

DC Stimulation for Spinal Fusion with a Piezoelectric Composite Material Interbody Implant: An Ovine Pilot Study

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Statement of Purpose: Over 600,000 spinal fusion surgeries are performed each year in the USA, of which about 60% are for patients in the high risk or difficult-to-fuse category (e.g., smokers, diabetics). Successful spinal fusion rates in the difficult-to-fuse population have been shown to be as low as 50-70% [1]. Direct current (DC) electrical stimulation has been used clinically to stimulate bone healing for over 25 years without adverse events or ectopic bone formation. There is one clinically available device set that provides DC stimulation to promote spinal fusion (Biomet SpF®). It requires a second surgery site to implant the battery pack, has electrodes over the transverse processes, and may require a later surgery to remove the battery pack. An alternative solution is an interbody device that incorporates a load-bearing tough piezoelectric composite material. Previous theoretical models have shown that a piezoelectric implant can generate the needed electrical stimulation levels for bone healing through the natural motion and loading of the body [2]. Bench-top testing showed that power levels sufficient to provide electrical stimulation levels to promote bone healing could be achieved in a composite piezoelectric implant [3,4]. The objective of this *in vivo* pilot large animal implant study was to test initial hypotheses that use of a piezoelectric composite lumbar spine interbody implant could reduce the time to achieve fusion and enhance fusion quality.

Methods: Four prototype implant interbody devices were manufactured using piezoelectric composite materials as previously described [3,4]. Two of the implants were poled and made electrically active with an externally mounted electrode and circuitry that was designed to deliver a DC density of 15 $\mu\text{Amps}/\text{cm}^2$ to the electrode with loading of the implant. The two control implants had identical size, shape and mechanical properties as the active implants, but were not poled and did not have an external electrode or circuitry. Two skeletally mature, female sheep underwent spinal fusion procedures at two sites (L2/L3 and L4/L5). An active cage was placed at one level and a control cage at the other, with the placement of control and active alternated in the two animals. The animal study was conducted at the Medtronic Physiological Research Laboratories facility (Minneapolis, MN) in accordance with an approved IACUC protocol. Post-implantation, the sheep were allowed to walk around normally, which provided for cyclic loading across the spine. CT scans were taken at six weeks and four months. At four months post-implantation, both sheep were sacrificed. The L2-L3 and L4-L5 spine segments from each sheep were loaded in displacement control to 5 Nm in flexion/extension, bilateral bending, and bilateral axial torsion using a Spine Testing Machine (ATS, Butler, PA) with displacement

measurement by an Optotrak sensor (NDI, Ontario, CA). Neutral zone (NZ) stiffness and range of motion (ROM), extension (EZ) stiffness and ROM, and overall ROM were calculated.

Results: CT scans at both six weeks and four months showed substantially greater new bone in the active piezoelectric implant compared to the control. Fusion sites of active implants were rated as grade 3 and control as grade 1 at both time periods. Figure 1 shows representative axial CT scans near the interbody device. Table 1 gives the average percent change between the control specimen and the active specimen for the most relevant biomechanical parameters. On average, the active implant fusion site was stiffer than the control in both the NZ and EZ regions and had a lower range of motion (ROM), indicating more bone formation in the active implants compared to the control.

Table 1. Percent change of biomechanical parameters between active and control implant fusion sites

	Average Percent Change		
	Flexion/Extension	Lateral Bending	Axial Rotation
NZ Stiffness (Nm/°)	86%	15%	100%
EZ Stiffness (Nm/°)	104%	74%	131%
NZ ROM (°)	-49%	-18%	-22%
Overall ROM (°)	-52%	-39%	-44%

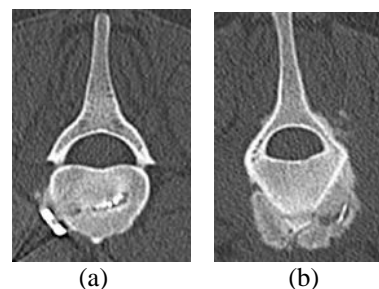


Figure 1. Axial CT scans of the (a) control and (b) active lumbar fusion sites.

Conclusions: The active specimen fusion level from both sheep consistently showed results indicative of more bony formation and better fusion when compared to the control. Although statistical significance cannot be determined due to the low numbers of specimens used in the pilot study, the results are promising. Further research in the use of piezoelectric composite biomaterials in spinal fusion implants is justified. A large animal study with greater numbers should progress to confirm the trends exhibited in this study.

References: 1. Kucharzyk DW et al., Spine. 1999; 24(5):465-8. 2. Tobaben et al., JBMR-A, 2014. 3. Goetzinger NC, Thesis, Univ. of KS, 2014. 4. Tobaben NJ, Thesis, Univ. of KS, 2014.