Power with a current density of 4-5 µA/cm² to stimulate stimulation devices require approximately 140 µW of to fuse population.[2,3] Clinically used DC electrical stimulation of bone has been proven to increase spinal fusion rates in this difficult population (e.g. tobacco users, diabetics), failure rates of as high as 29-46%.[1] DC electrical stimulation leading to nonunion or pseudarthrosis are as high as 29-46%.[1] A recent theoretical study investigated the potential use of a tough piezoelectric composite implant that could improve the rate of fusion and minimize complications associated with current adjunct therapies.[6] As with other interbody implants, the piezoelectric implant is placed in the interbody space and would provide the same benefits of current fusion cages. However, it will also generate an electrical potential that can stimulate the bone growth necessary to fuse adjacent segments as it is cyclically compressed between adjacent vertebrae during normal patient activities. The present study is an initial investigation of the electromechanical behavior of piezoelectric composite materials with a cross-sectional area similar to that of spinal interbody implants. The influence of frequency, applied load, and fiber loading as a function of electrical load resistance was determined. The purpose of this study is to elucidate the electromechanical response and power generation capability of these materials as a preliminary test of feasibility for their use in spinal fusion implants.

Methods: Composite specimens of three fiber volume fractions (5, 10 and 20%) were manufactured into 15.8 +/- 0.05 mm diameter cylinders using epoxy (EPO-TEK ® 302-3M) and 800 micron diameter PZT fiber (Smart Materials Corp.). Fibers were aligned along the length of the cylinder and distributed throughout the cross-section so that no fibers were in direct contact. Specimens were cut with a diamond saw perpendicular to the fiber direction to a height of 15.2 +/- 0.04 mm. Electrodes were formed on specimen ends by sputter-coating with Au. Specimens were immersed in an oil bath and poled at 10kV for 30 minutes using a high voltage power supply (Trek, Model 10/10B-HS). After cleaning and a consistent rest period, specimens were mechanically tested in cyclic compression using an MTS Model 858 with self-aligning platen at four frequencies (1, 2, 3 and 5 Hz) at three loads (100, 500, and 1000 N) across a series of varying electrical resistance loads. Generated voltage was measured and available power calculated for each test condition.

Results: Figure 1 gives the available power generated across the varying electrical load resistances for the three fiber volume fractions of piezoelectric composites at a conservative physiological loading rate of 2 Hz and 1000 N (simulating moderate walking). At 20% fiber volume fraction, power levels generated reached over 1,000 µW. Both voltage and power increased with increasing volume fraction, though the relationship was nonlinear. Figure 2 shows the power generated as a function of applied compressive load and frequency across varying electrical load resistances. As expected, as frequency was increased both voltage and power levels increased with maximum power generated of over 2,000 µW at 5 Hz. Increased mechanical loading levels also increased power output.

Conclusions: This preliminary proof of concept study shows that sufficient power can be generated to electrically stimulate fusion through a piezoelectric composite spinal interbody implant. While the power generated at normal physiological loading levels were far more than the 140 µW required for electrical stimulation of bone healing, the corresponding impedance values were also high. Power loss through the high source impedance and other required circuitry for electrical stimulation, storage and delivery is expected. Lowering of specimen source impedance while maintaining power output would be desirable for the proposed application. Further research on this concept is underway.