

Retrospective Review of Sacroiliac Joint Fusion with the iFuse Implant System® in Pelvic Trauma

Summary

- ▶ Retrospective, multicenter review of 50 patients with high and low energy pelvic trauma treated with the iFuse Implant System® in adjunct to traditional hardware fixation
- ▶ Average decrease in Visual Analog Scale (VAS) pain score from 8.9 at time of fracture to 1.9 at last follow-up
- ▶ On average, functional mobility was restored to pre-fracture status

Objective and Methods

- ▶ Clinical and radiographic outcomes were described in a retrospective case series studying the use of iFuse implants in patients with high and low energy injuries of the pelvic ring
- ▶ Eight (8) surgeons were identified who, in standard clinical practice, used iFuse or iFuse-3D™ implants during the treatment of high and low energy osseous injuries of the pelvis
- ▶ Physicians used a shared online platform to describe demographics, imaging and outcomes for all patients treated for whom 6 months of follow-up was available

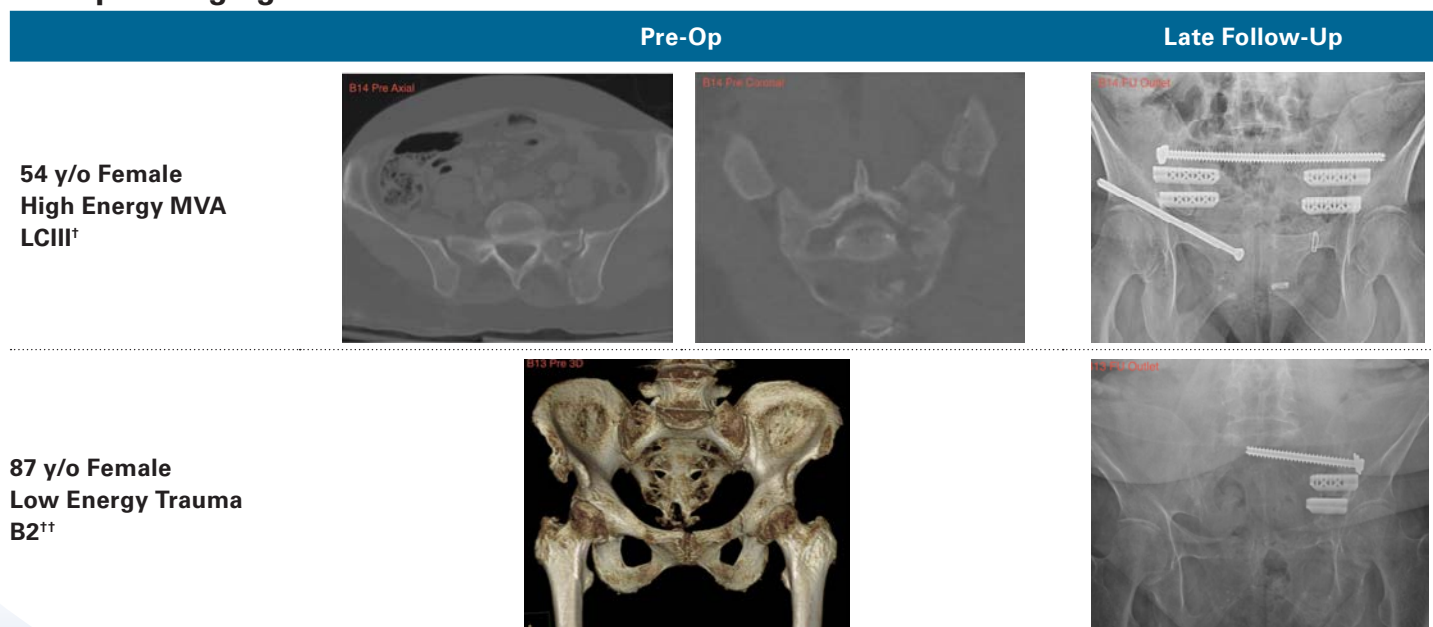
Patient Demographics

	Low Energy (n=33)	High Energy (n=17)
Age in Years*	74.1 (12), 54-94	47.5 (14.5), 23-65
Female Sex	29 (88%)	7 (41%)
Body Mass Index	26.3 (7.2), 15-41**	27.0 (5.9), 20-41

* Continuous variables reported as mean (SD), range; ordinal/nominal variables reported as n (%)

** BMI missing in one patient

Example Imaging

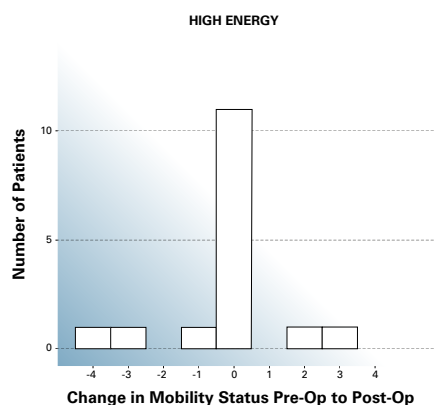
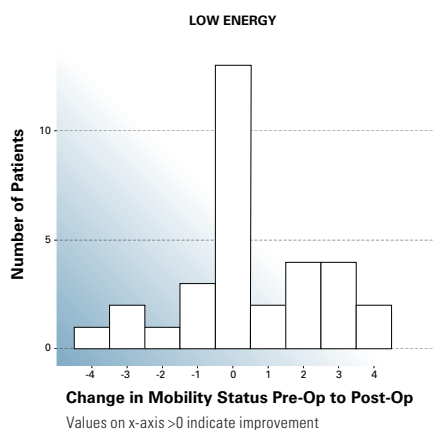
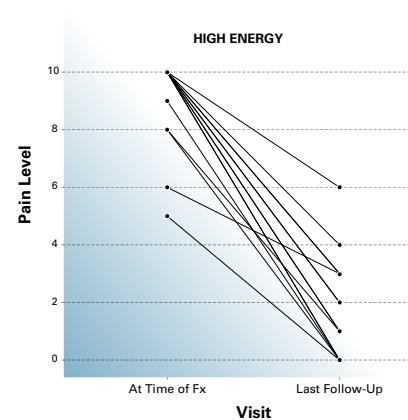
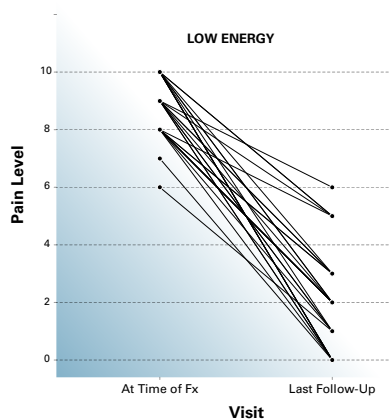


† Young-Burgess Classification System for High Energy Pelvic Trauma

†† Bakker Classification System for Low Energy Pelvic Trauma

Results

- ▶ Average months to last follow-up
 - » Low energy: 7.9
 - » High energy: 10.6
- ▶ Average decrease in VAS pain from 8.9 at time of fracture to 1.9 at last follow-up
 - » Low energy: 8.8 to 2.0
 - » High energy: 9.1 to 1.7
- ▶ On average, functional mobility was restored to pre-fracture status



Functional Mobility Scale

- 0: Bedbound
- 1: Uses wheelchair. (Even if patient can stand for transfers or can take some steps supported by another person or walker)
- 2: Can walk but only with walker
- 3: Can walk but only with crutches
- 4: Can walk but only with cane(s)
- 5: Can walk independently on level surfaces
- 6: Can walk independently on all surfaces (uneven ground, curbs)

Conclusion

This case series shows that iFuse implants can be used safely and effectively for SI joint fusion for patients with certain types of osseous injuries of the pelvic ring. iFuse implant placement was associated with large improvements in pain and restoration of function. Late imaging follow-up showed no evidence of device migration or breakage and did not impair bone healing.

iFuse Trauma™
Fix. Fuse. Fortify.™



For Minimally Invasive
Sacroiliac Fusion

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

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 patients may not benefit. For indications, risk, and safety information about the iFuse Implant System visit www.si-bone.com/label

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