Sacroiliac (SI) Joint Fusion with iFuse-3D™ in Non-Traumatic Sacral Fractures

Black JD. 2019 OTA Poster Presentation.[1]

SUMMARY

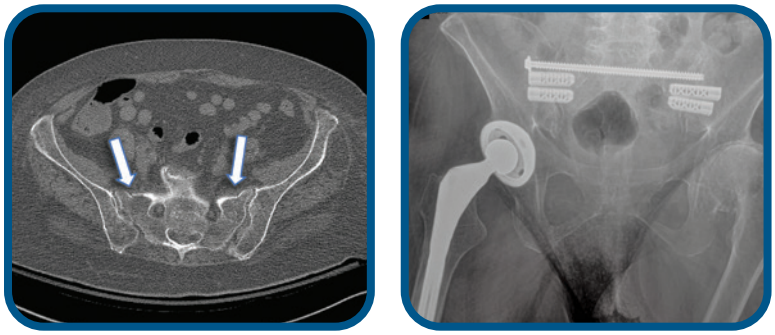
- Retrospective, single center study of 11 non-traumatic sacral fracture patients treated with a transiliac-transsacral screw and the iFuse-3D device
- Post-operatively all patients were able to walk, and average VAS pain score decreased from 9/10 to 4/10

BACKGROUND

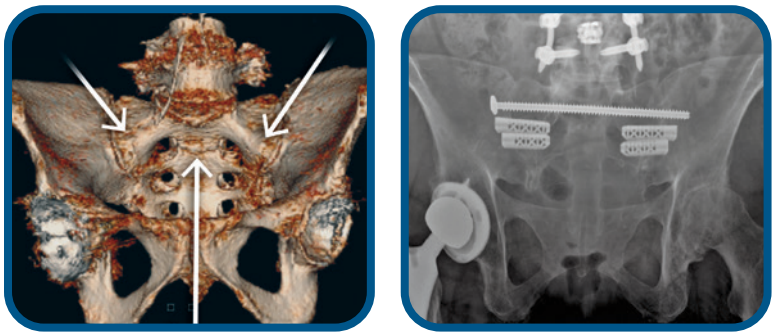
- Non-traumatic sacral fractures are common, with a yearly US incidence of 150k[2,3]
- After developing a non-traumatic sacral fracture(s), patients have a:
  - » 14-27% mortality rate at 1 year[3,4]
  - » 14-45 day average hospital stay[3-5]
  - » 29-61% risk of thromboembolic disorder[6,7]
  - » 50% risk of not returning to baseline function[4]
- Complications with alternative surgical treatments include:
  - » 20% rate of iliosacral screw backout[8]
  - » 32% rate of cement extravasation during sacroplasty[9]

METHODS

- **Patient Selection**
  - » Sacral fractures due to falls from standing height or less
  - » Unable to demonstrate safe ambulation within 24-48 hours after admission
- **Surgical treatment**
  - » 6.5 or 7.3 mm fully threaded cannulated transiliac-transsacral screw
  - » 1-2 iFuse-3D implants, either unilateral or bilateral based on fracture pattern



88 y/o woman, fall from standing, bilateral Denis zone 1 and transverse S2 sacral FXs. Bed bound for 1-2 weeks pre-op; post-op able to sit up and participate in PT.



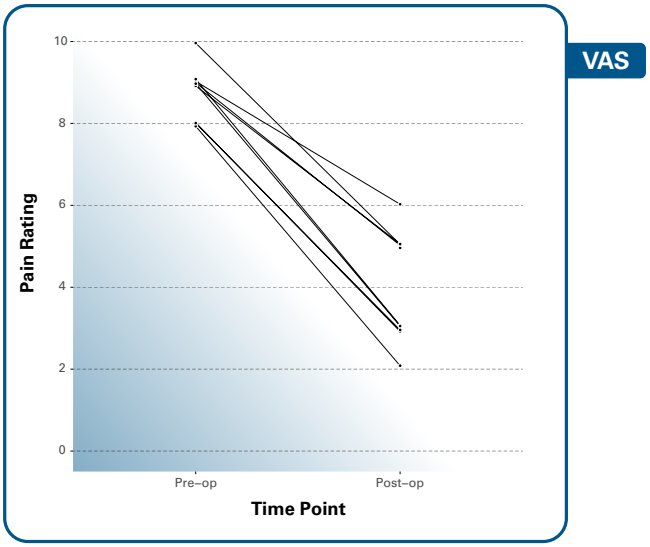
68 y/o woman, ground-level fall, vertically oriented Denis zone 1 and transverse S2 sacral FXs. Bed bound for 3-4 days pre-op; at 2-weeks post-op able to walk with assistance.

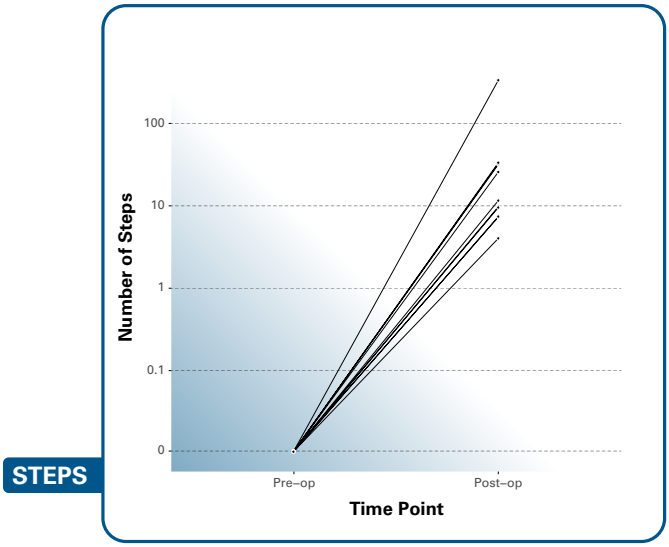
SI-BONE®

Clinical Brief – Non-Traumatic Fractures

KEY RESULTS

- 11 patients were treated (8 female)
- 8 had bilateral sacral fractures of which 6 also had a transverse fracture at S2 (U-shape)
- Mean age: 80.1 years
- Mean BMI: 24.4
- Mean surgery length: 50 minutes
- No intraoperative complications
- Mean pain scores improved from 9/10 at baseline to 4/10 at last follow-up (4.9, Wilcoxon p=.0034)
- Mean number of steps without assistance improved from 0 preoperatively (all were bed or chair-bound and unable to walk) to 45 at final follow-up (92, Wilcoxon p=.0037)
- Mean length of hospital stay: 4.6 days (2.7 if excluding the one outlier with pre-existing comorbidities)





Patient #	Sex	Age	Laterality	Mechanism	Fracture Pattern
1	F	54	Bilateral	Unwitnessed fall	Zone 2 sacral alar fractures with posterior extension, U-type variant
2	F	88	Bilateral	Fall at assisted living	Zone 1 sacral alar fractures with posterior extension, U-type variant
3	F	77	Unilateral	Fall at home	Left hip intertrochanteric fracture, right SI joint diastasis
4	M	94	Unilateral	Fall at home	Zone 1 fracture
5	F	87	Bilateral	No known mechanism or fall	Bilateral zone 1 fractures
6	F	79	Bilateral	Fall at home 3 weeks prior	U-type zone 2 fractures
7	F	83	Bilateral	Fall at home	Bilateral zone 1 fractures
8	M	83	Bilateral	Fall at home	U-type zone 2 fractures
9	F	81	Bilateral	Increasing pain for 1 week, no fall or trauma	Bilateral zone 1 with transverse S2 fracture, U-type equivalent
10	F	87	Unilateral	Fall in parking lot	Zone 1 sacrum with crescent fracture
11	F	68	Bilateral	Slip at home with fall	Bilateral zone 1 with transverse S2 fracture, U-type equivalent

References

1. Black JD. 2019 Orthopaedic Trauma Association (OTA). Denver, CO, USA. Poster Presentation.
2. Melton LJ, *et al. Clin Orthop Relat Res.* 1981;Mar-Apr; (155):43-7.
3. Morris R, *et al. Postgrad Med J.* 2000;76 (900):646.
4. Taillandier J, *et al. Joint Bone Spine.* 2003;70 (4):287–289.
5. Breuil V, *et al. Joint Bone Spine.* 2008;75:585–8.
6. Geerts WH, *et al. N Engl J Med.* 1994;331:1601-6.
7. Babayev M, *et al. Am J Phys Med Rehab.* 2000;79:404-09.
8. Eckardt H, *et al. Injury.* 2017;48(12):2717–23.
9. Bastian JD, *et al. Acta Orthop Belg.* 2012 Feb;78(1):100-5.

The iFuse Implant System® is intended for sacroiliac fusion for the following conditions:

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 6 months.

To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

Acute, non-acute, and non-traumatic fractures involving the SI joint.

SI-BONE recommends that surgeons reduce and stabilize fractures (*i.e.,* via conventional techniques such as screw fixation) prior to placement of the iFuse Implant™.

There are potential risks associated with the iFuse Implant System. It may not be appropriate for all patients and all patient may not benefit.

For information about the risks, visit *www.si-bone.com/risks*

SI-BONE, Inc.
471 El Camino Real,
Suite 101
Santa Clara, CA 95050
USA
info@si-bone.com

Sacroiliac (SI) Joint Fusion with iFuse in High-Energy Pelvic Trauma

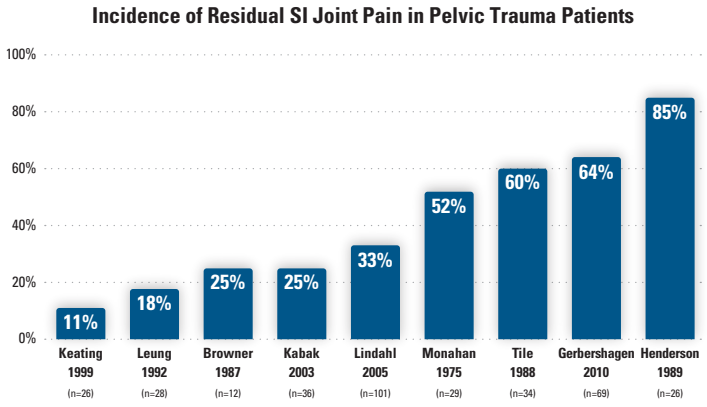
Bartlett CS. 2020 Pelvic Trauma Think Tank Meeting.

SUMMARY

- Retrospective, single center review of 4 patients with high-energy pelvic trauma treated with the iFuse Implants alongside screws/plates in the acute setting
- 75% of patients had excellent functional outcomes, the one with poor outcomes had comorbidities unrelated to the SI joint

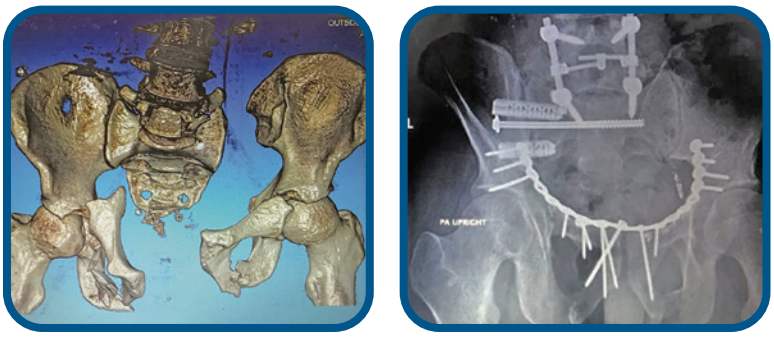
BACKGROUND

- There is a direct correlation between the quality of SI joint reduction following its traumatic disruption and patient outcomes[1-3]
- Despite attempted anatomical reduction of the joint, up to 85% of patients[4-12] continue to suffer from SI joint pain and poor function due to post-traumatic arthritis or malreduction

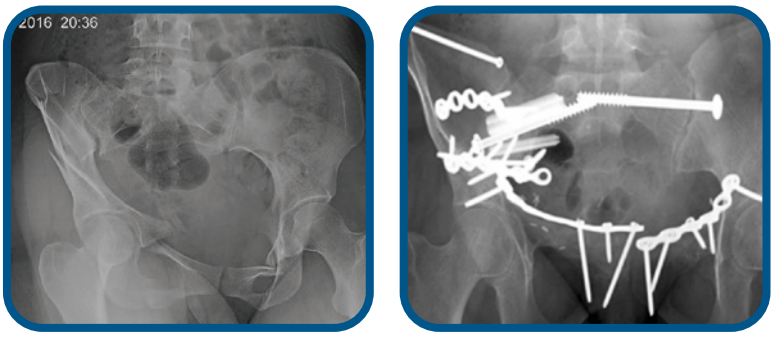


METHODS

- **Patient Selection**
  - » High-energy pelvic trauma
  - » Comminuted, impacted, or dislocated SI joint
- **Surgical treatment**
  - » Screws and/or plates
  - » 2 iFuse implants



32 y/o man hit by dump truck with multiple pelvic fractures, at 2.5-year follow-up has a pain score (visual analog scale) of 1/10 and is back to performing heavy labor.



23 y/o woman ejected through sunroof with type 3 lateral compression fractures, at 6-month follow-up has no pain and no complaints (declined further follow-ups).

SI-BONE®

KEY RESULTS

Operative Details

- 4 acute fusions
- Average BMI: 28.6
- Posterior construct:
  - » 3: screw (SI or transiliac-transsacral) + 2 iFuse
  - » 1: iliac plates + SI screw + 2 iFuse
- All had anterior plate fixation
- Average days in hospital: 11 (range: 6 - 20)
- All had good-excellent reductions, healed pelvic injuries, and no hardware failures
- Complications: mild canal encroachment of 1 - 2mm in 2 patients
  - » 1: no neurological findings
  - » 1: pre-existing sciatica flared post-op, resolved after pulling implant back 5mm

Outcomes at Last Follow-Up

- All had radiographically fused SI joints
- VAS for SI joint pain at follow-up: 0.9
  (91% improvement, average pre-op was 8.8)
- 0 infections
- All 4 were off pain medication
- 3/4 good-excellent qualitative functional outcomes
  - » 1: currently back to performing heavy labor
  - » 1: no pain and no complaints
  - » 1: court officer back to work with drastically improved functionality
  - » 1: right radicular pain unrelated to left fused SI joint

Patient #	Sex	Age	Mechanism	Fracture Pattern
1	M	32	Motorcycle vs. Dump truck	Vertical Shear
2	F	23	Motor vehicle accident, ejected	Lateral Compression III • R Crescent FX • L SI joint completely dislocated • Bilateral superior and inferior rami FXs
3	M	66	Motorcycle	Anteroposterior Compression III • L SI joint completely dislocated (only posterior ligaments remaining) • Avulsion of ala Zone1 (previous degenerative disc & arthritic changes)
4	M	53	Fell down two steps; legs flipped over head	Anteroposterior Compression II

References

1. Papakostidis C, *et al. Int Orthop.* 2009;33(2):329-338. doi:10.1007/s00264-008-0555-6
2. Hoffmann MF, *et al. Clin Orthop.* 2012;470(8):2161-2172. doi:10.1007/s11999-012-2247-1
3. Dujardin FH, *et al. J Orthop Trauma.* 1998;12(3):145-150; discussion 150-151.
4. Keating JF, *et al. J Orthop Trauma.* 1999;13(2):107-113.
5. Leung KS, *et al. Injury.* 1992;23(1):31-37.
6. Browner BD, *et al. J Trauma.* 1987;27(9):998-1006.
7. Kabak S, *et al. J Orthop Trauma.* 2003;17(8):555-562.
8. Lindahl J, *et al. Acta Orthop.* 2005;76(5):667-678. doi:10.1080/17453670510041754
9. Monahan PR, *et al. Injury.* 1975;6(4):325-333.
10. Tile M, *J Bone Joint Surg Br.* 1988;70(1):1-12.
11. Gerbershagen HJ, *et al. J Trauma.* 2010;69(1):128-136. doi:10.1097/TA.0b013e3181bbd703
12. Henderson RC, *J Orthop Trauma.* 1989;3(1):41-47

The iFuse Implant System® is intended for sacroiliac fusion for the following conditions:

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 6 months.

To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

Acute, non-acute, and non-traumatic fractures involving the SI joint.

SI-BONE recommends that surgeons reduce and stabilize fractures (*i.e.,* via conventional techniques such as screw fixation) prior to placement of the iFuse Implant™.

There are potential risks associated with the iFuse Implant System. It may not be appropriate for all patients and all patient may not benefit.

For information about the risks, visit *www.si-bone.com/risks*

SI-BONE®

SI-BONE, Inc.
471 El Camino Real,
Suite 101
Santa Clara, CA 95050
USA
info@si-bone.com