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Functional compressive mechanics of a PVA/PVP nucleus pulposus replacement

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Abstract

Emerging techniques as an alternative to the current treatments of lower back pain include nucleus replacement by an artificial material, which aims to relieve pain and restore the normal spinal motion. The compressive mechanical behavior of the PVA/PVP hydrogel nucleus implant was assessed in the present study.

PVA/PVP hydrogels were made with various PVP concentrations. The hydrogels were loaded statically under unconfined and confined conditions. Hydrogels were tested dynamically up to 10 million cycles for a compression fatigue. Also, hydrogel nucleus implants with a line-to-line fit, were implanted in the human cadaveric intervertebral discs (IVD) to determine the compressional behavior of the implanted discs.

Hydrogel samples exhibited typical non-linear response under both unconfined and confined compressions. Properties of the confinement ring dictated the observed response. Hydrogel moduli and polymer content were not different pre- and post-fatigues. Slight geometrical changes (mostly recoverable) were observed post-fatigue. In cadavers, hydrogels restored the compressive stiffness of the denucleated disc when compared with equivalent condition of the IVD.

The results of this study demonstrate that PVA/PVP hydrogels may be viable as nucleus pulposus implants. Further studies under complex loading conditions are warranted to better assess its potential as a replacement to the degenerated nucleus pulposus.

Keywords: Intervertebral disc; Hydrogel; Mechanical test; Spinal implant; Nucleus pulposus

1. Introduction

Lower back pain is an important socioeconomic disease and one of the most expensive health care issues today. In more than 75% of the cases, the origin of the lower back pain is a degenerated lumbar intervertebral disc (IVD) [1]. In the normal healthy disc, the hydrated nucleus pulposus (nucleus) exerts a hydrostatic pressure (intradiscal pressure (IDP)) on the annulus fibrosus (annulus) fibers [2]. This IDP is mainly responsible for load distribution in the disc, by creating tension in the annulus fibers near the interface with the nucleus. However, this load transfer mechanism is altered in degenerated discs. The water content of the nucleus in the degenerated disc is significantly reduced, resulting in a corresponding decrease in IDP [2–4]. An abnormal stress state of the annulus (which experiences compressive stresses) in the degenerated disc over repeated loading, may provide the stimulus for the formation of cracks and fissures in the annulus and thereby a path for nucleus migration from the center of the annulus toward the periphery.

Total disc arthroplasty [5–7] and nucleus replacement [8,9] are two non-fusion techniques emerging as potential

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solutions to this condition. The exploration of these concepts for the alleviation of lower back pain is motivated by the shortcomings of the current treatments, such as spinal fusion and discectomy. Both of these current procedures relieve pain, but do not restore the spinal biomechanics to that of a healthy disc [3,10–13]. Moreover, these procedures may promote further degeneration of either the initially affected disc, in the case of discectomy [12,13] or adjacent IVDs in the case of spinal fusion [14,15]. The ultimate goal of a non-fusion solution for the treatment of lower back pain is to eliminate pain and restore the motion and stress state to that of the normal physiological condition. Nucleus replacement with a synthetic material [8,9,16] or with a tissue engineered structure [17,18] targets earlier stages of disc degeneration (Galante grades I–III) [19], where the annulus is not fully compromised. This approach may help to preserve the annulus and be more amenable to minimally invasive surgical techniques. A classical approach to replacing a diseased or damaged tissue would involve matching the properties of the implant material to those of the normal biological tissue of interest. However, normal nucleus pulposus tissue properties vary with the state of degeneration and has been described with a wide range from a fluid [20] to an isotropic solid [4]. Without a well-defined tissue description, it is difficult to "match" the properties of the tissue.

In order to understand the mechanics of the implant, we need to concurrently understand the mechanics of the implant material. The implant material should be able to withstand mechanical loading states experienced under physiological conditions. While the ideal requirements for a nucleus replacement material have been described [20], test methodologies for determining the device behavior are yet to be agreed on by the regulatory and scientific communities.

Prior work in our laboratory has focused on the development of a chemically stable hydrogel polymer system of polyvinyl alcohol (PVA) and polyvinyl pyrrolidone (PVP) [21–23]. PVA/PVP interactions occur through interchain hydrogen bonding between the carbonyl group of PVP and hydroxyl group of PVA resulting in physical crosslinking of these two polymers. The objective of the current study was to characterize the compressive mechanical properties of a PVA/PVP hydrogel and assess the mechanical feasibility of the material as a potential replacement for the degenerated nucleus of the human lumbar IVD.

2. Materials and methods

2.1. Hydrogel preparation

PVA (Elvanol® Grade 71–30, $M_w = 120,000-140,000$ gm/mol) was obtained from Dupont (Wilmington, DE). PVP was obtained from Sigma Aldrich (St. Louis, MO) in two different molecular weights ($\overline{M}_n = 10,000$ and 40,000 g/mol). PVA and PVP powder mixtures were made containing varied PVA/PVP weight ratios between 1% and 5% PVP by weight (where previous data have shown no mechanical differences in modulus in this compositional range [21]) with an equilibrium water content of 84%. The mixtures were dissolved in deionized water at 90 °C for 24 h to yield polymer solutions. The solutions were stirred for 30 min and then cast into cylindrical molds. The molds were then exposed to six consecutive cycles of freezing at −20 °C for 21 h and thawing at 25 °C for 3 h to induce crystallization of the PVA and form physical crosslinking in the hydrogels.

2.2. Unconfined compression tests

Hydrogel samples were made using PVP with $\overline{M}_n = 10,000$ g/mol, as described above. Samples were immersed in phosphate buffered saline (PBS) solution (pH = 7.4) at 37 °C and unconfined compression tests were performed after 1 and 56 days of immersion. The hydrogel samples were loaded in an Instron mechanical testing system (Instron Model 4442, Park Ridge, IL) fitted with a 50-N load cell. Samples were compressed at a strain rate of 100% strain/min. Load and displacement data were recorded at 20 Hz with the Instron Series IX software. These data were converted to stress–strain values and a tangent compressive modulus for each hydrogel sample was calculated at 15%, 20%, and 25% strain. The average slopes of a linear trend line formed with the stress–strain data from 10–20%, 15–25%, 20–30% were assumed equal to the tangent slopes at 15%, 20%, and 25% strain, respectively.

2.3. Unconfined compressive fatigue behavior

2.3.1. Fatigue tests

Samples ($n = 9$) were made with PVP having $\overline{M}_n = 40,000$ g/mol, according to the methods described above. The hydrogel samples were axially compressed to 15% strain for 100,000, 1, and 10 million cycles at 5 Hz in PBS solution (pH = 7.4) at 37 °C with an Instron Model 1331. The tests were run with a preload of approximately 9 N. Three samples were tested under each condition. Surfaces with circular grooves were used on the testing apparatus to keep the test samples stationary during testing. The 15% strain represents the approximate strain corresponding to load on the intact IVD under physiological conditions [2,24]. The mass and dimensions of the samples were measured before and after fatigue cycling. Samples were placed back in PBS solution at 37 °C for 14 days, with mass and dimensions measured daily.

Unconfined compression tests were performed on each sample before and after fatigue test. The compressive modulus was calculated to determine the effect of fatigue cycling on the stiffness of the hydrogels. The samples were compressed at a strain rate of 100% strain/min. The tangent compressive modulus was calculated at 15%, 20%, and 25% strain as described earlier.