Characterization of a Novel PVA Meniscal Implant

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INTRODUCTION: The number of meniscus-related operations continues to rise due to a more active and aging population. In over 80% of meniscal tears, surgical treatment is indicated and in many of these cases partial meniscectomy is performed.[1,2] Partial meniscectomy can lead to changes in force across the articular surface, leading to an increased risk of osteoarthritis and cartilage damage within one year of surgery.[3] Scaffolds and meniscal replacements are being developed to replace the missing tissue with the ultimate goal of restoring native mechanics. Developing materials capable of restoring the native properties of the meniscus requires recapitulation of the distinct meniscus anisotropic fiber alignment essential to its function. Current techniques to recreate the meniscal fiber alignment, include such techniques as electropsun PCL[4] and collagen-based structures[5], however these techniques require the native cells to generate matrix and struggle to recreate the mechanical behavior of load-bearing tissue. Synethic approaches, such fiber reinforced[6] or double networks[7] structures, can lead to delamination at the interface between the two materials due to a large difference in mechanical properties. Poly(vinyl alcohol), or PVA, is a candidate hydrogel material for tissue repair due to its biocompabiliability and highly tunable mechanical, lubrication, and fatigue properties due to the many ways it can be manufactured and processed.[8,9] The objectives of this study were to develop a method of manufacture to empart controlled anisotropy to PVA hydrogels to generate a meniscal replacement and to quantify their ability to restore joint load distriubution in a human cadaveric knee. We hypothesized that modulus would increase as a function of circumferentially applied tensile strain during manufacture and that we will be able to restore joint forces after replacement of the meniscus with the PVA meniscus structure.

METHODS: *Sample Preparation:* PVA solutions comprising of 20%, 27.5%, and 30% PVA (weight/vol H_2O) were made and poured into custom-built 3D-printed molds, either in a dogbone shape for mechanical characterization or in a uniform pre-meniscal shape for meniscal structure generation. Cast PVA underwent three freeze/thaw (-20° C for 20 hours/ 20° C for 4 hours) cycles to partially crosslink the samples. Hydrogels were then removed from the molds and randomly assigned to an "Unloaded" (control) or a "Loaded" condition. For mechanical characterization, the dogbone samples were stretched to 100, 150, 200, or 250% strain for 3 days. For the meniscal samples, circumferential loads were achieved by stretching the structures around a 53.4 mm circumference post and clamped into a custom straining device at 200% strain for 3 days (**Figure 1**). All samples then underwent additional three freeze-thaw cycles before characterization; unloaded samples were removed from their molds and placed directly in the freeze/thaw machine while loaded samples were maintained in their loaded configuration during freeze/thaw cycles. *Mechanical Characterization:* Young's modulus was determined by straining the dogbone samples (n = 6) in tension at a rate of 0.1% strain/sec using the MTS Acumen electrodynamic test system. Samples were visualized under a circular polarizer to determine coherence using the ImageJ plug-in OrientationJ.[10] *Simulator Testing:* One knee that previously had a medial partial meniscectomy was used. A total meniscectomy was performed to quantify the ability of the "PVA Meniscus" to restore joint loads compared to a knee with a "Meniscectomy". The joint contact stresses was recorded using a Tekscan sensor placed under the medial meniscus on top the tibial plateau afterwhich, the knee was mounted on an AMTI VIVO joint simulator at half body weight for 0, 15, 30, and 60 degrees of flexion meniscectomized. The PVA meniscus was then sutured in to the remaining meniscus rim using 2-0 ethibond suture using an inside-out approach with long meniscal repair needles.

RESULTS: For the 20%, 27.5%, and 30% PVA, the modulus E in MPa (**Figure 2A**) can by expressed as a exponential function of the strain S in percent from 0 to 200%. For 20% PVA, the modulus ranged from 0.27 to 1.64 MPa. For 27.5 % PVA, the modulus ranged from 0.75 to 3.70 MPa. For 30% PVA, the modulus ranged from 0.66 to 3.88 MPa. The coherence increases linearly with % Strain (**Figure 2B**), and that coherence at a given strain is lower for a higher % PVA, both of which are consistent with physical theory. We found for the 20% PVA, for coherence C at strain percent S, that C = 0.031 * S + 0.0226, with R squared = 0.9553. For 27.5% PVA, we found C = 0.0025 * S + 0.0156 with R squared = 0.9712. For 30% PVA, we found C = 0.0023 * S + 0.0025 with R squared = 0.9977. Based on the mechanical characterization we chose to use 27.5% PVA stretched to 200% Strain to create a meniscus implant. When the implant was placed into the cadaver knee, we found it balanced the load distribution between the medial and lateral condyles of the joint. At 0° flexion, the peak stress of the medial and lateral meniscus without the implant (having undergone partial meniscectomy) was 0.66 and 1.08 MPa respectively. With the meniscus sutured in, the peak stress was 0.76 and 0.74 MPa on the medial and lateral mensicus respectively (**Figure 3**). Similar results were seen for other flexion angles tested.

DISCUSSION: We successfully characterized the modulus and degree of anisotropy as a function of applied strain in PVA hydrogels. The modulus values were within the range of values reported for other scaffolds but impart anisortpy that has been lacking in other materials.[8,9] All of these results are consistent with physical theory.[8,9] We also saw that the 27.5% PVA meniscus-analogue, generated under applied 200% strain, was able to restore forces in a cadaveric knee joint. Future work with the PVA meniscus implant will include performing simulator trials under dynamic simulated gait.[11] Additionally, suture pull-out tests to quantify the strength of the implants to retain sutures, and crack propagation studies to examine the long-term stability of these implants under stress will be performed. PVA menisci implants and restoration of balance in the medial and lateral compartments of the cadaveric knee after suturing in the PVA meniscus.

SIGNIFICANCE/CLINICAL RELEVANCE: Biomimetic PVA-hydrogels can be manufactured to control modulus and ansitropiy and may be a provide a potential novel solution for functional partial meniscectomy replacement.

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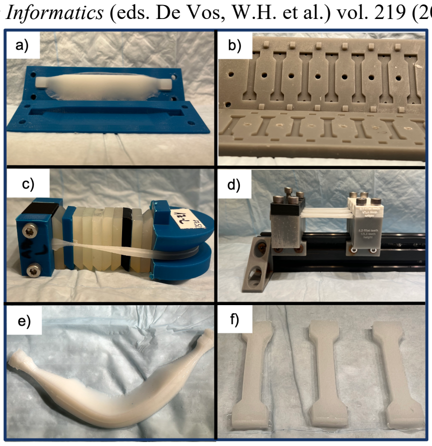

Figure 1: Manufacturing process for meniscal and dogbone samples. a) Meniscal and b) dogbone samples are manufactured in 3D printed mold. Both sample types then undergo three freeze/thaw cycles before stretching the b) meniscal samples to 200% strain and e) dogbone samples 100, 150, 200, or 250% strain. Finished c) Meniscal and f) dogbone samples.

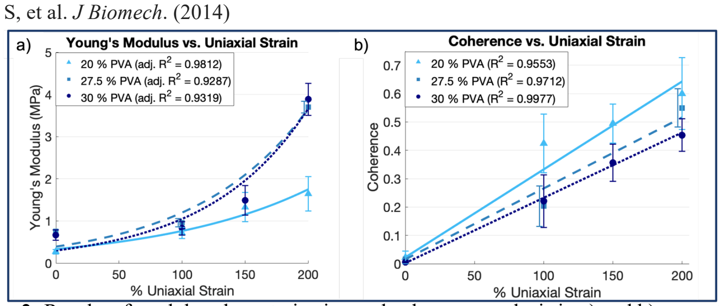

Figure 2: Results of modulus characterization and coherence analysis in a) and b) respectively.

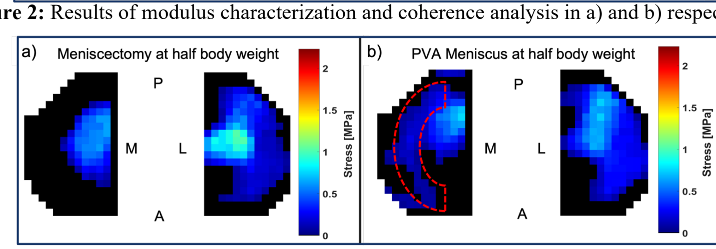

Figure 3: Tekscan sensor readings knee in AMTI VIVO simulator at half body weight for 0° flexion for a) meniscectomized knee and b) 27.5% PVA 200% Strain meniscus (approximate placement in red). Peak stress in the medial and lateral meniscus was a) 0.66 and 1.08 and b) 0.76 and 0.74 MPa.