

CASE REPORT

Proximal Humerus fracture repair using IlluminOss®

IlluminOss®: a new, patient-conforming, intramedullary implant for treatment of osteoporotic fractures

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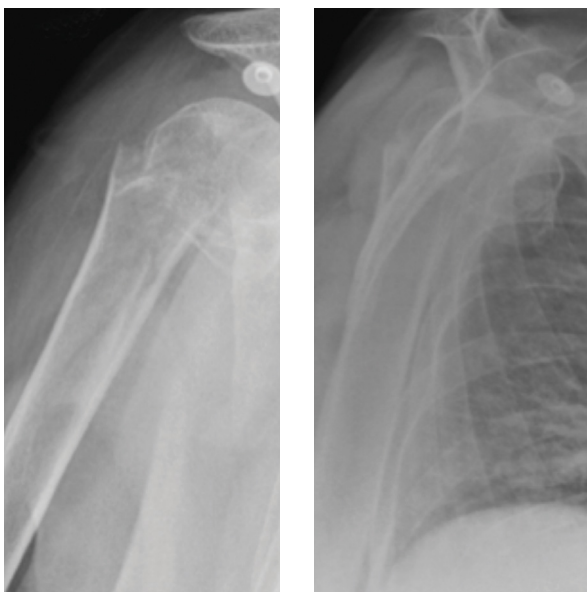
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Patient History and Diagnosis

A case study is presented of a 78-year-old female who sustained a low-energy fall on her right arm, resulting in an AO type 11-A2 extra-articular fracture.

Pre-operative X-rays show an AO type 11-A2 extra-articular fracture



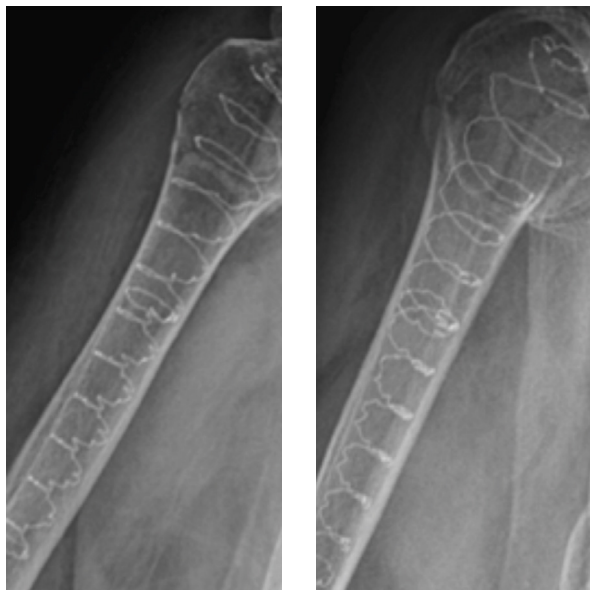
Treatment

The fracture was stabilized with a collar and cuff at the first aid department in preparation for placement of an IlluminOss intramedullary implant. The procedure was performed in a beach chair position. Following regional anesthesia and sedation, a closed reduction of the fracture was performed and a 1 to 2 cm incision was made over the top of the caput humeri. Entrance to the intramedullary canal was achieved with a straight awl. An 8 mm cannulated awl was then used to introduce a 2.0 mm guidewire into the medullary canal. The proximal aspect of the humerus was widened with a compacting instrument to allow the IlluminOss implant to fully expand to its 22 mm diameter.

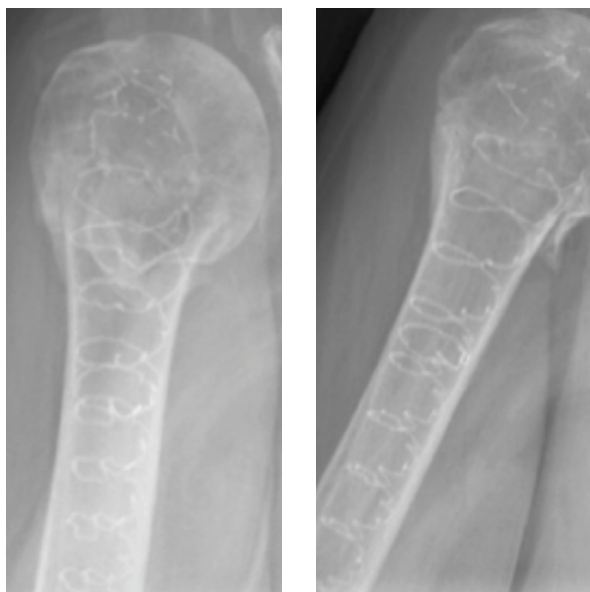
Next a radiopaque sheath and dilator were introduced over the guidewire under X-ray guidance and advanced through the intramedullary canal into position across the fracture site. The dilator and guidewire were removed and a balloon catheter was introduced through the sheath. Once in position, the sheath was removed and the balloon was infused and expanded with a liquid monomer conforming to the interior of the canal.

Final position of the implant was confirmed. The operator then attached an optical fiber residing in the balloon lumen to a light source and introduced a 436 nm light source to polymerize the monomer and create the implant in situ, thus stabilizing the fracture site.

Post-operative X-ray with IlluminOss implant



5-months post-operative X-ray with IlluminOss implant



Discussion

Proximal humerus fractures are commonly seen in elderly people and represent an important clinical challenge. A Cochrane database review of randomly controlled clinical trials found that surgery does not result in better treatment outcomes compared to non-surgical approaches, in part because of the frequent presence of osteoporosis that makes surgical placement of traditional implants difficult due to poor bone purchase.¹ Overall, there are no evidence-based guidelines for treatment of these fractures.² The IlluminOss implant offers a new treatment opportunity for this type of fracture by providing a stable intramedullary surface to accept implants and assist with bone purchase. The conforming implant also fills the canal space, stabilizing the fracture and providing broad support for the caput humeri, preventing a secondary collapse.

Additionally, the system uses a flexible delivery catheter that facilitates delivery of the implant more laterally, which may reduce the risk of injury to the rotator cuff. In fact, studies have shown that up to 28% of patients aged 60 have rotator-cuff lesions before they sustain a proximal humeral fracture; these patients typically have a worse outcome.² Early results suggest that the IlluminOss implant is able to achieve greater implant stability with less procedure-related trauma and a faster recovery time.

Outcome/Post-procedure notes

The patient was treated on an outpatient basis with a stand-alone IlluminOss implant. No additional hardware was used to stabilize the humerus fracture. She was sent home the same day as the procedure with instructions to use her arm as tolerated. She started physiotherapy the day after surgery. There was no infection, follow-up procedure, or delayed union.

Conclusion

The IlluminOss system provides a minimally invasive treatment option for proximal A2 and A3 humerus fractures. It offers an alternative to existing surgical approaches and may help to manage some of the challenges associated with humerus fractures in patients with osteoporotic bone disease. The IlluminOss solution for treatment of proximal humerus fractures is currently being studied in the United States and Europe. Outcomes of this research may demonstrate the utility of IlluminOss in this fracture type.

¹ Handoll HH, Brorson S. Interventions for treating proximal humeral fractures in adults. *Cochrane Database Syst Rev.* 2015 Nov 11;11:CD000434. doi: 10.1002/14651858.CD000434.pub4. Review.

² Burkhart KJ, Dietz SO, Bastian L, Thelen U, Hoffmann R, Müller LP. The Treatment of Proximal Humeral Fracture in Adults. *Deutsches Ärzteblatt International.* 2013;110(35-36):591-597. doi:10.3238/ärztebl.2013.0591.

This product has the CE mark and is available for sale in the EU. This product is investigational and not for sale in the United States.

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