

Natural Scaffold Fabrication as Alternative to Surgical Mesh for Stress Urinary Incontinence

Rebecca J. Thomson, Connor Basham, Jonathan Shaw, Katherine R. Hixon, Douglas W. Van Citters

Introduction: Over 25% of adult women experience pelvic floor disorders, including stress urinary incontinence (SUI). The most common surgical intervention for SUI is implantation of a mid-urethral sling composed of polypropylene (PP) mesh. Although highly effective for most patients, PP mesh carries a risk of erosion and exposure due to its host tissue-mesh incompatibility and friction in 3-7% of patients. Mesh erosion and exposure can cause an increased risk of infection, bleeding, and chronic pain. Autologous fascia, a biocompatible material harvested from the Iliotibial band, can be used as an alternative to PP mesh; however, it requires a second procedure for harvesting, resulting in donor site morbidity and prolonged surgery time.

Objective: The objective of this study is to fabricate and characterize composite electrospun scaffolds for the use as an alternative to synthetic mesh for pelvic floor reconstructive surgery to promote fibrous healing while the construct degrades *in vivo*.

Methods: The scaffolds were fabricated using an electrospinner (Bionicia®) to create a nanofibrous scaffold out of biologic polymers. To electrospin materials, polymers are dissolved in a volatile solvent before being ejected out of a needle tip. As the solution is ejected, a high voltage is applied to polarize the liquid, and the solvent evaporates as the thin polymer fiber is drawn toward the collecting drum by electrostatic forces. For this experiment two natural polymers, silk fibroin (SF) and polyhydroxybutyrate (PHB), were combined at different weight percents (wt%) within the solvents and fractional mix: 3 and 5 wt% concentration with the ratio of PHB/SF: 100/0, 75/25, and 50/50. All scaffolds were spun at 15cm, flow rate of ~7mL/hr, positive voltage of ~7kV, and a negative voltage on the drum of -4kV. Imaging samples were cut into 1cm² sections and gold sputter coated for scanning electron microscopy (SEM). Tensile samples were cut into 4x2.5cm sections along the length of the scaffolds and tested at a rate of 10mm/min on an Instron 68SC.

Results: SEM showed a statistical difference in fiber size, especially between the 3 and 5wt% scaffolds (Figure 1). Fiber size is relevant for subsequent fibroblast attachment during *in vitro* experiments. Fibers were more aligned in the 3wt% scaffolds, while fibers in the 5wt% scaffolds were observed to be more randomly aligned. Tensile tests indicated that aligned, 3wt% fibers had the largest ultimate tensile strength (Figure 2). There was high variation within samples for 3wt% samples compared to 5wt% samples; however, the max strength was consistently higher.

Conclusion: Our results demonstrate that natural polymers can be combined and electrospun to form nanofibrous scaffolds with varying fiber diameter and alignment. The more aligned fibers had higher ultimate tensile strength, but shorter elongation at break (Figure 3). Further, the failure modes were different for differing wt%s, as evidenced by the shape of the stress-strain curve. Work-to-failure is thus a promising metric to predict interactions with the

biological system and likely *in vivo* failure modes. Next steps include *in vitro* optimization for fibroblast growth, degradation profiling, and more extensive material characterization.

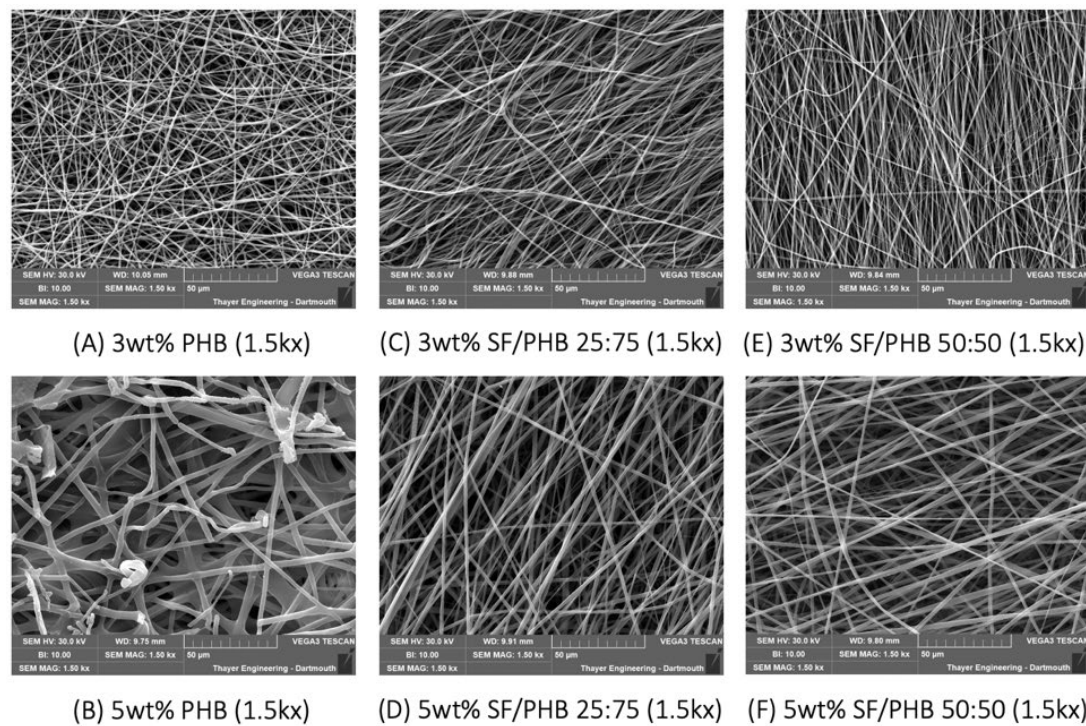


Figure 1: SEM images of all scaffolds fabricated, demonstrating fiber diameter and alignment differences between concentrations and ratios of polymers.

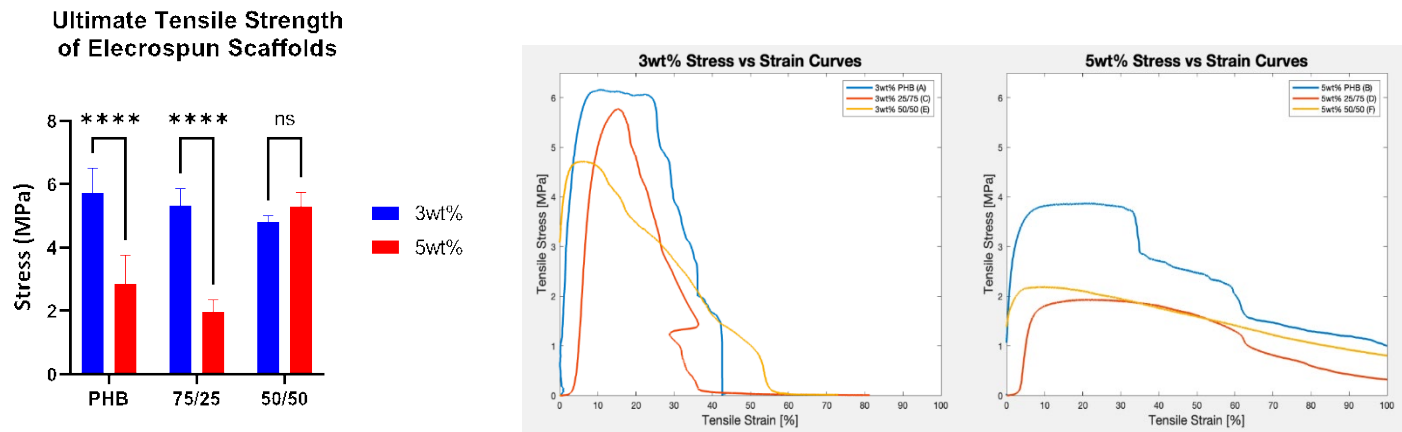


Figure 2: Ultimate tensile strength (a) and stress strain curves (b) of all electrospun scaffolds comparing 3 and 5 wt%.