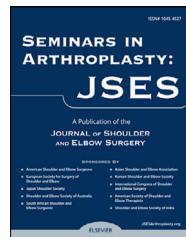




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## High prevalence of early stress shielding in stemless shoulder arthroplasty

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### ABSTRACT

**Introduction:** The rates of early stress shielding in stemless total shoulder arthroplasty (TSA) in current literature are very low and inconsistent with our observations. We hypothesized that the incidence of early stress shielding in stemless TSA would be higher than previously reported.

**Methods:** All stemless TSA in a prospective database using a single humeral implant comprised the study cohort of 104 patients, of which 76.0% (79 patients) had a minimum one year radiographic and clinical follow-up. Radiographs were reviewed for humeral stress shielding, humeral radiolucent lines, and humeral or glenoid loosening/migration. Stress shielding and radiolucent lines were classified by location. Demographics and clinical outcomes, including American Shoulder and Elbow Surgeons (ASES) score and visual analog scale (VAS) pain score, were compared between patient cohorts with and without stress shielding.

**Results:** At one year, 41.8% of patients had humeral stress shielding. Medial calcar osteolysis was seen in 32.9% of all patients and 78.8% of the stress shielding cohort. There were no cases of radiolucent lines or humeral or glenoid loosening/migration. There was no significant difference in age between cohorts ( $P = .308$ ), but there were significantly more females ( $P = .034$ ) and lower body mass index in the stress shielding cohort ( $P = .004$ ). There were no significant differences in preoperative ASES ( $P = .246$ ) or VAS scores ( $P = .402$ ) or postoperative ASES ( $P = .324$ ) or VAS scores ( $P = .323$ ).

**Conclusion:** Stress shielding in stemless TSA is more prevalent than previously published, largely due to infrequently reported medial calcar osteolysis. Stress shielding is more common in women and patients with lower body mass index. At early follow-up there were no significantly worse outcomes in the stress shielding cohort, but longer-term follow-up is needed to fully understand the impact of stress shielding on function and stability.

**Level of evidence:** Level IV; Retrospective Case Series Treatment Study

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Stemless humeral implants for total shoulder arthroplasty (TSA) represent a promising alternative to conventional stemmed implants. Improved patient reported outcomes and active range of motion with stemless prostheses are well-documented,<sup>3,9,13,17</sup> and studies have shown their equivalence with stemmed prostheses.<sup>7,22</sup> Multiple series have found no stress shielding, radiolucencies, or osteolysis at one to four years of follow-up.<sup>6,15,16,23</sup>

Stress shielding is a consequence of nonanatomic loads applied to the bone following arthroplasty, leading to bone remodeling in accordance with Wolff's Law. Stemless shoulder arthroplasty aims to better recreate anatomy than stemmed implants. Therefore, stemless implants should lead to less stress shielding than stemmed implants.<sup>26</sup> Less stress shielding means more preserved bone, which is a fundamental goal of orthopedic surgery. Stress shielding is defined variably across studies, but in the stemless implant it encompasses medial calcar osteolysis, tuberosity resorption, and cortical thinning.<sup>11</sup>

The purpose of this study was to assess early radiographic outcomes of a stemless humeral implant for TSA and, secondarily, to correlate these findings with clinical outcomes. We hypothesized that there would be more stress shielding around the humeral component than has been previously published in the literature, perhaps owing to a broader definition of stress shielding and to a more inclusive and comprehensive radiographic analysis, but there would be no correlation between radiographic findings and clinical outcomes.

## Materials and methods

### Study design

This was a retrospective cohort study of prospectively collected data using the Outcomes Based Electronic Research Database (OBERD, Columbia, MO, USA). The study received Institutional Review Board approval from our institution. All stemless TSA utilizing a Sidus (Zimmer Biomet, Warsaw, IN, USA) implant performed by a single surgeon in 2018 and 2019 with minimum one year radiographic and clinical follow-up were included in the study. Over this timeframe, all TSA performed by the surgeon used a stemless humeral component, and all but five utilized the Sidus implant. There was no patient-specific reason for choosing Sidus versus another implant. Of the 104 Sidus TSA over this timeframe, 79 patients (76.0%) had at least one year of radiographic and clinical follow-up.

### Surgical technique

Procedures were performed in the beach chair position with a standard deltopectoral approach and a lesser tuberosity osteotomy. The implant manufacturer does not advise a complete lesser tuberosity osteotomy to avoid compromising metaphyseal bone, but a very thin osteotomy was performed in these cases to anatomically reduce the subscapularis without compromising the underlying metaphyseal bone. The humeral head was cut just proximal to the lesser tuberosity,

slightly vertical to the patient's anatomic neck-shaft angle to facilitate glenoid exposure. Glenoid preparation and implantation were performed in a standard fashion. A glenoid component was always implanted. The stemless humeral head component was sized to match the patient's anatomy, erring on the side of slightly smaller. The anchor size was chosen to match the size of the cut humerus, generally a small in women and a medium in men. The anchor was placed with a fin just posterior to the bicipital groove. The shoulder was reduced, and the osteotomy was repaired with sutures looped through the implant prior to implantation.

### Clinical data collection

All clinical data were recorded prospectively. This data included patient demographics, including age, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) classification, primary diagnosis, prior surgeries, comorbidities, component sizing, and complications.

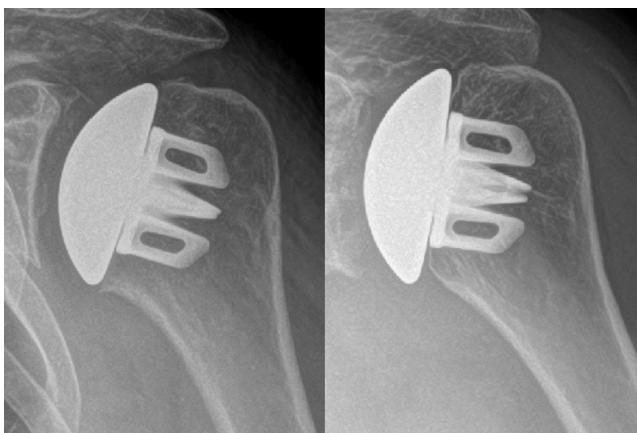
Clinical outcomes included active range of motion (AROM) and patient-reported outcomes (PROs). AROM in forward elevation (FE), external rotation (ER), and internal rotation (IR) was measured by the surgeon preoperatively and at minimum one year postoperatively. IR was scaled such that rotation to the hip was denoted 0, sacrum was denoted 1, L5 vertebra was denoted 2, L4 vertebra was denoted 3, and so forth for the ascending vertebrae. American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES) score and visual analog scale (VAS) score were collected at minimum one year postoperatively. Data from the most recent clinical follow-up visit were used.

### Radiographic data collection

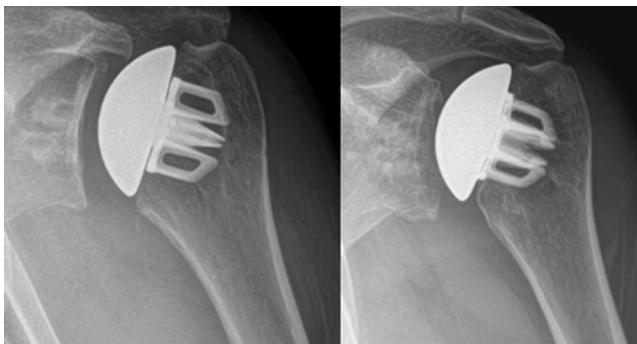
Anteroposterior (AP) and axillary lateral shoulder radiographs were obtained immediately postoperatively, every three months thereafter until one year, and at two years. The most recent postoperative radiographs were used.

AP Grashey radiographs were assessed by consensus of two authors, both orthopedic surgeons, for proximal humerus stress shielding (including medial calcar osteolysis, tuberosity resorption, and cortical thinning), radiolucent lines adjacent to the humeral implant, and humeral or glenoid component loosening/subsidence/migration. Radiographic interpretation followed recommendations of reporting of stress shielding published by Denard et al.<sup>11</sup> The best possible Grashey view, with visualization directly down the bone-implant interface, was used. Radiographs without clear presentation of the cortical-implant interface were excluded. Radiographs with acceptable views at later timepoints were utilized if necessary.

Stress shielding and radiolucent lines were specified by zone, as adapted by Denard<sup>11</sup> from Habermeyer.<sup>12</sup> When stress shielding involved the medial calcar (zone 3), it was classified as partial (Fig. 1) or full thickness (Fig. 2). Partial thickness cortical resorption of the medial calcar is defined as stress shielding in the inferomedial zone (zone 3) without exposure of the humeral anchor collar, while full-thickness resorption is defined as stress shielding in the inferomedial zone with full exposure of the anchor collar. Radiolucencies



**Figure 1 – Immediate postoperative (left) and 1 year postoperative (right) anteroposterior radiographs. The right image shows zone 3 partial cortical thickness resorption, i.e. medial calcar osteolysis or stress shielding, as well as zone 1 partial cortical thickness resorption.**



**Figure 2 – Immediate postoperative (left) and 1 year postoperative (right) anteroposterior radiographs. The right image shows zone 3 full cortical thickness resorption, i.e. medial calcar osteolysis or stress shielding.**

were measured in their maximum width, rounded to the nearest 0.5mm.

#### Statistical analysis

A descriptive analysis of patient characteristics and radiographic and clinical outcomes was performed within the overall population and within stress shielding and non-stress shielding cohorts. Demographics and clinical outcomes were compared between the cohorts.

P-values were derived from a Fisher's exact test for categorical variables and a Mann-Whitney U test, t-test, or z-test continuous variables. Statistical significance was set at  $P < .05$ . Statistical calculations were performed in R.

#### Results

Demographics are shown in Table I. Of the 104 patients with the Sidus TSA implant, 79 patients had one year radiographic

**Table I – Patient demographic and clinical data.**

Total	79
Age (yr)	$61.1 \pm 7.5$ (42 to 78)
Sex [n(%)]	
Female	31 (39.2)
Male	48 (60.8)
Follow-up (years)	$1.5 \pm 0.5$ (0.9 to 2.3)
BMI	$31.1 \pm 6.9$
ASA [n(%)]	
1	13 (16.5)
2	49 (62.0)
3	17 (21.5)
Comorbid conditions [n(%)]	
Depression	19 (24.1)
Diabetes	5 (6.3)
Obesity	34 (43.0)
Smoker	24 (30.4)
Current	3 (3.8)
Former	21 (26.6)
Previous surgery [n(%)]	23 (29.1)
VAS pain score	
Preop	$5.2 \pm 2.6$
Postop	$1.4 \pm 2.1$
$\Delta$	$-3.8 \pm 2.9$
ASES score	
Preop	$40.5 \pm 19.1$
Postop	$82.1 \pm 18.1$
$\Delta$	$40.6 \pm 23.4$
Forward flexion (degrees)	
Preop	$98.7 \pm 24.6$
Postop	$145.0 \pm 19.2$
$\Delta$	$46.6 \pm 26.9$
External rotation (degrees)	
Preop	$30.6 \pm 14.3$
Postop	$60.8 \pm 19.5$
$\Delta$	$30.1 \pm 20.9$
Internal rotation*	
Preop	$1.4 \pm 1.6$
Postop	$4.2 \pm 2.3$
$\Delta$	$2.7 \pm 2.5$

BMI, body mass index; VAS, Visual Analog Scale; ASES, American Shoulder and Elbow Surgeons' Score; ASA, American Society of Anesthesiologists.

\* Sequential point system with 0 representing rotation to the hip, and 9 representing rotation to T10.

and clinical follow-up (76.0%) with a mean age of  $61.1 \pm 7.5$  years and 39.2% female. Twenty-three patients had undergone prior surgery, of which 11 underwent rotator cuff repair and the remaining underwent débridement and/or capsulorrhaphy. The stress shielding cohort had a significantly higher proportion of females (54.5%, vs 28.3% in non-stress shielding;  $P = .034$ ) and lower BMI ( $28.7 \pm 6.4$ , vs  $32.9 \pm 6.8$  in non-stress shielding;  $P = .004$ ), but there was no significant difference in age ( $P = .308$ ; Table II).

Mean postoperative radiographic follow-up was  $1.5 \pm 0.45$  years (range 1-2.3). Mean postoperative clinical follow-up was  $1.5 \pm 0.5$  years (range 0.9-2.5). At minimum one year, 33 patients (41.8%) had humeral stress shielding. Medial calcar osteolysis in zone 3 was seen in 26 patients (32.9% of all patients, 78.8% of stress shielding cohort). Of medial calcar osteolysis cases, 3 (11.5%) were full thickness and 23 (88.5%) were partial thickness, while 9 (34.6%) also had stress

**Table II – Influence of stress shielding on clinical outcomes.**

Outcome	Stress shielding		P values
	Yes (n = 33)	No (n = 46)	
ASES Score			
Preop	43.5 ± 19.2	38.4 ± 19.0	.246
Postop	85.1 ± 15.0	79.8 ± 19.9	.324
Δ	41.7 ± 22.6	39.7 ± 24.1	.707
VAS pain Score			
Preop	4.9 ± 2.3	5.4 ± 2.8	.402
Postop	1.0 ± 1.7	1.6 ± 2.3	.323
Δ	-3.9 ± 2.9	-3.8 ± 2.9	.792
Forward elevation (Degrees)			
Preop	103 ± 27	96 ± 22	.231
Postop	152 ± 12	140 ± 22	.004*
Δ	48 ± 28	45 ± 26	.650
External rotation (Degrees)			
Preop	31 ± 9	30 ± 17	.645
Postop	66 ± 17	57 ± 21	.067
Δ	34 ± 20	28 ± 22	.240
Internal rotation <sup>†</sup>			
Preop	1.4 ± 1.7	1.4 ± 1.5	.572
Postop	4.9 ± 2.1	3.6 ± 2.2	.013*
Δ	3.5 ± 2.8	2.2 ± 2.1	.042*

ASES, American Shoulder Elbow Surgeon Score; VAS, Visual Analog Scale.

\* Denotes Statistical Significance.

<sup>†</sup> Sequential point system with 0 representing rotation to the hip, and 9 representing rotation to T10.

shielding in another zone. Of the 7 patients without medial calcar osteolysis, 5 had zone 6 (posterior) cortical resorption or tuberosity thinning. Overall, 6 patients (18.2%) had stress shielding in zone 6. There was no stress shielding seen in zones 2 or 5. There were no cases of peri-implant radiolucent lines or humeral or glenoid component loosening/migration.

A comparison of postoperative outcomes between cohorts is shown in Table II. There were no significant differences in preoperative ASES ( $P = .246$ ) or VAS scores ( $P = .402$ ) or post-operative ASES ( $P = .324$ ) or VAS scores ( $P = .323$ ). The only significant differences in AROM between cohorts were post-operative forward elevation ( $P = .004$ ) and internal rotation ( $P = .013$ ), both greater in the stress shielding cohort.

## Discussion

This single-surgeon study of 79 patients undergoing stemless TSA showed a 41.8% incidence of stress shielding, higher than prior reports of stress shielding in stemless TSA. The vast majority of stress shielding was present in the medial calcar. There were no instances of radiolucent lines or humeral or glenoid component loosening or migration.

Prior studies of outcomes of stemless TSA generally have not had a detailed focus on radiographic outcomes. Many report humeral implant loosening/migration or radiolucent lines alone.<sup>6,19,24,25</sup> Of the three outcomes studies using the Sidus implant, one reports these findings alone – with no loosening/migration, and radiolucent lines in 2.8%.<sup>2</sup> The other two studies reported radiolucency or osteolysis more broadly;

one found no osteolysis among 105 patients with 1 case of radiolucent lines (0.95%),<sup>17</sup> while the other found 1 radiolucency in the medial calcar out of 170 patients (0.006%).<sup>1</sup> Other studies reporting osteolysis in stemless TSA show very low rates of osteolysis: 0/149 Simplici (Wright Medical Group, Memphis, TN, USA) shoulders,<sup>9</sup> 0/72 TESS (Zimmer Biomet, Warsaw, IN, USA) shoulders,<sup>15</sup> 1/49 Eclipse (Arthrex, Naples, FL, USA) shoulders,<sup>13</sup> and 3/78 Eclipse shoulders.<sup>12</sup> A meta-analysis of stemless TSA reported 2.1% humeral osteolysis, alongside 18.4% humeral radiolucent lines and 1.8% humeral component displacement among 9 studies of 563 patients with multiple implant types.<sup>18</sup>

Habermeyer et al conducted a deeper radiographic analysis than other studies in their evaluation of 78 stemless TSA at a mean of 72 months.<sup>12</sup> In addition to 3.8% of patients with partial osteolysis, they separately noted decreased cancellous bone density in 41.3% of patients, the vast majority of which was in the greater tuberosity. This suggests that stress shielding may be more prevalent than previously thought.

Part of the discrepancy in rates of stress shielding in the literature is due to variable definitions of the term. Raiss et al classically defined it in stemmed TSA prostheses any one of external stress shielding (ie, bone becoming thinner), internal stress shielding (ie, bone becoming more porous), occurrence of spot welds, and occurrence of condensation lines around the tip of the step.<sup>21</sup> Stemless prostheses require a different definition. We used medial calcar osteolysis, tuberosity resorption, and cortical thinning as our criteria, as has been reported in the literature.<sup>11</sup> Multiple studies either do not define stress shielding<sup>15,19</sup> or equate tuberosity osteolysis/reduction in bone density alone with stress shielding,<sup>23</sup> but we believe that there is more to stress shielding in stemless TSA than this finding.

Medial calcar osteolysis, in particular, has been infrequently reported in prior studies of stemless TSA. Given that this was the most frequent finding in our study, this explains our much higher rate of stress shielding than elsewhere in the literature. Prior studies evaluating medial calcar osteolysis have done so inconsistently. Beck et al found 2/26 patients with stemless TSAs having a minor calcar defect; much more of their reported 38.5% rate of stress shielding was due to 'spot welds', which they defined as decreased cancellous bone density.<sup>4</sup> Habermeyer et al did not report medial calcar osteolysis specifically, though they found decreased bone density in zone 3 in 7.9% of patients. Moursy et al found that 11/13 patients with a well centered stemless implant had stress shielding in the form of increased medial calcar sclerosis, as opposed to osteolysis.<sup>20</sup> Medial calcar osteolysis is of unclear clinical significance, but accurately reporting its presence is important as we study the full effects of stemless implants on patients.

The literature is divided on whether proximal humerus bone resorption following TSA affects clinical outcomes. Multiple stemless TSA studies show no difference,<sup>5,8,12</sup> while some stemmed TSA studies have found worse PROs scores with radiographic bone resorption.<sup>5,10,21</sup> We found no difference in PROs between stress shielding and non-stress shielding cohorts, though this was limited by the short one year clinical follow-up. There was significantly increased postoperative range of motion in the stress

shielding cohort without a clear explanation. Stress shielding could reduce bony impingement or affect the insertion of soft tissue restraints in the shoulder, though this is unproven, and most cases of stress shielding in this study were relatively mild.

### Limitations

A limitation to this study, and many studies of radiographic findings in shoulder arthroplasty, is the variation in definitions of radiographic findings relative to the literature. For example, apparent decreased bone mineral density in the proximal humerus on radiographs may reflect true osteolysis—leading to high rates of osteolysis in some studies<sup>12</sup>—or may be a radiographic anomaly related to penetration of the x-ray beam.<sup>14</sup> We were conscious of the latter and thus may have been more conservative than some authors in calling radiographic lucencies osteolysis. Minor variations in shoulder rotation on x-ray may have had small effects on the ability to discern stress shielding and bone quality. Our follow-up time is relatively short. For radiographic follow-up, this was intentional to illustrate early radiographic outcomes. For clinical follow-up, it is shorter than optimal, which limits the conclusions drawn from our clinical data. Selection bias in this prospective study was controlled given that nearly all patients undergoing TSA by this surgeon over this time were performed with the same implant, and there was no clinical reason for use of an alternative implant. Surgeon technique could affect the results of this study, for example the aforementioned slightly varus neck cut to facilitate glenoid exposure, though the connection between such a neck cut and stress shielding is not obvious.

### Conclusion

We found that stress shielding in stemless TSA is more prevalent than previously published, largely due to infrequently reported medial calcar osteolysis. Stress shielding is more common in women and in patients with lower BMI. At early follow-up there were no significantly worse subjective patient outcomes in the stress shielding cohort, but longer-term follow-up is needed to fully understand the impact of stress shielding on patient function and implant stability.

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**Conflicts of interest:** Andrew Jawa is a paid speaker and consultant for DJO Global, a paid consultant for Ignite Orthopedics, receives royalties from Depuy Synthesis, and has equity in Boston Outpatient Surgical Suites. Anand Murthi is a paid consultant for Stryker Corporation, Globus Medical, Inc., and Ignite Orthopaedics. All other others, their immediate families, and research foundations with which they are affiliated did not receive any financial payments or other benefits from any commercial entity related to the subject of this article.

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