Aortica announces first Simplified FEVAR procedure using AortaFit™ System and Bolton TREO™

Successful case performed in Physician-Sponsored IDE study using Aortica's predictive software and a new investigational endograft from Bolton Medical

NOVEMBER 14, 2016—BELLEVUE, WA—Aortica Corporation today announced that Dr. Benjamin Starnes, Chief of Vascular Surgery at the University of Washington (UW), completed the first 3-vessel Fenestrated Endovascular Aneurysm Repair (FEVAR) using Aortica's AortaFit™ investigational automated case planning software and Bolton Medical's TREO abdominal stent-graft system as part of his physician-sponsored IDE study. EVAR is the gold standard for treatment of Abdominal Aortic Aneurysms (AAA). "FEVAR" is an effective treatment for more complex AAA cases in which holes (or fenestrations) are carefully placed on the endograft to line up with branch arteries that supply blood to vital organs. These branch arteries preclude reliably anchoring a standard graft. While highly effective, FEVAR is also highly complex and time-consuming given the technology available today. Dr. Starnes' IDE study is evaluating technologies and methods to dramatically simplify FEVAR. The AortaFit™ planning software has been a key part of the study since February, and with the addition of TREO, Dr. Starnes has used the AortaFit™ software with a total of 5 different endograft systems. The TREO is an investigational AAA endograft developed by Bolton Medical (Sunrise, FL). TREO is available commercially outside the U.S., but is still investigational within the U.S. Dr. Starnes recently received FDA approval to add the TREO to his IDE study.

The patient was a 68-year-old male with a 6cm aneurysm and a history of heart disease and COPD. He also had significant angulation of the aorta. The procedure took less than 2 hours, and the patient was released from the hospital 2 days later. "This is a patient with very challenging aortic anatomy," stated Dr. Starnes. "The arteries that supplied his kidneys were 10mm from the origin of the aneurysm, meaning there was not adequate space to anchor a standard endograft. In addition, the angulation of the vessel posed a challenge to accurately aligning the graft fenestrations with the branch arteries. Patients with this level of complexity end up with very few treatment options other than maximally invasive open surgery," he explained. "AortaFit's™ automated planning software enabled me to accurately and quickly generate a 3-fenestration graft. I was excited to use TREO for the first time because its design provides a nice mix of mechanical support and flexibility. This gave the endograft strong scaffolding characteristics, while still providing me a great deal of 'strut-free' area to place the fenestrations. The flexibility of TREO enabled me to easily navigate the vessel angulation." He continued, "I could place the graft higher up in the aorta to achieve a secure anchor and a great seal while still preserving blood flow to the kidneys and stomach. In all, we placed a graft that precisely matched the patient's anatomy, and we increased the effective seal zone length from 10mm to 54mm. This is a key factor in achieving a result that is not only effective in the short term, but durable for the long term."

“We have been fortunate over the past year to include our automated case planning software in Dr. Starnes IDE study as this has allowed us to demonstrate its ability to eliminate hours of upfront planning and complexity in a clinical setting,” stated Aortica CEO Tom Douthitt. “But our software is just one piece of a comprehensive approach we have taken toward simplifying the entire FEVAR procedure. The AortaFit™ System is comprised of two additional technology platforms currently under development—a process for quickly applying fenestrations to standard endografts at the manufacturing site and a purpose-built branch fenestration stent. We hope to advance all three platforms in a pivotal trial in the near future.”

About Abdominal Aortic Aneurysm (AAA) Disease

Each year approximately 525,000 people worldwide are diagnosed with abdominal aortic aneurysms (AAA). An aneurysm is a large bulge in the aorta (the largest artery in the human body). It can gradually expand over time—without any symptoms—until it bursts, causing massive internal bleeding that results in death if not treated at a specialized center immediately. For years, major open surgery was the only treatment option, which is risky due to its complicated nature and because it carries a 3.0% mortality rate within 30 days of surgery.

About Endovascular Aneurysm Repair (EVAR) & Fenestrated EVAR (FEVAR)

In the 1990’s, a new technique for controlling aneurysms was developed using a graft inserted through the femoral arteries. This technique is called **e**ndo**v**ascular **a**neurysm **r**epair (EVAR). EVAR is significantly less invasive than open surgery and is associated with a mortality rate six times lower. Patients recover faster, leave the hospital sooner, and return to activities of normal daily life more quickly. Consequently, EVAR has become the gold standard for treatment of AAA disease. Unfortunately, approximately 40% of patients are not candidates for EVAR because their aortic anatomy is structured in a manner that does not allow an endograft to be anchored properly without blocking blood flow to vital organs. These patients face either open surgery or may be treated sub-optimally with standard EVAR. FEVAR involves placing reinforced, radiopaque holes (or fenestrations) in the endograft that align with branch arteries. This allows the physician to place the graft higher up in the aortic anatomy allowing for reliable anchoring and secure seal, while preserving blood flow to vital organs.

About Aortica Corporation

Aortica Corporation was founded to design, manufacture, and market tools for treatment of patients with AAA disease who have aortic anatomy that limits their treatment options. Aortica is dedicated to simplifying Fenestrated EVAR (FEVAR), and advancing the science of Personalized Vascular Therapy.

For further information on Aortica, visit the company’s website at www.aorticacorp.com

Contacts

Aortica Corporation

Stacy Douthitt, 425-209-0023

stacydouthitt@aorticacorp.com