White Paper

SACROILIAC JOINT FUSION:

Performance Integrity of the Catamaran™ SI Joint Fixation Device in a Novel, Inferior-Posterior Approach for Sacroiliac Joint Fusion

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Introduction

Early biomechanical stability is critical to establishing a favorable fusion environment to help promote arthrodesis. How well an implantable device engages and interfaces with the surrounding cortical and cancellous bone structures is paramount to attaining sufficient stability.[1,2]

The anatomical design of the sacroiliac (SI) joint consists of an irregular-shaped, interlocking joint with a large surface contact area and strong ligamentous structures that form a self-bracing mechanism. The wedging of the sacrum between the pelvic bones further contributes to SI joint stabilization. The tight ligamentous band surrounding the SI joint provides substantial stability to the joint and limits it to relatively small motions that are approximately 2° to 3° in bending and translation in multiple planes of motion. The SI joint allows for greater resistance to shear and translation. Therefore, this joint is easier to stabilize mechanically compared to other areas of the musculoskeletal system that exhibit a greater range of motion.[3,4]

The SI joint is a strong load-bearing, weight-bearing synovial joint aligned along the longitudinal, load-bearing axis of the spine when in an upright posture. The SI joint serves as a force conduit to transfer axial loads from the spine to the pelvis and lower extremities, resulting in load sharing between these structures, aiding in attenuation of impact forces.[5,6] Although the rotational forces of the SI joint are relatively low, repetitive motion created by daily activities such as walking, jogging, twisting at the hips, and jumping can increase the stresses on the joint and create the potential for SI joint degeneration and pain.[5,6]

The Catamaran Fixation Device (Tenon Medical, Inc. Los Gatos, CA) is implanted with an Inferior-Posterior approach along the longitudinal axis of the caudal portion of the SI joint. This region of the joint has the strongest cortical bone for implant purchase and best potential for bony fusion.[7]

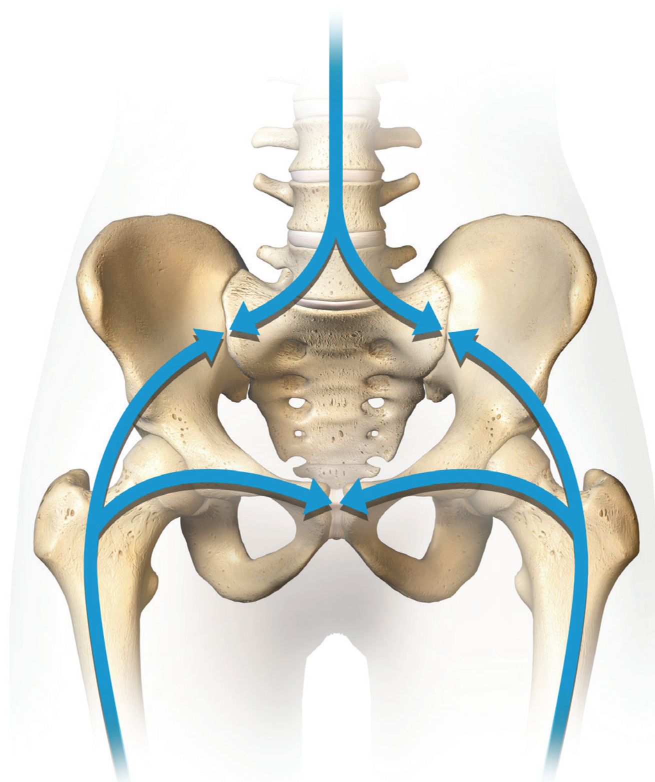

Figure 1: The SI joint is the largest joint in the body and allows for load transfer from the lumbar spine to the lower extremities.[8]

ABOUT THE CATAMARAN™ SI JOINT FIXATION DEVICE

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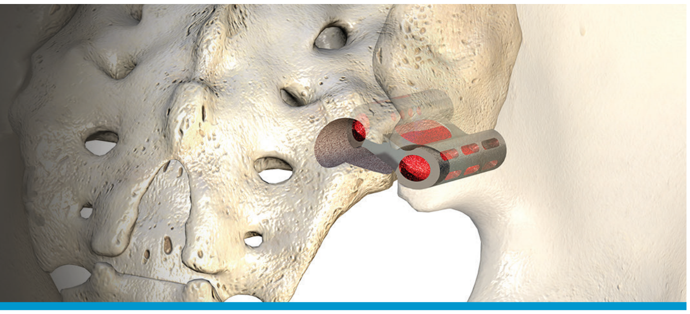

Mechanical Test Summary

STRENGTH AND ENDURANCE TESTING

In mechanical testing, the Catamaran Fixation Device demonstrated a strength that was at least 16 times greater and endurance 3-4 times greater than the forces exerted during normal human activity such as walking.[8] (*Figure 2, red arrow*). The Catamaran Fixation device is implanted through an Inferior-Posterior approach in the longitudinal direction of the SI joint (*Figure 2*). This is in contrast to devices aligned across the SI joint along the compressive force vector traversing the joint (*Figure 3, blue arrows*).

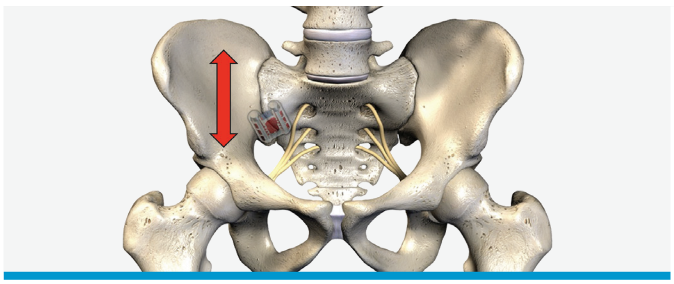

Figure 2. Implantation plane for the Catamaran Fixation Device in line with the SI joint.

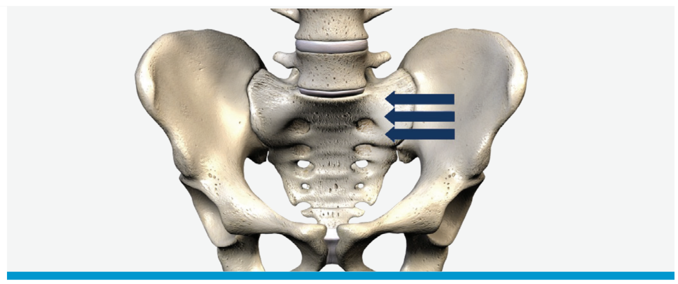

Figure 3. Implantation plane for lateral approach fixation across the SI joint.

STIFFNESS

The Catamaran Fixation Device demonstrated a stiffness under mechanical loading that was more than 60 times greater than forces exerted during normal human activity such as walking.[8]

AXIAL PULLOUT

The Catamaran Fixation Device resisted axial pullout twice that of the load imposed on the SI Joint during normal human activities, such as walking loads.[7,8]

CONCLUSION

In mechanical testing, the Catamaran Fixation Device performed favorably as a reliable sacroiliac joint fixation/stabilization system that greatly exceeded the biomechanical thresholds of the sacroiliac joint.

ASTM standards served as guides for determining test parameters

References

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Indications for use: The Catamaran SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.