

EXOGEN Case Study Report

MID-DIAPHYSEAL HUMERUS NONUNION

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

Patient Information:

Age: 27 years old

Sex: Female

Weight: Average

Fracture:

Mid-diaphyseal left humerus nonunion

Outcome:

This patient had a successful outcome. The fracture completely healed between months 4 and 8 of EXOGEN use and the patient was back to water skiing.

Cause of Injury:

Motor vehicle accident

Comorbidities/Risk Factors:

Multi-trauma

Treatment Objectives:

- Heal the nonunion
- Restore function (patient enjoys water skiing)

Prior Treatments:

Surgery: Open reduction internal fixation (ORIF) and plate at time of injury

Patient Motivation to Heal:

This patient was young and active. She is an avid water skier and wanted to get back out on the water.

Treatment Plan:

The patient was scheduled for revision surgery by her local surgeon but moved in the meantime.

Following her move, she was referred to Dr. Zura. Since she was pain free and her fracture was not infected and stable, Dr. Zura decided on a nonoperative approach by prescribing EXOGEN for 20 minutes a day.

At 9 months post-injury (4 months of EXOGEN use), there was subtle but persistent lucency through the transverse fracture of the left humeral diaphysis without evidence of complete osseous bridging. Since Dr. Zura saw biologic activity, he recommended continuing nonoperatively with EXOGEN. Conclusion, showed complete radiographic healing after 8 months of EXOGEN usage.

5 months post-op

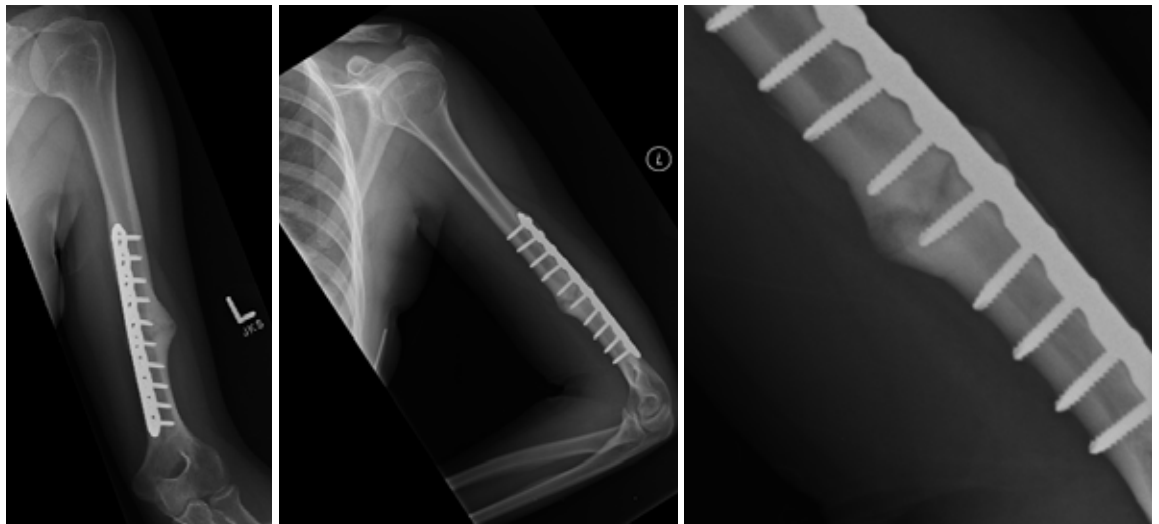
- Minimal biologic activity
- Persistent fracture/nonunion
- Hardware appears stable



9 months post-op

(4 months after initiating EXOGEN)

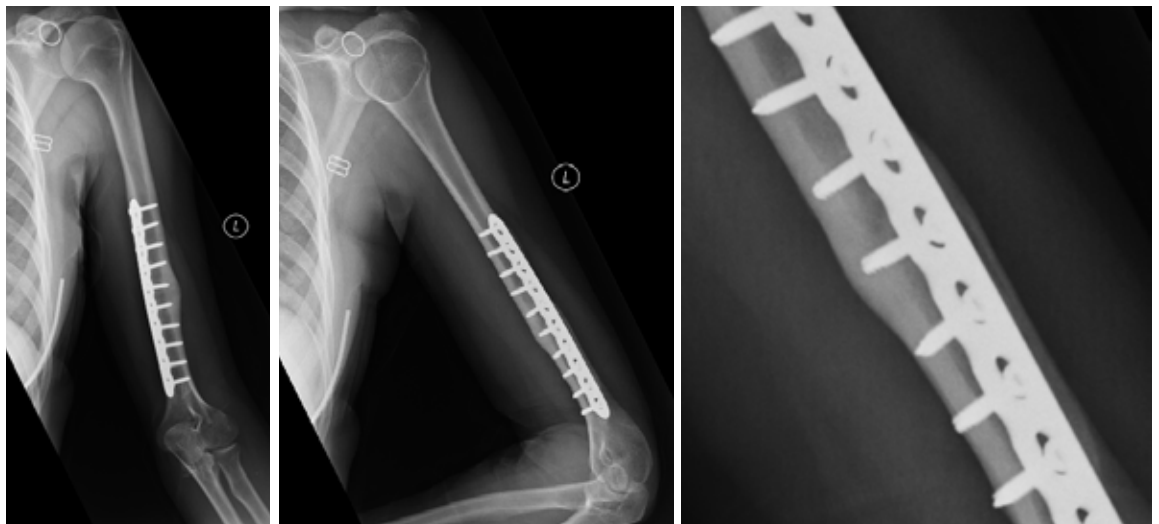
- Significant increase in biologic activity around the fracture line (also confirmed by CT)



13 months post-op

(8 months after initiating EXOGEN)

- Shows complete radiographic healing



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.