MATERIAL PROPERTY ANALYSIS AND FABRICATION OF TECOFLEX SCAFFOLDS

Joshua George, Xinzhu Gu, William Wagner
McGowan Institute of Regenerative Medicine, Department of Bioengineering, Swanson School of Engineering, University of Pittsburgh, Pittsburgh, PA, United States.

INTRODUCTION

Drug delivery coatings are a rapidly growing technology in the Medical Device Industry. The development and adoption of therapeutic coatings for medical devices has enhanced the functionality of devices and thus has improved patient outcomes. The therapeutic effect, duration of therapy and deliverability of these devices are influenced by the therapeutic agent, coating materials, and the means by which coatings are applied to the medical device. [1] Therapeutic coatings have been incorporated onto medical devices for a variety of applications, both acute and chronic.

The best known is a drug-eluting stent which provides controlled, site-specific delivery of anti-restenosis drugs. Selection of the appropriate coating materials enables a device to deliver the proper therapeutic effect. Durable polymers can allow for longer delivery times and the underlying matrix does not change over time. [1] These have a constant coating thickness due to their lack of degradation and as such can exude drugs over a long period of time.

Polyurethane (PU) elastomers are a family of copolymers consisting of hard crystalline segments between flexible amorphous segments. The combination of the two class of segments result in promoting toughness, flexibility and elastic recovery to the polymer. [2] The material properties of PUs prompted the study of these polymers for biomedical applications since the 1960s. [2]

Literature suggests that medical grade Tecoflex, a type of PU, has the potential to undergo electrospinning to create defect-free, bead-free fibers which are optimal for scaffolds to have a high tensile stress and strain capabilities. [2] This exhibits a strong need for more research to be done on different hardness grades of Tecoflex to determine future applications.

OBJECTIVE

Our purpose is to measure the thermal and mechanical properties of Tecoflex 80A, 85A, 93A, and 60D. We will then analyze the data to determine their effectiveness within a biological setting.

HYPOTHESIS/SUCCESS CRITERIA

The Tecoflex polymers should be amorphous or have a low crystallinity so that they maintain their elastic and mechanical properties. After the scaffolds are fabricated, scanning electron microscopy should reveal a continuous and homogenous structure of fibers. When mechanical testing has concluded, the analysis of the raw data should reveal that the Tecoflex scaffolds should be able to withstand a high yield stress before breaking. Future success criteria of the scaffold will also be the scaffold’s ability to allow cell proliferation while maintain its material properties.

METHODS

Medical grade Tecoflex polymers with hardness’s of 80A, 85A, 93A, and 60D were acquired from Lubrizol prior to experimenting. These different species were chosen because the varying hardness of each species could lead to different applications. Samples of each grade were weighed out to approximately 0.06 grams to fit specifications of the Differential Scanning Calorimeter, which heats and cools polymers and then measures how heat capacity changes during the temperature change to determine phase transitions. The settings for DSC included a Nitrogen atmosphere along with a starting temperature of -120 degrees Celsius which then underwent a change of 10 degrees till it reached 150 degrees, where one more set of cooling and heating occurred following the same protocol. After testing, the results were saved and the process was repeated for each Tecoflex species to provide consistency.

After analysis of the DSC for each species proved thermal properties which were biologically compatible fabrication of scaffolds then occurred. 10 ml polymer solutions of HFIP were then synthesized with a 6% weight percentage of each Tecoflex species. Each solution was allowed a day to mix thoroughly so that the composition would be homogenous.

After polymer synthesis occurred, the solution was loaded into the electrospinning machine, which uses an electrical charge to draw very fine fibers from a polymer solution, which is loaded into a syringe pump. [3] The parameters for fabrication included a ground voltage of -7 kV, a top voltage of 12 kV, a mandrel rotation speed of 200 rpm, a distance of 10 cm from the mandrel, an infusion rate of 3 ml/hr and a standard translation speed. Each scaffold underwent around 1.5 hours of electrospinning until the process was interrupted and scaffolds were cut from the mandrel.

Scaffolds were then stored to dry for several days. After drying scaffolds were then cut into shapes called “dogbones” so that they could fit the parameters required from the tensile tester. Each Tecoflex species had 3 dogbones created to ensure consistency. The dimensions of each scaffold were recorded before placed in the tester. The tester then stretched the dogbone from each end while recording the load being applied to it while also recording the elongation of the dogbone. The tester stops elongating the scaffold after it detects a break in the dogbone, where it automatically marks a yield stress in the data records. After the data records were recorded, stress-strain curves were created using the raw data.

Future application includes culturing cells onto each scaffold species. The cultures will be maintained with nutrient media for approximately 1-2 weeks. The scaffolds will then be observed to see if significant cell proliferation has occurred.
RESULTS

The figure below depicts how the average Tecoflex samples looked like on the second round of heating. There are no peaks and the change in the heat flow is relatively linear. There is no phase transition within this range so Tecoflex can be used within temperature ranges in the body.

![Figure 1: No rapid changes indicate no phase transitions in Tecoflex in this temperature range.](image)

Each Tecoflex species was deemed to have thermal compatibility with the body and 10 milliliter HFIP solutions were formed with a 6% Tecoflex composition. These solutions then underwent electrospinning to form scaffolds. After fabrication of the scaffolds, scanning electron microscopy took place. The SEM showed that the scaffolds did indeed have a smooth texture and homogenous concentration of Tecoflex throughout the scaffold. These scaffolds then underwent mechanical testing in a tensile tester. The figure below depicts the superposition of each scaffold for the stress strain curves of n=3.

![Figure 2: Stress Strain curves (n=3) for each Tecoflex Species](image)

The stress strain curves revealed that Tecoflex 80A exhibited a very high yield stress and strain, Tecoflex 85A exhibited a high yield stress and a moderate yield strain, Tecoflex 93A exhibited a moderate yield stress and strain, Tecoflex 60D exhibited a high yield stress and a moderate yield strain.

DISCUSSION

The DSC data points for all of our Tecoflex polymers revealed that during the second round of heating, the heat capacity change of the polymers was relatively linear with no sharp spikes or changes. This tells us that there are no phase transitions because a drastic change in the heat capacity would have been evident. It also told us that the polymer maintained its amorphous characteristics throughout. This positively reinforced the assumption that the polymers do have the thermal capability to survive in a biological temperature range.

Afterwards we used literature to determine an appropriate solvent for our Tecoflex scaffolds and an overwhelming amount of sources pointed towards Hexafluoroisopropanol. After 10 ml HFIP polymer solutions with 6% Tecoflex were formed, fabrication of scaffolds occurred. The scaffolds underwent SEM and were revealed to have a very smooth and homogenous structure which is indicative of a stable scaffold.

The mechanical testing of our scaffolds revealed that they were mechanically strong and could undergo relatively high strains, in 80A’s case, the strain approached 800%. This is telling of a scaffold which could survive in the rigorous conditions of the body and maintain its mechanical properties after high tensile loads.

Cell culturing onto the scaffolds will occur in the immediate future and hopefully the results will show that the mechanical properties of the Tecoflex scaffolds allow for cell proliferation to occur to a high degree. If this is the case then all of the success criteria for this experiment will have been met and Tecoflex will have been deemed as thermally, mechanically, and biologically compatible with surviving in biological conditions. Further analysis of Tecoflex will reveal drug release capabilities so that Tecoflex scaffolds can reach clinical applications, such as polymer coating of medical devices.

ACKNOWLEDGMENTS

I would like to thank Dr. Xinzhu Gu for her guidance, along with Dr. William Wagner and the

REFERENCES