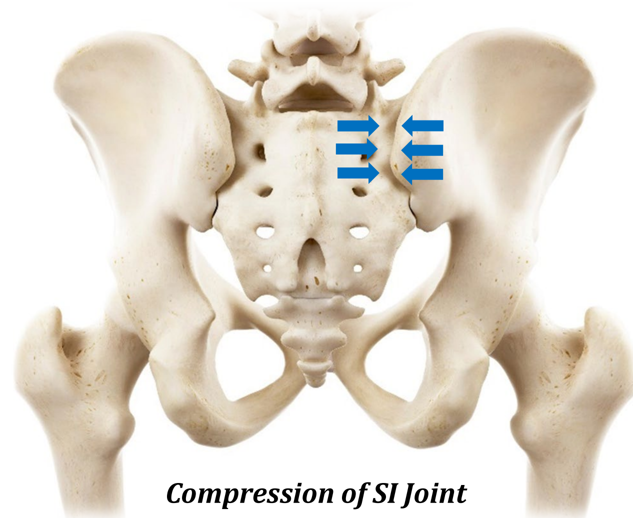
SACROILIAC JOINT FUSION: White Paper November 2023

Assessment of the Compressive Properties for the SurGenTec TiLink-P™ Sacroiliac Joint Fusion System: A Simulated and Cadaveric Biomechanical Evaluation

Lisa Ferrara, Ph.D.

Introduction



Compression of SI Joint

The sacroiliac joint (SIJ) is a strong weight bearing synovial joint situated between the lumbar spine and the pelvis where the joint is aligned along the longitudinal load-bearing axis of the human spine during upright posture. It functions as a force transfer conduit to transfer axial loads bi-directionally from the spine to the pelvis and lower extremities. Small motions of the SIJ have been measured through in vitro studies with the greatest motion consisting of translation that is coupled with a small forward bend motion about the hips.[1-6] The ligamentous structures surrounding the sacroiliac joint assist in resisting shear and rotational forces along the SIJ during ambulation. Additionally, the ligamentous complex aids in maintaining the compressive forces across the sacroiliac joint which preserves alignment and maintains stability along the joint. Degeneration or injury of the sacroiliac joint can alter the compressive forces across the joint, resulting in a loss of stability in the sacroiliac joint.[7,8,9]

Recently, fixation systems such as the TiLink-P™ Sacroiliac Joint Fusion System (SurGenTec, LLC. Boca Raton, FL), have been incorporated along the SIJ through a posterior 'in-line' surgical approach, as shown in Figure 1. Currently, there are no known studies that have evaluated the compressive properties of current FDA cleared posterior in-line sacroiliac fixation systems within the sacroiliac joint. Therefore, the basis of this study was to evaluate the compressive forces across the sacroiliac joint implanted with the SurGenTec TiLink-P™ Sacroiliac Joint Fusion System under static and repetitive axial loading.

Objective

The overall objective of the biomechanical study was to examine the compressive properties of the SurGenTec TiLink-P™ Sacroiliac Joint Fusion System under extreme physiological loads when implanted within the sacroiliac joint per a posterior in-line surgical approach, (Figure 1).

Beveled Anchor Edging to Aid in Compression of SI Joint

Figure 1: Image of an inline implantation of the SurGenTec TiLink-P™ Sacroiliac Joint System into the sacroiliac joint. The beveled edges on the anchor of the TiLink-P™ assist in providing sustained compression across the sacroiliac joint.

Overview

The compressive propensity for the posterior in-line implantation of the SurGenTec TiLink-P™ Sacroiliac Joint Fusion System (SIJ) was measured before and after implantation in two separate studies. An initial study utilized a simulated joint interface implanted with the TiLink-P™ that was positioned along the longitudinal axis (in-line) of the sacroiliac joint, (Figure 2A). The joint construct was then placed under static physiological loading and the compressive forces were measured at the implant and the bone foam interface before and after implantation of the TiLink-P™ for multiple test samples. Following this initial study, a human cadaveric biomechanical assessment was then performed under clinically relevant cyclical loading and the compressive forces measured to determine if compression across the sacroiliac joint was maintained after long-term repetitive loading.

Study 1: Simulated Joint Assessment

An initial bench top study using a simulated joint interface consisting of two bone foam test blocks (Grade 20 PCF polyurethane foam, Sawbones, Pacific Research CA) was implanted with the TiLink-P™ that was positioned along the longitudinal axis (in-line) to measure the compressive forces between the bone foam test blocks implanted with the TiLink-P™ SIJ System in-line with the simulated joint. Two thin-film force sensors were placed on each side of the TiLink-P™ device sandwiched between the test blocks, (Figure 2A).

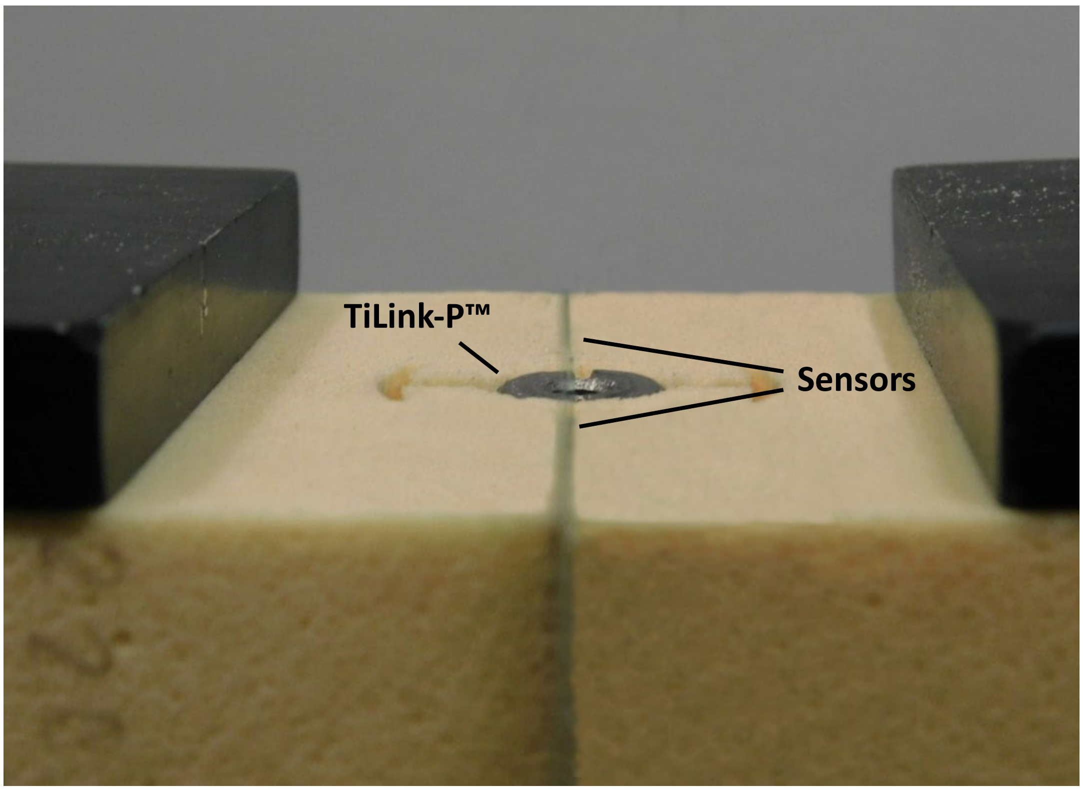


Figure 2A: Test setup for measuring the compressive forces at pre-implantation and after 1-hour post-implantation of the TiLink-P™ SIJ System sandwiched between simulated bone foam blocks. Two thin-film force sensors were placed on each side of the TiLink-P™ device at the interface of the bone foam block. The force sensors were used to measure the compressive forces across the simulated sacroiliac joint implanted with the TiLink-P™.

The force sensors were used to measure the compressive forces across the simulated sacroiliac joint implanted with the TiLink-P™ before and one-hour after implantation, (Figure 2B). Additionally, compressive profiles of the force distribution at the simulated bone foam and TiLink-P™ interface were also mapped to identify regions of increased compression, (Figure 3).

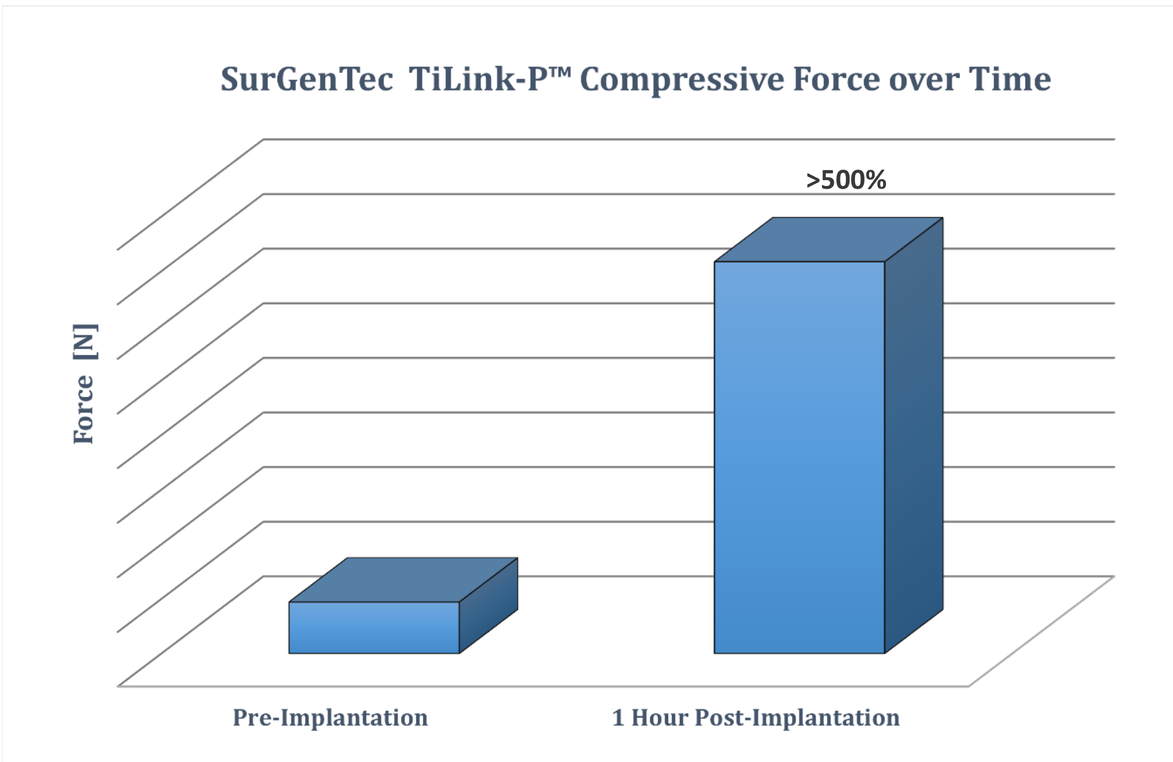
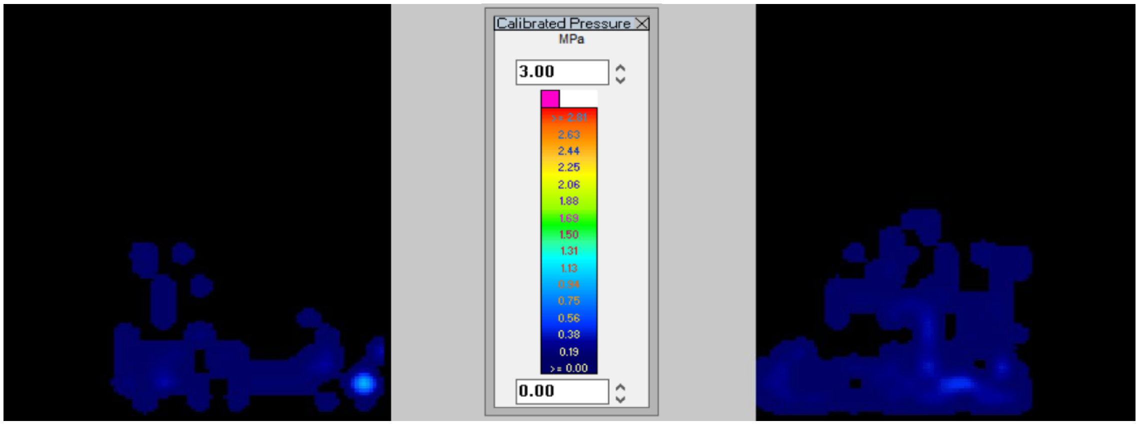


Figure 2B: Graphical representation of measured TiLink-P™ compressive force for pre-implantation and after 1-hour post-implantation. The results demonstrated a significant increase in compressive force after implantation of the TiLink-P™ with maintained compression after one hour.

Pre-Implantation of TiLink-P™



One Hour Post-Implantation of TiLink-

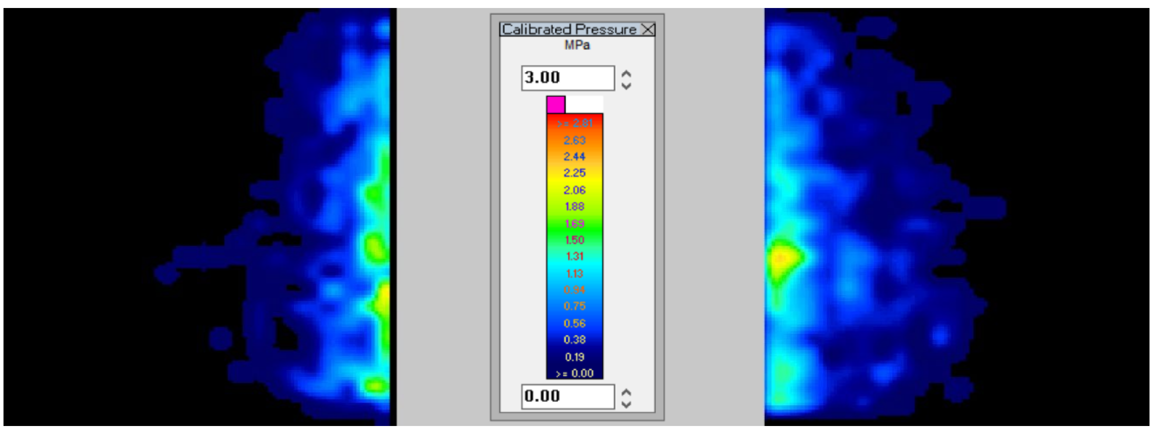


Figure 3: Compressive force maps for pre-implantation and after 1-hour post-implantation of the TiLink-P™ demonstrating increased forces with increased distribution of those forces at the bone foam interface.

Findings:

- The compressive forces of the TiLink-P™ and bone foam interface of the simulated sacroiliac joint demonstrated more than a 500% increase (greater than 5 times the pre-implantation) in compressive forces across the joint after implantation, (Figure 2B).
- The compressive force maps demonstrated increased compressive forces across a greater surface area surrounding the implant after one hour of implantation of the TiLink-P™. Greater forces are illustrated on the scale in green and yellow, (Figure 3).

Conclusion:

The SurGenTec TiLink-P™ demonstrated significant compressive forces across the simulated sacroiliac joint that were five times greater than the pre-implantation state after one hour of implantation.

Study 2: Cadaveric Biomechanical Assessment

Biomechanical assessments were conducted on **eight** human cadaveric lumbosacral spines with the pelvis attached. Non-destructive cyclical axial loading was conducted on each lumbosacral-pelvic complex for the intact and implanted scenario to assess long-term changes in the gap spacing across the sacroiliac joint. One TiLink-P™ was implanted into one side of the sacroiliac joint per a posterior in-line surgical approach, with a previously FDA cleared Predicate SIJ fixation screw placed from a lateral approach on the contralateral SIJ. Micro-transducers were placed across each sacroiliac joint and the gap spacing across the implanted SIJ for the post-implantation and post-cyclic testing was quantified.

A direct comparison of the sacroiliac joint gap measurements for the pre and post cyclic loading and the change in gap spacing for each fixation system were statistically compared, Figure 4. Additionally, at the completion of testing, each sacroiliac joint that was implanted with the TiLink-P™ was meticulously dissected to assess bone apposition at the implant and bone interface, Figure 5.

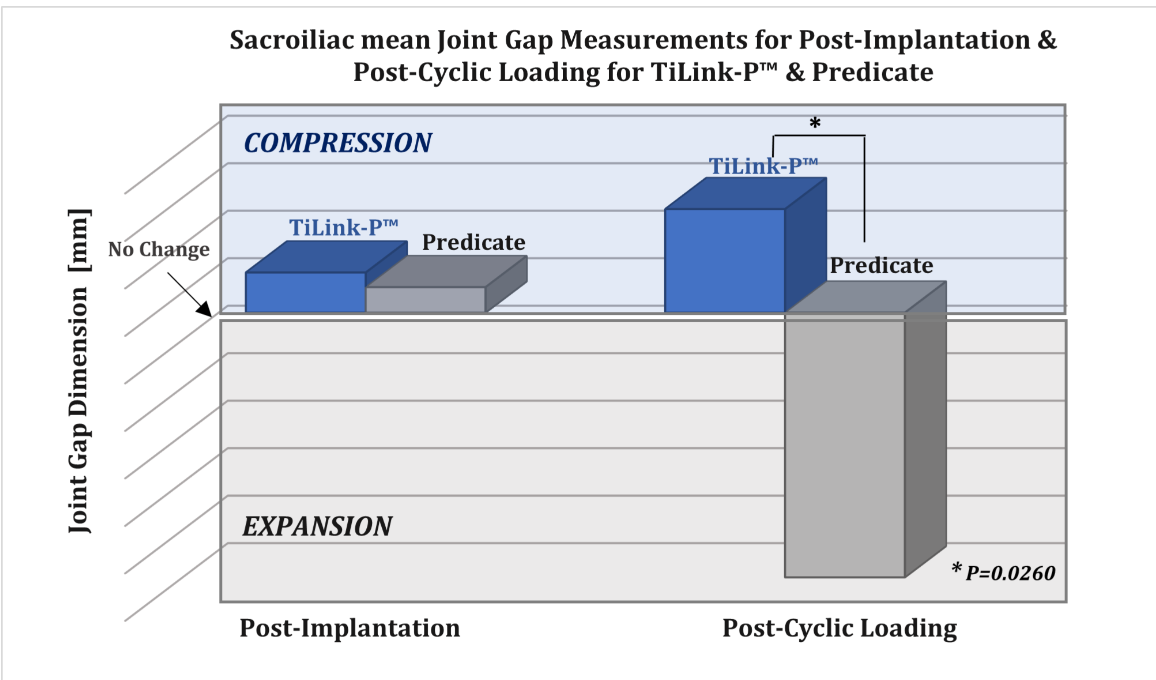


Figure 4: Sacroiliac mean joint gap (SIJ) measurements for the **eight** post-implantation cadaveric SIJ test specimens (prior to cyclic loading) demonstrated joint gap measurements under compression for the TiLink-P™ and the Predicate, (Figure 4 Post-Implantation). The TiLink-P™ remained in compression under cyclic loading and demonstrated a measured SIJ gap spacing of less than 0.1mm after cyclic loading, indicative of compression across the SIJ that was maintained throughout the duration of cyclic loading. Conversely, the Predicate failed to maintain compression upon cyclic loading and demonstrated a statistically significant increase in joint gap spacing, which was 4 to 5 times greater than the TiLink-P™ posterior in-line fixation system which demonstrated a maintained compression across the SIJ, (P=0.0260). The significant increase in gap spacing for the Predicate fixation system was indicative of sacroiliac joint expansion due to the loss of fixation across the SIJ.

Figure 5: Dissection of the cadaveric sacroiliac joint after cyclic testing showed significant circumferential bone apposition into each thread root along the length of the SurGenTec TiLink-P™ body.

Additional surrounding bone was captured between the anchor and body region which was assisted by the TiLink-P™ anchor's beveled design. This contributed to maintaining the compression across the SIJ.

Findings:

- Sacroiliac mean joint gap (SIJ) measurements for the **eight** cadaveric SIJ test specimens demonstrated initial compression upon implantation (prior to cyclic loading) of the SIJ implants for the TiLink-P™ and the Predicate, (Figure 4 Post-Implantation). However, only the TiLink-P™ maintained compression across the SIJ during and after cyclic testing.

- The Predicate failed to maintain compression upon cyclic loading and demonstrated a statistically significant increase in joint gap spacing of 4 to 5 times greater than the TiLink-P™ posterior in-line fixation system, (P =0.0260). This increase in the SIJ gap spacing resulted in expansion of the sacroiliac joint for the Predicate.

- The SurGenTec TiLink-P™ implanted SIJ demonstrated a reduction in joint gap spacing of less than 0.1mm that was measured before and after cyclic loading, indicative of maintained compressive forces across the SIJ under repetitive axial loading.

- The beveled design of the anchors for the TiLink-P™ implanted SIJ provided sustained compression across the sacroiliac joint (Figure 1). The bone captured between the anchor and body of the TiLink-P™ combined with the circumferential bone apposition along the body further contributed to the maintained compression across the SIJ implanted with the TiLink-P™, (Figure 5).

Conclusion:

The SurGenTec TiLink-P™ Sacroiliac Joint Fusion System compressed the sacroiliac joint upon implantation and maintained compression across the SIJ for the duration of cyclic loading under supraphysiological loads. The beveled design of the anchors for the TiLink-P™ contribute to maintaining the compressive properties across the sacroiliac joint.

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