Role of Bare Metal AMDS Stents for Repair of Acute DeBakey type I Dissections: Indications and Results

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Penn

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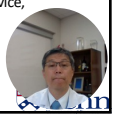
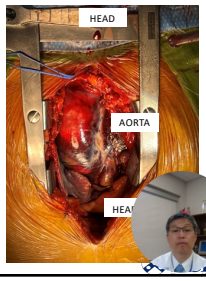


Acute Aortic Dissection (Intimal Tear of the Wall of the Aorta)

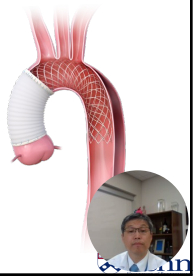
- 5 to 30 cases per 1 million people per year
- 75% occur between age 40-70 years old
- 3X more common in men
- Risk factors
  - HTN, pre existing aneurysm, genetic condition i.e. Marfans syndrome, family history, infect

If untreated, mortality approaches 50% during first 48 hours



Hemiarch + AMDS

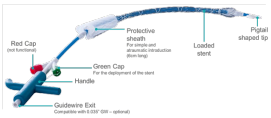
- AMDS Hybrid Prosthesis (AMDS) is a novel bare metal stent, with proximal PTFE cuff, designed to stabilize the true lumen, avoid distal anastomotic new entry (DANE) tears and enhance aortic remodeling in the arch.
- AMDS requires minimal change to the conventional surgical approach of replacing the ascending aorta.

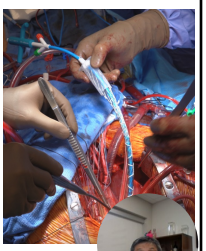


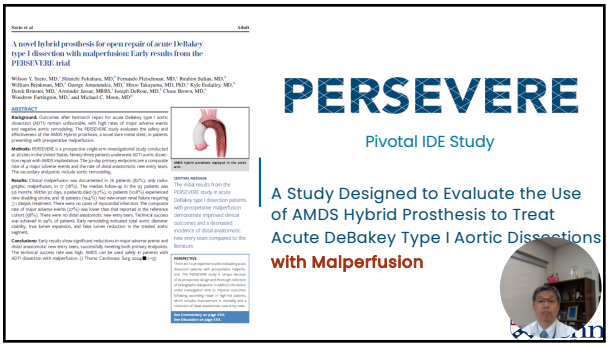
AMDS Hybrid Stent: Device Description

PTFE felt graft component made of a PTFE felt tube is used to buttress and strengthen the aortic tissue in preparation to perform the conventional polyester graft to aorta anastomosis

Uncovered nitinol wire braided stent enables the stabilization of the dissection flap within aortic arch and descending aorta thereby stabilizing the structure of the aortic wall and promoting its healing



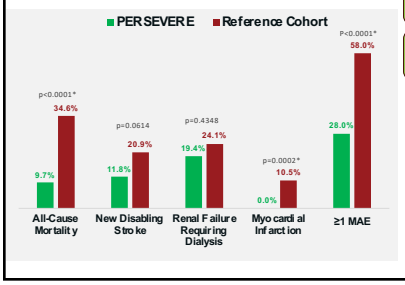




Peri-Operative Data

	Total # Patients (n=93)	
Operative Summary	**#**	**%**
Concomitant Procedure	79	84.9%
Root Repair or Replacement	35	37.6%
Aortic Valve Resuspension	34	36.6%
Valve Repair or Replacement	21	22.6%
CABG	5	5.4%
Other	24	25.8%
Guidewire Use	10	10.8%
Fluoroscopy Use	8	8.6%
Antegrade Cerebral Perfusion	43	46.2%
Retrograde Cerebral Perfusion	45	48.4%
	Median	
AMDS Deployment Time (mins)	4	
Total AMDS Implantation Time (mins)	15	
Circulatory Arrest Time (mins)	28	
Lowest Core Temperature (deg C)	24.7	
Time in ICU (days)	5	
Time in Hospital (days)	11	

Results: Primary Endpoints

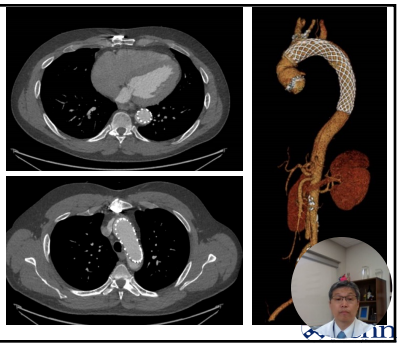


Total # Patients with ≥ 1 MAE: 26 (28%) — **GOAL: < 40%**

Total # Patients with DANE: 0 (0%) — **GOAL: < 10%**

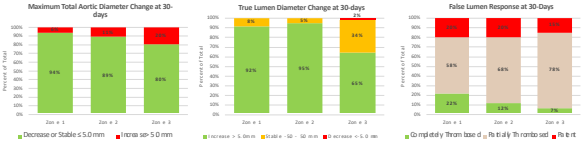
Primary 30-day Endpoint (Adjudicated)	Total # Patients (N=93)	%
All-cause mortality	9	9.7
New Disabling Stroke	11	11.8
New Onset Renal Failure Requiring Dialysis		
Myocardial Infarction		

Results: Positive Aortic Remodeling (1-Year)



Early Results: AMDS Associated with Positive Aortic Remodeling

- Most patients demonstrated TAD reduction/stability, TL increase and FL thrombosis in Zones 1-3 at 30-days



- Mean FLD change from baseline was -11.3 mm in Zone 1, -10.7 mm in Zone 2, in Zone 3

Conclusion

- The 30-day composite demonstrates that the use of AMDS **significantly reduces** MAEs in the surgical treatment of ADTI patients complicated by *malperfusion*
- 30- day mortality was **9.7%**
- There is an **absence** of DANE at 30-days and through longest follow-up
- Early remodeling data demonstrates true lumen expansion in majority of patients
- Technical success rate is high, with **minimal time** added to circulatory arrest
- AMDS is an effective adjunct to proximal aortic repair in ADTI patients w ***malperfusion***

[1]References: Zindovic I et al. J Thorac Cardiovasc Surg 2019; Pacini D et al. Eur J Cardiothorac Surg 2013; Girdauskas E. et al. J Thorac Cardiovasc Surg 2009; Geirsson A. et al J Thorac Cardiovasc Surg 2007; Bo... et al Ann J Cardiol 2002
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Penn Aortic Team

Thank You!