Compressive Testing of an Inferior Vena Cava Filter

The Challenge:

Measure Force of an Inferior Vena Cava Filter in Response to an Applied Displacement

Background

The vena cava filter is a small medical device implanted in the vena cava to protect against pulmonary emboli. The shape of the filter is designed to catch the embolus in the bloodstream, letting it break down by means of clot lysis before it potentially blocks the flow to the pulmonary artery. When an embolus enters the filter, it is directed to the center where is it ensnared until it deteriorates to a safe size.

Compressive testing of the inferior vena cava is important due to the inherent radiant pulsatile motion of the vasculature in the body. A device intended for use in the human vascular system must withstand repetitive compression with minimal loss of structural integrity. The goal is to compress the stent to 5% and 20% compression and determine a relationship between displacement and the resulting load on the device.

Meeting the Challenge

Bose has developed the ElectroForce® 3200 Series III test instrument for dynamic materials testing in both axial and torsional directions. A Series III system was used, and it can measure loads up

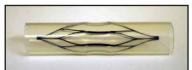


Figure 1 - Inferior Vena Cava Filter Placed within the Silicone Tubing for Testing

to 450 N and displacements of +/- 6.5 mm, or 13 mm total stroke. For the sake of this test, a 22.2 N load cell was used in place of the typical 225 N load cell for more representative load measurements. The system can accommodate tensile and compressive testing of many materials including vascular stents and filters. By placing the vena cava filter within silicone tubing (Figure 1), Bose was able to replicate the compressive motion of the filter within the vasculature of a human. Using the block waveform feature of WinTest[®] software, a waveform was set up to apply 300 cycles of 5% compression of the filter followed immediately by 50 cycles of 20% compression.

Experimental Setup and Tests

The 3200 Series III test instrument was selected to meet the needs of the filter size and properties. Since the system utilizes the Bose® High Accuracy Displacement Sensor (HADS) and is compatible with a 22 N load cell, it provides accurate displacement and load values even at very small loads. In addition to the precision of the system, it also comes equipped with the WinTest software package and the included block waveform capabilities.

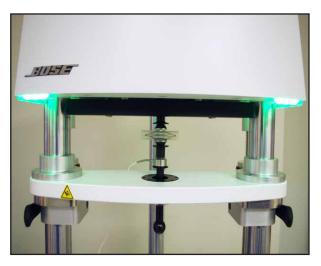


Figure 2 - The Bose $^{\otimes}$ 3200 Series III Test Instrument with IVC Filter Prepared for Compressive Testing

Diameter measurements of the filter-tube system were taken so that 5% and 20% displacement compression values could be calculated. The filter was placed between the platens of the 3200 Series III system as seen in Figure 2, and the constructed block waveform was run to apply 5% and 20% compression. Following data acquisition, the collected channels were imported into Microsoft[®] Excel for further analysis. By creating a plot of the resulting load vs. displacement, it can be seen that the load response followed the displacement changes very closely throughout the duration of the test.



Results

Following the data acquisition of displacement and load, a plot was made to demonstrate the resulting relationship. During the compressive test of the vena cava filter, forces ranging from 0 to 1.1 N, equivalent to 1/4 of a pound, were recorded. Similar to the ElectroForce[®] 3200 and 3300 Series II instruments, the Series III system is equipped with the HADS technology. The benefits of this technology include higher resolution, improved accuracy, and a drastically reduced noise floor.

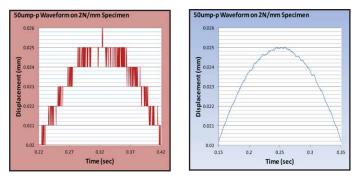


Figure 3 - Noise and Resolution Comparison of 3200 Original Series (Left) to 3200 Series III Equipped with the Integrated HADS Technology (Right)

In addition to these advantages, the Series III systems are calibrated to, and surpass, the highest accuracy class, Class A, of ASTM E-2309. The noise and resolution of the HADS technology is shown in Figure 3. For the collected data shown in Figure 4, the load never increased past 1.2 N, yet the measured relationship is a very good fit, closely following displacement over the course of many cycles.

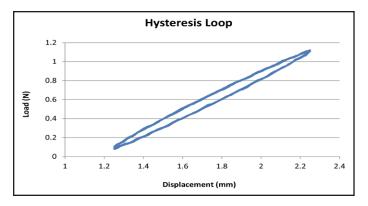


Figure 4 - Load-displacement Plot for the IVC Filter

Summary

The Bose[®] 3200 Series III test instrument is a powerful tool for the evaluation of mechanical properties pertaining to vascular implants. The system provides high-accuracy force measurements and precise control at frequencies as high as 300 Hz for a variety of test situations.

With the included HADS sensor integrated into the system, the Series III system is able to take measurements at 1 nm resolution, providing extremely accurate data even with small loads. The obtained data demonstrates a clear way to accurately evaluate the relationship between displacement on the filter and the resulting load experienced. In all, the Bose ElectroForce 3200 Series III test system is a compact and powerful instrument able to collect highly accurate data for a variety of test situations.

