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Discrete Fixation for Endovascular Aortic Grafting: Interim Results of the Phase I Multicenter Trial of the Aplus™ Endovascular AAA Repair System

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OBJECTIVES: This Phase I study evaluates the safety and feasibility of the Aplus Endovascular AAA Repair System to electively treat patients with abdominal aortic aneurysms. The system is characterized by a three piece modular endograft and discrete fixation system enabled by a novel endostapling system. The unique features of the endograft include a main body with unsupported mid-section and two radially supported limbs that physically lock to the main body. The fixation of the endograft is achieved with a helical staple (EndoStaple) measuring 4 mm (length) by 3 mm (diameter). The EndoStaple engages the full thickness of the aortic wall as it is implanted. The operator controls the number and position of EndoStaple implantations. The endograft delivery systems have an O.D. of either 16 or 18 Fr.. The endostapling system has a 16 Fr. O.D..

METHODS: This is a prospective, single arm observational study. The two primary endpoints are absence of major device-related adverse events at one month (safety) and ability to successfully deploy all endograft components and EndoStaples (feasibility). Secondary endpoints include freedom from endoleaks, rupture, migration, device integrity, blood loss, procedure time and other clinical parameters. Follow-up evaluations occur at 1, 6, and 12 months and annually. Inclusion criteria include a proximal neck length of 12 mm and distal iliac fixation zone of 10 mm.

RESULTS: Nineteen (19) patients were treated between July 2006 and April 2007. Eighteen patients have completed 1 month follow-up for evaluation of the primary endpoints of the study. Aneurysm diameter ranged from 46 mm to 85 mm with a mean diameter of 57 mm. All endograft components were successfully deployed, including a total of 85 EndoStaples. The range of EndoStaples implanted was 2 to 10, with a median of 4 per patient. There were no Type I, III or IV endoleaks at one month. Device related adverse events included two limb thromboses, at nine and thirty days. Adjunctive devices used were two proximal cuffs and one limb extension. There were no EndoStaple-related adverse events.

CONCLUSIONS: These results document the initial success of the first discrete fixation system for an endovascular device. These results support the continued clinical investigation of the Aplus Endovascular AAA Repair System, including expansion to a Phase II pivotal study.