Mechanical Testing of Pull-out Performance of a Threaded Screw versus the SI-Bone Implant for Sacroiliac Joint Fixation

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Abstract

Background

Sacroiliac joint (SIJ) pathology is increasingly being diagnosed and treated surgically. Prevalence has been reported of 22% among low back pain suffers and 43% after lumbar instrumented fusion. Surgical treatment options became popular using the SI-Bone direct lateral approach with metal plugs driven across the joint. Our study aims to evaluate and demonstrate the mechanical pullout strength of the SI-Bone sacroiliac fixation device compared to a threaded screw implant. Pull-out strength is a crucial factor for screw fixation so it is our hypothesis that a threaded screw will have greater pullout strength compared to a nonthreaded device.

Methods

Mechanical static axial pullout testing was performed on three (3) SI-Bone iFuse Implants and six (6) Sacrix SacroFuse Gen II threaded Implant. Pullout testing was conducted using an INSTRON 8874 Bi-Axial Tabletop Servohydraulic Dynamic Testing System (INSTRON, Norwood, MA) with a 2kN axial.

Findings

The pullout strength for SacroFuse Gen II Implant (SF) was greater than the SI-Bone iFuse implant by 614.76N with significance of p=0.021. The threaded implant showed an 400% increase in axial performance compared to its triangular counterpart. Ux (I-Fuse) < Uy (Sacrofuse) we find that $p = 8.78 \text{ X } 10^{-6}$, $p < 0.05$ therefore we reject the null hypothesis and conclude that the pull-out strength of I-Fuse is significantly less than the pull-out strength of sacrofuse.

Interpretation

Our study demonstrated a 400% increase in pull-out strength for threaded screw compared to the SI-Bone triangular wedge. This demonstrates the efficacy of threaded implant which will improve clinical outcomes.

Keywords

Sacroiliac Joint, SIJ Fusion, Pullout strength, Mechanical Testing, Sacrofuse, iFuse

Introduction

The sacroiliac joint (SIJ) is a synovial joint between the bones of the ilium and sacrum. The orientation of the joint is oblique and coronal. Its main function as a paired symmetrical joint is to allow for transfer of weight between and lower appendicular skeleton. (Butler et al., 2011; Durkin et al., 2006; Forst et al., 2006; Gnat et al., 2015; Papathanasopoulos et al., 2010; Rosse et al., 1997) The articular surfaces are formed by the irregularly shaped ilium and sacrum. (Butler et al., 2011; Rosse et al., 1997) Divided in thirds the upper one-third is a syndesmosis, middle third resembles a symphysis and lower third a synovium. Unlike other synovial joints, the articular facets of the sacral auricular surface are lined by fibrocartilage (Last, 1994).

Abnormal joint mechanics due to age, repetitive loading and trauma are mechanism which predispose to joint pathology such as sacroiliitis, sacroiliac dysfunction. In the case of trauma serval studies have shown the treatment of SIJ injuries is the application of compression across the joint. To decrease the motion and repetitive loading fixation techniques can be performed. It is however difficult to compare different fixation techniques in clinical applications due to variations in bone quality, bone anatomy, fracture patterns, and fixation location.
Our study aims to demonstrate the mechanical properties of a triangular implant vs. a threaded implant, comprised of varying thread types.

Methods

Mechanical static axial pullout testing was performed on three (3) iFuse Implants (SI-Bone Inc. 471 El Camino Real, Suite 101 Santa Clara, CA, USA) Figure 1 and six (6) Sacrofuse Gen II Implants (Sacrix LLC, Malden, MA, USA) Figure 2. Table 1 lists the implants.

Testing followed.

- LESspine Protocol EC100017 Rev D, "ASTM F543 and F2193 Testing of the Sacrofuse Sacroiliac Joint Fusion System."
- ASTM Standard F543-13, "Standard Specification and Test Methods for Metallic Medical Bone Screws."
- ASTM Standard F2193-02, "Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System."

The static axial pullout testing was conducted in ambient air using an INSTRON 8874 Bi-Axial Tabletop Servohydraulic Dynamic Testing System (INSTRON, Norwood, MA, USA) with a 2kN axial. The test blocks and assembled axial pullout specimens are shown in Figure 3 and 4. The test block consisted of Grade 15 (15lb density per ASTM F1839) polyurethane foam (Sawbones, Vashon, WA, USA). The specimen was held rigid by an aluminum fixture and an ETC provided Ø4.7mm flat point loader was applied to the inferior side of the specimen, to simulate a pullout test, which were in line with the actuator. The static axial pullout tests were conducted in displacement control at a rate of 5mm/min, collecting load and displacement data, using MTS's Basic TestWare. The ramp waveform was conducted until disengagement of the screw from the test block. The specimens were manually driven into a foam test block approximately 20mm. Table 2 contains the insertion depth, exposed length, grip span, test block thickness, pilot hole size, and if the specimen was broached for each specimen.

Results

Table 3 represents the axial pullout strength and the displacement at axial pullout strength for the IF implants and table 4 represents the axial pullout strength and the displacement at axial pullout strength for the SF implants. The pullout strength for SacroFuse Gen II Implant (SF) was greater than the SI-Bone iFuse implant by 614.76N. ANOVA testing for two sample of variances demonstrated statistical significance with P =0.021. The threaded implant showed an 400% increase in axial performance compared to its triangular counterpart. Testing the hypothesis of Ux (I-Fuse) < Uy (Sacrofuse) we find that $P = 8.78 \text{ X } 10^{-6}$, $P < 0.05$ therefore we reject the null

hypothesis and conclude that the pull-out strength of I-Fuse is significantly less than the pull-out strength of sacrofuse.

Discussion

Straight line pull-out strength of a screw from bone is an important factor in determining interfragmentary or plate fixation.(Daum et al., 1991) It is an important mechanical factor for a screw. Visible screw movement was defined as failure by Zindrick et al. (Zindrick et al., 1986)The determinant of strength is a function of the volume of bone purchase. (Daum et al., 1991) A complication of posterior pelvic ring fractures is sacroiliac screw loosening. This is related to vertical shear forces (Kim et al., 2013) and osteoporosis(Müller and Füchtmeier, 2013; Ohtori et al., 2013). The incidence of sacroiliac screw loosening is reported to be as high as 17.3%, with a screw failure rate of 11.8%. (Kim et al., 2013) Prevention of screw loosening is critical as the associated complications include pseudoarthrosis, breakage, and decreased biomechanical strength.

Our study compared sacroiliac joint screw implant to industry leader SI-Bone's triangular trans-articular wedge. We were able to demonstrate that the pull-out strength of the Sacrofuse implants was 400% (four times) stronger with a mean of 814.90 N compared to the iFuse implant of 200.14 N. Based on the determinant of strength this result suggests that bone purchase would be less for a trans-articular wedge.

The current study notes the following limitations. The use of foam molding compared to cadaveric bone. This was chosen to eliminate the variable factor of bone density from cadaveric bone. The strength of this study was that testing was performed independent of the manufacturing company.

Conclusion

The authors have demonstrated the increase strength of a threaded sacroiliac screw compared to a triangular unthreaded wedge. We believe the increased pullout strength will improve compression forces and decrease the risk of loosening two features for fusion across the sacroiliac joint. Clinical studies are needed to demonstrate correlation with these mechanical results.

Figure Citations

Figure 1: SI-Bone iFuse Implant Specimen

Figure 2: SacroFuse Gen II Implant Specimen

Figure 3: Broached Test Blocks (A) and Pull-out test setup (B) for SI-Bone iFuse Implant

Figure 4: Test Blocks with pilot holes (A) and Pull-out test setup (B) for Sacrix SacroFuse Gen II Implant

Figure 5. Example of Static Pullout Failure: Specimen IF

Figure 6. Example of Static Pullout Failure: Specimen SF

References

Butler, J.S., Burke, J.P., Dolan, R.T., Fitzpatrick, P., O'Byrne, J.M., McCormack, D., Synnott, K., Poynton, A.R., 2011. Risk analysis of blood transfusion requirements in emergency and elective spinal surgery. European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society 20, 753-758.

Daum, W.J., Patterson, R.M., Cartwright, T.J., Viegas, S.F., 1991. Comparison of cortical and cancellous screw pull-out strengths about the posterior column and sacroiliac joint. Journal of orthopaedic trauma 5, 34-37.

Durkin, A., Sagi, H.C., Durham, R., Flint, L., 2006. Contemporary management of pelvic fractures. The American journal of surgery 192, 211-223.

Forst, S.L., Wheeler, M.T., Fortin, J.D., Vilensky, J.A., 2006. The sacroiliac joint: anatomy, physiology and clinical significance. Pain physician 9, 61-67.

Gnat, R., Spoor, K., Pool-Goudzwaard, A., 2015. The influence of simulated transversus abdominis muscle force on sacroiliac joint flexibility during asymmetric moment application to the pelvis. Clinical Biomechanics 30, 827-831.

Kim, J.W., Oh, C.W., Oh, J.K., Lee, H.J., Min, W.K., Kyung, H.S., Yoon, S.H., Mun, J.U., 2013. Percutaneous iliosacral screwing in pelvic ring injury using three-dimensional fluoroscopy. J Orthop Sci 18, 87-92.

Last, R.J., & McMinn, R. M. H., 1994. Last's anatomy, regional and applied. . Churchill Livingstone., Edinburgh.

Müller, F., Füchtmeier, B., 2013. [Percutaneous cement-augmented screw fixation of bilateral osteoporotic sacral fracture]. Der Unfallchirurg 116, 950-954.

Ohtori, S., Inoue, G., Orita, S., Yamauchi, K., Eguchi, Y., Ochiai, N., Kishida, S., Kuniyoshi, K., Aoki, Y., Nakamura, J., Ishikawa, T., Miyagi, M., Kamoda, H., Suzuki, M., Kubota, G., Sakuma, Y., Oikawa, Y., Inage, K., Sainoh, T., Takaso, M., Toyone, T., Takahashi, K., 2013. Comparison of teriparatide and bisphosphonate treatment to reduce pedicle screw loosening after lumbar spinal fusion surgery in postmenopausal women with osteoporosis from a bone quality perspective. Spine 38, E487-492.

Papathanasopoulos, A., Tzioupis, C., Giannoudis, V., Roberts, C., Giannoudis, P., 2010. Biomechanical aspects of pelvic ring reconstruction techniques: Evidence today. Injury 41, 1220-1227.

Rosse, C., Gaddum-Rosse, P., Hollinshead, W.H., 1997. Hollinshead's textbook of anatomy.

Zindrick, M.R., Wiltse, L.L., Widell, E.H., Thomas, J.C., Holland, W.R., Field, B., Spencer, C.W., 1986. A biomechanical study of intrapeduncular screw fixation in the lumbosacral spine. Clinical orthopaedics and related research 203, 99-112.

Figure 1

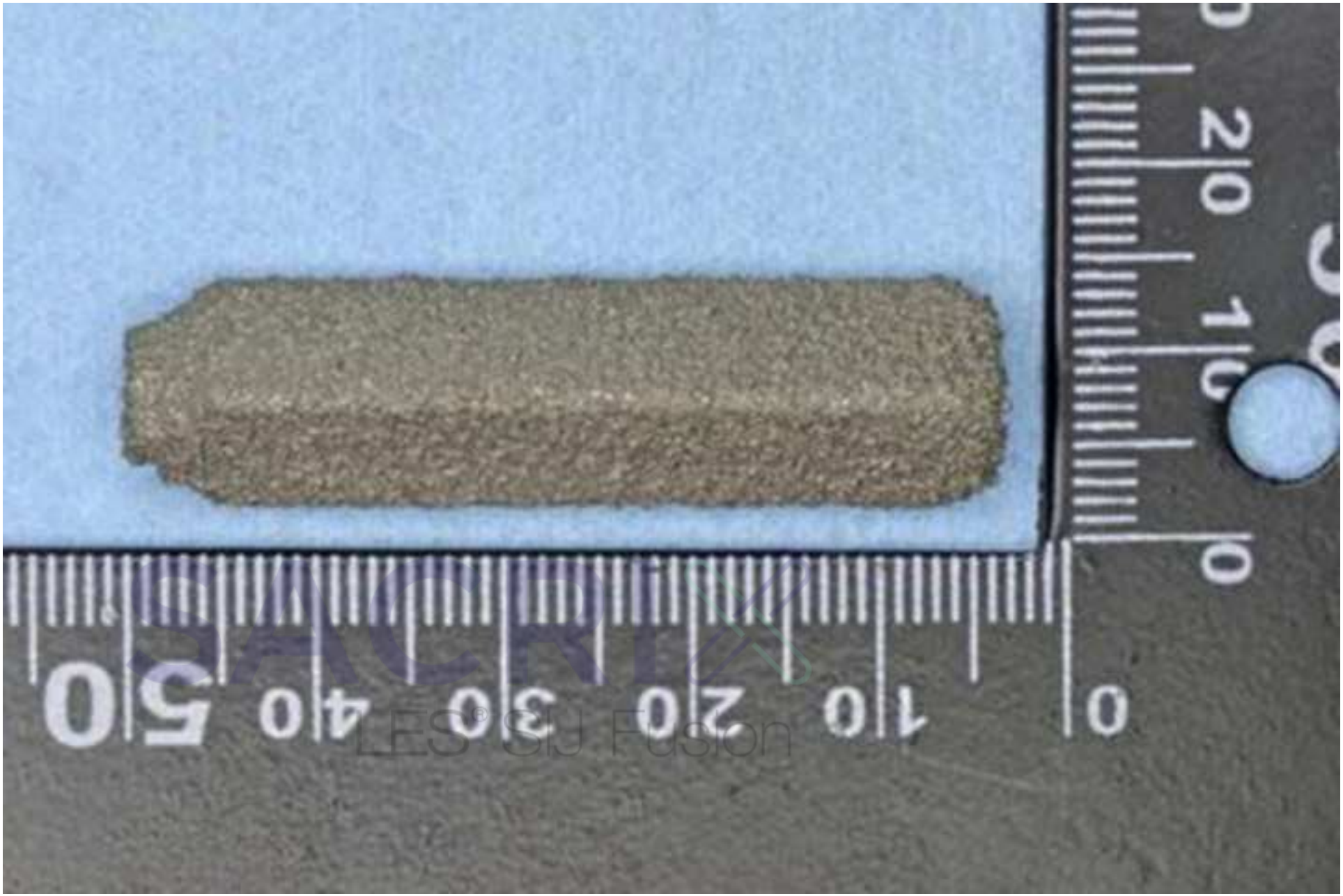

Figure 2

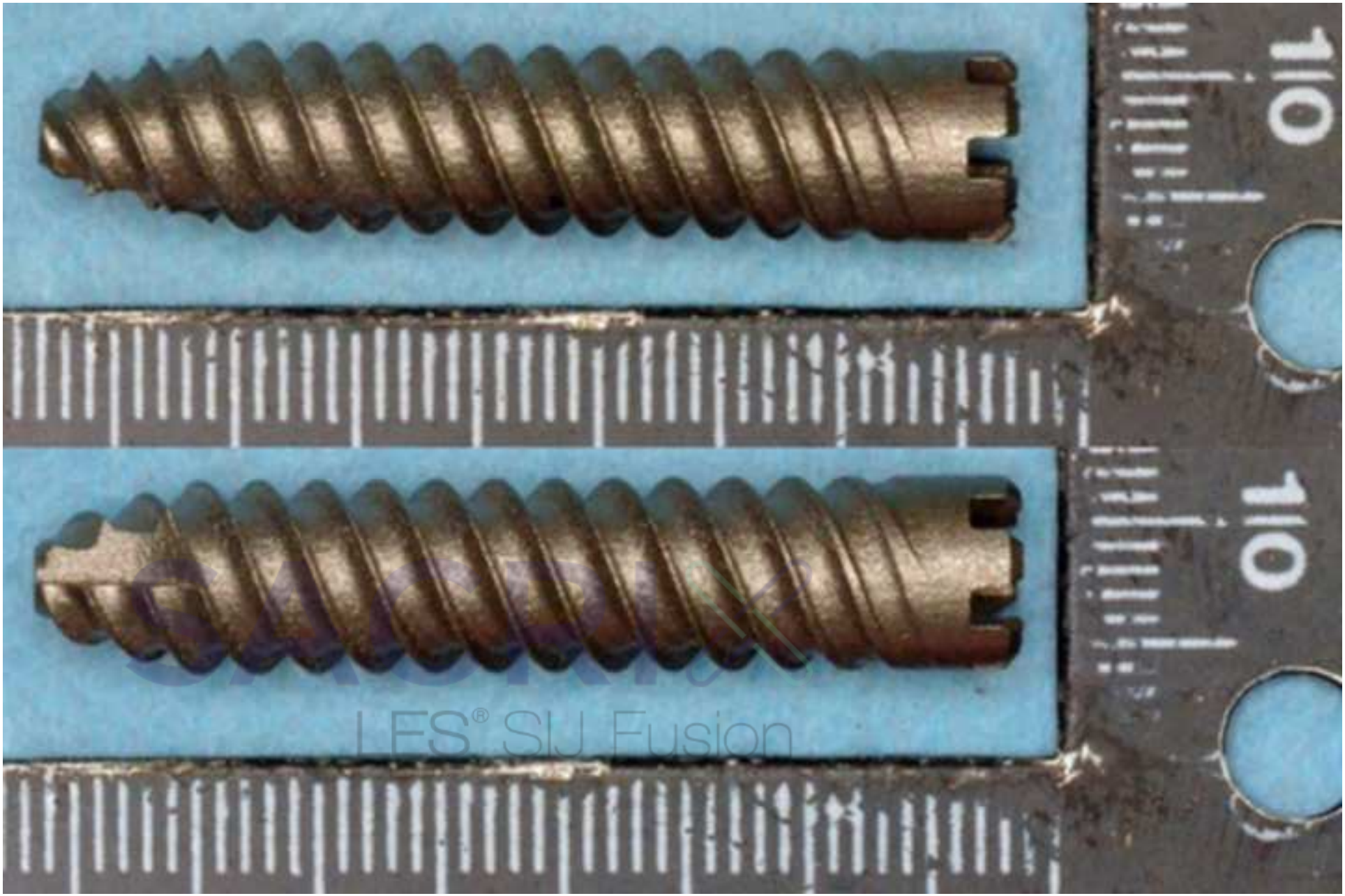

Figure 3

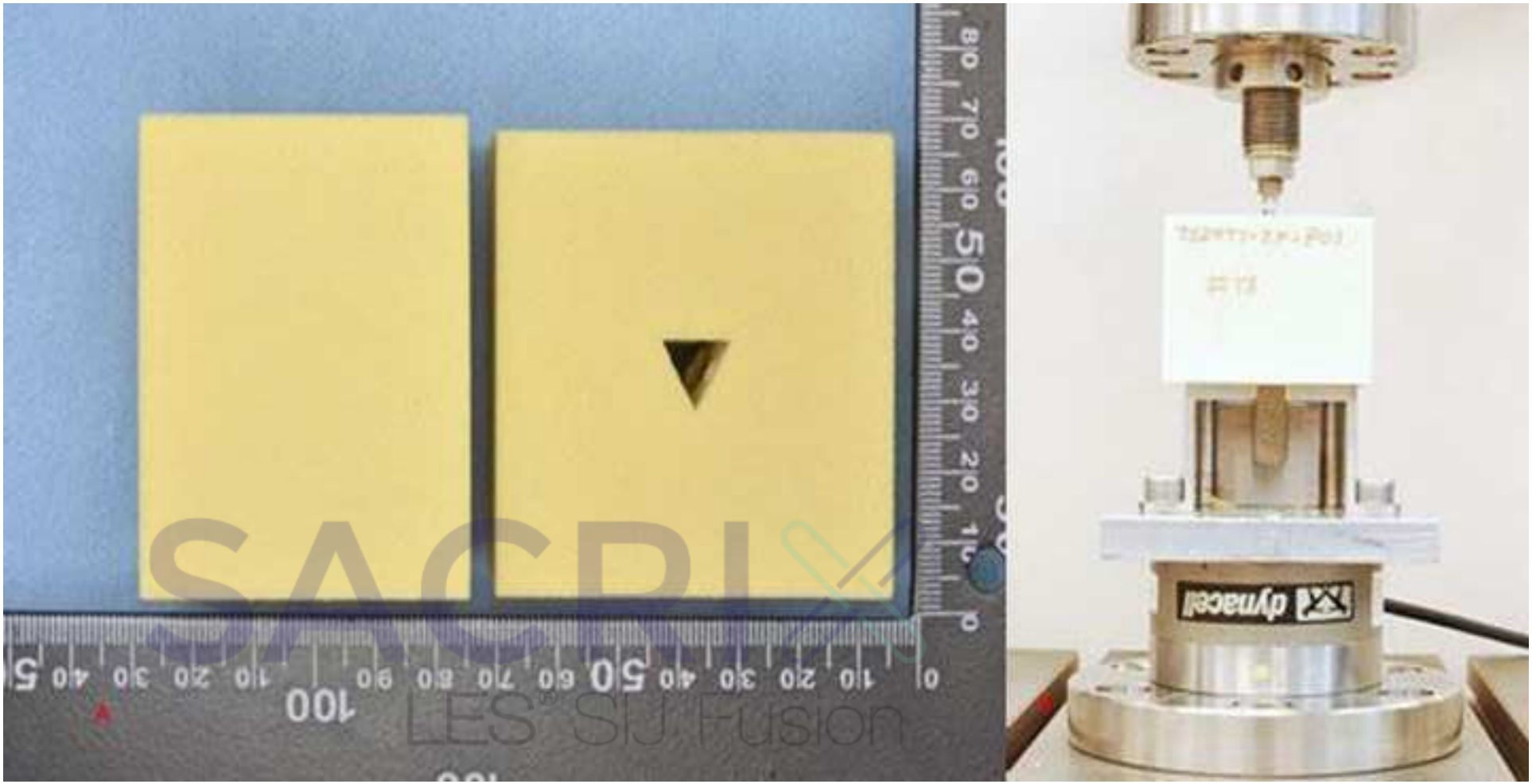

Figure 4

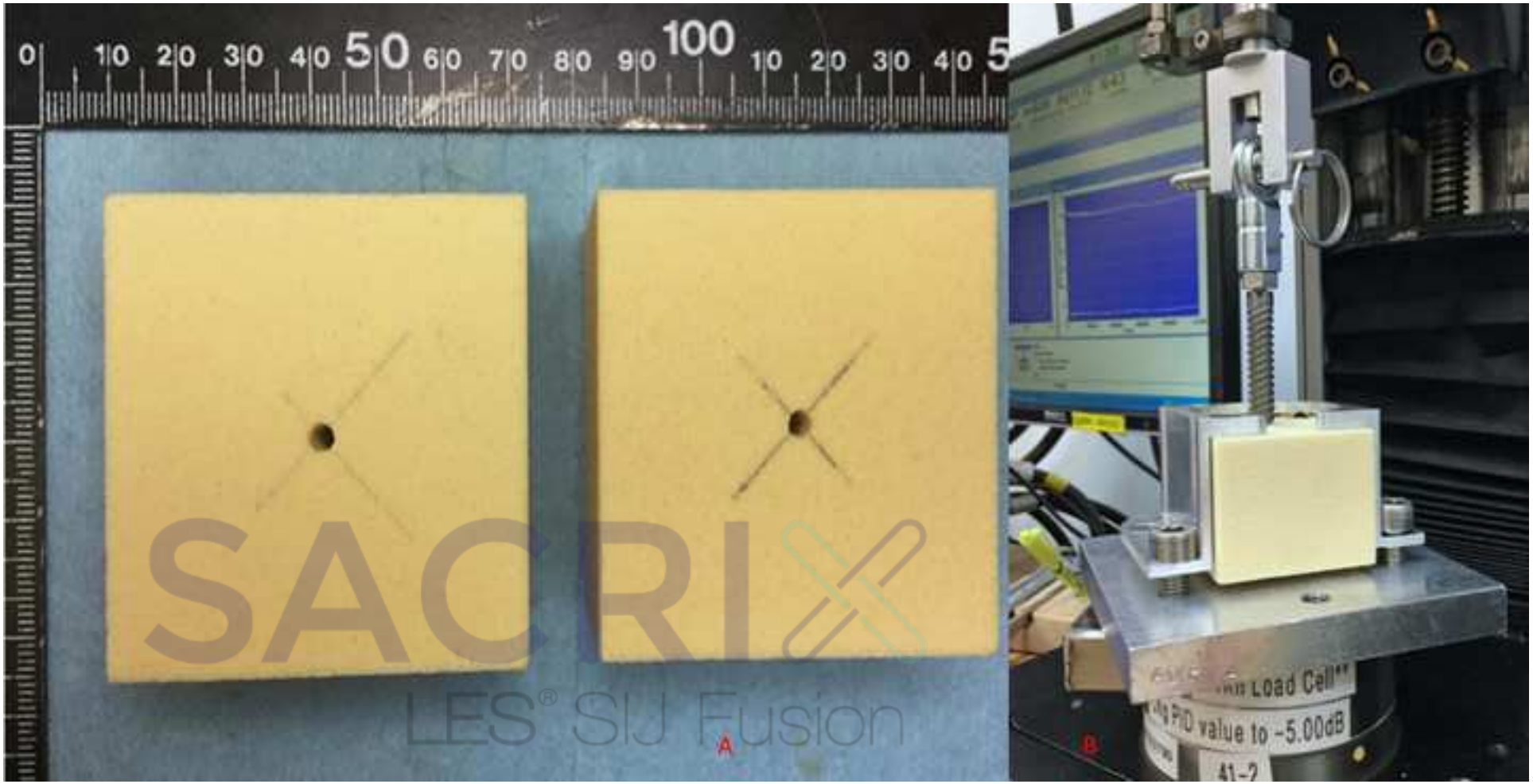
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Figure 5

Figure 6

Table 1

Table 1 lists the size of the specimen.

Description	Size (Length)	Size (Diameter)	Group
Ø7.0 iFuse Implant	45mm	7.0mm	IF
Ø8 mm SacroFuse Gen I Implant	40mm	8.0mm	SF

Table 2: Test Parameters

Specimen	Insertion Depth (mm)	Exposed Length (mm)	Grip Span (mm)	Test Block Thickness (mm)	Pilot Hole Size (mm)	Broached?
IF	20	26.2	35	50.8	3.18	Yes
SF	20	20.0	45	38.0	3.07	No

Table 3. Results of Static Axial Pullout for IF Group

Specimen	Axial Pullout Strength (N)	Displacement @ Pullout Strength (mm)
IF-1	184.10	0.84
IF-2	212.06	0.93
IF-3	204.27	1.27
Mean	**200.14**	**1.02**
Std Dev	**14.428**	**0.227**

Table 4. Results of Static Axial Pullout for SF Group

Specimen	Axial Pullout Strength (N)	Displacement @ Pullout Strength (mm)
SF-1	967.72	1.19
SF-2	856.72	1.10
SF-3	778.48	1.07
SF-4	860.93	1.02
SF-5	709.60	0.91
SF-6	715.95	0.93
Mean	**814.90**	**1.04**
Std Dev	**99.428**	**0.107**

Table 5 ANOVA analysis

F-Test Two-Sample for Variances

	Axial Pullout Strength	*Axial Pullout Strength (N)*
Mean	814.9	200.1433333
Variance	9885.44692	208.2124333
Observations	6	3
df	5	2
F	47.47769747	
P(F<=f) one-tail	0.02075586	
F Critical one-tail	19.29640965	