Catheter Tensile Testing Project

Trine University
Biomedical Engineering

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Introduction:

Catheters are imperative for patient sustainability and treatment. Cook Medical manufactures a variety of catheters used for specific applications ranging from drug delivery to stent placement. There is a high importance for the use of catheters; however, there is a lack of guidelines regarding tensile testing to ensure they don't fail during use. Cook Medical has provided the senior design team with the resources to improve on the prevalent issue for the catheter industry around the country and ultimately reduce the risk to the patient. The goal of the Cook Medical Catheter Project is to develop a methodology procedure for baseline catheters and a testing apparatus to accurately test tensile and elongation properties of balloon catheters.

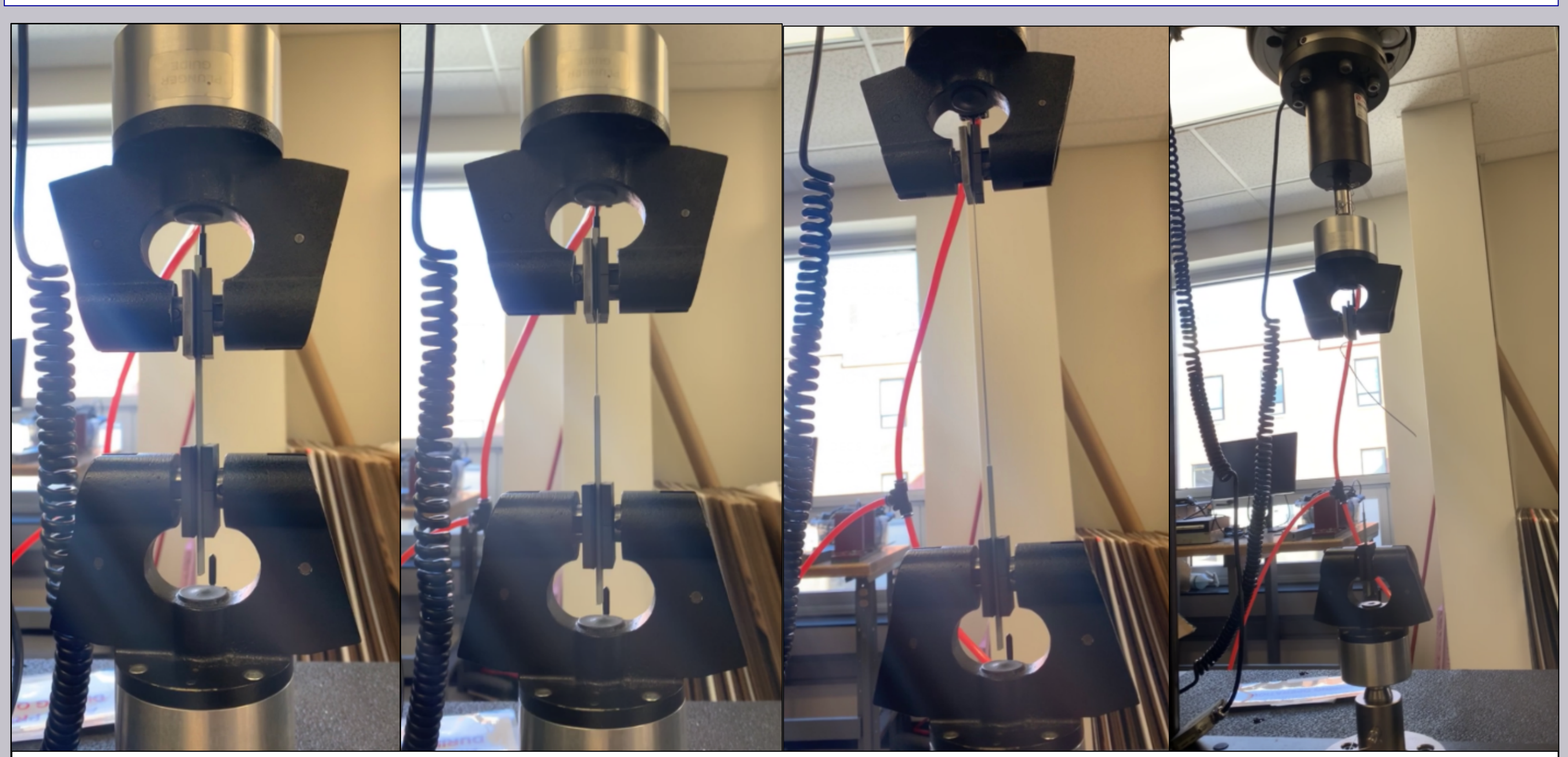

Figure 1- Tensile testing of catheter sample from start to breakage.

Methodology Procedure Testing

To determine the most efficient and accurate way to test catheters at Cook Polymer Technology (CPT), methodology testing was conducted on three different catheter sizes. *Figure 1* shows the process of a catheter being tensile tested. The following addresses the procedure:

- Pneumatic side-action grips were used during all tests.
- Each catheter was tested 30 times for each method, unless the catheter failed to break within the first five samples.
- To minimize grip slippage, pressure was consistently set at 90 psi.
- Each method is within the requirements in provided ISO standards.
- **The following methods were tested (Grip Distance / Pull Rate):**
  - **Method 1 – 20mm / 400mm/min**
  - **Method 2 – 25mm / 500mm/min**
  - **Method 3 – 28mm / 560mm/min**
  - **Method 4 – 30mm / 600mm/min**
  - **Method 5 – 33mm / 660mm/min**
  - **Method 6 – 35mm / 700mm/min**
  - **Method 7 – 38mm / 760mm/min**
- Load at break, max load at break, time at break, and standard deviation were collected through BlueHill Software.

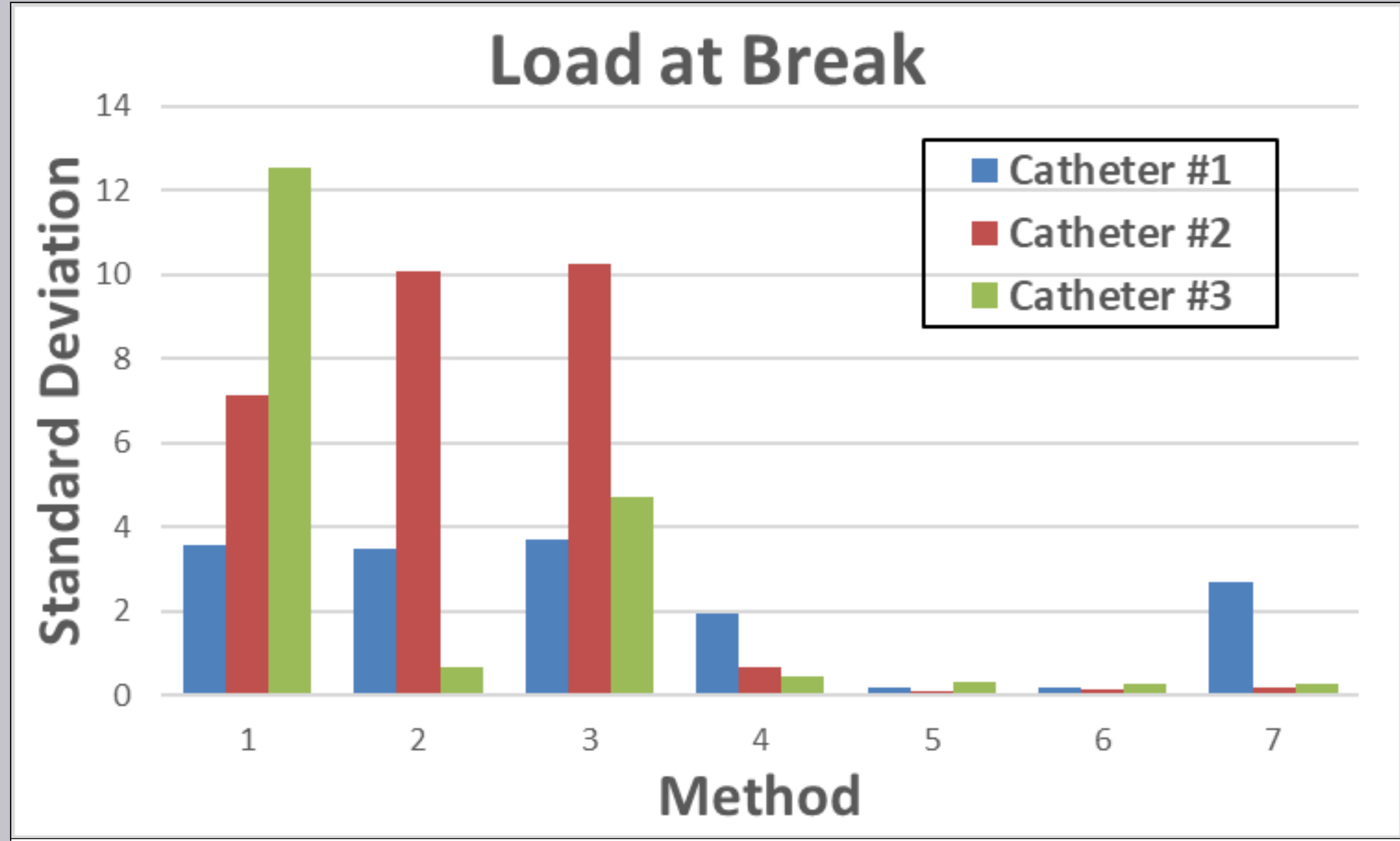

Table 1-Standard Deviation of Load at Break for Methods 1-7.

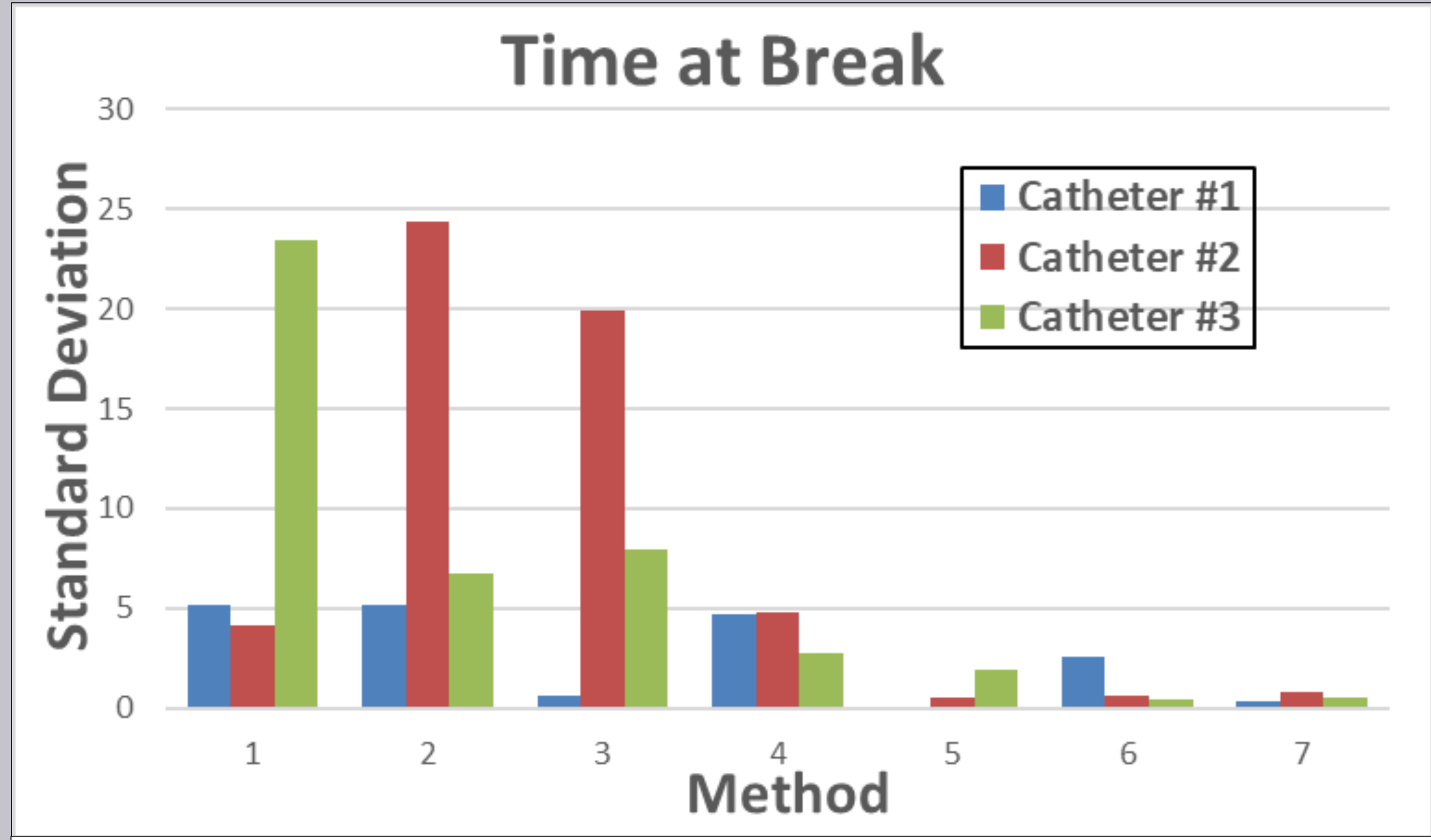

Table 2- Standard Deviation of Time at Break for Methods 1-7.

Results and Discussion:

The data collected was analyzed to determine the most efficient and accurate methodology to tensile test medical catheters. *Table 1* depicts the standard deviations of the load at break for each catheter type at each method. *Table 2* depicts the standard deviations of the time at break for each catheter type at each method. **Method 6 was determined to be the best method to tensile test each catheter type.** The standard deviations were low across all three types for both load at break and time at break. Lower standard deviations indicated consistency within the testing. Using the same method for each catheter type will save CPT set-up time and ultimately result in efficient testing. Additionally, all 30 samples broke during each test and the time of breakage was near the desired value of 30 seconds (determined from an ASTM standard for plastic tensile testing).

Testing Apparatus:

The pneumatic side-action grips result in slippage when testing the balloon catheters. To resolve the problem, many grip fixtures were considered for purchase. Testing on new grip fixtures was outsourced and the results were analyzed before purchase. While multiple grips were tested, each failed to accurately test the balloon catheters. Each grip apparatus that didn't meet the requirements provides beneficial information in moving forward. The grip fixture in *Figure 2* is a promising solution as a similar fixture nearly accomplished effective balloon testing. Unfortunately, testing wasn't completed as the grip company and Instron became inaccessible.

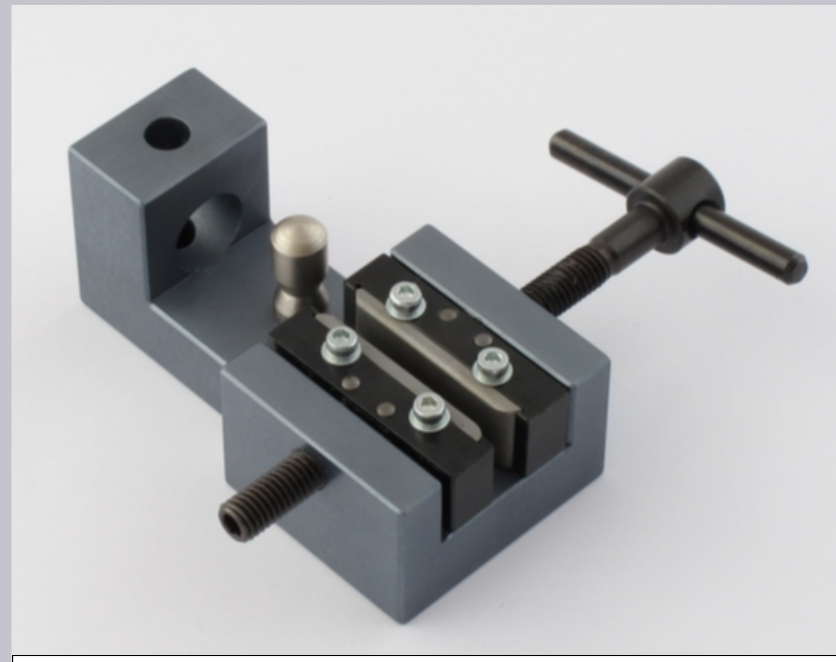

Figure 2- A promising testing apparatus for balloon catheters.

Figure 3- The elongation measurement device in casing.

Elongation Measurement Device:

The device measures the distance from the cross head to the lower jaw holding the sample, *Figure 3*. To measure elongation of the samples, an Arduino was programmed with an Ultrasonic sensor which provides non-contact measurement functions by detecting reflected ultrasonic waves up to 4 meters. The distance measured is then outputted via the serial output in Excel from the Arduino. To verify the device, a fixture was constructed that had measurement points up to 42 inches. The device was then used to collect measurement data to measure the accuracy and precision of this device. The maximum variation of the device was .29 inches. If the device could take multiple readings and average the data the variation is less; however, due to the intended applications of measuring a moving distance, the average would lead to less precise recordings.

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