Effects of a Nucleus Pulposus Implant on the Diurnal Biomechanics of the Human Intervertebral Disc—A Finite Element Analysis Study

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Statement of Purpose: Intervertebral disc (IVD) degeneration occurs with aging, and may be a major cause of back pain. Lower back pain was reported in more than 80% of the cases exhibiting degeneration of lumbar intervertebral discs[1]. Alterations in the major biochemical constituents of the IVD have been shown to coincide with aging and disc degeneration and can subsequently alter the disc's ability to support load. A significant biochemical change that takes place in disc degeneration is the loss of proteoglycans (PGs) in the inner region of the disc, the nucleus pulposus (NP)[1]. In this study we have investigated the effects of implanting a polymeric hydrogel nucleus pulposus implant on the stress distribution in the NP and annulus fibrosus (AF, outer region) of the IVD using an axisymmetric poroelastic model with incorporated osmotic swelling developed in our lab. The goal of this study is to analyze the effect of denucleation and subsequent implantation of a nucleus pulposus replacement using an osmo-poroelastic finite element model. This is the first study to consider the effects of osmotic swelling throughout the intervertebral disc due to the fixed charge density of the implant at various grades of degeneration.
In a dehydrated disc, the function of the nucleus, namely load transfer to the annulus through creation of an intradiscal pressure, is no longer occurring at a normal level[2]. The mechanics of the degenerated disc are clearly altered compared to those of the intact disc[3].
Methods: An axisymmetric, osmo-poroelastic model was created using ABAQUS v6.5 finite element software (SIMULIA, Providence, RI). The model consists of a nucleus pulposus, an annulus fibrosus, cartilaginous and bony portions of the adjacent endplates, and cancellous and cortical portions of the corresponding vertebrae. The standard poroelastic theory included in ABAQUS is utilized, but a user-defined material was incorporated to include the effects of osmotic swelling. The model response was validated against experimental results such as axial displacement, radial displacement of the outer annulus fibrosus, and total fluid lost.
The first step in a nuclear implant replacement procedure is to denucleate the specimen. The amount of nucleus pulposus tissue removed in the model was based on an axisymmetric approximation of 80% of the total volume of the nucleus, leaving the remaining 20% in the radial direction only, as denucleation is more easily achieved from endplate-to-endplate than closer to the entrance point of the incision through the annulus. The hydrogel implant was incorporated into the denucleated model to simulate the implanted condition. This process was performed on each of five models representing the varying Thompson grades of degeneration[4].
Results: The stress profile of the annulus fibrosus is restored to the previous degenerative grade's stress state after implantation (Figure 1). This implies that the implant can delay degeneration of the annulus fibrosus by absorbing a more substantial portion of the stress than the nucleus pulposus tissue does. The degenerative cascade begins with a loss of proteoglycans in the nucleus pulposus, decreasing the ability of the nucleus to maintain its hydration. The fluid in the nucleus helps distribute the applied load on the disc, and the loss of this fluid increases the stress on the annulus fibrosus. This is the beginning of the degenerative cascade, as the additional stress on the annulus causes its degeneration, increasing the stress on the nucleus, which degenerates further in response, etc. The hydrogel implant decreases the stress on the annulus fibrosus, and since the hydrogel itself does not degenerate, this could potentially halt the degenerative process. Although this effect is seen at each degenerative grade, early intervention (Grades 2 or 3) by nucleus implant replacement offers the largest potential since the tissue is likely still viable and halting the progress of degeneration could put an end to the cascade.
Increasing the elastic modulus and fixed charge density, independently, decreases the stress in the annulus fibrosus. Poisson's ratio, initial void ratio, and initial permeability have little to no effect on the stress profile of the annulus.

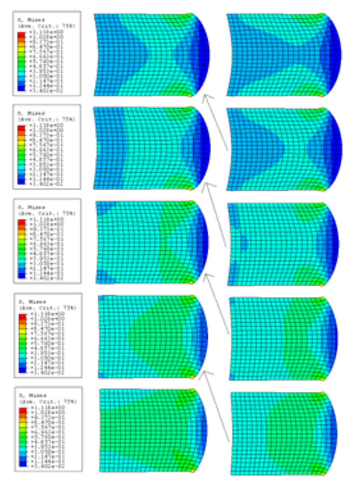

Figure 1. Stress in Grade 1 (top) to Grade 5 (bottom) AF after implantation

Conclusions: A hydrogel nucleus pulposus replacement produces major decreases in the stress experienced by the annulus fibrosus, possibly slowing down or halting the degenerative process. Although early intervention seems to be most beneficial due to the lessening of stress on the annulus, this study shows no distinct advantage to denucleation and implantation of a hydrogel nucleus pulposus replacement at any particular grade.

References: [1]Luoma K, et. al. *Spine* 25(4): 487-492, 2000. [2]Raj, P.Prithvi, *Pain Practice* 8(1), 18-44, 2008. [3]Guerin H, et. al. *Journal of Biomechanics* 39:1410-1418, 2006. [4] Thompson, J., et al., Spine, 1990. **15**(4): p. 411-415.