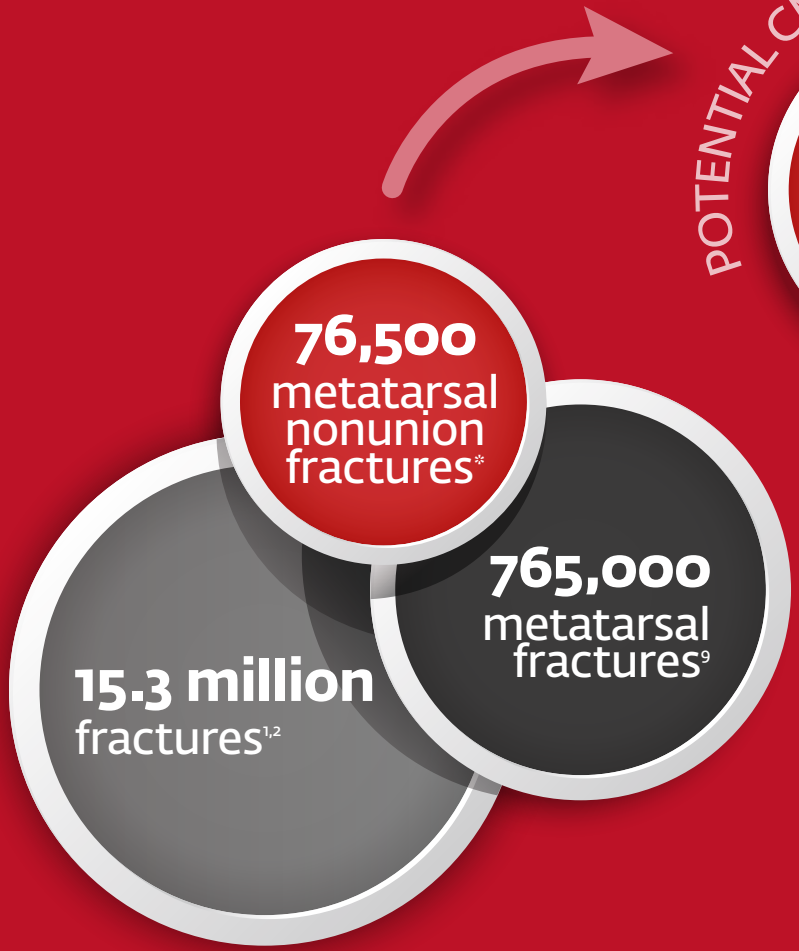
CMF™

Bone Growth Stimulation
Metatarsal Case Series

30 minute solution

DJO™ GLOBAL

The Advantages are Clear

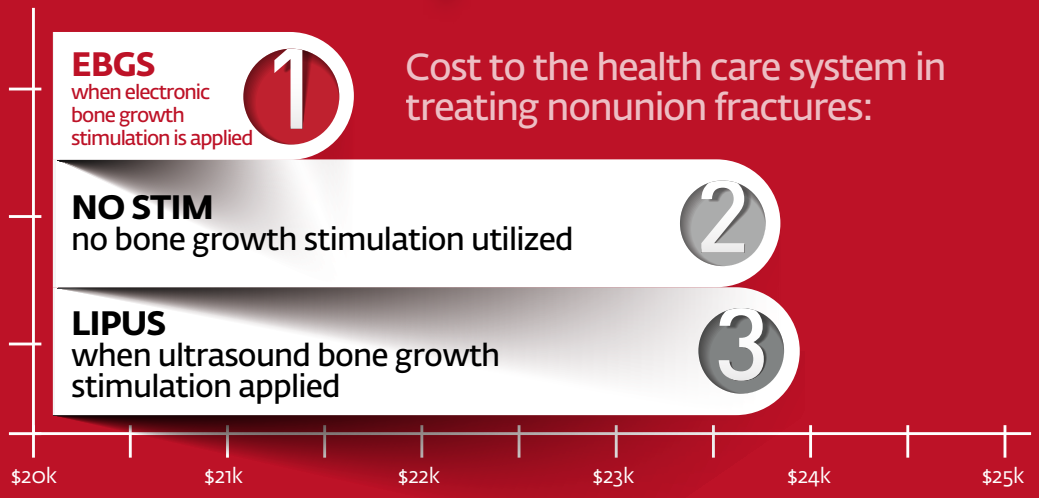


POTENTIAL CMF PATIENTS

76,500 metatarsal nonunion fractures*

CMF is:

- **clinically supported** (in level 1 PMA trial)[7]
- **scientifically shown to promote growth factors**[6]
- **financially cost effective in treating nonunion fractures**[10]



financial breakdown

Recent published health economic data confirms electrical bone growth stimulation is the most cost effective treatment (21,632) vs. no stim (23,843) vs. LIPUS (23,964) to the health care system in treating nonunion fractures.[10]

* indicates estimated annually U.S. data only.

FOOT & ANKLE HIGHLIGHTS

The only post-market registry data FDA reviewed with a ***high heal rate of 86% for nonunion metatarsal fractures in 81 days***[8].

30 min 

Effective in just one 30 minute treatment to best mimic cell replication

0 need 

Zero need to cut a hole in cast for treatment

Promotes bone formation by short exposure and continuous operation within low frequencies optimal to heal bone[3,4]

Potent signal targets the production of IGF-II, one of the most abundant growth factors in bone[5,6]

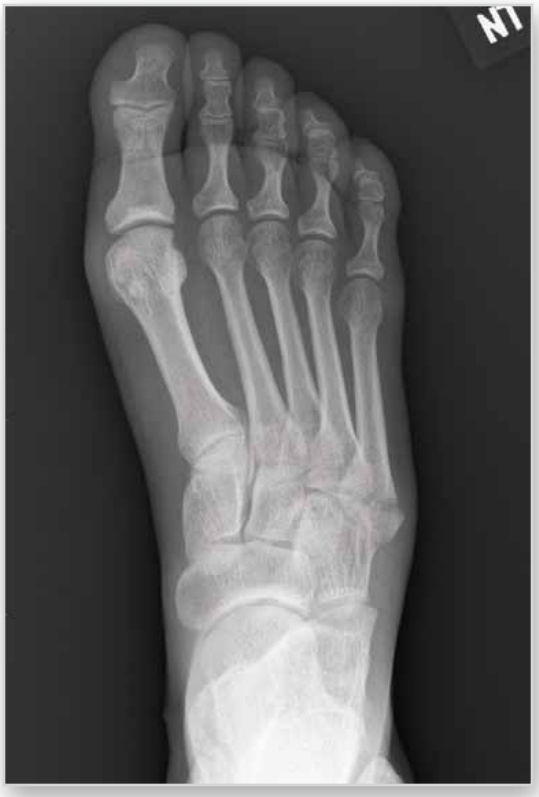
Built in monitor promotes improved patient compliance

Targeted treatment field, signal strength does not diminish as it passes through tissue

Simple one button operation, no gels or electrode placement required

CLINICAL PRESENTATION

Initial x-ray

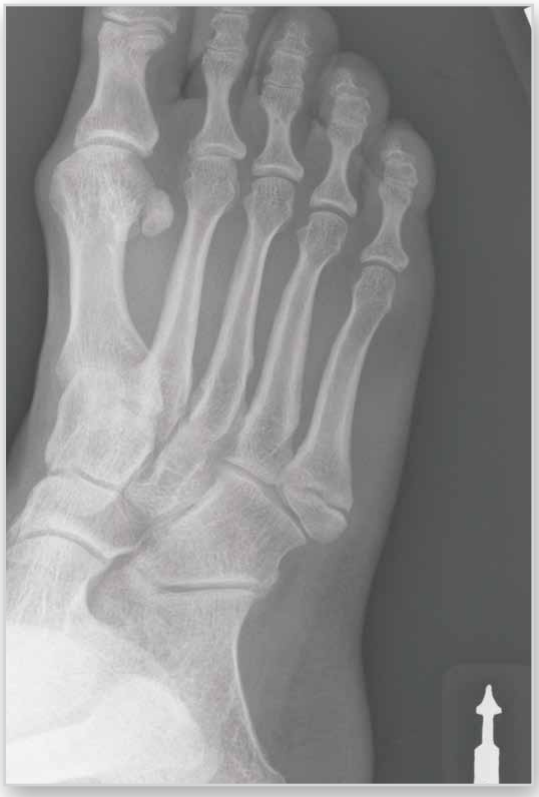


26 year old female
7-day history right lateral foot pain

Non-displaced base of the 5th metatarsal fracture identified

Treated conservatively with short CAM walker

3 months later



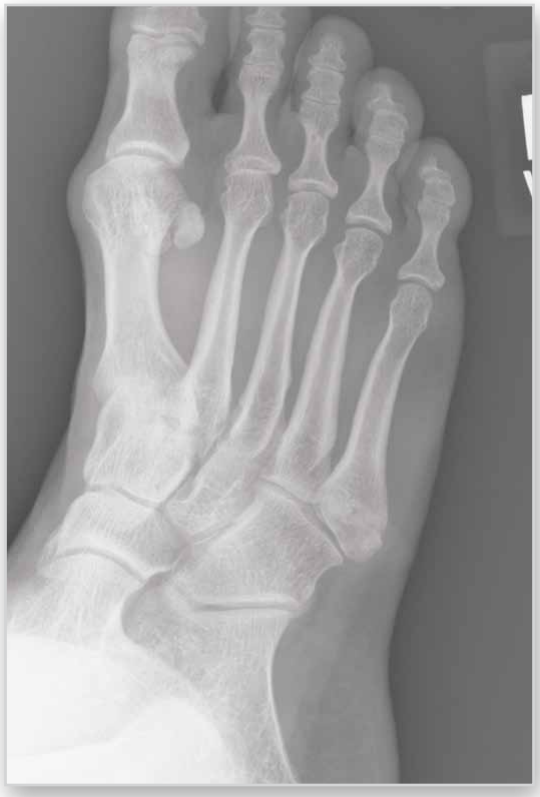
No clinical progression toward healing, nonunion diagnosis

Persistent fracture gap of 2mm

Initiated CMF bone growth stimulator treatment for 30 min once daily

CLINICAL OUTCOME

6 months - post diagnosis



Clinical Outcome Healed Fracture

6 months post diagnosis
Well-united fracture site noted
92 days utilizing the CMF bone growth stimulator

Patient asymptomatic

CMF offers multiple sizes to accommodate your foot and ankle fracture sites.

Case Study Provided by Dr. Carroll Kratzer
Raleigh Orthopedic Clinic

CMF OL1000 BONE GROWTH STIMULATION BRIEF PRESCRIBING INFORMATION

INDICATION: Noninvasive treatment of an established nonunion acquired secondary to trauma, excluding vertebrae and all flat bones. A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

CONTRAINDICATIONS: Use of this device is co traindicated in individuals having a synovial pseudarthrosis. Demand-type pacemaker or implantable cardiovertor defibrillator (ICD) operation may be adversely affected by exposure to magnetic fields. Physicians should not prescribe CMF OL1000 for applications that may place the treatment transducers in close proximity to the pacemaker. Further screening by the attending cardiologist is recommended (such as with an electrocardiogram). CMF OL1000 should not be used in the presence of external or internal fixation devices that are constructed from magnetic materials. (NOTE: Almost all fracture fixation devices implanted today are made from non-magnetic materials.)

WARNINGS: The safety and effectiveness of the use of this device on individuals lacking skeletal maturity have not been established. Animal studies conducted to date do not suggest any long-term significant adverse effects from use of this device. However, longterm effects in humans are unknown. Teratological studies have not been performed with this device. The safety of use of this device during pregnancy or nursing in humans has not been established.

PRECAUTIONS: Weight bearing is not advised in the presence of extreme motion at the nonunion site. In the presence of a malaligned nonunion, careful consideration of the use of this device must be undertaken on an individual basis, as treatment with this device is not intended to alter or affect the degree of malalignment. The safety and effectiveness of the use of this device on individuals with nonunion secondary to, or in conjunction with, a pathological condition have not been established. This device should not be used if there are mental or physical conditions that preclude patient compliance with the physician and device instructions. When conditions of atrophy are present or when fractures have remained unhealed for long periods of time, there may be less successful results.

ADVERSE EFFECTS: No known significant adverse effects have resulted from the use of this device. Clinical studies, animal studies, and tissue culture experiments conducted with the OL1000, which has the same treatment signal as the OL1000 SC1, have not indicated any evidence of significant adverse effects.

CAUTION: Federal law (U.S.A. and Canada) restricts this device to sale, distribution or use by or on the order of a physician.

CMF OL1000 POSTMARKET PATIENT REGISTRY DATA

CMF OL1000 Bone Growth stimulator Post market Patient Registry Data: As of June 30, 1998, the CMF OL1000 had been applied to 5300 patients with physician diagnosed nonunion with varying times from injury, two months or greater. Patient registry data was collected from December 1994 to December 1998. At the time of database closure, we expected follow-up on 4100 patients and received follow-up on 2370 patients (57.8%). Physician diagnosed healing determined patient outcome in the patient registry. All patients were treated for 30 minutes per day, and devices were programmed to provide a maximum of 270 days of treatment. The results of these 2370 patients are presented above.

** The success rate of 51/84 patients in pre-marketing clinical data was 60.7% and was maintained at 2 years post treatment with 90% follow-up of all healed fractures. In the pre-marketing clinical data was 60.7% and was maintained at 2 years post treatment with 90% follow-up of all healed fractures. In the pre-market study nonunion was considered to be established when a minimum of nine months had elapsed since injury and the fracture site showed no visibly progressive signs of healing for a minimum of 3 months. Patient success was defined as three out of four corticies bridged on radiographic and no pain or motion at the fracture site. For additional detailed information on pre-market prospective study, contact DJO.

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3. McLeod, K.J., Rubin, C.T., the Effect of Low-Frequency Electical Fields on Osteogenesis. J. Bone Joint Surg., 74A:920-929, 1992.

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8. Windram, WW and Jacob, JM, "Combined Magnetic Field Heals Long Bones of the Foot", DJO Whitepaper #11-2451, DJO, Vista, CA.

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10. Wu N, Lee Y, Segina D, Murray H, Wilcox T, Boulanger L. Economic Burden of Illness Among US Patients Experiencing Fracture Nonunion. Orthopedic Research and Reviews. 2013;5:21-33.

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