Preliminary *in vitro* Investigations of a Cervical Disc Replacement using a Synthetic Hydrogel Contained within Woven Bicomponent Polyester Fabric

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Statement of Purpose: Approximately 175,000 anterior cervical spine surgeries are performed each year to correct disc disease.[1] Currently, the gold standard to treat cervical degenerative disc disease is anterior cervical discectomy and fusion (ACDF). This procedure, although deemed successful, has been criticized for accelerated adjacent disc degeneration from increased adjacent segment motions.[2] Recently cervical artificial intervertebral discs (AID) have been approved to market by the Food and Drug Administration (FDA). The objective of this study was to determine if a synthetic polyester annulus that contains an investigational nucleus pulposus replacement biomaterial can provide functional support as a cervical disc replacement. This hypothesis was investigated by materials characterization, prototype development, and prototype characterization.

Methods: A nucleus containment prototype was constructed using a woven bicomponent fusible polyester fabric surrounding a dissolvable core. The fabric and core were placed in a teflon mold and heat-set at 205°C for 15 mins. This gives the prototype a specific contour for the disc space. It is hypothesized that the fusing of the woven fabric during the heat-set will assist in containment of the nucleus replacement material and mechanical function of the disc replacement. The prototype was stitched around edges to secure the layers of fabric, and the core was dissolved to produce a hollow cavity. This cavity is then injected with a proprietary nucleus replacement hydrogel (Spine Wave, Shelton, CT). Figure 1 shows an image of the prototype. Characterizations performed include tensile strength testing, pore area determination, cytotoxicity studies, functional prototype compression testing, and cadaveric fitting.

Figure 1: Image of the final assembled nucleus containment prototype. Width between seams is 13 mm and length between seams is 17 mm.

Results: Fabrics were found to have an ultimate tensile strength in a range of 498-573 MPa. Also, tensile loading of the fabrics showed that the heat set treatment of the fabric was found to increase the total work until failure of the fabric by roughly 200%. After the heat-set treatment the pore area decreased by 80-85% to an average pore area of 762 μm^2. All prototype materials were shown to have good preliminary biocompatibility and confirmed acceptable early cell growth with this material and manufacturing procedure (Figure 2). Compression testing of the nucleus containment prototypes ranged between 130.8-507.9 N which is in the reported limits of the normal daily loads of the cervical spine.[3] However, eight of nine prototypes failed by hydrogel expulsion at the seam.

Discussion and Conclusions: This fabric material had an increase in total work until failure (toughness) after application of the heat-set treatment which would be beneficial in the disc where cyclic loads are experienced. Currently with rigid metal spine implants, such as graft and plates seen in fusion, accelerated adjacent disc degeneration[2] has been observed. A fabric and hydrogel AID such as this prototype may have a more natural range of motion and could slow adjacent disc degeneration. There is also a concern that stiffer metal AIDs may cause osteoporotic endplates of the spine to collapse after implantation[3], which a less stiff medical textiles nucleus containment device could avoid. The fabric's reduced pore size may be very beneficial to the nucleus replacement material before and after its polymerization step for different reasons. The pores are essential for nucleus replacement hydrogel hydration but must be small enough to prevent the hydrogel from ejecting through the fabric weave during loading.

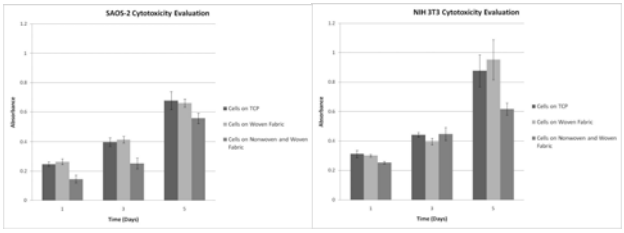

Figure 2: Cytotoxicity study for prototype materials using SaOS-2 osteosarcomas and 3T3 fibroblasts.

The cadaveric evaluation illustrates the appropriate thickness or number of layers that is feasible for implantation from a surgical standpoint. Understanding the handling characteristics during implantation for nucleus containment prototypes is useful feedback for possible prototype modifications in sizing, stiffness, and numbers of layers in future nucleus containment prototypes. It was observed through compression testing that the prototypes did handle compressive loads observed during daily living in the cervical spine. Typical compression loading in day to day living in the cervical spine ranges from 70-150 N [3]. However, the seam was inappropriately designed for this initial prototype and steps have been taken to reinforce the seam. Further bench top functional testing of future prototype designs are necessary and planned for complete biomechanical characterization of the nucleus containment prototypes.

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References:

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