Biomechanical Evaluation of Standard and Novel Sacroiliac Joint Fusion Bone-Implant Interfaces in a Sawbones Model

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ABSTRACT

Integrity-SI® Fusion implants with standard bone-implant interfaces based on common buttress threads and identical implants with a Mechanical Integration interface using UnifiMI were biomechanically compared for maximum compression force, peak stripping torque, and cantilever bending/lever-out yield load in bone-foam blocks. Implants with UnifiMI demonstrated significantly higher compression forces (22% increase) and peak stripping torques (20% increase) than implants with standard buttress threads. In addition, cantilever bending/lever-out testing data demonstrated significantly higher yield loads (58% higher) for implants with UnifiMI as well as qualitative differences in failure modes.

INTRODUCTION

SI Fusion has become an increasingly common procedure to address pain caused by disfunction at the SI joint. Implants used to promote compression and stability via bone fusion at the SI joint, such as the Integrity-SI® Fusion screws (OsteoCentric Technologies, Austin, TX) to-date have employed standard buttress threads used throughout the orthopedic industry as the universally accepted method of compression-based fixation at the bone-implant interface. The purpose of this study was to compare the biomechanical performance of implants utilizing the traditional buttress or V-thread design to the same implants utilizing the Mechanical Integration method of fixation provided by Unifi*MI*. To assess performance of the different interfaces, the implants were tested for maximum axial compression generated, peak stripping torque, and cantilever bending/lever-out load resistance.

METHODS

Peak Stripping/Compression Testing:

Five (5) 75mm Integrity-SI Fusion implants with standard buttress threads (Integrity Screws) and five (5) 75mm Integrity-SI® Fusion implants with UnifiMI threads and self-tapping geometry (Integrity Fasteners) were tested. The implants were identical in material, major diameter, minor diameter, and thread pitch, while the only differences were in the thread geometry and inherent self-tapping lead-in geometry. For this test, the implants were tested in 20 pcf foam blocks (Sawbones, USA, Vashon Island, WA) using an electrodynamic axial-torsion material testing machine (eXpert 8900 Series, Admet, Norwood, MA) and a compression load cell (Admet 2800 Series Bi-Axial Load Cell, Admet Through-Hole Donut Load Cell) in a fixture configuration designed to elicit maximum physiologic compression and stripping forces. The test protocol was designed following the guidelines of ASTM F1839-*Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments.* Testing was completed at NexTek Innovations (Logan, UT). The setup consisted of solid foam blocks mounted in a vise that had pre-drilled holes prepared for the minor diameter of the implants (Fig 1), drilled to a depth that was 15mm short of the full implant depth. The test samples were placed through the donut-shaped compression load cell as well as 4mm thick foam sheets that were placed on either side of the load cell with pre-drilled with holes concentric to the load cell through-hole. Each implant was then tightened using a 5/16-inch hex drive at a rate of 30 RPM (Fig 2). The implants were rotated for at least three revolutions past the point of stripping to ensure that the correct maximum values were recorded. After each test, a new hole was used for additional samples. Both compression (N) vs time and torque (Nm) vs time were recorded by the test frame. The highest compression value during the test was taken as the maximum compression value for each sample, and the highest torque value was recorded as the peak stripping torque for each sample.

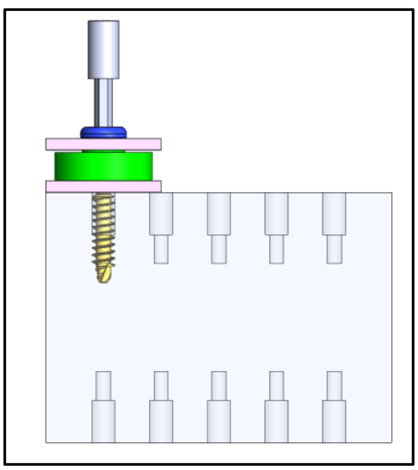

Figure 1 Test setup schematic of the compression/stripping test showing the pre-drilled holes that stop short of full depth.

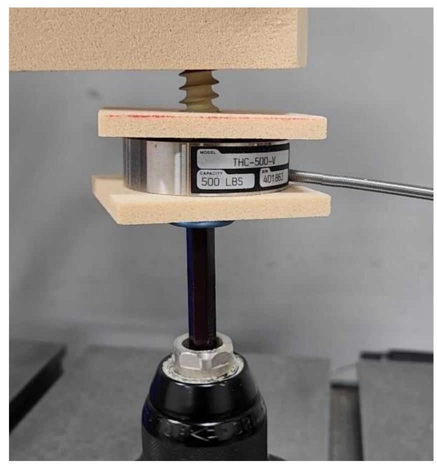

Figure 2 Photo of the compression/stripping test setup showing the foam blocks and load cell configuration.

Cantilever Bending/Lever-Out:

Using the same implant designs, five (5) 70mm Integrity Screws and five (5) 70mm Integrity Fasteners were inserted 40mm thick, 15 pcf bone foam test blocks (Sawbones USA, Vashon Island, WA) for biomechanical testing at NexTek Innovations (Logan, UT). Each sawbones block was pre-drilled to 7.5mm via a CNC mill to match the surgical technique for drilling the implant minor diameter. To challenge the fixation on the compression side of the load and to observe any differences in the thread-foam interaction, drill holes were placed with the center at 4.88mm from the edge of the test block, or 1.33mm from the edge of the hole to the edge or the test block (Fig 3). Each implant (actual end to end length of 75.4mm) was inserted until the head of the implant was 80mm above the bottom of the test block, leaving about 35mm inserted into the foam (Fig 4). Once implanted, the implants were placed into an electrodynamic axial-torsion material testing machine (eXpert 8900 Series, Admet, Norwood, MA) perpendicular to the test frame actuator. A braided cable was placed around the neck of the screw and was used to load the implant in a direction perpendicular to the long axis of the screw (Fig 5). Each implant was loaded quasi-statically under displacement control at a rate of 2500mm/min until construct yield occurred, or until the displacement limit reached 80mm, a value that ensured full removal of the implant from the test block (Fig 6). Force and displacement data were captured to measure implant yield and plot load-displacement curves.

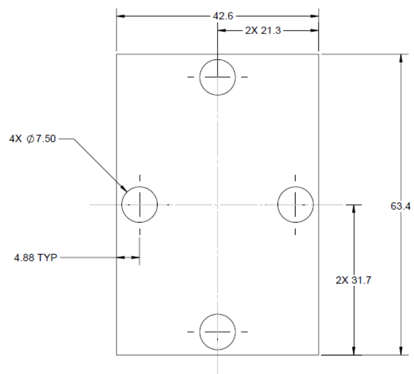

Figure 3 Engineering schematic of the bone block and pre-drilled hole locations

Figure 4 Example test specimen and level of insertion into the bone block

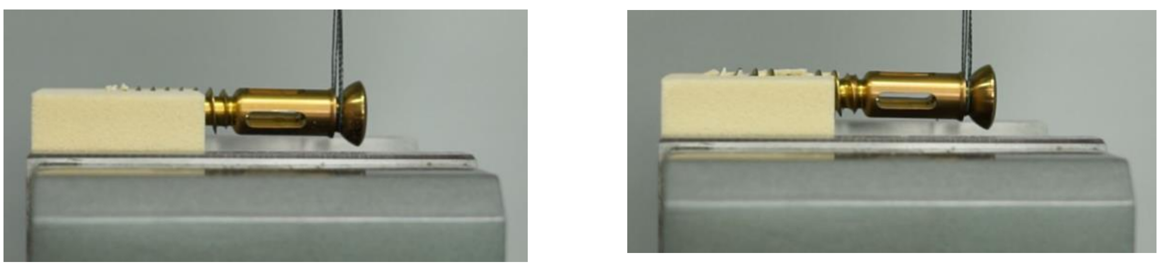

Figure 5 LEFT: Pre-test view of Integrity-SI Fastener (UnifiMI) test setup, RIGHT: Pre-test view of Integrity-SI Screw (buttress) test setup

RESULTS

Peak Compression Force:

Maximum peak compression forces were measured for both the Integrity Screws and the Integrity Fasteners during insertion into the foam block setup (Table 1). The mean peak compression for the Integrity Screws (standard buttress interface) was 173.7N ± 24.6N while the mean peak compression for Integrity Fasteners (UnifiMI interface) was significantly higher 221.2N ± 6.1N ($p < .01$).

Table 1 Peak compression data and mean values.

Compression (N)	**Sample 1**	**Sample 2**	**Sample 3**	**Sample 4**	**Sample 5**	**Mean**
Buttress	152.0	172.4	215.6	160.6	167.9	**173.7** ± 24.6
UnifiMI	224.0	212.9	216.9	224.6	227.7	**221.2** ± 6.1

Peak Stripping Torque:

Peak stripping torque was measured for both the Integrity Screws and the Integrity Fasteners during insertion into the foam block setup (Table 2). The mean peak stripping torque for the Integrity Screws (Buttress) was 9.92Nm ± 0.94Nm while the mean peak stripping torque for the Integrity Fasteners (UnifiMI) was significantly higher at a value of 12.34Nm ± 0.52Nm (p <.002).

Table 2 Peak stripping torque data and mean values.

Stripping (Nm)	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Mean
Buttress	9.1	10.5	11	8.8	10.2	**9.9** ± 0.9
UnifiMI	12.3	13.1	12.1	11.7	12.5	**12.3** ± 0.5

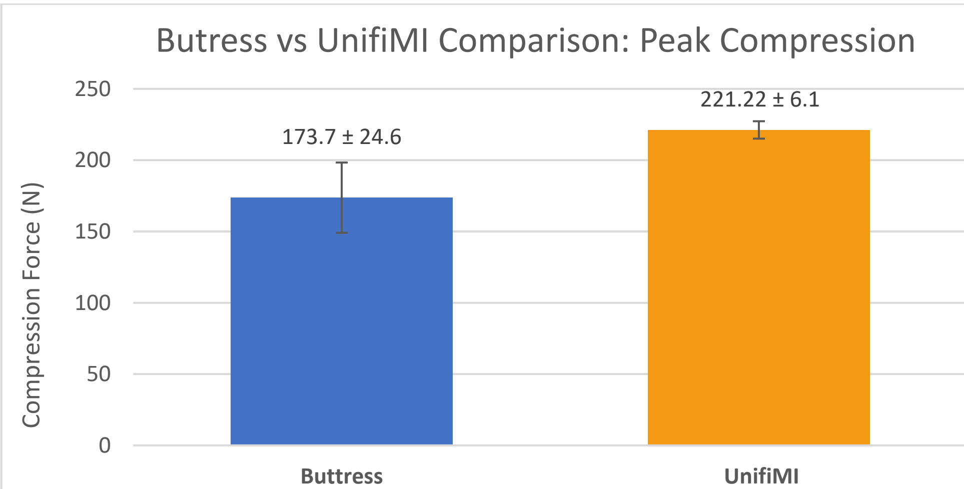

Figure 6 Mean peak compression loads for Integrity Screws (Buttress) and Integrity Fasteners (UnifiMI)

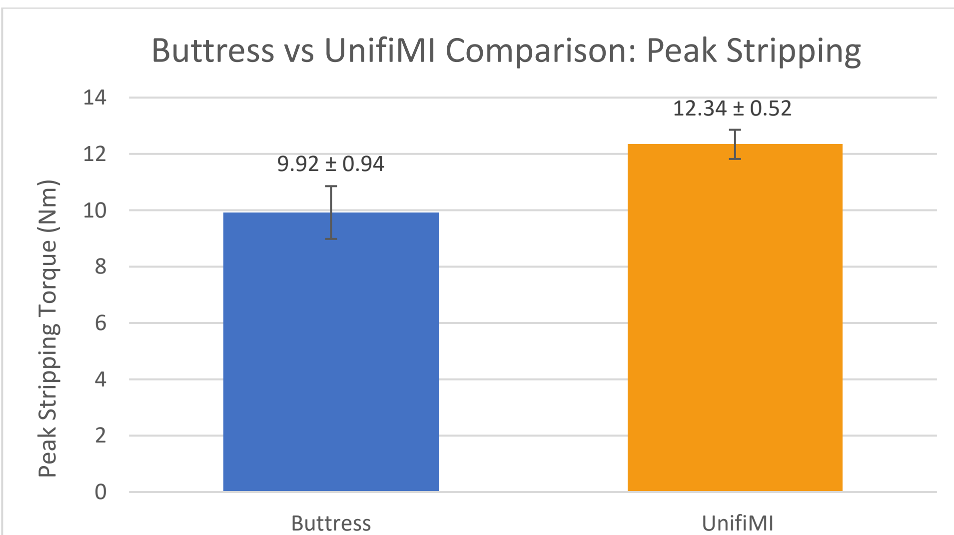

Figure 7 Mean peak stripping torques for Integrity Screws (Buttress) and Integrity Fasteners (UnifiMI)

Cantilever Bending/Lever-Out:

All testing in the cantilever bending resulted in eventual implant-foam interface failure via the implant pulling out of the test block. For the Integrity Screws the mean yield load was 67.40 ± 3.79 N while the mean yield load for the Integrity Fasteners was significantly higher at 107.44 ± 6.59 N ($p < .01$) (Table 3). Mean yield vs displacement curves are shown in Figure 8. It was also qualitatively observed during testing that Integrity Screws pulled through the foam to failure, while Integrity Fasteners broke large chunks of the foam from the block that remained integrated to the UnifiMI threads after failure (Fig 9 and 10).

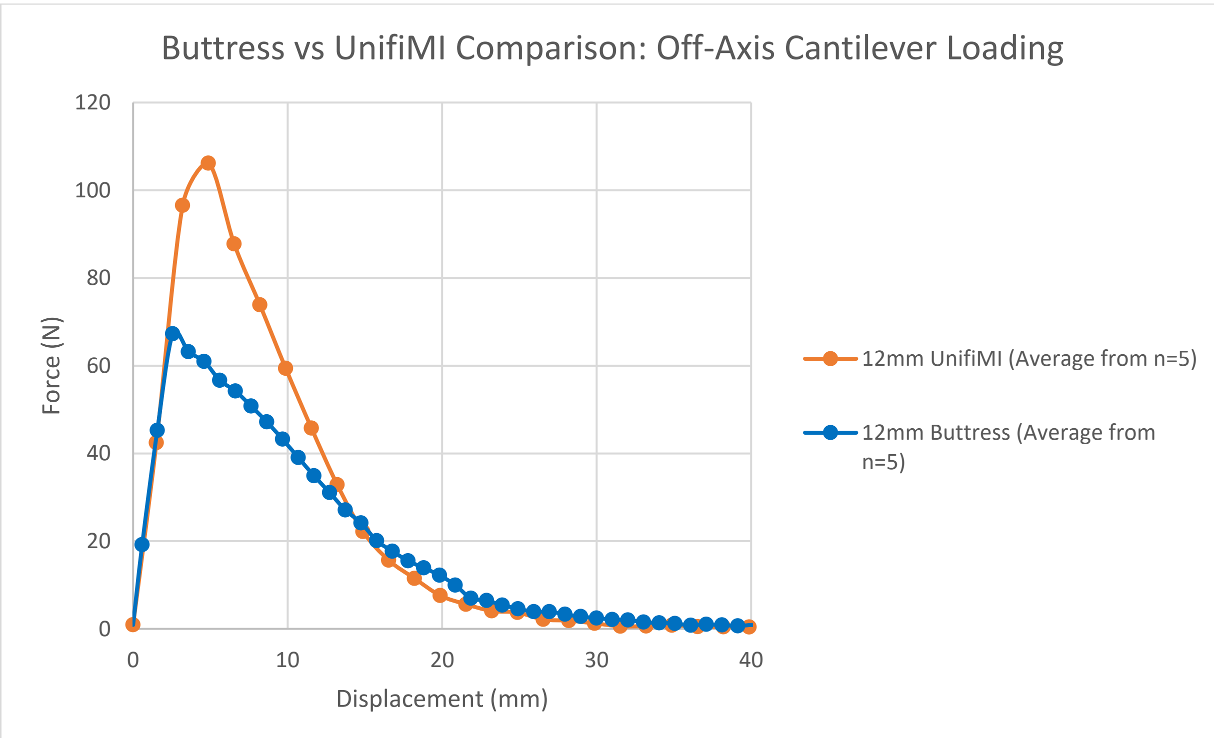

Figure 8 Mean Force V Displacement Data for Integrity Fasteners with UnifiMI and Integrity Screws with Buttress Threads

Table 3 Mean Yield Load (N) and Standard Deviation Data for all Specimens

Sample #	Integrity Screws (Buttress) Yield Load (N)	Integrity Fasteners (Unifi*MI*) Yield Load (N)
1	61.96	102.97
2	65.89	106.08
3	71.65	118.36
4	67.38	108.07
5	70.12	101.72
Mean ± S.D.	**67.40 ± 3.79**	**107.44 ± 6.59**

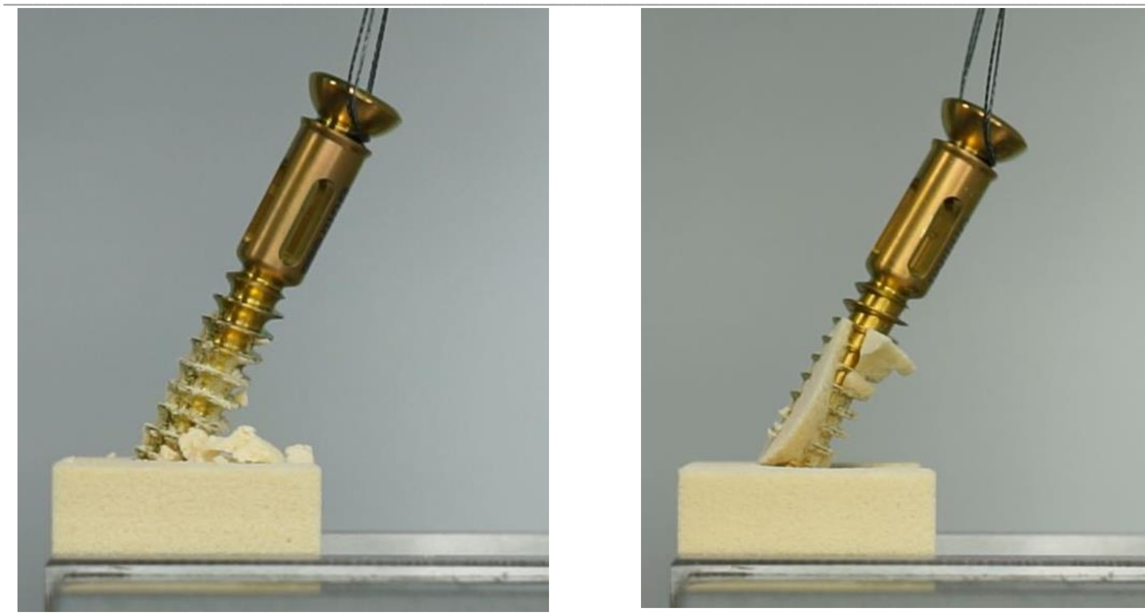

Figure 9 LEFT: Post-test view of Integrity-SI Screw (buttress) RIGHT: Post-test view of Integrity-SI Fastener (UnifiMI)

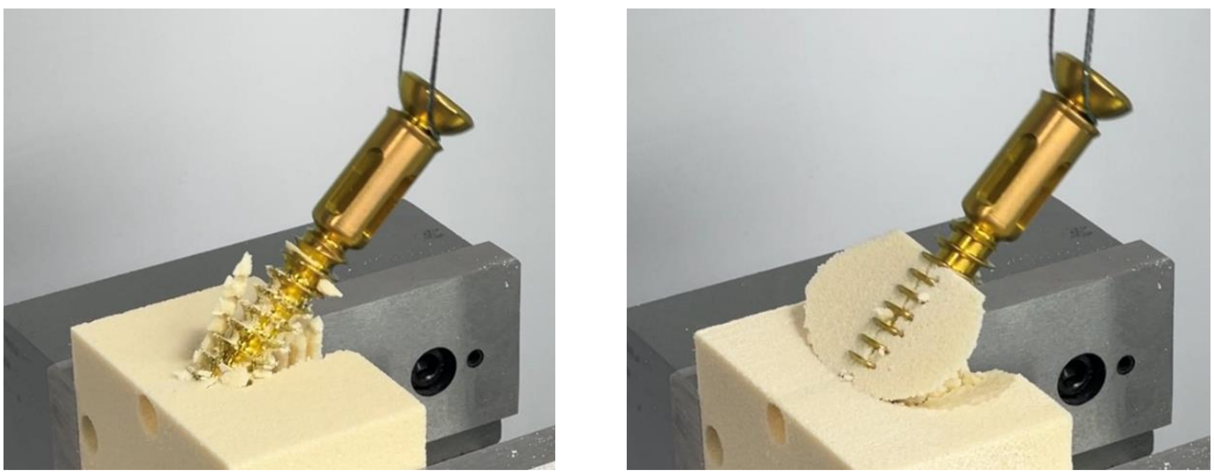

Figure 10 LEFT: Post-test isometric view of Integrity Screw (buttress) test showing very little foam still attached to the implant RIGHT: Post-test isometric view of Integrity Fastener (UnifiMI) test illustrating the foam still attached to the implant

Discussion:

Integrity Fasteners with Unifi*MI* exhibited superior biomechanical performance in all three test modalities. Peak compression of the bone foam test constructs by the Integrity Fasteners with the Unifi*MI* interface was on average, 22% higher than Integrity Screws with a standard buttress thread interface. This has important clinical implications as compression is a key element of joint stability and can contribute to the subsequent bony fusion in an arthrodesis procedure. The ability for the Integrity Fasteners to generate more compression may result in added stability of the construct, which could also potentially affect fusion rates. The higher peak stripping torque (20%) also observed for the Integrity Fasteners is also important clinically as it potentially allows the surgeon to advance the implant to reach a point of optimal compression and torque without the risk of stripping the interface and compromising the implant's stability and compression at that joint.

With regards to the cantilever bending/lever-out testing, the Integrity Fasteners with the Unifi*MI* interface had significantly higher yield loads as compared to the Integrity Screws with a standard buttress-style bone-implant interface. There were no significant differences in the displacement to yield observed in the experiments; however, failure modes were visually observed to show distinct characteristics. Integrity Fasteners failed via an avulsion type fracture of the foam in which large chunks of the test block on both the compression and tension side of the implant were removed and remained integrated into the UnifiMI thread form, even after the implant was completely separated from the test block. Conversely, Integrity Screws with buttress threads ripped through the bone foam and pulled out, taking only small bits of foam with the threads (Fig 9 and 10). These different failure modes, when combined with the yield data, serve to illustrate that Integrity Fasteners are more integrated into the test medium and distribute loads more broadly across the implant-foam interface, thereby providing greater resistance to load. The differences also suggest that Integrity Fasteners actively resist loads circumferentially, and on both the compression and tension side of the implant during off-axis loading.

While inserting the implants into the test blocks prior to testing, it was observed that the bone foam between the threads was more preserved with the Integrity Fasteners, while the bone foam with the Integrity Screws was crushed and compromised more between the threads (Fig 11). Insertion of the Integrity Screws was more difficult, as the implants demonstrated a tendency to migrate out of the hole and break out of the test block. Conversely, the Integrity Fasteners were easy to insert and quickly followed the pilot hole through full insertion.

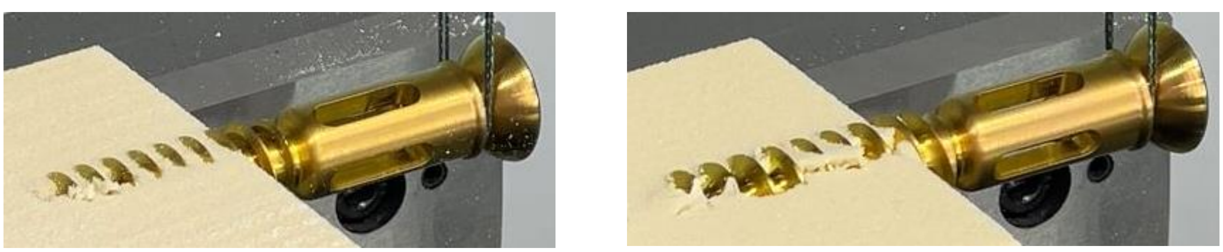

Figure 11 LEFT: Close-up View of UnifiMI threads and the Preserved Foam Between the Threads; RIGHT: Close-up View of the Buttress Threads and Associated Foam Damage

These observed differences highlight the contrasting manner by which the two methods of fixation work to potentially engage bone. The standard buttress interface relies on compression and radial outward loading to generate friction between the implant and the surrounding medium. Through this process, the material around the implant is plowed or crushed during insertion, which was illustrated in this test by the destruction of that foam between the threads on the outer edge of the test block. In contrast, the UnifiMI interface of

Mechanical Integration utilizes a unique self-tapping design that creates a precision “female thread form” or pathway for the implant thread. The Unifi*MI* thread geometry then uses a combination of angles and opposing faces to physically capture the surrounding foam between the threads, rather than pushing the material away or compressing the material to generate friction. Therefore, the material surrounding the implant remains more intact and capable of bearing immediate loads. Demonstration of these phenomena have been shown in trauma application such as acute fracture repair and pelvic reconstruction using UnifiMI fasteners, however, this should be further studied clinically in this specific SI joint fusion application to address differences in acute and long-term stability, fusion rates, and other outcome measures.

Summary: Integrity-SI Fusion Fastener implants with Unifi*MI* demonstrated significantly higher peak compression, peak stripping torque, and cantilever bending yield loads when tested in bone-foam constructs. These results demonstrate the marked improvement in biomechanical performance and stability that Mechanical Integration can provide an existing implant when converted to Unifi*MI.*