Optimizing Silicone Content in Thermoplastic Silicone-Urethanes Used in Chronically-Implanted Medical Devices

R. Ward, Y. Tian, K. White, K. McCrea, E. Christenson, J. Anderson, M. Ebert, and K. Stokes

1The Polymer Technology Group, Berkeley, CA, 94710 2Medtronic, Inc., Minneapolis, MN, USA
3Institute of Pathology & Dept. of Macromolecular Sci., Case Western Reserve Univ., Cleveland, OH, 44106

INTRODUCTION: We have developed several thermoplastic polyurethanes that combine two different soft segments, and a hard segment, and which also have surface modifying endgroups. Two useful combinations are: silicone + polyalkylene carbonate and silicone + polyalkyleneoxide (i.e. polyether). Silicone content can be varied during synthesis from <1 to >60 wt % at 85A Shore hardness. When compatibility of the two soft segments is indicated by DSC and optical clarity, bulk properties like permeability and tensile strength vary monotonically with the weighted average concentrations of the soft segments.

RESULTS: As shown in Figure 2, soft segment reduction in the region probed by IR-ATR (10^2-10^5 monolayers) varied linearly with silicone content from ca. 33% for silicone-free Bionate PCU to 13% for CarboSil 20 80A TSPU. Extrapolation of this plot to zero soft segment loss gives a silicone content of about 30 wt %.

CONCLUSIONS: Considering the biostability and tensile property curves, and that strain levels in well-designed devices are << 400%, we conclude that a nominal 85A silicone-polycarbonate urethane will perform optimally at ≤ 30% total silicone by weight. Large, load-bearing components used in orthopedic applications, for example, require lower silicone levels for maximum toughness. In components with greater surface-to-volume, like lead insulation, somewhat higher silicone levels may be indicated. Under the same test conditions harder homologues are expected to require less silicone, based on the well-established increase in biostability with hardness in silicone-free TPU's. Future testing will include harder grades of both silicone-polycarbonate-urethanes and silicone-polyether-urethanes.

REFERENCES:
2. US patent 5,589,563