

## Presentation of The First Uses Of The Illuminoss Lightfix Implant In The United States.

Felix H Cheung, MD, Sinan Ozgur, MD, Franklin Shuler, MD  
(Department of Orthopaedic Surgery, Joan C Edwards School of Medicine, Marshall University)

Background: Internal fixation of pathologic fractures and prophylactic fixation of impending pathological fractures have demonstrated significant clinical benefit, including less blood loss, faster procedure time, shorter length of hospitalization, reduction of pain, improvement in activities of daily living, and better quality of life. IlluminOss is a new technology enabling percutaneous, customized, intramedullary stabilization formed from a monomer. The theoretical benefits of this implant includes new and flexible entry sites, smaller incisions, rotational stability without screws, MRI compatibility, and the ability to place screws through the implant for additional stability if needed.

**Comment [RAR1]:** Light cureable monomer contained within a PET ( Dacron ) balloon

Purpose: To evaluate the use of a new percutaneously introduced intramedullary implant formed out of a light curable monomer and a Dacron balloon for the treatment of metastatic cancer, and to report its first uses in the United States of America.

Methods: From February 2015 until June 2015, two patients were enrolled in the recently approved FDA Clinical Study: *Lightfix; A Prospective, Multi-Center Study of the Photodynamic Bone Stabilization System for the Treatment of Impending and Actual Pathological Fractures from Metastatic Bone Disease in the Humerus* at our institution. These represented the first two patients enrolled nationwide in the study. Inclusion criteria included patients with metastatic carcinoma, lymphoma or multiple myeloma to the humerus, with resulting pathologic fracture or impending fracture as defined by Mirel's Criteria >8 and greater than 50% cortical destruction. Institutional IRB was obtained, and informed consent was obtained from each subject. Patients underwent the Lightfix procedure and were followed at 2, 6, 12 weeks post op with radiographs and outcome surveys.

Procedure: A sharp curved awl or a cannulated drill bit is used to create a starting site just lateral to the greater tuberosity for antegrade insertion or at the distal lateral condyle for retrograde insertion. A 2mm ball tipped guide wire is passed into the intramedullary canal into the far fragment. While the fracture is held reduced, a 7mm flexible reamer is passed. A 7mm cannulated obturator and a sheath are passed into the intramedullary canal and the obturator is removed. The Dacron balloon is inserted through the fracture site while protected by sheath. The sheath is then removed. While reduction is held, the balloon is inflated to fill the shape of the intramedullary canal with a light curable monomer. A fiber optic is then connected to a light source and the monomer is cured insitu. Reduction is held in place by the implant, and rotational stability is obtained by the irregular shape of the intramedullary canal / balloon. Once hardened, the monomer may be drilled and screws and plates may be used for additional fixation if needed. Postoperatively, the arm is placed into a sling for comfort, with encouragement for early range of motion.

Patients: The first patient was a 57 year old male with stage IV metastatic lung cancer with an impending pathologic fracture of his left humeral diaphysis who had completed the fracture by the time of scheduled surgery. The Lightfix implant (22 x 160 mm) was inserted in an antegrade fashion without complication (Figure 1). He was discharged on POD1, and reported improvement in his pain. He died from unexpected complications from his lung cancer prior to formal follow up. The second patient was a 71 year old female with stage IV metastatic breast cancer with a pathologic extra-articular fracture of her right distal humerus. Because of an impending fracture to the right hip, immediate weight bearing was desired to help with rehabilitation. The Lightfix implant (17 x 220 mm) was inserted in a retrograde fashion, and a distal lateral humeral locking plate was placed through the device for reinforcements (Figure 2). Follow up was still pending at the time submission.

Conclusions: The IlluminOss Lightfix implant has the potential to improve the way pathologic fractures and impending fractures are treated in the United States of America. We have reported on the first two uses of this

device in the US, which were performed without implant complications. More subjects will have to be treated to refine surgical techniques and to evaluate complications and benefits.



Figure 1: Patient 1 pre and post op



Figure 2: Patient 2 pre and post op. Note the spiral Lightfix Implant up the medullary canal, and the plate and screw construct through the implant for better fixation.