

# Use of Preoperative CT Scans and Patient-Specific Instrumentation May Not Improve Short-Term Adverse Events After Shoulder Arthroplasty

## Results from a Large Integrated Health-Care System

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**Background:** Ongoing innovation leads to a continuous influx of new technologies related to shoulder arthroplasty. These are made available to surgeons and marketed to both health-care providers and patients with the hope of improving outcomes. We sought to evaluate how preoperative planning technologies for shoulder arthroplasty affect outcomes.

**Methods:** This was a retrospective cohort study conducted using data from an integrated health-care system's shoulder arthroplasty registry. Adult patients who underwent primary elective anatomic or reverse total shoulder arthroplasty (2015 to 2020) were identified. Preoperative planning technologies were identified as (1) a computed tomography (CT) scan and (2) patient-specific instrumentation (PSI). Multivariable Cox regression and logistic regression were used to compare the risk of aseptic revision and 90-day adverse events, respectively, between procedures for which technologies were and were not used.

**Results:** The study sample included 8,117 procedures (in 7,372 patients) with an average follow-up of 2.9 years (maximum, 6 years). No reduction in the risk of aseptic revision was observed for patients having either preoperative CT scans (hazard ratio [HR] = 1.22; 95% confidence interval [CI] = 0.87 to 1.72) or PSI (HR = 1.44; 95% CI = 0.71 to 2.92). Patients having CT scans had a lower likelihood of 90-day emergency department visits (odds ratio [OR] = 0.84; 95% CI = 0.73 to 0.97) but a higher likelihood of 90-day venous thromboembolic events (OR = 1.79; 95% CI = 1.18 to 2.74). Patients with PSI use had a higher likelihood of 90-day deep infection (OR = 7.74; 95% CI = 1.11 to 53.94).

**Conclusions:** We found no reduction in the risk of aseptic revision with the use of these technologies. Patients having CT scans and PSI use had a higher likelihood of venous thromboembolism and deep infection, respectively. Ongoing research with extended follow-up is being conducted to further examine the effects of these technologies on patient outcomes.

**Level of Evidence:** Diagnostic Level III. See Instructions for Authors for a complete description of levels of evidence.

New technologies have emerged over recent years with the stated purpose of improving the outcomes of shoulder arthroplasty, including anatomic total shoulder arthroplasty (TSA) and reverse total shoulder arthroplasty (RTSA). These new shoulder technologies include the use of preoperative computed tomography (CT) scans, preoperative 3-dimensional (3D) planning technology, and patient-specific instrumentation (PSI) as well as other innovations, including implant component design modifications<sup>1</sup>. The primary reasons for using the new technologies, which all likely add to total procedure costs, include (1) facilitating decisions regarding procedure selection through the

use of preoperative CT scans, (2) improving the anatomic placement of implants, especially via the use of PSI, and (3) optimizing functional and implant survival results through accuracy in reconstruction. Potential benefits include reduced rates of glenoid loosening, baseplate failure, or other complications leading to aseptic revision surgery<sup>2</sup>.

Published evidence, however, has yet to demonstrate improved outcomes in the years since these technologies have become available. Specifically, reported outcomes using standard legacy components have yet to be surpassed by outcomes with the use of these new technologies<sup>3-6</sup>. Furthermore, preoperative

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3D CT planning can lead to the use of more complex components and insertion techniques, which may be associated with higher costs, increased operative time, and the potential for risk<sup>7,8</sup>.

With this study, we sought to understand (1) how preoperative 3D scans and PSI have been adopted over time by surgeons in a large integrated health-care system and (2) the association between these technologies and outcomes of patients undergoing shoulder arthroplasty. We hypothesized there would be no reduction in the risk of aseptic revision with the use of these technologies.

## Materials and Methods

### Study Design, Setting, and Data Sources

This was a retrospective cohort study conducted using data from Kaiser Permanente's shoulder arthroplasty registry (SAR). This integrated health-care system covers >12 million people throughout 8 geographic regions in the U.S. Membership is representative of the population served, demographically and socioeconomically<sup>9,10</sup>.

A detailed summary of data collection procedures, patients included, and participation rates for the SAR was previously published<sup>11,12</sup>. Briefly, a predefined set of patient, procedure, implant, surgeon, and hospital information for all shoulder arthroplasties performed within the system is prospectively collected into this surveillance tool using electronic intraoperative forms that are completed by the operating surgeon. The registry is then supplemented using data from the electronic health record (EHR) and administrative claims, membership, and mortality records. Once in the registry, patients are longitudinally monitored for adverse events, including revision surgery, until death or health-care membership termination using electronic screening algorithms; identified events are validated using the EHR. The prospective data collection and validation of adverse events ensure a high level of data integrity and increased internal validity. Full inclusion of all arthroplasties performed in all geographic regions has been in place since 2009. Information on CT imaging was obtained from the EHR, an Epic-based platform.

### Study Sample

The study sample comprised patients  $\geq 18$  years of age who underwent primary elective TSA or RTSA for a diagnosis of osteoarthritis or rotator cuff arthropathy only during the period of January 1, 2015, to December 31, 2020. Only procedures performed in the 4 regions with institution-owned hospitals (Northern California, Southern California, Hawaii, the Northwest) were included. The study sample included 8,117 arthroplasties (in 7,372 patients) performed by 130 surgeons at 40 hospitals. The mean patient age was 70.6 years, and 3,630 (44.7%) of the procedures were in male patients.

### Preoperative Planning Technologies

The exposure was the use of preoperative planning technologies for the primary arthroplasty compared with the non-use of preoperative CT scans or PSI. Preoperative planning technol-

ogies specifically addressing glenoid morphology were identified as (1) a CT scan within 1 year before the procedure and/or (2) the use of a PSI computer software system supported by an implant manufacturer (Blueprint preoperative planning software [PPS]; Wright Medical) that, on occasion, included the creation and use of a patient-specific guide. PSI use is reported by the surgeon using intraoperative forms collected into the registry. CT scan and PSI use were documented separately. Specific implants are on contract for use within the health-care system. Of those on contract, only Tornier implants had PSI technology available for use during the study period; therefore, only patients who received Tornier implants were included in the PSI analysis ( $n = 3,553$ ).

### Outcome of Interest

The primary outcome was the risk of aseptic revision during follow-up. Aseptic revision was defined as a procedure in which an implant was exchanged, removed, or added for any reason other than infection. Septic revisions were not evaluated, so as to focus on revisions related to the accuracy of implant placement. The average follow-up for the study cohort was 2.9 years (maximum, 6 years).

Secondary outcomes included 90-day deep infection, emergency department (ED) visit, readmission, and venous thromboembolism (VTE). Deep infection was defined as that supported clinically by  $>1$  of the following criteria: purulent drainage from the deep incision, fever, localized pain or tenderness, a positive culture, and/or a diagnosis of deep infection by the surgeon based on intraoperative findings. ED visits and readmission were identified using outpatient and inpatient encounters documented in the EHR. VTE was defined as any deep venous thrombosis or pulmonary embolism identified according to Agency for Healthcare Research and Quality indicators<sup>13</sup>.

### Covariates

Patient factors included were age, body mass index (BMI), sex, American Society of Anesthesiologists (ASA) classification, total medical comorbidity burden (identified using the Elixhauser comorbidity algorithm<sup>14,15</sup>), Walch glenoid classification (A1, A2, B1, B2, C), utilization of an upper-extremity walking aid (at least 1 Current Procedural Terminology code of E0100-E0159 within 1 year before or after the index procedure date), and indication. Procedure factors included procedure type, surgeon procedure volume 1 year prior, and operative time.

### Statistical Analysis

The adoption of preoperative planning technologies over time was described using frequencies and proportions. The crude cumulative incidence of aseptic revision was calculated as 1 minus the Kaplan-Meier estimator. There was no minimum follow-up requirement. Follow-up for those with revision was defined as the time from the index procedure date to the revision date; follow-up time for those without revision was defined as the time from the procedure date to health-care plan termination, death, or the study end date (March 31, 2021), whichever came first. Patients who underwent revision

**TABLE I Adoption of Preoperative Planning Technologies within an Integrated Health-Care System from 2015 through 2020, by Procedure Type\***

	Operative Year†					
	2015	2016	2017	2018	2019	2020
TSA (n = 3,984)						
CT scan	31.1% (211/679)	34.4% (241/701)	41.6% (278/668)	29.5% (215/729)	19.8% (141/713)	20.0% (99/494)
PSI	1.0% (3/292)	5.4% (17/315)	10.7% (31/289)	10.6% (36/339)	12.4% (40/323)	24.8% (68/274)
RTSA (n = 4,133)						
CT scan	35.7% (159/446)	36.9% (185/501)	36.3% (217/597)	31.1% (246/792)	31.0% (342/1,104)	27.8% (193/693)
PSI‡	0.0% (0/225)	0.8% (2/239)	4.7% (12/253)	10.5% (41/391)	12.7% (78/614)	15.6% (72/461)

\*TSA = total shoulder arthroplasty, CT = computed tomography, PSI = patient-specific instrumentation, and RTSA = reverse total shoulder arthroplasty. †The values are given as the percentage (no./N). ‡In the PSI comparison, non-PSI cases in 2015 and 2016 were excluded because PSI was not available at that time.

for infection were censored. Completeness of follow-up was calculated as the sum of observed follow-up times divided by the sum of potential follow-up times<sup>16</sup>. Multivariable Cox proportional hazards regression was used to evaluate aseptic

revision risk. Hazard ratios (HRs) and 95% confidence intervals (CIs) are presented. The proportional hazards assumption was tested, and the assumption was met. The crude incidence of 90-day events was calculated as the number of incident adverse

**TABLE II Characteristics of 8,117 Primary Elective Shoulder Arthroplasty Procedures in an Integrated Health-Care System (2015 to 2020), by Use or No Use of Preoperative CT\***

Characteristic	CT	No CT
Total no.	2,527	5,590
Patient characteristics		
Age† (yr)	70.5 ± 8.6	70.7 ± 8.3
BMI† (kg/m <sup>2</sup> )	30.2 ± 6.2	29.9 ± 6.0
Male (no. [%])	1,142 (45.2)	2,488 (44.5)
ASA classification III/IV/V (no. [%])	1,109 (48.2)	2,522 (47.1)
Total medical comorbidity burden†‡	3.4 ± 2.5	3.6 ± 2.6
Utilization of upper-extremity walking aid (no. [%])	169 (6.7)	309 (5.5)
Osteoarthritis (no. [%])	1,545 (61.1)	3,238 (57.9)
Walch glenoid classification (no. [%])		
A1	<b>572 (22.6)</b>	<b>1,796 (32.1)</b>
A2	<b>298 (11.8)</b>	<b>613 (11.0)</b>
B1	<b>348 (13.8)</b>	<b>469 (8.4)</b>
B2	<b>271 (10.7)</b>	<b>329 (5.9)</b>
C	<b>65 (2.6)</b>	<b>93 (1.7)</b>
Missing	<b>973 (38.5)</b>	<b>2,290 (41.0)</b>
Procedure characteristics		
RTSA (no. [%])	1,342 (53.1)	2,791 (49.9)
Operative time† (min)	<b>119.1 ± 37.1</b>	<b>106.0 ± 39.1</b>
Surgeon procedure volume in prior 12 mo†	43.78 ± 30.3	44.99 ± 31.2

\*CT = computed tomography, BMI = body mass index, ASA = American Society of Anesthesiologists, RTSA = reverse total shoulder arthroplasty. Bold = standardized mean difference of >0.1, indicating imbalance between the 2 treatment groups for the given characteristic. Missing: BMI = 2 (<1%), comorbidities = 36 (<1%), ASA classification = 464 (5.7%), and operative time = 395 (4.9%). †The values are given as the mean and standard deviation. ‡Medical comorbidities identified using the Elixhauser comorbidity algorithm.

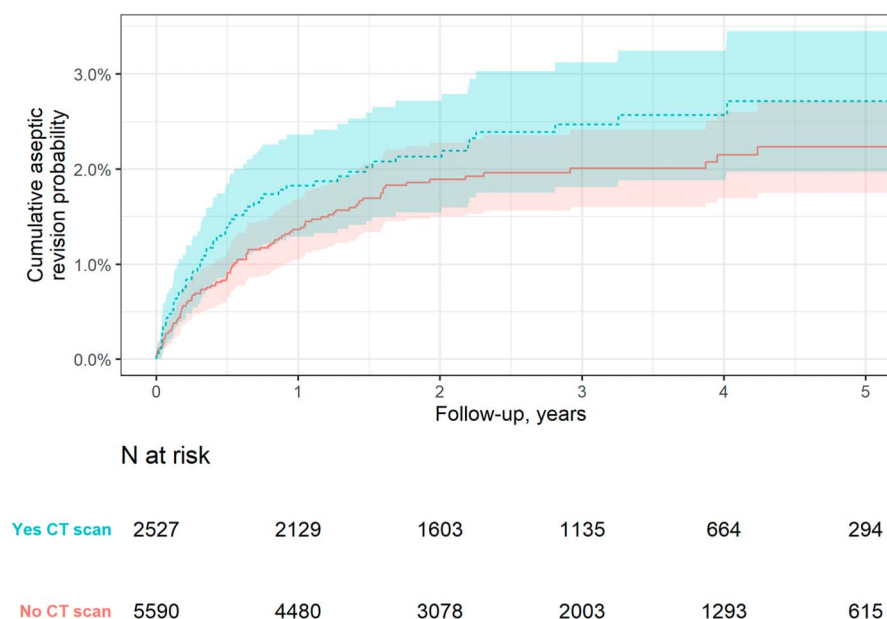


Fig. 1  
Crude cumulative incidence of aseptic revision following primary shoulder arthroplasty by computed tomography (CT) scan use. The dashed and solid lines represent the cumulative incidence, and the shaded area represents the 95% confidence interval. The table below the x axis presents the number of procedures still at risk at each year of follow-up.

events divided by the total number of patients at risk. Multi-variable logistic regression was used to evaluate 90-day events. Odds ratios (ORs) and 95% CIs are presented. Cox and logistic regression models included the confounders mentioned above and a cluster term to adjust for surgeon differences. Missing values for BMI ( $n = 2$ , <1%) and ASA classification ( $n = 464$ , 5.7%) were handled by mean imputation, and missing values for the Walch classification were handled by analyzing them as a separate category. The PSI analysis for RTSA procedures was restricted to 2017, when the technology for this procedure type was available.  $P < 0.05$  was the significance threshold used for this study, and all tests were 2-sided. Analyses were performed using R software (version 3.6.2; R Foundation for Statistical Computing).

This study was approved by our health-care system's institutional review board (#5527).

#### Source of Funding

No outside funding was received for this study.

## Results

### Trends in the Use of Preoperative Planning Technology

Table I presents data on the use of CT scans and PSI in the health-care system from 2015 to 2020. The utilization of preoperative CT scans grew steadily from 2015 to 2017, with a peak of 42% and 36% in 2017 for TSA and RTSA, respectively. Utilization then declined to 20% and 28% in 2020 for TSA and RTSA, respectively. Utilization of PSI increased from 1% in 2015 to 25% in 2020 for TSA and from 5% in 2017 to 16% in 2020 for RTSA.

### Preoperative CT Scans

Of the 8,117 arthroplasties in the study sample, 2,527 (31.1%) had preoperative CT scans. The group with preoperative CT scans had a higher proportion with a Walch type-B or C native glenoid and a longer mean operative time (+13 minutes). Other characteristics were similar between the study groups (Table II). Completeness of follow-up was 96.0% and 96.2% for those with and without a preoperative CT scan, respectively.

Figure 1 presents the cumulative incidence of revision during follow-up according to CT scan use. The incidence of aseptic revision at 1 year of follow-up was low: 1.8% versus 1.4% for patients with and without a CT scan, respectively. After adjustment for confounders, we did not observe a difference in aseptic revision risk ( $HR = 1.22$ ; 95% CI = 0.87 to 1.72) when comparing CT scan and no scan use (Table III). The most common reason for revision for both groups was dislocation/instability; the frequencies of reasons for revision are reported in Table IV. A comparison of the crude incidence of 90-day events between those with and without CT scans is presented in Table III. In multivariable analysis, patients with preoperative CT scans had a lower likelihood of 90-day ED visits ( $OR = 0.84$ ; 95% CI = 0.73 to 0.97) but a higher likelihood of VTE ( $OR = 1.79$ ; 95% CI = 1.18 to 2.74) compared with those without CT scans.

### PSI

Four hundred (11.3%) of the 3,553 procedures that received a Tornier implant had use of PSI; these 400 represent 4.9% of the full study sample ( $n = 8,117$ ). Patients with PSI were more likely to

**TABLE III Crude Incidence of Events and Adjusted Risk Following Primary Shoulder Arthroplasty with and without Use of Preoperative CT Scans\***

Outcome	CT Scan (N = 2,527)†	No CT Scan (N = 5,590)†	Adjusted Estimate‡ (95% CI)	P Value
Longitudinal event				
Aseptic revision	57 (1.8%)	98 (1.4%)	1.22 (0.87-1.72)	0.257
90-day events				
Deep infection	2 (0.1%)	10 (0.2%)	0.44 (0.10-2.03)	0.296
ED visit	293 (11.6%)	769 (13.8%)	<b>0.84 (0.73-0.97)</b>	<b>0.021</b>
Readmission	105 (4.2%)	238 (4.3%)	1.01 (0.80-1.29)	0.915
VTE	39 (1.5%)	48 (0.9%)	<b>1.79 (1.18-2.74)</b>	<b>0.007</b>

\*CT = computed tomography, CI = confidence interval, ED = emergency department, and VTE = venous thromboembolism. †Percentages are calculated as 1 minus the Kaplan-Meier estimate at 1-year follow-up for aseptic revision and no./N for 90-day events. ‡Cox proportional hazards regression for aseptic revision (estimate = hazard ratio), and logistic regression for 90-day events (estimate = odds ratio). All models included patient age, body mass index, sex, American Society of Anesthesiologists classification, medical comorbidity burden, use of an upper-extremity walking aid, osteoarthritis, Walch glenoid classification, procedure type, operative time, and operating surgeon. Bold indicates a significant result:  $p < 0.05$ .

be male and to have a Walch type-B or C native glenoid. They also had a longer mean operative time (+10 minutes) and were operated on by higher-volume surgeons (+17 procedures annually) (Table V). Of those without PSI, 28% (875) had a preoperative CT scan. Completeness of follow-up was 97.5% and 95.9% for those with and without PSI, respectively.

Figure 2 presents the cumulative incidence of revision during follow-up according to PSI use. The incidence of 1-year aseptic revision was 1.8% versus 1.3% for patients for whom PSI was and was not used, respectively. A comparison of the crude incidence of 90-day events between those with and without PSI is presented in Table VI. After accounting for potential confounders, we did not observe a difference in aseptic revision risk (HR = 1.44; 95% CI = 0.71 to 2.92) for patients with versus without PSI, but patients with PSI had a

higher likelihood of a deep infection (OR = 7.74; 95% CI = 1.11 to 53.94). The most common reason for revision in both groups was dislocation; the frequencies of reasons for revision are reported in Table IV.

### Discussion

CT and PSI were originally presented as means of achieving more accurate arthroplasty, with the aim of improving outcomes, particularly among patients with difficult glenoid anatomy. In this study, no difference was found in the risk of aseptic revision between procedures that utilized these advanced technologies and those that only used conventional imaging. It should be noted that, in a report from the Australian Orthopaedic Association National Joint Replacement Registry, glenoid component failure at the 5-year mark was

**TABLE IV Reported Reasons for Revision\***

Revision Reason†	CT Scan (N = 57)	No CT Scan (N = 98)	PSI (N = 6)	No PSI (N = 46)
Arthrofibrosis	2 (3.5)	6 (6.1)	0 (0.0)	2 (4.3)
Dislocation/instability	25 (43.9)	38 (38.8)	4 (66.7)	18 (39.1)
Glenoid fracture	4 (7.0)	0 (0.0)	0 (0.0)	2 (4.3)
Glenoid component loosening	6 (10.5)	17 (17.3)	1 (16.7)	6 (13.0)
Polyethylene liner wear	2 (3.5)	0 (0.0)	1 (16.7)	0 (0.0)
Humeral component loosening	3 (5.3)	5 (5.1)	0 (0.0)	4 (8.7)
Malpositioning	3 (5.3)	6 (6.1)	0 (0.0)	4 (8.7)
Malunion	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)
Periprosthetic fracture	4 (7.0)	6 (6.1)	0 (0.0)	6 (13.0)
Rotator cuff tear	15 (26.3)	25 (25.5)	2 (33.3)	12 (26.1)
Other	7 (12.3)	9 (9.2)	0 (0.0)	2 (4.3)

\*The values are given as the number of patients, with the percentage in parentheses. CT = computed tomography, and PSI = patient-specific instrumentation. †Patients could have >1 reason for revision reported.

**TABLE V Characteristics of 3,553 Primary Elective Shoulder Arthroplasty Procedures in an Integrated Health-Care System (2015 to 2020), by Patient-Specific Instrumentation (PSI) Use\***

Characteristic	PSI	No PSI
Total no.	400	3,153
Patient characteristics		
Age† (yr)	70.7 ± 8.0	70.0 ± 8.4
Body mass index† (kg/m <sup>2</sup> )	30.0 ± 5.6	29.8 ± 6.0
Male (no. [%])	<b>200 (50.0)</b>	<b>1,439 (45.6)</b>
ASA classification III/IV/V (no. [%])	164 (42.6)	1,368 (45.1)
Total medical comorbidity burden†‡	3.3 ± 2.4	3.5 ± 2.5
Utilization of upper-extremity walking aid (no. [%])	24 (6.0)	216 (6.9)
Osteoarthritis (no. [%])	255 (63.8)	1,959 (62.1)
Walch glenoid classification (no. [%])		
A1	<b>59 (14.8)</b>	<b>1,092 (34.6)</b>
A2	<b>33 (8.2)</b>	<b>366 (11.6)</b>
B1	<b>142 (35.5)</b>	<b>280 (8.9)</b>
B2	<b>71 (17.8)</b>	<b>285 (9.0)</b>
C	<b>41 (10.2)</b>	<b>67 (2.1)</b>
Missing	<b>54 (13.5)</b>	<b>1,063 (33.7)</b>
Procedure characteristics		
RTSA (no. [%])	205 (51.3)	1,516 (48.1)
Operative time† (min)	<b>120.4 ± 35.1</b>	<b>110.7 ± 38.3</b>
Surgeon procedure volume in prior 12 mo†	<b>61.5 ± 27.7</b>	<b>44.0 ± 31.0</b>

\*ASA = American Society of Anesthesiologists, and RTSA = reverse total shoulder arthroplasty. Bold = standardized mean difference of >0.1, indicating imbalance between the 2 treatment groups for the given characteristic. Missing: comorbidities = 1 (<1%), ASA classification = 132 (3.7%), and operative time = 109 (3.1%). †The values are given as the mean and standard deviation. ‡Medical comorbidities identified using the Elixhauser comorbidity algorithm.

7.4% for TSA and 4.3% for RTSA<sup>4</sup>, suggesting that longer follow-up may be necessary to discern differences attributable to these new technologies.

In the present study, higher likelihoods of VTE and deep infection were associated with CT and PSI use, respectively. The reasons for this require further study. A report from the International Consensus Meeting on VTE stated that longer orthopaedic procedures are associated with a higher incidence of VTE<sup>17</sup>. However, operative time was not implicated as a risk factor for VTE by Kolz et al.<sup>18</sup>. Procedures for which PSI is used can take longer, especially during the initial surgeon learning curve<sup>19</sup>. Longer operative times and the use of extra instrumentation may increase the infection risk.

In contrast to the present study, prior reports on new technologies have focused on the accuracy and precision of component placement in relation to a predefined plan. Werner et al.<sup>20</sup> found that preoperative 3D planning allowed for improvement of virtual glenoid positioning and influenced decision-making. Iannotti et al.<sup>7</sup> compared the accuracy of glenoid placement in primary TSA among various instrumentation used with 3D CT planning. They concluded that 3D CT planning had the greatest impact on improving the accuracy of glenoid component placement in all of the treatment groups<sup>7</sup>. Yoon et al.<sup>21</sup> showed that the use of PSI reduced variabilities in glenoid and humeral

component positioning and prevented extreme positioning errors in RTSA.

Conversely, some studies have questioned the accuracy of PSI. In a study of 11 shoulder arthroplasties, Lau and Keith<sup>22</sup> found that in vivo accuracy of PSI-guided glenoid positioning was not as great as previously suggested. Cabarcas et al.<sup>23</sup> performed a meta-analysis that revealed no significant differences in accuracy between PSI and standard instrumentation, concluding that further investigations regarding long-term outcomes, impact on operating room time, and cost-effectiveness are warranted before PSI can be routinely recommended. Furthermore, a recent study comparing 3D imaging programs found variance according to the region of the glenoid from which version and inclination are measured<sup>24</sup>.

Little evidence indicating whether CT scans and PSI improve shoulder arthroplasty outcomes is available. In a meta-analysis evaluating the results of 114 studies published over 20 years, Schiffman et al.<sup>25</sup> did not find evidence of improvement in patient outcomes, concluding that there was insufficient literature showing a clinical benefit of individual technologies. The authors suggested that additional research regarding the clinical value (benefit divided by cost) of these new technologies to patients is required<sup>25</sup>. While Tashjian<sup>26</sup> suggested that the most important finding of Schiffman et al.

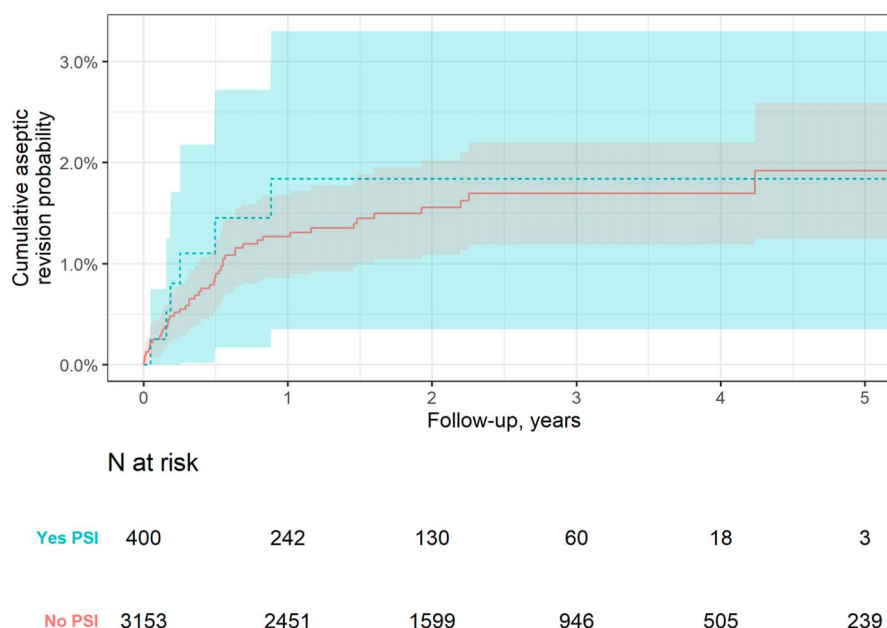


Fig. 2

Crude cumulative incidence of aseptic revision following primary shoulder arthroplasty by patient-specific instrumentation (PSI) use. Only patients who received a Tornier implant were included ( $n = 3,353$ ). The dashed and solid lines represent the cumulative incidence, and the shaded area represents the 95% confidence interval. The table below the x axis presents the number of procedures still at risk at each year of follow-up.

was that outcomes were not inferior to those reported for older implants, as noted, preoperative planning can lead to the use of more complex components and insertion techniques, which may lead to higher costs, increased operative time, and potential risk<sup>7,8</sup>.

Burrus et al.<sup>27</sup> compared clinical outcomes following 84 TSAs using preoperative 3D CT performed with or without PSI to those of 84 matched TSAs without CT-based planning. Within the 3D CT cohort, no differences in patient-reported outcomes or range of motion were observed between TSAs with and without PSI. TSA performed after 3D CT planning with or without the use

of PSI was associated with greater improvement from baseline in American Shoulder and Elbow Surgeons (ASES) scores and external rotation at 90° of abduction compared with TSA performed without 3D CT planning. However, the authors noted that the clinical relevance of this finding was unclear, as the differences did not meet a threshold of clinical importance<sup>27</sup>. Elsheikh et al.<sup>28</sup> reviewed 35 patients who received RTSA and 18 patients who received RTSA with PSI. The RTSA group treated with use of PSI did not achieve better clinical outcomes than with standard imaging and instrumentation, and PSI did not negatively impact the waiting time for surgery or operative time<sup>28</sup>.

**TABLE VI Crude Incidence of Events and Adjusted Risk Following Primary Shoulder Arthroplasty with and without Patient-Specific Instrumentation (PSI) \***

Outcome	PSI (N = 400)†	No PSI (N = 3,153)†	Adjusted Estimate‡ (95% CI)	P Value
Longitudinal event				
Aseptic revision	6 (1.8%)	46 (1.3%)	1.44 (0.71-2.92)	0.311
90-day events				
Deep infection	2 (0.5%)	2 (0.1%)	<b>7.74 (1.11-53.94)</b>	<b>0.039</b>
ED visit	40 (10.0%)	393 (12.5%)	0.76 (0.54-1.08)	0.130
Readmission	18 (4.5%)	114 (3.6%)	1.58 (0.92-2.74)	0.099
VTE	4 (1.0%)	33 (1.0%)	0.82 (0.29-2.32)	0.709

\*CI = confidence interval, ED = emergency department, and VTE = venous thromboembolism. †Percentages calculated as 1 minus the Kaplan-Meier estimate at 1-year follow-up for aseptic revision and no./N for 90-day events. ‡Cox proportional hazards regression for aseptic revision (estimate = hazard ratio), and logistic regression for 90-day events (estimate = odds ratio). All models included patient age, body mass index, sex, American Society of Anesthesiologists classification, medical comorbidity burden, use of an upper-extremity walking aid, osteoarthritis, Walch glenoid classification, procedure type, operative time, and operating surgeon. Bold indicates a significant result;  $p < 0.05$ .

Holzgrefe et al.<sup>29</sup> compared 113 primary RTSAs using an intraoperative navigation system for glenoid drilling and 113 non-navigated RTSAs. They found that the navigated and non-navigated RTSAs yielded similar rates of improvement in range of motion and functional outcome scores at early follow-up.

It is not clear whether such innovations are necessary to achieve a good shoulder arthroplasty outcome. Gunther and Tran<sup>30</sup> used an inset glenoid component placed in deformed arthritic glenoid bone without the use of advanced imaging or instrumentation and found long-term efficacy and safety of shoulder arthroplasty. In a series reported on by Service et al.<sup>31</sup> in which no 3D imaging or PSI was used, the authors found that postoperative glenoid retroversion was not associated with inferior clinical results at 2 years after TSA. They concluded that it was possible to effectively manage arthritic glenohumeral joints without specific attempts to modify glenoid version either by asymmetric reaming or by using augmented glenoid components. Dekker et al.<sup>32</sup> also demonstrated that TSA with minimal, noncorrective glenoid reaming yielded reliable increases in patient satisfaction and clinical outcomes in patients with up to 40° of native retroversion. They found that higher values of retroversion were not associated with early deterioration of clinical outcomes, revisions, or implant failure. Utilizing a two-thirds glenosphere (rather than a half-sphere as in the current study), Elmallah et al.<sup>33</sup> concluded that baseplate retroversion does not affect postoperative functional outcomes, range of motion, or complications after RTSA in patients who had baseplate retroversion of ≤15° versus those who had retroversion of >15°. These studies call into question whether it is clinically important to use CT scans and PSI to target a specific value for postoperative glenoid version.

There were limitations to our study. Only associations are reported in this observational study. Challenging cases were possibly planned with the use of CT scans or PSI, and thus, selection bias may be present. We did attempt to address potential confounding but are limited to information collected in the registry; there is the potential for residual confounding due to unmeasured factors. Only preoperative planning for the glenoid was assessed, as technology for humeral planning was not available during the period. Furthermore, as only 1 implant with PSI technology was evaluated, the results may not be generalizable to other implants with PSI technology. Other outcomes of clinical relevance, including patient-reported outcomes, range of motion, pain, postoperative medical conditions, and cost-effectiveness, could not be evaluated as this information is not collected by the registry. In addition, not every CT scan may have been associated with the use of enhanced proprietary preoperative planning or

PSI, as some surgeons may have ordered a CT scan to study the glenoid morphology without using enhanced proprietary preoperative planning or the creation of PSI. Not every procedure that utilized PSI may have been captured via the registry. However, this misclassification would bias the effect estimates toward the null value of 1, and therefore, the reported results may be conservative. Furthermore, we restricted the PSI analysis to only procedures for which an implant with PSI capability was used and did not differentiate between the use of software and obtaining an actual 3D-printed guide for pin placement. Finally, reasons for a return to the ED and/or readmission are not collected by the registry and could not be compared.

### Conclusions

We found no reduction in the risk of aseptic revision with the use of CT scans or PSI within 6 years of follow-up. The findings of a higher likelihood of VTE and deep infection associated with the use of CT and PSI warrant further study. The orthopaedic community is eager for new technologies to be validated by patient-reported outcomes. It remains to be seen whether clinical benefit of these innovations will be realized and whether their use is justified in view of their cost in money and time. ■

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