EXOGEN Case Study Report

DISTAL TIBIAL PILON NONUNION

Physician: Damien Billow, MD, Assistant Professor of Surgery, Orthopaedic Surgery, Cleveland Clinic

Patient Information:
- Age: 52 years old
- Sex: Male
- Weight: 270 lb (BMI 39 kg/m²)

Fracture:
- Closed comminuted distal tibial pilon nonunion
  (commination involved all of distal tibial metaphysis and extended into distal tibial diaphysis)

Outcome:
- Fracture healed with approximately 3 months use of EXOGEN

Cause of Injury:
The patient fell from a ladder

Comorbidities/Risk Factors:
- Obesity
- Former smoker
- Location of fracture

Treatment Objectives:
- Achieve bony healing
- Eliminate the need for additional surgery

Prior Treatments:
- Exfix
- ORIF

Patient Motivation to Heal:
- Avoid further surgery

Treatment Plan:
- January 28, 2017: Exfix
- February 13, 2017: ORIF
- Post Op: NWB
- April 5, 2017: No progression of healing shown, EXOGEN prescribed
- May 17, 2017: Advanced to WBAT. X-rays showed some healing and increased density in the zone of fracture
- July 19, 2017: Fracture healed
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January 28, 2017 At Injury AP Ankle

January 28, 2017 At Injury Lat Ankle

February 7, 2017: CT Post Exfix

February 13, 2017 Flouro: ORIF Intraop Lat1

April 5, 2017 Post Op: AP Ankle; Initiate EXOGEN Use

April 5, 2017 Post Op: Lat Ankle; Initiate EXOGEN Use

April 5, 2017 Post Op: Lat Tibia; Initiate EXOGEN Use

July 19, 2017: AP Tibia; ~ 3 Months EXOGEN Use
The EXOGEN Ultrasound Bone Healing System is indicated for the non-invasive treatment of established nonunions excluding skull and vertebra. In addition, EXOGEN is indicated for accelerating the time to a healed fracture for fresh, closed, posteriorly displaced distal radius fractures and fresh, closed or Grade I open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopaedically managed by closed reduction and cast immobilization. There are no known contraindications for the EXOGEN device.

Safety and effectiveness have not been established for individuals lacking skeletal maturity, pregnant or nursing women, patients with cardiac pacemakers, on fractures due to bone cancer, or on patients with poor blood circulation or clotting problems. Some patients may be sensitive to the ultrasound gel. Full prescribing information can be found in product labeling, at www.exogen.com, or by calling customer service at 1-800-836-4080.

A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

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