Silk-Reinforced Biomaterials for Load-Bearing Fixation Devices

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Statement of Purpose: Every year more than 6.3 million bone fractures occur in the US, and more than 30% require the use of an internal fixation devices.[1] Fixation devices are materials implanted on the fractured bone to ensure proper healing, and the current standard for such a device lies in the use of metallic materials due to their superb mechanical properties.[2] However, metallic fixation devices have been known to cause stress shielding, where the surrounding bone degrades around the implant further weakening the bone. Additionally, metal ion leaching can cause an inflammatory response around the implant, leading to the need for a second surgery to remove/replace the implant. Previous efforts to make degradable fixation devices have resulted in materials with poor mechanical properties or have adverse effects when degrading *in vivo*. As such, this research aims to create a viable solution for a load bearing fixation device with the use of silk fibroin (SF) that fully degrades in the body over time.

Methods: The material made in this study is a composite that contains both long fiber reinforcement and particle reinforcement, leading to many possible combinations of materials. To test the real-world effects of each component in the composite, a design of experiments (DOE) was performed. For this study, either silk fibroin or poly-L-lactic acid (PLLA) was used as the long fiber reinforcement, hydroxyapatite (HA) was used as the particle reinforcement, and polylactic acid (PLA) or polycaprolactone (PCL) was used as the matrix polymer to bind the materials together. For the DOE, the composite materials either contained PLLA/HA/PCL or SF/HA/PLA (long fiber/HA/matrix).

To start, the fibers were dip-coated in a suspension of varying amounts of matrix and either no HA or a predetermined maximum amount of HA. Following the dip-coating, the fibers were run through a pultrusion die that flattens the fiber bundle into a ribbon shape, and were subsequently dried. The dried fibers were then dip-coated a second time, followed by another run through the pultrusion die, and dried and consolidated on a metal frame. The coated fibers were then compression molded at 165 °C to melt the PLA and bind the composite together. Following the compression molding, the samples were tested using a three-point bending fixture on an Instron at a strain rate of 20 mm/min. The modulus and strength for the samples were recorded, as well as relative toughness values, which were determined by taking the area under the three-point bending stress vs. strain curve up to the strain at which the sample lost 20% of its highest stress value. The results from the DOE indicated ample error was present in the process when HA was added to the system. As such, optimal values for the other variables were determined using results from the DOE, and the further investigation was done to determine the optimal HA content. For this, SF/HA/PLA composites were made with varying amounts of HA in the dip-coating suspension, and subsequent mechanical analysis was carried out.

Results: Results from the DOE indicate the combination of variables that provide the most desirable mechanical properties is when SF and PLA are the fiber reinforcement and matrix, respectively. As such, these were the chosen materials to move forward to optimize the HA content. Figure 1 shows the strength and modulus of the materials made using SF and PLA with varying amounts of HA in the dip-coating suspension. Figure 1 shows a flexural modulus and strength up to 13.5 GPa and 450 MPa, respectively, were able to be achieved.

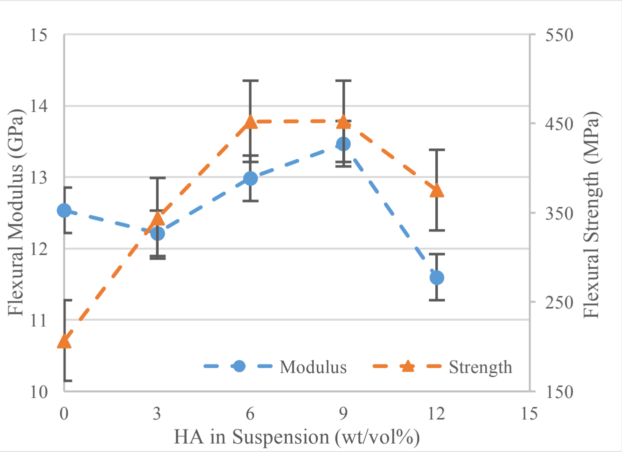

Figure 1: Flexural modulus and strength with varying amount of HA.

Conclusions: The present study shows the use of fully degradable internal fixation devices is plausible. The reported value for flexural modulus is well within the range of natural bone, while the reported strength far exceeds that of natural bone, with both values being higher than what is found literature for biodegradable, non-metallic fixation deivces.[3] In addition to the desirable mechanical properties, it has been shown in literature that the materials used in the reported composite are fully degradable in 1-2 years *in vivo*, which provides enough time for the bone fracture to heal while eliminating drawbacks of metal fixation devices and the need for a second surgery. Work will be done in the future to ensure the degradation time is appropriate for use as an internal fixation device.

References:

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