Injectable Polyurethane for Vertebroplasty and Kyphoplasty

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Introduction: Vertebral hemangioma and metastases, as well as osteoporotic vertebral fractures are painful conditions that can inhibit patient mobility in performing normal daily activities.[1] Vertebroplasty and kyphoplasty are surgical procedures that are used to treat individuals who suffer from vertebral compression fractures. Both procedures involve the injection of bone cement into the compressed vertebral body.[2] The principal material used for these two procedures is poly (methyl methacrylate). However, its fatigue, mechanical, and thermal properties are not ideal for mechanical stabilization and associated pain relief.[5] Polyurethane (PU) is being investigated as a potential material for this application, due to its biocompatibility and its ability to be modified to exhibit desired mechanical properties by varying the hard to soft segment ratios.[3,4] In this study we have systematically manipulated the chemistry of PU with the goal of controlling material modulus while keeping viscosity in a range that would enable injectability of the material to restore mechanical strength to fractured or compressed vertebrae. The effect of varying PU hard and soft segment ratios on modulus, crystallization temperature and melting temperature were investigated. The incorporation of a catalyst was also examined for its effect on PU injectability.

Materials and Methods: PU formulations were synthesized by solvent free reactions using the prepolymer method.[4] PU consists of a hard segment and a soft segment: the hard segment is formed by 4,4'-methylene diphenyl diisocyanate (MDI) , while the soft segment consists of poly(tetramethylene oxide) (PTMO) and poly (hexyl, ethyl) carbonate diol (PHEC). Cis-2-butene-diol (C2BD) acts as the chain extender, and stannous oxide (SO) as the catalyst. Samples were prepared by altering the soft segment ratio while maintaining the other reagents constant. The PTMO to PHEC ratios formed include: no PHEC, 5:1, and 2:1. Samples were synthesized in a glove box under nitrogen atmosphere at a temperature of 60°C in order to control porosity. To ensure homogeneity, samples were manually stirred. Uniaxial compression tests were performed in an Instron at a strain rate of 1mm/min strain and a total displacement of 5mm. The samples had an average height of 37.2±2.6mm and a diameter of 26.0mm.

Results and Discussion: Pilot experiments have shown that even small amounts of the catalyst (SO) resulted in formulations which set up within minutes. This did not allow time for injection, thus the compositions reported did not include SO. In the absence of catalyst, the resulting setup times were no less than 30 minutes. The modulus of each sample was taken to be the linear elastic region of the stress-strain curve. When no PHEC was used, the sample had a modulus of 20MPa. At a ratio of PTMO:PHEC ratio of 5:1, the modulus is found to be 8MPa, and with a 2:1 ratio, 4MPa. Thus, a decrease in modulus is observed as the amount of PHEC is increased and PTMO is decreased.

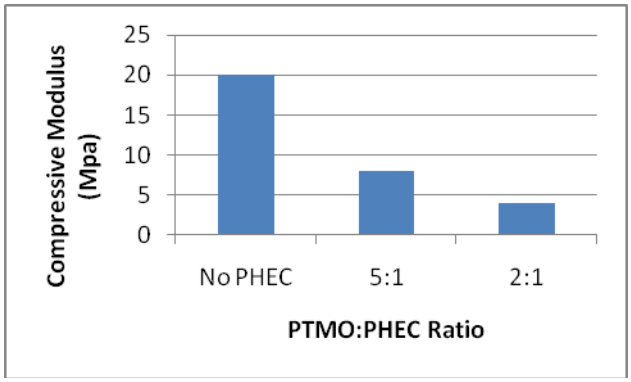

Fig 1: Compressive Modulus vs Soft Segment Ratio

DSC results of a previous formulation (molar ratio of MDI:PTMO:PHEC of 8:1:1) showed a hard segment crystallization temperature around 137°C. The hard segment melting occurred at 175°C and soft segment melting at 23°C. FTIR data showed no peaks at 2250 cm^{-1}, which is indicative of the nitrile bond in the isocyanate group, demonstrating that all of the MDI was reacted in the formulations.

Conclusion: This study observes how different formulations of PU affect the material properties. The highest modulus resulted from eliminating the PHEC completely and only using PTMO as the soft segment. As the amount of PHEC was increased, it resulted in a lower compressive modulus for the sample. In future studies the hard to soft segment ratios will be further varied to optimize the mechanical properties of the system, while maintaining a viscosity that allows injection through the 18 gage needle required for this application.

References: 1. Gailbert P, Chirurgie, 116, 326, 1990; 2. Armsen N., Euro. Jour. of Trauma, 5, 433, 2005; 3. Guelcher S, Tissue Eng., 12, 1247, 2006; 4. Rogers M, Synthetic Methods in Step Growth Polymers, Wiley, 2003: 197-2585. 5. Belkoff S., Spine, 28, 1555, 2003.