Device Testing News
April 2015
MDT
Medical Device Testing Services

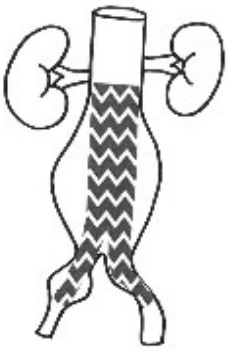

Figure 2: A common AAA graft design that includes a bifurcated scaffold with a sheath attached

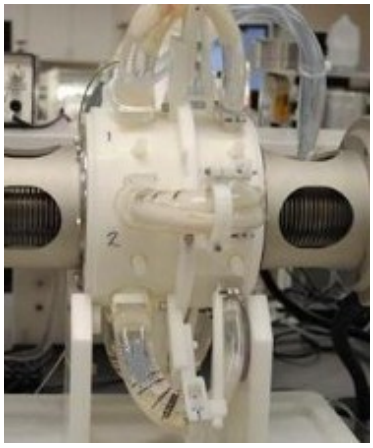

Figure 3: Bose SGT 9120 with curved, bifurcated vessels

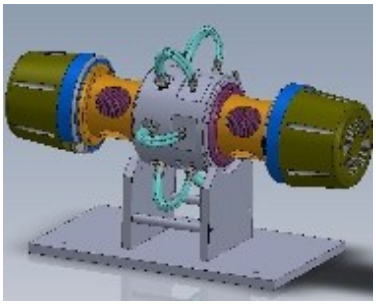

Figure 4: Solidworks drawing of Bose SGT 9120 with curved, bifurcated vessels

Abdominal Aortic Aneurysm (AAA)

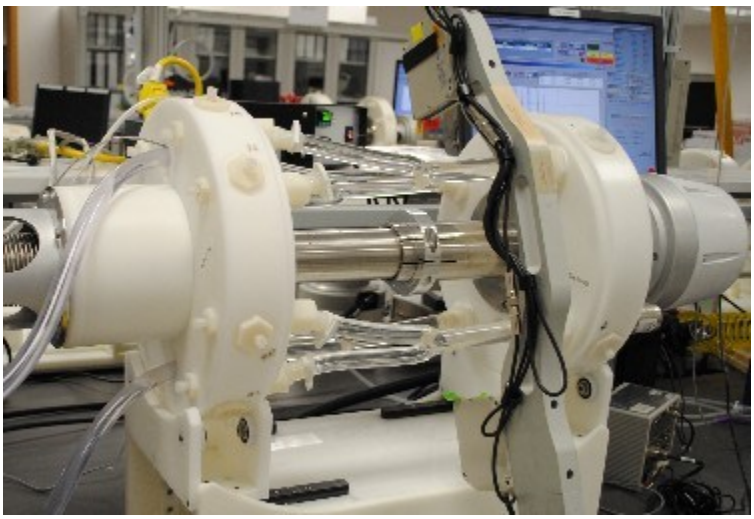

Figure 1: Bose SGT 9120 with straight bifurcated vessels

AAA (abdominal aortic aneurysm) is a localized enlargement of the abdominal aorta such that the diameter is more than 50% larger than normal. The condition affects between 2% and 8% of males over the age of 65. Mortality if ruptured is 85% to 90%, making it a leading cause of death in the U.S.

The Challenge

AAA devices are much larger than their smaller coronary cousins both in diameter and length. For this reason, a larger test instrument and mock arteries are required. Additionally, the strains experienced in-vivo may include bending as well as radial dilation. The challenge is to replicate these strains in vivo using existing test instruments or components of existing test instruments.

The Solution

MDT utilizes a Model 9120 Test Instrument (Figure 1), which accommodates larger mock artery diameters and length. This MDT system also pushes greater fluid volumes to achieve radial strain levels of up to 9%.

Simulating the bending strains often involved in AAA indications requires a more physiological representative approach. The specimen in Figure 3 has been bent to 180 degrees.

Not unlike peripheral vascular devices, repeated bending strains can be more dominant than radial fatigue strains. In

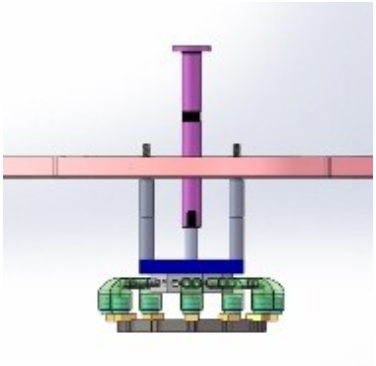

Figure 5: Bend fixture compatible with Bose ElectroForce 3300 or Instron ElectroPuls

these cases, special fixturing may be needed to impart the strains due to bending. Figure 5 shows a test fixture developed by MDT engineers that can be fitted to either a Bose ElectroForce 3300 or an Instron ElectroPuls Test Instrument. The fixture features a multi-station lower platen outfitted with the appropriate aortic fittings, as well as an upper manifold outfitted with the appropriate iliac fittings. The test fixture is lowered into an environment chamber filled with temperature-controlled saline. The fixture can accommodate up to 12 specimens and can be run at frequencies up to 40Hz.

Summary

AAA Intravascular Devices represent a promising new approach to treating AAA disease. Patient outcomes continue to improve as companies develop more robust designs that decrease endoleak, migration, and other risk profiles. AAA devices are challenging to test due to their larger than traditional sizing when compared to coronary devices and their indication for areas of the body where there is considerable bending. MDT engineers have learned to adapt the various pieces of equipment in our inventory to virtually any test application, and the examples shown reveal only a sampling of our capabilities.

Contact Us

Medical Device Testing
5929 Baker Road, Ste 430
Minnetonka, MN 55345

Ph: 952-933-1152
Fax: 952-933-1186
info@devicetesting.com
www.devicetesting.com

Durability Test Specialists

Since 1990, MDT has been providing quality test services to meet FDA requirements at competitive prices. Call us today to learn more about how our AAA device testing capabilities will enhance your test program. Visit us on the web at www.devicetesting.com.