LMU KLINIKUM DER UNIVERSITÄT MÜNCHEN | CAMPUS GROSSHADERN CAMPUS INNENSTADT | GEFÄSSCHIRURGIE | 550 Jahre LMU MEDIZIN Exzellenz seit 1472

Multicenter Study Of Physician Modified Endografts (PMEGs) For TAAA And Complex AAA Repairs: What Does It Show About Their Advantages And Limitations

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On behalf of the investigators of the International Multicenter Study on Physician Modified Endografts


Circulation
ORIGINAL RESEARCH ARTICLE
Multicenter Study on Physician-Modified Endografts for Thoracoabdominal and Complex Abdominal Aortic Aneurysm Repair

VEITH SYMPOSIUM

Conflicts of interest

- Proctor for Cook medical
  Research funding from Cook Medical, Bentley
  Advisory boards for Medtronic, Terumo Aortic, Siemens

Reasons for using PMEGs in complex AAAs and TAAAs

No wide availability of Custom-made or off-the-shelf devices

Use in urgent cases

High cost of CMDs / off-the-shelf devices

Minimize waiting time and logistics

PMEG Valiant Medtronic

PMEG CMD fen Cook

PMEG TX2 Cook

Background

International Multicenter Study on the use of Physician-Modified Endografts for Thoraco-abdominal and Complex Abdominal Aneurysm Repair

- Main aim was to analyze the outcomes of PMEGs in the elective and urgent treatment of Complex AAAs and TAAAs
- **1274 patients collected**
- **19 centers agreed to participate**
  - Ludwig Maximilian University Hospital, Germany (Nikolaos Tsilimparis, Ryan Melo)
  - University of Texas Health, Houston; McGovern Medical School, USA (Gustavo Oderich, Emanuel Tenorio, Marina Dias Neto)
  - University of Southern California, Keck Medical Center, USA (Suleju Han)
  - Mayo Clinic, USA (Bernardo Mendes, Jesse Chait)
  - The University of California, San Diego Health System, San Diego, USA (Mahmoud Malas, Andrew Barleben, Rohini Patel)
  - Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, USA (Marc Schermerhorn)
  - University of North Carolina at Chapel Hill, Chapel Hill, NC, USA (Mark Farber, Vivian Gomes)
  - University of Washington, Seattle, WA, USA (Benjamin Starnes; Mathew Sweet, Sara Zettervall)
  - University of Florida, USA (Salvatore Scali; Adam Beck)
  - University of Texas Southwestern Medical Center, Dallas, USA (Carlos Timaran; Jésus Porras Colon)
  - Università degli Studi di Perugia, Perugia (UNIPG), Italy (Gisele Simonte and Enrico Cieri)
  - University of Birmingham, Heart of England NHS Foundation Trust, UK (Donald Adam; Anno Elbouihi)
  - Hôpital Henri-Mondor, Creteil, France (Frédéric Cochennec and Jean-Pierre Becquemin)
  - University of Turin, Italy (Fabio Verzini)
  - University Clinic Leipzig, Germany (Daniela Branzan)
  - Hamburg Aortic Center, Germany (Tilo Kölbel)
  - Christian Medical College Vellore, India (George Joseph)
  - Ospedalle San Raffaele, Milan, Italy (Luca Bertoglio)
  - Centro Hospitalar Universitário Lisboa Norte, Lisbon, Portugal (Luis Mendes Pedro, Ryan Melo)

Principal Investigators


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ORIGINAL RESEARCH ARTICLE

Multicenter Study on Physician-Modified Endografts for Thoracoabdominal and Complex Abdominal Aortic Aneurysm Repair

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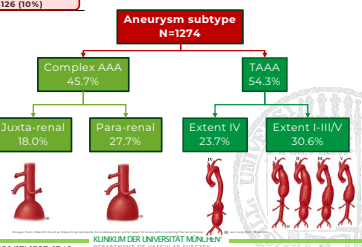
Results of the Multicenter study

Elective	Symptomatic	Rupture
N=834 (65%)	N=314 (25%)	N=126 (10%)

Baseline Data



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DEPARTMENT OF VASCULAR SURGERY

Results of the Multicenter study

Variable	N	Total	Elective N=834	Symptomatic N=314	Rupture N=126
Type of repair	1124				
• fl-EVAR		• 934 (83.1)	• 567 (80.6)	• 257 (85.4)	• 110 (91.7)
• b-EVAR		• 40 (3.6)	• 26 (3.7)	• 11 (3.6)	• 3 (2.5)
• fb-EVAR		• 150 (13.4)	• 110 (15.6)	• 33 (11.0)	• 7 (5.8)
Three or more TV included	1222	1049 (85.8)	680 (86.3)	275 (88.4)	94 (76.4)
Four or more TV included	1222	796 (65.1)	512 (65.0)	220 (70.7)	64 (52.0)
Used Low profile graft for main modification	1220	393 (32.2)	302 (38.4)	73 (23.5)	18 (14.6)
Used straight graft for main modification	1063	1002 (94.3)	625 (95.0)	278 (91.3)	99 (92.5)
Included a distal component	1061	630 (59.4)	583 (64.5)	173 (58.1)	33 (31.1)
• Straight		• 111 (10.5)	• 74 (11.3)	• 31 (10.4)	• 6 (5.7)
• Bifurcated		• 519 (48.9)	• 350 (53.3)	• 142 (47.7)	• 27 (25.9)
Removed barbs from distal bifurcated component	473 with distal bif component	93 (19.7)	53 (23.9)	32 (16.3)	8 (14.5)
Included preloaded catheter or wires	785	145 (18.5)	99 (21.4)	30 (13.4)	16 (16.3)

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Results of the Multicenter study

Variable	N	Total	Elective N=834	Symptomatic N=314	Rupture N=126
Planning for arc distances	892				
• Used formula with inner vessel diameter and clock positions		• 688 (77.1)	• 473 (89.4)	• 151 (59.4)	• 64 (58.7)
• Directly measured on CTA		• 101 (11.3)	• 3 (0.6)	• 79 (31.1)	• 19 (17.4)
• Used only clock positions		• 62 (6.9)	• 37 (7.0)	• 6 (2.4)	• 19 (17.4)
• Used 3d model		• 41 (4.6)	• 16 (3.0)	• 18 (7.1)	• 7 (6.4)
Diameter reducing ties	680				
• Not used		• 176 (25.9)	• 28 (7.6)	• 107 (65.1)	• 41 (53.9)
• Single		• 248 (36.5)	• 180 (49.0)	• 45 (19.0)	• 23 (30.3)
• Double		• 256 (37.6)	• 159 (43.3)	• 85 (35.9)	• 12 (15.8)
Type of reducing ties used:	601				
• Used wire from delivery system		• 335 (55.7)	• 206 (60.8)	• 97 (46.6)	• 32 (59.3)
• Used separate wire		• 14 (2.3)	• 7 (2.1)	• 6 (2.9)	• 1 (1.8)
• No wire, direct suture and later blow-out with balloon dilation		• 252 (41.9)	• 126 (37.2)	• 105 (50.5)	• 21 (38.9)
Which device used for graft holes	678				
• Ophtalmic cauthery		• 606 (89.4)	• 357 (95.9)	• 185 (82.2)	• 64 (83.1)
• Scalpel		• 35 (5.2)	• 8 (2.1)	• 16 (7.1)	• 11 (14.3)
• Other		• 37 (5.5)	• 11 (2.9)	• 24 (10.7)	• 2 (2.6)
Soaked graft in antibiotic	686	178 (25.9)	23 (6.0)	109 (48.4)	46 (56.8)

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Results of the Multicenter study

Type of devices used (main modified device)	N	Total	Elective N=834	Symptomatic N=314	Rupture N=126
COOK TX2 dissection (ZDEC)	1065	413 (38.8)	204 (30.9)	145 (48.7)	64 (59.8)
COOK TX2 aneurysm (ZTEQ		151 (14.2)	114 (17.3)	31 (10.4)	6 (5.6)
COOK Zenith Alpha thoracic		360 (33.8)	280 (42.4)	65 (21.8)	15 (14.0)
COOK Zenith Flex abdominal		35 (3.3)	16 (2.4)	11 (3.7)	8 (7.5)
COOK Zenith Alpha abdominal		15 (1.4)	12 (1.8)	3 (1.0)	0
COOK Renu		6 (0.6)	5 (0.8)	0	1 (0.9)
COOK Zfen		4 (0.4)	3 (0.4)	1 (0.3)	0
COOK CMD		2 (0.2)	1 (0.1)	0	1(0.9)
COOK T-Branch		1 (0.1)	0	1 (0.3)	0
COOK ESBE		1 (0.1)	0	1 (0.3)	0
COOK AUI		1 (0.1)	1 (0.1)	0	0
Medtronic Valiant		58 (5.5)	15 (2.3)	33 (11.1)	10 (9.3)
Medtronic Navion		3 (0.3)	2 (0.3)	0	1 (0.9)
Medtronic Endurant II		12 (1.1)	4 (0.6)	7 (2.3)	1 (0.9)
Other					
• Core C3		• 1 (0.1)	• 1 (0.1)	• 0	• 0
• Endologix AFX		• 1 (0.1)	• 1 (0.1)	• 0	• 0
• Terumo Relay		• 1 (0.1)	• 1 (0.1)	• 0	• 0

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Results of the Multicenter study

Variable	N	Total	Elective N=834	Symptomatic N=314	Rupture N=126
Technical Success	1175	1104 (94.0)	703 (94.0)	284 (93.4)	117 (95.1)
30-day mortality	1274	74 (5.8)	34 (4.1)	24 (7.6)	16 (12.7)
Major adverse events at 30-days	1100	277 (25.2)	157 (23.1)	83 (27.8)	37 (30.3)
Early reintervention (30-day)	1042	144 (13.8)	85 (12.9)	34 (12.7)	25 (20.7)
• Aortic/branch related		• 105 (10.1)	• 62 (9.4)	• 24 (9.0)	• 19 (16.5)
• Non-aortic/branch related		• 39 (3.7)	• 23 (2.5)	• 10 (3.7)	• 6 (5.2)
Spinal cord ischemia (any grade)	1274	83 (6.5)	52 (6.2)	19 (6.0)	12 (9.5)
• Grade 1		• 27 (2.1)	• 11 (1.3)	• 9 (2.9)	• 7 (5.6)
• Grade 2		• 26 (2.0)	• 20 (2.4)	• 6 (1.9)	• 0
• Grade 3		• 30 (2.3)	• 21 (2.5)	• 4 (1.3)	• 5 (4.0)
Acute kidney injury (any)	1151	134 (11.6)	74 (10.2)	47 (15.9)	12 (9.6)
• Increase in creat x2 (no dyalisis)		• 89 (7.7)	• 58 (8.0)	• 24 (8.0)	• 7 (5.6)
• Temporary dyalisis		• 22 (1.9)	• 9 (1.2)	• 11 (3.6)	• 2 (1.6)
• Permanent dyalisis		• 23 (2.0)	• 7 (1.0)	• 13 (4.3)	• 3 (2.4)
Bowel ischemia	1223	71 (5.8)	45 (5.7)	16 (5.1)	10 (8.1)
Access related complications	1274	131 (10.3)	93 (11.1)	22 (7.0)	16 (12.7)

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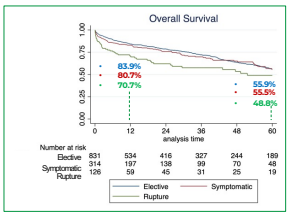
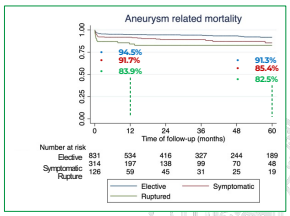
Results of the Multicenter study





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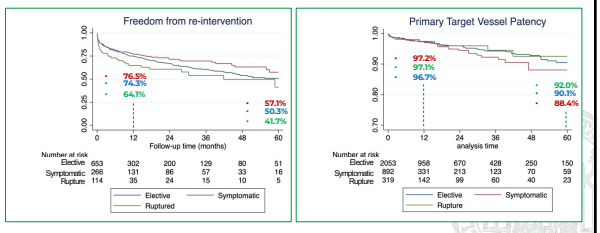
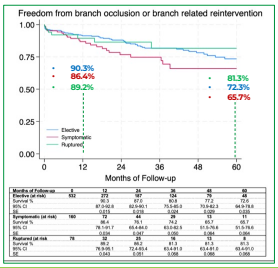
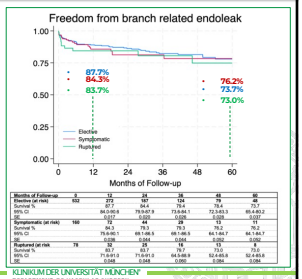


Results of the Multicenter study





Results of the Multicenter study

Predictors of Technical Success

Predictors of Technical success	Number of cases reported	Univariable analysis (OR, 95%CI, pvalue)	Multivariable analysis (n=1079) (OR, 95%CI, pvalue)
Design type including branches	1124	**0.45 (0.26–0.76), p=0.003**	**0.48 (0.27–0.87), p=0.016**
Including an additional target artery (accessory renal/additional visceral branch)	1124	0.42 (0.17–1.03), p=0.058	**0.35 (0.14–0.89), p=0.027**
Previous aortic repair (open and/or endovascular)	1175	**0.46 (0.28–0.75), p=0.002**	**0.44 (0.26–0.75), p=0.002**
Thoracoabdominal aortic aneurysm (versus complex abdominal aortic aneurysm)	1106	0.91 (0.55–1.49), p=0.70	1.18 (0.69–2.03), p=0.54
eGFR (every 10 unit increase)	**1148**	**1.15 (1.04–1.27), p=0.006**	**1.17 (1.05–1.30), p=0.005**
Three or more TV included	**1123**	0.55 (0.23–1.28), p=0.17	0.43 (0.16–1.13), p=0.09
Clinical presentation (versus elective repair) • Symptomatic Aneurysm • Ruptured Aneurysm	1175	• 0.91 (0.53–1.57), p=0.73 • 1.25 (0.52–3.00), p=0.62	• 0.82 (0.46–1.46), p=0.50 • 1.34 (0.51–3.53), p=0.55

Results of the Multicenter study

Predictors of 30-day mortality

Predictors of 30–day mortality	Number of cases reported	Univariable analysis (OR, 95%CI, pvalue)	Multivariable analysis (n=860) (OR, 95%CI, pvalue)
Age (for every 10 year increase)	1274	**1.55 (1.16–2.07), p=0.003**	**1.60 (1.12–2.30), p=0.011**
CAD	1274	**1.73 (1.08–2.78), p=0.024**	1.75 (0.93–3.29), p=0.08
CHF	1274	**2.14 (1.25–3.68), p=0.005**	1.69 (0.85–3.36), p=0.13
Tobacco use	1266	**0.56 (0.35–0.91), p=0.020**	**0.41 (0.22–0.78), p=0.005**
Peripheral arterial disease	1150	**2.11 (1.24–3.57), p=0.006**	**2.06 (1.07–3.97), p=0.031**
ASA score ≥3	1052	4.36 (0.59–31.93), p=0.15	4.22 (0.55–31.9), p=0.16
Aortic diameter (for every 10mm increase)	1235	1.18 (1.04–1.34), p=0.009	1.09 (0.93–1.28), p=0.26
Clinical presentation (compared to elective cases): • **Symptomatic** • **Ruptured**	1274	• **1.95 (1.13–3.34), p=0.015** • **3.42 (1.83–6.40), p<0.001**	• **2.00 (1.03–3.88), p=0.040** • **2.74 (1.26–5.92), p=0.011**
Thoracoabdominal aortic aneurysm (versus complex abdominal aortic aneurysm)	1205	**2.10 (1.26–3.53), p=0.005**	**1.85 (1.00–3.43), p=0.050**
Three or more TV included	1222	**0.52 (0.29–0.91), p=0.023**	**0.37 (0.19–0.73), p=0.004**
Technical success of procedure	1175	**0.23 (0.12–0.44), p<0.001**	**0.30 (0.13–0.69), p=0.005**
Total operation time (for every 10min increase)	1184	**1.03 (1.01–1.05), p<0.001**	**1.03 (1.00–1.05), p=0.022**

Conclusions

- PMEGs seem to be a **safe** and **effective** treatment option for **elective**, **symptomatic** and **ruptured** complex aortic aneurysms in **experienced** centers.
- More complex designs such as inclusion of directional branches or extra target vessels increases risk of technical failure and adverse events
- Outcome research of different techniques will provide opportunity for standardisation
- A PMEG modification kit would be a great add-on

THANK YOU