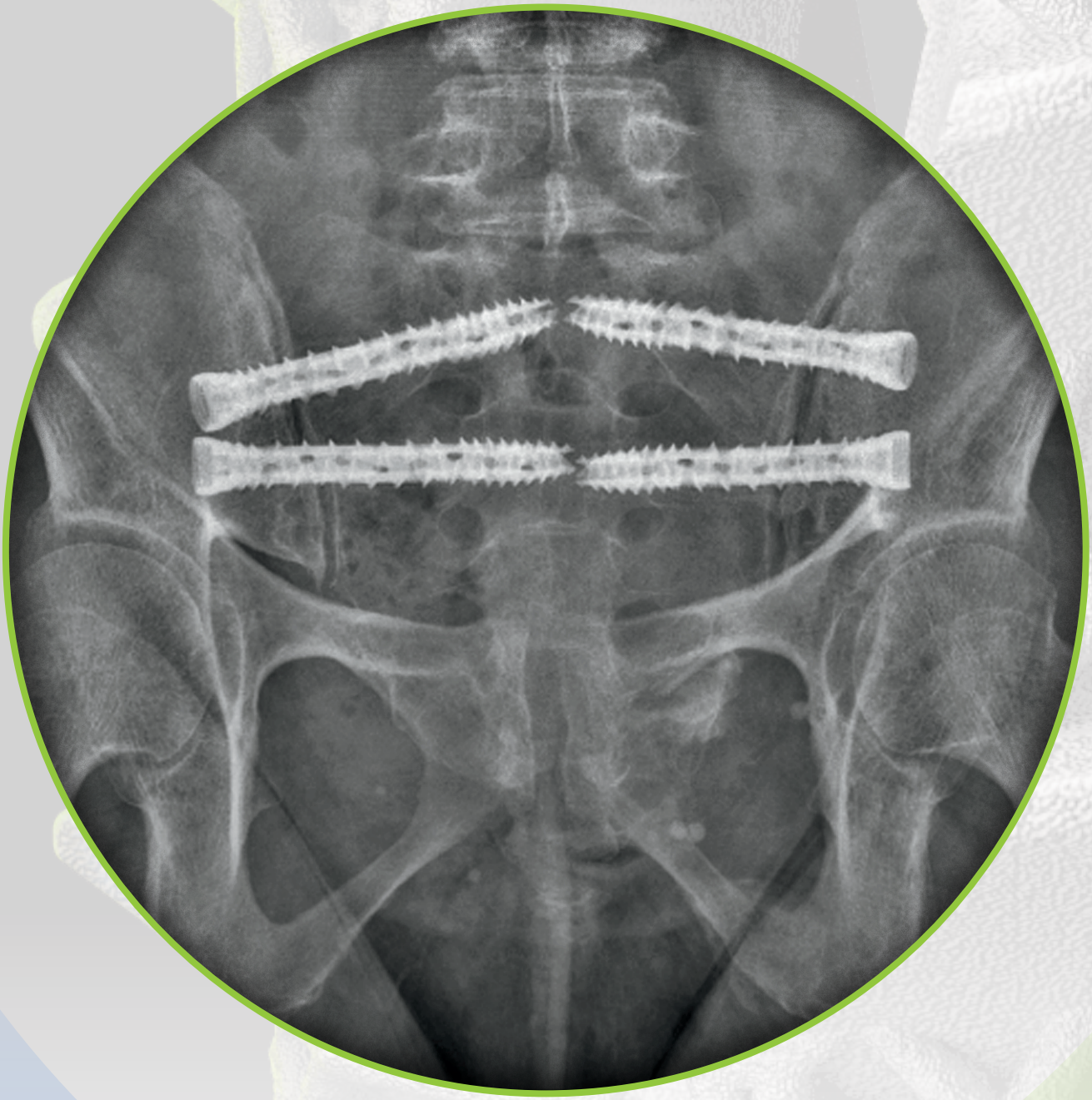
iFuse TORQ™

Cutting-Edge Pelvic Fixation & Fusion™



SI-BONE®

Sacropelvic Solutions™

Contents

Indications

The iFuse TORQ™ Implant System is intended for sacroiliac joint fusion and fracture fixation, including use in high and low energy fractures of the pelvic ring.

Navigation Tracking Instruments

SI-BONE Trackers and Universal Pin Guide are intended to enable navigation of SI-BONE instrumentation during spinopelvic surgical procedures that utilise Medtronic StealthStation™ Systems and Stealth™ Technology.

Healthcare professionals should refer to the Instructions For Use for indications for use, contraindications, warnings and precautions at *https://si-bone.com/label.*

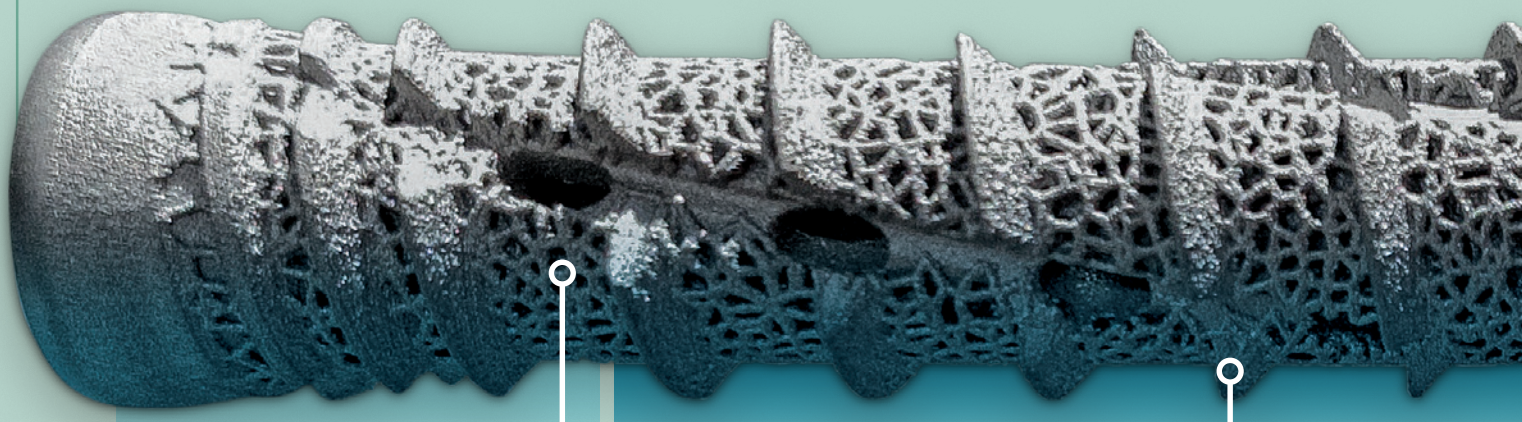
There are potential risks associated with iFuse TORQ™ Implant System procedures. They may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit *https://si-bone.com/risks.*

Complaints and adverse events relating to use of the procedure and/or device should be reported to SI-BONE, Inc., Toll Free: ***+1 (855) 511-1545*** or E-mail ***qara@si-bone.com***

Cutting-Edge Pelvic

iFuse TORQ™ 3D-printed implants are designed with cutting-edge featur

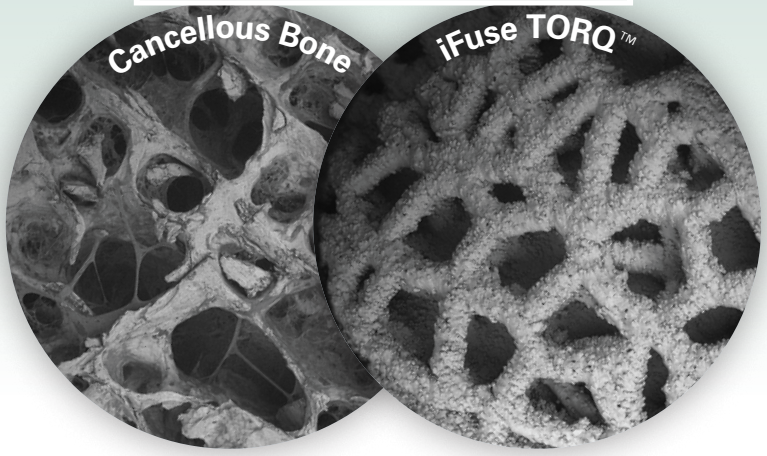
Fully-Threaded iFuse TORQ™ Implant – SI Joint Specific



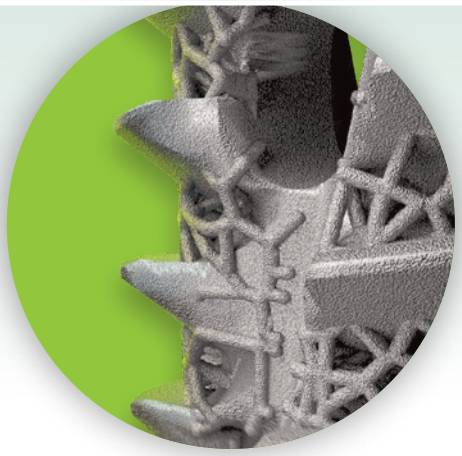
FIXATION

FUS

FuSIon 3D™ Surface
3D Printed Porous Lattice
Designed for osseointegration [1]



TORQLock™ Threads
Hooked Profile
Designed to reduce toggle

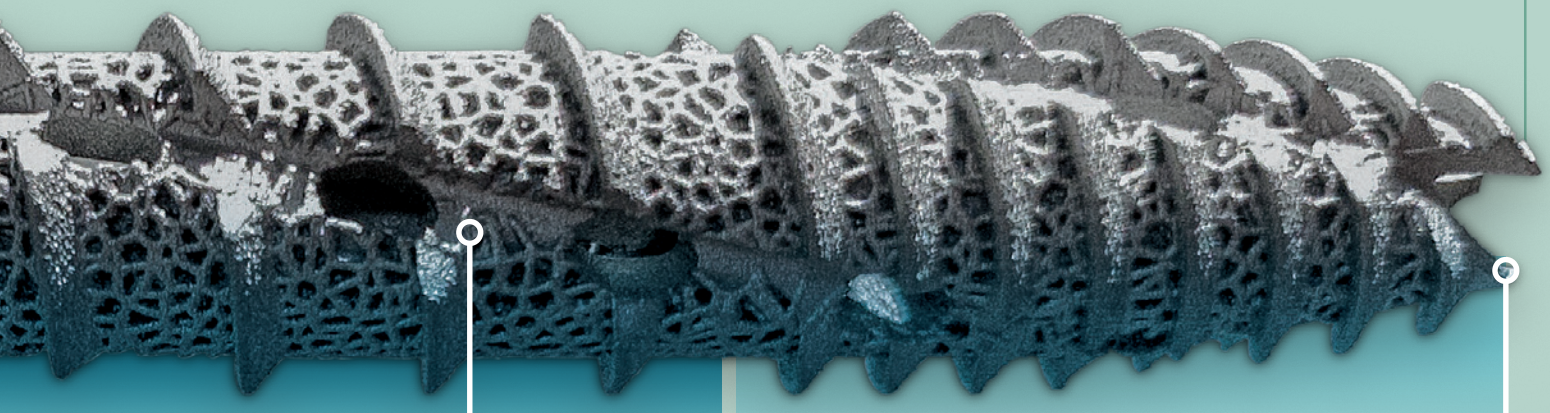


For safety and indications, please refer to the back cover.

c Fixation & Fusion™

es to optimize system performance in sacroiliac joint fusion procedures.

c Thread Pattern for Osseous Fixation and SI Joint Fusion

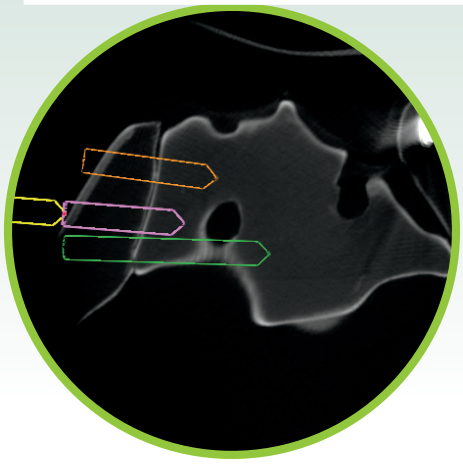


ION

FIXATION

IntelliHarvest™ Technology
Helical Flutes and Fenestrations
Self-harvest bone

iFuse TORQ™ NAV
Minimally Invasive Surgery
Navigation compatible



EZDrive™ Tip
Self-Drilling, Self-Tapping
Decreases surgical steps

SI-BONE™ Implants & Sacral Corridors: Gardner *et al.* 2010[2]

Takeaway:

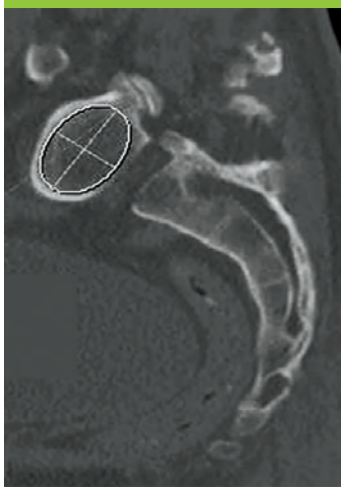
- In the 50-patient study (22% female); at the S1 level there is adequate space to safely accommodate a 10 mm diameter iliosacral style implant (12 mm diameter safe zone) in 100% of normal pelvises and 91% of pelvises with dysmorphic morphology.
- At the S2 level, a 10 mm diameter implant (12 mm diameter safe zone) will safely fit in 11% of normal pelvises and 81% of dysmorphic pelvises*.

* Gardner MJ *et al., J Orthop Trauma.* 2010 Oct;24(10):622-9

Sacral Corridors:

- S1 corridor is typically an oval shape meaning it has a major and minor diameter.
  - » Focus on the minor diameter (bold text in Table 2) when planning implant size.
- S2 corridor is typically more cylindrical.

Normal



Dysmorphic

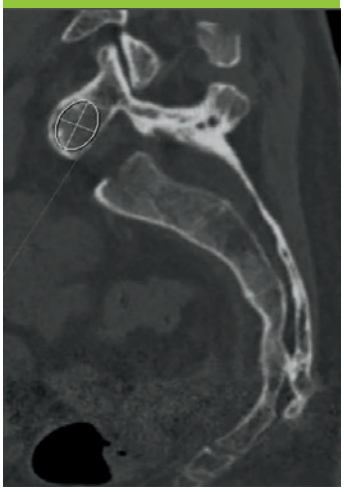


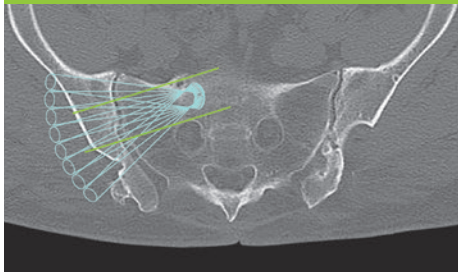
Table 1: Shows the implant diameters and safe zones (additional 1.0 to 1.5 mm around the implant) for trauma screws, iFuse TORQ™ and iFuse 3D™ implants.

Implant	Diameter	Safe Zone
Trauma Screws	7.3 mm & 8.0 mm	10 mm
iFuse TORQ™	10 mm, 11.5 mm & 13.5 mm	**12 mm** (for 10 mm)
iFuse 3D™	14.2 mm OD, 11.35 mm Height	14 mm – 17 mm

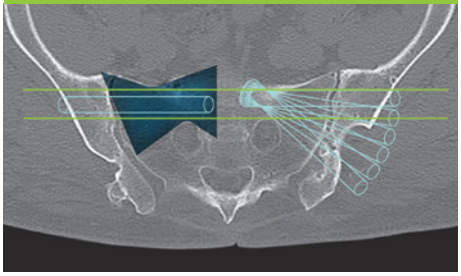
Table 2: Analysis of sacral corridor sizes of 50 patients using pelvic CT scans. *(Bold numbers represent the minor diameter of the corridor; plain text numbers represent the major diameter of the corridor.)*

S1 Unilateral	S1 Transverse	S2 Transverse
Diameter: Normal 24.1 mm x **18.1 mm**	Diameter: Normal 20.0 mm x **12.9 mm**	Diameter: Normal **10.3 mm** x 11.2 mm
Diameter: Dysmorphic 20.5 mm x **13.6 mm**	Diameter: Dysmorphic 9.9 mm x **2.6 mm**	Diameter: Dysmorphic **14.0 mm** x 14.4 mm

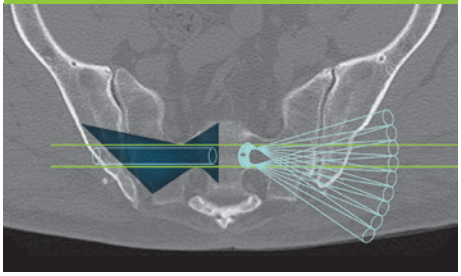
S1 – Unilateral



S1 – Transverse



S2 – Transverse



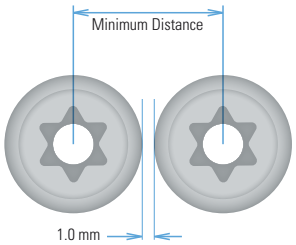
NOTE: *This retrospective multisite study used CT analysis to compare safe screw corridors in normal and dysmorphic sacra, confirming that safe iliosacral fixation is feasible in most cases despite anatomical differences.*

iFuse TORQ™: Specs and Navigation

Specifications (all sizes in mm)

	iFuse TORQ™ Implant, Fully-Threaded		
Major Diameter	**10.0**	**11.5**	**13.5**
Minor Diameter	7.5	9.0	11.0
Inner Diameter	3.4	3.4	3.4
Head Diameter	11.5	12.0	13.75
Length	35-90	35-90	35-90
Drill Bit Diameter	7.0	8.5	10.5
Tap Diameter	9.25	10.75	12.75

Minimum Implant Distance



2 Fully-Threaded Implants

Minimum Implant Distance*

iFuse TORQ™ Implant, Fully-Threaded			
	10.00	**11.5**	**13.5**
10.0	12.50		
11.5	12.75	13.00	
13.5	13.63	13.88	14.75

iFuse 3D™ to iFuse TORQ™ Implant Spacing*

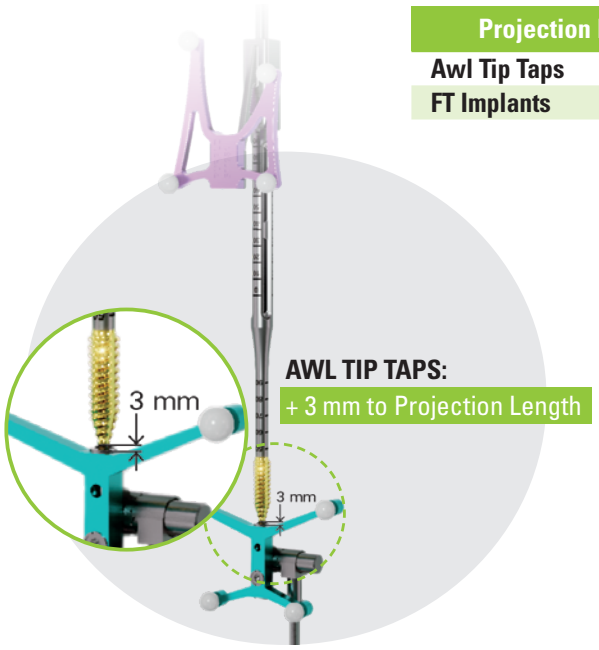
iFuse 3D™	iFuse TORQ™ Implant, Fully-Threaded		
	10.0	**11.5**	**13.5**
7.0 – Flat	11.00	11.25	12.13
7.0 – Point	13.85	14.10	14.98

* All values are in millimeters and represent center to center spacing.

PRECAUTION:

Center to center spacing assumes parallel pins. Consider adding additional distance between pins and/or Implant placement in order to prevent Implants from contacting each other during insertion.

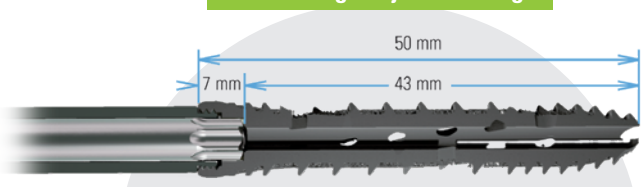
Navigation Projection – Updates for Medtronic® Stealth Station™



AWL TIP TAPS:
+ 3 mm to Projection Length

Projection Length Update	
Awl Tip Taps	+3 mm
FT Implants	-7 mm

Determining Projection Length



FULLY-THREADED IMPLANT

Example: 11.5 mm x 50 mm
50 mm Implant Body
– **7 mm of Driver in Implant**
= 43 mm Projection Length
– 7 mm from Implant
Projection Length when on Driver

Sheep Study: Comparison of the iFuse TORQ™ Implant to a Fenestrated SI Device and Trauma Screw[3]

Summary

- **Objective:** Compare the removal torque and histology of the iFuse TORQ™ implant to a 12 mm fenestrated sacroiliac (SI) device and 7.3 mm trauma screw at 3 and 6 weeks in sheep cancellous bone.
- **Results:** Histology demonstrated ongrowth and ingrowth with iFuse TORQ™ at 3 weeks which was greater at 6 weeks. Removal torque at 6 weeks showed iFuse TORQ™ was 7x greater than a 12 mm SI device and 23x greater than a 7.3 mm trauma screw.
- **Conclusion:** iFuse TORQ™ provides improved biomechanical stability within sheep bone compared to machined implants as a result of advanced design features and manufacturing processes*.

* Sheep model data is not necessarily indicative of human clinical outcomes.

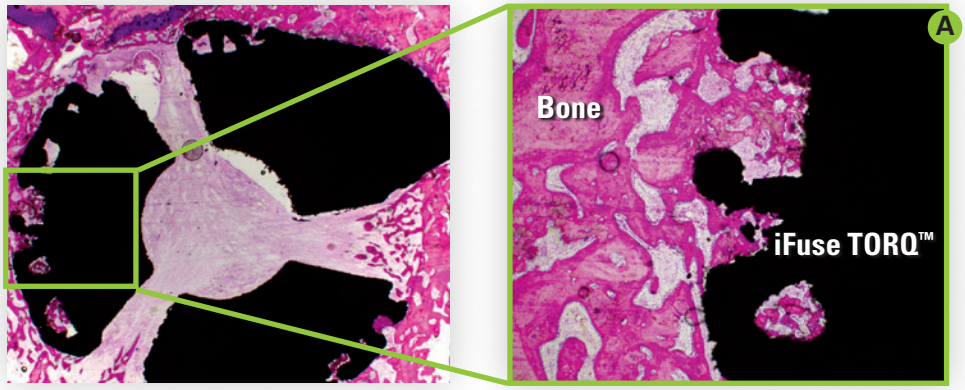
David Polly *et al. J Spine Surg* 2024 Dec 20;10(4):616-626. doi: 10.21037/jss-24-67. Epub 2024 Nov 11. Osseointegration and fixation opportunities of sacroiliac instrumentation: a preclinical evaluation in a large animal model.

Study Design

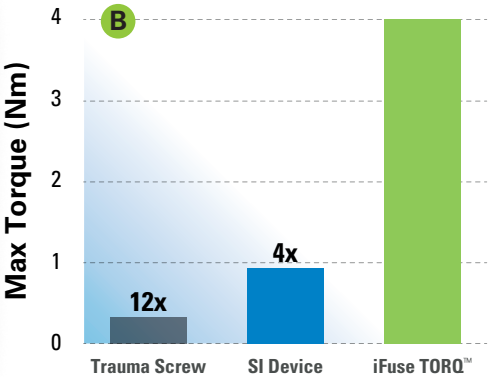
- **Test groups:** Titanium alloy implants: 11.5 mm iFuse TORQ™, 12 mm fenestrated SI device and a 7.3 mm trauma screw.
- **Implantation sites:** Cancellous bone of sheep distal femur and proximal tibia (n=4 per group).
- **Time and endpoints:** Implants were harvested at 3 and 6 weeks and in vivo responses were evaluated using radiographs, torsional testing, and histologic examination.

Group	Description
iFuse TORQ™	11.5 mm x 40 mm
SI Device	12 mm x 40 mm
Trauma Screw	7.3 mm x 40 mm

3-Week Histology Imaging & Torque Out



iFuse TORQ™

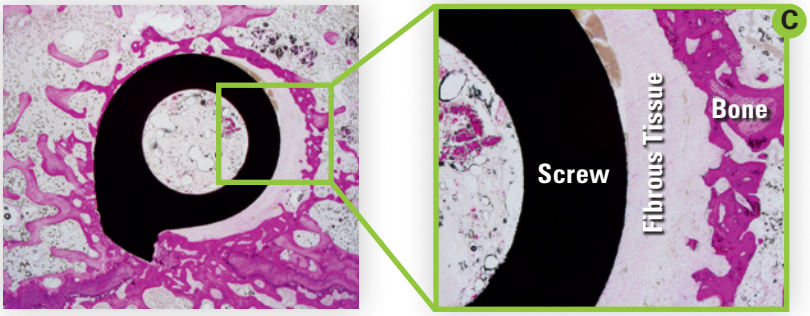


3-week histology of sheep bone demonstrates bone ongrowth and ingrowth with the iFuse TORQ™, 3D printed porous surface **(Fig. A).** Torque out testing shows iFuse TORQ™ has 4x greater torque out *vs.* the SI device, and 12x greater torque out *vs.* the trauma screw **(Fig. B).**

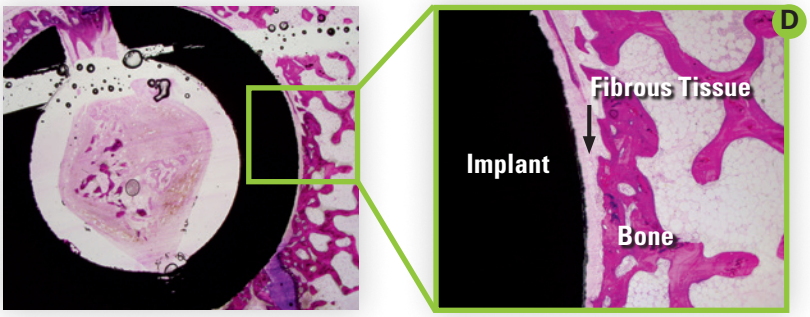
Sheep Study: 6-Week Histology Imaging, Torque Out & Gross Imaging

6-week histology imaging of sheep bone shows a layer of fibrous tissue at the bone and implant interface for both the trauma screw and SI device **(Figs. C, D)**. iFuse TORQ™ shows sheep bone incorporation into the implant surface and between the hooked threads **(Fig. E).**

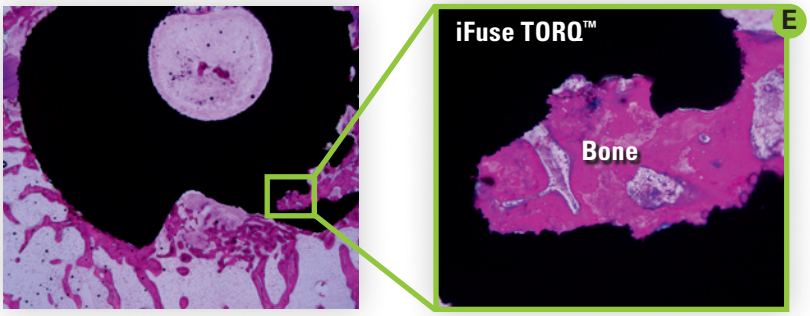
6-week torque out testing shows iFuse TORQ™ torque out improves to 7x *vs.* the SI device, and 23x *vs.* the trauma screw **(Fig. F).** 6-week gross imaging of iFuse TORQ™ shows sheep bone incorporation into the porous surface and fenestrations of the 3D printed implant **(Fig. G).**



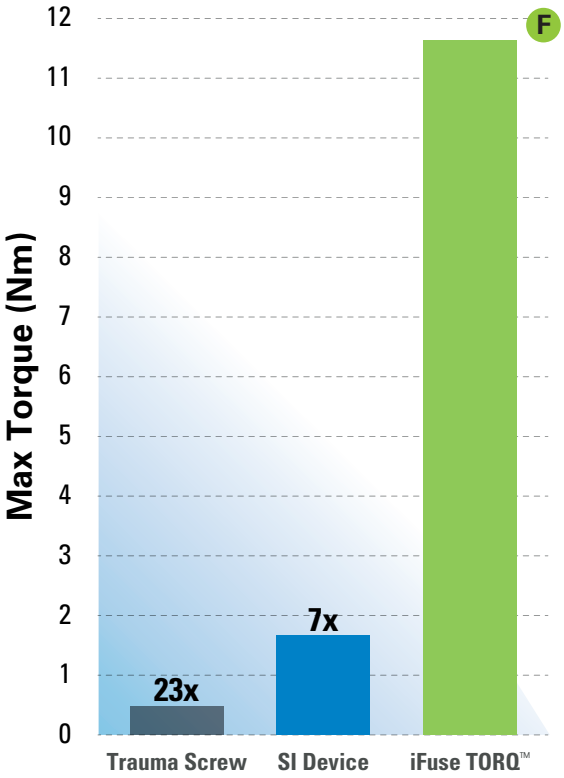
7.3 mm Trauma Screw



12 mm SI Device



11.5 mm iFuse TORQ™



iFuse TORQ™

iFuse TORQ™ case: SI Joint Pain Masked As Hip Pain for 10 Years

"A diagnosis that is often present but rarely detected."

Robert Limoni, M.D.◊
Orthopedic Surgery
Froedtert & Medical College of Wisconsin

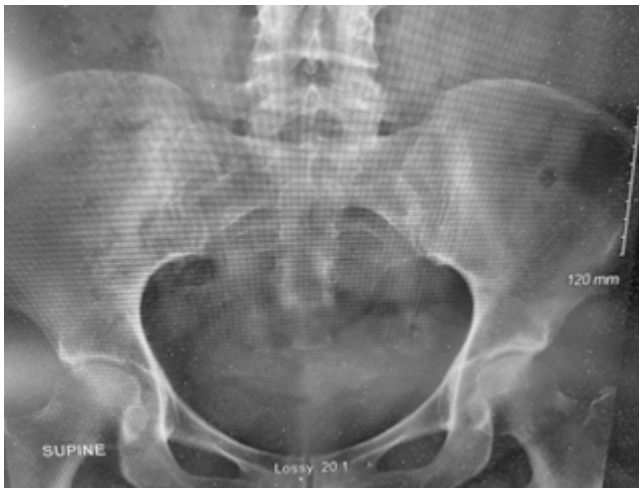
Medical School: Medical College of Wisconsin, Milwaukee, WI.
Residency: Grand Rapids Medical Education & Research Center, Grand Rapids, MI.

Dr. Limoni is a board-certified Orthopedic Surgeon specializing in total joint replacement procedures and hip and knee surgeries.

◊ Paid Consultant for SI-BONE, Inc.

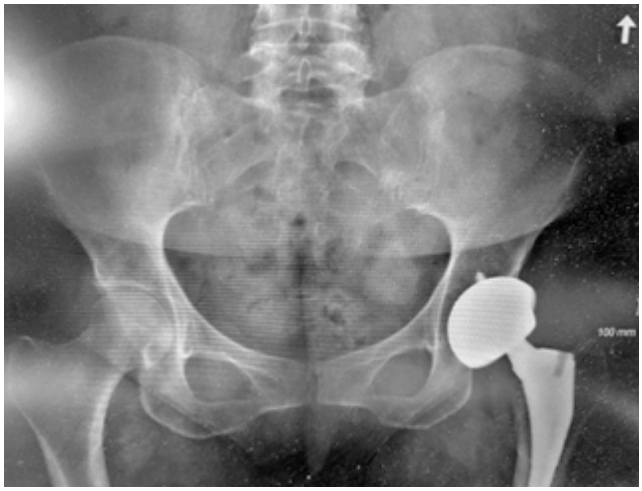
Patient History:

- 53 yo female.
- 10-year history of left posterior hip pain.
- Initial diagnosis determined by MRI was a superior labral tear with a pincer lesion.
- Managed by multiple providers including hip arthroscopy specialist, joint arthroplasty surgeon and interventional pain specialist.



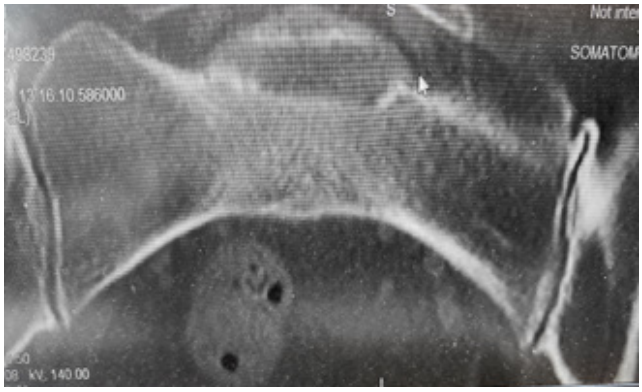
Treatment History:

- Hip arthroscopy and rim trimming with no resolution of posterior hip pain.
- Underwent a second hip arthroscopy a year later and still no resolution of posterior hip pain.
- Referred for total hip arthroplasty (THA) with no pain improvement 3 months post-op.
- Subsequently referred to interventional pain management for SI joint injections which provided short durations of posterior hip pain relief over the course of 5 years.



iFuse TORQ™ case: SI Joint Pain Masked As Hip Pain for 10 Years

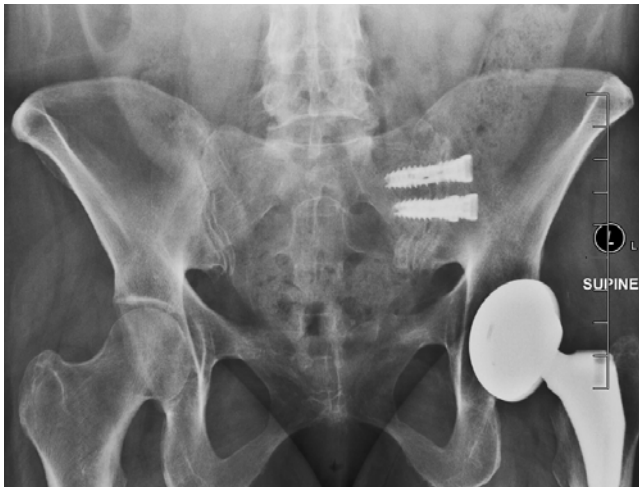
- Patient returned to her hip surgeon who performed a CT scan of the pelvis which showed no problems with the THA. Note degenerative changes in the left SI joint.
- Patient went for a second opinion to Dr. Limoni who performed a thorough SI joint evaluation.



Through history, physical exam and positive response to diagnostic injections, the left SI joint was determined to be her pain generator.

Surgical Treatment:

- MIS SI joint fusion with iFuse TORQ™ was performed.

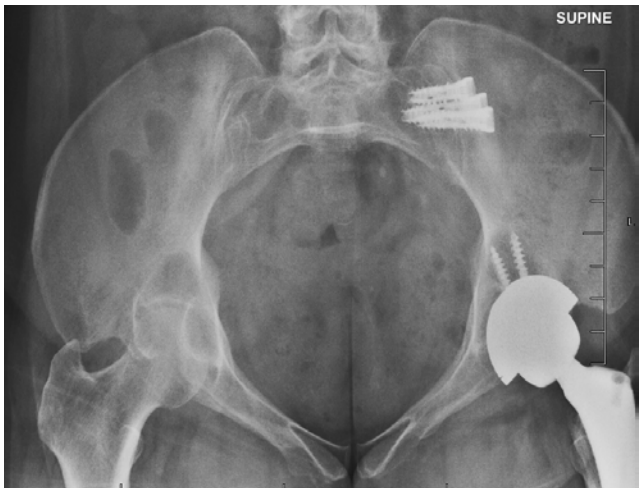


PostOp: *(Patient results may vary)*

Patient had marked pain improvement at 6-week follow-up.

Discussion:

The diagnosis and treatment of hip pain should include history, physical examination and diagnostic imaging. Femoral acetabular impingement (FAI) may result in damage to the labrum and joint surfaces. FAI may also result in altered hip biomechanics with resultant increased force transfer to the SI joint and pelvis. FAI patients may experience pain in the pubic symphysis, sacroiliac joint and/or lumbar spine in early stage and radiographically evident degeneration of these structures in later stages. Hip surgeons should consider the lumbar spine and sacroiliac joint in the differential diagnosis and workup of patients presenting with hip pain.



iFuse TORQ™ case: A New Dimension in SI Joint Fusion

"iFuse TORQ™ expands opportunities for SI joint stabilization"

◊ Paid Consultant for SI-BONE, Inc.

Malcolm R. DeBaun, M.D.◊
Director of Orthopaedic Trauma
Duke University

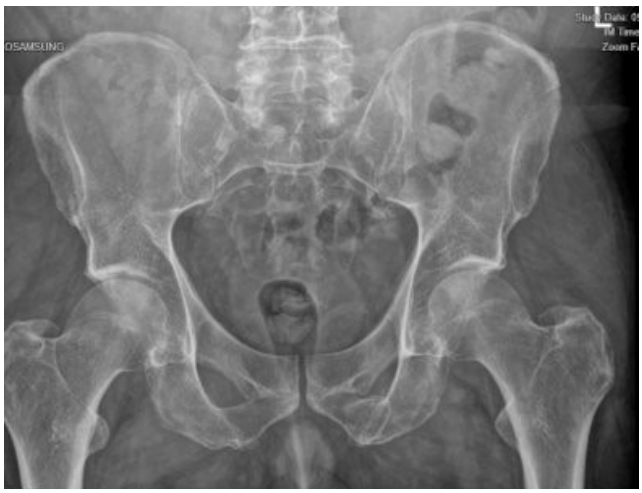
Medical School: Stanford University School of Medicine, CA.
Residency: Orthopaedic Surgery, Stanford University, CA.
Fellowship: Orthopaedic Trauma, Harborview Medical Center, Seattle, WA.

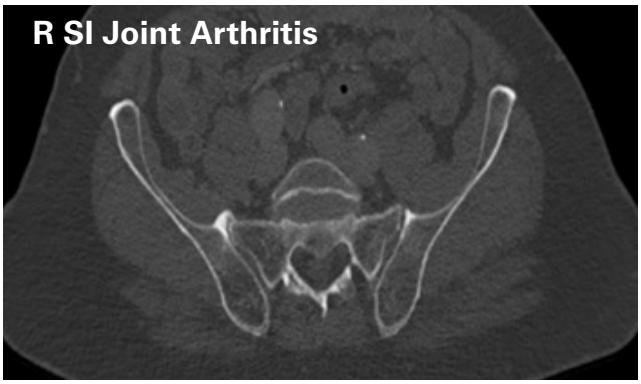
Malcolm DeBaun, M.D. is an Orthopaedic trauma surgeon at Duke University Hospital focusing on musculoskeletal innovation and surgical tactics for pelvis/acetabulum, periarticular and revision fracture surgery.

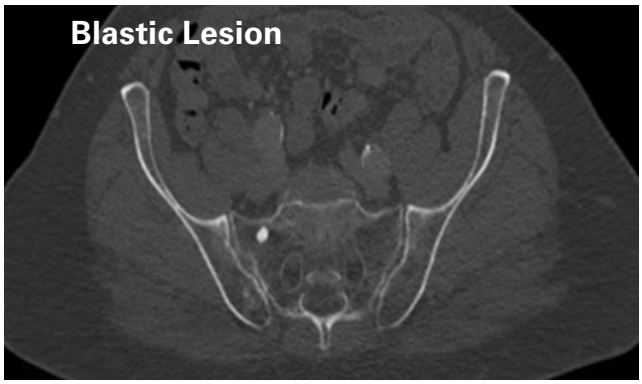
CASE 1: SI Joint Dysfunction after metastatic sarcoma

Patient History:

- 68 y/o male with metastatic liposarcoma.
- Mets to right Ilium.
- Underwent radiation therapy.
- Presented with SI joint pain and physical examination consistent with SI joint dysfunction.
- Positive response to diagnostic injection.
- Temporary pain relief with SI joint injection (10 days).
- Wanted to avoid open procedure.



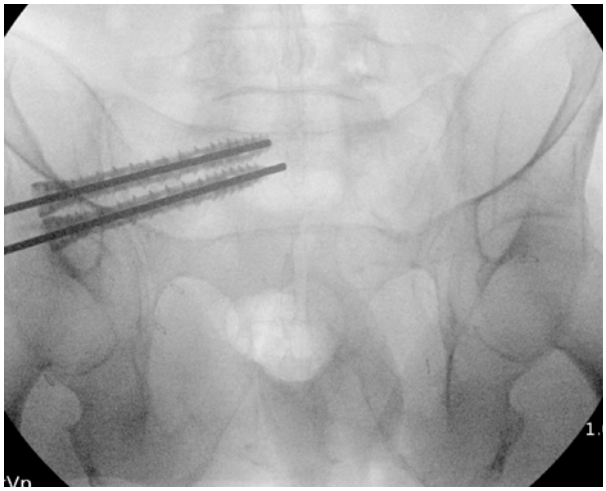


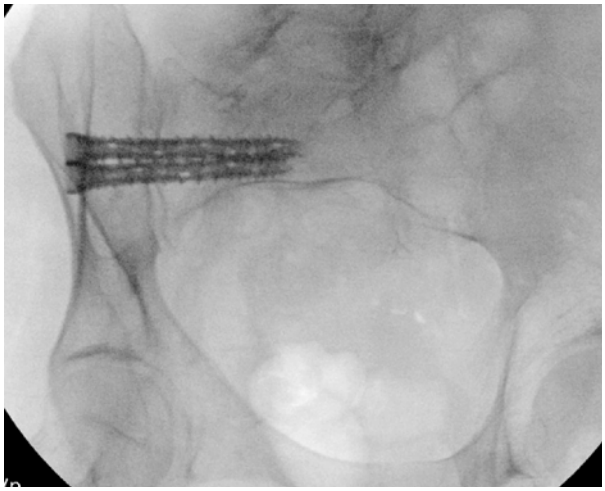


iFuse TORQ™ case: A New Dimension in SI Joint Fusion

Surgical Treatment:

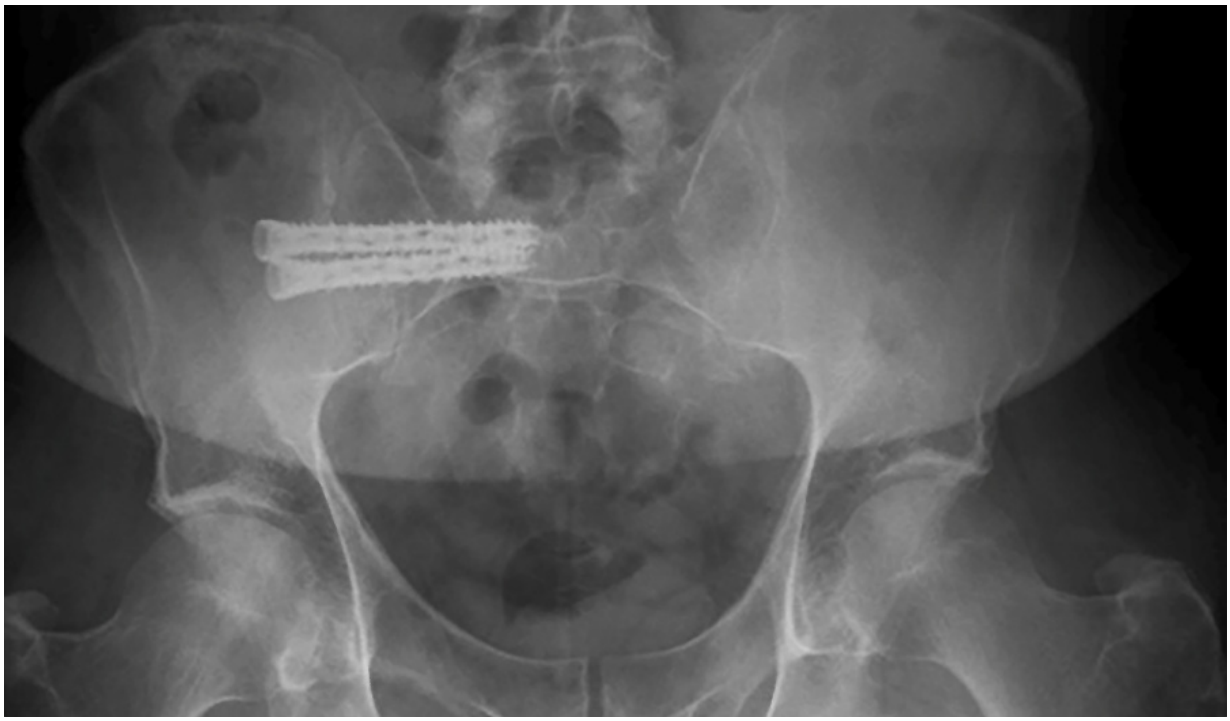
Percutaneous Right SI joint Fixation x 2 iFuse TORQ™ implants.





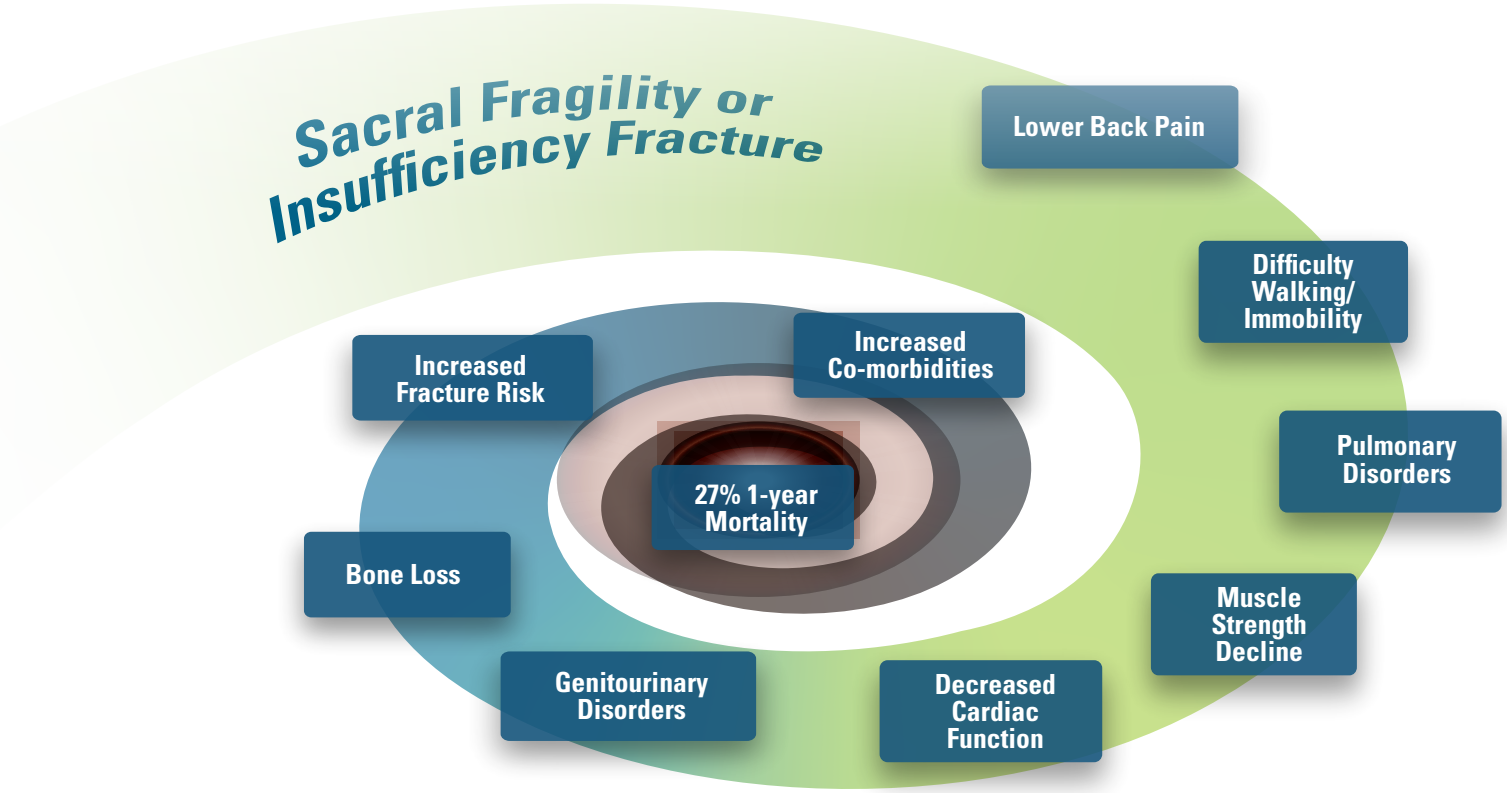
PostOp: *(Patient results may vary)*

- Tolerated procedure well.
- Immediate weight bearing as tolerated.
- Marked pain improvement at 2 weeks post-op.
- Patient very satisfied with minimally invasive option.
- No assisted devices required.



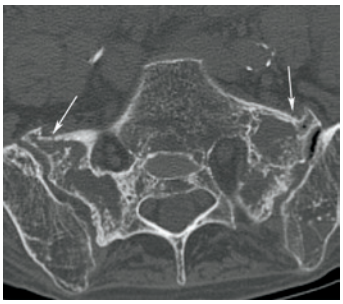
Sacral Fragility and Insufficiency Fractures

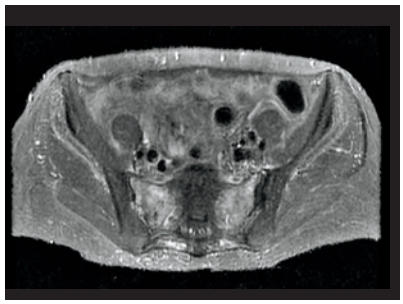
DOWNWARD SPIRAL OF CONSERVATIVE TREATMENT [4,5]



PATIENT CARE CONTINUUM [6]

Offending event
A fall from standing height or no recalled traumatic event.





ADVANCED IMAGING
CT (60-75%) or MRI (nearly 100%) needed for sensitivity in diagnosis of sacral fragility or insufficiency fracture.[7]

Observation
24 to 48-hour monitoring for pain control and mobility.

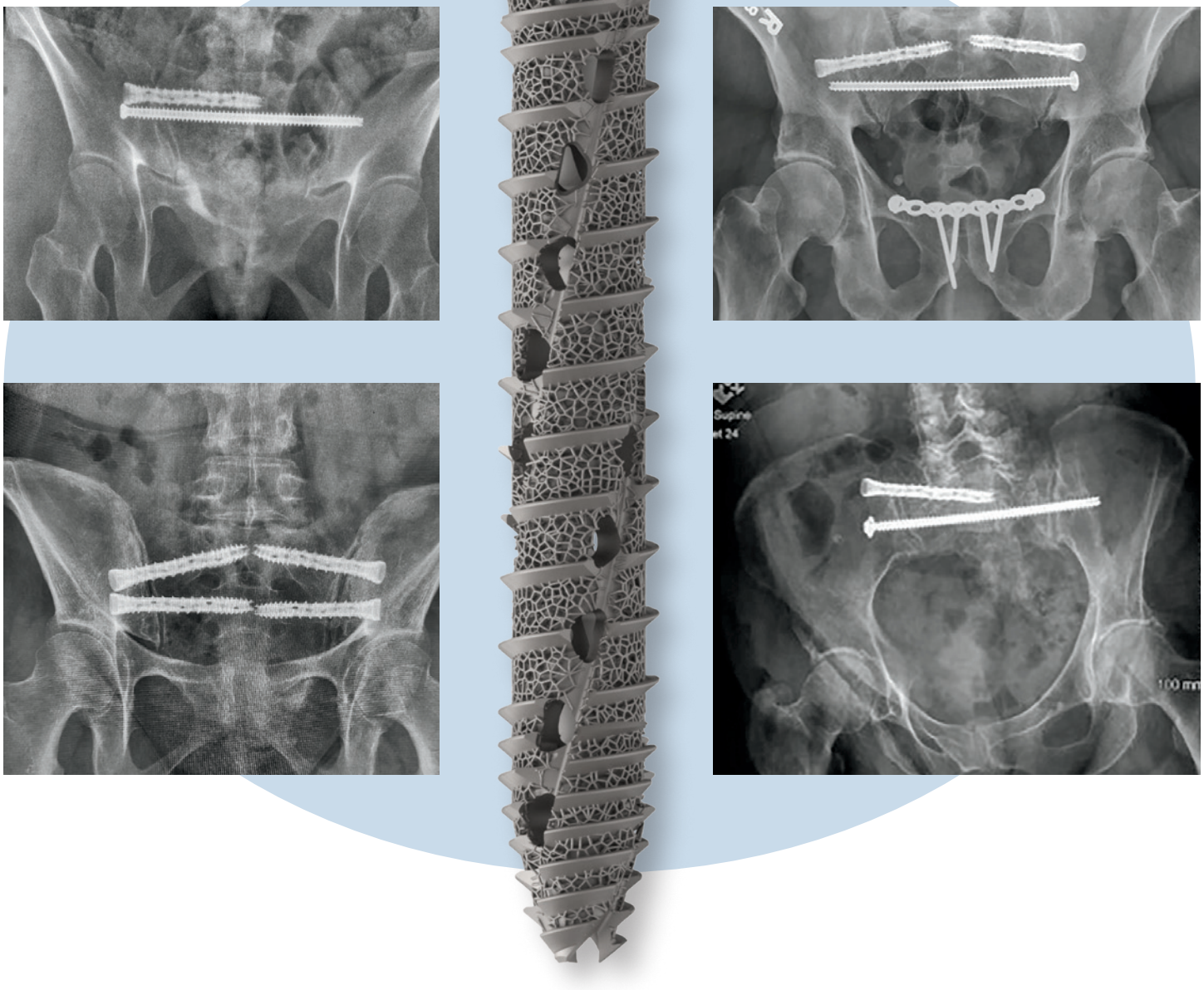
CONSIDER:

MINIMALLY INVASIVE SURGERY
if patient **non-ambulatory** after observation

OR

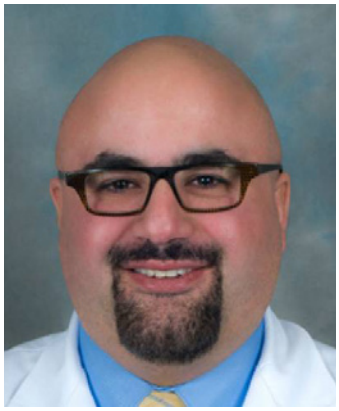
NON-SURGICAL MANAGEMENT
if patient **ambulatory** after observation

Pelvic Fracture Fixation with iFuse TORQ™ Implants



iFuse TORQ™ case: A Novel Approach to Pelvic Fracture Fixation

"Unique implants with specific indications"



Reza Firoozabadi, M.D., M.A.◊
Orthopaedic Trauma Surgeon. Harborview Medical Center and a UW Associate Professor of Orthopedics and Sports Medicine

◊ Paid Consultant for SI-BONE, Inc.

Medical School: Boston University School of Medicine.
Fellowship: Harborview Medical Center/University of Washington.
Residency: University of California, San Francisco.

Dr. Firoozabadi is a board-certified orthopedic surgeon whose interests focus on both the clinical and technical aspects of orthopaedic trauma surgery and the injured patient. He has a specific interest in pelvic and acetabular surgery, both from a clinical as well as a research standpoint.

Fracture Fixation of U-Type Sacral Fragility Fracture†

Patient History:

- 75 yo female with inability to mobilize 6 weeks after a fall.
- Minimal improvement in posteriorly-based pain and can only mobilize from bed to a chair at rehab facility.
- CT scan confirmed U-type fracture at 6 weeks **(Figs. 1 and 2).**
- S1 osseous corridor would not accommodate trans-sacral style screws therefore decision was made for bilateral iliosacral style implants.
- Family was not interested in additional lumbopelvic fixation due to the patient's thin soft tissue envelope, and the posterior spinal instrumentation would most likely be symptomatic.

† Pain and disability improvement consistent with early SAFFRON (NCT05426356) trial outcomes. SI-BONE data on file.

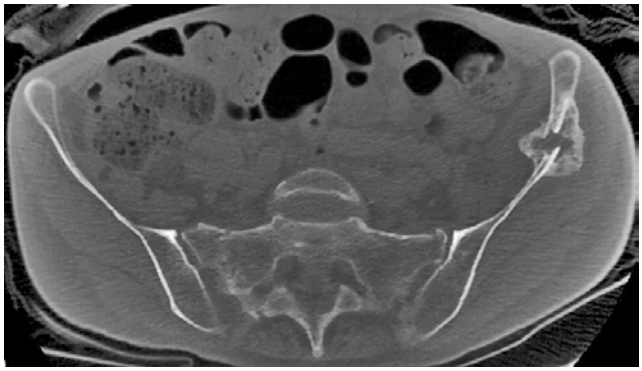


Fig. 1: Axial CT scan demonstrating bilateral nondisplaced sacral fractures.

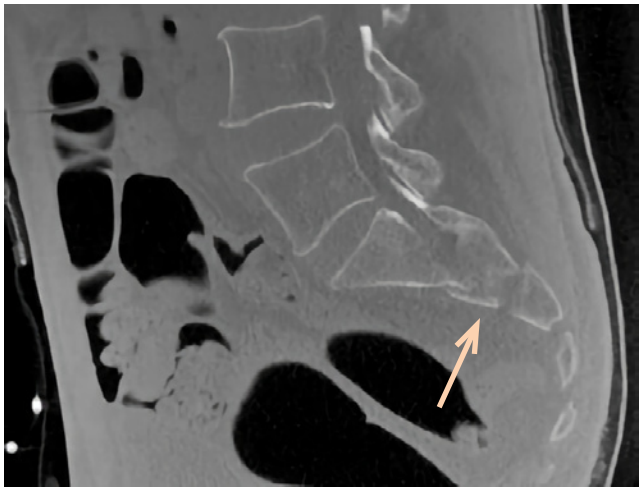


Fig. 2: Sagittal CT scan demonstrating transverse component at the junction of S1 and S2 making this a sacral U-type of fracture.

iFuse TORQ™ case: A Novel Approach to Pelvic Fracture Fixation

Surgical Treatment:

8.0mm ilio-sacral style screw was placed across the fracture with poor purchase, most likely due to patient being severely osteopenic. Surgical options were to add percutaneous lumbopelvic fixation or utilize a "rescue screw" **(Fig. 3).**

Surgeon elected to remove the screw and replace with a 11.5mm iFuse TORQ™ implant which had excellent purchase. Another 11.5mm iFuse TORQ™ implant was placed on the contralateral side to allow immediate weightbearing. No implants placed in S2 since the fracture was cranial to S1/S2 junction **(Fig. 4).**

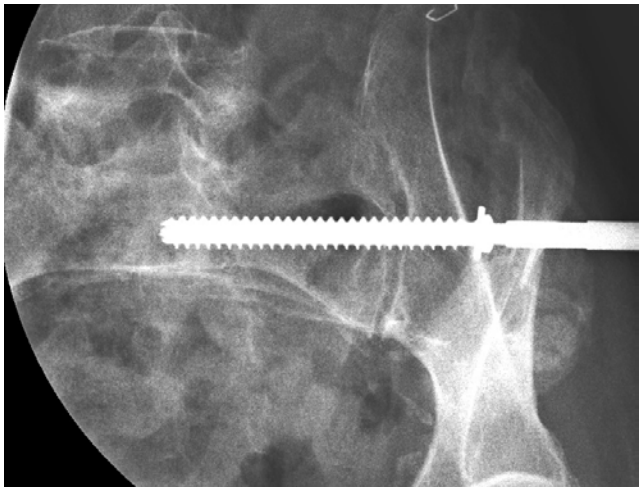


Fig. 3

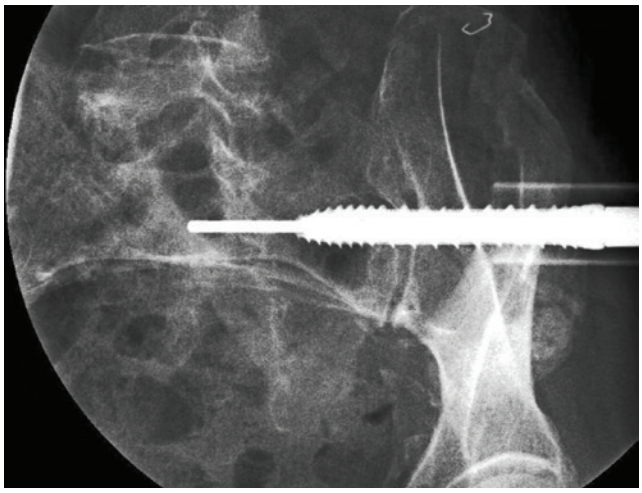


Fig. 4

PostOp: *(Patient results may vary)*

Outlet radiograph demonstrating placement of bilateral 11.5 iFuse TORQ™ implants (**Fig. 5).**

Patient was able to immediately weight-bear postoperative day 1. Patient had marked improvement in posterior pelvic pain. She had slight discomfort bilaterally at her surgical sites. She was able to be discharged on postoperative day 2 to her home.

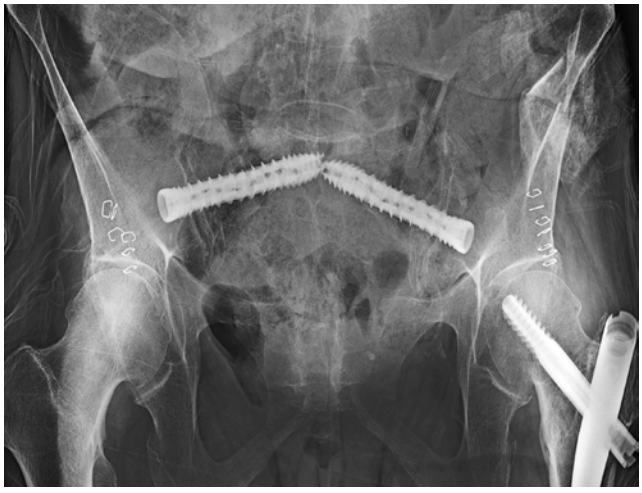


Fig. 5

iFuse TORQ™ case: A New Dimension in SI Joint Fusion

"iFuse TORQ™ expands opportunities for SI joint stabilization"

Malcolm R. DeBaun, M.D.◊
Director of Orthopaedic Trauma
Duke University

Medical School: Stanford University School of Medicine, CA.
Fellowship: Orthopaedic Trauma, Harborview Medical Center, Seattle, WA.
Residency: Orthopaedic Surgery, Stanford University, CA.

Malcolm DeBaun, M.D. is an Orthopaedic trauma surgeon at Duke University Hospital focusing on musculoskeletal innovation and surgical tactics for pelvis/acetabulum, periarticular and revision fracture surgery.

◊ Paid Consultant for SI-BONE, Inc.

CASE 2: Lumbopelvic Instability after Chronic Sacral U- Fracture†

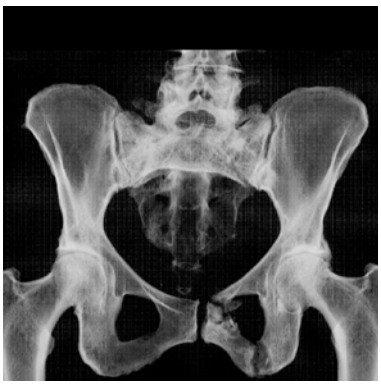
Patient History:

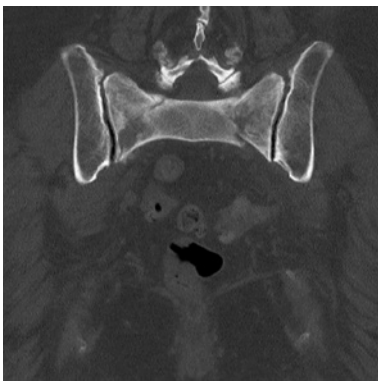
- 76 yo female; fall 3 months prior.
- Managed non-operatively by outside hospital.
- 10/10 pain; difficulty ambulating for 3 mo.
- MRI done and self-referral to IR for sacroplasty.
- Referred to ortho by IR for pelvic fixation.

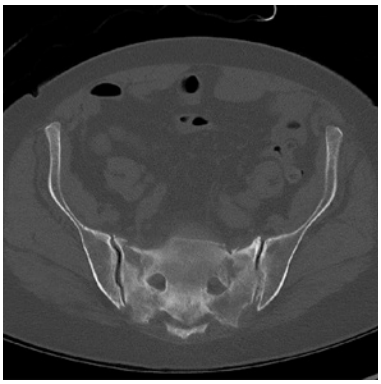
Diagnosis:

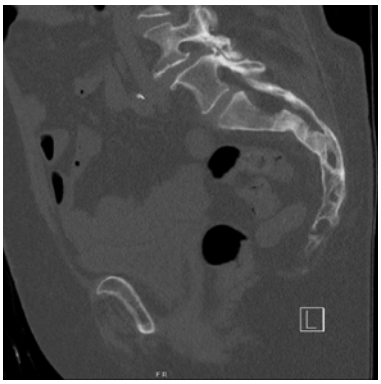
- Chronic Sacral U-type fracture with kyphotic deformity.
- Anterior ring disruption.
- Osteopenia.

† Pain and disability improvement consistent with early SAFFRON (NCT05426356) trial outcomes. SI-BONE data on file.





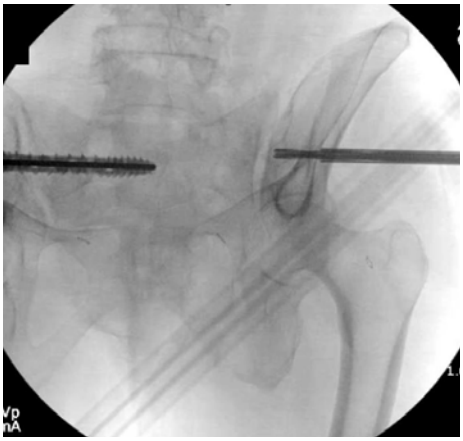


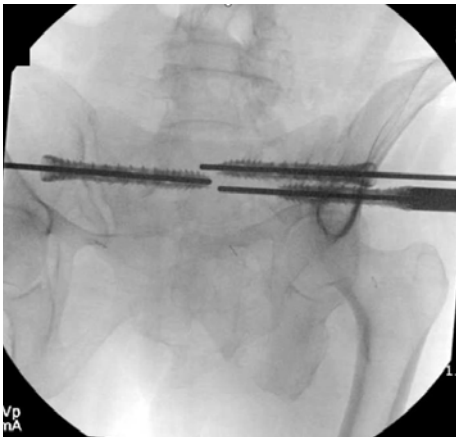


iFuse TORQ™ case: A New Dimension in SI Joint Fusion

Surgical Treatment:

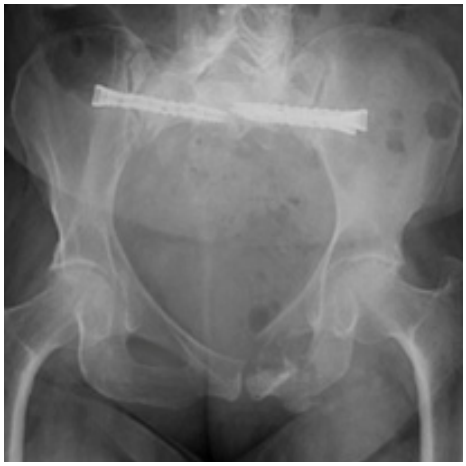
Bilateral sacral fracture fixation with iFuse TORQ™.

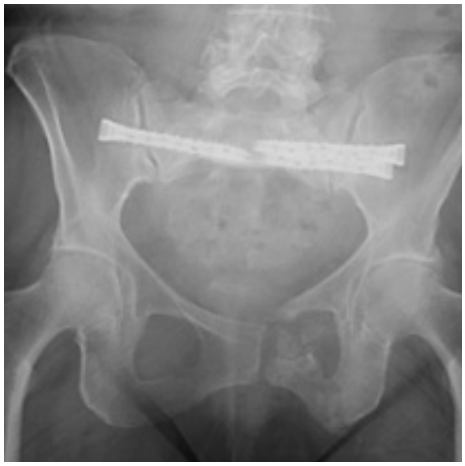


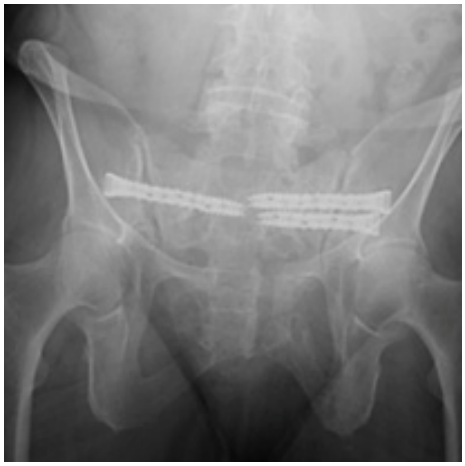


PostOp: *(Patient results may vary)*

- Tolerated procedure well.
- Immediate weight bearing as tolerated.
- Ambulated 150 feet POD 1 and discharged hom.
- Pain improvement and healed fracture at 2 months.
- No progression of kyphotic deformity.







iFuse TORQ™ case: A Novel Approach to Pelvic Fracture Fixation

"iFuse TORQ™ is a thoughtfully designed fusion device that offers immediate fixation"

◊ Paid Consultant for SI-BONE, Inc.

Michael Gardner, MD◊
Professor and Vice Chair Chief,
Orthopaedic Trauma
Stanford University School of Medicine

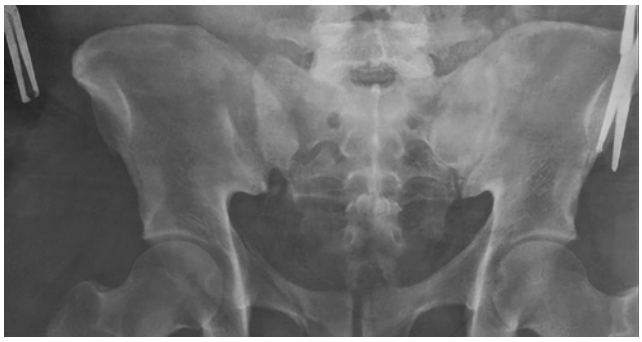
Medical School: Drexel University College of Medicine Orthopaedic Surgery Program (2001), Philadelphia, PA.
Harborview Medical Center, Seattle, WA, Orthopaedic Trauma Surgery.
Residency: Hospital for Special Surgery Orthopaedic Surgery Residency, New York, NY.

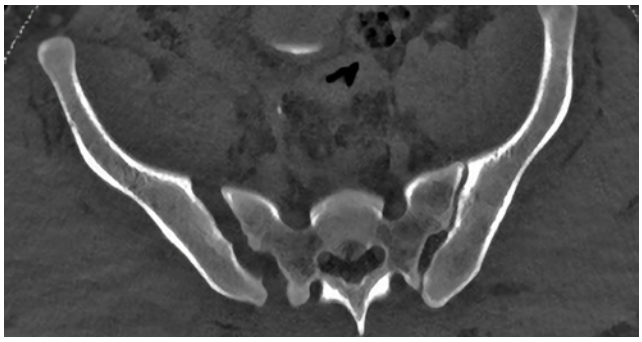
Dr. Gardner specializes in orthopaedic trauma surgery, and treating all aspects of fractures of the upper extremity (except the hand), lower extremity, and pelvis, as well as nonunions and malunions.

CASE 1: High Energy SI Joint Disruption

Patient History:

- 34 yo male.
- Unrestrained passenger highway motor vehicle crash.
- Complete right SI joint injury.
- Associated aortic root injury.
- Placed in circumferential resuscitative sheet.



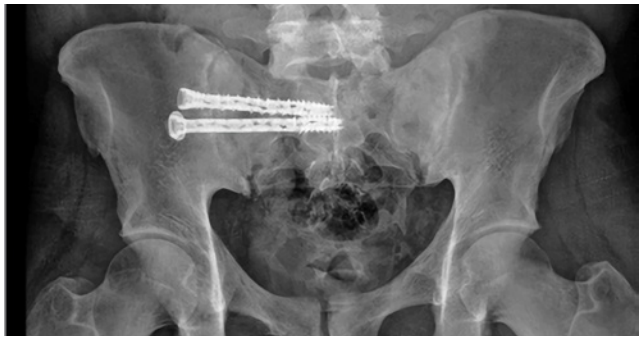


Surgical Treatment:

- Taken to the OR on day of injury.
- Reduction initially with C-clamp.
- Fixation with iFuse TORQ™ x 2.

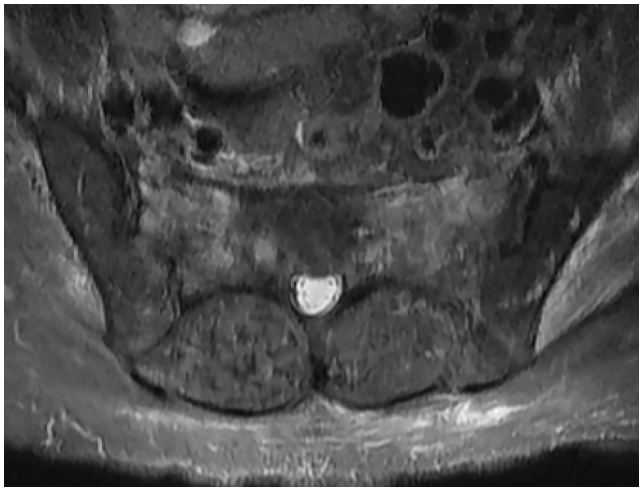
PostOp: *(Patient results may vary)*

- Tolerated procedure well.
- Mobilized at 4.5 weeks.
- Stable fixation.
- Marked pain improvement.
- Returned to full functional activities at 5-month follow-up.



iFuse TORQ™ case: A Novel Approach to Pelvic Fracture Fixation

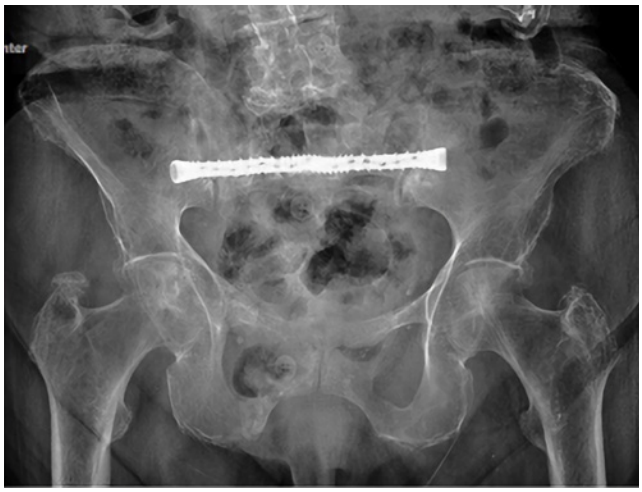
CASE 2: Pelvic Insufficiency Fracture†



Patient History:

- 88 yo female.
- No history of trauma.
- Inability to ambulate due to pain in bilateral sacral region for 5 weeks.
- X-ray normal.
- MRI confirmed bilateral sacral insufficiency fractures.

Surgical Treatment:



- Treated with bilateral iFuse TORQ™ implants.

PostOp: *(Patient results may vary)*

- Immediate pain relief postoperatively.
- Mobilized weight-bearing on Postop day 1.
- Marked improvement in pain at 3-month follow-up.

† Pain and disability improvement consistent with early SAFFRON (NCT05426356) trial outcomes. SI-BONE data on file.

References

1. SI-BONE 301067-TS
2. Gardner MJ, *et al. J Orthop Trauma.* 2010 Oct;24(10):622-9
3. Polly DW, *et al. J Spine Surg* 2024 Dec 20;10(4):616-626
4. Morris R, *et al. Postgrad Med J.* 2000;76 (900):646.
5. Babayev M, *et al. Am J Phys Med Rehab.* 2000;79:404-09
6. Rommens PM, *et al. Injury.* 2013; 44: 1733–44.
7. Lyders EM, *et al. Amer J Neurorad* 2010;31(2): 201-210.

iFuse TORQ™ Implant System Cutting-Edge Pelvic Fixation & Fusion™

Specifications (in mm)			
Diameter	10.0	11.5	13.5
Length	35-90	35-90	35-90
Part Numbers			
Implant	100XXT	115XXT	135XXT

SI-BONE® | **iFuse** TORQ™
Implant System

Indications

The **iFuse TORQ™ Implant System** is intended for sacroiliac joint fusion and fracture fixation, including use in high and low energy fractures of the pelvic ring.

Navigation Tracking Instruments

SI-BONE Trackers and Universal Pin Guide are intended to enable navigation of SI-BONE instrumentation during spinopelvic surgical procedures that utilise Medtronic® StealthStation™ Systems and Stealth™ Technology.

There are potential risks associated with iFuse procedures. They may not be appropriate for all patients, and all patients may not benefit.

Healthcare professionals should refer to the Instructions For Use for indications, contraindications, warnings, and precautions at *https://si-bone.com/label*

For information about the risks, visit *https://si-bone.com/label*

℞ ONLY

SI-BONE S.r.l. (European HQ)
Via Postcastello, 6
21013 Gallarate (VA),
Italy
t +39 0331 1561179
infoeurope@si-bone.com

SI-BONE Deutschland GmbH
Steubenstraße 46
D - 68163 Mannheim,
Germany
t +49 (621) 976860 00
infodeutschland@si-bone.com

SI-BONE UK Ltd.
Building 81, Greenham Business Park
Newbury, Berkshire
RG19 6HW, United Kingdom
t +44 1423 860025
Infouk@si-bone.com

SI-BONE S.r.l. (France)
6 Rue des Merisiers
FR-68920 Wettolsheim les Erlen,
France
t +33 (0)9 73 79 03 92
france@si-bone.com

OUS | Providers | PM-12072-OUS-B1
September 2025

ous.si-bone.com

SI-BONE, Inc.
471 El Camino Real,
Suite 101
Santa Clara, CA 95050
USA
t 408.207.0700
f 408.557.8312
info@SI-BONE.com
www.SI-BONE.com