

EXOGEN Case Study Report

DISTAL FIBULAR NONUNION

Physician: Robert Zura, MD, Professor, the Robert D'Ambrosia Chair of Orthopaedics at the Louisiana State University Health Sciences Center.

Patient Information:

Age: 69 years old

Sex: Male

Weight: Overweight

Fracture:

Distal fibular nonunion fracture, oblique, Weber b, SERII

Outcome:

All three objectives were met by 10 months post-injury (3 months EXOGEN use). The patient healed and was pain free. The sclerosis at fracture margins were resolved and healed with bridging bone.

Cause of Injury:

The patient was injured by a golf cart.

Comorbidities/Risk Factors:

Age, sclerotic border around the fracture.

Treatment Objectives:

- Achieve union
- Increase function
- Eliminate pain

Prior Treatments:

Nonoperative: boot and cast

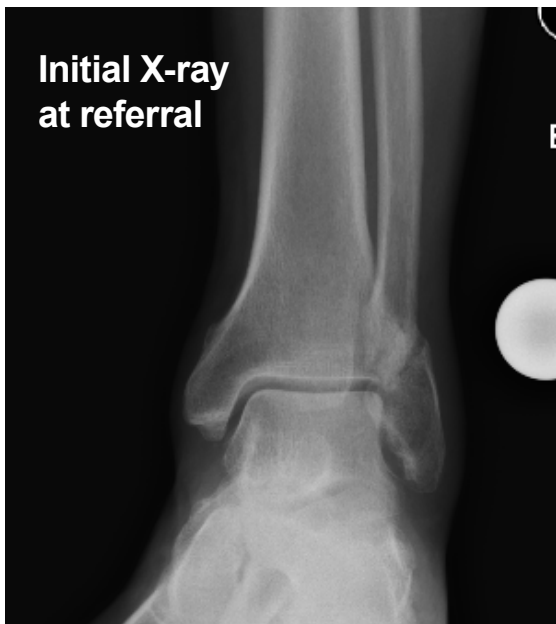
Patient Motivation to Heal:

The patient was in pain. He had trouble walking and wanted to get back to playing golf.

Treatment Plan:

Since the nonoperative treatments were not effective for a symptomatic nonunion, the patient was referred to Dr. Zura. Dr. Zura recommended surgery, but the patient declined. Because the fracture was stable and not infected, Dr. Zura felt it was reasonable to continue nonoperative care and decided to utilize EXOGEN, which he prescribed for 20 minutes a day.

Initial X-ray
at referral



CT at
referral

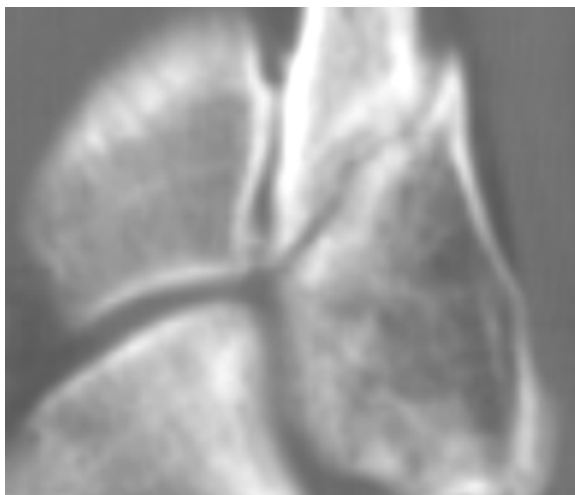


Images taken:
X-rays and CT
7 months
after injury

X-ray: 3 months
post-initiation
of EXOGEN,
10 months
after injury



Side-to-side
comparison of
pre- and post-
EXOGEN



7 months after injury



After 3 months of EXOGEN

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 non-union is considered to be established when the fracture site shows no visibly progressive signs of healing.