Pilot Trial of the Fortron Abdominal Aortic Aneurysm Stent Graft System: Four-Year Results

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The Fortron abdominal aortic aneurysm (AAA) stent graft _system (Cordis) consists of a fully supported modular seamless polyester bifurcation device supported by a nitinol endoskeleton. There is a suprarenal attachment system containing barbs designed to implant at the infrarenal level. The stent rings are separated, creating a fabric hinge that allows conformity to tortuous anatomy. The delivery stent is flexible and 20F in external diameter. An important feature of the graft is an in situ sizing technique, requiring only three limb lengths to treat aneurysmal segments ranging from 130 to 200 mm.

The Fortron stent graft was implanted in 29 patients at four centers from December 1999 through August 2000 as part of a prospective pilot trial sponsored by the US Food and Drug Administration. At 30 days there were no deaths, ruptures, migration, stent fractures, limb occlusions, or conversions. There were 10 type II endoleaks and no type I or III leaks. One contralateral limb could not be deployed because of excessive tortuosity; a second device was successfully deployed.

Four patients have died of causes unrelated to the graft or aneurysm at 9, 17, 19, and 25 months. The remaining patients have been followed up for a minimum of 4 years. There were no type I or III endoleaks, aneurysm ruptures, graft migrations, or graft explants.

Four type II endoleaks persisted at 4 years. One aneurysm associated with a type II leak enlarged; the patient underwent open ligation of lumbar arteries without complications. Stent fractures in the suprarenal segment were detected by the Core laboratory in three patients; no adverse sequelae have been identified

The Fortron AAA stent graft system performed up to expectations over a 4-year period. All aneurysms were excluded with a limited number of devices and low intraoperative complication rates. Mid-term results indicated a minimal number of device related complications.

Results of the pivotal trial, a prospective randomized comparison of 200 patients receiving the Fortron graft and 100 patients receiving open surgery, will be available next year.