Stephen A. Boppart, MD, PhD, Philip B. Johnson, MD

Foley Catheter Tensile Strength Testing after Failure in a Hospitalized Patient

To the Editor:

We wish to share a case report of our recent clinically-relevant biomedical engineering experience and biomaterials analysis to illustrate the importance of understanding the impact that biomaterials have on patients. A 75-year-old male patient with a 100% silicone-rubber Foley catheter was 12 hours status-post right total knee replacement. As sedation lessened, the patient became increasingly agitated and delirious. The patient proceeded to forcibly remove his Foley catheter without deflating the balloon at the tip. The catheter fractured midway along its length. Radiographic films showed the distal portion of the catheter retained within the distal urethra. Cystoscopy was performed to remove the remaining portion of the catheter. No further complications were noted during recovery.

Based on this experience, we sought to test the mechanical tensile strength of a silicone and a latex rubber Foley catheter. A new 16 French 100% silicone rubber and a new 100% latex rubber Foley catheter from the same manufacturer were obtained and mounted separately in a tensile strength testing apparatus (Instron Corp., Model 5567) as shown in Figure 1. Catheters were clamped to expose a 5 cm length along the mid-region of the catheter. Strain (stretch) was applied at a rate of 8.5 mm/s to the catheter as the apparatus recorded the stress. Strain was applied until either the apparatus reached its maximum length limit or catheter failure occurred.

Figure 2 plots the stress versus strain relationship for the silicone and latex catheters. Despite an elongation exceeding 5000% (50 times initial length), the latex catheter did not fail. The silicone catheter failed after an elongation of approximately 1000% (10 times initial length). The initial tensile moduli (initial slope of curves) are comparable; however, with increasing strain, the silicone catheter exhibited a higher tensile modulus (greater stiffness) compared to the latex catheter. We note that while only one catheter of each type was tested for this report, we expect that the mechanical properties shown to be representative of these catheter types, barring any material defects that may have been present in these tested catheters. A more rigorous investigation with larger numbers of catheters would be necessary to establish if there are statistically-significant differences between these catheter types.

The use of silicone-based rubbers in Foley catheters and other medical and surgical supplies has been implemented in healthcare facilities to reduce the likelihood of patient and healthcare worker allergic sensitization and reaction from contact with latex rubber. The mechanical properties of silicone rubber, however, differ significantly from those of latex rubber. A previous report documented failures and retention of silicone rubber surgical drains and determined that the tensile strength of silicone drain catheters was significantly less than that of polyvinyl chloride catheters. The tensile strength of Foley catheters has also been found to decrease after aging and use. In this case report and in our mechanical testing, we found that the silicone Foley catheter was unable to accommodate as great of strain as the latex catheter. While our tensile strength testing may not have emulated the exact magnitude and rate of the applied forces exerted on the catheter by this patient, our data suggests that the different mechanical properties of the silicone catheter may have contributed to the catheter failure.[1-3]

We thank Abby Morgan and Dr. Russell Jamison of the Department of Materials Science and Engineering, UIUC, for their assistance with operating the tensile strength testing apparatus.

References:

1. McKenzie, J.M., C.M. Flahiff, and C.L. Nelson Retention and strength of silicone-rubber catheters A report of five cases of retention and analysis of catheter strength. J. Bone Joint Surg Am. 75:1505-1507, 1993.

2. Joseph R., P. Ramesh, and R. Sivakumar. Tensile set behavior of Foley catheter balloons. J Biomed. Mater. Res. 48:27-31, 1999.

3. Ramesh P., R. Joseph, and M.C. Sunny. A comparative evaluation of coefficient of friction and mechanical properties of commercially available Foley catheters. J. Biomater. Appl. 15:344-350, 2001.

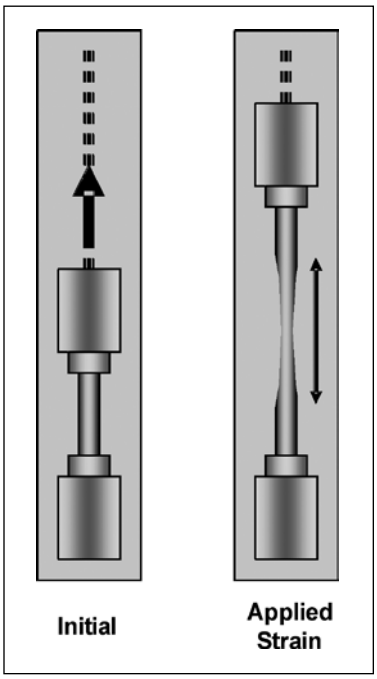

Figure 1 *Tensile strength testing apparatus. A catheter was clamped within the apparatus and a calibrated strain (stretch) was applied.*

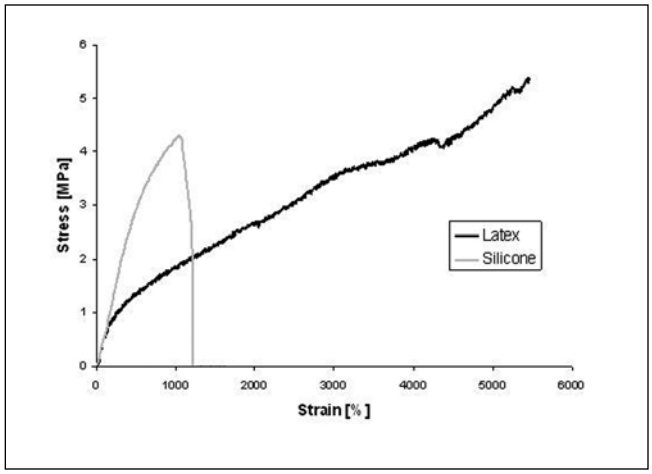

Figure 2 *Tensile strength testing data of latex and silicone Foley catheters.*

Stephen A. Boppart, MD, PhD, Associate Professor of Electrical Engineering, Bioengineering, and Medicine University of Illinois college of Medicine; Urbana, IL.

Philip B. Johnson, MD, Clinical Assistant Professor for the Department of Internal Medicine, University of Illinois College of Medicine; Urbana, IL.