

Case Study

The Use of Pulsed Electromagnetic Field (PEMF) Non-invasive Bone Stimulation in the Treatment of Fracture Nonunions:
Segmented Atypical Intra-Articular Fracture Nonunion of the Distal Tibia and Fibula

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BIOMET[®]

Non-invasive Stimulation
OPTIONS • EVIDENCE • EXPERIENCE



The Bone Healing Process

Bone healing is dependent on the process of osteogenesis, angiogenesis and chondrogenesis. Osteogenesis occurs when bone precursor cells (stem cells) differentiate into osteoblasts, or bone forming cells. Osteoinduction refers to a material's ability to stimulate the body to differentiate these precursor cells into bone forming cells to promote bone healing. Multiple growth factors that are naturally occurring in the body regulate bone healing.*

Another aspect of bone healing is osteoconduction. The ability of a material to serve as a scaffold on which bone cells can attach, migrate, grow into and divide is important for normal healing.

There are a variety of bone growth stimulation devices currently on the market. One such device is the EBI Bone Healing System[®] which is indicated for the treatment of fracture nonunions, failed fusions and congenital pseudarthrosis in the appendicular system.¹ This device utilizes Pulsed Electromagnetic Field (PEMF) signal technology.

An electromagnetic field is induced by a small electrical current passing through a coil. This field is similar to the body's own natural current which promotes bone healing. A specific electromagnetic field is created by the treatment coil which may be worn with a cast or on the skin overlying the fracture nonunion site.

The EBI Bone Healing System[®]

- **Options:** 20 different treatment coils (0.20 lbs to 0.84 lbs) available to accommodate virtually every nonunion fracture site in the appendicular system
- **Evidence:** 85% success rate in tibia nonunions^{1**}
- **Experience:** Biomet is the pioneer for non-invasive electrical stimulation and has been prescribed for the treatment of over one million patients



Patient Background

This patient presented to the hospital emergency room after a motor-vehicle accident in which he suffered a Tibio/Fibular fracture and an atypical intrarticular fracture of the tibial plafond of the right leg. He was treated surgically in the hospital with the application of the EBI® DynaFix® Hybrid System² and fibular locking plate from the OptiLock® Periarticular Plating System for Distal Tibial Fractures.³ After 12 weeks of care including weight bearing for dynamization, and no visible signs of bony healing, an EBI Bone Healing System® non-invasive bone stimulator was applied.

Two months later, the patient showed almost complete healing of the tibia and fibula. The frame was removed three weeks later and the patient went on to heal uneventfully.

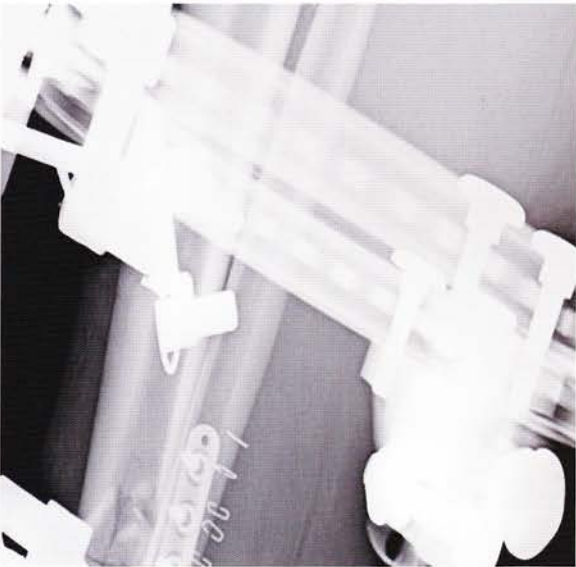
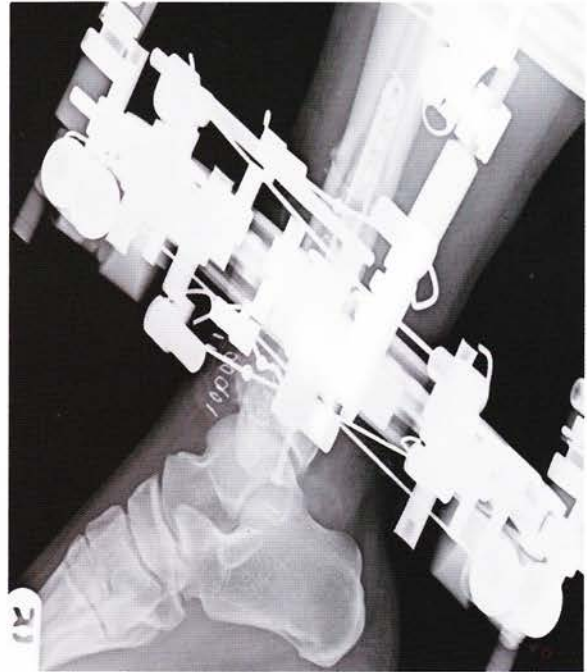
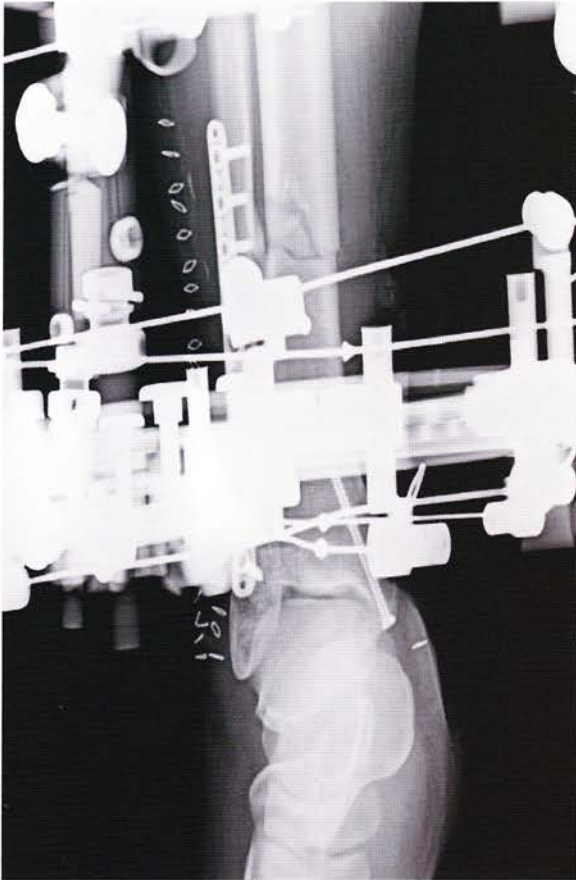
Pre-operative

Pre-operative films showing a segmental fracture with a tibio/fibular fracture and an atypical intra-articular fracture of the distal tibia and fibula.



Immediately Post-Operative

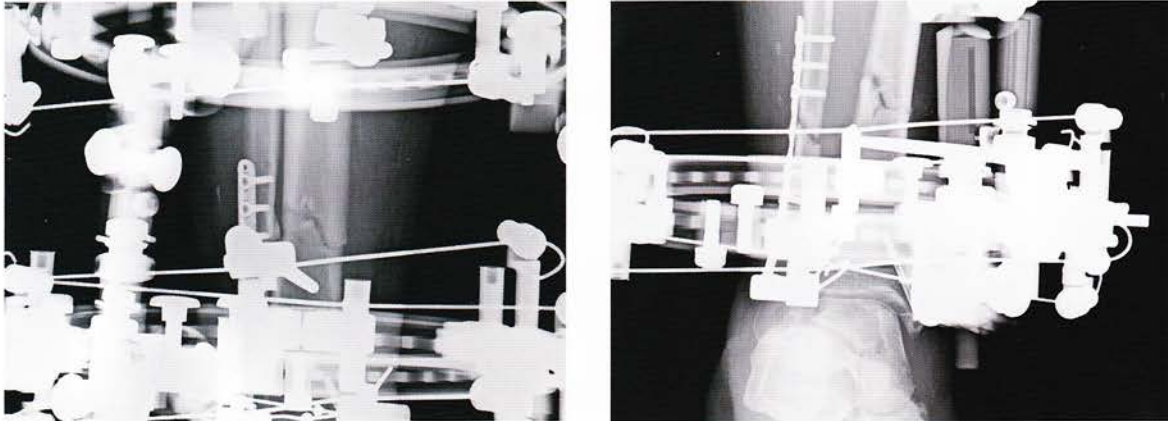
Post-Operative X-Rays and picture showing stabilization with the The EBI® DynaFix® Hybrid System.



Patient Background (Continued)

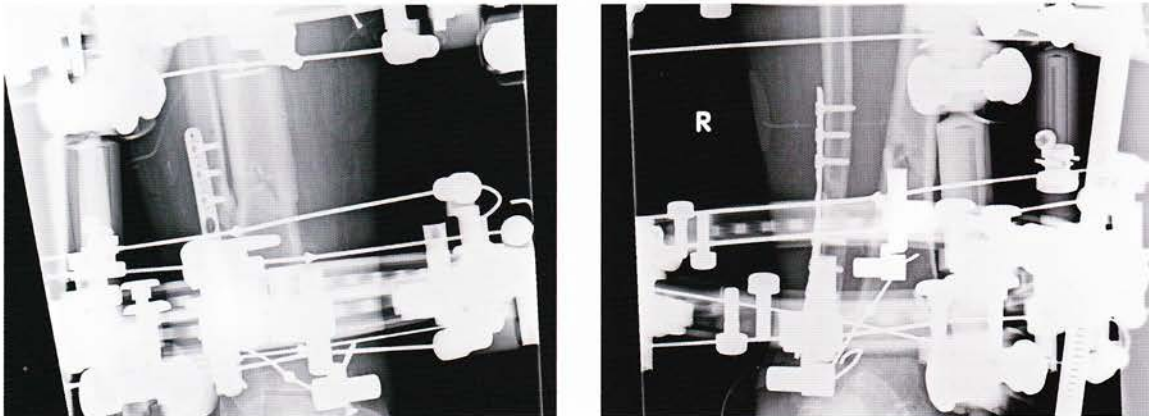
Three Months Post-Operative

Radiographs showing complete healing of the tibial plafond but little bone formation of both the tibia and fibula.



Five Months Post-Operative

X-Rays showing significant bone formation after two months of using the EBI Bone Healing System®.



Final X-Rays

Final radiographs showing complete healing of the tibia and fibula.



OPTIONS

The industry's most comprehensive options:

- PEMF, CC and DC
- Anatomy specific coils
- Wear-time choice

EVIDENCE

- Backed by proven science
- Multiple scientific papers
- The proof is in the patient

EXPERIENCE

Recognized as an industry
pioneer with EBI lineage, Biomet
has helped over one million people

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To learn more about this product,
contact your local Biomet Sales Representative today.

References

- 1) PMA P790002/S020/S022/S023. The EBI Bone Healing System[®] is indicated for the treatment of fracture nonunions, failed fusions and congenital pseudarthrosis in the appendicular system. A nonunion is considered to be established when there are no visible progressive signs of healing.
- 2) K000319. The EBI XFIX[®] DFS[®] System is a unilateral external fixation device intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality.
- 3) K042237. OptiLock[®] Periarticular Plating System for Distal Tibial Fractures is indicated for the fixation of fractures of the distal tibia including, but not limited to, ankle fractures, periarticular, intraarticular and distal tibia fractures with a shaft extension, malleolar and distal fibular fractures.

* The exact mechanisms by which bone development is triggered remains unclear, but is thought to involve growth factors.

** The average success rate of the EBI Bone Healing System[®] is 77%. Success rates of 85% were achieved in the tibia (P790002).



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