THE EFFECT OF PULSED ELECTROMAGNETIC FIELDS ON THE QUALITY OF CAGE-INSTRUMENTED LUMBAR FUSION IN THE OVINE MODEL

+*Ghanayem, A (A-Medtronic and Orthofix); **Larson, M (A-Medtronic and Orthofix); ***McDermott, K (E-Orthofix)
+*Loyola University of Chicago, Maywood IL. Department of Orthopaedic Surgery, 2160 South 1st Ave, Maywood IL 60153, 708-216-3475, Fax: 708-216-5858, aghanay@luc.edu

Introduction

Threaded interbody fusion devices or cages have come into widespread use over the last 3 years. The cage is filled with morselized bone graft and then placed into position in the intervertebral disc space, usually two cages side by side per level. Over time, bone grows into the cage pores, incorporating bone graft inside the cage thus promoting an arthrodesis. Fusion rates are high but not perfect. Problems noted on post-operative radiographs after cage insertion include radiolucency around the cage which would indicate a fibrous tissue at the bone-cage interface and a failed arthrodesis. Other problems include normal appearing post-operative radiographs (i.e. no lucencies) but failure of bony consolidation of the fusion construct.

Intrinsic and extrinsic factors have been modified in search of increasing fusion rates in a variety of spinal arthrodesis procedures including cage constructs. These factors can include cage design, the use of bone graft substitutes, and electromagnetic stimulation. Electrical stimulation has been shown to improve the fusion/bone graft incorporation process. Implantable direct current stimulation as been shown to increase the cage fusion rate in an experimental sheep model. External pulsed electromagnetic fields (PEMF) is another way to provide electrical stimulation to improve the fusion/bone graft incorporation process and may enhance bony ingrowth around or through a fusion cage. Evaluation of this process is suited to the animal model where the tissue specimen including the cage can be processed histologically to evaluate bone growth and consolidation around and through the cage along with corresponding plain radiographs. This study examines the efficacy of using an externally applied PEMF in promoting bone growth through and around an anterior cage-instrumented lumbar fusion construct in the ovine model.

Methods

Twelve sheep underwent an anterior cage fusion procedure at the L4-5 level using a left retroperitoneal surgical approach. A discectomy was performed via a lateral approach. The anterior annulus and longitudinal ligament were preserved. The interspace was distracted and a single working tube placed on the left lateral surface of the disc space. The interspace was then reamed and then tapped. A threaded titanium fusion cage (Interfix, Medtronic-Sofamor Danek, Memphis, TN) was then placed transversely across the disc space. Cages were packed with morselized autogenous bone graft that was harvested from the ipsilateral iliac crest. The operative site was then irrigated and closed in layers. Anterior-posterior and lateral radiographs were taken immediately post-op to document position of the cage.

Six animals were randomly selected and fitted with a customized canvas jacket housing an external pulsed electromagnetic field (PEMF) device (Spinal Stim, Orthofix Inc, Richardson, TX). The devices were programmed to operate for 4 hours out of every 24-hour cycle and to turn itself off after treatment was complete. The other six animals were not receive PEMF stimulation and served as the control group. At 16 weeks post-op, animals were euthanized in accordance with AVMA guidelines. Specimens were removed en bloc from T12 to S1 and radiographed in the AP and lateral projections. Lateral flexion and extension radiographs were also obtained. The radiographs obtained after the spine was explanted were blindly evaluated for the following characteristics:

1) Obvious lucency at the cage-vertebral endplate junctions
2) Sclerotic or reactive bone at the cage-vertebral endplate junctions
3) No lucency or reactive bone at the cage-vertebral endplate junctions
4) Evidence of bridging bone across the interspace
5) Definite bridging bone across the interspace
6) Motion (2 mm or greater) or the appearance of lucencies at the cage-vertebral endplate junctions on flexion or extension radiographs
7) No motion of lucencies at the cage-vertebral endplate junctions on flexion or extension radiographs

Specimens were prepared for histologic evaluation using the method of Barron et al. Once embedded the spines were sectioned in 1-mm thick sections. These sections were mounted, ground and polished to a thickness of 30-50 microns, and surface-stained with hematoxylin and eosin with Saffron. Histologic analysis was completed blindly using the following criteria:

1) The presence or absence of a tight interface between the cage and the surrounding bone with or without fibrous tissue at cage surface
2) The presence or absence of bridging bone from one vertebral body, through the cage, to the other vertebral body
3) The presence or absence bridging bone from one vertebral body, through the cage or around a portion of the cage, that extended to the other vertebral body

Fusion success was evaluated from the radiographic and histologic data. Criteria for a successful fusion included no lucency or motion on plain radiographs, the presence of tight cage-bone interfaces without fibrous tissue interposition, and bridging bone through the cage on histologic evaluation. The lack of lucencies and motion on plain radiographs would not qualify as a successful fusion unless there confirmation of fusion on the histologic analysis. Lucencies around the cages, motion on flexion-extension radiographs, fibrous tissue interposition at the cage-vertebral body interface and the lack of bridging bone on histology would be classified as not fused.

Results

All 12 sheep complete the protocol. There was 1 early superficial wound dehiscence requiring wound irrigation and re-closure without subsequent problem. One animal experienced transient weakness in the hind limb opposite to the side of cage insertion, which resolved spontaneously over the course of 3 days. Radiographs with lucencies always correlated with fibrous tissue at cage surface on histologic evaluation. The absence of lucencies, however, did not always predict histologic fusion. Radiographic evidence of bridging bone across the interspace did seem to correlate with a histologic fusion.

Four of the 6 animals in the PEMF stimulation group were judged to have a successful fusion. In the control group, 1 animal was judged to be successfully fused and 1 was thought to have a partial fusion. In this partial fusion, a radiographic lucency was noted on one vertebral body-cage interface but evidence of bridging bone across the interspace was noted. The histologic analysis was consistent with the radiographic picture with a tight interface on one side of the cage and fibrous tissue on the other. Bone was seen to bridge from one vertebral body, partially through the cage and around the cage to the other vertebral body. If this control animal is considered a fusion success, then the fusion rate was 2 of 6 in the control group compared to 4 of 6 in the PEMF stimulation group.

Discussion

Previous studies in the sheep model have shown rhBMP-2 or internal, direct current stimulation of an anterior cage fusion construct can increase the fusion rate. It should be noted that radiographs without evidence of lucencies or motion did not always predict a successful fusion histologically, thus reaffirming a shortcoming of plain radiographs in assessing the success of a cage fusion. Radiographic bridging bone, however, was predictive of a successful fusion. This study has shown that the use of a non-implantable PEMF device, with 4 hours of stimulation per day, also yields a significant increase in the fusion rate of an anterior cage-autogenous graft filled fusion construct at four months post insertion.

Acknowledgments—This study was supported in part by a grant from Medtronic and Orthofix.

**Private Veterinary Practice, Logan UT.
***Orthofix Inc, Richardson TX.