Deployment of a Novel Hybrid Stent for Open Repair of Acute DeBakey Type I Aortic Dissection with Malperfusion

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Disclosure Statement

Wilson Y. Szeto: Edwards, Medtronic, Artivion, Terumo Aortic, Abbott – investigator, advisory board, speaker

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Central Message
The AMDS Hybrid Prosthesis is a novel hybrid device for the treatment of acute DeBakey I aortic dissection in patients without an intimal tear in the arch.

Central Picture Legend:
The AMDS Hybrid Prosthesis is deployed antegrade during circulatory arrest.
Introduction

The AMDS Hybrid Prosthesis is a novel device for the treatment of acute DeBakey I aortic dissection in patients without an intimal tear in the arch [1-3]. Comprised of an uncovered nitinol braided stent with a proximal PTFE felt component (Figure 1), the AMDS is deployed antegrade during circulatory arrest. The felt portion is incorporated into the distal ascending aortic anastomosis to prevent distal anastomotic new entry tears (DANE). The bare metal stent stabilizes the true lumen and induces aortic remodeling over time. This manuscript and accompanying video demonstrate our technique of implanting this device.

Case Report

The Institutional Review Board (IRB) at the University of Pennsylvania approved the study protocol and publication of data (850575, 11/9/2023). The patient provided informed written consent for the publication of the study data. A 45-year-old male with history of hypertension presented to an outside hospital with acute onset chest pain radiating to his back. On exam, he had clinical evidence of malperfusion with absence of a right femoral pulse and lacked sensation from the mid-thigh distally. CT angiography revealed an acute DeBakey I aortic dissection. The root and ascending aorta were aneurysmal with an entry tear above the sinotubular junction. While there was no obvious arch tear, the innominate artery was dissected and there was severe compression with compromised flow in the right common carotid artery. The dissection continued into the right iliac artery, which was occluded. This patient was transferred directly to our operating room for surgical repair (Video).
In this case, which was our first AMDS deployment, circulatory arrest was initiated at 18°C and retrograde cerebral perfusion was instilled via the superior vena cava. Since then, for cases with AMDS deployment, we have utilized moderate hypothermic circulatory arrest at 28 °C with antegrade cerebral perfusion via axillary cannulation. The aorta must be transected at least 10 mm proximal to the innominate artery for AMDS deployment. After this step, the arch was carefully inspected for intimal tears, which would preclude utilization of the AMDS. Selection of the appropriate AMDS size is based on preoperative imaging. The AMDS delivery system was then brought to the field and advanced into the aorta (Figure 2a). A slight curve was applied to the length of the device to mimic the contour of the aorta. Once the device had been fully advanced, a 10 mm felt strip was then placed circumferentially around the cuff of the transected aorta. Four tacking sutures were placed at 90-degree intervals with 4-0 polypropylene (Figure 2b). Each stitch carefully incorporated the proximal PTFE felt component of the AMDS, the aorta, and the external felt strip. The stent was then deployed and the delivery system was removed.

The AMDS was secured to the aorta and the felt strip with a running 4-0 polypropylene suture (Figure 2c). It is critical that each bite incorporates both layers of felt to avoid DANE. The ascending aortic graft was then anastomosed to the felt-aorta cuff with a running 4-0 polypropylene suture (Figure 2d). The cerebral circulation was de-aired and cardiopulmonary bypass was reinitiated via the ascending graft. Given the extensive nature of this patient’s dissection, he also required a root replacement. Following the termination of cardiopulmonary bypass, a strong femoral pulse was appreciated.
The patient’s postoperative course was unremarkable and he was discharged home on day 6. At 30 days, surveillance CTA demonstrated an intact repair, remodeling of the innominate artery with dramatically increased flow in the right common carotid, near complete expansion of the true lumen with obliteration of the false lumen throughout the course of the stent graft, and flow throughout the entire right iliofemoral system.

Discussion

In prior study by Rylski and colleagues, DANE was identified in 70% after isolated ascending or hemiarch repair of acute Type A dissection [4]. The resulting continued pressurization of the false lumen can lead to aneurysmal growth that may require additional surgical repair [5]. The AMDS was designed to seal the distal anastomosis and expand the true lumen, thereby preventing DANE and inducing positive aortic remodeling. In the prospective, nonrandomized Dissected Aorta Repair Through Stent Implantation (DARTS) trial, in which 46 patients with acute DeBakey I dissection underwent AMDS implantation in Canada and Germany, mortality at 30 days and 3 years was 13.0%, and 21.7%, respectively [1]. Moreover, at 3 years, there was no incidence of DANE, and the false lumen was partially or completely thrombosed in 90.5% in zone 0, 60.0% in zone 1, and 68.2% in zone 2 [1]. Similarly, in a series of 100 patients by Montagner and colleagues in Germany, 30-day mortality was 18% and partial or complete thrombosis of the false lumen in the mid-descending aorta was 76% [2]. In the United States, the ongoing study, titled Prospective, Single Arm, Multicenter Clinical Investigation to Evaluate the Safety and Effectiveness of AMDS in the Treatment of Acute DeBakey Type I Dissection (PERSEVERE), has enrolled 93 patients [6]. At 30 days, mortality was 9.7% and incidence of
DANE was 0% [3]. While the early results are promising, additional follow-up is needed to assess the long-term efficacy of the AMDS compared to established therapies.

Conclusion

This manuscript and accompanying video demonstrate our technique of implanting the AMDS in a patient with an acute DeBakey I aortic dissection with preoperative malperfusion.
References


3. Szeto WY, Fukuhara S, Fleischman F, et al. Results of a Novel Aortic Arch Hybrid Prosthesis for Open Repair of Acute DeBakey Type I Dissection with Malperfusion 30-day Results from the PERSEVERE Study. 60th Annual Meeting of the Society of Thoracic Surgeons; January 27-29, 2024; San Antonio, TX.


   https://clinicaltrials.gov/study/NCT05174767
Figure Legends

Figure 1: The AMDS consists of a PTFE felt proximal component with uncovered nitinol stent.

Figure 2: Steps in AMDS deployment: (a) The device is advanced into the aorta. (b) A 10 mm felt strip is placed around the aorta and secured in 4 places. (c) A running suture secures the PTFE component of the device to the aorta and external felt ring. (d) The final distal suture line of ascending graft.

Video Legend

This video demonstrates our technique of AMDS deployment.
PTFE felt-reinforced anastomosis

Uncovered nitinol stent

Ascending aortic replacement