BIOMECHANICAL SIMULATIONS OF AXIAL COMPRESSION ON SACROILIAC JOINT FUSION IN A COMPETITIVE COMPARISON WITH THE RIALTO™ SI FUSION SYSTEM

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SUMMARY

From a biomechanical perspective, the sacroiliac (SI) joint is one of the most variable and poorly characterized joints with wide variations in surface anatomy, its orientation, and ligamentous support. SI inflammation, caused by joint dysfunction due to disrupted ligaments and abnormal motion, can cause debilitating pain which may require an interventional treatment to stabilize and fuse the joint to relieve the pain. In this biomechanical analysis, the objective was to computationally assess and compare the sacroiliac joint (SIJ) fixation biomechanics of an intact joint and one instrumented with the Rialto SI Fusion System (Medtronic, Inc.) and the iFuse Implant System® (SI-BONE Inc.). Using a comprehensive finite element model (FEM) of the pelvis, these biomechanical simulations were compared for instrumentations recommended by the surgical techniques of each system.

Important points:

§ With the simulation of two Rialto devices under an axially compressive load on the pelvis:
  - The translational motion at the sacroiliac joint fixed with two Rialto implants was decreased by 47% from the intact state. With three iFuse implants, the simulated translations were decreased by 53% from the intact case.
  - For rotational stability, two Rialto implants decreased the motion from the intact joint by 50%. Using three iFuse implants reduced the rotations by 49% from the intact joint.
  - While the two Rialto implants tended towards better rotational stability, and the three iFuse implants better translational stability, the differences were less than 10% with small displacements (<0.2mm) and rotations (~1 deg).

§ In these simulations, the number and placement of the threaded devices affected the integrity of the interosseous ligament (IOL), as it spans a majority of the joint area. By intersecting the IOL, the devices' trajectories intersected the IOL and adding more implants was not as effective due to increased damage to the IOL.

Conclusions:

When two devices of the Rialto SI Fusion System were simulated and compared to three implants of the iFuse Implant System, reductions in both translation and rotation for these implants systems were comparable with an approximately 50% reduction in the motion of the intact, uninstrumented sacroiliac joint.

INTRODUCTION

The sacroiliac (SI) joints are the two diarthrodial joints connecting the sacrum to the left and right ilia (pelvic bones) to form the pelvic girdle. As such, the SI joints (SIJ) transmit all the weight-bearing forces of the upper body from the spine to the pelvis and lower limbs and are subjected to dynamic combinations of compressive, shear, and torsional force components. Stabilized by a network of ligaments and muscles, each SIJ provides relatively small ranges of motion, normally a few millimeters of translation and a few degrees of rotation. Biomechanically, the SIJ is one of the most variable and poorly characterized joints in the human body – due to wide variations in the surface anatomy of the bony articulation, its orientation with respect to a vertical axis, and the condition of the ligamentous complex which holds the joint together.[1]

The SIJ is well innervated and is frequently the site of low back pain. Sacroiliitis (inflammation), caused by joint dysfunction due to disrupted ligaments and abnormal motion, can cause debilitating pain which may require an interventional treatment to stabilize and fuse the joint to relieve the pain.

In recent years, several fixation devices to fuse symptomatic SIJ have become commercially available for surgeons. The Rialto SI Fusion System (Medtronic, Inc.) is intended for SIJ fusion for conditions including SIJ disruptions and degenerative sacroiliitis. The system consists of cannulated, fenestrated threaded devices designed to enhance SIJ fusion. The devices are offered in various lengths to accommodate patient anatomy. For fusion of the SI joint, one, two, or three devices may be placed at surgeon's discretion. The iFuse Implant System is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than six months. Clinical studies have demonstrated that treatment with the iFuse Implant System improved pain, patient function, and quality of life. The procedure typically involves the insertion of three small titanium implants across the SI joint and is designed to stabilize and fuse the SI joint. To better understand the effect of device design and implant placement, this study simulated SIJ biomechanics in the intact and instrumented pelvis to compare two instrumentation scenarios for SIJ fixation.

In the study, the following objectives were addressed:

§ Assess the reference translations and rotations of the intact pelvis under axially compressive loads on the sacrum.

§ Quantify the changes in joint motion with fixation using Rialto and iFuse devices in typical scenarios based on manufacturer-recommended surgical techniques.

BIOMECHANICAL ANALYSIS

A comprehensive, finite element model of the pelvis was analyzed to biomechanically simulate two devices for SIJ fixation: Rialto SI Fusion System and iFuse Implant System. Based on a cadaveric biomechanical study, the simulations replicated the application of a vertical, or axially compressive, load on the sacrum at S1 and experimental boundary conditions.[2] With the Rialto devices, the same diameter (12mm), length (50mm), and number of devices (2) were modeled in this study to appropriately match the pelvis model anatomy and implant trajectory with experimental conditions and surgical technique.[2,3] To compare systems, three devices were simulated with the iFuse Implant System, based upon published experimental usage and surgical technique.[4,5]

FINITE ELEMENT MODELING OF THE PELVIS, IMPLANTS, AND BOUNDARY CONDITIONS

Pelvis

The three-dimensional (3D) pelvic geometry was reconstructed with a computerized tomography (CT) scanset (0.6mm slice thickness) of the pelvis of a 50th percentile human volunteer (32yo, European male, 75 kg, 1.75 m) with no known or observable spinopelvic pathology. The details of the modeling process, cancellous, and ligamentous properties, and experimental calibration have been previously published, but are briefly described here.[2]

Using the reconstructed pelvis geometry and previously developed modeling techniques, the comprehensive FEM was built with the ability to include the 3D CAD geometry of the implants (**Figures 1, 2a, 2b**).[6-8] The implants and their placement are further described in the following section. The pelvic bony structure was modeled with internal trabecular and external cortical bone. The cortical layers had region-specific thicknesses ranging from 0.05 to 5 mm (**Figure 2c**).[6-9] The finite element mesh was also optimized to achieve smaller elements sizes around the implants and accurately simulate peri-implant fixation (**Figures 2a and 2b**).

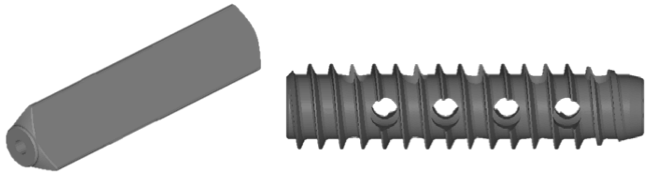


Figure 1: iFuse Implant System (*left*) and Rialto SI Fusion System (*right*)

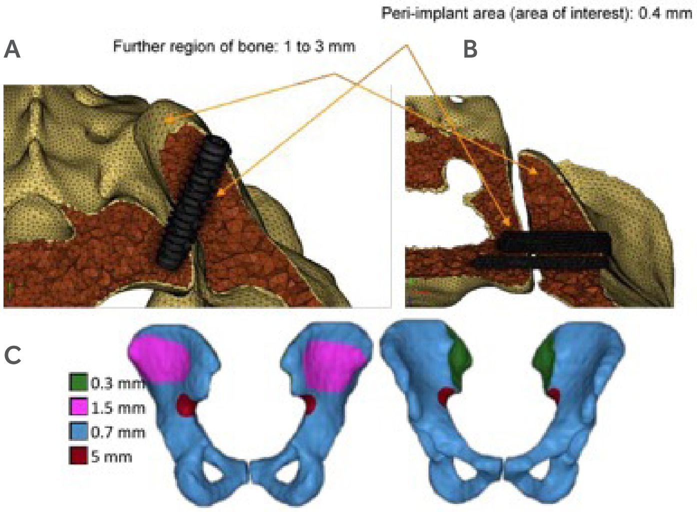


Figure 2: Modeling details of the Rialto SI Fusion System (A), iFuse (B), and cortical thickness (C)

The major pelvic ligaments (sacroiliac anterior, sacroiliac posterior, sacrotuberous and sacrospinous) and pubic symphysis were modeled from anatomic descriptions (**Figure 3**). As the largest and strongest pelvic ligament, the interosseous ligament (IOL) has a major role in the SIJ movement and its tensile strength is critical for the pelvic stability.[8] As the primary stabilizer, special care was taken to model the attachment site and area of the IOL at the SIJ.

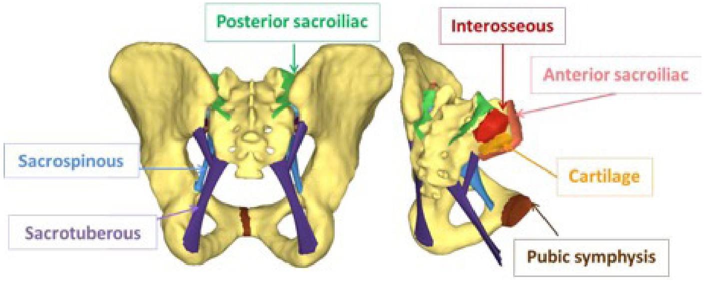


Figure 3: FEM details of the ligaments in a full pelvis view (*left*) and cutaway view (*right*) of a SIJ

The left and right SI joints were considered symmetric and non-pathologic with no ossification or arthrosis of the joint. As reported in Bruna-Rosso *et al.*, material properties were derived from the scientific literature or calibrated and validated with an experimental loading of cadaver pelvises in axial compression.[2] The tissues were considered homogenous and isotropic and are summarized in **Table 1** for the primary properties; other nonlinear measures are further tabulated in Bruna-Rosso *et al.*[2] The procedural simulations to assess the pelvic and bone-implant biomechanics were run using the explicit dynamic FEM solver RADIOSS v11 (Altair Engineering, Troy, MI, USA.).

Table 1: Material properties used in the FEM

	Cortical Bone	Trabecular Bone	Ligaments	Pubic Symphysis	SIJ Articular Cartilage
Density (kg-m^3)	2	0.2	2	2	1.05
Young Modulus (MPa)	2625	48.75	40	397	150
Poisson Ratio	0.3	0.25	0.3	0.3	0.2
Yield Stress (MPa)	105	1.95	-	-	-
Hardening modulus (MPa)	875	16.3	-	-	-
Failure plastic strain	0.04	0.04	-	-	-

IMPLANTS AND PLACEMENT

Two sacroiliac joint fixations devices, already shown in **Figure 1**, were assessed using the FEM:

- Rialto (12 mm diameter in 50mm lengths) – with medial approach trajectory for two devices[3]
- iFuse (7mm diameter in 40, 50, 60mm lengths) – with lateral approach trajectory for three devices[5]

The modeling process simulated the insertion trajectory and primary biomechanical structures (e.g. bone tissue and ligaments) around the approach and insertion points (**Figure 4**). These simulations, however, did not incorporate the insertion step, and there was no press fit effect and the tapping diameter was the same as the implant diameter. The bone-implant interface was modeled with friction coefficients of 0.2 for the Rialto and 0.5 for the rougher iFuse device.[7] Both devices were considered as rigid bodies due to the higher elastic modulus for metals compared to bone. Lastly, due to the functional importance of the interosseous ligament (IOL), damage to the ligament caused by implant placement was modelled by modifying its geometry consistently with the device trajectories (**Figure 5**).[8] Specifically, the attachment area was reduced where implant placement would cause disruption of the ligament itself.

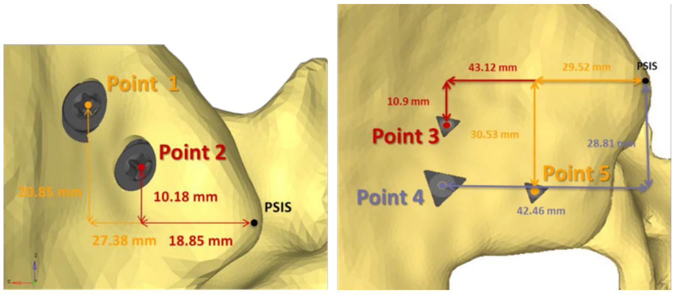


Figure 4: Specimen-specific distances for insertion based on the posterior superior iliac spine (PSIS)

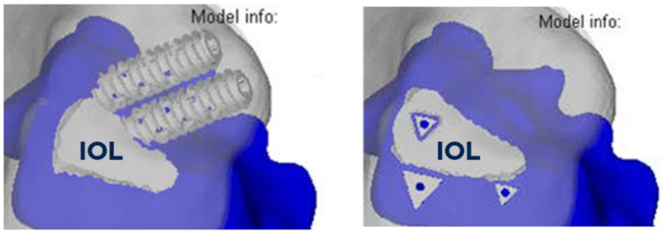


Figure 5: Area of the interosseus ligament (IOL) with the two Rialto implants (left) in a medial trajectory and the three iFuse ones (right) in a lateral trajectory. (*Blue represents the cross-sectional area of the sacrum in this view*)

BOUNDARY AND LOADING CONDITIONS

The pelvis was oriented (**Figure 6**) as in a physiological standing position (neutral pelvic tilt, iliac crest and pubic symphysis in the same vertical plane) to replicate weight-bearing. The simulations replicated the application of an 800N vertical load on S1 with the bottom part of the pelvic bone completely fixed (no translation nor rotation).

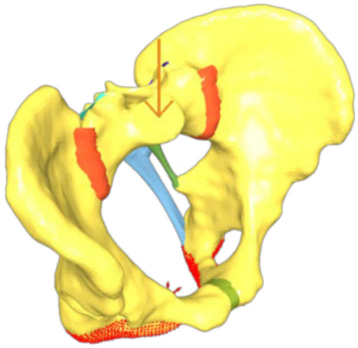


Figure 6: Simulated boundary conditions: red points (bottom) were fixed and the vertical force (orange arrow) was applied at S1

The biomechanical response to this loading was assessed using local SIJ displacements: the relative motion between the sacrum and the ilium at the joint. Local displacements within the SIJ were computed both in rotation in the sagittal plane and in translation. The rotation was computed using the local axes of the ilium and the sacrum at the SIJ (**Figure 7a**), while the relative translation was computed as the average of the relative linear displacement between 14 pairs of facing points on each part of the articular surfaces after the simulated load (**Figure 7b**). For each simulated configuration (**Table 2**), the percentage of displacement reduction (in rotation and translation) was calculated with respect to the reference uninstrumented configuration.

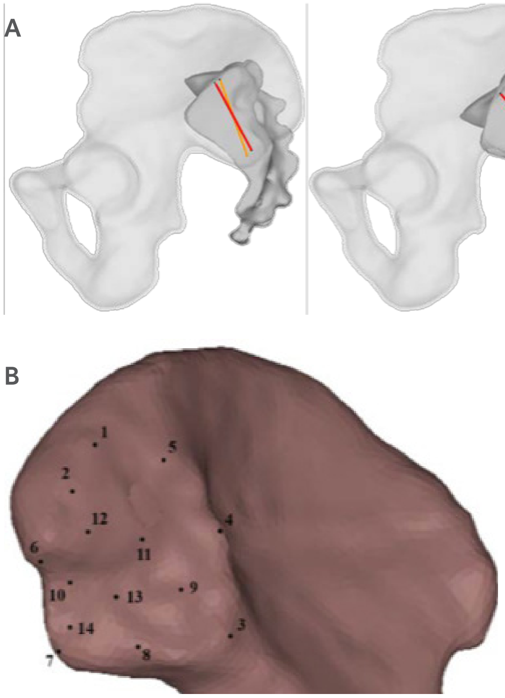


Figure 7: Biomechanical response was measured as the sacral tilt (A) measured with respect to the ilium and the mean relative motion at several points (B) across the SI joint.

Table 2: Simulated scenarios with implant number, size, placement, and orientation.

(*see Figure 5 for Insertion Point definitions)

Implant System	Implant Number	Length (mm)	Insertion Points	Orientation
None	0	-	-	-
Rialto	2	50-50	1-2	medial
iFuse	3	60-50-40	3-4-5	lateral

Rialto	Rialto SI Fusion System (Medtronic, Inc.)
iFuse	iFuse Implant System® (SI-Bone, Inc.)

RESULTS

Intact Pelvis Scenario

The reference simulation calculated a combination of rotational and translational motion in the sagittal plane (shearing) as represented previously.[10-12] It replicated the sacral nutation where the axis of rotation shifts as the joint undergoes small rotations (**Figure 8**). The magnitude of the relative translation at the SI joint was 0.32mm and the rotation was 2.05 degrees.

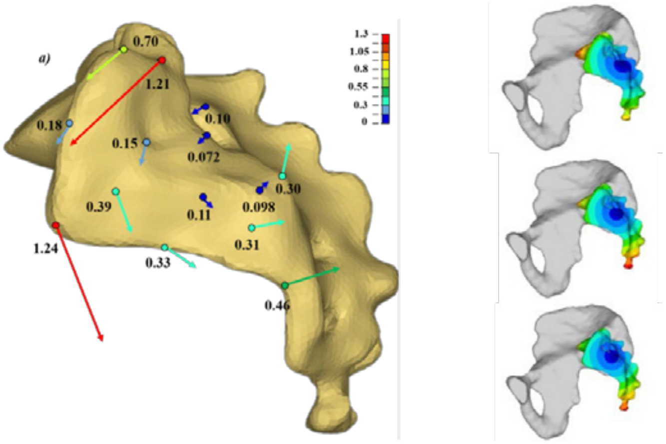
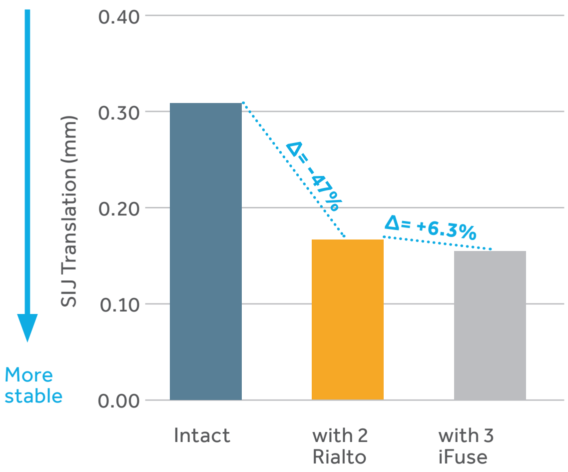


Figure 8: Uninstrumented model displacements with the color scale in millimeters. (*Left*) The arrows (magnified for visualization purposes) represent the sacral nutation. The vector plot displacement at three different time steps (*Right*) illustrate the displacement of the center of rotation.

MANUFACTURER-RECOMMENDED SCENARIOS

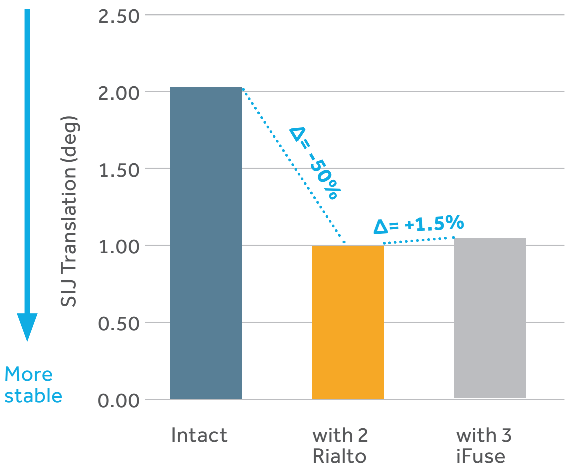
When the implant systems were modeled at the SI joint as shown in **Figure 4**, the relative translation and rotation at the joint were reduced. In general, with two Rialto devices and three iFuse devices, the motions were decreased by 50% from the intact, uninstrumented joint (**Figure 9**). For two Rialto implants, the translational motion was 0.17mm and rotation was 1.02 degrees (**Figure 10**). With three iFuse, these motions were 0.15mm and 1.05 degrees, respectively.

Figure 9: Translational motion at the sacroiliac joint for the intact and instrumented configurations



Simulated Configuration
Rialto Rialto SI Fusion System (Medtronic, Inc.)
iFuse iFuse Implant System® (SI-Bone, Inc.)

Figure 10: Rotational motion at the sacroiliac joint for the intact and instrumented configurations



Simulated Configuration
Rialto Rialto SI Fusion System (Medtronic, Inc.)
iFuse iFuse Implant System® (SI-Bone, Inc.)

DISCUSSION AND CONCLUSIONS

This computational model assessed the biomechanics of the intact sacroiliac joint and instrumentation with the Rialto Sacroiliac Joint Fusion System and the iFuse Implant System in different implant configurations. The simulated, uninstrumented pelvis, under a vertical load, yielded nutational motion, with relative rotation in combination with translation in the sagittal plane. The intra-articular simulated SIJ displacements were on the same order of magnitude (0.1mm – 1mm) as those published in the literature, but with specimens of different ages and conditions.[12]

Sacroiliac stability was increased with instrumentation across the SI joint. Both implant systems reduced the translation and rotation at the joint by 50% to even smaller magnitudes of motion less than 0.2mm and around 1 deg. Despite requiring more implants to achieve the same degree of stability, the iFuse system, as modeled with the manufacturer-recommended insertion, reduced the area of the interosseus ligament and the IOL's ability to contribute to joint stability and resist joint shear. While it was expected that more implants would further reduce joint motion, three iFuse implants in these simulations did not yield larger reductions in joint motion compared to two implants with the Rialto SI Fusion System. As modeled, the simulated damage to the IOL had a greater impact on the joint stability than using a third implant in these trajectories.

From the previous validation, the model appropriately replicated the reduction of movement between the instrumented configurations and the uninstrumented reference with small differences between the simulated and experimental data (≤3%).[2] However, limitations exist for the analyses in this comparative study. First, only one loading case was simulated, a vertical load applied on the S1 endplate inducing rotation and translation at the SIJ. This load could be conceptually considered as favorable to the iFuse considering its triangular shape and potential ability to resist rotation. Second, the implant insertion process was simplified in this study; the effects of drilling, tapping for Rialto, and broaching for iFuse were not modeled. Bone compaction arising from under-tapping or broaching might create more stable scenarios that were not represented with these bony material properties. Likewise, the IOL material model did not account for the strain-dependent rigidity of the ligament. However, considering that the loads applied are physiologic, the strains remained relatively low and again, represented the more elastic behavior of the ligament.

With the simulation of two Rialto devices under an axially compressive load on the pelvis. The translational motion at the sacroiliac joint fixed with two Rialto implants was decreased by 47% from the intact state. With three iFuse implants, the simulated translations were decreased by 53% from the intact case. For rotational stability, two Rialto implants decreased the motion from the intact joint by 50%. Using three iFuse implants reduced the rotations by 49% from the intact joint. It is important to note that while the two Rialto implants tended towards better rotational stability, and the three iFuse implants better translational stability, the differences can be considered small and not clinically significant. The integrity of the interosseous ligament (IOL) was affected by the trajectory of the devices. Configurations involving extensive damage of the IOL showed a lower SIJ stability and adding more implants was not as effective due to increased damage to the IOL. Thus, based on the number of implants, the Rialto procedure had a better efficiency when used in a manufacturer-recommended configuration than in the iFuse-recommended configuration. The clinical metrics for how much joint stability is required are unknown, but in this computational model, reductions in both translation and rotation for both implants systems were on the order of 50% compared to the intact, uninstrumented sacroiliac joint.

RISKS

Risks of SI fusion procedures with these implants include, but are not limited to:

- Post-operative infection, wound necrosis, or wound dehiscence
- Pain, discomfort, or abnormal sensations caused by the presence of the implant
- Metal sensitivity, or allergic reaction to a foreign body, debris, corrosion products including metallosis, staining, tumor formation and/or autoimmune disease
- Migration, loosening, or fracture of the implant
- Decrease in bone density due to stress shielding

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