STATIC AND DYNAMIC MECHANICAL TESTING OF A POLYMER WITH POTENTIAL USE AS HEART VALVE MATERIAL

Andrés F. Aguirre (1), Mariana Oliva (1),
Richard T. Schoephoerster (1), Vladimir A. Kasyanov (2)

(1) Cardiovascular Engineering Center
Biomedical Engineering Institute
Florida International University
Miami, Florida

(2) Biomedical Engineering Laboratory
Riga Stradins University
Riga, Latvia

INTRODUCTION

Since the 1960's heart valve prostheses have been efficiently used in helping patients with heart disease improve their overall quality of life. Not only have heart valve prostheses extended life, but may have also lessened the symptoms due to valvular heart disease. Nevertheless, as reported by NIH's Working Group on Heart Valves, 10-year mortality rates range from 30-55%, indicating that advancements in valve design are still necessary. Moreover, efforts need to be directed toward improving morbidity and mortality outcomes, and should focus on minimizing structural degradation and thrombotic potential [1].

Currently, there are three kinds of heart valve prostheses: mechanical, bioprosthetic, and flexible membrane trileaflet made from synthetic resinous materials. Mechanical valves generally show excellent durability, but also require most patients to receive permanent anticoagulant therapy due to thrombotic reactions [2]. Bioprosthetic valves exhibit advantages in hemodynamic properties, producing the central flow characteristic of natural valves. However, they also show leaflet stiffening due to mineralization, which results in short fatigue life (usually less than 10 years) [3]. Flexible membrane trileaflet valves are fabricated from biochemically inert synthetic materials, with polyurethane the typical material of choice. These valves present natural hemodynamics while also having the potential for long-term durability. Unfortunately, they have not been successful to date due to long-term material degradation. Because the leaflet material is isotropic, these valves show stress concentrations in the leaflets. This, along with the thickness of the leaflet material, is an important factor limiting the long-term function of polymer valve prostheses [4-6].

It seems reasonable to assume that synthetic flexible membrane trileaflet valves might be improved with a suitable material choice. A new material for implant applications, polystyrene-polyisobutylene-polystyrene (SIBS) is a certain proprietary polymer that has been found to be less likely to degrade in vivo than polyurethane [7]. In order to assure that SIBS possesses the appropriate material properties for valve leaflets, a SIBS/polypropylene composite was compared to an already implant-approved polyurethane (IAP).

MATERIALS AND METHODS

A new material for implant applications, polystyrene-polyisobutylene-polystyrene (SIBS) embedded with polypropylene fibers was tested and compared with an implant-approved polyurethane (IAP).

Materials tested included: SIBS, an IAP, 10-0 monofilament (0.025 mm diameter) polypropylene threads (PPTh) (Prolene, Ethicon), and a composite of SIBS and PPTh. The composite specimens were fabricated with 3, 6, or 12 evenly spaced threads aligned with the long axis of the specimen at mid-thickness. Dog-bone shaped specimens were prepared from each material following ASTM standard D 638 – 89, Type M-III. All specimens had a 0.3 mm thickness. The PPTh were tested individually.

The materials went through two phases of testing aimed at exploring their static and dynamic mechanical properties. Outcome measures for static tests included: Young's Modulus (E), ultimate tensile stress (UTS), ultimate strain (US), and Poisson's ratio. Tensile properties of all the materials were performed according to ASTM standards D 638M – 89 (plastics), D 882 – 88 (thin plastic sheets), D 3039 (composites), and E 132-97 (Poisson's ratio). The fibre/matrix interface property determination was performed following the methods described by Marshall and Price [8].

Two types of fatigue life analyses were performed: a standard tension-tension fatigue test to create S/N (stress vs. number of cycles) data, and a unique bending fatigue test to assess long-term bending effects on material properties. The purpose of the dynamic test was to provide fatigue properties of the material under tension and bending conditions. The tension fatigue properties were assessed according to ASTM standard D 3479M – 96. The test was load controlled; that is, the specimen was cycled between two tensile loads. The load frequency was 100 Hz. At this frequency, heating of the specimen could occur. Therefore, the temperature of the specimens was periodically monitored to insure it did not exceed 100 °C. Specimens were tested in air. Cycling was performed for each polymer until failure. Since there could be significant fatigue damage without actual fracture, failure was defined as a strain of 0.5. After 350 million cycles without failure the test was stopped and the material was considered with infinite life for that stress.

The bending fatigue test produced physiological curvatures on the specimen. After cycling, each specimen was tested according to the Static Test Protocols listed above. A change in the material properties indicated impairment due to fatigue. Characterization of the viscoelastic properties was also performed on all the materials.

Tensile and tension fatigue tests were performed using the Electroforce™ (ELF) materials tester (Enduratec Systems Corp., Minnetonka, MN). Bending tests were performed using the MTS 858 Mini Bionix® system (MTS Systems Corp., Eden Prairie, MN).

RESULTS

Results of the tensile tests of the materials tested are shown in Figure 1 and Table 1. The ultimate strain for SIBS and the IAP was above 0.5 mm/mm, while for the composite it was around 0.3 mm/mm in each case.

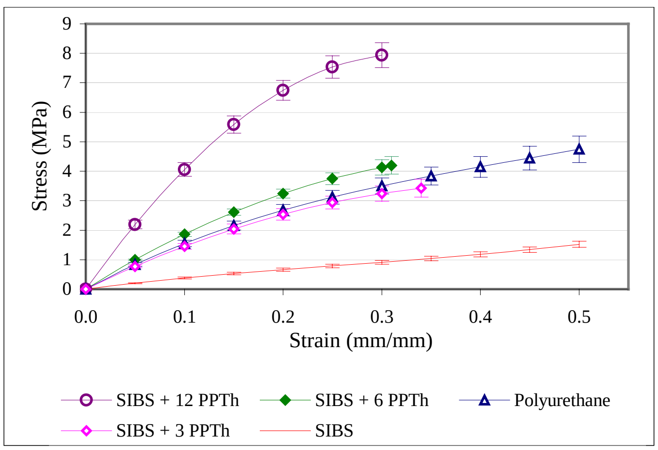

Figure 1. Tensile test

Material	E (MPa)	US (mm/mm)	UTS (MPa)	N
SIBS	3.88 ± 0.40	> 0.5	1.43 ± 0.15	22
PPTh	6,633 ± 492	0.43 ± 0.05	1,543 ± 124	14
SIBS+3 PPTh	14.93 ± 2.67	0.34 ± 0.05	3.40 ± 0.55	8
Polyurethane	18.53 ± 1.23	> 0.5	5.44 ± 0.41	13
SIBS+12 PPTh	45.44 ± 2.85	0.30 ± 0.03	7.92 ± 0.87	10

Table 1. Tensile test

Figure 2 shows the results for the tension-tension fatigue test. The IAP shows an endurance limit above 1.0 MPa after being fatigued for 350 million cycles without resulting in failure. After being fatigued for 130 million cycles SIBS shows an endurance limit of 0.3 MPa. Subsequently, SIBS was reinforced with 3 PPTh its endurance limit increased to 0.5 MPa. Twelve PPTh without SIBS (but assuming a cross-sectional area that included SIBS) were fatigued showing an endurance limit above 2.0 MPa. After 350 million cycles there was no failure. SIBS embedded with 12 PPTh showed an even higher endurance limit of 2.5 MPa. After being fatigued for 350 million cycles there was no failure. None of the specimens that reached 350 million cycles failed, hence infinite life was assumed for this stress.

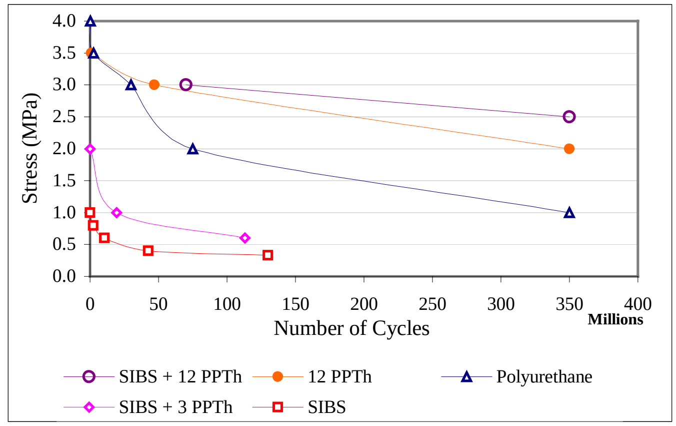

Figure 2. Tension-Tension Fatigue Test

CONCLUSION

Preliminary results show that the reinforcement of SIBS with PPTh improves both its static and dynamic properties as compared to the IAP. Hence, this composite has the potential to be a better material for synthetic flexible membrane trileaflet heart valves.

REFERENCES

1. Schoephoerster, R., Gallocher, S., Pinchuk, L., and Kasyanov, V., 2001, "A Novel Trileaflet Synthetic Heart Valve," ASME 2001, Advances in Bioengineering.
2. Schoephoerster, R., and Chandran, K., 1991, "Velocity and Turbulence Measurements Past Mitral Valve Prostheses in a Model Left Ventricle," J. Biomechanics, Vol. 24, pp.549-562.
3. Chandran, K.B., Fatemi, R., Schoephoerster, R., Wurzel, D., Hanse, G., Pantalos, G., Yu, L.S., and Kolff, W.J., 1989, "In vitro Comparison of Velocity Profiles and Turbulent Shear Distal to Polyurethane Trileaflet and Pericardial Prosthetic Valves," Artif. Organ, Vol. 13, pp. 148-154.
4. Imammura, E., and Kaye, M. M., 1977, "Function of Expanded Polytetraflouroethylene Laminated Trileaflet Valves in Animals," Mayo Clinic. Proc., Vol. 52, pp. 770-775.
5. Reul, H., 1983, "In-vitro evaluation of artificial Herat Valves," Adv. Cardiol. Phys., Vol. 5 (Part IV), pp. 16-30.
6. Bernacca, G.M., O'Connor, B., Williams, D.F., and Wheatley, D.J., 2002, "Hydrodynamic Function of Polyurethane Prosthetic Heart Valves: Influences of Young's Modulus and Leaflet Thickness," Biomaterials, Vol. 23, pp 45-50.
7. L. Pinchuk, L., Khan I.J., Martin, J.B., and Wilson, G.J., 1999, "Polyisobutylene-based thermoplastic elastomers for ultra long-term implant applications," Proceedings of the Society of Biomaterials.
8. Marshall, P., and Price J., 1991, "Fibre/matrix Interface Property Determination," Composites, Vol. 22, pp 53-57.