendix 1 (supplementary material). Two independent reviewers (DMB, TF) screened the titles and abstracts of all retrieved studies for potential relevance. Full-text review was then conducted for final selection according to the eligibility criteria. Reference lists of the retrieved manuscripts were also hand searched for potentially relevant studies not identified by the database search. Disagreements were resolved by discussion between the two reviewers and the senior author. No blinding of author, journal, or institutional names was performed.

Data extraction

A single reviewer performed the data extraction on eligible papers. The primary outcome for this study was glenoid component positioning error, defined by version, inclination, and offset errors. Secondary outcomes extracted when available included number of outliers (defined as version or inclination error greater than 10° or offset error greater than 4 mm),^{2,19,26,33} number of aborted procedures, operative time increase, and cost increase. In addition to primary and secondary outcomes, the study design, type of subject (human or cadaver), type of implant (anatomic or reverse), and NAV or PSI system used was extracted.

Methodological quality assessment

Two independent investigators (DMB, TF) graded risk of bias and methodological quality of controlled trials using the Cochrane Collaboration's Risk of Bias Tool for Randomized Trials.³⁴ Therapeutic level of evidence was graded according to Wright et al.³⁵ Disagreements were resolved by discussion between the two investigators and the senior author.

Statistical analysis

Meta-analysis of positioning outcomes from controlled studies was performed with a mean difference (MD) random effects model, using the restricted maximum-likelihood estimator method. Heterogeneity of studies comparing the same treatments was quantified by calculation of the I^2 statistic and assessed for statistical significance by calculation of the P-value for the heterogeneity statistic Q. Publication bias is assessed using

Figure 1. PRISMA flow diagram, depicting the flow of information through the stages of this systematic review.

Begg's Rank Correlation Test³⁶ and Egger's Regression Test³⁷ to detect funnel plot asymmetry.

Using the Begg and Pilote's³⁸ method for incorporating historical controls into meta-analysis, a multivariate mixed effects model was implemented incorporating the full dataset of controlled and uncontrolled studies. The effect of subject type (human versus cadaver) and study type (case series versus controlled study) was assessed independently for significance as moderators in the multivariate model.

Pooled estimates (meta-means) for radiographic outcome performance were calculated for the NAV, PSI, and SI groups using a random effects

model, with the restricted maximum-likelihood estimator method.

Statistical analyses were performed using R (R Foundation for Statistical Computing, Vienna, Austria) using the *metafor* package.³⁹

Results

Search results

The results of the literature search, study screening, and selection are detailed in a flow diagram (Figure 1). The database and bibliography searches yielded 329

Table 1. Summary of study characteristics.

Study	Design	Level of evidence	n (NAV)	n (SI)	Subject	Implant(s)	Error outcomes	Navigation system
Group 1: Surgical navigation (NAV)								
Verborgt et al. ⁷	NRS	II	7	7	Cadaver	rTSA	V, I	Praxim Nano Station
Kircher et al. ²⁹	RCT	II	10	10	Human	aTSA	V	Praxim Nano Station
Study	Design	Level of evidence	n (PSI)	n (SI)	Subject	Implant(s)	Error outcomes	PSI system
Group 2: Patient-specific instruments (PSI)								
Lau and Keith ⁹	PC	IV	11	0	Human	aTSA, rTSA	V, I	Zimmer-Biomet
Gauci et al. ⁸	PC	IV	28	0	Human	aTSA	V, I, O	Tornier
Dallalana et al. ¹²	PC	IV	20	0	Human	aTSA, rTSA	V, I, O	DJO Surgical Match Point
Throckmorton et al. ¹⁹	RCT	I	35	35	Cadaver	aTSA, rTSA	V, I, O	Custom
Suero et al. ²⁵	PC	IV	7	0	Human	aTSA, rTSA	O	Custom
Hendel et al. ²⁶	RCT	I	15	16	Human	aTSA	V, I, O	ArthroPlan
Study	Design	Level of evidence	n (NAV)	n (SI)	Subject	Implant(s)	Error outcomes	
Group 3: Standard instrumentation (SI)								
Gregory et al. ⁵	RC	IV	0	68	Human	aTSA	V, I, O	

NAV: navigation; NRS: nonrandomized controlled study; PC: prospective cohort; PSI: patient-specific instruments; RC: retrospective cohort; RCT: randomized controlled trial; SI: standard instrumentation; V,I,O: version,inclination,offset.

potentially relevant studies. Screening of the titles and abstracts yielded 26 relevant articles^{5,7–30,40} for full-text review and assessment for eligibility criteria. Nine studies met our inclusion criteria of which three were prospective randomized controlled studies,^{19,26,29} one was a prospective NRS,⁷ four were prospective uncontrolled cohort studies,^{8,9,12,25} and one was a retrospective uncontrolled cohort study.⁵ Study characteristics and level of evidence are reported in Table 1. Assessment of methodological quality and individual study risk of bias is summarized in Figure 2 for the controlled studies. The sum total sample size was 135 for the included controlled studies alone and 258 for all included studies.

Radiographic outcome effects: Controlled studies

The radiographic outcome meta-analyses for controlled studies are summarized with forest plots in Figures 3 and 4 for NAV and PSI groups, respectively.

NAV use resulted in a statistically significant reduction in version error (MD -5.0° ; 95% CI -1.8° to -8.2° ; $P=0.002$) with little heterogeneity ($I^2=0\%$,

$P=0.37$). Only a single NAV study reported inclination error,⁷ demonstrating a significant beneficial effect (MD -8.0° ; 95% CI -2.8° to -13.2° ; $P=0.002$), and no NAV studies reported offset error.

PSI use resulted in modest but statistically significant reductions in version error (MD -2.2° ; 95% CI -4.1° to -0.3° ; $P=0.02$), inclination error (MD -5.6° ; 95% CI -0.0° to -11.1° ; $P=0.05$), and offset error (MD -1.0° ; 95% CI -0.6° to -1.4° ; $P<0.001$). Heterogeneity was low for version error ($I^2=0\%$, $P=0.76$) and offset error ($I^2=0\%$, $P=1.0$), but large for inclination error ($I^2=86\%$, $P=0.01$).

Radiographic outcome effects: All studies

Meta-analysis of radiographic outcomes using the full dataset of controlled and uncontrolled studies was performed using a mixed effects model. There was no significant effect of NAV on version error (MD -2.15° ; 95% CI 5.3° to -9.6° ; $P=0.57$) or inclination error (MD -2.0° ; 95% CI 7.3° to -11.2° ; $P=0.68$). There was a statistically significant effect of PSI on version

Figure 2. Risk of bias assessment for controlled studies.

Figure 3. Meta-analysis of glenoid positioning outcomes for controlled studies comparing NAV versus SI.

Figure 4. Meta-analysis of glenoid positioning outcomes for controlled studies comparing PSI versus SI.

error (MD -6.3° ; 95% CI -0.7° to -11.8° ; $P=0.03$) and inclination error (MD -8.2° ; 95% CI -2.0° to -14.4° ; $P<0.01$). However, there was no significant effect of PSI on offset error (MD -1.3 mm; 95% CI 0.7 to -3.3 mm; $P=0.21$).

Absolute radiographic outcomes

Meta-analysis of the radiographic outcome means (meta-means) on the full dataset was conducted to derive pooled estimates of performance and quantify heterogeneity in

the full sample. The results of this analysis are summarized in Table 2 and forest plots (Figures 5 to 7).

Subject type and study type effects

Two multivariate meta-analysis models were fit to the full dataset (all studies) to assess the effect of subject type (cadaver versus patient) and study type (case series versus controlled study).

With positioning method and subject type as moderators, there was no significant effect of using human

Table 2. Summary of absolute glenoid positioning outcomes (meta-means) and heterogeneity for each positioning method.

Method	Version error (°)		Inclination error (°)		Offset error (mm)	
	Mean (95% CI)	I^2 , p(Q)	Mean (95% CI)	I^2 , p(Q)	Mean (95% CI)	I^2 , p(Q)
NAV	6.1 (2.0, 10.3)	70%, p=.07	8.0 (5.3, 10.7)	0%, p=1.0	–	–
PSI	4.5 (2.2, 6.9)	88%, p<.01	2.7 (1.4, 4.1)	82%, p<.01	1.9 (1.0, 2.8)	94%, p<.01
SI	8.6 (6.6, 10.7)	65%, p=.03	11.1 (6.9, 15.2)	88%, p<.01	3.4 (2.8, 4.0)	66%, p=.04

NAV: navigation; PSI: patient-specific instruments; SI: standard instrumentation.

versus cadaver subjects for version error ($P=0.40$), inclination error ($P=0.76$), and offset error ($P=0.97$).

With positioning method and study type as moderators, there was no significant difference in positioning outcome between single arm and controlled studies for version ($P=0.55$), inclination ($P=0.54$), and offset ($P=0.77$).

Positioning outliers

Outliers, defined as version or inclination errors greater than 10° or offset errors greater than 4 mm, were reported in only several studies in the PSI group.^{9,12,19,26} There was a statistically significant reduction in the number of outliers with PSI in comparison to SI in the controlled studies of Hendel et al.²⁶ (27% versus 75%; $P<0.05$) and Throckmorton et al.¹⁹ (17% versus 66%; $P<0.05$). Meta-analysis of outlier raw proportion was performed for the PSI groups and is summarized in Figure 8 forest plot. The pooled estimate for outlier proportion is 20%, 95% CI (0%, 50%), with significant heterogeneity present ($I^2=91\%$, $P<0.01$).

Complications

There were no intraoperative complications for any NAV or PSI procedures in the included studies. The SI case series by Gregory et al.⁵ reported five (7%) glenoid vault perforations by the keel of the aTSA glenoid component on postoperative imaging, but did not assess long-term complications or revisions associated with this. Hendel et al.²⁶ reported a postoperative axillary nerve palsy in their study's SI group. Long-term follow-up was only reported by Lau and Keith⁹ (to one year), with one case of scapular notching not requiring revision and one soft tissue infection in their PSI cohort of 11 patients.

Time, cost, and aborted procedures

Procedural time associated with NAV was only measured in the Kircher et al.²⁹ study, with a mean 31

additional minutes for navigated procedures in comparison to controls. In addition, Kircher abandoned NAV in six of the 16 navigated procedures (37.5%) due to problems registering the glenoid anatomy. Verborgt et al.⁷ estimated that 20 min would be required for surgical NAV once a surgeon was accustomed to using the NAV system. No studies assessed the effect of PSI on surgical time, and no studies assessed the effect of NAV or PSI on procedure cost.

Effect on clinical outcomes

Of the studies included in this review, only Gregory et al.⁵ assessed the effect of malposition on clinical and radiographic outcomes in anatomic total shoulder arthroplasty. At one year postoperatively, glenoid malposition was associated with inferior range of motion. Retroversion and superior inclination of the glenoid was associated with an inferior Mole score (for radiolucent lines around the glenoid).

Bias across studies

The number of included studies permitted limited assessment of publication bias for the PSI intervention only. There was no evidence of funnel plot asymmetry with the Rank Correlation Test for version error ($\tau=0.40$, $P=0.48$), inclination error ($\tau=0.40$, $P=0.48$), or offset error ($\tau=0.00$, $P=1.0$) outcomes; or the Egger Regression Test for version error ($t=2.8$, $P=0.07$), inclination error ($t=2.1$, $P=0.12$), or offset error ($t=1.1$, $P=0.33$). Note, however, the sensitivity of these tests to detect publication bias is limited by the sample size and number of studies included in this review.

Discussion

This systematic review and meta-analysis supports that both NAV and PSI improve positioning outcomes for the glenoid implant in total shoulder arthroplasty. This support is derived chiefly from a patient pool of 135 in four controlled studies (three RCTs, one NRS) that

Figure 5. Meta-analysis of glenoid absolute positioning outcomes (meta-means) for NAV.

were evaluated as fair to good in quality but suffered from moderate to large heterogeneity for some positioning outcomes.

Heterogeneity of the glenoid positioning outcomes is particularly apparent when examining absolute outcomes across the full set of controlled and uncontrolled studies (see Figures 5 to 7). Heterogeneity is high in positioning system groups (NAV, PSI) and also in the SI group. The source of this heterogeneity is unknown; however, differences in surgical technique, implant, surgeon, radiographic image analysis technique, and positioning system are all potential significant factors. Although the multivariate meta-analysis demonstrated no significant effect of study type on outcome, the results of single arm studies should be interpreted with trepidation as there is little validity in comparing single arm positioning outcomes to such heterogeneous historical controls.

Twenty-six studies were identified that were relevant to our research question; however, only nine were ultimately included in the synthesis and analysis. The majority of exclusions resulted from study methodologies that were judged a priori to be noncomparable to the clinical setting; such as by using a synthetic scapula model without a soft tissue envelop, measuring

accuracy from a guide-pin only (no prosthesis implantation), or using a single cadaver specimen for multiple procedures and data points. However, despite the measures taken to exclude what was considered nonrepresentative studies from analysis, significant heterogeneity still remains in the sample.

The pooled radiographic outcome meta-means calculated in this review corroborate the existing literature indicating glenoid positioning with SI is inaccurate.^{5,40} Pooling data from the positioning system controls and the SI series by Gregory et al.,⁵ we calculated meta-mean positioning errors (8.6°, 11.1°, 3.4 mm) very near to what is considered clinically significant positioning error values (10°, 10°, and 4 mm) for version, inclination, and offset, respectively.^{2,33} Pooled outlier proportion using these definitions remains high (20%) even for procedures guided with PSI.

In vitro and finite element studies have demonstrated that nonneutral anatomic TSA glenoid component version and inclination results in eccentric loading; increased stresses at the bone-prosthesis interface; and adverse effects on shoulder range of motion, kinematics, and stability.^{1,2,33,41-43} It has been inferred from the biomechanical data that malposition imparts a higher risk of fixation failure,^{1,2,44} with version or

Figure 6. Meta-analysis of glenoid absolute positioning outcomes (meta-means) for PSI.

inclination errors greater than 10° ^{2,19,26,33} and offset errors greater than 4 mm¹⁹ considered clinically significant. Clinical studies have shown that malposition is common in failed TSA,⁴⁵ and that malposition is associated with reduced range of motion,⁵ and increased radiolucent lines.^{5,46}

The biomechanically optimal glenosphere base-plate position in reverse TSA is less clear. In vitro and finite element studies by Gutiérrez et al.^{47,48}

indicate that neutral version and inferior inclination is desirable for concentric and laterally eccentric implants, but that neutral inclination is desirable for inferiorly eccentric implant designs. Malposition of the glenosphere (particularly superior offset and superior inclination) is associated with scapular notching, a radiographic finding commonly observed after rTSA with varying severity. Scapular notching in turn is associated with inferior clinical outcomes (range of motion,

Figure 7. Meta-analysis of glenoid absolute positioning outcomes (meta-means) for SI.

strength, pain) and the development of worrying radio-lucent lines.^{1,49–51} A link between scapular notching and early glenoid component failure has been suggested,^{52,53} but not conclusively demonstrated.⁵⁴

Little to no data was found to support NAV or PSI from a health care economics perspective. No study identified in this review estimated the costs associated with use of NAV or PSI. Kircher et al.²⁹ reported a

31 min increase in operative time associated with successful NAV procedures and aborted use of NAV in 37.5% of cases due to technical challenges.

No studies identified in the literature search directly compare NAV to PSI for shoulder arthroplasty, and the large heterogeneity in observed outcomes within positioning groups preclude meaningful indirect comparison (network meta-analysis). It is apparent that

Figure 8. Meta-analysis of malposition proportion for PSI.

there has been a trend away from NAV and toward PSI in terms of publication activity. This may reflect the notion that NAV can be more labor intensive, time consuming, costly, and unreliable than PSI and SI for total shoulder arthroplasty.⁷ The logistic challenges associated with PSI, chiefly the cost and time required to template, manufacture, and order a custom device may have better acceptability to clinicians than the disadvantages associated with NAV.

This study demonstrates that use of either NAV or PSI provides a statistically significant improvement in radiographic positioning outcomes in total shoulder arthroplasty. The magnitude of the improvement over SI is substantial; however, it is unclear to what extent these improvements will improve prosthesis longevity or patient functional outcomes. There is insufficient data to evaluate or compare the cost-effectiveness of these interventions, and therefore we cannot recommend widespread adoption at this time. However, this study should alert shoulder surgeons to the high rate of glenoid component malposition that can occur with use of SI and supports either NAV or PSI as potential options for reducing the incidence of glenoid malposition in total shoulder arthroplasty.

Conclusions

SI for glenoid positioning in total shoulder arthroplasty is inaccurate; however, the clinical significance of this has not been well established. NAV and PSIs improve glenoid positioning outcomes, but with significant heterogeneity of results across studies. Whether the improvement in positioning outcomes achieved with these technologies translate to better clinical outcomes for patients undergoing total shoulder arthroplasty is unknown.

Supplementary Material

Supplemental material for this article is available online.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Ethical Review and Patient Consent

Not required for this article.

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