Original Article

A comparative biomechanical study of a non-threaded triangular titanium implant versus a fully threaded screw: assessing pullout strength of two sacroiliac joint fixation implant designs

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Background: Considering that implant backout is a recognized mode of failure, evaluating the pullout strength is critical for assessing anchoring efficacy. The Sacrix® fully threaded screw (TS) was designed specifically for Less Exposure Spine Surgery (LESS) to reduce incision size, surgical time, and blood loss, using two implants for sacroiliac joint (SIJ) fixation. This study compares the Sacrix® design with the SI-Bone iFuse non-threaded triangular titanium implant (TTI) design, which is widely regarded as the industry standard, and represents the first comparative biomechanical pullout strength study of these implant designs currently used in SIJ fusions.

Methods: We conducted mechanical static axial pullout tests on three 7.0 mm × 45 mm iFuse non-threaded TTIs and six 8.0 mm × 40 mm Sacrix® fully TS embedded in polyurethane foam blocks. An INSTRON 8874 Bi-Axial Tabletop Servohydraulic Dynamic Testing System was used to perform the tests by applying a 2.5 kN axial load.

Results: The effective surface areas of the iFuse non-threaded TTI and Sacrix® fully threaded TS were comparable, measuring 294.15 and 289.81 mm^2, respectively. The TS exhibited a significantly higher mean static axial pullout strength of 814.90 N [standard deviation (SD), ±99.428 N] compared to the TTI 200.14 N (SD, ±14.428 N). Statistical analyses, including Welch's *t*-test and Mann-Whitney *U* test, revealed significant differences in pullout strength between the two implants ($P<0.05$). Variance analysis confirmed the differences in pullout strength variances between the implants ($P=0.040$), suggesting that the variability in pullout strength was distinct for each implant.

Conclusions: The Sacrix® fully threaded TS demonstrated a threefold increase in pullout strength compared with the SI-Bone iFuse non-threaded TTI, suggesting that future SIJ fusion designs should favor threaded over non-threaded implants for improved anchoring capability.

Keywords: Pullout strength; Sacrix® screw; SI-Bone; sacroiliac joint fixation (SIJ fixation); fully threaded screw (fully TS)

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Introduction

The sacroiliac joint (SIJ), a synovial joint connecting the ilium and sacrum bones, plays a crucial role in weight transfer within the lower appendicular skeleton owing to its oblique and coronal orientation (1-7). Abnormal joint mechanics due to age, repetitive loading, and trauma predispose the SIJ to pathologies, such as sacroiliitis and sacroiliac dysfunction. Randomized clinical trials have demonstrated that SIJ fusion outperforms nonoperative treatments in terms of pain improvement and enhancement of quality of life in patients diagnosed with SIJ dysfunction (8). Compared to traditional open SIJ fusion surgeries, minimally invasive surgery (MIS) is considered disruptive due to fewer complications and wider adoption among older, more comorbid patients (9).

To address the need for less invasive procedure, Less Exposure Spine Surgery (LESS) was developed, aiming to minimize incision size, reduce blood loss, shorten surgical duration, and accelerate recovery time (10). Sacrix (Sacrix LLC, Burlington, MA, USA) was specifically designed for the LESS technique, offering a fully threaded screw (TS) that allows for effective SIJ fixation with minimal surgical exposure.

There are two major categories of implant designs for SIJ fusions in the market: non-threaded triangular titanium implant (TTI) design (iFuse, SI-Bone Inc., Santa Clara, CA, USA) (8,11) and fully TS design, such as Sacrix Generation I (12,13). No biomechanical study has compared the anchoring strengths of these two categories of SIJ fusion devices. Pullout strength is the average force that an implant can withstand before breaking or pulling out. Costăchescu *et al.* (14) outlined factors that can affect pullout strength, including the diameter of the implant, length of the implant, depth of the penetrated portion of the implant, thread geometry, quality of the bone into which the implant is being inserted, and use of augmentation, such as polymethylmethacrylate (PMMA), which has been shown to increase the pullout strength of pedicle screws by 241% (15) compared with that of standard screws. The straight-line pullout strength of a screw from the bone is an important factor in determining interfragmentary or plate fixation (16). Fixation surgery for osteoporotic patients presents a significant challenge because of the fragile nature of the bone, its susceptibility to micromotions, and the excess force at the bone-metal interface, which increases the risk of hardware pullout (17). Therefore, failure along the axis of the SIJ fixation implant is a potential clinical problem.

A biomechanical study by Freeman *et al.* (18) showed that two TTIs spaced 13 mm apart exhibited no resistance to the pullout forces (4 N). Based on this finding, the authors recommended using three TTIs, and the pullout strength was improved when the TTIs were angled as low as 10°. In a study of SIJ fixation using a screw (19), finite element analysis showed that pullout strength increased with larger diameter and longer screws. In the first clinical study to describe the successful revision of failed TTI by threaded fixation, the mode of failure was due to loosening and migration along its axis (12). Although axial failure is rare in clinical scenarios, pullout strength testing is an

Highlight box

Key findings

- The Sacrix® fully threaded screw (TS) experienced a significant increase in pullout strength compared to the iFuse non-threaded triangular titanium implants (TTIs) due to its threaded design.
- During static axial pullout tests, the Sacrix implant exhibited significantly higher mean pullout strength (814.90 N) compared to the iFuse implant (200.14 N).
- Failures in both Sacrix® and iFuse designs occurred at the foam block interface, emphasizing the importance of implant design and contact surface area in ensuring secure fixation.

What is known and what is new?

- It is known that sacroiliac joint (SIJ) fusion implants vary in effectiveness due to different design approaches and anchoring capabilities, and while traditional TTI implants have been commonly used, they can fail to provide sufficient mechanical retention.
- We found the Sacrix® fully threaded TS demonstrated superior pullout strength compared to the non-threaded TTI (iFuse).

What is the implication, and what should change now?

- The Sacrix® fully TS design should be considered for SIJ fusion surgeries due to its enhanced anchoring strength, potentially reducing the incidence of implant loosening and failure.
- The superior performance of Sacrix® TS could inspire further research into the design and development of SIJ fusion devices, ensuring greater stability and reliability in clinical outcomes.

effective and reproducible means of comparing an implant's anchorage within bone (20,21). A clinical study by Spain *et al.* (8), sponsored by SI-Bone, compared fully threaded stainless steel screws to SI-Bone iFuse non-threaded TTI using the direct lateral approach and found a higher failure rate for the TSs SIJ fixation (30.8%) compared to the TTI SIJ fusion (5.7%). These findings raised questions about the effectiveness of threaded implants in SIJ fusion, particularly when using different surgical techniques or varying bone quantities are considered. To address these concerns, our study eliminated these clinical variables by comparing the biomechanical pullout strength of the implants under standardized conditions using the same material.

This is the first biomechanical study to compare the pullout strength of the Sacrix® fully threaded TS with the SI-Bone iFuse non-threaded TTI. We focused on the intrinsic design features of the devices and did not simulate SIJ bone quality, which varies across patients. The data gathered from this study could expand our knowledge of future implant designs and clinical expectations.

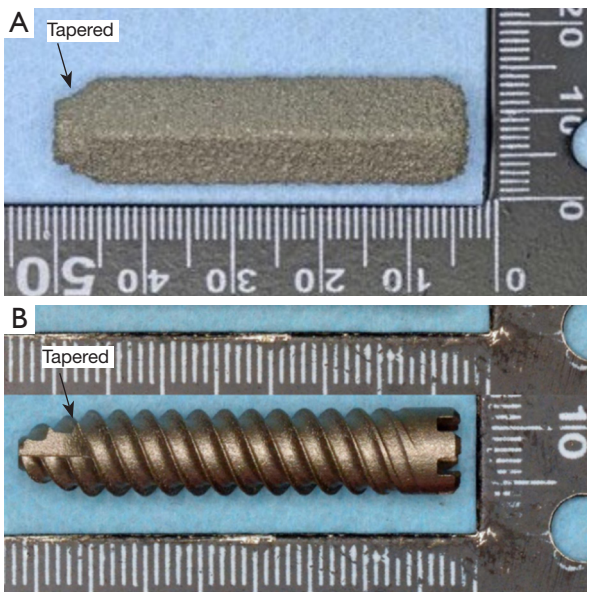

Figure 1 iFuse non-threaded TTI (A) and fully threaded Sacrix® titanium screw (B). TTI, triangular titanium implant.

Methods

Mechanical static axial pullout testing was performed on two titanium implant designs: three [3] iFuse non-threaded TTIs with dimensions of 7.0 mm × 45 mm and six [6] Sacrix® fully threaded TS measuring 8.0 mm × 40 mm (*Figure 1*). The selected implants had the smallest available sizes at the time of testing, with both designs featuring tapered ends. Testing was outsourced to an independent testing facility (Empirical Technologies, Colorado Springs, CO, USA) to ensure unbiased results.

Static axial pullout testing was conducted in ambient air using an INSTRON 8874 Biaxial Tabletop Servohydraulic Dynamic Testing System (INSTRON, Norwood, MA, USA) with 2.5 kN axial and polyurethane foam test blocks consisting of grade 15 (15 lbs. density according to ASTM F1839) (Sawbones, Vashon, WA, USA). Polyurethane foam, which is recognized as a synthetic bone substitute material (22,23), eliminated bone density variables for more reproducible results. Pilot holes were created in the test block measuring 3.07 mm for the TS and 3.18 mm for the TTI. The foam test blocks were held rigid using a custom aluminum fixture, while a custom stainless-steel fixture was applied to the implant in line with the actuator. The implants were driven into the foam block at a 90° angle to a standardized depth of 20 mm. Static axial pullout tests were conducted with displacement control at a rate of 5 mm/min, and the load and displacement data were collected. The ramp waveform was conducted until the disengagement of the implant from the test block indicating failure mode. The specific test parameters are listed in *Table 1*. The polyurethane foam test blocks and axial pullout test setups for iFuse and Sacrix® are depicted in *Figures 2,3*, respectively.

The effective surface areas were calculated from the non-tapered surfaces which were 14.15 mm in length for

Table 1 Pullout strength test parameters for iFuse and Sacrix implants

Implant	Insertion depth (mm)	Tapered length (mm)	Non-tapered length (mm)	Effective surface area (mm^2)	Exposed length (mm)	Grip span (mm)	Test block thickness (mm)	Pilot hole size (mm)
iFuse	20.03	5.88	14.15	294.15	26.2	35	50.8	3.18
Sacrix	20.00	8.47	11.53	289.81	20.0	45	38.0	3.07

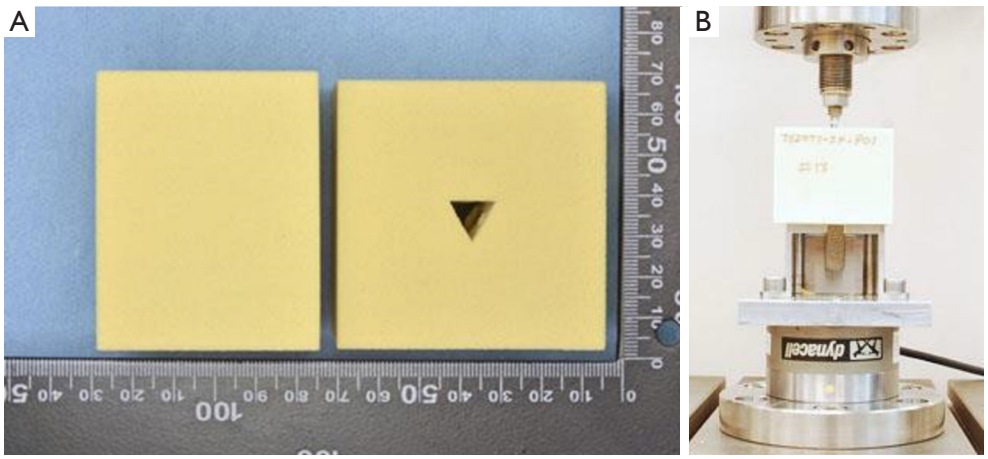

Figure 2 Test blocks (A) and pullout test setup (B) for iFuse non-threaded TTI. TTI, triangular titanium implant.

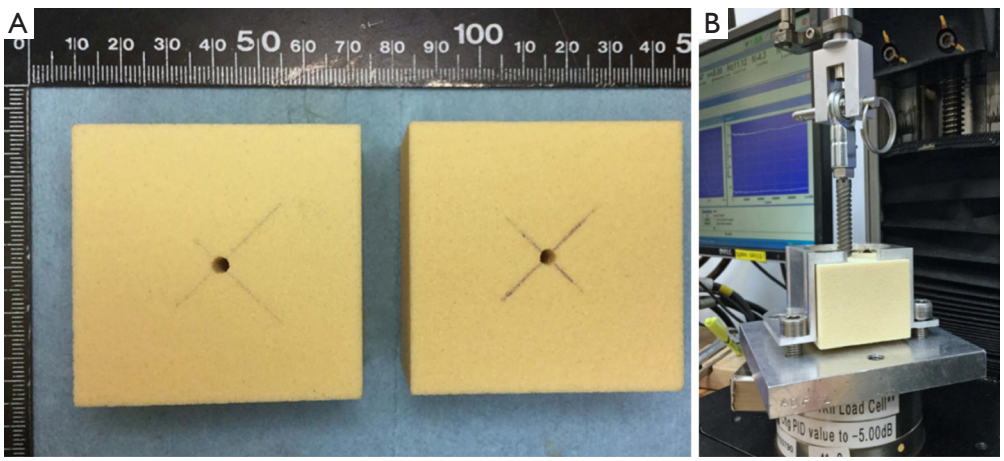

Figure 3 Test blocks (A) and pullout test setup (B) for fully threaded Sacrix® titanium screw.

iFuse and 11.53 mm for Sacrix® (*Figure 1*). The effective surface area for iFuse was computed based on a triangular prism model with a 7.0 mm side equilateral triangle base and a non-tapered depth of 14.15 mm, yielding a 294.15 mm^2 (*Table 1*). The Sacrix's effective surface area was determined using the cylinder's radius of 4.0 mm and a non-tapered length of 11.53 mm, resulting in a surface area of 289.81 mm^2 (*Table 1*), exclusive of the ends.

Statistical analysis

Statistical analyses were executed utilizing Visual Studio (VS) Code (version 1.87.1), the anaconda3 (Python 3.12.0) kernel within VS Code, and a comprehensive suite of Python coding and statistical packages including: 'pandas', 'scipy.stats', 'matplotlib', and 'seaborn'.

Two samples *t*-test was applied to determine any statistically significant difference in mean scores between the independent groups. The Mann-Whitney *U* test for pairwise comparisons was applied to compare non-normal distribution of data. The level of significance was set at $P<0.05$ for all assessed variables.

Results

The effective surface areas of both implants embedded in the test blocks were comparable, with 294.15 mm^2 for the iFuse implant and 289.81 mm^2 for the Sacrix® implant. *Table 2* presents the non-threaded iFuse implant, which demonstrated a mean static axial pullout strength of

Table 2 Results of static axial pullout for non-threaded iFuse implant group

Implant	Axial pullout strength (N)	Displacement at pullout strength (mm)
iFuse-1	184.10	0.84
iFuse-2	212.06	0.93
iFuse-3	204.27	1.27
Mean	200.14	1.02
SD	14.428	0.227

SD, standard deviation.

Table 3 Results of static axial pullout for fully threaded SacroFuse implant group

Implant	Axial pullout strength (N)	Displacement at pullout strength (mm)
SacroFuse-1	967.72	1.19
SacroFuse-2	856.72	1.10
SacroFuse-3	778.48	1.07
SacroFuse-4	860.93	1.02
SacroFuse-5	709.60	0.91
SacroFuse-6	715.95	0.93
Mean	814.90	1.04
SD	99.428	0.107

SD, standard deviation.

200.14 N [standard deviation (SD), ±14.428] and a mean displacement of 1.02 mm (SD, ±0.227). In comparison, *Table 3* represents the Sacrix® fully threaded TS exhibited a mean static axial pullout strength of 814.90 N (SD, ±99.428) and a mean displacement of 1.04 mm (SD, ±0.107) at axial pullout strength. The standard deviation relative to the mean pullout strength was 12.20% for the fully threaded TS and 7.21% for the non-threaded TTI.

Two-sample *t*-tests, including Welch's *t*-test (P<0.001), were used to compare the means, assuming normality. Additionally, the Mann-Whitney *U* test was used as a non-parametric alternative (P=0.02). The results indicated a significant difference in pullout strength between the iFuse and Sacrix® implants, with Sacrix® fully threaded TS demonstrating superior performance.

Variance analysis through Levene's test revealed a significant difference (P=0.040), suggesting that the variability in pullout strength differs between the two implants. The Sacrix implant exhibited significantly higher pullout strength than the iFuse implant, suggesting superior mechanical retention.

Discussion

This comparative biomechanical study assessed the pullout strength of two titanium SIJ fixation implants, a non-threaded TTI, and a fully threaded implant. In our analysis, we observed a notable increase in pullout strength from non-threaded TTI iFuse (200.14 N) to fully threaded TS Sacrix (814.90 N). Varghese *et al.* (24) observed mean foam model pullout forces of 300 and 1,100 N for osteoporotic and normal vertebral bone density and investigated the relationship between bone density, insertion depth, and insertion angle, and concluded that bone density was the most important driver of pullout strength.

There are concerns pertaining to the correlation between sacral bone density and surgical outcomes of SIJ fusion procedures due to implant loosening as the mode of failure, particularly on the sacral side (25). Loosening or failure of an implant is often attributed to compromised bone quality in the sacral region. The association between sacral bone density and the success rate of lumbosacral fusion has been investigated, with findings indicating that up to 45% of sacro-pelvic fixations fail, often as a result of S1 screw haloing or pullout (26).

While the diameter and length of an implant contribute to its pullout strength, proper threading, and material are the most significant factors affecting the pullout strength of an implant in osteoporotic patients (17). The insertion angle is another important factor in implant fixation in patients with reduced bone density. While screws inserted in healthy bone near the angle of axial pullout performed well, in osteoporotic bone, the best pullout strength was achieved when the insertion angle was approximately 10° to the axial force to increase the concentration of bone around the screw (17). Biomechanical stability testing of non-threaded TTI implants showed improved pullout strength when the 2-implant linear pattern was converted to a 3-implant triangular pattern, with the most significant force occurring when the implants were angled to 10° (18). In a clinical setting, three iFuse non-threaded TTI (16) showed good clinical results. In contrast, Sacrix® fully threaded TS reported successful fusion and good outcomes, with only two implants angled at 10–20° (12,13,27,28). Thus, Sacrix® may offer a potential advantage by decreasing the number

of implants required and shortening the procedure time. SI-Bone has subsequently developed and released a threaded lag screw (29), and thus, these data will provide an increased rationale for their decision and for other companies who are developing TSs for SIJ fusion. Insurance companies could benefit from these data when considering coverage for TTI and threaded implants (30). Our findings suggest the potential advantages of fully threaded implants in bone purchase to enhance fixation and reduce the risk of loosening over time for threaded implants compared to non-threaded implants.

Spain *et al.* (8) observed a higher failure rate in when fully threaded stainless steel screws were compared to the non-threaded SI-Bone iFuse TTI in a direct lateral approach. Our biomechanical study, conducted under standardized conditions with uniform polyurethane foam blocks, focused on comparing the intrinsic design properties. The Sacrix fully threaded TS demonstrated significantly higher pullout strength than the non-threaded TTI, suggesting that its efficacy may be more evident when isolated from clinical variability.

While the fully threaded TS showed a stronger pullout strength, it also exhibited greater variability in its performance, as indicated by a higher standard deviation (12.20% of the mean pullout strength) compared to the non-threaded TTI (7.21%). This suggests that although the TS provides superior anchoring strength, its consistency may be less predictable. The greater variability observed in the TS could be partially attributed to non-linear interactions or deformation within the polyurethane foam blocks at higher pullout forces, a phenomenon that might not occur to the same extent in human bone.

This study has several limitations. First, the use of polyurethane foam blocks does not replicate the biomechanics and heterogeneity of human bones, which can vary significantly across patients. This decision was made to provide a controlled comparison of the intrinsic mechanical properties of non-threaded TTIs and fully threaded TSs. However, this means that the study did not simulate the SIJ bone quality or the normal forces across the SIJ and thus did not present a complete failure model. This limitation implies that our results, which are significant for understanding pullout strength, may not fully capture the complex biomechanical environment of the SIJ. Additionally, the study did not evaluate vertical shear forces, which are expected in a clinical setting and could impact the performance of the implants. Despite revealing a significant difference in pullout strength between the iFuse and Sacrix® implants, the small sample size limits the generalizability of these findings and may affect the robustness of the statistical conclusions. Further studies with larger and more varied sample sizes are essential to validate the advantages suggested by our biomechanical findings and to understand the clinical significance of the substantial increase in pullout strength observed in fully threaded implants.

In this study, we examined the differences between threaded and non-threaded implant designs using two distinct approaches currently used for SIJ fusion implants. Our findings demonstrated that the use of a threaded design conferred significantly greater pullout strength, highlighting its potential advantages in clinical settings. This increase in pullout strength suggests that the fully threaded TS offers superior anchoring stability, particularly in compromised bones. Given that implant backout is a recognized failure mode, enhanced performance of the threaded design could be crucial for improving patient outcomes. The implications of these results are substantial for the future design and clinical practice of SIJ implants, guiding surgeons towards selecting implants that are more likely to withstand implant loosening or failure and ultimately reduce the need for revision surgeries. Clinically, the stronger pullout strength observed also indicates that a specially designed, robust removal instrument would be needed to extract the fully TS during revision procedures if it is well fixated. Further studies are needed to evaluate the use of a threaded implant in a direct lateral approach based on the findings of the Spain and Holt study, which observed higher failure rates in that context.

Conclusions

A strong anchor is crucial for the success of SIJ implants and to prevent the risk of loosening along the implant axis. This study demonstrated that fully TSs possess a threefold increase in pullout strength compared with non-threaded TTIs, indicating a potential for improved anchoring capability in SIJ fusion procedures. Clinically, this greater pullout strength implies that in cases where revision surgery is necessary, a strong and secure removal instrument will be essential to extract the fully TS if well fixated. Considering these findings, the Sacrix® fully TS design should be considered in future implant development and clinical applications over the SI-Bone iFuse TTI non-threaded implant design, with further research needed to validate

these results and expand their applicability to diverse patient populations.

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Footnote

Data Sharing Statement: Available at https://jss.amegroups.com/article/view/10.21037/jss-24-99/dss

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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