Pre-clinical Study in an Animal Model of a Vascular Sutureless Device for Rapid Anastomosis During Open Aortic Arch Reconstruction

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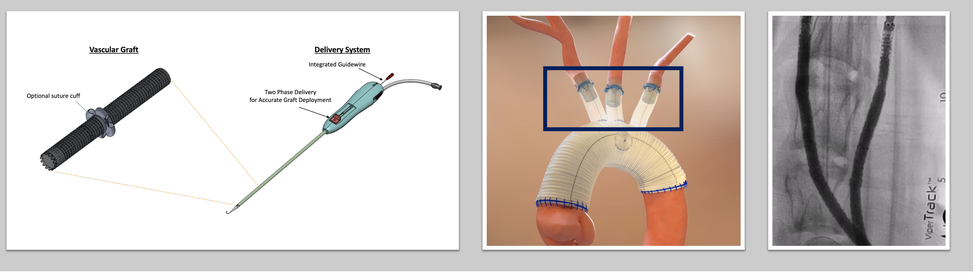

PURPOSE

To evaluate the use of a rapid sutureless device to facilitate supra-aortic vessel anastomoses during open aortic arch surgery.

METHODS

In six pre-clinical animal studies, researchers simulated vessel reconstruction in 13 ovine subjects, deploying 52 devices in a variety of arteries. When aortic arch reconstruction was simulated, a thoracotomy was performed and a 6mm bifurcated Dacron graft was tunneled through the thoracic inlet to reach the carotid arteries in the neck. The bifurcated graft was sutured to the aorta using a Cooley clamp. Using the sutureless, rapid anastomotic device, researchers connected the two branch grafts of the Dacron graft to the carotid arteries. Ultrasound and angiography were used to assess blood flow and patency at the end of the procedure.

RESULTS

The studies demonstrated that the sutureless anastomotic devices could be deployed in ≤ 3 minutes and provided rapid reconstruction between the native vessel and branch of the Dacron graft. Rapid hemostasis was achieved in all cases. At follow-up, all connecting grafts were fully patent, without evidence of thrombus as evidenced by imaging. Graft adherence was confirmed with an endothelial tissue layer noted throughout the anastomotic device and the Dacron branch graft. Gross examination noted that all distal and proximal transitions between tissue and graft were free of thrombus. With the 30-day chronic subject, transitions that were present initially between the branch grafts and arteries demonstrated good layers of endothelialization.

CONCLUSION

This investigatory device enabled reproducible, sutureless aortic arch vessel anastomosis. Reduction of arch vessel reconstruction time could lead to a decrease in the hypothermic circulatory arrest period and, thus, reduce the morbidity and mortality associated with open aortic arch surgery. Clinical studies are expected soon.

SOURCE OF FUNDING

Research collaboration with Aquedeon Inc, (the company producing the device).