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CASE STUDIES

Spinalogic® as an adjunct to Lumbar Spine Fusion in patients with risk factors

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Combined Magnetic Field Technology

Cases delivered by Chi Lim, MD
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CLINICAL ADVANTAGE

There are many variables that can prevent successful spinal fusion—from patient risk factors to post-op treatment compliance. Spinalogic® and its efficient bone growth technology has been shown to help increase the likelihood of lumbar fusions—giving your patients every advantage to support a full recovery.[4]

- Designed to best mimic the body's natural healing frequencies
- 97% lumbar fusion success observed[4]
- 21% increase in lumbar fusion over placebo device[3]
- 30 minute daily wear time

THE SCIENCE

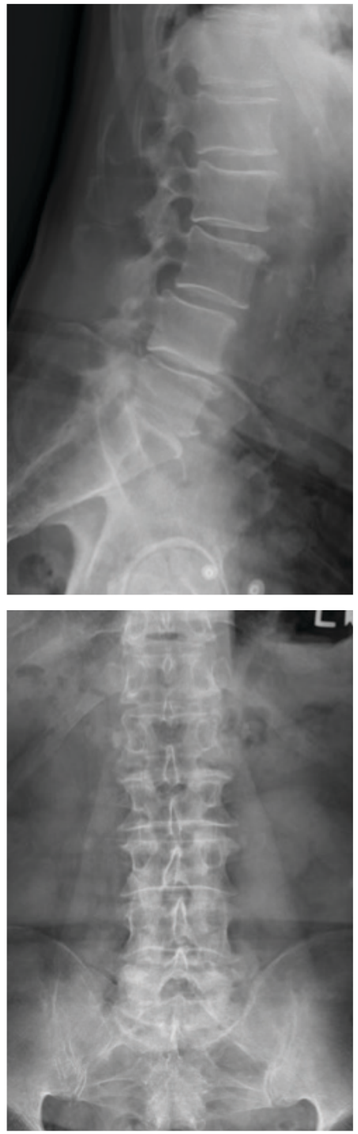
Early researchers determined that maximum bone cell response occurred within frequencies similar to those generated intrinsically by functional activity (0-150Hz). Further research showed 76.6Hz to be the more efficient frequency for bone healing—the frequency offered by the Spinalogic [1,2,3]

"We are scientists and want to know data behind the technology. There is a big difference is the data DJO has.

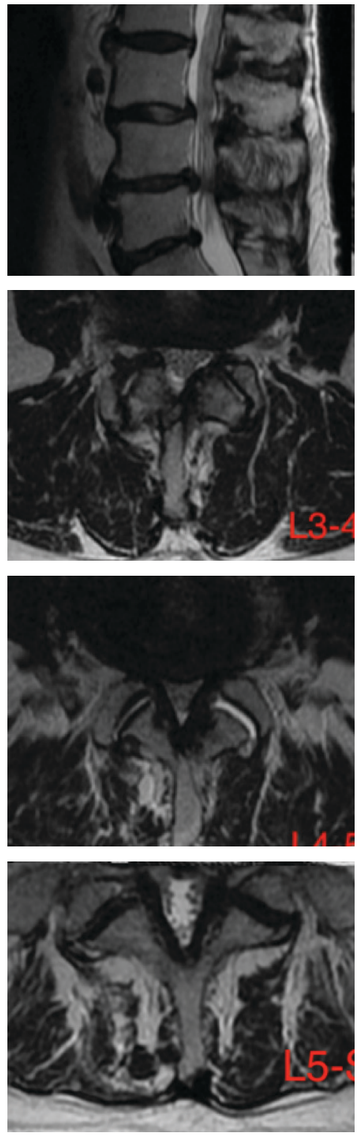
I know there is new research from March that further confirms how CMF device is helpful in fusions with patients especially with high-risk factors. I read through the data, When you look at the data, the 97% vs 62% fusion rates of DJO vs. non-DJO is something to note."[4]

CASE I:

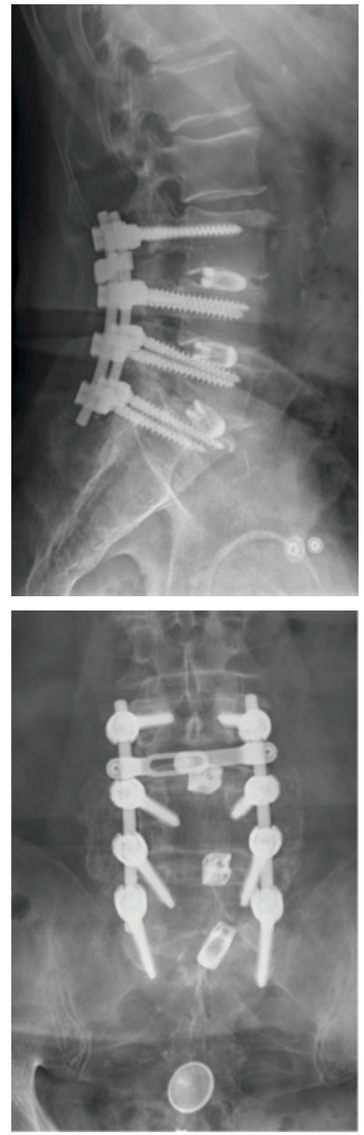
73 year old male presents with weakness, inability to ambulate any distances and unable to stand fully upright. Patient is a smoker. Pre-operative x-rays show severe degeneration at L5-S1, L4-5 and instability at L3-4. Pre-operative MRI confirms x-ray finding and patient undergoes a L3-S1 TLIF. At 6 months post-op mature fusion mass is visible after use of the Spinalogic stimulator.



Pre-Op X-rays



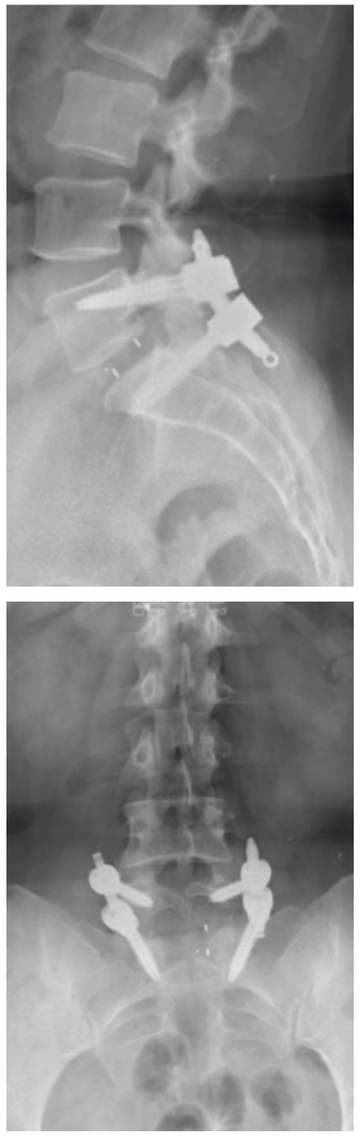
Pre-op MRI



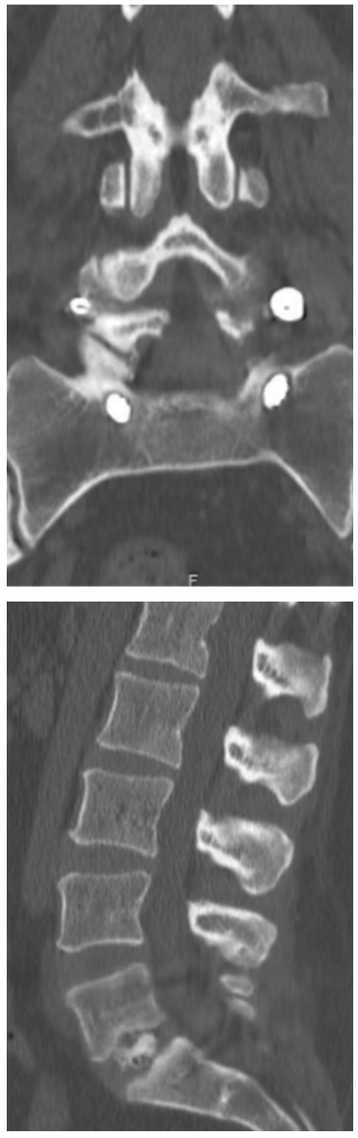
6 months post op x-ray

CASE II:

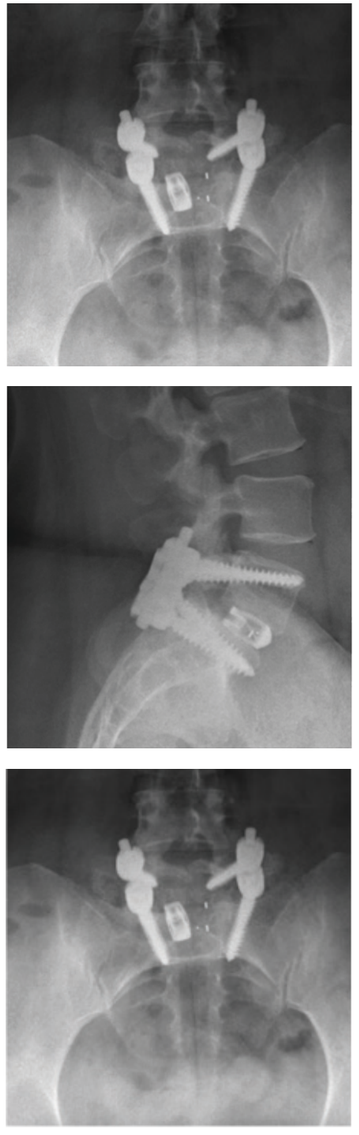
44 year old female presents with history of prior L5-S1 fusion complaining of back pain, radicular pain leg pain. Patient is unable to walk without leg pain. Patient risk factors include diabetes mellitus and obesity (BMI 42). Pre-op x-ray shows prior fusion lacking fusion mass; pseudoarthrosis confirmed with pre-op CT. Patient underwent revision fusion and achived complete fusion at 6 months post-op.



Pre op xray



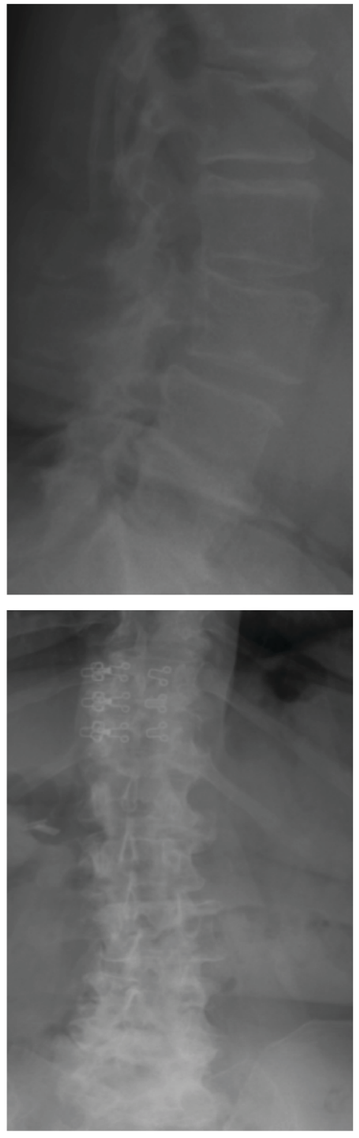
Pre Op CT



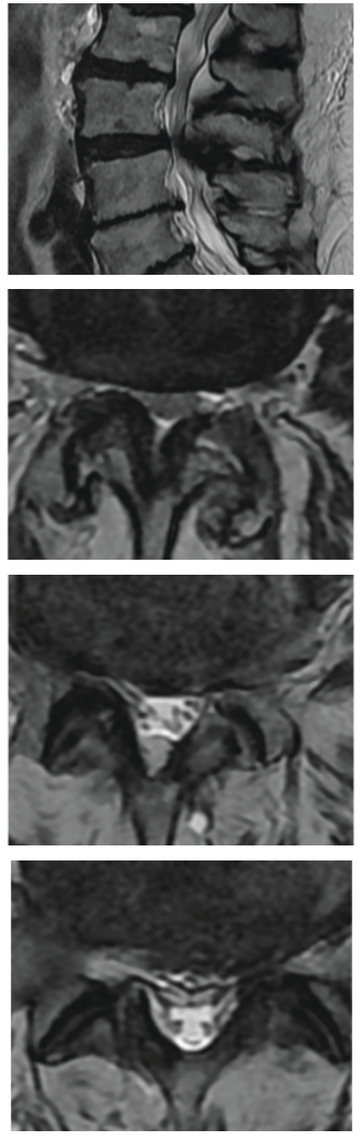
6 months post op x-ray / Comparison

CASE III:

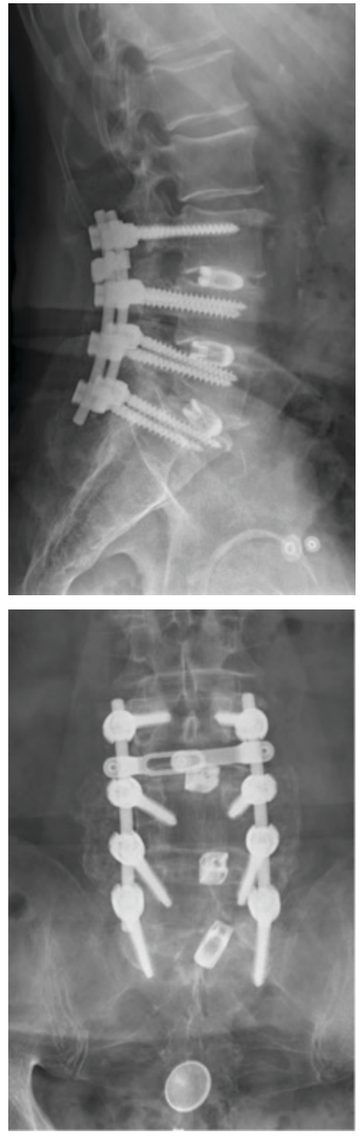
70 year old male presents with leg pain, back pain, inability to stand upright or walk any distance due to leg pain. Patient risk factors include obesity (BMI 44) and diabetes. Pre-op x-rays show back pain instability at L3-4 with slip; L3 is unstable with degeneration. MRI confirms L3-4 stenosis, loss of disc height at L4-5, stenosis at L5-S1. Patient underwent multi-level fusion. Post-op x-ray at 8 months shows bony mass visible and patient reports no pain.



Preop x rays



Preop MRI



Post op x ray 8 months

NOTES

NOTES

CMF™ Spinalogic® BONE GROWTH STIMULATION
BRIEF PRESCRIBING INFORMATION

INDICATION: CMF™ Spinalogic® is a portable, battery powered, microcontrolled, noninvasive bone growth stimulator indicated as an adjunct electromagnetic treatment to primary lumbar spinal fusion surgery for one or two levels.

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

WARNINGS: Do not use the CMF™ Spinalogic® near products that may have strong magnetic fields, such as audio speakers. The device may not work properly around these products.

- **WARNING!** This device is intended only for single patient use. Secondary use can cause serious injury, including infection.
- Care must be taken when operating this device adjacent to other equipment. Potential electromagnetic or other interference could occur with this or other equipment. Try to minimize this interference by increasing the separation between this device and nearby equipment, and by not using other equipment (i.e.cell phones, MRI, electro surgery, defibrillation, etc.) when you are using this device.
- The equipment should not be used adjacent to or stacked with other equipment and, if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
- Do not use the CMF™ Spinalogic® while smoking or near heat, fire or flammable gases because the device may be damaged.
- Do not use the CMF™ Spinalogic® if there are exposed wires or the device appears damaged.
- Do not modify or repair this device because you may damage it.
- Do not put the device or any of its parts in any liquid.
- Do not drop the device or bend the coils because this may damage it.
- Device is designed to comply with electromagnetic safety standards. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment on and off. Try to correct the interference using one or more of the following:
  - Reorient or relocate the receiving device
  - Increase the separation between the equipment
  - Contact DJO® Customer Care
- Some people, with very sensitive skin, may experience redness. Generally, this redness is totally harmless and usually disappears after 10 to 20 minutes. However, never start another treatment on the same area if the redness is still visible.
- If the performance of the device varies in any way from the described operation, call Customer Care.
- The use of other cables and accessories may affect EMC performance.
- This device and its accessories must be kept out of the reach of children, Pets, and Pests.
- Do not use device in contact with open wounds.
- Contamination by Patient could be sweat, expired gases, saliva, on the CMF™ Spinalogic®. Clean the applied part of the coil once a week using soap and a damp cloth.
- Do not use device while in bath or shower

CAUTIONS: DO NOT operate this unit in an environment where other devices are being used that intentionally radiates electromagnetic energy in an unshielded manner. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

ADVERSE EFFECTS: No known significant adverse effects have resulted from the use of this device. Clinical studies, animal studies, and tissue culture experiments conducted with the CMF™ Spinalogic®, which has the same treatment signal as the OL1000™ and OL1000™ SC[1], have not indicated any evidence of significant adverse effects.

REFERENCES:

1. McLeod, K.J., Rubin, C.T., The Effect of Low Frequency Electrical Fields on Osteogensis. J. Bone Joint Surg., 2. Ryaby, J.T., et al., The Role of Insulin-like Growth Factor in Magnetic Field Regulation of Bone Formation, Bioelectrochemistry Bioenergetics, 35: 87-91, 1994.
2. Fitzsimmons, R. J., Ryaby, J.T., Magee, F.P. and Baylink, D.J. (1995), IGF-II receptor number is increased in TE-magnetic fields. J Bone Miner Res, 10: 812-819.
3. Linovitz R, Pathria M, Bernhardt M, et al. Combined Magnetic Fields Accelerate and Increase Spine Fusion: A Placebo Controlled Study, Spine. 2002 July; 27(13):1383-1388.
4. Raiszadeh, Ramin, et al. "Effectiveness of combined magnetic field bone growth stimulation on lumbar spinal retrospective analysis comparing combined magnetic field to no-stimulation." International Journal of Research retrospective study that utilized radiographic fusion criteria, included data from 4 surgeons, consisted of a heterogenous had minimum 6 months follow up.

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MKT00-11100 Rev B