**THE EFFECT OF EXTERNAL PULSED ELECTROMAGNETIC FIELD STIMULATION IN PROMOTING LUMBAR FUSION IN A RABBIT MODEL**

+*Ghanayem, A (A-Orthofix); *Stanwood, W (A-Orthofix); *Voronov, L; *Havey, R; *Patwardhan, A (A-Orthofix)
+*Loyola University of Chicago and Hines VA Medical Center, Maywood, IL, Department of Orthopaedic Surgery, 2160 South 1st Ave, Maywood IL 60153, 708-216-3475, Fax: 708-216-5835, aghanay@luc.edu

**Introduction** The posterolateral fusion is the most common arthrodesis procedure performed in the lumbar spine. Failure to obtain a successful arthrodesis has been reported to be as low as 5% and high as 35%. Multiple adjuvants have been developed to help increase the fusion rate. Many of these have been studied in the rabbit model of posterolateral lumbar fusion developed by Boden et al. Implantable direct electrical stimulation has been shown to improve the lumbar fusion success rate. An experimental high frequency signal (non-FDA approved) pulsed electromagnetic field (PEMF) stimulation has been shown to be effective in improving fusion quality in the rabbit model (Glaser et al. Spine 1998) using 4 hours of stimulation per day. Kahanovitz et al (Spine 1994) attempted to use an experimental PEMF signal in a dog model without success, stimulating only 30 or 60 minutes per day. This study evaluates the efficacy of the approved externally applied PEMF signal to enhance a posterolateral fusion in the accepted rabbit model using 4 hours of stimulation per day.

**Methods** Twenty-four rabbits underwent a posterolateral fusion at the L4-5 level using autogenous iliac crest bone graft. Between 2.0 to 2.5 cc of bone graft was harvested from each iliac crest, morsilized and placed into the posterolateral gutters after decorication of the transverse processes. The rabbits were then randomized into 2 study groups of 12 animals each. The first received four hours of external PEMF utilizing a rabbit-sized SpineStim device (Orthofix, Richardson TX). The second group did not receive stimulation and served as a control. Animals were euthanized at 6 weeks post-surgery and spines explanted. Each spine was radiographed in the AP and lateral plane. Four spines from each of the 2 groups were randomly designated for histologic analysis. The other eight spines from each of the 2 groups were prepared for biomechanical analysis.

The spines selected for histologic analysis were decalcified and trimmed to include the vertebral bodies on the left side and L3-4 on the right. Longitudinal sections through the fusion masses were obtained and permanent slides mounted at 1000 and 2000 micrometers into the fusion mass from a dorsal to ventral direction. Slides were stained with H & E. Histologic evaluation was completed by judging the quality of the fusion mass based on the degree and maturity of bone. Grading was performed blindly as to the treatment groups.

Biomechanical evaluation included two different evaluations. The lumbar spines were first mounted in an MTS machine and non-destructively tested. Measurements of range of motion at an applied load of 1.0 Nm were determined in flexion and extension from the neutral position. Total range of motion was also calculated.

After range of motion testing was completed, the spines were prepared for a destructive tension test of the fusion mass itself. The vertebral bodies on either side of the fusion were mounted in an Instron test machine. The annulus, disc space, facet caps and interspinous ligaments were sharply divided with a knife. The fusion mass was loaded in tension until failure of the fusion with the load to failure recorded.

Mean flexion, extension and total ROM, and load to failure in tension was calculated for each group. Statistical analysis between the means was done using a t-test.

**Results** Twenty-two of the 24 animals completed the study without problem. One animal in the PEMF stimulation group demonstrated failure to thrive and had to be euthanized at 2.5 weeks postop. One other animal in the PEMF group was found to have had the fusion procedure performed at the L4-5 level on the left side and L3-4 on the right. Both of these animals were pre-randomized into the mechanical test arm of the study. Therefore, 6 animals were mechanically evaluated in the PEMF stimulation group and 8 in the control groups. Four animals from each group complete histologic evaluation without problem.

The results of mechanical testing is summarized in the following table. Mean values are noted with standard deviations in parenthesis.

<table>
<thead>
<tr>
<th>Mechanical Test</th>
<th>PEMF Group</th>
<th>Control Group</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion ROM (deg)</td>
<td>5.5 (2.7)</td>
<td>9.8 (4.9)</td>
<td>0.10</td>
</tr>
<tr>
<td>Extension ROM (deg)</td>
<td>5.3 (2.4)</td>
<td>8.3 (2.9)</td>
<td>0.08</td>
</tr>
<tr>
<td>Total ROM (deg)</td>
<td>9.5 (4.4)</td>
<td>15.4 (5.8)</td>
<td>0.07</td>
</tr>
<tr>
<td>Tension Test (N)</td>
<td>182 (38)</td>
<td>126 (22)</td>
<td>0.03</td>
</tr>
</tbody>
</table>

Histologic analysis of the PEMF stimulation group revealed an excellent result in 2 spines and good result in the other 2 spines. In the control group, a good result was seen in 2 spines and fair result in the other 2. There were no poor results in either group.

Review of lumbar radiographs was not helpful in differentiating the 2 treatment groups. Within a treatment group, there was not a significant correlation between the objective mechanical data and subjective radiographic appearance of the fusion mass.

**Discussion** Externally applied pulsed electromagnetic stimulation did improve the mechanical and qualitative characteristics of a posterolateral fusion mass in this rabbit model. Flexion and extension testing revealed statistical trends while the tension test was statistically significant. The flexion-extension testing is a more physiologic test in that is does reproduce an in vivo activity. This test, however, allows for other factors to come into play when evaluating the fusion mass. Because of the anatomical position of the posterolateral gutter relative to the rabbit lumbar functional spine unit center of rotation, the fusion mass would be placed in compression during flexion testing. Therefore, fibrous clefts in a fusion mass would be compressed into a position of greater stability during flexion testing. Extension testing will place the fusion mass in relative tension thus exploiting deficiencies in consolidation of the fusion mass. While the anterior longitudinal ligament and disc anulus provides extension stability, we believe extension testing is more useful than flexion testing of the posterolateral fusion mass in the rabbit. The tension test is not a physiologic test but does clearly evaluate the fusion mass in isolation from other supporting structures. Our results reveal a statistically significant difference in the tension test between the two treatment groups with the PEMF stimulation group improving the mechanical characteristics of the fusion mass.

Plain radiographs were not helpful in evaluating the fusion masses between the 2 treatment groups or within each treatment group. Histologic analysis did reveal qualitative differences in the fusion masses with the PEMF stimulation group out-performing controls. We do not recommend the use of plain radiographs as a tool to assess a lumbar posterolateral fusion mass in the rabbit.

**Conclusion** Four-hours of externally applied external pulsed electromagnetic stimulation did improve the mechanical and histologic properties of a posterolateral fusion in the rabbit model. This study underscores the need to evaluate not only the nature of an applied external signal but also the daily dose or duration of signal application.

Acknowledgements – This study was supported in part by a grant from Orthofix.