



exogen[®]
ultrasound bone healing system

Clinical Case Studies Series

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EXOGEN® Ultrasound Bone Healing System has been on the market in the United States for 25 years. In that period of time, EXOGEN has helped numerous physicians across the country in their delivery of fracture care. This case study series (unpublished) demonstrates EXOGEN's adjunctive treatment benefit when a physician has stabilized the fracture, allowing the patient's biology to be stimulated by the low-intensity pulsed ultrasound technology, and ultimately, heal the nonunion fracture.

No complications or adverse events were reported for the cases in this series.



Distal Fibular Nonunion Fracture

Physician:

Robert Zura, MD

Professor, the Robert D'Ambrosia
Chair of Orthopaedics at LSU Health
Sciences Center

Patient Information:

Male, 69 years old, overweight

Fracture:

Distal fibular nonunion fracture,
oblique, Weber B, SERII

Cause of Injury:

The patient was involved in a golf
cart accident.

Treatment Objectives:

- Achieve union
- Increase function
- Eliminate pain

Prior Treatments:

Nonoperative, boot and cast

Treatment Plan:

The patient's healthcare provider referred him to Dr. Zura because the nonoperative treatments were not effective for a symptomatic nonunion. 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.

Results:

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.

Individual results may vary.



X-ray and CT images taken 7 months after injury



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

Mid-diaphyseal Humerus Nonunion Fracture

Physician:

Robert Zura, MD

Professor, the Robert D'Ambrosia
Chair of Orthopaedics at LSU Health
New Orleans School of Medicine

Patient Information:

Female, 27 years old, average
body weight

Fracture:

Mid-diaphyseal left humerus
nonunion

Cause of Injury:

The patient was involved in a motor
vehicle accident.

Comorbidities/ Risk Factors:

Multi-trauma

Treatment Objectives:

- Heal the nonunion
- Restore function

Prior Treatments:

Surgery, open reduction internal
fixation (ORIF) and plate at time
of injury

Treatment Plan:

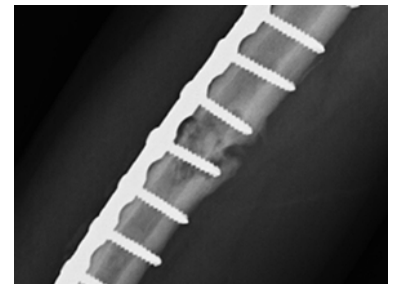
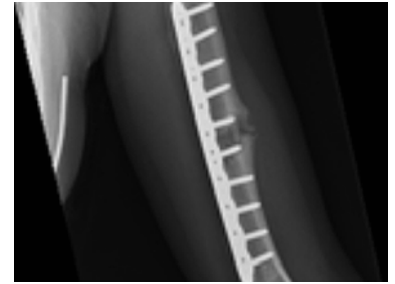
The patient was scheduled for
revision surgery by her local
surgeon, but moved to a different
location before the surgery could
take place.

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

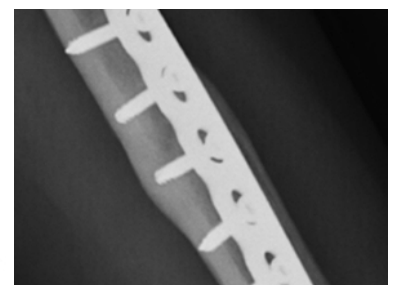
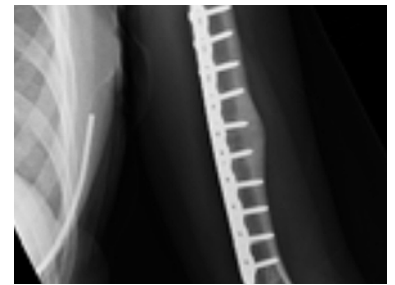
At 9 months post-injury (4 months
of EXOGEN use), there was subtle
but persistent lucency through
the transverse fracture of the left
humeral diaphysis without evidence
of complete osseous bridging.
Because Dr. Zura saw biologic
activity, he recommended continuing
nonoperatively with EXOGEN.
The patient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

Results:

The patient had a successful
outcome. The fracture completely
healed between 4 and 8 months of
EXOGEN use.



X-ray images taken 5 months post-op



X-ray images taken 13 months post-op; 8 months after initiating treatment with EXOGEN

Distal Tibial Nonunion Fracture

Physician:

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

Patient Information:

Male, 36 years old, 224 lbs

Fracture:

Distal tibial fracture with non-displaced posterior malleolus fragment that progressed to nonunion

Cause of Injury:

The patient is a police officer who suffered a fracture while making an arrest

Treatment Objectives:

- Avoid further surgery
- Achieve bony healing
- Restore function

Prior Treatments:

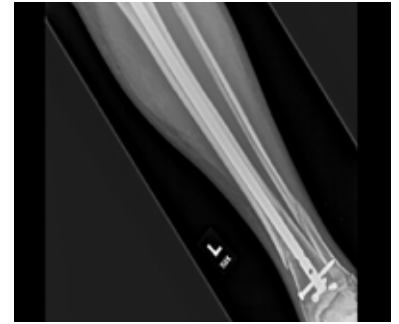
The patient had surgery for percutaneous screw fixation of posterior malleolus fragment and suprapatellar nailing post injury.

Treatment Plan:

The patient was non-weight bearing post-op due to distal fracture and posterior malleolus involvement. Approximately two months post-op, the patient was able to advance to weight bearing as tolerated, and Dr. Billow prescribed EXOGEN at three months. X-rays taken nine weeks after EXOGEN was prescribed showed evidence of progressive healing.

Results:

Successfully healed nonunion, allowing the patient to avoid further surgery



X-ray at injury, pre-op and x-ray ~2 months post-op



X-rays taken at ~2 months and ~9 months post-EXOGEN treatment

Midshaft Femoral Nonunion Fracture

Physician:

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

Patient Information:

Female, 84 years old, BMI
33.2 kg/m²

Fracture:

Closed midshaft femoral nonunion
above a cemented long-stem
revision TKA

Cause of Injury:

Fell from standing

Comorbidities/ Risk Factors:

Multi-trauma
Osteoporosis
Pulmonary hypertension

Treatment Objectives:

- Achieve union
- Return to weight bearing

Prior Treatments:

ORIF
Revision ORIF

Treatment Plan:

The patient initially had an ORIF procedure with lag screws to lock the distal femur plate and cables. Three months later, X-rays showed progression towards healing. However, the patient was non-weight bearing. Due to a broken plate, after ten weeks the patient had a second surgery that included plate, cables, femoral allograft strut and allograft chips and was non-weight bearing post-op. Dr. Billow prescribed EXOGEN as adjunct therapy. Two months later, the patient achieved significant callus formation and advanced to partial weight bearing. The patient was fully weight bearing seven weeks later.

Results:

Fracture healed with full union



X-ray at injury and X-ray of broken plate ~5 months post injury



X-rays post revision surgery ~2 and ~6 months of EXOGEN use.

Distal Tibial Pilon Nonunion Fracture

Physician:

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

Patient Information:

Male, 69 years old, 167 lbs

Fracture:

Closed 43-C1 distal tibial pilon nonunion

Cause of Injury:

Fall from standing

Comorbidities/ Risk Factors:

Smoker
History of alcohol abuse
Peripheral artery disease
COPD

Treatment Objectives:

- Exfix
- ORIF

Prior Treatments:

The patient initially had temporary spanning ExFix, followed by an ORIF procedure three weeks later. The patient was admitted to the ICU 8 weeks later due to issues unrelated to the fracture.

Treatment Plan:

Seventeen weeks post-op, the patient advanced to weight bearing and Dr. Billow initiated EXOGEN use. X-rays taken nine weeks later showed some callus formation and a follow-up set of X-rays 13 weeks later showed radiographic evidence of progression.

Results:

Achieved union in patient with comorbidities



X-rays taken immediately after injury



X-ray taken 7 weeks post-op; no progression of healing shown and X-ray taken 3 months post-EXOGEN use

Distal Tibial Pilon Nonunion Fracture

Physician:

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

Patient Information:

Male, 52 years old, BMI 39/kgm²

Fracture:

Closed comminuted distal tibia pilon nonunion (comminution involved all of distal tibia metaphysis and extended into distal tibia diaphysis)

Cause of Injury:

The patient fell from a ladder

Comorbidities/ Risk Factors

Former smoker

Treatment Objectives:

- Achieve bony healing
- Eliminate the need for additional surgery

Prior Treatments:

ORIF
Revision ORIF

Treatment Plan:

The patient was initially treated with external fixation on the day of injury, and an ORIF procedure two weeks later. The patient was non-weight bearing post-op. X-rays taken at a follow-up appointment seven weeks later revealed no evidence of progression to healing. Dr. Billow then prescribed an EXOGEN device. X-rays taken six weeks after EXOGEN was prescribed showed some evidence of healing, with increased density in the zone of the fracture.

Results:

Fracture healed with approximately 3 months of EXOGEN use.



X-ray at injury and X-ray 17 weeks post-op (EXOGEN use initiated)



X-rays taken ~2 months and ~7 months post-EXOGEN use

Femur Nonunion Fracture

Physician:

Michael Prayson, MD
Professor, Orthopaedic Surgery
and Director, Orthopaedic
Trauma Fellowship, Wright State
University, Valley Hospital,
Dayton, OH

Patient Information:

Female, 47 years old

Fracture:

Right reverse obliquity
subtrochanteric femur fracture

Cause of Injury:

Tripped on uneven pavement

Comorbidities/Risk Factors:

History of smoking
Obesity
Fracture pattern

Prior Treatments:

Post-op locked cephalomedullary
nailing
Persistent pain/lack of healing
Underwent nail dynamization at 9
months post-injury

Treatment Plan:

The patient was referred to Dr.
Prayson from an outside physician
after a nail dynamization failed.

11 months post-injury, CT scan
showed persistent hypertrophic
nonunion, and the patient was
considered for nonunion repair
surgery. However, since the fracture
and hardware were stable, Dr.
Prayson prescribed EXOGEN.

Results:

Nonunion healed, symptoms
resolved, and additional
surgery avoided.



Initial fracture



Post-op



11 months post-injury



3 months of EXOGEN use
14 months post-injury

Tibia Nonunion Fracture

Physician:

Robert Anderson, MD
Tiletown Sports Medicine,
Green Bay, WI

Patient Information:

Female, 53 years old;
school principal

Fracture:

Tibia fracture at external fixation
pin site

Comorbidities/Risk Factors:

History of nonunion of prior midfoot
deformity correction

Diabetes

Neuropathy

Prior Treatments:

Closed reduction with long-leg cast
Non-weight bearing

Treatment Plan:

After 3 months, the fracture showed
no progression of healing. Dr.
Anderson prescribed EXOGEN
and kept the patient in a long-leg
cast. At 5 months, the patient
showed significant bone healing and
progressed to a short-leg
walking cast.

Results:

At 7 months, the nonunion was
healed and additional bone healing
was evident. The patient avoided
surgery.



5 months - Progressed to short-leg walking cast



5 months - Significant bone healing



7 months - Nonunion healed

Metatarsal Nonunion Fracture

Physician:

Robert Anderson, MD
Bellin Health Tittletown Sports
Medicine & Orthopedics,
Green Bay, WI

Patient Information:

Male, 20 years old; college
football player

Fracture:

Refractured metatarsal on right foot

Cause of Injury:

Motor Vehicle Accident

Comorbidities/Risk Factors:

History of Jones fracture
Two prior surgeries
No comorbidities

Prior Treatments:

Treated conservatively with cast
and boot

Treatment Plan:

No progression to healing;
nonunion diagnosis

Screw from prior surgery
was bending

EXOGEN prescribed at 3 months
post-op

Boot with weight bearing continued

Results:

Complete union noted 17 weeks
after initiating EXOGEN. Patient was
asymptomatic and additional surgery
was avoided. Patient returned to
football 8 months post-op.



Initial fracture



Healed fracture
17 weeks EXOGEN use



The physicians in this case series are paid consultants of Bioventus LLC. They received compensation from Bioventus LLC related to these cases.

Indications for 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.

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

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.

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