THERE IS A LINEAR RELATIONSHIP AMONG DISC HEIGHT, INTRADISCAL PRESSURE AND IMPLANT VOLUME FOR NUCLEUS PULPOSUS AUGMENTATION

*Cannella, M., *Orana, A., **A. Arthur, *Marcolongo, M.
*Drexel University, Department of Materials Science and Engineering, Philadelphia, PA; **Synthes Spine, West Chester, PA

INTRODUCTION: The cause of lower back pain associated with degenerative disc disease is poorly understood. However, one theory is that degeneration of the nucleus pre-dates annular degeneration and significant radial bulging of the disc or tearing of the annulus. It has been hypothesized that supplementing the nucleus with a material or device intended to restore disc height and/or some biomechanical disc function may lead to a clinical treatment for patients with early indication of disc degeneration and chronic lower back pain. We have investigated minimally invasive augmenting to the nucleus of the intervertebral disc (without removal of the nucleus tissue) and performed compressive/tensile testing on human lumbar anterior column units (ACUs) to establish a relationship among implant volume, disc height and intradiscal pressure.

METHODS: Seven human lumbar anterior column units (ACUs), average age 66.6 (16.4) years, were prepared. Initial intervertebral disc (IVD) height was measured by a calibrated X-ray image. The specimens were potted and placed onto an Instron-1331 mechanical testing machine. Preconditioning was performed in displacement control at 3% of initial disc height for 50 cycles. The intact disc was tested in load control with a 5 cycle sawtooth load from a tension of 150N to compression of 1500N. A pressure transducer (PMC–Model 060S), embedded in a 14 gauge needle, was inserted in the nucleus pulposus (NP) through the anterior annular wall and the loading protocol was repeated.

Under a 50N compressive load (to simulate lying prone), the implant was inserted in the NP in a minimally invasive posterolateral approach through the annulus until the disc height was increased by 2.5%. Implant volume and disc height were recorded. The same loading protocol was performed and intradiscal pressure, load and displacement were recorded using Labview software. This procedure was repeated for disc heights that increased in 2.5% increments to develop an understanding of the relationships among disc height, implant volume and intradiscal pressure. The effect of implantation on disc stiffness was examined using the 5th loading cycle and compared statistically to the intact state using a one-way ANOVA ($p<0.05$). After testing, the discs were dissected and blindly graded according to a modified Thompson scale (1-5) for the degenerative state by an expert.

RESULTS: Disc height (at 50N implantation load) and intradiscal pressure (at 1500N) increased linearly with volume of implant inserted into the NP, as seen in Figure 1 for a typical (L2/L3, 43y male) specimen. Among specimens, the variation in the slopes of the linear relationship between disc height and implant volume was linear with the r^2 values range from 0.59-0.99. The axial stiffness of the augmented discs was not statistically different from intact at load levels above 400N in compression. However, in tension and through the zero load condition, there was a significant ($p<0.02$) increase in stiffness of the implanted disc compared to intact, regardless of increased disc height (Figure 2).

CONCLUSION: Nucleus augmentation results in a linear increase in disc height and intradiscal pressure for a given volume of implanted material and the implantation increases disc stiffness in tension and through the zero-load condition, but not in the higher compressive load levels that correspond to function (such as walking). Little, if any, data has been published on nucleus augmentation to date, although mechanical behavior associated with nucleus replacement has been described by several groups as summarized recently by Yuan et al (1).

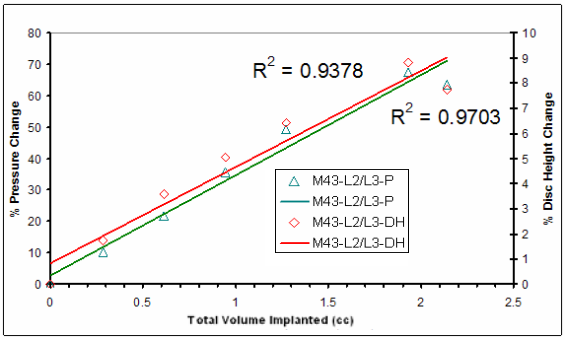

Fig 1: There is a linear relationship among disc height, intradiscal pressure and implant volume for an augmented nucleus.

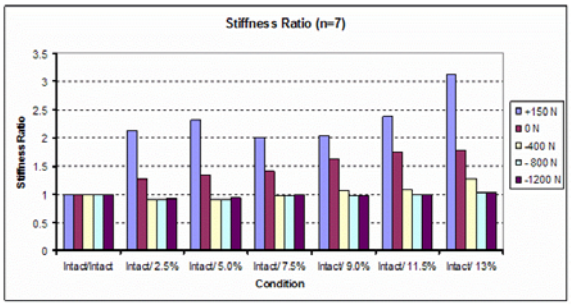

Figure 2: The stiffness of the augmented ACU is increased over the intact in tension ($p<0.02$) and through zero loading ($p<0.02$), but not at higher loading levels.

REFERENCES

(1) Carl, A., Ledet, R., Yuan, H., Sharan, A., Spine J., 4(6):1:S325-S329.

ACKNOWLEDEMENTS Synthes for Funding E. Vresilovic for grading of disc specimens.