

LMU KLINIKUM DER UNIVERSITÄT MÜNCHEN CAMPUS GROSSHADERN CAMPUS UNIVERSITÄT GEFÄSSCHIRURGIE 550 Jahre LMU MEDIZIN

Transatlantic Multicenter Study on the Use of a Modified Preloaded Delivery System for Fenestrated Endovascular Aortic Repair (MPDS-FEVAR Study)

Univ. Prof. Nikolaos Tsilimparis
 Head of Department of Vascular Surgery
 University Aortic Center of
 Ludwig Maximilian University Hospital Munich

On behalf of the investigators of the International Study on Preloaded Fenestrated Endografts with a Modified Biport Handle

VEITH SYMPOSIUM KLINIKUM DER UNIVERSITÄT MÜNCHEN DEPARTMENT OF VASCULAR SURGERY

Conflicts of interest

- Proctor for Cook medical
- Research funding from Cook Medical, Bentley

KLINIKUM DER UNIVERSITÄT MÜNCHEN DEPARTMENT OF VASCULAR SURGERY

The Device – modified preloaded delivery system

The design

As Made and Loaded Anterior Markers Tick Mark B

Manifold with Labels and Catheters

Second Release Delivery Catheter

KLINIKUM DER UNIVERSITÄT MÜNCHEN DEPARTMENT OF VASCULAR SURGERY

Background

Theoretical advantages:

- Reduce the need for large sheaths on the contralateral side
- Easier cannulation of renal arteries
- Less access complications in patients with stenosed iliacs
- Allows treatment of patients with contralateral iliac artery occlusion
- Decrease overall procedure time

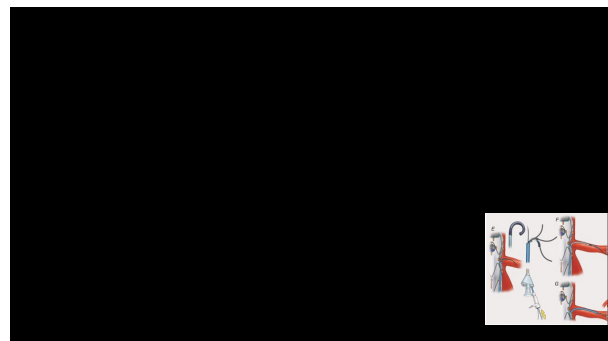
KLINIKUM DER UNIVERSITÄT MÜNCHEN DEPARTMENT OF VASCULAR SURGERY

Preloaded fenestrated with biport handle – additional vessels

Preloaded fenestrated with ipsilateral biport handle allows for up to 6 target vessels to be targeted for below

Rerouting of the renal preloaded catheter in the SMA/ celiac to facilitate 3rd/4th vessels from above

KLINIKUM DER UNIVERSITÄT MÜNCHEN DEPARTMENT OF VASCULAR SURGERY



Results

- 712 patients collected
- 16 centers included

- Ludwig Maximilian University Hospital, Germany - **Wolfram Teitelbaum / Ryan C. Hale**
- University and ASST Spedali Civili Hospital of Brescia, Brescia - **Luca Bergaglio**
- University of Massachusetts, USA - **Andras Schenker**
- University of Lille, France - **Jonathan Sobocinski / Thomas Mesnard**
- University of Maastricht, Germany - **Matthias Auberger**
- Osedale San Raffaele, Italy - **Roberto Chiesa / Oreste Locati**
- Copenhagen University - **Tim Beuch / Nicola Leone**
- University of Bologna, Italy - **Mauro Gargiulo / Enrique Gallo / Paolo Spah**
- University of Southampton, Dublin, USA - **Carlo Timaran / Jesus Colon**
- Nantes University, France - **Stéphane Meuret**
- University Hospitals Birmingham - **Donald Adam / Amro Elbousfi**
- U. Lund, Malmö, Sweden - **Nuno Dias / M. Wachsmister / B. Sennson**
- UTMS, Houston, USA - **Guillermo Odehik, Emanuel Tenorio**
- Hamburg Heart Center, Germany - **Theo Kibitz / Giuseppe Panico**
- Dorset Heart Hospital, Valencia, Spain - **Francisco Coma Palones**
- Santa Maria della Misericordia Hospital, Perugia, Italy - **Gioele Simoni / Giacomo Isarita**
- Roma San Giovanni-Addolorata Hospital, Italy - **Becco Giudice**

KLINIKUM DER UNIVERSITÄT MÜNCHEN
DEPARTMENT OF VASCULAR SURGERY

Results n=712

Baseline Data

Patient demographics and risk factors	Total N(%)
Age (in years)	73 (68-78)
Sex (male)	591 (83)
ASA risk: 3	631 (89.2)
Coronary artery disease	295 (41.4)
Hypertension	645 (90.6)
Hyperlipidemia	507 (71.0)
Smoking	464 (65.2)
COPD	261 (36.7)
Peripheral arterial disease	151 (21.1)
Type 2 Diabetes Mellitus	96 (13.5)
Chronic kidney disease	223 (31.4)
IGFR <60	
Previous stroke or TIA	79 (11.1)

Aneurysm subtype

- Complex AAA: 460 (64.6%)
 - Juxta-renal: 288 (40.4%)
 - Para-renal: 172 (24.2%)
- TAAA: 252 (35.4%)
 - Extent IV: 99 (13.9%)
 - Extent I-III/V: 153 (21.5%)

KLINIKUM DER UNIVERSITÄT MÜNCHEN
DEPARTMENT OF VASCULAR SURGERY

Preloaded Target vessels=1628

Preloaded target vessels

Device Design	Target vessels	Median 4 (IQR: 3-4)
>4 target vessels	4.6%	
Total number of preloaded TV	1628 (59% of all included TVs)	

Accessed from below 1442 (88.5%)

Renals	SMA	CT
1375 (49.9%)	40 (1.4%)	25 (0.9%)

Accessed from above 188 (11.5%)

SMA	CT
95 (3.4%)	93 (3.4%)

KLINIKUM DER UNIVERSITÄT MÜNCHEN
DEPARTMENT OF VASCULAR SURGERY

Results

Anatomical details:

- 34.1% had moderate-severe iliac calcification
- 4.2% of patients had only one patent iliac axis
- 24% of patients had iliac access <6.5mm

KLINIKUM DER UNIVERSITÄT MÜNCHEN
DEPARTMENT OF VASCULAR SURGERY

Results

Reported reasons for using the system

ROUTINE USE	Percentage
DONWARD FACING RENALS	36.1%
STENOSED ACCESS	12.1%
PREVIOUS EVAR WITH SR	9.2%
ILIAC OCCLUSION	4.5%
ADDITIONAL TARGET VESSEL	2.1%
ACCESS/AORTIC TORTUOSITY	1.5%
PREVIOUS RENAL STENTING	1.1%
STENOSED RENAL ARTERIES	0.5%
PREVIOUS OPEN AORTIC...	0.3%

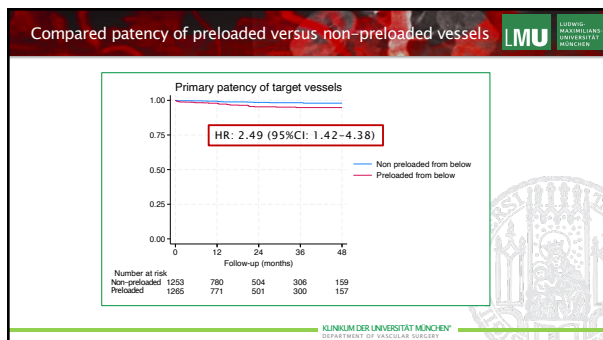
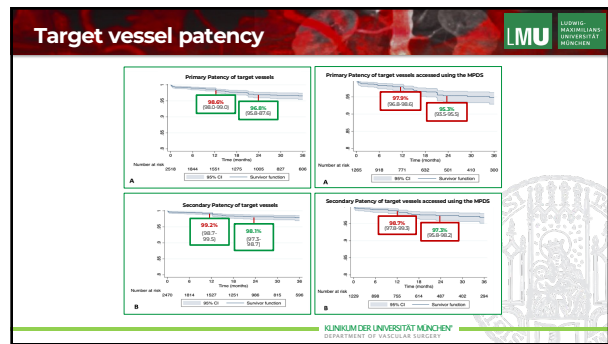
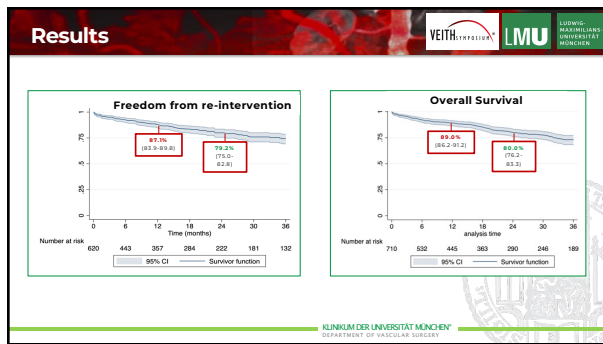
KLINIKUM DER UNIVERSITÄT MÜNCHEN
DEPARTMENT OF VASCULAR SURGERY

Results

Outcomes (30-day)

	N	Total N (%)
Technical success	712	684 (96.1)
Technical success using the MDPS	685	664 (96.9)
30-day mortality	712	34 (4.8)
Major adverse events	502	86 (17.1)
Access related complications	710	48 (6.8)
Early re-intervention	710	50 (7.0)
Aortic or side-branch related		42 (5.9)
Non-aortic or side-branch related		8 (1.1)

KLINIKUM DER UNIVERSITÄT MÜNCHEN
DEPARTMENT OF VASCULAR SURGERY



Conclusions

- The COOK® Modified Preloaded Delivery System with the biport handle seems to be **safe and effective** in the treatment of complex aortic aneurysms
- Overall benefits include reducing contralateral sheath size, easier cannulations in challenging anatomies and reducing surgery duration

KLINIKUM DER UNIVERSITÄT MÜNCHEN
DEPARTMENT OF VASCULAR SURGERY

THANK YOU

550 Jahre
LMU MEDIZIN
Exzellenz seit 1472

KLINIKUM DER UNIVERSITÄT MÜNCHEN
DEPARTMENT OF VASCULAR SURGERY