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Biomechanical Stability of Primary and Revision Sacroiliac Joint Fusion Devices: A Cadaveric Study

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Abstract

Study Design: An in vitro biomechanics study.

Objective: To evaluate the efficacy of triangular titanium implants in providing mechanical stabilization to a sacroiliac joint with primary and revision sized implants.

Methods: Ten lumbopelvic cadaveric specimens were tested in 4 stages: intact, pubic symphysis sectioned, primary, and simulated revision. Primary treatment was performed using 3 laterally placed triangular titanium implants. To simulate revision conditions before and after bone ingrowth and ongrowth on the implants, 7.5-mm and 10.75-mm implants were randomly assigned to one side of each specimen during the simulated revision stage. A 6 degrees of freedom spinal loading frame was used to load specimens in 4 directions: flexion extension, lateral bending, axial torsion, and axial compression. Biomechanical evaluation was based on measures of sacroiliac joint rotational and translational motion.

Results: Both primary and revision implants showed the ability to reduce translational motion to a level significantly lower than the intact condition when loaded in axial compression. Simulated revision conditions showed no statistically significant differences compared with the primary implant condition, with the exception of flexion-extension range of motion where motions associated with the revised condition were significantly lower. Comparison of rotational and translation motions associated with the 7.5- and 10.75-mm implants showed no significant differences between the treatment conditions.

Conclusions: These results indicate that implantation of laterally placed triangular titanium implants significantly reduces the motion of a sacroiliac joint using either the primary and revision sized implants. No statistically significant differences were detected when comparing the efficacy of primary, 7.5-mm revision, or 10.75-mm revision implants.

Keywords

sacroiliac, fusion, spine, revision, biomechanics

Introduction

Non-autoimmune sacroiliac joint (SIJ) dysfunction is responsible for 15% to 30% of chronic low back pain.[1,2] SIJ fusion has become an increasingly popular approach to treat this chronic pain and minimally invasive techniques have become the most common.[3-5] It is often noted that SIJ diagnosis is one of the more sensitive and specific diagnoses for low back pain, and fusion procedures have been associated with improved pain, disability, and quality of life with relatively high satisfaction rates.[6,7] The mechanism of pain relief with these surgical techniques is thought to be two-fold with early pain relief as a result of immediate surgical joint stabilization and late pain relief as a result of fusion.[8]

Fixation and fusion procedures are generally seen as a last resort for patients experiencing SIJ pain as nonoperative

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Table 1. Specimen Demographics and Bone Mineral Density (BMD).

Specimen	Age	Sex	Height (in.)	Weight (lbs)	L1-L4 BMD
IN16042714	77	Male	72	250	1.102
MD170329115	57	Female	64	270	1.17
MD170427104	67	Female	61	110	1.211
MD170428108	66	Female	67	300	0.963
MD170429112	69	Female	57	192	1.286
MD17051963	69	Female	62	350	1.376
PA17052789	54	Male	74	350	1.132
VA17042189	49	F	64	300	1.255
VA17050211	41	Female	69	350	1.151
VA17052069	66	Male	69	350	1.388

management consisting of physical therapy and rehabilitation is often undertaken first. A wide variety of techniques have been introduced, with Smith-Petersen publishing their method for arthrodesis in 1921.[9] Initially, most procedures consisted of decorticating the joint surface and placing autograft,[10] until the introduction of the iliosacral screw in 1995. Currently, numerous minimally invasive SI fixation or fusion devices are available and variation in their outcomes has been reported.[11] Although previously reported revision rates are low, common reasons for surgical revision include implant malpositioning or symptom recurrence.[12,13] Existing gaps in the literature regarding SIJ fixation include the efficacy of revision procedures and the response to axial compressive loading.

The objective of this study was to evaluate the biomechanical efficacy of triangular titanium implants used for SIJ fusion in response to flexion-extension (FE), lateral bending (LB), axial torsion (AT), and axial compression (AC) loading protocols. After primary fixation, a simulated revision surgery was performed, and its biomechanical effects evaluated in the same manner. Two sizes of implants were evaluated: (1) a 7.5-mm implant used for short-term revisions (prior to bone ingrowth and ongrowth) and (2) a 10.75-mm implant used for a long-term revision (after ingrowth and ongrowth has occurred where additional chiseling is required to remove the primary implant). Comparisons will be made between the efficacy of primary and revision implants with respect to rotational and translational motion in order to compare the efficacy of the various cohorts.

Materials and Methods

Treatment Groups and Stages

Left and right SIJs of 10 cadaveric specimens were treated as 2 independent joints, which were both instrumented with the triangular titanium TPS (titanium plasma spray)-coated implants for a total sample size of 20 fusion procedures. All specimens were subject to 4 stages of testing; intact, pubic symphysis sectioned, primary, and revised. Primary testing was performed directly after implantation of 3 primary 7.0-mm triangular titanium implants using a pin, drill, broach, implantation procedure following the manufacturer's recommendations (iFuse Implant System, SI-BONE) under fluoroscopic guidance.[14] Revision procedures were simulated by removing the most cephalad implant by 1 of 2 methods: (1) direct implant removal (simulating no ingrowth or ongrowth) or (2) chiseling along the implant surfaces (simulating ingrowth and ongrowth). For implants directly removed (method 1), a 7.5-mm triangular titanium TPS coated implant was placed into the existing void. For implants chiseled out (method 2), a 10.75-mm triangular broach was used to prepare the existing void, and a 10.7- mm triangular titanium TPS coated implant was placed into void. The revision methods were randomly assigned to either the left or right side.

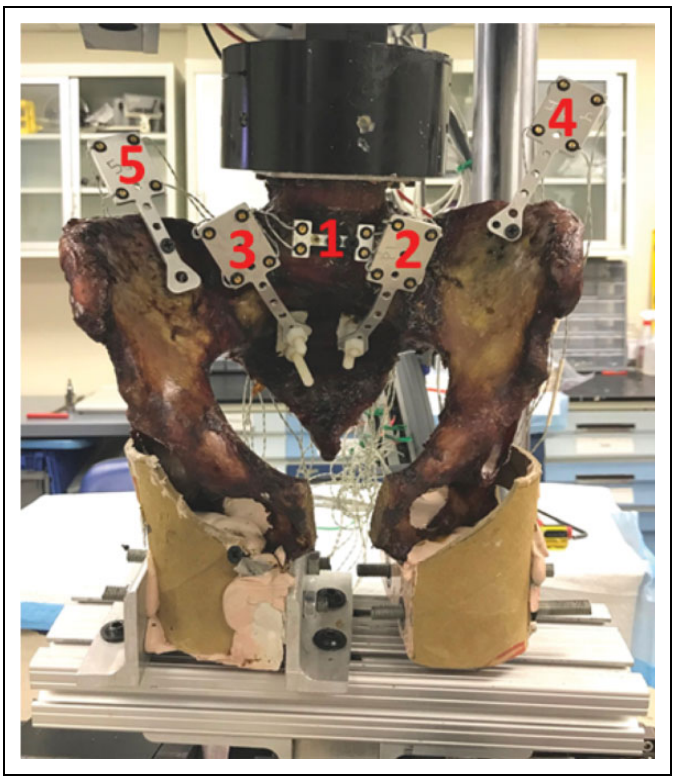

Figure 1. Test setup showing markers used to track motion of the L5 vertebrae (1), sacrum (2 and 3), and ilium (4 and 5).

Specimen Preparation

This study was a cadaveric investigation and did not involve human subjects; institutional review board approval was therefore not necessary for the research presented in this article. Ten (7 female, 3 male) fresh frozen human lumbopelvic cadaveric specimens, consisting of at least L4 and the entirety of the pelvis, were obtained following institutional approval. Each specimen was DEXA scanned for bone mineral density of the L4 vertebra (Table 1). The specimens were stripped of all soft tissue except for the osteoligamentous structure. Each specimen was potted at L4 as well as the left and right ischia using thermosetting polymer (Bondo, 3M) and custom potting rings, with care taken to preserve the L5-S1 disc space. Prior to testing, 5 sensors consisting of 4 infrared markers each were

rigidly fixed to the specimen (Figure 1). Marker motion was tracked using an optoelectric tracking system (Optotrak Certus, NDI). All specimens were wrapped in saline-soaked gauze and stored in double sealed bags at −20 °C when not in use. Implants were placed according to the surgical technique guide by a trained neurosurgeon and implant position was verified using fluoroscopy.

Testing Procedures

Biomechanical testing was conducted under a standard pure moment flexibility protocol using a custom spine loading frame (Bose SmartTest) with independent motors driven in load control.[15] All testing was performed using a single-leg stance model in which the ipsilateral ischium was held while the contralateral ischium was allowed to move freely.[16,17] This protocol consists of 4 modes of loading: axial compression, flexion extension, lateral bending, and axial torsion. Each specimen was subjected to ±7.5 N m with no compressive preload in each mode of loading with the exception of axial compression, during which the specimen was subjected to 200 N. The magnitude of force applied in each mode of loading was intended to correspond with physiologic conditions observed in everyday life to avoid the accumulation of tissue damage throughout the test protocols. While some studies may report failure loads significantly larger than these values, the goal of the test is to subject the specimen and implants to conditions they would be exposed to in common clinical applications while maintaining the boundary conditions. Each test consisted of 3 loading cycles for each mode of loading with the third cycle being used for analysis. Treatments were carried out from least invasive to most invasive as follows: intact, pubic symphysis sectioned, primary fixation, and revised fixation. Intact represents the healthy condition and occurs immediately after the specimen has been potted and prior to any instrumentation or surgical intervention. Pubic symphysis sectioned is intended to represent the destabilized condition and involves sectioning of the pubic symphysis and iliolumbar ligaments; this allows for the left and right sides to be independently tested and compared. Primary fixation represents the conditions immediately following placement of the iFuse implant system and revised fixation represents conditions immediately following removal and replacement of the superior-most implant.

Calculations of rotational range of motion (ROM) as well as translational motion within the SIJ were made based on motion of the sacrum relative to that of the ilium. Measurements of sacral movement were based on markers attached to the sacrum using a dowel driven through the first sacral foramen on the ipsilateral side of testing. Ilium motion was based on the movement of markers attached to the ipsilateral ilium (Figure 1). All calculations are presented in an anatomically relevant coordinate system based on landmarks surrounding the SIJ.

Calculations of SIJ translation were performed using the positional data from the ipsilateral ilial and sacral markers. The relative difference between the maximum and minimum position values of each rigid body direction were used to determine x, y, z movement of the joint. These 3 values were then combined into one vector for analysis.

Statistics

To elucidate statistically significant trends within the SIJ ROM data a Friedman Test was performed followed by a Wilcoxon signed-rank post hoc analysis (the data failed to pass the check of sphericity). The statistical significance for SIJ translational motion was determined using a repeated-measures ANOVA with a pairwise post hoc analysis using a Bonferroni correction. P values <.05 were considered statistically significant.

Results

After intact testing 3 specimens were identified as having autofused SIJs or other anatomical deficiencies and therefore disqualified from the remainder of the study. All specimens included in the analysis were successfully instrumented according to the standard operating procedures. Implant lengths ranged from 40 to 60 mm (cephalad), 30 to 55 (middle), and 35 to 60 (caudal). All 7.0-, 7.5-, and 10.75-mm implants were placed per manufacturer's recommendations with final placement confirmed fluoroscopically.

Revision Size Comparisons

The translational and rotational ROM data of the SIJ was used to compare the efficacy of the 7.5- and 10.75-mm implants used in the study. A pairwise analysis showed there was no significant difference in performance based on the radial size of the implant. As this was the case, the results from the 7.5- and 10.75-mm stages were pooled into one revision cohort during analysis in order to increase the size of the group and improve statistical accuracy.

SIJ Rotational Range of Motion

The SIJ rotational ROM results are shown in Table 2. Results of the Friedman test for rotational ROM during FE loading showed a significant difference between the various stages of testing ($\chi^2[3] = 19.64$, $P = .000\,005$). Pairwise analysis revealed a significant reduction in motion for all instrumented specimens and in all modes of loading when compared with the pubic symphysis sectioned condition. Motion in response to AC loading was reduced such that rotations during both the primary ($P = .0006$) and revised ($P = .0036$) stages were significantly lower than the intact condition. In addition, rotation measured in response to FE loading was shown to be significantly lower in the revised stage than during the primary stage ($P = .033$). These trends are illustrated in Figure 2.

SIJ Translation Range of Motion

The results associated with SIJ translation ROM can be found in Table 3. Results of the Friedman test for translational motion showed a significant difference between the various stages of

Table 2. Sacroiliac Joint Range of Motion (°).

		Flexion extension					Lateral bending					Axial torsion					Axial compression				
					Revision					Revision					Revision					Revision	
Side	Side	Intact	Sectioned	Primary	7.5	10.75	Intact	Sectioned	Primary	7.5	10.75	Intact	Sectioned	Primary	7.5	10.75	Intact	Sectioned	Primary	7.5	10.75
MD170427104	Left	0.683	1.428	1.373	1.294	—	0.508	1.712	1.578	1.801	—	0.931	2.195	1.777	1.982	—	0.238	0.573	0.287	0.354	—
MD170427104	Right	0.706	1.104	0.622	—	0.603	0.442	1.138	0.983	—	1.288	1.035	1.561	1.392	—	1.702	0.363	0.431	0.232	—	0.277
MD170428108	Right	0.828	2.199	0.453	0.412	—	0.503	1.355	0.554	0.610	—	0.875	2.639	0.786	0.846	—	0.236	0.439	0.125	0.080	—
MD170428108	Left	0.688	1.100	0.454	—	0.462	0.375	0.674	0.533	—	0.661	0.603	1.504	0.653	—	0.752	0.106	0.150	0.130	—	0.111
MD170429112	Left	3.010	4.947	3.206	0.956	—	1.626	3.691	1.889	1.454	—	1.978	3.997	3.578	1.393	—	0.656	0.759	0.172	0.448	—
MD170429112	Right	2.641	3.989	2.012	—	1.722	1.286	2.626	1.932	—	2.188	2.116	3.961	2.541	—	2.926	0.659	0.744	0.140	—	0.057
MD17051963	Right	1.870	2.434	1.193	1.485	—	1.350	2.396	1.941	1.051	—	2.184	3.797	2.918	3.598	—	0.686	0.959	0.213	0.175	—
MD17051963	Left	1.750	2.248	0.704	—	0.525	1.541	2.983	0.557	—	0.466	2.266	4.296	2.016	—	1.904	0.822	0.881	0.124	—	0.160
VA17042189	Right	1.389	1.700	0.659	0.485	—	0.800	1.499	0.565	0.563	—	1.149	1.513	0.568	0.489	—	0.529	0.379	0.087	0.081	—
VA17042189	Left	1.797	3.508	0.696	—	0.227	1.087	3.035	1.014	—	0.167	1.372	2.658	0.953	—	0.690	0.350	0.678	0.150	—	0.240
VA17050211	Left	1.420	3.249	0.556	0.403	—	0.535	1.982	0.646	0.594	—	0.961	2.630	0.594	0.574	—	0.654	0.895	0.091	0.131	—
VA17050211	Right	1.613	2.154	1.708	—	0.226	0.307	1.284	0.279	—	0.217	1.016	3.162	0.387	—	0.306	0.663	0.969	0.072	—	0.062
VA17052069	Right	1.272	1.864	1.522	1.768	—	0.695	1.607	0.959	1.285	—	0.747	2.278	1.880	2.067	—	0.411	0.530	0.099	0.218	—
VA17052069	Left	1.264	2.076	1.952	—	1.887	0.537	1.915	1.702	—	1.497	0.679	2.924	2.796	—	2.664	0.335	0.351	0.199	—	0.209
Average		1.495	2.429	1.222	0.972	0.808	0.828	1.993	1.081	1.051	0.926	1.279	2.794	1.631	1.564	1.564	0.479	0.624	0.151	0.212	0.159
SD		0.703	1.119	0.798	0.559	0.698	0.457	0.849	0.603	0.487	0.754	0.596	0.951	1.030	1.099	1.017	0.215	0.256	0.062	0.140	0.087

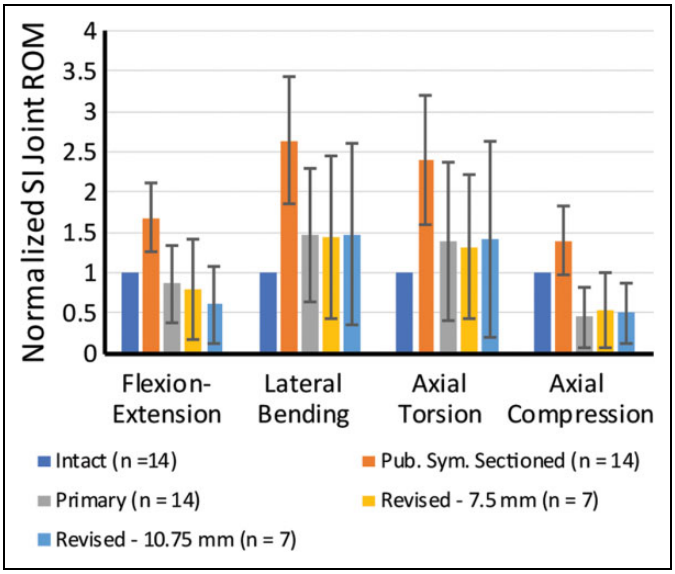

Figure 2. Normalized sacroiliac joint range of motion results.

testing ($\chi^2[3] = 19.64$, $P = .000\,005$). Pairwise analysis revealed a significant reduction in motion for all instrumented specimens under FE, AT, and AC loading when compared to the pubic symphysis sectioned condition. Motion in response to AC loading was reduced such that translation during the primary ($P = .005$) stage was significantly lower than the intact condition. In addition, translational motion measured in response to AT loading was shown to be significantly lower in the revised stage than during the intact stage ($P = .044$). These trends are illustrated in Figure 3.

Discussion

This study evaluated the efficacy of a primary and revision triangular titanium implant system's ability to reduce motion of a destabilized SIJ. A single-leg stance model was utilized to replicate the forces transmitted through the SIJ during common activities such as walking, running, or climbing stairs.[16,17] Biomechanical evaluation included measurement of rotational and translational motion under 4 separate conditions: intact, pubic symphysis sectioned, primary, and revised. Following the same trend as previous publications related to the biomechanics of the SIJ,[18-20] the magnitude of rotational motion observed in the intact condition was relatively low, with values of 1.495°, 0.828°, 1.279°, and 0.479° in FE, LB, AT, and AC, respectively. Sectioning of the iliolumbar ligament and pubic symphysis lead to significant increases in motion during the pubic symphysis sectioned phase of testing, with ROM measuring 2.429°, 1.993°, 2.794°, and 0.624° in FE, LB, AT, and AC, respectively.

Primary and revised stages of testing represent the time period immediately postoperatively for the primary and revision surgeries, respectively. For each condition the specimens were subject to 4 modes of loading: FE, LB, AT, and AC, which represent the 4 major modes of loading seen in vivo. Overall, our results confirm the well-documented ability of the triangular titanium implants to significantly reduce the motion of a destabilized SIJ. In fact, both rotational and translational motions of the treated destabilized SIJ were consistently reduced to levels comparable to and, in some cases, lower than an intact SIJ. Our results demonstrate that the revision implants perform as well if not better than the primary implants in all modes of loading. Furthermore, these significant reductions in ROM and translation seen during AC modes of loading have not yet been reported in the literature, to the best of the researchers' knowledge. The SIJ spans multiple anatomic planes and plays a significant role in load bearing; the data associated with AC is valuable and could offer insight into the mechanism of SIJ stabilization.

Findings of particular interest to this report are the results associated with the simulated revision surgeries and axial compression loading. The results within the groups show that in the absence of infection or implant associated bone loss further SIJ stabilization is possible in revision situations where a larger implant is required after removal (eg, implant malpositioning). This is an important finding because it demonstrates the ability of the larger implants to reduce the motion associated with destabilized SIJs to values comparable to or even lower than the intact and primary values. Revision surgeries may therefore be useful in a clinical setting under circumstances where the primary implants were malpositioned or pain attributable to destabilization was not relieved after primary fixation. Data associated with axial compression is notable for multiple reasons. The ability of the triangular titanium implants to reduce motion of the SIJ related to axial compression forces to values below those seen in the intact condition could play a significant role in the clinical success of the implant system. Previous studies have demonstrated that significant forces are transmitted through the SIJ as a result of trunk loading.[21] Such loading creates shear forces within the SIJ that may contribute to instability and pain. Given that this is the first biomechanical study to investigate the ability of an SIJ fixation system to reduce motion in response to AC loading, the reduction in motion back to levels similar to the intact condition is a significant finding. This reduction in rotational and translational motion could be an implication that axial compressive stabilization plays a critical role in SIJ treatment and pain relief.

There are, of course, some limitations associated with the results of our study. Perhaps the most impactful is lack of biological fixation, which is believed to play a major role in the long-term efficacy of the system in a clinical setting. Furthermore, the lack of biological fixation or scar tissue formation limits the ability of this protocol to evaluate the full effect revision procedures may have on the efficacy of the system. Our analysis and procedure are also based on the assumption that each joint behaves independently of the other during testing. This idea combined with a relatively small sample size could lead to some bias in our results. However, precautions were taken in the study design to reduce bias (eg, randomizing the distribution of 7.5 mm or 10.75 mm implants). An additional source of potential bias is the industry funding provided for this study. The complexity of the SIJ itself is another major limitation associated with our study. Due to its unorthodox geometry,

Table 3. Sacroiliac Joint Translation (mm).

		Flexion extension					Lateral bending					Axial torsion					Axial compression				
					Revision					Revision					Revision					Revision	
Specimen	Side	Intact	Sectioned	Primary	7.5	10.75	Intact	Sectioned	Primary	7.5	10.75	Intact	Sectioned	Primary	7.5	10.75	Intact	Sectioned	Primary	7.5	10.75
MD170427104	Left	0.733	1.400	1.158	1.200	—	0.632	1.666	1.653	1.853	—	0.784	1.880	1.604	1.703	—	0.310	0.640	0.371	0.425	—
MD170427104	Right	0.438	0.796	0.338	—	0.306	0.531	1.014	1.106	—	1.310	0.615	1.034	0.847	—	0.962	0.432	0.500	0.333	—	0.362
MD170428108	Right	0.735	1.299	0.484	0.301	—	0.420	0.807	0.517	0.312	—	0.522	0.879	0.481	0.240	—	0.338	0.508	0.393	0.166	—
MD170428108	Left	0.419	0.535	0.333	—	0.300	0.220	0.266	0.362	—	0.447	0.318	0.387	0.246	—	0.288	0.219	0.233	0.220	—	0.186
MD170429112	Left	2.143	3.246	2.466	1.421	—	0.868	1.186	0.475	1.476	—	1.296	2.142	1.583	1.984	—	0.791	0.801	0.373	0.910	—
MD170429112	Right	1.244	1.870	0.791	—	0.610	0.800	1.356	0.795	—	1.373	1.219	1.967	1.323	—	1.489	0.717	0.817	0.213	—	0.349
MD17051963	Right	1.132	1.529	0.532	0.582	—	1.348	2.007	3.147	0.943	—	0.896	1.707	1.458	1.325	—	0.725	0.999	0.281	0.238	—
MD17051963	Left	1.328	1.511	0.613	—	0.459	1.969	3.464	0.802	—	0.582	1.840	—	1.651	—	1.387	0.872	0.940	0.221	—	0.229
VA17042189	Right	1.077	0.947	0.361	0.319	—	0.620	0.550	0.335	0.245	—	—	—	—	—	—	0.605	0.426	0.151	0.159	—
VA17042189	Left	0.989	1.937	0.423	—	0.769	0.690	1.083	0.464	—	0.789	1.151	1.227	0.951	—	1.427	0.420	0.843	0.252	—	0.464
VA17050211	Left	1.144	2.363	0.418	0.389	—	0.497	1.536	0.481	0.450	—	0.799	2.278	0.476	0.501	—	0.729	0.964	0.166	0.198	—
VA17050211	Right	1.766	1.478	1.540	—	0.262	0.342	1.160	0.281	—	0.284	0.606	1.871	0.429	—	0.533	0.736	1.045	0.170	—	0.174
VA17052069	Right	0.858	1.261	0.563	0.792	—	0.708	1.231	0.472	0.470	—	0.619	1.786	0.666	0.774	—	0.470	0.627	0.174	0.287	—
VA17052069	Left	0.837	1.482	1.158	—	1.057	0.552	1.020	0.840	—	0.825	0.626	1.714	1.109	—	1.247	0.393	0.419	0.251	—	0.404
Average		1.060	1.547	0.798	0.715	0.537	0.728	1.310	0.838	0.821	0.801	0.869	1.573	0.987	1.088	1.047	0.554	0.697	0.255	0.340	0.310
SD		0.472	0.676	0.605	0.446	0.295	0.447	0.759	0.759	0.627	0.414	0.410	0.567	0.502	0.693	0.473	0.208	0.254	0.083	0.267	0.113

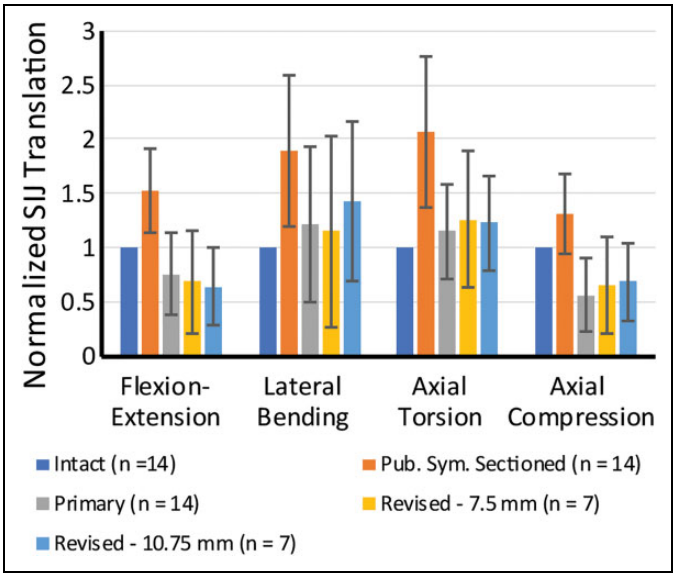

Figure 3. Normalized sacroiliac joint translation results.

the SIJ spans multiple anatomic planes, making motion difficult to quantify and leading to considerable intra- and inter-specimen variability with regard to analysis. This was addressed by presenting motion data in a coordinate reference frame based on anatomical landmarks of the SIJ. Future work could include investigation of the stability provided by revision procedures associated with conventional screw-based systems, larger sample sizes, clinical studies in which SIJ motion is examined before and after implantation, and further investigation into the role axial compression plays in SIJ instability and pain. Last, as a cadaveric experiment, it is not possible to simulate all clinical revision scenarios (eg, implant loosening, infection); as such, application of these results to all potential revision situations should be made with caution.

Conclusion

The results of this cadaveric biomechanics study indicate that triangular titanium implants placed across the SIJ are able to provide biomechanical stability in both the primary and revised conditions. Both rotational and translational motions were significantly reduced in the primary and revised conditions when compared to a destabilized condition. Furthermore, motions measured in response to FE and AC loading were reduced to levels significantly lower than the intact condition. No significant difference was found between the stability provided by primary and revision implants, indicating that in the absence of bony ingrowth and/or infection, revision procedures provide similar stability as the primary implant system. In conclusion, triangular titanium implants are effective in stabilizing the SIJ as necessary in sacroiliac fusion procedures.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Derek Lindsey and Scott Yerby are employees and stockholders of SI-BONE, Inc.

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