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Bone Growth Stimulators

Clinical Policy Bulletins | Medical Clinical Policy Bulletins

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Last Review
07/09/2025
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Review History

Definitions

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Policy

Scope of Policy

This Clinical Policy Bulletin addresses bone growth stimulators.

I. Medical Necessity

Aetna considers the following bone growth stimulators medically necessary:

A. *Ultrasonic osteogenesis stimulator*

1. The use of an ultrasonic osteogenesis stimulator (e.g., an ultrasonic accelerated fracture healing device) as durable medical equipment (DME) to accelerate healing of fresh fractures, fusions, or delayed unions at *any* of the following high-risk sites:

    i. Fresh closed or grade I* open, short oblique or short spiral fractures, fusions, or delayed unions of the shaft (diaphysis) of the tibia that are treated with closed reduction and cast immobilization; *or*
    ii. Fresh fractures, fusions, or delayed unions of the scaphoid (carpal navicular); *or*
    iii. Fresh fractures, fusions, or delayed unions of the 5th metatarsal (Jones fracture); *or*
    iv. Fresh fractures, fusions, or delayed unions of the distal radius (Colles fracture) treated with closed reduction and cast immobilization.

    This system uses pulsed ultrasound to speed healing. Fractures on these sites are difficult to heal because of poor vascular supply.

    * Grade I indicates that skin opening is 1 cm or less and minimal muscle contusion.

2. An ultrasonic osteogenesis stimulator for non-unions, failed arthrodesis, and congenital pseudarthrosis (pseudoarthrosis) of the appendicular skeleton if there has been no X-ray evidence of progression of healing for 3 or more months despite appropriate fracture care, and the following criteria are met:

    a. Bone is non-infected; *and*
    b. Bone is stable on both ends by means of cast or fixation; *and*
    c. The two portions of the involved bone are separated by less than 1 centimeter (cm);

B. *Electrical stimulation*

1. Direct current electrical bone-growth stimulators, as well as inductive coupling or capacitive coupling non-invasive electrical stimulators for *any* of the following non-spinal indications:

   a. Delayed unions of fractures or failed arthrodesis at high-risk sites (e.g., open or segmental tibial fractures, carpal navicular fractures, 5th metatarsal fractures, distal radius, and sesamoid bones (fibular sesamoid in the foot); *or*
   b. Non-unions, failed fusions, and congenital pseudarthrosis where there is no X-ray evidence of progression of healing for 3 or more months despite appropriate fracture care;

   And when the following criteria are met:

   a. Bone is noninfected; *and*
   b. Bone is stable on both ends by means of cast or fixation; *and*
   c. The two portions of the involved bone are separated by less than 1 centimeter (cm);

2. Direct current electrical bone-growth stimulators, as well as inductive coupling or capacitive coupling non-invasive electrical stimulators for *any* of the following spinal indications:

   a. A multiple level fusion entailing 3 or more vertebrae (e.g., L3 to L5, L4 to S1, etc.), *or*
   b. Grade II or worse spondylolisthesis, *or*
   c. One or more failed fusions.

II. **Experimental, Investigational, or Unproven**

The following bone growth stimulators are considered experimental, investigational, or unproven for the specified indications because their effectiveness for these indications has not been established:

A. *Ultrasonic osteogenesis stimulator*

1. For fractures (including lumbar compression fracture, stress fracture and avulsion fracture of the hip), failed fusions, or non-unions of the axial skeleton (skull and vertebrae);
2. For all other indications, including the following (not an all-inclusive list) because the medical literature does not support its use for these indications:
   a. Avascular necrosis of the femoral head;
   b. Calcaneal apophysitis (Sever disease);
   c. Charcot arthropathy;
   d. Fractures with post-reduction displacement of more than 50% (i.e., fractures in which the opposing broken bone ends are out of alignment by more than one half of the width of the bone);
   e. Iliac apophysitis;
   f. Pathological fractures due to malignancy (unless the neoplasm is in remission);
   g. Pre-operative use for fractures that require surgical intervention or internal or external fixation;
   h. Stress fractures;
   i. Talar dome lesion following osteochondral autograft transfer system (OATS);

B. *Electrical bone-growth stimulator*

For the treatment of all other indications, including the following (not an all-inclusive list) because of a lack of adequate evidence for these conditions:

1. Avascular necrosis of the hip
2. Charcot arthropathy
3. Charcot foot
4. Comminuted toe fracture
5. Fractures of the scapula or pelvis
6. Loosened hip prosthesis
7. Loosened knee prosthesis
8. Lunate fractures
9. Odontoid fractures

10. Pre-operative use for fractures that require surgical intervention or internal or external fixation
11. Sacroiliac fusion
12. Spondylolysis (also known as pars inter-articularis fracture)
13. Stress fractures.

C. *Semi-invasive bone growth stimulators*

For all indications including treatment of orthopedic and neurosurgical conditions (e.g., delayed unions, failed spinal fusions, fracture non-unions, fresh fractures, and pseudoarthroses) because of a lack of adequate evidence of their effectiveness;

III. Related Policies

- CPB 0175 - High-Frequency Pulsed Electromagnetic Stimulation (../100_199/0175.html)

CPT Codes / HCPCS Codes / ICD-10 Codes

Ultrasonic osteogenesis stimulator:

Code	Code Description
CPT codes covered if selection criteria are met:	
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)
97035	Application of a modality to one or more areas; ultrasound, each 15 minutes
HCPCS codes covered if selection criteria are met:	
E0760	Osteogenesis stimulator, low intensity ultrasound, non-invasive
ICD-10 codes covered if selection criteria are met:	
M43.10 - M43.19	Spondylolisthesis [acquired]

Code	Code Description
Numerous options	Malunion of fracture
Numerous options	Nonunion of fracture
Q74.0 – Q74.9	Other congenital malformations of limbs [congenital pseudarthrosis]
Q76.2	Congenital spondylolisthesis
S52.531A – S52.539S	Colles fracture
S62.001A – S62.036S	Fracture of navicular (scaphoid) bone of wrist
S82.101A – S82.199S	Fracture upper end of tibia
S82.201A – S82.299S	Fracture of shaft of tibia
S82.51xA – S82.56xS	Fracture of medial malleolus
S82.831A – S82.839S	Other fracture of upper and lower end of fibula
S82.841A – S82.846S	Bimalleolar fracture of lower leg
S82.851A – S82.856S	Trimalleolar fracture of lower leg
S82.871A – S82.876S	Pilon fracture of tibia
S92.301A - S92.356S	Open or closed fracture of metatarsal bone(s) [Jones (5th metatarsal) fracture]
ICD-10 codes not covered for indications listed in the CPB:	
C40.00 - C40.32, C41.4	Malignant neoplasm of scapula and long bones of upper limb, short bones of upper limb, pelvic bones, sacrum, and coccyx, long bones of lower limb, or short bones of lower limb
C79.51 - C79.52	Secondary malignant neoplasm of bone and bone marrow

Code	Code Description
M14.671 - M14.679, M14.69	Charcot's joint, ankle and foot
M84.30xA – M84.38xS	Stress fractures
M84.40xA – M84.68xS, M80.011A – M80.88xS	Pathologic fracture
M87.051 - M87.059, M87.151 - M81.159 M82.251 - M87.256, M87.351 - M87.353 M87.851 - M87.859, M90.551 - M90.559	Idiopathic aseptic necrosis of head and neck of femur
M92.60 - M92.62	Juvenile osteochondrosis of tarsus [calcaneal apophysitis (Sever disease)]
M92.8	Other specified juvenile osteochondrosis [iliac apophysitis]
M92.9	Juvenile osteochondrosis, unspecified [iliac apophysitis]
M93.98	Osteochondropathy, unspecified other [iliac apophysitis]
S02.0xxA – S02.92xS	Fracture of skull
S02.0xxA – S02.92xS, S12.000A – S12.9xxS, S22.000A – S22.089S	Fracture of vertebral column [with or without spinal cord injury]

Code	Code Description
S32.000A - S32.050S	Fracture of lumbar vertebra
S32.311A - S32.316S	Avulsion fracture of ilium
S32.611A - S32.616S	Avulsion fracture of ischium
Electrical Stimulation:	
CPT codes covered if selection criteria are met:	
20974	Electrical stimulation to aid bone healing; noninvasive (non-operative)
20975	invasive (operative)
HCPCS codes covered if selection criteria are met:	
E0747	Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
E0748	Osteogenesis stimulator, electrical, noninvasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted
ICD-10 codes covered if selection criteria are met:	
M43.10 - M43.19	Spondylolisthesis [acquired]
M43.20 - M43.28	Fusion of spine
Numerous options	Malunion of fracture
Numerous options	Nonunion of fracture
Q74.0 - Q74.9	Other congenital malformations of limbs [congenital pseudarthrosis]
Q76.2	Congenital spondylolisthesis
S62.001A – S62.036S	Fracture of navicular (scaphoid) bone of wrist
S82.101A – S82.199S	Fracture upper end of tibia

Code	Code Description
S82.201A – S82.299S	Fracture of shaft of tibia
S82.51xA – S82.56xS	Fracture of medial malleolus
S82.831A – S82.839S	Other fracture of upper and lower end of fibula
S82.841A – S82.846S	Bimalleolar fracture of lower leg
S82.851A – S82.856S	Trimalleolar fracture of lower leg
S82.871A – S82.876S	Pilon fracture of tibia
S92.251A – S92.256S	Fracture of navicular (scaphoid), foot
S92.301A - S92.356S	Open or closed fracture of metatarsal bone(s) [Jones (5th metatarsal) fracture]
S92.811A - S92.819S	Other fracture of foot, except ankle [Sesamoid bones fracture of foot]
ICD-10 codes not covered for indications listed in the CPB:	
M14.671 - M14.679	Charcot's joint, ankle and foot
M43.28	Sacroiliac fusion
M84.30xA – M84.38xS	Stress fractures

Code	Code Description
M87.051 - M87.059, M87.151 - M81.159 M82.251 - M87.256, M87.351 - M87.353 M87.851 - M87.859, M90.551 - M90.559	Idiopathic aseptic necrosis of head and neck of femur
Q76.2	Spondylolysis [lumbar region]
S12.100A – S12.131S	Fracture of second cervical vertebra [odontoid fractures]
S32.401A – S32.599S	Fracture of acetabulum
S42.101A – S42.199S	Fracture of scapula
S62.121A – S62.126S	Fracture of lunate [semilunar]
T84.032A – T84.033S	Mechanical loosening of prosthetic joint [hip and knee joint]
Semi-Invasive Bone Growth Stimulators:	
No specific code	
ICD-10 codes not covered for indications listed in the CPB (not all inclusive):	
M84.750A – M84.759S	Atypical femoral fracture

Code	Code Description
S02.0xxA – S02.19xS, S12.00xA – S12.9xxS, S22.000A – S22.9xxS, S32.000A – S32.9xxS, S42.001A – S42.9xxS, S52.001A – S52.92xS, S62.001A – S62.92xS, S72.001A – S72.92xS, S82.001A – S82.92xS, S92.001A – S92.919S	Fractures of skull, neck, trunk, upper limbs and lower limbs [malunion and nonunion]

Background

Bone growth stimulation is utilized to promote bone healing in difficult to heal fractures or fusions by applying electrical or ultrasonic current to the fracture/fusion site.

An electrical osteogenesis stimulator is a device that provides electrical stimulation to augment bone repair. Electrical stimulation can be applied either from the outside of the body (noninvasive) or from the inside of the body (invasive). A noninvasive electrical stimulator is characterized by an external power source which is attached to a coil or electrodes placed on the skin or on a cast or brace over a fracture or fusion site.

An ultrasonic osteogenesis stimulator is a noninvasive device that emits low intensity, pulsed ultrasound. The ultrasound signal is applied to the skin surface at the fracture location via ultrasound conductive coupling gel in order to stimulate fracture healing.

Ultrasonic Osteogenesis Stimulators for Fresh Fractures

Ultrasonic fracture healing utilizes a signal generator and a transducer, which when placed over the fracture site on the skin, emits low intensity ultrasound signals that are emitted directly to the fracture. Examples of ultrasonic bone growth stimulators include, but may not be limited to, the Exogen 4000+, Exogen 3000, Exogen 2000+ and Exogen 2000 (also known as the SAFHS Model 2000 or the Exogen Pulsed Low-Intensity Ultrasound Bone Healing System Model 2000).

When applied over a fracture site, an ultrasonic accelerated fracture healing device produces an ultrasonic wave, which delivers mechanical pressure to the bone tissue at the fracture site. Although the mechanism by which the low-intensity pulsed ultrasound device accelerates bone healing is uncertain, it is thought to promote bone formation in a manner comparable to bone responses to mechanical stress.

In October 1994, the Food and Drug Administration (FDA) approved the SAFHS, manufactured by Exogen, Inc. (West Caldwell, NJ), to accelerate the healing of new bone fractures in the tibial diaphysis and Colles' fractures of the distal radius in adults. The FDA approval of the device was based in part on its review of 2 multi-center randomized controlled trials of the device on tibial diaphyseal fractures and distal radius (Colles') fractures.

SAFHS low-intensity pulsed ultrasound has been demonstrated to significantly accelerate the time to clinical healing of fractures of the tibial diaphysis. Tibial fractures are notorious for prolonged healing and a high incidence of delayed union and nonunion. The average fresh uncomplicated tibial fracture takes 4 months to heal, and a majority of cases of nonunion involve the tibia. A study by Heckman, et al. (1994) demonstrated the effectiveness of SAFHS low intensity pulsed ultrasound in accelerating fracture healing in 96 patients with 97 closed or grade I open fractures of the tibial shaft. Patients were randomly assigned to

treatment with either SAFHS or to a placebo device, and treatment with SAFHS was begun within 7 days of injury. Thirteen fracture patients were lost to follow-up, and 17 fracture patients were excluded because of deviations from the study protocol (the latter group of patients were included in an intention-to-treat analysis), so that 66 patients with 67 fractures remained in the study to its conclusion. Beginning 7 days after fracture, patients received one 20-minute treatment each day either with ultrasound or with the placebo device for up to 20 weeks. Two clinical outcomes and two radiological outcomes were measured. The clinical outcomes examined were time to clinical healing (defined as the time at which the physician thought that, on clinical examination, the fracture was stable and was not painful to palpation) and the time to discontinuation of the cast (defined as the time at which the physician removed the cast). The radiological outcomes included cortical bridging (the gradual disappearance of interruption of cortex at the fracture site as a result of callus formation) and endosteal healing (the gradual disappearance or obliteration of the fracture line and its replacement by a zone of increased density formed by endosteal callus). The time to radiographic healing was defined as the time to bridging of all four cortices. A fifth outcome, time to complete healing, was defined as the time to complete radiographic and clinical healing. Given that clinical healing typically occurs before radiographic healing, the time to complete healing was primarily a reflection of the time to radiographic healing.

All patients were completely healed at the end of the study, regardless of whether they were treated with low-intensity pulsed ultrasound (Heckman, et al., 1994). There was a statistically significant reduction in time to healing in the treatment group by each of the outcomes measured. The reductions in time to healing measured clinically were smaller than the reductions in time to healing measured radiographically. The time to overall (clinical and radiographic) healing was 96 $\pm$ 4.9 days in the treatment group compared with 154 $\pm$ 13.7 days in the placebo group ($p = 0.0001$). In general, the magnitude of reductions in time to healing tended to be greatest in tibial fracture patients which factors that tend to prolong healing time. Older patients and women tend to have greater times to healing than younger patients and men, and the reduction in time to healing from SAFHS tended to be greater in older patients and in women. Healing times tended to be greater with larger fracture gaps, and spiral and oblique fractures tended to take longer to

heal than transverse fractures. The effect of SAFHS in reducing the time to complete healing of tibial fractures tended to be greater where there was a larger fracture gap, and also in patients with spiral or oblique fractures. The greatest reductions in healing time occurred in patients with oblique and spiral fractures who also had the largest fracture gaps. The magnitude of the benefit of SAFHS was also affected by the location of the fracture on the tibia, with the greatest reduction in fracture healing time occurring in patients with fractures of the distal portion of the tibial diaphysis. The magnitude of prereduction displacement also appeared to have an effect on time to complete healing and on the amount of reduction of fracture healing time with SAFHS. Patients with less than 20 percent prereduction displacement tended to have less time to a healed fracture and less reduction in fracture healing time than patients with prereduction displacement of 20 percent or more. Long-term follow-up of trial participants was done at the request of the FDA to determine whether all healed fractures in both groups remained healed at a minimum of two years after the injury. Fifty-five patients (56 fractures) of the 66 patients (67 fractures) who had been enrolled in the protocol were contacted, and all of the 56 fractures were still healed up to four years after fracture. The conclusions about the effectiveness of low-intensity pulsed ultrasound on fracture healing from this study are limited to new fractures of the tibial diaphysis that are closed or open grade I. Excluded from the study were patients with severe fracture complications Also excluded from the study were patients with pathological fractures (fractures due to bone diseases or malignancy).

Although SAFHS low-intensity pulsed ultrasound has been demonstrated to accelerate the time to radiologic healing of fresh closed Colles' (wrist) fractures, it has not been shown to significantly reduce the time to clinical healing of these fractures. Kristiansen, et al. (1997) examined the effectiveness of SAFHS in Colles' fractures of the distal radius showed significantly less time to radiographic healing in SAFHS-treated patients, but was not able to detect any significant difference in time to clinical healing. The study only included patients with closed Colles' fractures in which the primary fracture line was predominantly transverse and occurred within the distal 1.5 inches of the radius. The fracture was required to be satisfactorily reduced, based upon radial length, radial angle, and volar tilt. Eighty five fractures were entered into the study, with 40 fractures randomly assigned to the ultrasound treatment, and 45

fractures assigned to the placebo device. Patient's were treated with ultrasound or the placebo device for 20 minutes each day for 10 weeks, starting within 7 days of fracture. Three of these fractures were lost to follow-up, and 21 were excluded because of lack of adherence to protocol (the latter group were included in an intention-to-treat analysis), so that 61 fractures remained in the study to its conclusion. The outcomes examined in this study were similar to those examined in the study of tibial fractures described above: measures of clinical healing, radiographic healing, and time to complete healing were reported. Colles' fractures were considered clinically healed when the fracture site was solid and free of tenderness and pain upon palpation. (In contrast to the study of SAFHS and tibial fractures, the time to cast removal was not reported in this study.) Time to endosteal healing and time to cortical healing were measured. Colles' fractures were considered radiographically healed when all cortices were bridged. Time to complete healing, defined as the time to full clinical and radiographic healing, was also measured. Because clinical healing of fractures usually occurs well before radiographic healing, the time to complete (radiographic and clinical) healing was primarily a factor of the time to radiographic healing. Thus, the time to radiographic healing and the time to complete healing were approximately equal.

Both patients treated with low-intensity pulsed ultrasound and patients receiving placebo were healed by the end of the study; there was no difference in the final healing rates between the treatment and control groups (Kristiansen, et al., 1997). There was a statistically significant difference time to radiographic healing between patients receiving active treatment (60.2 $\pm$ 3.5 days) and patients receiving placebo (97.9 $\pm$ 5.2 days), as well as a statistically significant difference in time to complete healing between actively treated patients (61 $\pm$ 3.4 days) and placebo recipients (98 $\pm$ 5.2 days). There was no statistically significant difference in time to clinical healing between patients receiving active treatment (30 $\pm$ 1.9 days) and patients receiving placebo (32 $\pm$ 2.1 days). The authors noted, however, that the measurement of clinical healing was complicated by the subjectivity of the clinical assessment. Furthermore, clinical healing was assessed when the initial cast was removed, and the initial cast removal did not occur at the same time following fracture in each patient. The failure to find a significant reduction in the time to clinical healing of Colles' fractures with SAFHS, however, calls into

question whether the reductions in healing time reported in this study were of clinical significance. First, the total healing time and reduction in healing time with SAFHS of Colles' fractures were much smaller than that of tibial fractures. This is because trabecular bone heals much more rapidly than cortical bone due to its greater surface area, cellularity, and vascularity. Among fractures of cortical bone, tibial fractures are particularly likely to be slow-healing. Second, radiographic healing is an outcome of questionable clinical relevance, given that the primary reason to accelerate fracture healing is to reduce the duration of morbidity due to pain and loss of function. There was evidence that the greatest reductions in time to complete healing with SAFHS were achieved by older patients and female patients -- patients who also tend to have longer healing times. Actively treated patients age 50 or older healed 40 days sooner than placebo recipients of the same age, whereas actively treated patients less than 50 years old healed only 29 days sooner than their counterparts in the placebo group. Similarly, the reduction in time to complete healing of Colles' fractures tended to be greater in women (40 days saved) than men (30 days saved). Excluded from the study were patients with nonunions, pathologic fractures, or patients with fractures requiring open reduction, skeletal fixation, or surgical intervention. Thus, evidence of healing was limited to patients with fresh closed distal radius (Colles') fractures that can be managed with closed reduction and cast immobilization. At the request of the FDA, attempts were made to contact all clinical trial participants two or more years after fracture to determine whether their fractures were still healed. Over 92 percent of the patients were contacted and all remained healed. Children were excluded from both clinical trials because the effects of low intensity pulsed ultrasound on the immature skeleton are unknown.

SAFHS is most likely to result in clinically significant benefits when applied to fresh fractures with poor vascularity that are slow to heal and at high risk of non-union. Tibial fractures that are open or segmental are notorious for prolonged healing and a high incidence of delayed union and non-union. Healing of femur fractures is also prolonged, and the femur is the second most common site of fracture nonunion. However, repair of femur fractures requires open surgery. Fractures of the scaphoid (carpal navicular) and the fifth metatarsal (Jones fracture) are uncommon,

but when they occur, they are at high-risk of delayed union and non-union. Hence, use of SAFHS may be particularly helpful in patients with these fractures.

Literature from the manufacturer suggests that low intensity pulsed ultrasound could be targeted to patients who are likely to have a slow healing fractures, either because of fracture characteristics, comorbid conditions, or because of age. Fractures involving trabecular bone tend to heal much more rapidly than fractures of cortical bone, and comparison of clinical trials of SAFHS in patients with fractures of the tibia (comprised primarily of cortical bone) and Colles' fractures (involving primarily trabecular bone) suggest that the reduction in healing time with SAFHS is greatest in fractures involving cortical bone.

Smokers tend to have longer times to fracture healing. A subsequent analysis of the SAFHS tibial fracture study showed that greater reductions in fracture healing time were achieved in patients with a history of smoking, with the greatest reductions in fracture healing time occurring in current smokers (Cook et al, 1997).

There is evidence that patients receiving steroids or anticoagulants tend to have prolonged fracture healing times. However, patients on these medications were excluded from clinical trials of SAFHS, so that the effect of SAFHS in reducing healing times in these patients is uncertain . Patients with circulatory problems (e.g., vascular insufficiency, thrombophlebitis) are more likely to experience prolonged fracture healing, but patients with these problems were also excluded from study participation.

Open fractures and severe fractures are susceptible to delayed healing. However, patients with the most severe fracture complications were excluded from study participation. Patients with pathologic fractures (fractures occurring through diseased bone due to tumor, infection, Paget's disease, etc.) are more likely to have fractures that are slow to heal or fail to heal altogether. However, patients with pathologic fractures were excluded from the clinical trials of SAFHS. Moreover, it is uncertain whether SAFHS would significantly accelerate healing in patients with pathologic fractures due to malignancy unless the underlying neoplasm is treated.

Obese patients and patients with diabetes tend to have delayed fracture healing. However, there are no clinical studies that demonstrate that SAFHS results in a greater reduction in fracture healing time in these patients compared to other patients.

There are no contraindications to the use of low intensity pulsed ultrasound, and no known side effects. The intensity of ultrasound used for fracture healing (30 milliwatts (mW) per centimeter squared (cm^2)) is at the same low level as diagnostic ultrasound (0.5 to 50 mW/ cm^2). Ultrasound of this intensity produces very little heat in tissue, in contrast to high intensity ultrasound used for surgical (5 to 125 watts (W)/ cm^2) or therapeutic (0.2 to 3 W/ cm^2) purposes.

SAFHS will not correct or alter post reduction aspects of a fracture, such as displacement, angulation, or malalignment. It does not obviate the need for open reduction and internal fixation in fractures where this is indicated.

The safety and effectiveness of the use of SAFHS has not been established for fractures with post-reduction displacement of more than 50% (i.e., fractures in which the opposing broken bone ends are out of alignment by more than one half of the width of the bone).

Ultrasonic bone growth stimulation has also been studied for accelerating healing of stress fractures. In a prospective, randomized, double-blind clinical trial, Rue et al (2004) ascertained if pulsed ultrasound reduces tibial stress fracture healing time. A total of 26 midshipmen (43 tibial stress fractures) were randomized to receive pulsed ultrasound or placebo treatment. Twenty-minute daily treatments continued until patients were asymptomatic with signs of healing on plain radiographs. The groups were not significantly different in demographics, delay from symptom onset to diagnosis, missed treatment days, total number of treatments, or time to return to duty. Findings of this study demonstrated that pulsed ultrasound did not significantly reduce the healing time for tibial stress fractures. Furthermore, Zura and colleagues (2007) surveyed the attitudes of members of the Orthopaedic Trauma Association (OTA) concerning the use and effectiveness of bone growth stimulators. A questionnaire regarding bone growth stimulators was sent to the active members of the OTA. Descriptive statistics was performed using

frequencies and percentages. All analyses were performed using Stata for Linux, version 8.0 (Intercooled Stata, Stata Corporation; College Station, TX). A response rate of 43 % was obtained. Respondents indicated that they only occasionally used bone stimulators for the treatment of acute fractures and stress fractures. A majority of respondents have utilized stimulators for the treatment of delayed unions and non-unions. The authors concluded that many members of the OTA utilize bone stimulators for delayed unions and non-unions, but not routinely for the treatment of acute fractures or stress fractures.

Watanaba and colleagues (2010) stated that low-intensity pulsed ultrasound is a relatively new technique for the acceleration of fracture healing in fresh fractures and non-unions. It has a frequency of 1.5 MHz, a signal burst width of 200 micros, a signal repetition frequency of 1 kHz, and an intensity of 30 mW/cm2. In 1994 and 1997, 2 milestone double-blind randomized controlled trials revealed the benefits of pulsed ultrasound for the acceleration of fracture healing in the tibia and radius. They showed that pulsed ultrasound accelerated the fracture healing rate from 24 % to 42 % for fresh fractures. Some literature, however, has shown no positive effects. The beneficial effect of acceleration of fracture healing by pulsed ultrasound is considered to be larger in the group of patients or fractures with potentially negative factors for fracture healing. The incidence of delayed union and non-union is 5 % to 10 % of all fractures. For delayed union and non-union, the overall success rate of pulsed ultrasound therapy is approximately 67 % (humerus), 90 % (radius/radius-ulna), 82 % (femur), and 87 % (tibia/tibia-fibula). The authors noted that pulsed ultrasound likely has the ability to enhance maturation of the callus in distraction osteogenesis and reduce the healing index. They concluded that the critical role of pulsed ultrasound for fracture healing is still unknown because of the heterogeneity of results in clinical trials for fresh fractures and the lack of controlled trials for delayed unions and non-unions.

Ultrasound Osteogenesis Stimulators for Nonunions

SAFHS low-intensity pulsed ultrasound was approved by the FDA in February 2000 for the treatment of established non-unions, excluding the skull and vertebrae. The FDA approval of the device was based on a review of retrospective studies of 79 patients with non-unions treated with

SAFHS. Patients with pathologic fractures due to malignancy were excluded from these studies. Of the 74 completed cases, 86 % healed both radiographically and clinically and 14 % were failures of SAFHS treatment. The mean time to a healed fracture was 5½ months.

Other evidence of the effectiveness of SAFHS for non-unions include a registry of prescription use of SAFHS for non-unions in the United States, which showed a heal rate of 82 % of 429 completed cases, and a retrospective study of non-unions which showed a heal rate of 90 % of 30 completed cases.

Medicare allows ultrasonic osteogenesis stimulators only if all of the following criteria are met: (i) nonunion of a fracture documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days; and (ii) the fracture is not of the skull or vertebrae; and (iii) the fracture is not tumor related. Medicare requires that each radiograph set include multiple views of the fracture site accompanied by a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs. Medicare considers not medically necessary use of an ultrasonic osteogenesis stimulator with other noninvasive osteogenesis stimulators.

Ultrasonic Osteogenesis Stimulator for the Treatment of Lumbar Compression Fracture

An UpToDate review on “Osteoporotic thoracolumbar vertebral compression fractures: Clinical manifestations and treatment” (Rosen and Walega, 2021) does not mention osteogenesis stimulator / low-intensity ultrasound as a management / therapeutic option.

Ultrasonic Osteogenesis Stimulator for the Treatment of Stress Fracture and Avulsion Fracture of the Hip

Stafford et al (2019) presented the findings of a case of an 18-year old with a 2-year history of buttock pain who failed extensive treatment for a perceived hamstring strain. Upon evaluation, he was diagnosed with an ischial tuberosity nonunion avulsion fracture. The patient underwent

bone grafting via an ultrasound (US)-guided leukocyte rich platelet-rich plasma (PRP) injection followed by the use of a bone stimulator to enhance the bone healing. At 3 months, he was asymptomatic and had radiographic evidence of excellent bone healing. He remained asymptomatic at 1 year and had resumed full activities. The authors concluded that this case report was the 1st in the literature to describe the treatment of a chronic ischial tuberosity nonunion avulsion fracture with the use of PRP as a bone graft.

Furthermore, an UpToDate review on "Pelvic trauma: Initial evaluation and management" (Fiechtl, 2021) does not mention bone growth stimulator as a management / therapeutic option.

Electrical Stimulation

Electrical stimulation can be applied either from the outside of the body (noninvasive) or from the inside of the body (invasive). Noninvasive (external) electrical bone growth stimulators (BGS) are devices worn on the outside of the skin. They utilize treatment coils situated externally around the fracture or fusion site and an external power supply. There are three types of noninvasive electrical bone growth stimulators:

- Capacitive coupling (CC) devices use metal electrodes, which are applied to the skin to deliver the current. An example of a CC device includes, but may not be limited to, the EBI OrthoPak 2 Bone Growth Stimulator.
- Pulsed electromagnetic field (PEMF) devices use an externally applied coil to deliver the current, which can be pulsed on and off. Examples of PEMF devices include, but may not be limited to, the EBI Bone Healing System, the Orthofix Cervical-Stim, the Orthofix Physi-Stim, the Orthofix Spinal-Stim and the SpinalPak II Spinal Fusion Stimulator.
- Combined magnetic field (CMF) devices use an external coil system with a combination of direct and alternating current to produce both static and alternating magnetic fields. Examples of CMF devices include, but may not be limited to, the OrthoLogic (OL) 1000 Bone Growth Stimulator and the SpinaLogic Bone Growth Stimulator.

The surgically implanted or invasive electrical BGS utilize direct current to the nonhealing fracture or bone fusion site. Examples of invasive (implantable) electrical bone growth stimulators include, but may not be limited to, the EBI OsteoGen Bone Growth Stimulator, the OsteoGen Dual Lead Bone Growth Stimulator, the OsteoGen-M Bone Growth Stimulator, the SpF PLUS-Mini Spinal Fusion Stimulator, the SpF-XL IIb Spinal Fusion Stimulator and the Zimmer Direct Current Bone Growth Stimulator.

Electrical Stimulation for Spinal Fusion

Spinal fusion is a general term which describes the surgical results of a procedure designed to eliminate motion across a spinal segment. All fusions involve the placement of a bone graft across the spinal segment with or without a wide variety of internal fixators and techniques for postoperative immobilization.

There are 3 general indications for spinal fusion: (i) to restore the integrity of the spine, to replace bone deficits, i.e., in fracture, tumor, infection; (ii) to maintain the correction of spinal deformity or prevent the progression of deformity, i.e. scoliosis; and (iii) to produce an arthrodesis to suppress painful instability. The correction of painful instabilities probably the most common and controversial indication for fusion. The controversy centers around the treatment of low back pain and whether laminectomy and discectomy should be accompanied by a fusion. This is in turn related to whether instability itself is contributing to the low back pain or whether the surgical procedure, for example, discectomy and laminectomy, will produce an iatrogenic instability. Because of the potential for failed fusion, electrical stimulation techniques have been investigated as a method to improve the chances for a successful fusion.

Two general types of electrical stimulation devices are available for spinal fusion. An implantable device (e.g., SpF-2) uses direct current to stimulate osteogenesis. The implantable device consists of a battery pack which provides direct current over four cathodes. The device is implanted during the fusion procedure; the cathodes are implanted at the fusion site while the battery pack is implanted just beneath the dorsal fascia or in the soft tissue above the iliac crest. An external device (e.g.,

Spinal Stim) uses pulsating electromagnetic energy to induce weak electrical currents in the underlying tissue. The external electrical stimulation device consists of the magnetic coils incorporated into a corset like device which the patient wears 8 to 10 hours per day, usually while sleeping. The external device can either be used immediately after surgery, or only when fusion failure becomes apparent.

There have been several clinical studies on either device. In a randomized prospective controlled trial of the implanted electrical stimulation device in difficult spinal fusion patients, subjects were randomized to undergo a spinal fusion procedure either with or without simultaneous implantation of an electrical stimulation device. At 18 month post- surgery, successful fusion was achieved in 54 % of the control group and 81 % of the treatment group (Kane, 1988).

In a randomized double blind prospective study of an external electrical stimulation device, 195 patients were randomized to receive either a functioning or nonfunctioning brace following surgery (Mooney, 1990). A total of 40 % of patients were non-compliant. In those compliant patients who received an active brace, the fusion success rate was 92.2 % versus a success rate of 67.9 % of the compliant patients in the control group.

In a retrospective, case-controlled, pilot study, Welch and colleagues (2004) examined the safety and effectiveness of an implantable direct current bone growth stimulator (IDCBGS) as an adjunct to cervical arthrodesis in patients at high risk for non-union after undergoing cervical fusion in region from the occiput to C3. A total of 20 patients underwent para-axial cervical arthrodesis for the correction of instability. All were at high-risk for non-union due to advanced age, rheumatoid arthritis, prior failed fusion attempts, infection, or immunosuppressive drug use. An IDCBGS was used to augment the surgical procedure. The mean follow-up period was 19 months, and 16 patients were available for follow-up. Radiographical evidence of fusion was demonstrated in 15 of 16 patients (94 %). After surgery, all patients demonstrated clinical stabilization, a resolution of symptoms in combination with an improvement in neurological status, or both. The mean elapsed time before fusion occurred was 4.6 months. No neurological complications related to cathode or generator placement were observed. The use of the stimulator as an adjunct to instrument- or non-instrument-assisted

surgical fusion of the para-axial region in these high-risk patients appeared both safe and effective. The authors concluded that further investigation is needed to define the possible role and clinical utility of the IDCBGS in selected patients requiring cervical fusion, particularly those at high-risk for non-union.

Aetna's policy on electrical stimulation for spine fusion is supported by current Medicare policy, which allows electrical stimulation for spine fusion for the following indications:

(i) failed spinal fusion where a minimum of nine months has elapsed since the last surgery; or (ii) following a multilevel spinal fusion surgery; or (iii) following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site. Medicare notes that a multilevel spinal fusion is one which involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc). Kaiser and colleagues (2014) noted that the relationship between the formation of a solid arthrodesis and electrical and electromagnetic energy is well-established; most of the information on the topic, however, pertains to the healing of long bone fractures. The use of both invasive and non-invasive means to supply this energy and supplement spinal fusions has been investigated. Three forms of electrical stimulation are routinely used: (i) direct current stimulation (DCS), (ii) PEMF stimulation (PEMFS), and (iii) capacitive coupled electrical stimulation (CCES). Only DCS requires the placement of electrodes within the fusion substrate and is inserted at the time of surgery. Since publication of the original guidelines, few studies have investigated the use of bone growth stimulators. Based on the current review, no conflict with the previous recommendations was generated. The use of DCS is recommended as an option for patients younger than 60 years of age, since a positive effect on fusion has been observed. The same, however, cannot be stated for patients over 60, because DCS did not appear to have an impact on fusion rates in this population. No study was reviewed that investigated the use of CCES or the routine use of PEMFS. A single low-level study demonstrated a positive impact of PEMFS on patients undergoing revision surgery for pseudarthrosis, but this single study was insufficient to recommend for or against the use of PEMFS in this patient population.

PEMF for Cervical Fusion

Pulsed electromagnetic field (PEMF) therapy has been studied as an adjunct to cervical spinal fusion, with mixed evidence regarding its efficacy. The most relevant high-quality evidence is a randomized, controlled, prospective multicenter trial in patients undergoing anterior cervical discectomy and fusion (ACDF) with risk factors for nonunion (smoking, multilevel fusion) (Foley, et al., 2008). This study found that PEMF significantly increased the fusion rate at 6 months postoperatively (83.6% vs. 68.6%, p=0.0065), but the difference was not statistically significant at 12 months (92.8% vs. 86.7%, p=0.11). No differences in adverse events or clinical outcomes (pain, disability) were observed between groups, indicating that PEMF is safe but may only accelerate, rather than increase, ultimate fusion rates in this population.

Systematic reviews and meta-analyses of electrical stimulation modalities (including PEMF) for spinal fusion generally suggest a modest increase in fusion rates, but the quality of evidence is moderate and heterogeneity is high. One meta-analysis found that electrical stimulation increased the odds of successful fusion (OR 2.53, 95% CI 1.86–3.43), but did not identify a significant difference between stimulation types or by spinal region (Akhter, et al., 2020; Luo, et al., 2024). Another meta-analysis focusing on noninvasive electrical stimulation found no significant difference in fusion rates for PEMF compared to control, and highlighted the high risk of bias and limited number of studies (Matur, et al., 2022).

According to OrthoFix, the CervicalStim device is the only bone growth stimulation therapy approved by the (FDA as a non-invasive, adjunctive therapeutic option for cervical fusion in patients at high-risk for non-fusion. The device uses a pulsed electromagnetic field (PEMF) to induce a low-level electrical field at the fusion site, which stimulates bone healing at a molecular, cellular, and tissue level. With an overall clinical success rate of 84 %, the CervicalStim device increases fusion success significantly by 22 % when used adjunctively to surgery.

Mackenzie and Veninga (2004) presented a case report of anterior cervical fusion non-union that was successfully treated with PEMF stimulation. In this case, a C6 to C7 non-union was identified clinically and radiographically 1 year after surgery. Imaging revealed non-union

with partial resorption of the bone graft compared with imaging studies performed 8 months earlier. The patient wore a PEMF stimulation device for 3 hours/day for 10 months. After 3 months of treatment, the patient's symptoms were resolved. X-rays obtained after 15 weeks of stimulation showed improvement in bone fusion, and X-rays obtained at 31 weeks after stimulation showed even bone density around the C7 screws. The patient remained symptom-free 13 months after the termination of PEMF stimulation at last assessment. The authors concluded that PEMF stimulation demonstrated its clinical potential in healing established non-union of anterior cervical spine fusion. Its use is non-invasive and can be considered an alternative to surgical intervention in selected patients. Foley et al (2008) stated that multi-level fusions, the use of allograft bone, and smoking have been associated with an increased risk of non-union after anterior cervical discectomy and fusion (ACDF) procedures; PEMF stimulation has been shown to increase arthrodesis rates after lumbar spine fusion surgery, however, there are minimal data concerning the effect of PEMF stimulation on cervical spine fusion. In a prospective, multi-center, randomized controlled trial (RCT), these researchers examined the safety and efficacy of PEMF stimulation as an adjunct to arthrodesis after ACDF in patients with potential risk factors for nonunion. A total of 323 patients with radiographic evidence (computed tomography-myelogram [CT-myelo] or magnetic resonance imaging [MRI]) of a compressed cervical nerve root and symptomatic radiculopathy appropriate to the compressed root that had failed to respond to non-operative management were enrolled in the study. Subjects were either smokers (more than 1 pack per day) and/or were undergoing multi-level fusions. All patients underwent ACDF using the Smith-Robinson technique. Allograft bone and an anterior cervical plate were used in all cases. Measurements were obtained pre-operatively and at each post-operative interval and included neurologic assessment, visual analog scale (VAS) scores for shoulder/arm pain at rest and with activity, SF-12 scores, the neck disability index (NDI), and radiographs (antero-posterior, lateral, and flexion-extension views). Two orthopedic surgeons not otherwise affiliated with the study and blinded to treatment group evaluated the radiographs, as did a blinded radiologist. Adverse events (AEs) were reported by all patients throughout the study to determine device safety. Patients were randomly assigned to 1 of 2 groups: those receiving PEMF stimulation after surgery (PEMF group, 163 patients) and those not receiving PEMF stimulation (control group, 160 patients). Post-

operative care was otherwise identical. Follow-up was carried out at 1, 2, 3, 6, and 12 months post-operatively. The PEMF and control groups were comparable with regard to age, gender, race, past medical history, smoking status, and litigation status. Both groups were also comparable in terms of baseline diagnosis (herniated disc, spondylosis, or both) and number of levels operated (1, 2, 3, or 4). At 6 months post-operatively, the PEMF group had a significantly higher fusion rate than the control group (83.6 % versus 68.6 %, p = 0.0065). At 12 months after surgery, the stimulated group had a fusion rate of 92.8 % compared with 86.7 % for the control group (p = 0.1129). There were no significant differences between the PEMF and control groups with regard to VAS pain scores, NDI, or SF-12 scores at 6 or 12 months. No significant differences were found in the incidence of AEs in the groups. The authors concluded that this was the 1st RCT that examined the effects of PEMF stimulation on cervical spine fusion. PEMF stimulation significantly improved the fusion rate at 6 months post-operatively in patients undergoing ACDF with an allograft and an anterior cervical plate, the eligibility criteria being patients who were smokers or had undergone multi-level cervical fusion. At 12 months post-operatively, however, the fusion rate for PEMF patients was not significantly different from that of the control group. There were no differences in the incidence of AEs in the 2 groups, indicating that the use of PEMF stimulation was safe in this clinical setting.

Coric et al (2018) noted that PEMF stimulation was evaluated after ACDF procedures in a RCT performed for FDA approval. PEMF significantly increased fusion rates at 6 months, but 12-month fusion outcomes for subjects at elevated risk for pseudarthrosis were not thoroughly reported. The objective of the current study was to examine the effect of PEMF treatment on subjects at increased risk for pseudarthrosis after ACDF procedures. Two evaluations were performed that compared fusion rates between PEMF stimulation and a historical control (160 subjects) from the FDA investigational device exemption (IDE) study: a post-hoc (PH) analysis of high-risk subjects from the FDA study (PH PEMF); and a multi-center, open-label (OL) study consisting of 274 subjects treated with PEMF (OL PEMF). Fisher's exact test and multi-variate logistic regression was used to compare fusion rates between PEMF-treated subjects and historical controls. In separate comparisons of PH PEMF and OL PEMF groups to the historical control group, PEMF treatment significantly (p < 0.05, Fisher's exact test) increased the fusion rate at 6

and 12 months for certain high-risk subjects who had at least 1 clinical risk factor of being elderly, a nicotine user, osteoporotic, or diabetic; and for those with at least 1 clinical risk factor and who received at least a 2- or 3-level arthrodesis. The authors concluded that adjunctive PEMF treatment can be recommended for patients who are at high risk for pseudarthrosis. They stated that a limitation of this trial was that it was an open-label study that compared results with a historical control rather than a randomized concurrent control. Moreover, these researchers stated that appropriately powered studies are needed to confirm these findings and examine the effect of PEMF on other patient populations. They stated that PEMF treatment may be a valuable adjunct for augmenting cervical spinal fusion rate in some cases with high-risk subjects.

There are no major U.S. society guidelines specifically recommending routine use of PEMF for cervical spinal fusion. In summary, PEMF may accelerate early fusion in high-risk cervical fusion patients, but does not significantly improve long-term fusion rates or clinical outcomes, and routine use is not currently supported by strong consensus (Akhter, et al., 2020; Luo, et al., 2024; Matur, et al., 2022).

Electrical Stimulation for Nonunion

In nonunion, or interrupted bone healing, the normal process of calcification fails to take place. The fracture gap remains occupied by cartilage and/or fibrous tissue and vascular penetration cannot proceed. Factors predisposing to nonunion include infection, extensive comminution, inadequate blood supply, a large fracture gap, damage to surrounding muscles, and torsional or bending stresses.

Under a definition adopted by the FDA, a nonunion is established when at least 9 months have elapsed since injury and the fracture site shows no visibly progressive signs of healing for a minimum of three months. Others have suggested that nonunion may be suspected as early as 3 months after fracture if fracture healing has failed to progress during that time. It has been estimated that approximately 5 % of all long bone fractures will result in nonunion.

Electrical stimulation devices use low-energy electromagnetic fields to promote healing by creating weak electrical currents across the fracture site. Weak electrical currents have been found to stimulate bone formation and calcification. Physicians are not certain why it works, but many speculate that the currents stimulate osteocytes (bone cells) and may change the structure of the cell wall, enhancing bone union.

In 1979, the FDA approved electrical stimulation therapy devices for treatment of nonunion, congenital pseudarthrosis, and failed fusion. A number of prospective studies, including controlled clinical trials, have demonstrated the effectiveness of electrical stimulation in nonunions of long bones. These studies have primarily examined the effectiveness of electrical stimulation therapy in the treatment of nonunions of the tibia and femur. The studies have defined healing endpoints both radiographically (as evidenced by cortical bridging on x-ray) and clinically (no pain or motion at fracture site). There is evidence that electrical stimulation therapy is also effective in healing nonunions of other bones of the appendicular skeleton.

Electrical stimulation therapy has not, however, been adequately evaluated for treatment of nonunions of the flat bones, such as the pelvis, scapula, and skull. Nor has electrical stimulation therapy been well evaluated for treatment of fractures of the ribs or sternum.

Electrical stimulation has been used as an adjunct or alternative to bone graft surgery in the treatment of nonunions. In bone graft surgery, a section of bone taken from another skeletal site is used to bridge the ununited gap. The major advantage of non-invasive electrical stimulation over bone graft surgery is that it minimizes the risk of infection and avoids the trauma of surgery. Electrical stimulation therapy has also been shown to be an alternative to bone graft surgery in the conservative management of congenital pseudarthrosis, the absence at birth of the mid-portion of bone, and has been approved by the FDA for that purpose.

Three types of electrical stimulators were approved by the FDA in 1979 for treatment of nonunions and congenital pseudarthrosis: (i) invasive, (ii) semi-invasive, and (iii) non-invasive. An invasive electrical stimulator that uses constant direct current is implanted at the nonunion site. The

major advantage of implantation is that the electrical therapy is provided constantly without the patient having to take an active role, so that compliance is not an issue. The major disadvantage is that it requires 2 operations, one to implant the electrical device and one to remove the device.

A semi-invasive system which uses percutaneous cathodes that provide constant direct current is not currently in production.

Non-invasive electrical stimulator systems use inductive coupling or capacitive coupling. With inductive coupling, pulsed electromagnetic fields (PEMFs) are delivered by a pair of external magnetic coils placed parallel to each other on top of the cast at the nonunion site. Treatment times vary from 10 to 16 hours per day. Because precise placement of the coils is necessary, the patient must remain relatively immobile during treatment.

With capacitive coupling, 2 electrodes are applied to the skin through windows cut through the cast, and are placed on either side of the nonunion site. Because the system comes with a portable battery pack and no precise placement of the electrodes is necessary, the patient can remain relatively mobile.

Available evidence suggests that each of these systems gives comparable success rates of 80 to 90 % in properly selected patients. There are no known side effects to treatment with electrical stimulation.

According to the manufacturer's website, ActaStim is a non-invasive, wearable capacitive coupling BGS designed to enhance spinal fusion. Pre-clinical studies suggested that applying electrical stimulation (ES) could aid the body in recruiting and using calcium ions to promote bone growth (Theragen, 2025; Brighton, et al., 2001). The capacitive coupling electrical signal ActaStim-S delivered to the fusion site helps supposedly would mimic this natural process by opening cell membrane channels that allow calcium ions to enter resulting in up-regulation of bone cell proliferation, which is needed in both growth and repair. There is no reliable evidence in peer-reviewed medical journals that the ActaStim System brand is superior to other brands of capacitive coupling electrical stimulation devices for enhancement of spinal fusion.

More recently, the FDA approved the OrthoLogic 1000, a non-invasive electrical stimulation device, for the treatment of nonunions (OrthoLogic Corp., Phoenix, AZ). The OrthoLogic differs from standard non-invasive electrical stimulation therapy in that it uses both static and pulsating magnetic fields. In addition, the OrthoLogic uses magnetic fields that are of lower energy (peak amplitude 400 milligauss) than standard PEMFs (peak amplitude greater than 20 gauss). The chief advantage of the OrthoLogic device is that it needs to be worn only 30 mins per day, compared to 10 hrs per day with standard pulsed electromagnetic field therapy.

In nonunions and congenital pseudarthrosis treated with electrical stimulation therapy, progression of healing should be monitored both clinically and radiologically. On x-ray, progression of healing is evidenced by the appearance of consolidated bone stress lines gradually bridging the fracture gap until continuity of the cortices occurs. When cortical continuity is established and no motion exists at the treatment site, pulsed electromagnetic field therapy may be discontinued, generally within 3 to 6 months, and rarely more than 9 months after electrical stimulation therapy is initiated.

Electrical stimulation devices may be used in fractures where fixation devices, such as rods or pins, are already in place, if the fixation devices are non-magnetic.

Electrical stimulation therapy is effective in uniting previously open fractures as well as closed fractures. Electrical stimulation therapy has also been found to be effective in healing nonunions that have persisted for many years. Surgical intervention is necessary before electrical stimulation therapy where there is malalignment of the fractured bone.

Electrical stimulation therapy is generally not indicated where the fracture gaps are greater than 1 centimeter or where they are greater than half the diameter of the bone at the level of the nonunion. This is because larger gaps do not contain enough responsive osteocytes to form bone when stimulated by electricity.

Electrical stimulation therapy is also generally not indicated where there is a synovial pseudarthrosis, or "false joint" -- a nonunion that has developed a membrane-lined fluid-filled cavity between the fracture fragments. Poor results with electrical therapy occur unless the lining of the false joint is removed. Nonunions with a large gap or synovial pseudarthrosis are thought to be better treated with bone grafting and internal fixation before electrical stimulation.

Electrical stimulation therapy is also contraindicated in persons with pacemakers.

The effects of electrical stimulation therapy on epiphyseal growth plates are not known, so that use of electrical stimulation therapy in children, who lack skeletal maturity, should be closely monitored.

Aetna's policy on non-spinal electrical stimulation is supported by Medicare policy, which allows non-spinal electrical stimulation for the following indications: (i) nonunion of a long bone fracture, defined as radiographic evidence that fracture healing has ceased for three or more months prior to starting treatment with the osteogenesis stimulator; or (ii) failed fusion of a joint other than in the spine where a minimum of nine months has elapsed since the last surgery; or congenital pseudarthrosis. Medicare requires that nonunion of a long bone fracture be documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days, each including multiple views of the fracture site, and with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs. Medicare policy states that a long bone is limited to a clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal, or metatarsal.

A decision memorandum from the Centers for Medicare and Medicaid Services reviewed the evidence for electrical stimulation for fracture healing and concluded: "Fracture nonunion is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of two

sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days." The CMS decision memorandum (CMS, 1999) concluded that the quality and quantity of the evidence is not enough for CMS to make a positive determination on expanding coverage of electrical bone growth stimulators to nonunions other than for long bones.

Simonis et al (2003) reported on a prospective, randomized, double-blind study of the effectiveness of electyrical stimulation in tibial nonuions. The study included 34 consecutive patients with a tibial non-union met that met criteria for study inclusion. Each patient had an oblique fibular osteotomy, followed by a unilateral external fixator. Subjects were then randomly allocated one of two groups: group 1, the active group, received electrical stimulation from an active device; group 2, the control group, had an identical device but without any current passing through the active coils. Subjects were then followed up for 6 months and evaluated clinically and radiologically for bony union. The investigators noted that there was a chance imbalance in smoking between the 2 groups. The union rate in the subgroup that smoked was 75 %(6/8) in the active group as compared to 46 %(6/13) in the control group. Overall 24 out of the 34 patients progressed to union. The investigators reported a statistically significant positive association between tibial union and electrical stimulation (odds ratio 8, 95 % CI: 1.5 to 41, p = 0.02). Out of 18, 16 (89 %) in the active group showed bony union as compared to 8/16 (50 %) in the control group. However, when the overall result was adjusted for smoking, the association was weaker and not statistically significant (odds ratio 5.4, 95 % CI: 0.85 to 34, p = 0.07). The authors noted, however, that electrical stimulation in both smokers and non-smokers produced a higher rate of union than in the control group.

Electrical stimulation has been investigated as a treatment for Charcot arthropathy. Hockenbury and associates (2007) reviewed the results of arthrodesis of the Charcot hindfoot when an implantable bone growth stimulator was added to the procedure. Arthrodesis of the Charcot hindfoot has a high non-union and complication rate. A total of 10 patients (aged 50 to 69 years) with Charcot neuroarthropathy of the ankle, hindfoot, or both had arthrodesis with use of rigid internal fixation and an implantable bone growth stimulator were included in the study.

There were 6 tibio-talo-calcaneal, 2 pantalar, and 2 tibio-calcaneal arthrodeses. An intra-medullary nail was used in 9 patients and a blade plate was used in 1 patient. All but 1 patient was diabetic. Four of the 10 patients had pre-operative osteomyelitis or post-operative infection. Another patient had purulent drainage, although cultures were negative. Four patients had a pre-operative ulceration. Five patients had a 2-stage procedure for debridement of infected bone, removal of hardware, and placement of antibiotic beads. Autogenous bone graft from the distal fibula or proximal tibia was used in all patients. One patient with a pre-operative osteomyelitis developed a stable ankle pseudarthrosis. The other 9 patients fused at an average of 3.7 months after surgery for a fusion rate of 90 %. There were 2 major complications and 8 minor complications. There were no amputations. All patients were ambulatory in a double upright brace or shoes for diabetic patients and were free of ulceration at the time of follow-up. Average American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot score improved from 21 pre-operatively to 59 post-operatively. The authors concluded that the adjunctive use of an implantable bone growth stimulator in conjunction with rigid internal fixation, autogenous bone grafting, and sound operative technique may enhance the outcome and fusion rate in patients undergoing arthrodesis for Charcot neuroarthropathy of the ankle and hindfoot. The findings of this study need to be validated by well-designed studies.

Hanft et al (1998) evaluated the effectiveness of OrthoLogic combined magnetic field (CMF) bone growth stimulation in the treatment of acute, phase 1, Charcot neuroarthopathy; 31 subjects were studied. Initially 10 controls and 11 study patients were examined. When the initial results were analyzed, 10 additional study patients were added. The result was a statistically significant reduction in time to consolidation, 23.8 weeks for the control versus 11 weeks for the study group. The authors also reported that there was less destruction of the bony architecture in the study group as compared to the control. A systematic evidence review of treatments for Charcot foot (Smith et al, 2007) commented on the study by Hanft et a., stating that the findings from the preliminary trial may be biased arising from the small sample size, selection bias and awareness to group allocation by subjects owing to a lack of blinding.

Perlman et al (1999) reported on a reviews of charts for a series of 88 ankle fusions at a single institution. A total of 67 of these had adequate follow-up for evaluation for union of the fusion, including adequate records or x-rays; 19 of 67 ankle fusions progressed to nonunion (28 %). The authors reported a trend toward increased risk of nonunions in patients who were smokers, drank alcohol, had diabetes, had a psychiatric disorder, or used illegal drugs. However, statistical significance was not achieved for any one of these factors. Other evidence for use of electrical stimulation for Charcot joint consists of case reports (Bier et al, 1987).

Bigliani and colleagues (1983) reported on treatment with pulsing electromagnetic fields as an adjunct in a series 20 patients who had had a knee fusions after failure of a total joint replacement at a single institution; 18 had had an infected arthroplasty; 1, mechanical loosening; and 1, recurrent dislocation. Arthrodesis had been attempted 25 times in these 20 patients prior to application of the coils. These procedures included the use of 22 external fixation frames, 1 compression plate, 1 intramedullary rod, and 1 cylinder cast. Two groups of patients were identified: those with non-union and those with delayed union. Fourteen patients began treatment 6 months or more after arthrodesis and were considered to have a nonunion. The other 6 patients started treatment less than 6 months after attempted arthrodesis because there was no evidence of progression toward union. They were considered to have delayed union. In 17 of the 20 patients, a clinically solid arthrodesis with x-ray evidence of bone-bridging was achieved. The average time to union after coil therapy was started was 5.8 months, with a range of 3 to 12 months. The authors stated that the patients who started coil treatment earlier after arthrodesis showed a tendency to heal faster. The authors stated that three patients who had failures were the only ones who did not adhere to the protocol, and all three were in the nonunion group. They stated that all patients with a solid arthrodesis were free of pain and able to walk at the time of follow-up, 9 to 31 months after the completion of treatment. Limitations of this study included the small size, retrospective nature, and lack of a comparison group.

There is little evidence to support electrical stimulation for lumbar spondylolysis (also known as pars inter-articularis fracture). According to eMedicine (Malanga et al, 2009), "The use of external electrical

stimulation for the healing of spondylolysis has been reported in 2 cases in the literature. Electrical stimulation has been used to heal fractures in all areas of the body. Although the literature supports the efficacy of electrical stimulation in healing fractures, the use of electrical stimulation for healing of spondylosis is not well studied and generally not necessary".

UpToDate reviews on "Overview of stress fractures" (deWeber, 2012) and "Stress fractures of the metatarsal shaft" (Clugston and Hatch, 2012) do not mention the use of bone growth stimulator for the management of patients with stress fractures.

Kennedy et al (1993) carried out a double-blind trial of pulsed electromagnetic fields (PEMFs) for loosened cemented hip prostheses. Of the 40 patients who enrolled, 37 met entry criteria and were available for analysis. All patients completed 6 months of treatment (either active or control units). Success was determined clinically by a Harris hip score of greater than or equal to 80 points (or an increase of 10 points if initially greater than or equal to 70 points). Ten of the 19 active units were successes (53 %), whereas 2 of the 18 controls (11 %) exhibited a placebo effect, a statistically significant and clinically relevant result. A 60 % relapse rate among the active successes was seen at 14 months post-stimulation, and despite maintenance therapy of 1 hour/day, the relapse rate increased to 90 % at 3 years. The authors concluded that these findings suggested that for loosened cemented hip prostheses, use of PEMFs is a treatment option only to delay revision hip surgery. The main drawback of this study was its small sample size.

Konrad et al (1996) noted that aseptic loosening is the most common problem of hip arthroplasties, limiting its long term success. These investigators reported a study of PEMF treatment in 24 patients with this complication. At the end of treatment, 6 months and 1 year later, pain and hip movements improved significantly with the exception of flexion and extension. There was significant improvement in both isotope scans and ultrasonography, but not in plain X-ray. The authors concluded that the decreased pain and improved function suggested that PEMF is effective in improving symptoms of patients with loosened hip

replacement. No improvement, however, can be expected in patients with severe pain due to gross loosening. The main drawbacks of this study were its small sample size and short follow-up.

Semi-Invasive Bone Growth Stimulators

Semi-invasive direct current stimulation devices entail implantation of induction wires, but the power-pack is worn externally. The cable connecting the two passes through the skin, requiring careful attention to prevent infection. To date, no semi-invasive electrical bone growth stimulator devices have been approved or cleared by the FDA for clinical uses.

Electrical Bone-Growth Stimulators for Comminuted Toe Fracture

Kohata and colleagues (2013) stated that the effectiveness of an alternating current (AC) stimulation in prevention of bone deformity for comminuted intra-articular fracture of distal radius were verified by comparing post-operative results treated with a wrist-bridging external fixator combined with or without an AC stimulator (EF and NEF, respectively), and a palmar locking plate (LP). This study evaluated 92 cases of type C2 and 60 cases of type C3 distal radius fractures, as classified by the Association for Osteosynthesis. A total of 55 and 24 cases were treated with EF and NEF, respectively; and 73 cases were treated with LP. Callus appeared 27.5 ± 4.6 days post-operatively and the external skeletal fixation period was significantly shorter in the EF group than in the NEF group. The decrease in radial length was significantly lower in the EF group when compared to the LP group. There were no significant differences among the groups for the other radiographic and functional parameters. The authors concluded that AC stimulation combined to the external fixation may be a promising method to prevent post-operative deformity in the severely comminuted intra-articular fractures by accelerating callus maturation and facilitating new bone bridging across the gap of fracture site.

An UpToDate review on “General principles of definitive fracture management” (Beutler and Titus, 2019) stated that “Several non-pharmacologic interventions have been used to aid fracture healing. Among these are electromagnetic stimulation (“bone stimulators”) and

ultrasound. Electromagnetic stimulation is used most often to hasten healing after internal fixation or bone grafting that has been performed for fractures that failed to heal with standard treatment (i.e., non-unions). Electromagnetic bone stimulation is often used to augment a trial of conservative therapy in atypical or stress fractures that would otherwise require surgery, and limited evidence suggests that these interventions are effective".

Pulsed Electromagnetic Fields (PEMF) Stimulation for Enhancement of Spinal Fusion

In a prospective, randomized, double-blind study Mooney (1990) examined the effectiveness of PEMF for interbody lumbar fusions (n = 195 subjects). There were 98 subjects in the active group and 97 subjects in the placebo group. A brace containing equipment to induce an EMF was applied to patients undergoing interbody fusion in the active group, and a sham brace was used in the control group. In the active group there was a 92 % success rate, while the control group had a 65 % success rate ($p > 0.005$); thus, the authors concluded that the effectiveness of bone graft stimulation with the device was established.

Goodwin et al (1999) noted that previous studies have established the effectiveness of direct current (DC) and EMF stimulation as adjuncts for some forms of spinal fusion. None of the previous placebo-controlled studies on external bone stimulation included posterolateral fusion techniques, and most were conducted with prior generations of internal fixation hard-ware. In a prospective, randomized, double-blind study, these investigators examined the effect of non-invasive capacitively coupled ES (CC-ES) on the success rate of lumbar spine fusion surgery, and compared active with placebo stimulators as adjuncts to contemporary fusion techniques. This trial was carried out by 28 U.S. surgeons. Patients with a primary diagnosis of degenerative disc disease (DDD) with or without other degenerative changes were selected. The study protocol defined success as a clinical outcome rated as excellent or good and a fusion documented as solid by both the investigator and the blinded independent radiologist. Disagreements on radiographic success were resolved by a 2nd blinded independent reviewer. For the 179 patients who completed treatment and evaluation, the overall protocol success rate (both clinical and radiographic results rated as successes)

was 84.7 % for the active patients and 64.9 % for the placebo patients. This difference was highly significant according to the Yates corrected Chi-square test (p = 0.0043). Best improvements in patient outcomes (20 % or greater success rate) occurred when active stimulation was used in conjunction with posterolateral fusion (p = 0.006) and when internal fixation also was incorporated (p = 0.013). The findings of this study was consistent in that active stimulation improved results for each stratification, although some strata had insufficient numbers of patients for the results to have statistical significance. Improved success rates when CC-ES was added to internal fixation were hypothesized to result from overcoming the biochemical effects of stress shielding. The authors concluded that CC-ES was an effective adjunct to primary spine fusion, especially for patients with posterolateral fusion and those with internal fixation. These preliminary findings need to be validated by well-designed studies.

The authors stated that this study had several drawbacks. First, this trial did not collect pre-treatment clinical data, nor did it include validated patient-reported outcomes measures (PROMs) such as those obtained by the North American Spine Society (NASS) low back pain (LBP) outcome assessment instrument. Second, this trial was quite complex with a large array of indications and procedures. Some surgeons chose internal fixation for all their patients undergoing fusions, while others nerve used fixation. A simpler study could have resulted in stronger conclusions over a narrower range of variables. Third, the impact of workers' compensation as well as the incidence of subsequent surgery were not evaluated prospectively. The use of a follow-up surgery did not exclude the possibility of selection bias because it was not possible to contact all patients with 2-year follow-up. These researchers stated that future plan for this clinical trial include completion of enrollment as well as follow-up so that a larger number of patients could be analyzed. The complete study data-base will be subjected to logistic regression analysis for further investigation of the impact exerted by such variables as the type of fusion procedures, the sue of internal fixation, 1-level versus 2-level fusions, smoking, previous surgery, and the like.

Kaiser et al (2014) stated that the relationship between the formation of a solid arthrodesis and electrical and electro-magnetic energy is well established; most of the information on the topic, however, pertains to the

healing of long bone fractures. The use of both invasive and non-invasive means to supply this energy and supplement spinal fusions has been examined – 3 forms of ES are commonly employed: DC stimulation (DCS), PEMF stimulation (PEMFS), as well as CC-ES. Only DCS requires the placement of electrodes within the fusion substrate and was inserted at the time of surgery. Based on available evidence, no conflict with the previous recommendations was generated. The use of DCS is recommended as an option for patients younger than 60 years of age, since a positive effect on fusion has been observed. The same, however, could not be stated for patients over 60, because DCS did not appear to have an impact on fusion rates in this population. No study was reviewed that examined the use of CC-ES or the routine use of PEMFS. These researchers noted that a single, low-level study reported a positive impact of PEMFS on patients undergoing revision surgery for pseudarthrosis; however, this single study was insufficient to recommend for or against the use of PEMFS in this patient population.

Cruz et al (2021) noted that lumbar spinal fusion is a commonly performed procedure to stabilize the spine, and the frequency with which this operation is performed is increasing. Multiple factors are involved in achieving successful arthrodesis. Systemic factors include patient medical co-morbidities (e.g., rheumatoid arthritis and osteoporosis) as well as smoking status. Surgical site factors include choice of bone graft material, number of fusion levels, location of fusion bed, adequate preparation of fusion site, as well as biomechanical properties of the fusion construct. Rates of successful fusion could vary from 65 % to 100 %, depending on the afore-mentioned factors. Diagnosis of pseudoarthrosis is confirmed by imaging studies, often a combination of static and dynamic radiographs and computed tomography (CT). Once pseudoarthrosis is identified, patient factors should be optimized whenever possible and a surgical plan implemented to provide the best chance of successful revision arthrodesis with the least amount of surgical risk. These investigators noted that ES in the post-operative period has been used to augment fusion. Passage of an electric current results in increased collagen synthesis and fibrocyte recruitment to the fusion site -- DCS requires intra-operative placement of electrodes in contact with the fusion mass; PEMFS and CC-ES may be applied externally. In an updated clinical guideline for use of BGS as an adjunct

for lumbar fusion, Kaiser et al (2014) found limited evidence for the use of DCS in patients younger than 60 years, but insufficient evidence to recommend for or against the use of PEMFS or CC-ES.

Patel et al (2021) stated that the incidence of 3- and 4-level lumbar arthrodesis is rising due to an aging population, and fusion rates affect clinical success in this population. PEMFS is used as an adjunct to increase fusion rates following multi-level arthrodesis. In a retrospective, multi-center study, these researchers examined the fusion rates for subjects who underwent 3- and 4-level lumbar interbody arthrodesis following PEMFS. Patient charts that listed 3- or 4-level lumbar arthrodesis with adjunctive use of a PEMFS device were evaluated. Inclusion criteria entailed patients who were diagnosed with lumbar degenerative disease, spinal stenosis, and/or spondylolisthesis (grade-1 or grade-2). A radiographic evaluation of fusion status was carried out at 12 months by the treating physicians. Fusion rates were stratified by graft material, surgical interbody approach, and certain clinical risk factors for pseudoarthrosis. A total of 55 patients were identified who had a 12-month follow-up. The radiographic fusion rate was 92.7 % (51 patients) at 12 months. There were no significant differences in fusion rates for patients treated with allograft or autograft, for patients with different interbody approaches, or for those with or without certain clinical risk factors. The authors concluded that PEMFS may be a useful adjunct for treatment of patients with surgical risk factors, such as multi-level arthrodesis, and clinical risk factors. Level of Evidence = IV.

The authors stated that drawbacks of this trial included the lack of a concurrent control. This was a retrospective study that examined the standard clinical practice of 4 surgeons using PEMFS for multi-level arthrodesis and no non-PEMF comparator was available. Another drawback was that the treating surgeon determined the fusion status, and surgeon bias was known with respect to consideration of other clinical outcome parameters. In addition, retrospective studies have the potential for selection bias, and no assessment of patient accountability was possible with the data collected; however, data from all patients who met the inclusion and exclusion criteria were reported in this study. Certain risk factors for pseudoarthrosis such as at least grade-2 spondylolisthesis, scoliosis, trauma, being morbidly obese, as well as an active bacterial infection were excluded from the study; therefore, the

effect of PEMFS on a population with these risk factors is unknown. Although PEMFS was prescribed for 3 to 6 months, PEMFS compliance was not measured.

Javeed et al (2023) stated that DC-ES may serve as a promising non-pharmacological adjunct promoting osteogenesis and fusion. In a computational study, these researchers examined the use of electro-active spine instrumentation in the focal delivery of therapeutic ES to enhance lumbar bone formation and interbody fusion. A finite element model of adult human lumbar spine (L4 to L5) instrumented with single-level electro-active pedicle screws was simulated; DC-ES was routed via anodized electro-active pedicle screws to target regions of fusion. The electrical fields generated by electro-active pedicle screws were examined in various tissue compartments including isotropic tissue volumes, cortical, and trabecular bone. Electrical field distributions at various stimulation amplitudes (20 to 100 μA) and pedicle screw anodization patterns were analyzed in target regions of fusion (e.g., intervertebral disc space, vertebral body, and pedicles). Electrical stimulation with electro-active pedicle screws at various stimulation amplitudes and anodization patterns enabled modulation of spatial distribution and intensity of electric fields within the target regions of lumbar spine. Anodized screws (50 %) versus un-anodized screws (0 %) induced high-amplitude electric fields within the intervertebral disc space and vertebral body but negligible electric fields in spinal canal. DC-ES via anodized screws induced electrical fields, at therapeutic threshold of greater than 1 mV/cm, sufficient for osteo-induction within the target interbody region. The authors concluded that selective anodization of electro-active pedicle screws may enable focal delivery of therapeutic ES in the target regions in human lumbar spine. Moreover, these researchers stated that the findings of this study warrants pre-clinical as well as clinical testing of integrated electro-active system in inducing target lumbar fusion in-vivo. They stated that this study provided a foundation for clinically examining electro-active instrumentation to enhance spinal fusion.

Weinstein et al (2023) noted that lumbar spinal fusion surgeries are increasing steadily due to an aging and ever-growing population. Patients undergoing lumbar spinal fusion surgery may present with risk factors that contribute to complications, pseudarthrosis, prolonged pain,

and reduced quality of life (QOL). PEMFS represents an adjunct non-invasive intervention that has been reported to enhance fusion as well as patient outcomes following spinal surgery. In a prospective, multi-center study, these investigators examined the use of PEMFS as an adjunctive treatment to lumbar spinal fusion procedures in patients at risk for pseudarthrosis. Patients with at least 1 of the following risk factors were enrolled: prior failed fusion, multi-level fusion, nicotine use, osteoporosis, or diabetes. Fusion status was determined by radiographic imaging, and patient-reported outcomes (PROs) were also evaluated. A total of 142 patients were included in the analysis. Fusion status was examined at 12 months follow-up where 88.0 % (n = 125/142) of patients showed successful fusion. Fusion success for patients with 1, 2+, or 3+ risk factors was 88.5 %, 87.5 %, and 82.3 %, respectively. Significant improvements in PROs using the Short Form 36 (SF-36), EuroQol 5 Dimension (EQ-5D) survey, Oswestry Disability Index (ODI), and VAS for back and leg pain were also observed compared with baseline scores ($p < 0.001$). A favorable safety profile was observed. PEMFS revealed a positive benefit-risk profile throughout the 6-month required use period. The authors concluded that the addition of PEMFS as an adjunctive treatment in patients undergoing lumbar spinal surgery may result in improved fusion and PROs, regardless of risk factors.

The authors stated that study drawbacks included potential variability in the determination of fusion status via X-ray/CT imaging and clinical impression per each incidence and standard of care (SOC). This trial did not have a control arm, which impeded the direct comparison of fusion success and PROs in patients who were treated with PEMFS versus without PEMFS. In lieu of no control arm, the reported rates serve as an initial basis for these researchers' exploration into the benefit of PEMFs using SpinalStim following lumbar spinal surgery and provided rates in keeping with other reported clinical evidence. Moreover, these investigators stated that another study is currently underway to further examine the impact of PEMFS compared with untreated control patients.

Patel et al (2024) noted that certain risk factors predispose patients to pseudarthrosis, which is associated with prolonged pain, reduced function, and decreased QOL. These researchers examined cervical spine fusion rates in subjects with risk factors for pseudarthrosis who received PEMFS. Subjects in the PEMFS group were treated with

PEMFS for 6 months post-operatively. The primary outcome measure was fusion status at the 12-month follow-up period. Fusion status was determined using anterior/posterior, lateral, and flexion/extension radiographs and CT (without contrast). A total of 213 patients were examined (PEMFS, n = 160; Control, n = 53). At baseline, the PEMFS group had a higher percentage of subjects who used nicotine ($p = 0.01$), had osteoporosis ($p < 0.05$), multi-level disease ($p < 0.0001$), and were over the age of 65 years ($p = 0.01$). The PEMFS group showed over 2-fold higher percentage of subjects that had 3 or more risk factors (n = 92/160, 57.5 %) compared with the control group (n= 14/53, 26.4 %). At the 12-month follow-up, the PEMFS group showed significantly higher fusion rates compared with the control (90.0 % versus 60.4 %, $p < 0.05$). A statistically significant improvement in fusion rate was observed in PEMFS subjects with multi-level surgery ($p < 0.0001$) and high body mass index (BMI) (greater than 30 kg/m2; $p =0.0021$) when compared with the control group. No significant safety concerns were observed. The authors concluded that the adjunctive use of PEMFS provided significant improvements in cervical spine fusion rates in subjects having risk factors for pseudarthrosis. When compared with control subjects that did not use PEMFS, treated subjects showed improved fusion outcomes despite being older, having more risk factors for pseudarthrosis, and undergoing more complex surgeries. The authors stated that a drawback of this trial included comparison to a retrospective cohort for control rather than a randomized concurrent control. Furthermore, the smaller sample size in the control group (n = 53) was limiting. These researchers stated that future investigations should aim to prospectively study larger, enrolled control groups for comparison. Another drawback was the lack of a central reading center to determine fusion status, which was evaluated independently by each study site.

Luo et al (2024) stated that ES is an important adjuvant therapy for spinal surgery; however, whether receiving ES could enhance the fusion rate following spinal surgery is still controversial. In a systematic review and meta-analysis, these researchers examined the effect of ES on the fusion rate following spinal surgery. They systematically searched for related studies published in the PubMed, Embase and Cochrane Library databases on or before September 30, 2023. The odds ratio (OR) with 95 % confidence interval (CI) and the fusion rates of the experimental group and the control group were calculated by a random-effects meta-

analysis model. The analysis demonstrated that receiving ES significantly increased the probability of successful spinal fusion (OR 2.66; 95 % CI: 1.79 to 3.97), and the average fusion rate of the ES group (86.8 %) was significantly greater than that of the control group (73.7 %). The fusion rate in the DC stimulation group was 2.33 times greater than that in the control group (OR 2.33; 95 % CI: 1.37 to 3.96), and that in the PEMF group was 2.60 times greater than that in the control group (OR 2.60; 95 % CI: 1.29 to 5.27). Similarly, the fusion rate in the CC-ES group was 3.44 times greater than that in the control group (OR 3.44; 95 % CI: 1.75 to 6.75), indicating that regardless of the type of ES, the fusion rate following spinal surgery improved to a certain extent. The authors concluded that ES as an adjuvant therapy appeared to improve the fusion rate following spinal surgery to a certain extent; however, the specific effectiveness of this therapy needs to be further studied.

Piazzolla et al (2024) stated that capacitively coupling electric fields (CCEF) is a non-invasive method of biophysical stimulation that enhances fracture repair and spinal fusion. In a randomized-controlled, multi-center study, these investigators examined the roles of CCEF in the resolution of vertebral bone marrow edema (VBME) using a follow-up MRI study, as well as pain relief, analgesic drug consumption and QOL improvement in stimulated patients who were referred with acute vertebral fragility fractures (VFFs) compared to non-stimulated patients. Between September 2016 and December 2019, patients who were referred to the spine centers that participated in this trial with acute VFFs of type OF1 or OF2 were included. All the VFFs were conservatively managed according to Good Clinical Practice. Subjects were randomized into 2 groups: the CCEF group received, as an adjunct to the clinical study protocol, biophysical stimulation with a CCEF device for 8 hours/day for 60 days, whereas the control group was treated according to the clinical study protocol. At baseline (T0), the 30-day follow-up (T1), the 60-day follow-up (T2), and the 6-month follow-up (T3), each subject underwent clinical evaluation using the VAS for pain and the ODI. Analgesic therapy with paracetamol 1,000 mg tablets for 7 days or longer, depending on the pain intensity, was carried out; participants were required to report their paracetamol consumption on a specific sheet between study day 8 to 180 days of follow-up. MRI studies of the thoraco-lumbar spine were conducted at 0 (T0), 30 (T1) and 60 days of follow-up (T2) using a 1.5-T MRI system in all of the centers that took part

in the study. For each VBME area examined via MRI, the vertebral body geometry (i.e., anterior wall height/posterior wall height and vertebral kyphosis) were assessed. A total of 66 patients (9 men [13.63 %]; mean age of 73.15 years) with 69 VFFs were included in this trial and randomized as follows: 33 patients were included in the control group and the remaining 33 patients were randomized into the CCEF group. In the CCEF group, good compliance with CCEF therapy was observed (adherence = 94 %), and no adverse effects were recorded. In the stimulated patients, faster VBME resolution and significantly less vertebral body collapse during follow-up were observed compared to the control patients. Furthermore, in the active group, faster pain reduction as well as improvement in the ODI mean score were observed. Stimulated patients also reported a significantly lower paracetamol consumption rate from the 3rd follow-up after treatment until the 6-month follow-up. In terms of sex-related differences, in the CCEF group, VBME showed a faster resolution in male patients compared with females. The authors concluded that biophysical stimulation with CCEF, as an adjunct to traditional conservative treatment, was a useful tool to hasten the VBME resolution process and prevent vertebral body deformation. These MRI findings also correlated with faster back pain resolution and QOL improvement. From the 3rd follow-up after treatment until the 6-month follow-up, stimulated patients reported a significantly lower paracetamol consumption than control patients, even though back pain and QOL showed no significant differences between the 2 groups. Level of Evidence = II.

The authors stated that the principal drawback of this trial was the lack of a placebo device in the control group; however, the effectiveness of capacitive biophysical stimulation over a placebo device has already been documented; consequently, the use of a placebo device was considered unnecessary in this study. Moreover, these researchers stated that further investigations are needed to examine if capacitive biophysical stimulation could be useful in preventing acute VFFs in osteoporotic patients. In addition, considering the cross-talk between bone and muscle as well as the concomitant sarcopenia in osteoporotic patients, future studies should examine the role of CCEF in the treatment and prevention of para-spinal sarcopenia in patients suffering from osteosarcopenia.

Ganse (2024) noted that bone regeneration is a complex pathophysiological process determined by molecular, cellular, and biomechanical factors, including immune cells and growth factors. Fracture healing usually takes several weeks to months, during which patients are often immobilized and unable to work. As immobilization is associated with negative health and socio-economic effects, it would be desirable if fracture healing could be accelerated and the healing time shortened. However, interventions for this objective are not yet part of current clinical treatment guidelines, and there has never been a comprehensive review specifically on this topic; thus, this narrative review provided an overview of the available clinical evidence on methods that accelerate fracture healing, with a focus on clinical applicability in healthy patients without bone disease. The most promising methods identified are the use of axial micromovement, electromagnetic stimulation with electromagnetic fields (capacitive coupling or inductive coupling) and direct electric currents, as well as the administration of growth factors and parathyroid hormone. Some interventions have been shown to reduce the healing time by up to 20 % to 30 %, potentially equivalent to several weeks. As a combination of methods could decrease the healing time even further than 1 method alone, especially if their mechanisms of action differ, clinical studies in human patients are needed to examine the individual and combined effects on healing progress. Studies are also needed to determine the ideal settings for the interventions, i.e., optimal frequencies, intensities, and exposure times throughout the separate healing phases. The authors stated that more clinical research is also desirable to create an evidence base for clinical guidelines. To make it easier to carry out these investigations, the development of new methods that allow better quantification of fracture-healing progress and speed in human patients is needed.

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