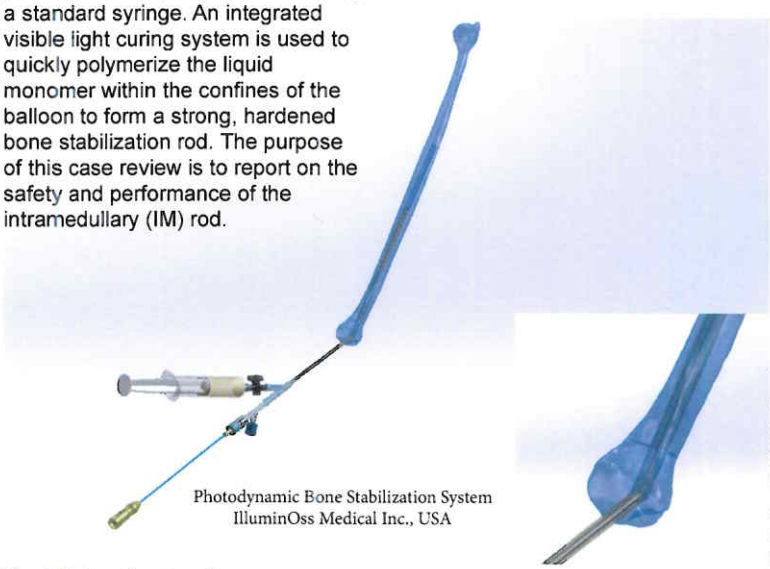
Ankle Fracture Fixation with a Novel Intramedullary Photodynamic Polymeric Rod: A Case Series Review

Thomas Gausepohl*, MD, PHD, Ahmad Rashid, Marius Baluch, MD, Frank Hoffmann, MD
Parcelsus Klinik - Marl, Germany

The FDA has not cleared this medical device for the use described in this poster.

Purpose

Ankle fractures in the elderly population are a common problem, with an incidence rate of approximately 187 per 100,000 people each year.[1] The presence of poor bone quality related to osteoporosis, combined with critical soft tissue conditions, can provide technical challenges during fracture fixation. A novel minimally invasive intramedullary implant formed by the use of a balloon catheter and a light curable monomer recently received CE mark clearance for use in light to low load bearing fracture treatment (IlluminOss Medical Inc., USA). The device forms a patient customized, intramedullary polymer implant. The balloon catheter is inserted into the medullary canal and positioned across the reduced fracture. Once in correct alignment and position, it is infused with a biocompatible photodynamic liquid monomer through a standard syringe. An integrated visible light curing system is used to quickly polymerize the liquid monomer within the confines of the balloon to form a strong, hardened bone stabilization rod. The purpose of this case review is to report on the safety and performance of the intramedullary (IM) rod.



Photodynamic Bone Stabilization System
IlluminOss Medical Inc., USA

Methods

The first 13 patients treated with a polymeric IM rod were assessed for fracture-related pain, time to full weight bearing, return to pre-fracture mobility, as well as clinical and radiographic healing. Pain was assessed by necessity for use of analgesics, and by local examination of the fracture site (pain on palpation). Radiographs were obtained prior to surgery, post-operatively, and at follow-up visits per standard hospital protocol. Clinical healing was defined as the return to pre-fracture function with no pain on palpation. Radiographic healing was defined as continuous bridging across the plane of the fracture for metaphyseal fractures. Patients were followed for a minimum of six weeks and a maximum of one year post treatment at the time of data analysis.

Results

Twelve female patients and one male patient were treated for ankle fractures from June 2011 until August 2012. The average age at the time of surgery was 79 years (range: 69-88 years). All patients presented with metaphyseal fractures and were osteoporotic. Twelve patients presented with unilateral fractures, and one patient presented with fractures of the tibia and fibula. In all cases, the surgical incision was bandaged, and no further casting or bracing was used for patients with isolated fibula fractures.

All patients were allowed full weight bearing on the second post-operative day as tolerated. Patients resumed activities of daily living upon discharge from the hospital. No physical therapy prescriptions were written for any patient. There were no intra-operative adverse events reported for the 13 patient cohort. There were no adverse device effects, no infections and no secondary procedures performed related to the polymeric IM rod. Only over the counter analgesics were used to manage pain on an as-needed basis. All patients were clinically healed by the six-week follow up visit, and were radiographically healed by the three-month follow up visit.

Sample Images

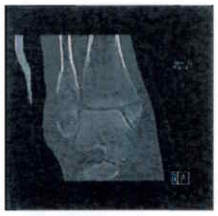


Image 1: Baseline
72 Year Old Female

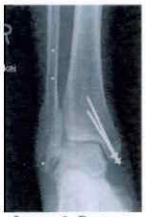


Image 2: Post-op

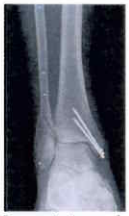


Image 3: 1 month

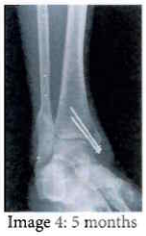


Image 4: 5 months

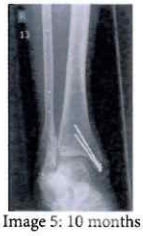


Image 5: 10 months

Conclusions

This case series reports the use of a polymeric IM rod for ankle fracture fixation. The intramedullary device provided stability to the fractured bone, and maintained alignment during the healing process. The rod has been well tolerated and has not been associated with complications. The use of the customed IM rod has the potential to reduce recovery time and may be associated with a faster return to baseline mobility than comparable stabilization techniques. Further use and investigation is warranted for this IM rod.

*Financial disclosure information on file

1. Egol KA, Koval KJ, Zuckerman JD. 2010. Handbook of Fractures, 4E. Pennsylvania: Lippincott Williams & Wilkins.