Testing Parameters that Effect the Compressive Mechanical Behavior of the Intervertebral Disc

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Introduction: Several mechanical tests are performed on human intervertebral discs to characterize newly developed disc and nucleus implants. Since one of the primary functions of the human intervertebral discs is to support load in the axial direction, a general test is to apply compressive loads in the axial direction. This experiment is usually conducted in force control with cyclic application of the load between predefined limits. Most protocols have been performed in the same range of loads limits, but other parameters like load application time and load shape are not consistent[1]. A long application time (several minutes) may introduce creep effects and a fast period (less than a second) may amplify the effect of mechanical inertia[2]. Loading frequencies in the literature vary between 0.1-1Hz. A sinusoidal waveform is considered to be more physiological, while a triangular waveform allows maintenance of constant load application velocity during the loading and unloading phases.

The goals of this study are: (1) to evaluate how different waveform or load application times may effect an intervertebral disc test and (2) to quantify changes in the mechanical behavior of the intervertebral disc in response to the insertion of a pressure transducer through the annulus to record the nucleus pressure.

Methods: Three human lumbar disc were harvested from a 64 years old male. The specimens were potted and placed onto an Instron-8874 biaxial mechanical testing machine. Preconditioning was performed in displacement control at 3% of initial disc height for 50 cycles at 1Hz, using a triangular waveform.

A 50N compressive load was applied to simulate the normal preload on the disc. The intact disc ("intact") was tested in load control with 5 cycles under a tension of 150N to compression of 1500N with five different frequencies (0.01, 0.05, 0.1, 0.5 and 1 Hz) and two different load shapes (triangular and sinusoidal). Each test was performed after a recovery time of 10s and for each specimen, load period and load shape were randomly alternated. A pressure transducer, embedded in a 14 gauge needle, was inserted in the nucleus pulposus (NP) through the anterior annular wall ("intact+pt"). The specimens were then tested using the same protocol. Finally, some of the disc nucleus was removed with a posterolateral approach by a 5 minute application of a Clarus Medical Nucleotome System ("denucleated"). The denucleated disc waas tested using the same protocol and the removed nucleus tissue. During the experiment (~3 hours), the specimen was kept moist by spraying PBS.

Results: The position and load of the fifth cycle for each test was post processed to evaluate range of motion (ROM), neutral zone (NZ) and hysteresis (HYS). ROM is the difference between the maximum and the minimum displacement recorded. The NZ is the intercept of the tangent to the displacement vs force curve at 1400N during the loading phase. HYS is the area of the loading cycle in the displacement vs force plane.

Figure 1 shows the percentile difference between the same parameter measured with a triangular load waveform and a sine waveform for the different frequencies tested.

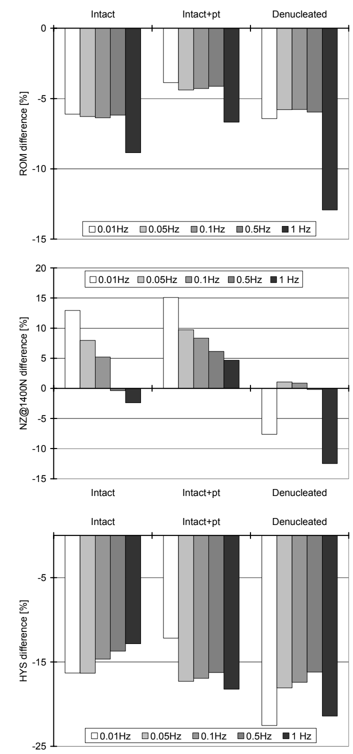

Fig 1: Percentage differences of ROM, NZ and HYS between triangular and sine load shape for frequencies from 0.01-1Hz in compression loading for intact, intact+pt and denucleated intervertebral disc specimens.

Conclusion: Within the same load wave shape ROM, NZ, and HYS for the same disc condition show differences of less than 5% in the range of frequency between 0.05Hz and 1Hz, for 0.01Hz these differences increase to about 10-20%. The change in these parameters caused by introduction of the pressure transducer is within experimental error.

The comparison between wave shape is less homogeneous: ROM and HYS with triangular waveform are respectively almost 5% and 17% smaller than with a sine wave form. However, the NZ changes consistently through frequencies and results generally higher with a triangular wave form than with a sine load shape.

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[1] Huber G., Linke B., Morlock M.M., and Ito K, "The influence of in vitro testing method on measured intervertebral disc characteristic," Spinal Implants: Are we evaluating them appropriately, ASTM STP 1431, M.N. Melkerson, S.L. Griffith, and J.S. Kirkpatrick, Eds., ASTM International, West Conshohocken, PA, 2003.

[2] Whilke H.J., Wenger G., Claes L., Testing criteria for spinal implants: reccomandations for the standardization of in vitro stability testing of spinal implants, Eur Spine J. 7:148-154, 1998.