University Heart Center Hamburg

GERMAN AORTIC CENTER HAMBURG

The New Cook Custom Single Branch Endograft For TEVAR Of Lesions Close To Or Involving The LSA: Advantages And Results

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Disclosures

- Consultant: Cook Medical, Philips, Getinge, Terumo Aortic, Arterica
- Research-grants: Cook Medical, Philips, Terumo Aortic, Medtronic
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- Speaking fees: Cook Medical, Philips, Getinge
- Shares: Mokita-Medical, Arterica
- IP: Cook Medical, Terumo Aortic, Mokita Medical
- Royalties: Cook Medical, Terumo Aortic
- Devices and Techniques in this presentation are not approved by the FDA

Cook Zenith Custom Arch Endografts

Branched SG

Fenestrated SG

Branched vs. Fenestrated Arch TEVAR

Branched versus fenestrated endografts for endovascular repair of aortic arch lesions

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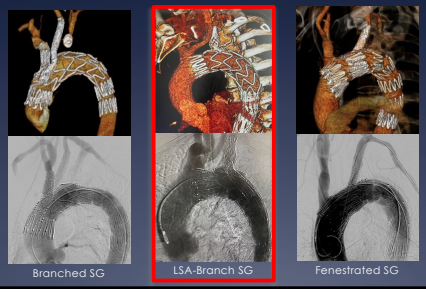
- Single center, 2012-2014, 29 patients
  - Fenestrated TEVAR: 15
  - Branched TEVAR: 13
- F-TEVAR faster, simpler, shorter hospital stay

	fTEVAR (n = 15)	bTEVAR (n = 14)	P
Procedure time, minutes	153 ± 23	270 ± 26	.02
Fluoroscopy time, minutes	36 ± 8	47 ± 8	NS
Intensive care unit stay, days	3.3 ± 1.2	3.8 ± 0.6	NS
Hospital stay, days	7 ± 5	14 ± 8	.02
Thirty-day mortality	3 (20)	0	NS
Myocardial infarction	0	1 (7)	NS
Relevant respiratory complications	2 (14)	0	NS
Major stroke	2 (14)	1 (7)	NS
Retrograde type A dissection	0	0	NS
Cardiac infarction	1	0	NS
Acute kidney injury (no dialysis)	2 (14)	1 (7)	NS
Acute kidney injury (dialysis)	0	0	NS
Pancreatitis	0	1 (7)	NS
Access site complications (minor and major)	3 (20)	1 (7)	NS

Tsilimparis et al. 2016, J Vasc Surg 64:592-9

Cook Zenith Custom Arch Endografts

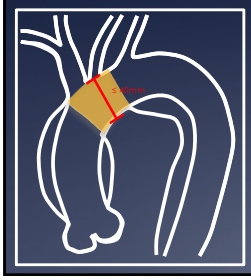


Branched SG

LSA-Branch SG

Fenestrated SG

Custom LSA Single Branch Device: Anatomical Suitability



- Diameter ≤ 40mm
- Proximal landing zone ≥ 20mm
- Appropriate access vessels

Landing zone in mid-arch

Retrograde Branches

Multicenter global early feasibility study to evaluate total endovascular arch repair using three-vessel inner branch stent-grafts for aneurysms and dissections

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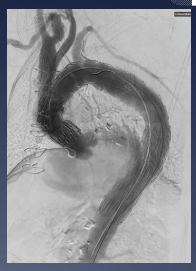
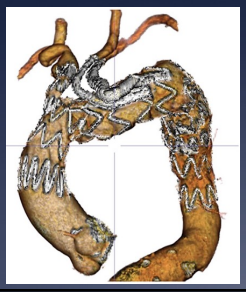
Variable	No. (%)
Early death	2 (5)
Any major adverse event	10 (26)
Estimated blood loss ≥1 L	2 (5)
Acute kidney injury	2 (5)
New-onset dialysis	1 (2.5)
Myocardial infarction	2 (5)
Respiratory failure	4 (10)
Any spinal cord injury	0 (0)
Any stroke	2 (5)
Major stroke	1 (2.5)
Minor stroke/TIA	1 (2.5)
Bowel ischemia	1 (2.5)

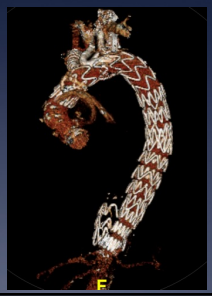
TIA, Transient ischemic attack.



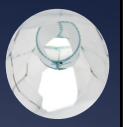
Tenorio et al. 2021, J Vasc Surg 74:1055-65

Retrograde Branches: 1,2 or 3



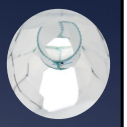


Custom LSA Single Branch Device



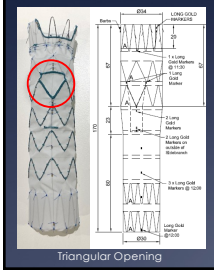
- Retrograde branch for LSA/LCCA
  - 8,10,12mm diameter;
  - @ 47-67mm
- +/- proximal scallop for LCCA/IA
  - 20 or 30mm wide;
  - 8-21mm deep
- Proximal diameter 32-46mm
  - Seal zone diameter 28-40mm

Custom LSA Single Branch Device

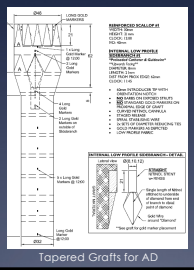


- Straight and tapered configurations
- Stainless steel and Nitinol stents
- Sealing stents on inside of the graft
- Low profile dacron fabric
- Gold markers as in other Zenith arch devices

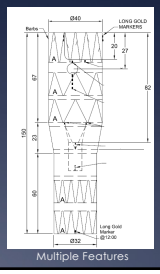
Other Configurations



Triangular Opening



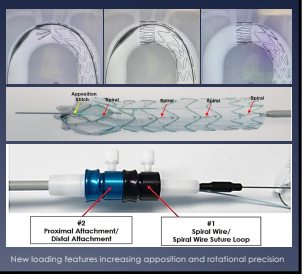
Tapered Grafts for AD



Multiple Features

Delivery System

18-22F precurved Z-track delivery system +/- preloaded catheter



New loading features increasing apposition and rotational precision

Hamburg Experience (2014-2023)

- 12 elective patients
  - 71.7±17 years, 67% males
- 2 (17%) previous aortic repair
  - 1 hemiarch repair & 1 ascending repair
- Mean aortic diameter 60±7mm
- 58% aortic-dissection
  - 1 residual type A
- 100% upper access (left brachial)

Type of lesion	Number of cases (%)
TAAA type I or II	8 (66.6)
TAA	1 (8.3)
Arch aneurysm	3 (25)
Extend of disease	**Number of cases (%)**
Ishimaru zone 2	6 (50)
Ishimaru zone 3	6 (50)
Arch type	**Number of cases (%)**
Type I	2 (16.7)
Type II	8 (66.6)
Type III	2 (16.7)
Bovine arch	2 (16.7)

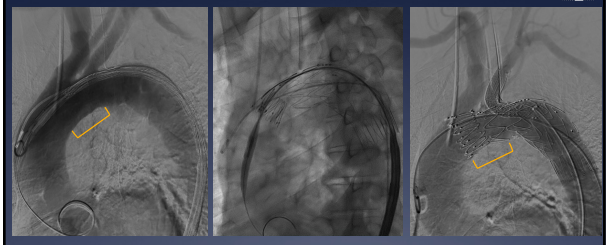
Hamburg's experience (2014-2023)

- 100% Technical success
- Intra-operative details
  - 75% TEVAR extensions
  - 43% False lumen endograft
  - 8% CSFD
  - 17% EL Ia at completion
- Bridging stents
  - 33% BCS and 67% SCV
  - 25% relining

30-day outcomes	Number of cases (%)
Mortality	1 (8.3)
Stroke	0 (0.0)
SCI - Grade 2	1 (8.3)
Retrograde dissection	0 (0.0)
AKI	0 (0.0)
Reinterventions	2 (16.7)
-Access	1 (8.3)
-ET Ia embolization	1 (8.3)

Median follow-up 12 months (1-48 months)
No death
5 reinterventions
-3 scheduled

Advantages:



Maximising the proximal seal-zone by using scallop design and orthogonal landing

Conclusion

- LSA branch graft is an easy to use custom device to avoid cervical debranching
- Proximal scallop can increase inner curvature wall contact up to 20mm.
- Preloaded technology facilitates easy access to retrograde LSA branch.
- Precurved delivery system orientates the graft. No T&T arm access needed.
- custom program allows tailoring endovascular arch repair by combining most beneficial features.

Image courtesy of Gustavo Oderich