Proceedings of BioMed2007
Frontiers in Biomedical Devices Conference
June 7-8, 2007, Irvine, California, USA

BIOMED2007-38071

CHARACTERISTIC MOTION SIGNATURES DERIVED FROM THE THEKEN EDISC UNDER MULTI-AXIAL LOADING

James P. Price, Brian E. Rich, Christopher P. Cole and Richard R. Navarro
Theken Disc, LLC
Akron, OH 44319
Email: jprice@thekendisc.com

INTRODUCTION

The motions and loads experienced by the human spine are complex and have been the subject of much study over the years. The emerging field of intervertebral disc arthroplasty offers products that must function within this complex loading environment over long periods of time. So-called "first generation" intervertebral disc designs accomplish this through one or more articulating surfaces. Second generation artificial discs attempt to mimic the multi-axial disc motion and stiffness exhibited by the natural human disc. The eDisc not only provides this type of viscoelastic motion, but also provides the first capability to sense loads and motions to improve patient outcomes.

The eDisc design includes three coplanar dynamic force sensors embedded in the lower titanium endplate beneath the elastomer core. The sensors are connected to an internal microelectronics module that has onboard signal processing capability, non-volatile memory storage, rechargeable battery, and wireless data transmission. The spatial arrangement of the force sensors yields both load magnitude in the spine and relative motion of the spine segment during a load event.

EXPERIMENTAL METHODS

The eDisc was tested on a four-axis spine simulator (BOSE-Enduratec Systems) capable of independently applying static or dynamic angular motions and compressive loads to a disc specimen. Resultant moments and shear forces are recorded with a 6 degree-of-freedom load cell. Multiple combinations of cyclic compression and angular motions were applied to the eDisc and the resultant sensor signals were recorded.

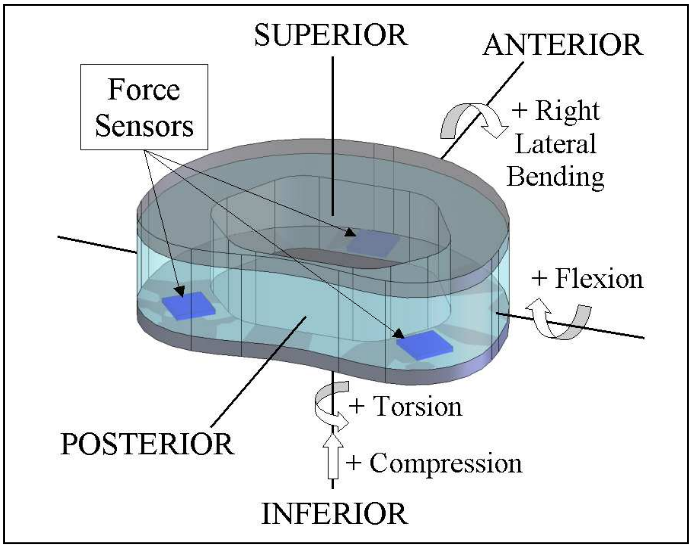

FIGURE 1. eDISC AND TESTING ORIENTATION

RESULTS AND DISCUSSION

The piezoelectric sensors yield a voltage that is proportional to the compressive load rate. In production, the relationship between change in compressive load and sensor output would be determined through a cyclic compression pre-implant calibration. A 1Hz sinusoidal loading function (200 – 2000N) resulted in voltage amplitudes of 1.13, 1.47 and 1.43 for the anterior, posterior left, and posterior right sensors respectively of this test specimen. The elevated posterior signals correspond to increased regional stiffness of the elastomer as shown in FEA studies.

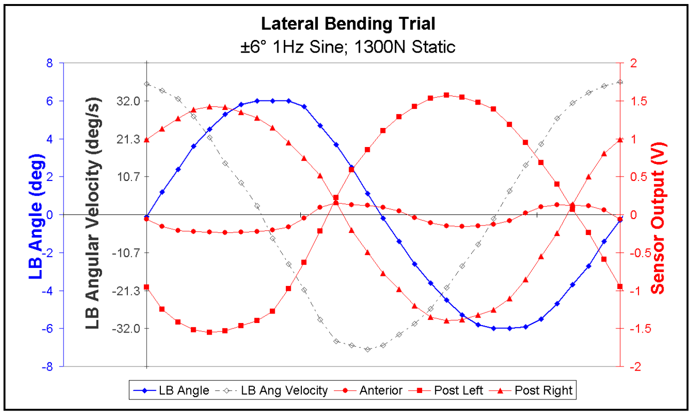

FIGURE 2. LATERAL BENDING TRIAL

A lateral bending load pattern and signal response is depicted in Fig. 2. The loading function was a bending motion (1Hz sine wave, +3° to 3°) with a static axial compression (1300N). The posterior left sensor indicates a decrease in compression while bending to the right and an increase in compression while bending to the left. The posterior right sensor responds in a similar fashion for the opposing side, while the anterior sensor produces a very small signal because of it's position along the bending axis. The load derivative indicates the rate sensitive nature of the load sensors and their capacitive phase lag character.

A series of bending trials were run to determine if the sensor output agrees with expectations for various motions. Fig. 3 depicts the results of this bending series. The magnitude and polarity of the sensor signals accurately reflect the relative compressive or tensile stress in the elastomer for a given movement. (The disc as a whole remains under compression due to the static load.) For instance, the polarity of the signals is inverted between the pure flexion and pure extension cases, with the signal magnitudes proportional to the motion excursion. Even small changes in coupled loading patterns can be differentiated with the eDisc. The trials were also repeated with a superimposed cyclic axial compression (900-1700N, 1Hz sine). In all cases this additional compression component was reflected in an increased amplitude of the positive sensor signals and decreased amplitude for the negative signals. In the cases with negative signal amplitudes, the "tensile" elastomer stress is offset by the superimposed dynamic compression, therefore reducing the overall amplitude.

DISCUSSION

Resolving the relative three-dimensional motion of an FSU using three coplanar dynamic force sensors is an indeterminate problem. However, it has been demonstrated that some basic, dynamic motions yield characteristic sensor signatures. The force sensors are limited to detection of dynamic changes in compression. It is plausible to integrate the sensor signals to convert to dynamic load readings, but the initial static offset remains unknown. Work is ongoing to compare analytical models to actual test scenarios.

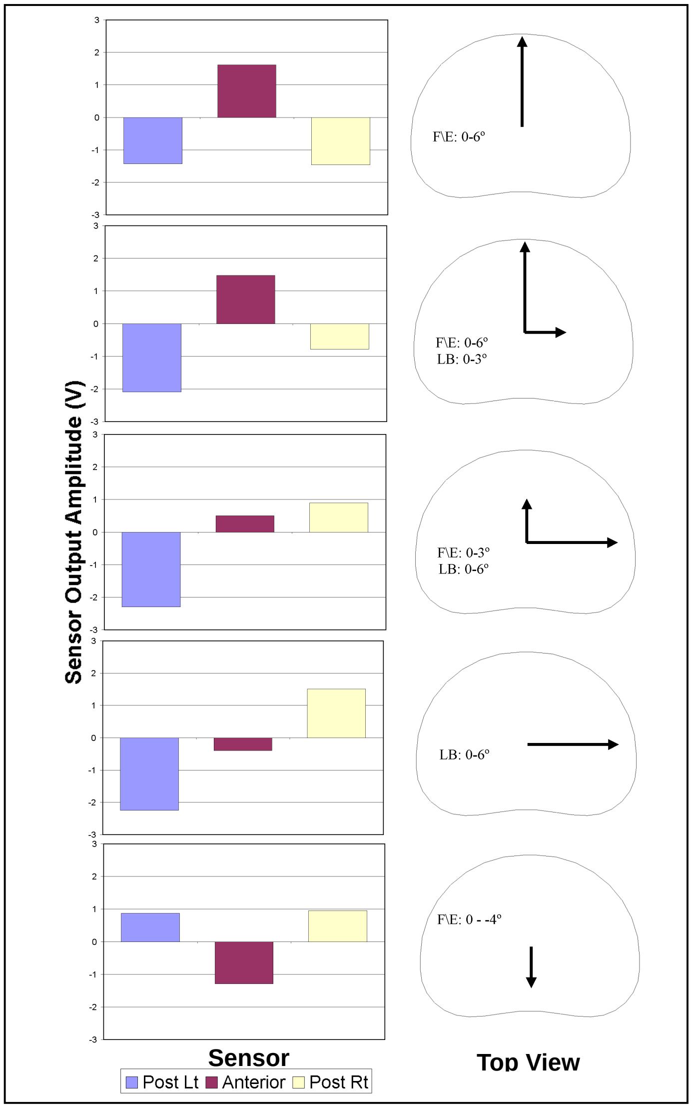

FIGURE 3. BENDING SERIES RESULTS

CONCLUSIONS

The eDisc sensor configuration has demonstrated the ability to not only measure dynamic loads, but also distinguish various motion profiles. The data from the eDisc will provide unique insights into the complex loadings of the spine and biofeedback to physicians and patients to minimize dislodgement complications and accelerate patient's return to work.