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MULTI-AXIS TESTING OF AN ELASTOMERIC PROSTHETIC LUMBAR DISC COMPARED TO A CADAVERIC HUMAN DISC

Njus, Glen (1,2); Price, James (3); Parikh, Anand (1); Chokhandre, Snehal (1); Konicek, John (1); Navarro, Richard (3)

(1) Department of Biomedical Engineering
The University of Akron
Akron, OH

(2) Calhoun Research Laboratory
Akron General Medical Center
Akron, OH

(3) Theken Disc, LLC
Akron, OH 44319
Email:
rnavarro@thekendisc.com

INTRODUCTION

As motion preservation implants begin to replace fusion devices for lumbar degenerative disc disease, preclinical mechanical testing of these devices is critical to predicting their in vivo safety and efficacy. ISO and ASTM standards committees have tried for years to develop a universal test standard for all lumbar disc implants. The eDisc, an elastomeric/titanium disc replacement, is substantially different in its mechanical performance than the Synthes ProDisc or J&J Charite disc. These discs rely on ball and socket motion about a fixed or moving center or rotation to provide motion restoration in 3 to 5 axes. In contrast, the eDisc has viscoelastic motion in 3 translation and 3 rotational directions, just as in the natural human disc.

The design goal of the eDisc, with its proprietary polyurethane elastomer, is to mimic the stiffness of the natural human disc [1,2,3] in multiple degrees of freedom. Additionally, standards bodies and the FDA subscribe to accelerated fatigue testing to represent decades of in-vivo life for these devices. The eDisc was tested on a 4-axis test machine to determine stiffnesses compared to human cadaveric discs.

MATERIALS AND METHODS

Four human cadaveric lumbar motion segments were tested. Two L1-L2 and two L3-L4 motion segements from multiple cadaveric spines have been tested. The specimens were non-osterporotic, determined by bone mineral density scans using dual energy x-ray absorptiometer. Preparation of the specimens consisted of overnight thawing of the lumbar spine at room temperature, followed by dissection of the required motion segment. The posterior elements of the motion segment were removed, with the remaining vertebral body, anterior and posterior ligament, and intervertebral disc (IVD) forming the test specimen. Superior and inferior bodies of the disc

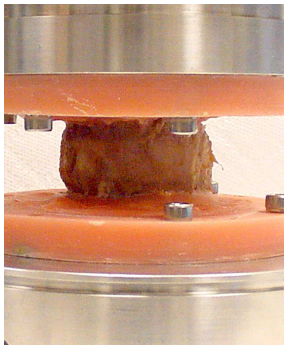

Figure 1. Superior and inferior bodies of the disc specimen embedded and assembled on the test jig.

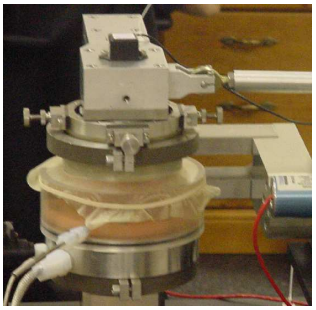

Figure 2. Test specimen loaded on spine simulator.

Test no.	AC (Newton)	FE (degree)	LB (degree)	AR (degree)	Frequency (Hertz)
1	500	4 - 2	-	-	0.25
2	300 - 700	4 - 2	-	-	0.25
3	500	-	2 - 2	-	0.25
4	300 - 700 ‘a’ Hz.	4 - 2	2 - 2	-	a: 0.50 b: 0.75
5	500	-	-	3 - 3	0.25
6	300 - 700 ‘a’ Hz.	6 - 3 ‘a’ Hz.	2 - 2 ‘b’ Hz	2 - 2 ‘b’ Hz	a: 0.50 b: 0.75
7	modified ISO	6 - 3 ‘a’ Hz.	2 - 2 ‘b’ Hz	2 - 2 ‘b’ Hz	a: 0.50 b: 0.75

Table 1. Testing protocol.

specimens were embedded using polymethylmethacrylate as shown in Figure 1.

The embedded specimen was assembled on the jig and loaded on a four independent axis custom built electromagnetic EnduraTEC Systems Corp. spine simulator with an active temperature control system. A 6 degree of freedom load cell measured the forces transmitted. During the entire testing sequence, the specimen was immersed under physiological conditions in a saline solution at 37ºC, Figure 2.

Axial compression (AC), flexion-extension bending (FE), lateral bending (LB) and axial rotation (AR) were the independent variables of a complex loading protocol. The specimen was preloaded to 100 N AC. To understand the response of IVD to complex motion and to depict failure, each variable was introduced over time. Initially, AC was cycled from 100-600 N at 0.25 Hz and this test protocol was periodically rerun for a structural stability check (SSC). The main output parameters analyzed were anterior-posterior shear, lateral shear, FE bending moment, LB moment, axial torque, axial displacement and temperature.

Loading conditions were increased in sequential steps as shown in Table 1. Consider test no. 6, loading protocol was cyclic axial compression from 300-700 N at 0.5 Hz, 6 degrees

Figure 3. eDisc.

flexion to 3 degrees extension at 0.5 Hz, 2 degrees lateral bending on either side at 0.75 Hz, and 2 degrees axial rotation at 0.75 Hz. SSC was performed after each step in the testing protocol as an evaluation of the specimen integrity. Test no. 7 was a fatigue test protocol of the modified ISO draft standard 18192-1.3, increasing the AC in steps of a few hundred newtons. Failure during testing was defined by an excessive axial displacement. Minor changes in the testing protocol were made depending upon specimen behavior.

A similar testing protocol as described in Table 1 was carried out for an eDisc (Figure 3). Comparisons between the analysed data of four cadaveric specimens and the eDisc was conducted.

RESULTS AND DISCUSSION

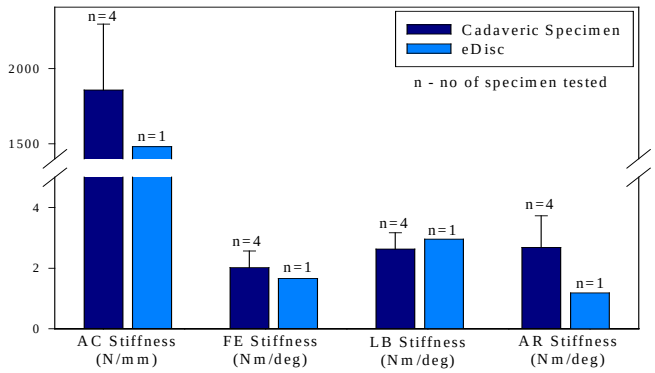

Figure 4. Complex loading stiffness comparison between cadaveric specimens and eDisc of Test no.6

Stiffness during AC, FE, LB, and AR were calculated for the cadaveric specimens and the eDisc. Figure 4 shows that the stiffness was comparable between them.

The eDisc was subjected to the modified ISO fatigue test protocol in 37ºC saline for over 7M cycles without failure. The natural disc, while not failing catastrophically, had an average 3.5 mm axial shift representing a collapse of bone and 20% decrease in axial stiffness in less than 2500 cycles. Post-test radiographic-image analysis for the four cadaveric specimens following fatigue testing depicted transverse bone fracture and compression / compaction of the cancellous region of the vertebral bodies. Clearly the ISO draft standard represents extreme loading for a natural human disc. Testing under these conditions should lead to robust designs capable of withstanding decades of human implantation.

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