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IN VIVO EVALUATION OF CALCIUM SULFATE AS A BONE GRAFT SUBSTITUTE, pp. 34-35

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Purpose: The most commonly performed lumbar spine stabilization procedure is a posterolateral intertransverse process fusion. Fusion with autologous bone graft may lead to non-union, and bone graft harvesting has significant donor site morbidity. Extensive research is currently being performed to assess alternatives to autologous bone grafts. We performed an in vivo evaluation of calcium sulfate pellets (OsteoSet®, Wright Medical Technology, Inc., Arlington, TN) and direct current electrical stimulation (Electro-Biology, Inc., Parsippany, NJ), using a rabbit posterolateral spinal fusion model. This model (Boden et al, *Spine*, 1997) has been demonstrated to have a pseudarthrosis rate of 40% using autologous bone graft. We hypothesized that calcium sulfate and autologous bone marrow aspirate could be used as a bone graft substitute, and that the addition of direct current electrical stimulation would enhance fusion formation in a dose dependent manner.

Methods: Three groups of twelve New Zealand White rabbits (4.0-4.5 kg) were used. In Group I, bilateral L5-6 intertransverse process fusion was attempted using 3 cc's of calcium sulfate pellets mixed with autologous iliac crest bone marrow as a bone graft substitute. Group II animals were treated in the same way, with the addition of 40μA direct current electrical stimulators placed across the L5-6 transverse processes. For Group III, the same bone graft substitute and 100μA stimulators were used. All animals were housed individually, and allowed to eat and ambulate ad libitum. Animals were sacrificed at 8 weeks by injection of sodium pentobarbital, and the lumbar spines were harvested en bloc, with surrounding soft tissues intact. The fused (L5-6) and non-surgical control (L3-4) functional spinal units (FSUs) were then isolated for further testing. The three-point bending test was employed to evaluate the mechanical competence of each segment using an Instrom Model 8511 hydraulic testing machine (Instron, Canton, MA). A 10.0N pre-load was applied under displacement control, followed by four preconditioning cycles to 2.0mm deformation at rate of 0.1mm/sec, followed by a ramp load applied to 7.0mm of deformation at a rate of 0.1mm/sec to a frank failure of the specimen. The yield load, ultimate failure load, neutral zone (NZ), and the elastic zone (EZ) stiffness were estimated from the load-displacement curves using Lab View (National Instruments, Austin, TX). Radiographic scoring and the outcome of the palpation tests were analyzed using non-parametric ANOVA (JMP, SAS, USA). A two way ANOVA was employed to test for differences in the measured mechanical parameters between the three test groups (in-between) and surgical versus non-surgical (between) group. Significance level was set at the 5% level.

Results: One rabbit died post-operatively in Group I and one in Group II, leaving 11 animals in each. All 12 animals assigned to Group III survived to eight weeks. There were two superficial infections that were treated effectively with a short course of antibiotic therapy.

Radiographic Analysis:
Group I All Bilateral Non-union
Group II 1 Unilateral Fusion/ 10 Non-union
Group III 4 Unilateral Fusion / 8 Non-union

Manual Palpation:
Group I No Fusion
Group II No Fusion
Group III 2/12 Fused (17%)

Mechanical Testing: The operated spinal segments in Groups II and III with electrical stimulation had an increase in the yield load and elastic zone stiffness ($P<0.05$) than their corresponding non-surgical levels. No such difference was found for the calcium sulfate Group I. By contrast, the neutral zone stiffness for all three groups was significantly higher ($P<0.05$) for the operated segments. No significant differences were found in stiffness indexes, or failure load between any of the groups tested.

Discussion: The use of calcium sulfate mixed with autologous iliac crest bone marrow aspirate as a bone graft substitute in the rabbit posterolateral spinal fusion model failed to produce fusion. When direct current electrical stimulation was added, a trend toward successful fusion was observed, in a dose dependent manner, but no statistical significance could be demonstrated. Other bone graft substitutes, such as coralline hydroxyapatite, have demonstrated the ability to achieve fusion when combined with direct current electrical stimulation in our laboratory (Bozic et al, *Spine* 1999). The successful use of calcium sulfate in surgeries to fill mandibular, calvarial, and long bone defects should not be extrapolated to the dissimilar application in the lumbar spine.