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Comparison of a Novel Posterior Integrated Transfixation Sacroiliac Joint Fusion Approach to the Posterolateral and Lateral Approaches: A Cadaveric Biomechanical and Computational Analysis of the Fixation, Invasiveness, and Fusion Area

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Purpose: To concurrently assess and compare the fixation efficacy, invasiveness, and fusion potential of a posterior integrated transfixation cage system to the posterolateral threaded implant and lateral triangular rod systems, in a cadaveric model.

Methods and Materials: Twelve (12) cadaveric sacroiliac joint specimens were utilized and tested within the single-leg stance multidirectional pure moment bending model. Each specimen was tested in the intact, destabilized, treated (using posterior, posterolateral, and lateral systems), and post-fatigue conditions by applying 0 to ± 7.5 Nm of moment in flexion-extension, axial rotation, and lateral bending while measuring the angular range of motion between the sacrum and ilium. Computational models were reconstructed from Computed Tomography (CT) scans and manufacturer surgical technique guides. The models were utilized to quantify the volume of bone removed during implantation and the surface area available for fusion.

Results: The posterior integrated transfixation cage system and the lateral triangular rods produced equivalent motion reduction in all motion planes ($P > 0.583$). The posterolateral cylindrical threaded implant produced less motion reductions than the posterior and lateral implants in flexion-extension (6% ± 3% vs 37% ± 10% and 33% ± 11%, respectively, $P < 0.05$). The posterior system removed 22%-60% less bone volume from the sacrum and ilium ($P<0.10$), introduced 200%-270% more implant surface to the joint space ($P<0.01$) and decorticated 75%-375% more joint surface area ($P<0.01$).

Conclusion: The posterior integrated transfixation single-implant cage system is superior to the posterolateral cylindrical threaded single-implant system. Its performance in osteopenic bone is equivalent to the lateral triangular rod system in healthy bone; however, the posterior integrated transfixation cage system requires a single implant, while the lateral triangular rod system requires three. The posterior implant removes the least bone volume and has the most surface area for fusion, providing a significantly better opportunity for robust sacroiliac joint arthrodesis.

Keywords: arthrodesis, integrated fixation, bone volume, fatigue, durability, sacroiliac joint fusion

Introduction

The sacroiliac joints (SIJs) constitute two out of five joints within the spine-pelvic-hip complex and thus are responsible for facilitating load transfer to the torso and lower extremities.[1–3] Dysfunction of these joints may arise due to adjacent

Received: 26 June 2024
Accepted: 17 October 2024
Published: 25 October 2024

segment disease, joint degeneration, infection, or instability.[4–6] While in some cases, especially in men, the joint may auto-fuse without pain, in other cases, primarily in women, the joint becomes a significant pain source, impacting the quality of life, and leading to disability, especially with daily activities such as gait, sitting, rise-to stand, lifting, etc.[7,8] The SIJ has been reported to be the cause of 15–30% of low back pain; however, this has yet to be confirmed in a sufficiently powered rigorous study.[9–12]

Various conservative methods exist to treat SIJ-induced pain, such as physical therapy, bracing, and injections.[2,5] When these methods fail to provide consistent relief, arthrodesis techniques may be utilized to fixate and fuse the joint, by ensuring adequate joint surface decortication, physiological apposition of bony surfaces, and rigid stabilization until fusion.[13,14] These techniques vary significantly but can be distinguished based on the incision site and implantation trajectory, which include the anterior, lateral, posterolateral, posterior, and posteromedial approaches.[13,15–17] The anterior intrapelvic approach involves the retraction of the contents of the pelvic bowl to access the joint and the utilization of a plate spanning the anterior surface of the sacrum and ilium.[18–20] This technique has been typically utilized in trauma wherein the pelvis needs to be rebuilt or for the revision of failed fusion attempts.[21–23] The lateral approach[24–26] has also been described extensively, involving the retraction or dilation of the gluteal muscles to access the lateral iliac surface of the joint, initially utilizing only bone grafts, and subsequently utilizing two to three hollow screws[27] or rods[28] aimed medially into the sacrum in the direction of the S1 and S2 sacral body roots. The posterolateral approach, otherwise known as the posterior-oblique approach, was subsequently developed as a modification of the lateral approach, to avoid traversing the gluteal muscles, by following an oblique trajectory from the posterolateral extent of the posterior superior iliac spine (PSIS) to the anteromedial extent of the sacral ala, using one or two hollow screws or threaded implants.[29–32] The posterior approach, while first described in the same period as the introduction of the lateral approach, has undergone several iterations, due in part to the intra-articular, extra-articular, and trans-articular options it allows.[33–37] The intra- and extra-articular variations involve the dilation of the posterior sacroiliac ligaments for the superior approach or the gluteus maximus for the inferior approach, and the placement of one to three bone graft(s) with or without metallic cage(s) in the cartilaginous or ligamentous portion to either distract or interpose the joint.[16,38] The extra-articular variation may also involve plating over the joint similar to the anterior approach,[13,23,39,40] and the trans-articular variation may involve the use of integrated screws or anchors deployed within the metallic cages or may utilize a bridging anchor recessed within both the sacrum and ilium.[41,42] The Posteromedial approach otherwise referred to as the S2AI approach, utilizes a rigid or cannulated screw following an oblique trajectory from the posteromedial extent of the sacrum, to the anterolateral extent of the ilium.[43–45] This approach allows for one or two implants to be placed; however, it is typically utilized as an adjunct to fusion constructs involving the lower back, and as a prophylactic measure for preventing adjacent segment disease or fusion construct failure.[46–48]

There is yet to be a comparative analysis between the three approaches designed specifically for treating SIJ pain (lateral, posterolateral, and posterior) within an equivalent clinical or cadaveric biomechanical cohort. Sayed et al performed a comparative biomechanical literature analysis between the posterior intra-articular approach and the lateral approach in an intact pelvis model.[16] Their findings showed equivalent unilateral and bilateral stabilization of flexion-extension motions (45–48% vs 34–50%) and the posterior approach demonstrated superior stabilization of axial rotation (33–42% vs 6–22%) and lateral bending (47–53% vs 8–33%) motions; however, the number of samples differed significantly between both groups (n= 6-posterior vs 16-lateral).[16] Whang et al, published a systematic review and meta-analysis comparing complications in the posterolateral (0%, 0%), posterior (0.2%, 0%), and lateral approaches (0.43%, 0.15%) as pertained to symptomatic implant malpositioning and wound infection rates.[49] They reported no statistically significant differences in pain relief obtained between the various approaches. Again, similar to Sayed et al, the number of patients differed by an order of magnitude between both groups (n= 2126-lateral, 228-posterolateral, and 497-posterior).[16] In contrast to Whang et al, Claus et al in a retrospective clinical trial of 156 patients, reported that, except for procedure duration, there was no difference in safety and efficacy between the lateral and posterolateral approaches using the triangular rod and threaded implant at 6-month and 1-year follow-up.[49,50] These limitations, in addition to various interpretations of the term "SIJ transfixation" - initially defined as internal fixation with the involvement of SIJ penetration, contribute to the lack of consensus concerning the biomechanical efficacy, safety profile, and fusion potential of sacroiliac joint arthrodesis techniques.[51]

Thus, in this study, we aimed to concurrently assess and compare the fixation efficacy, invasiveness, and fusion potential of a novel posterior integrated transfixation single-implant cage (V1™, Nevro, California, USA) to a posterolateral trans-articular single-implant threaded implant (RIALTO™, Medtronic, Minnesota, USA) within the same cadaveric sample, and to the biomechanical literature[52] on the lateral trans-articular triple-implant triangular rod (iFuse™, SI-Bone, California, USA), within identical and destabilized cadaveric samples, and the same biomechanical multidirectional bending flexibility model (Figure 1). We compared the motion reduction in each plane after destabilization. We compared the volume of bone displaced during implantation. We compared the total SIJ surface area decorticated and available for the fusion mass.

Materials and Methods

Specimen Preparation

Twelve (12) fresh-frozen sacroiliac joints (SIJ) specimens from six eviscerated L4-Pelvis-Proximal Femur were procured from an accredited tissue bank (United Tissue Network) affiliated with the American Association of Tissue Banks (AATB). The selection process adhered to specific criteria, including an age range of 26 to 70 years at the time of death, an equal male-to-female ratio, and a Body Mass Index (BMI) below 40. Computed tomography (CT) scans were analyzed to screen for osteoporosis, spine surgery, spinopelvic pathology, fragility fractures, and bridging/fusion.[53] The selected specimen's average age, height, weight, BMI, and L4 bone density (T-score) were 50 ± 16 y/o, 67 ± 3 inches, 161 ± 53 lb, 25 ± 8, and −1.1 ± 1.1, respectively.

The specimens, extending from the L4 vertebra to the proximal femur, underwent dissection to remove soft tissue while preserving key structures such as the pubic symphysis and various ligaments (including the iliolumbar, anterior SIJ, articular capsule of the hip joint, anterior longitudinal, supraspinous, long posterior SIJ, short posterior SIJ, interosseous, sacrotuberous, and sacrospinous). Each hip was oriented to align the specimen in the anatomic standing position using the mediolateral, anteroposterior, and axial views.[54,55] The proximal femur was fixed relative to the ilium using wood screws; additionally, the L4 was fixed relative to L5 in the same manner. While maintaining the specimen alignment, the specimens were potted at the femur and L4 vertebra using Smoothcast 300 (Smooth-On, Inc., Macungie, Pennsylvania). Lastly, the SIJ was marked by placing set screws at the left lateral, right lateral, and anteromedial extents adjacent to the S1 endplates, to define the anatomic coordinate system using the transverse plane.

Test Order and Instrumentation

The specimens underwent testing in the sequence of intact, destabilized, treated, and post-fatigue conditions. The destabilized condition involved the transection of the pubic symphysis, as well as the interosseous and posterior ligaments, inevitably isolating the left and right SIJs. For the treated condition, the SIJ was randomly instrumented with either a posterolateral threaded implant (RIALTO™, Medtronic, Minnesota, USA) or a posterior cage (V1™, Nevro, California, USA) with deployable anchors using the manufacturer's instrumentation and following surgical

Figure 1 Photos Of Each Implant In Order Of Posterior, Posterolateral, And Lateral From Left To Right.

technique as shown in Figure 2. The representative fluoroscopic images showing the placement of the three triangular implants in the biomechanical studies[51] are shown in Figure 3. The procedure for posterior instrumentation involved using the flat Bailey joint finder and anteroposterior + 20° Oblique fluoroscopic views to locate the joint. Subsequently, the dilator and working cannula were introduced. Following this, a 3-stage decortication up to the tip of the cannula was performed, first using a drill guide and bit, then a box chisel, and finally a trial rasp. Upon decortication, the implant was inserted up to the cannula tip, and in its final position, the integrated transfixing anchors were deployed.

Biomechanical Testing

Motion markers were attached to the sacrum (lateral to the sacral endplates) and ilium (rigidly along the iliac crests, affixed to the PSIS) bodies. The set screws placed on the pelvis were used to digitize the points used to define the SIJ. The relative rotational motions of the ilium and sacrum were tracked using the Optotrak system (3D Investigator, Northern Digital Inc., Waterloo, Ontario, Canada). The motion data were recorded for 5 seconds at 100 hz during each load step.

Multidirectional bending tests were conducted on each side of the pelvis.[15,52,56–60] The pure moment load was applied in flexion, extension, contra-axial rotation, ipsi-axial rotation, contra-lateral bending, and ipsi-lateral bending using the MTS 858 mini Bionix II and moment ring cable system.[61] The specimen was rigidly mounted on an unconstrained sliding table on the test frame in a single-leg stance, as shown in Figure 4. The potted femur of the side to be tested was clamped on the sliding table while the other side was free to move. Each static test had three pre-conditioning cycles, from 0 Nm to 7.5 Nm at 0.25 deg/s, and then the final loading, where data was recorded. The final loading cycle was from 0 Nm to 7.5 Nm at 1.5 Nm increments with a 45-second holding time. After testing the implanted group, each side of each specimen was fatigue-loaded between 0 Nm and 5.625 Nm in the extension direction for 18,500 cycles at 1 hz. After fatigue cycling, post-fatigue testing was conducted using the static test method described above. The on-axis range of motions (ROM) was calculated as the angular rotations of the sacral body relative to the ilium in motion planes between extents of loading.[60,62,63]

Computational Analysis

3D models of the intact and instrumented male and female specimens, as well as the implant systems, were reconstructed and assembled from CT scans using image segmentation software (Mimics, Materialise, Leuven, Belgium) and CAD softwares (SpaceClaim, ANSYS Inc. Canonsburg, Pennsylvania; Onshape, PTC Inc., Boston, Massachusetts;

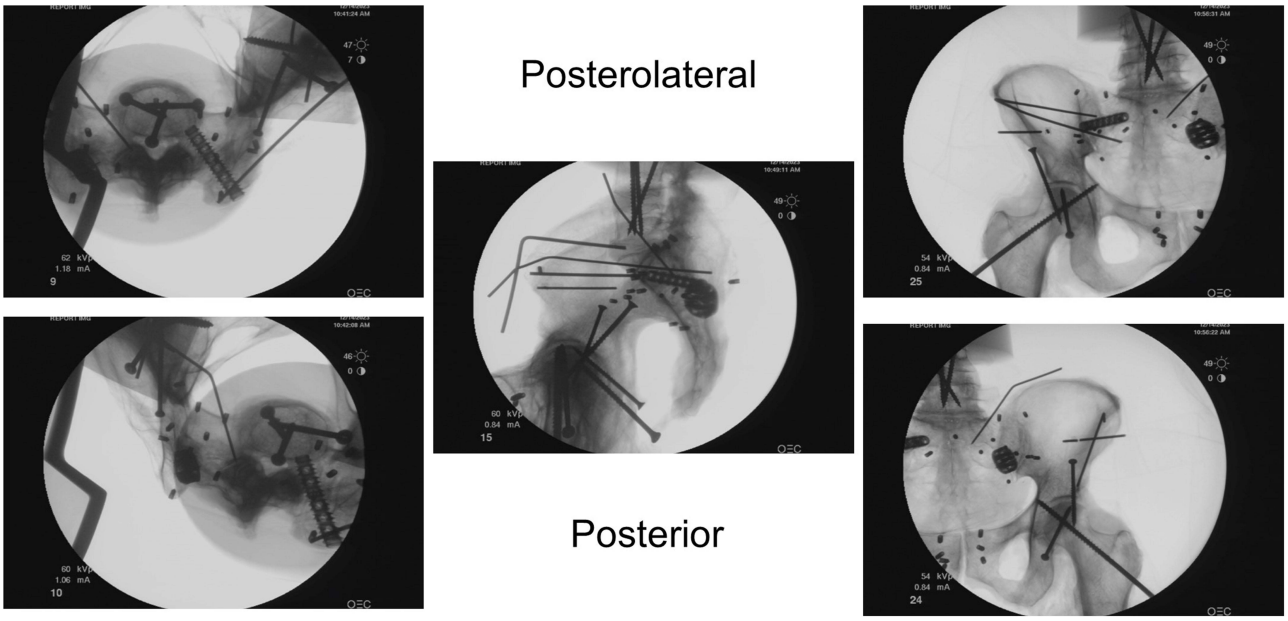


Figure 2 Fluoroscopic Images Of Posterolateral (Top) And Posterior Fixation (Bottom) In Order Of Transverse, Sagittal, And Coronal Views From Left To Right.

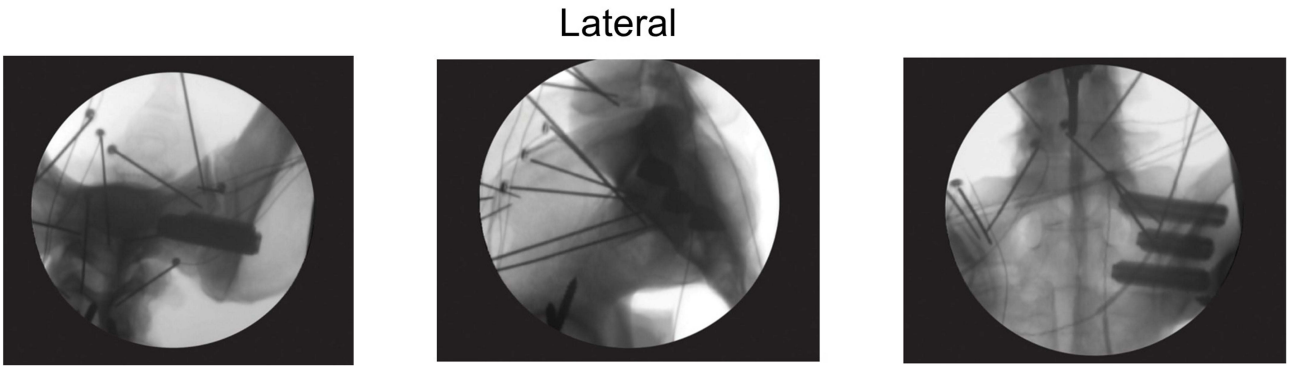


Figure 3 Fluoroscopic Images Of Lateral Fixation In Order Of Transverse, Sagittal, And Coronal Views From Left To Right.[52] (International Journal Of Nanomedicine 2014 7131–137. Originally Published By, Adapted, And Used With Permission From Dove Medical Press Ltd).

Figure 4 Test Setup Of The Left Side In An Intact Pelvis Under Left (Ipsi) Lateral Bending Moment Load.

SolidWorks, Dassault Systèmes SE, Vélizy-Villacoublay, France) as shown in Figure 5. The volume of bone removed and the surface area available for fusion were calculated and measured using the 3D model assembly in SolidWorks. The total bone volume removed was calculated as the total volume of bone displaced within the sacrum and ilium bones upon implant placement. The total surface area available for fusion was defined as the sum of the total implant surface area exposed within the SIJ after implantation, and the total SIJ surface area remaining after decortication. The total implant surface area exposed was defined as both the internal and outer implant surface area between the joint surfaces available to support the bone on growth and fusion through the implant. The total SIJ surface area was defined as the remaining surface of the sacral and iliac endplates, not in contact with the implant.

Statistical Analysis

The reduction or increase of motion between testing conditions was calculated by taking the average of the ROM relative change per specimen instead of just finding the relative change of the testing condition's ROM average. Median absolute

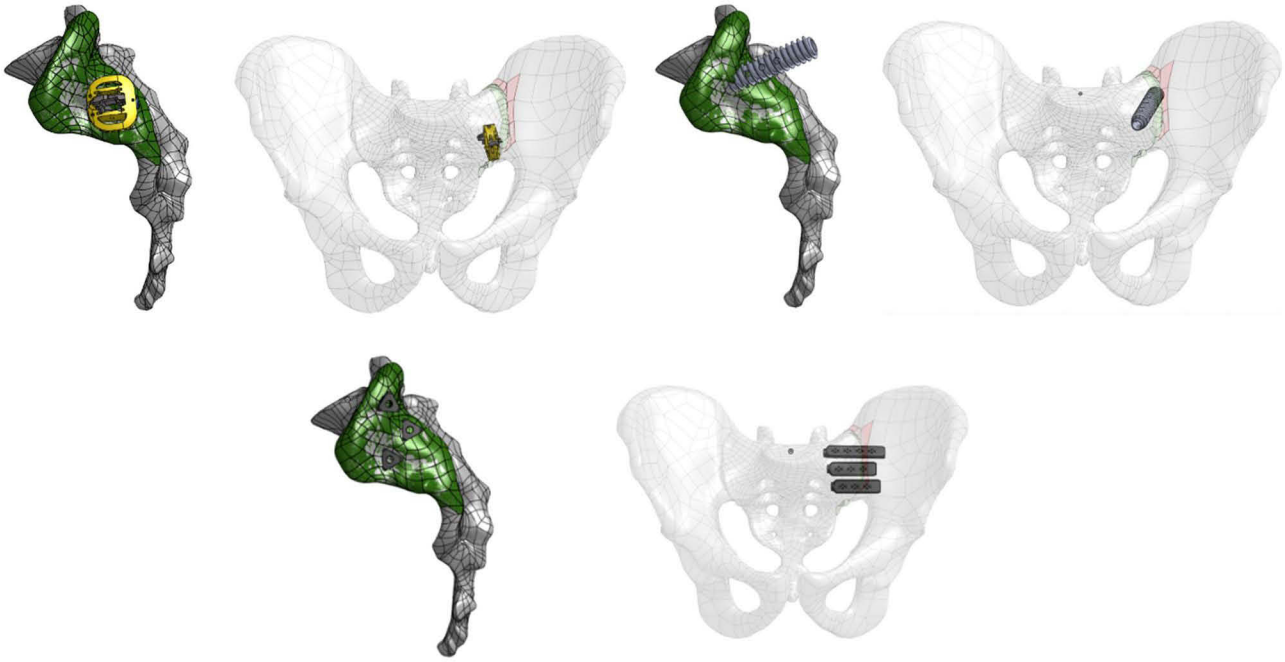


Figure 5 Digital Model Of Assembled Pelvis And Implant Systems. Top Left: Posterior Cage; Top Right: Posterolateral Threaded Implant; Bottom: Lateral Rod.

deviation (MAD) outlier analyses were performed on the effect sizes with the outlier threshold of ±3 x MAD. Statistical comparisons were performed using two-tailed paired t-tests at $p \leq 0.05$, to find significant changes in outcome measures, while unpaired t-tests were utilized for comparisons between study groups of the lateral rods literature dataset, the posterior cage, and the posterolateral threaded implant.[52]

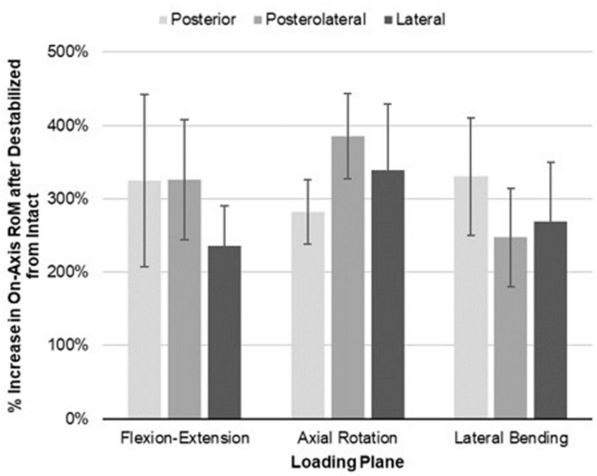
Results

Table 1 shows each device group's baseline demographic and on-axis range of motion for intact SIJs. The age and baseline/intact range of motions between each group were equivalent. However, the bone density was significantly lower and wider in range in the posterior and posterolateral groups varying between normal and osteopenic bone density, in comparison to the samples of the lateral group which had healthy bone density ($P = 0.007$). Additionally, the difference between the flexion-extension ROM of the lateral vs the posterior and posterolateral groups trended toward significance. Figure 6 displays the percentage increase in ROM for the destabilized condition relative to the intact condition. The amount of destabilization between the posterior cage, posterolateral threaded implant, and lateral triangular rod groups in all planar motions was not significantly different ($P > 0.278$).

Table 1 Baseline Demographic and Range of Motion.[52]

Study Group	Statistics	Male: Female	Age	Bone Density (T-Score)	Flexion-Extension (deg)	Axial Rotation (deg)	Lateral Bending (deg)
Posterior Cage	Average p-value vs Posterolateral	3:3	50.0 ± 16.2 1.000	−1.1 ± 1.1 1.000	1.1 ± 0.2 0.624	1.5 ± 0.2 0.658	0.6 ± 0.1 0.249
Posterolateral Implant	Average p-value vs Lateral	3:3	50.0 ± 16.2 0.246	−1.1 ± 1.1 0.007*	1.1 ± 0.1 0.062	1.5 ± 0.3 0.651	0.7 ± 0.2 0.280
Lateral Triangular Rod	Average p-value vs Posterior	3:4	59.0 ± 6.3 0.246	0.8 ± 0.2 0.007*	2.3 ± 0.5 0.057	1.7 ± 0.3 0.703	1.1 ± 0.3 0.183

Notes: Asterisks (*) represent statistically significant differences between groups.

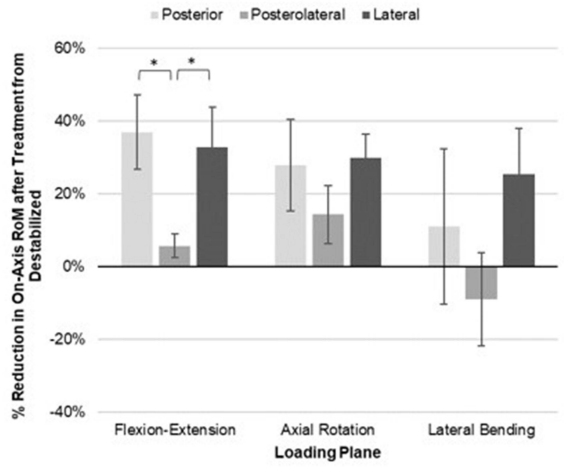


Destabilized vs. Intact (Increase)	Posterior	Posterolateral	Lateral
Flexion/ Extension Loading (%)	324 ± 117	326 ± 82	236 ± 55
Left/Right Axial Loading (%)	282 ± 44	386 ± 58	339 ± 90
Left/Right Lateral Loading (%)	331 ± 80	247 ± 67	269 ± 81

Figure 6 Percentage Range Of Motion Increase After Destabilization From Intact. All Data Are Represented As Mean ± Std Error.

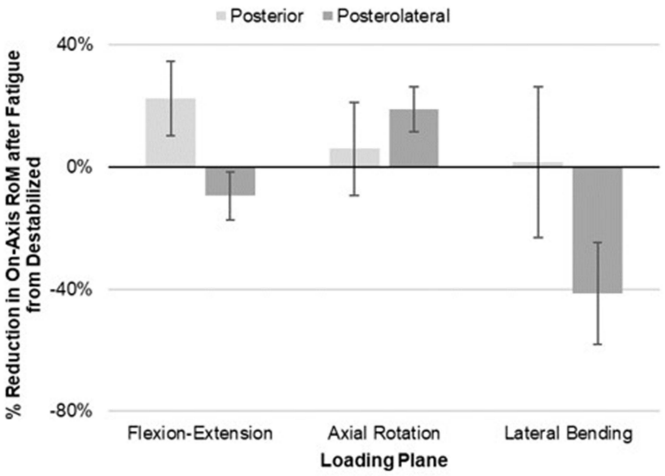
Figure 7 displays the average percentage reduction in on-axis ROM for the instrumented/treated condition relative to the destabilized condition. The posterior cage device significantly reduced the ROM in flexion-extension (P =0.010) and axial rotation (P =0.036). Conversely, the Posterolateral threaded implant did not significantly reduce the ROM (P >0.260) in any loading plane. The lateral triangular rod reported statistically significant reductions in flexion-extension (P =0.045), and a trend towards significance in axial rotation (P =0.058) and lateral bending (P =0.083).[52] The reductions in the flexion-extension ROM of both the posterior cage (P =0.027) and the lateral triangular rod (P =0.049) groups were statistically larger than that of the posterolateral threaded implant and equivalent in both axial rotation (P >0.158), and lateral bending (P >0.085). The motion reduction of the posterior cage was equivalent to the lateral triangular rod, in all planes (P >0.583).

Figure 8 displays the percentage reduction in ROM after fatigue loading relative to the pre-fatigue destabilized condition. The post-fatigue ROM of the posterior cage increased significantly from the treated condition, in axial rotation (P =0.017) but not in other planes (P >0.056). While the post-fatigue ROM of the Posterolateral cage increased significantly from the treated condition, in lateral bending (P =0.028) but not in other planes (P >0.099). The posterior cage's reduction in ROM was equivalent to that of the posterolateral threaded implant in all directions (P >0.058).



Treated vs Destabilized (Reduction)	Posterior	Posterolateral	Lateral
Flexion/ Extension Loading (%)	37 ± 10*	6 ± 3	33 ± 11*
Left/Right Axial Loading (%)	28 ± 13*	14 ± 8	30 ± 6
Left/Right Lateral Loading (%)	11 ± 21	-9 ± 13	25 ± 13

Figure 7 Percentage Range Of Motion Reduction After Treatment From Destabilization. All Data Are Represented As Mean ± Std Error. Asterisks (*) Denote Statistically Significant Differences Between Groups And Test Conditions.



Post-Fatigue vs Destabilized (Reduction)	Posterior	Posterolateral
Flexion/ Extension Loading (%)	23 ± 12	-9 ± 8
Left/Right Axial Loading (%)	6 ± 15	19 ± 7
Left/Right Lateral Loading (%)	2 ± 25	-41 ± 17

Figure 8 Percentage Range Of Motion Reduction After Fatigue From Destabilization. All Data Are Represented As Mean ± Std Error.

Fatigue conditions of the lateral triangular rod varied between specimens. Thus, only comparisons between posterior and posterolateral systems are presented.

Volume of Bone Removed

Figure 9 displays the total volume of bone removed in the sacrum and iliac bones upon installation of each implant system.[42] The posterior cage implant albeit not significant, removed less bone volume in comparison to the posterolateral threaded implant (687 mm^3, P =0.097) and lateral triangular rod (3418 mm^3).

Surface Area Available for Fusion

Figure 10 displays the total surface area available for fusion upon installation of each implant system.[42] The implant surface area on the posterior cage was larger in comparison to the posterolateral threaded implant (P =0.003) and the lateral triangular rod. The joint surface area decorticated was larger for the posterior cage, and thus, the remaining joint surface available for fusion on the posterior cage was smaller in comparison to the posterolateral threaded implant

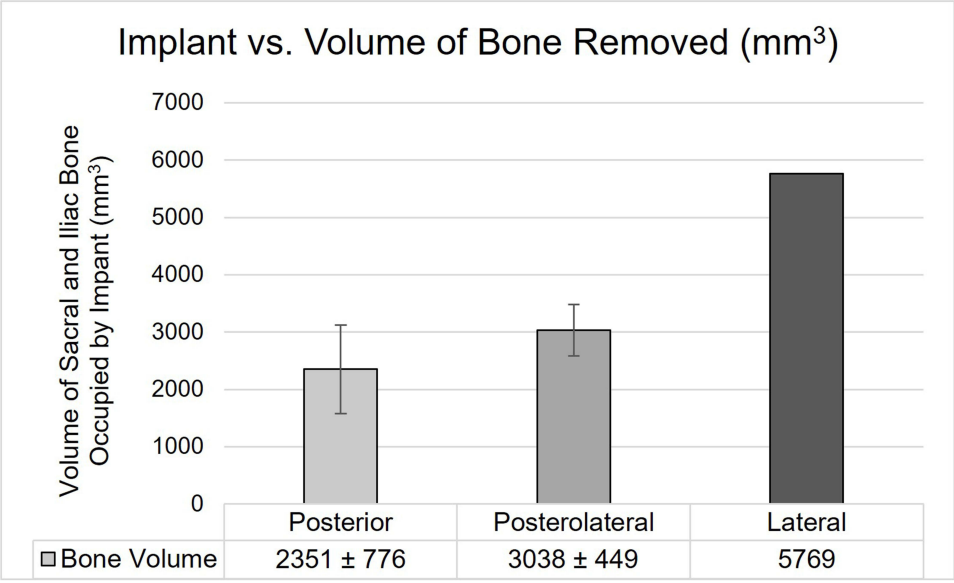
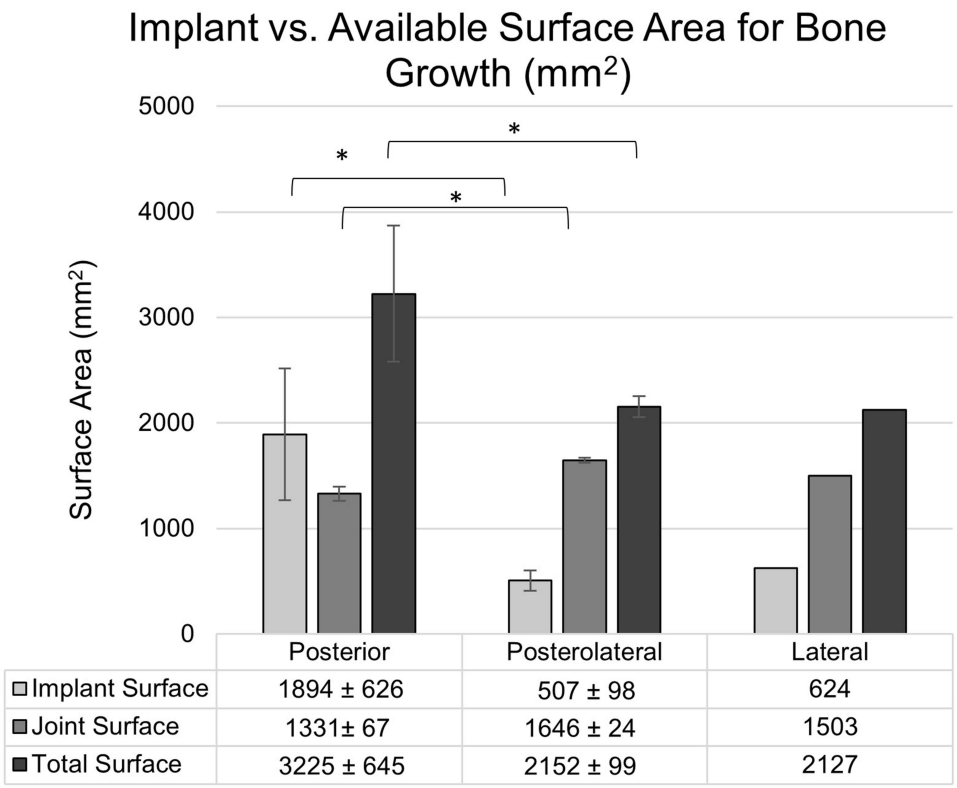


Figure 9 Volume Of Bone Removed By Each Implant. All Data Are Represented As Mean ± Std Dev.



	Posterior	Posterolateral	Lateral
Implant Surface	1894 ± 626	507 ± 98	624
Joint Surface	1331± 67	1646 ± 24	1503
Total Surface	3225 ± 645	2152 ± 99	2127

Figure 10 Surface Area For Bone Growth. All Data Are Represented As Mean ± Std Dev. Asterisks (*) Denote Statistically Significant Differences Between Groups.

(P <0.001), and the lateral triangular rod. The posterior cage produced the most total surface area for fusion compared to the posterolateral threaded implant (P =0.009) and lateral triangular rod.

Discussion

This study aimed to provide an in-situ side-by-side analysis of the posterior integrated transfixation cage and the posterolateral cylindrical threaded implant while comparing to the literature on the lateral triangular rod for sacroiliac joint arthrodesis, within the same biomechanical single-leg stance, pure moment loading protocol.[52] We compared the baseline demographic characteristics, intact range of motion, and destabilized ROM of our sample to that of the published literature on the lateral triangular rod and found no significant differences between our samples except in bone density for which our samples were of lower bone density (T-Score = −1.1 ± 1.1 vs 0.8 ± 0.2). Thus, based on the reductions in ROM for samples treated with the posterior cage, our results indicate that the performance of the posterior cage in specimens with normal and osteopenic bone qualities was equivalent to the published performance of the lateral triangular rod in specimens with healthy bone quality. Furthermore, flexion-extension and axial rotation were the most mobile loading planes, for which motion reductions (relative to the destabilized condition) of the posterior cage were statistically significant, however, only flexion-extension motion reductions in the lateral triangular rod group were statistically significant. The results from our treated group also indicate that the performance of the posterior cage is superior in flexion-extension, but equivalent in axial rotation and lateral bending, to the performance of the posterolateral threaded implant placed in the contralateral side of the same specimens. In our experiment using a single-leg stance, we observed statistically insignificant motion reductions of 6% ± 3% in flexion-extension which agrees with prior evaluations reporting mean reductions of −14% to 9% motion reductions.[64,65]

We analyzed and compared the post-fatigue performance between the implanted specimens, in the most robust cadaveric fatigue model reported for sacroiliac joint. Our fatigue parameters included 18,500 cycles vs 5000 cycles reported in the biomechanical literature of the lateral triangular rod. 18,500 cycles represent significant joint bending for

1 year (53 weeks), while 5000 cycles represent 3 months (14 weeks) of significant bending without bone apposition.[66] Three months is a fraction of the clinically reported duration of 1 year required for bone apposition across 99–100% of patients instrumented with the lateral triangular rod.[67,68] Our study also utilized a consistent fatigue load of 0–5.625Nm of extension across all specimens following the American Society for Testing and Materials (ASTM) guidelines.[69] In contrast, the reported biomechanical literature of the lateral triangular rods utilized inconsistent loading parameters between specimens varying between 0Nm and 3.75Nm, 5.625Nm, or 7.5Nm of flexion-extension. Our post-fatigue results indicate that while the ROM reduction provided by the posterior cage diminished from 37% ± 10% (ROM reduction before fatigue loading) to 23% ± 12% (ROM reduction after fatigue loading) in flexion-extension, it still provided reduced ROM after fatigue loading. In contrast, the SIJs treated with the posterolateral threaded implant became more unstable from 6% ± 3% to −9% ± 8% in flexion-extension. Additionally, the fixation of the posterior cage in flexion-extension still trended towards being significantly superior to the posterolateral threaded implant (23% ± 12% vs −9% ± 8%; $P = 0.058$), and equivalent to its predominant plane of fixation ie axial rotation (23% ± 12% vs 19% ± 7%; $P = 0.808$) These results indicate sustained performance in normal and osteopenic patients, even without bony apposition or fusion for up to one-year post-implantation in the posterior cage group. Approximately 70% of patients requiring SIJ arthrodesis are middle-aged women[29,69–71] who are much more likely to be osteopenic,[72–74] thus, in contrast to the lateral triangular rod study, our results are more applicable to the target demographic for this treatment. Given the reported effect of bone density on fixation performance and durability, it is expected that the performance of the posterior cage and posterolateral threaded implant in specimens with good bone quality (as in the lateral group) would increase significantly.[75–79]

We compared the invasiveness of each approach by analyzing the volume of bone displaced by the implantation of each system. Our results indicated that both the posterior cage and posterolateral threaded implant removed an equivalent amount of bone during implantation. However, the lateral triangular rod has been reported to remove twice as much bone from the sacroiliac joint compared to the posterior cage (5769 mm^3 vs 2351 mm^3). This may be due in part to most of the posterior cage's volume being within the joint space in contrast to the posterolateral and lateral systems, which are mostly embedded in the sacrum and iliac bones. Another factor to be considered is the number of implants utilized. As per manufacturer recommendations, the lateral rod system requires three triangular rods, while the posterior cage and posterolateral threaded implants require only one implant. The number of implants necessary to achieve sufficient stability may be indicative of the destructiveness of each technique, as excessive bone removal may diminish the integrity of the sacroiliac joint, as well as the ability to revise a failed arthrodesis, due to the lack of sufficient bone stock. This also has implications for the motion reduction performance, as the posterior cage system using a single implant generated equivalent stability to the lateral triangular rod system which utilized three implants. The utilization of two posterolateral threaded implants may likely result in improved stability, as reported by Dube-Cyr et al (9% ± 15% vs 19% ± 15%), with no additional benefit introduced by a third posterolateral implant.[65] However, this is still approximately 50% less than the motion reduction generated by a single posterior cage (19% vs 37%), while effectively doubling the risks associated with the invasiveness of the approach with more bone volume removed.[65]

We compared the available fusion area provided by the implant and retained within the joint. Our results indicate that the portion of the posterior cage within the joint space provides a larger surface area for bone on-growth and through-growth, in comparison to both the posterolateral threaded implant and the lateral triangular rods. While all implant systems utilize fenestrations, or hollow architectures, for bone through-growth, this area was larger in the posterior cage in comparison to the other systems. Additionally, both the posterior cage and the lateral triangular rods, employ 3D printed surface texture, to increase the surface roughness, and encourage bone on-growth, while the posterolateral system, employs thread features to increase its available surface area. However, this surface contact area was larger in the posterior cage. Our results also indicate that the posterior cage involves decortication of a significantly larger surface area of the joint, in comparison to both the posterolateral and lateral systems (399 mm^2 vs 84 mm^2 and 227 mm^2, respectively), which increases the joint surface area prepared to facilitate bony fixation.

FDA Cleared SIJ fusion devices that internally fixate the joint are assigned the "OUR" product code without regard to anatomical positioning or surgical approach but rather as to whether robust in-vitro and in-situ biomechanical testing such as outlined by the American Society for Testing and Materials (ASTM, F3574-22 Standard Test Methods for

Sacroiliac Joint Fusion Devices) demonstrates immediate and adequate mechanical fixation of the joint to allow for long term fusion that is substantially equivalent in safety and efficacy to one or more previously cleared predicate devices.[80] These test methods are intended to provide a basis for the mechanical comparison among past, present, and future nonbiologic SIJ fusion device assemblies. These test methods allow for comparison of SIJ fusion device assemblies intended to be implanted with a trajectory in line with the joint space (in-line implant) or for comparison of SIJ fusion devices intended for implantation across the joint space (transverse implant). These test methods are intended enable the user to compare SIJ fusion device assemblies mechanically and do not purport to provide performance standards for SIJ fusion device assemblies. Selection of the specific testing methods will vary depending on device design. For example, testing of "cantilever bending strength" for screw type devices is not relevant to fixating cage devices which do not have this failure mode. This is anticipated in the ASTM standards (section A2.1.2): Static and dynamic tests will evaluate the SIJ fusion device assembly.[80] The user of these test methods must decide which series of tests are applicable to the to the SIJ fusion device assembly in question. The user of these test methods may choose to use all, or a section of the tests described in these test methods for testing a particular SIJ fusion device assembly. The analysis presented in this publication compares across design types consistent with FDA guidelines.

While other studies have utilized literature comparisons only, our study is the first to have performed side-by-side testing of the posterior and posterolateral approaches to sacroiliac joint arthrodesis in the same cadaveric model as the lateral approach.[16,52] The single-leg stance multidirectional bending model was utilized as it has been implemented in multiple studies to reliably and consistently assess the performance of sacroiliac fusion devices.[15,52,56] Our sample sizes were equivalent between each study group (Posterior-6, Posterolateral-6, Lateral-7), as well as our specimen demographic, with each group including at least three male and three female specimens, and specimens aged 59.0 ± 6.3 years. Albeit lower than those utilized in the lateral approach, the bone density of our samples was more representative of the clinical population,[72–74] and the results are expected to be the same or better in specimens with good bone quality. To provide reliable results, we ensured that the motion markers were placed rigidly and as close as possible to the sacroiliac joint to eliminate the influence of bone deformation reported by Hammer et al and Pool et al.[81,82]

Our study has many limitations. Pure moments were applied on a single plane with minimal compressive loads; however, this model cannot simulate the complex multiplanar motion of in-vivo loading. Osteoporotic specimens were not utilized in any of the study groups, as such the results presented may only apply to patients with osteopenic or normal bone quality. Additionally, although our fatigue parameters were based on published clinical evidence as previously described[66] and our computational models were matched to high-resolution CT scans (at 0.65 mm slice thicknesses), these evaluations cannot simulate the biological changes (eg bone apposition). Thus, these results describe the worst-case performance. All implantations were performed using consistent techniques as shown in Figures 2 and 5, in contrast to Sayed et al which utilized multiple trajectories, and compared to lateral approach literature in an intact joint model.[16] As such, the results of this study are only applicable to the devices used in this study, when placement matching Figures 2, 3, and 5 are utilized, and do not account for variability in the surgical technique. These strengths and limitations outlined should be considered when applying the findings to a clinical context.

Conclusion

Our study results demonstrate that the posterior integrated transfixation cage system using a single implant in normal-to-osteopenic bone is equivalent in performance to the lateral triangular rod system using three implants in good bone, and superior to the posterolateral cylindrical threaded single-implant system. We also conclude that while the posterior and posterolateral cage systems are less invasive and destructive to the sacroiliac joint than the lateral system, the posterior cage system decorticates more of the joint surface, and in addition to its surface area, provides a significantly better opportunity for robust arthrodesis of the sacroiliac joint.

Ethics Approval and Informed Consent

This research is exempt from IRB review because it does not meet the definition of the human subject as defined in 45 CFR 46.102. Specifically, the investigator is not conducting the research to obtain information or biospecimens from

living individuals. The following location was used in the research: Medical Device Development, 2390 Mission Street, San Francisco, California 94110.

Funding

This study was funded by Vyrsa Technologies. Test implant and instrumentation were provided by Vyrsa Technologies. ORR, JHT, SM and JML are employees of Medical Device Development and their institution received support to conduct this research. AE: Medical advisory board Nevro, Medtronic, Vertos and consultant for Painteq. BAH: Consultant for Nevro and Novo Source Orthopedics. DPB: Consultant for Nevro, Genesys, CornerLoc, Spinal Simplicity, PainTEQ, SI Bone, and Wenzel Spine and has received research funding from Nevro. DLC is an employee of Nevro Corporation.

Disclosure

ORR, JHT, SM and JML are employees of Medical Device Development and their institution received supports from Nevro and Vrysa to conduct this research. AE is part of the medical advisory board of Nevro, Medtronic, Vertos and consultant for Painteq. BAH is a consultant for Nevro and Novo Source Orthopedics. DPB is a consultant for Nevro, Genesys, CornerLoc, Spinal Simplicity, PainTEQ, SI Bone, and Wenzel Spine and has received research funding from Nevro. He also reports non-financial supports from Medtronic, Merit Medical, Johnson & Johnson, IZI, Techlamed, Peterson Enterprises, Medical Metrics, Avanos, Boston Scientific, Simplify Medical, Stryker, Lenoss Medical, Spine BioPharma, Piramal, ReGelTec, Nanofuse, Spinal Simplicity, Pain Theory, Spark Biomedical, Bronx Medical, Smart Soft, Tissue Tech, RayShield, Stayble, Thermaquil, Vivex, Stratus Medical, Genesys, Abbott, Eliquence, SetBone Medical, Amber Implants, Cerapedics, Neurovasis, Varian Medical Systems, Companion Spine, DiscGenics, Discure, SpinaFX, PainTEQ, SI Bone, Orthoson, Choice Spine, Saluda Medical, Aurora Spine, Arts Surgical, AIS Healthcare, Wenzel Spine; grants from Medtronic, Medical Metrics, Avanos, Relievant, Boston Scientific, Stryker, Sollis Pharmaceuticals, Simplify Medical, Lenoss Medical, Spine BioPharma, Eliem Therapeutics, Smart Soft, Tissue Tech, Vivex, Stratus Medical, Restorative Therapies, Kolon TissueGene, Companion Spine, DiscGenics, SI Bone, Choice Spine. DLC is an employee of Nevro Corporation. The authors report no other conflicts of interest in this work.

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