BORDEAUX
PERSPECTIVES 2019
November Friday 29

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FEVAR with Physician modified Stentgrafts assisted by 3 D printing

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Urgent Complex Aortic Pathologies in High Risk Patients

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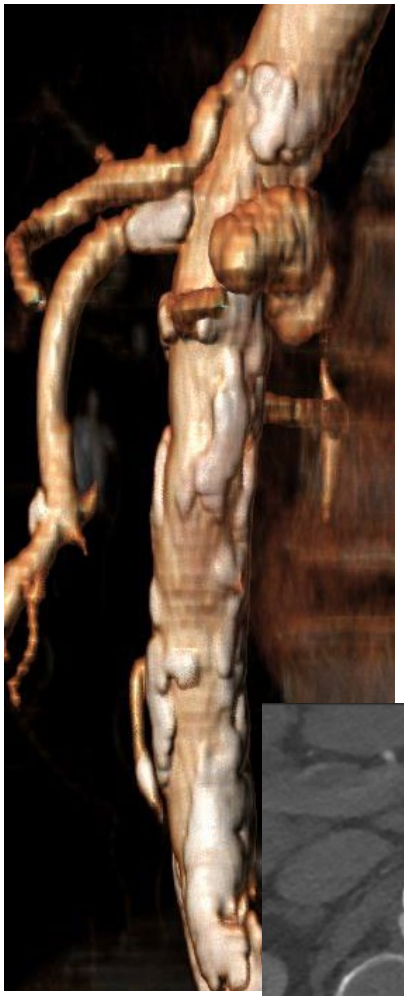





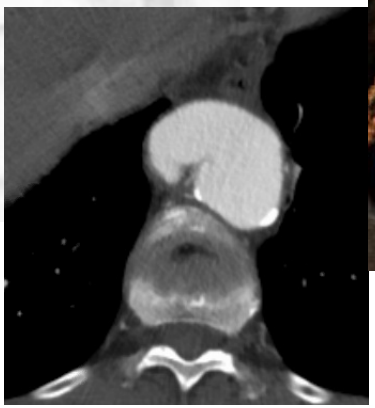



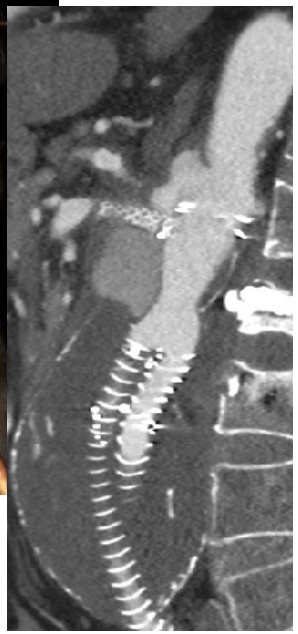

Endovascular Treatment Options for Complex Aortic Pathologies

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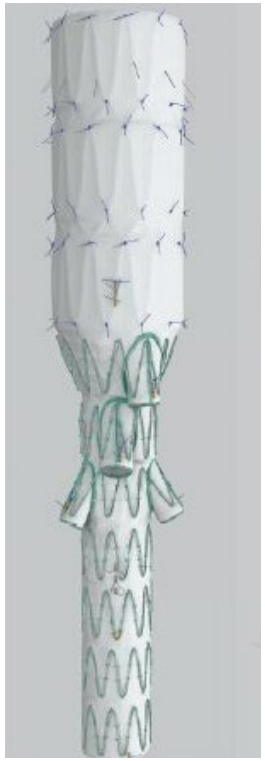
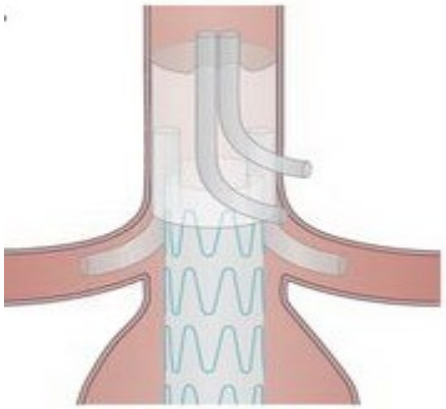
Manufactured fenestrated and branched stentgrafts (CMD)



„Off the shelf“ fenestrated and branched devices



Parallel stenting approaches („chimney“, „sandwich“, etc.)



Physician modified fenestrated stent graft (PMSG)

Commercially Manufactured CMD Device

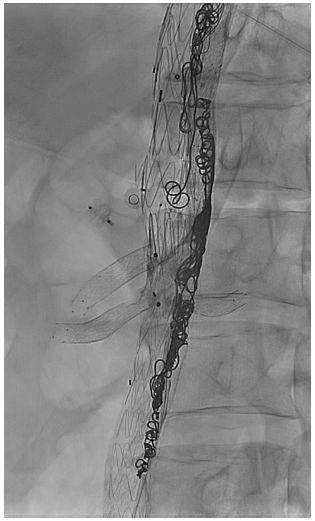
- Not suitable for emergent setting:
  - Rapidly expanding AAA
  - Symptomatic AAA
  - (Contained) Ruptured AAA hemodynamically stable



Parallel Techniques

- Complex procedures
- Uncertain long-term patency of reconstructed visceral vessels
- High risk of Type I Endoleak which is very difficult to treat





Physician Modified Fenestrated Stent Grafts

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J Vasc Interv Radiol. 2006 Dec;17(12):1935-42.

Clinical experience with a customized fenestrated endograft for juxtarenal abdominal aortic aneurysm repair.

Uflacker R[1], Robison JD, Schonholz C, Ivancev K.

- 2006: first description in a series of 3 patients
  - Technical success: 100%
  - FU 4-14 months:
    - No procedure-related complications
    - No Endoleak

VERY FEW STUDIES ARE AVAILABLE ON

PM- FENESTRATIONS

J Endovasc Ther. 2015 Oct 23. pii: 1526602815611887. [Epub ahead of print]

Systematic Review of Off-the-Shelf or Physician-Modified Fenestrated and Branched Endografts.

Georgiadis GS[1], van Herwaarden JA[2], Antoniou GA[3], Hazenberg CE[2], Giannoukas AD[4], Lazarides MK[5], Moll FL[2].

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- Meta-analysis from January 2001 - March 2015
  - 15 articles on PMSG vs. 8 on off-the-shelf devices / 308 patients (mean age 72.93)
  - 1/3 emergencies
  - Mean aneurysm diameter: 75.9 mm vs. 68.1 mm
  - 458 vs. 478 target vessels
  - MAEs: 12.8% vs. 7.4%
- Technical success: 91.4% vs. 95% Mortality: 3.2% (1.1% aneurysm related) vs. 0%
- Overall target vessel patency: 96.7% vs. 97.9%

Leipzig's Experience with PMSG: August 2015 - October 2019

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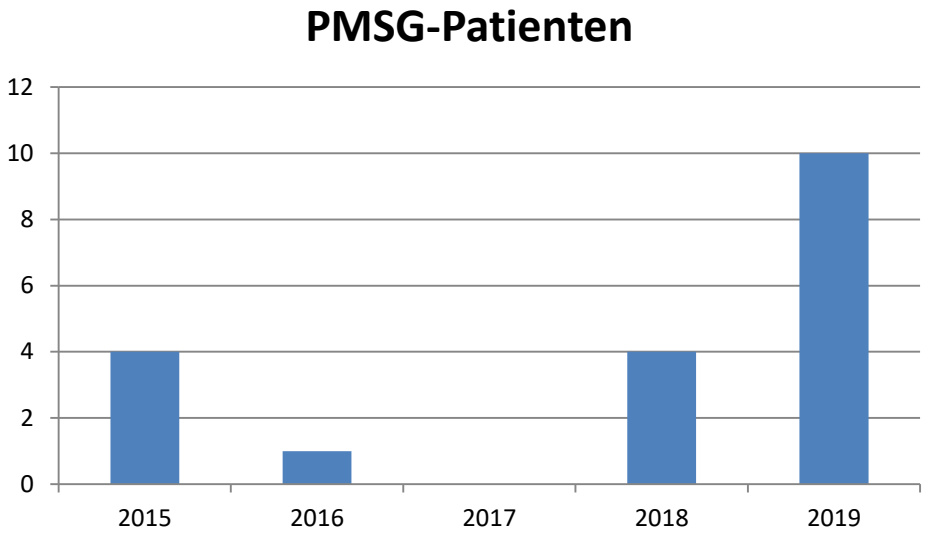
Variables			***N***
Total			19
	Male		17
Age	Mean ±SD(y)		69,8±9,4
Hypertension			19
DM			6
KHK			1
Smoker			11
COPD			4
PAOD			3
HLP			13
Renal Insufficiency			6
BMI	Mean±SD		26,5±3.1
	Median (Range)		27,4 (20,8-30)
ASA Classification		4	1
		3	16
		2	2



Data under review

Characteristics of Patients with Acute Aortic Pathologies

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	Variables		N
Clinical presentation*	Contained Rupture		6
	Symptomatic		13
Diameter (mm)	Mean±SD		72,1±9.6
Localization of aortic pathology			
thoraco-abdominal AAA	Type III	Aneurysm	1
	Type IV		10
		Aneurysm	6
		PAU	4
Juxtarenal AAA			8
		Aneurysm	6
		PAU	1
		Suture Aneurysm	1
Previous abdominal surgery			4

**no elective Patients*



Data under review

Manufacturing of PMSG 2015-2016

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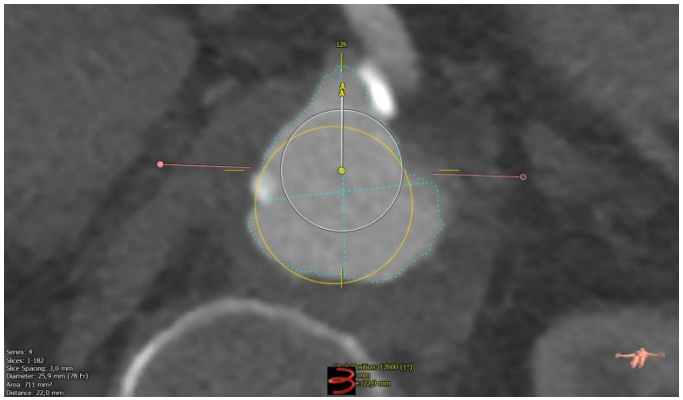
- Device sizing and planning of the fenestrations based on CTA and 3D reconstructions – 3Mensio Software

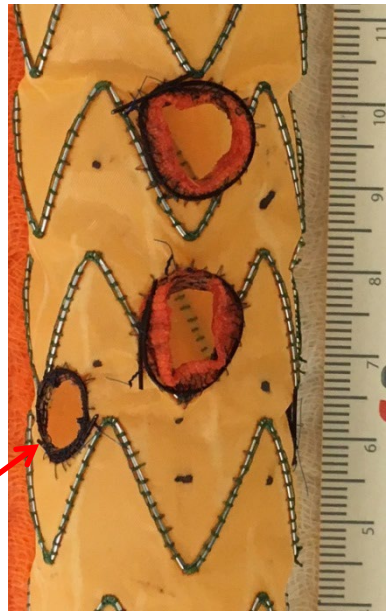


- Graft is manufactured according to measurements under sterile conditions pre Intervention:
  - Location of the fenestrations is pre-marked between struts with sterile marker
  - Hole created in the fabric with a scalpel

Manufacturing of PMSG 2015-2016



- Large Fenestrations: 8mm
  - Reinforced with 8mm Dacron Graft sewn with 6/0 Prolene suture
  - the tip of a V18 guidewire is used as a radio-opacifier





- Small Fenestrations:7mm
  - 7mm Snare sewn with 6/0 Prolene sutureis used as a radio-opacifier

Potential Limitations in the Treatement with PMSG

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- The time needed to measure and position the fenestrations.
- The accuracy of the position of the fenestrations.

Scali ST et al J vasc surg 62 (5), 1148-59.e2.

May the use of sterilized 3-DAM facilitate the planning of the fenestrations?

3-D Aortic Models (3-DAM)

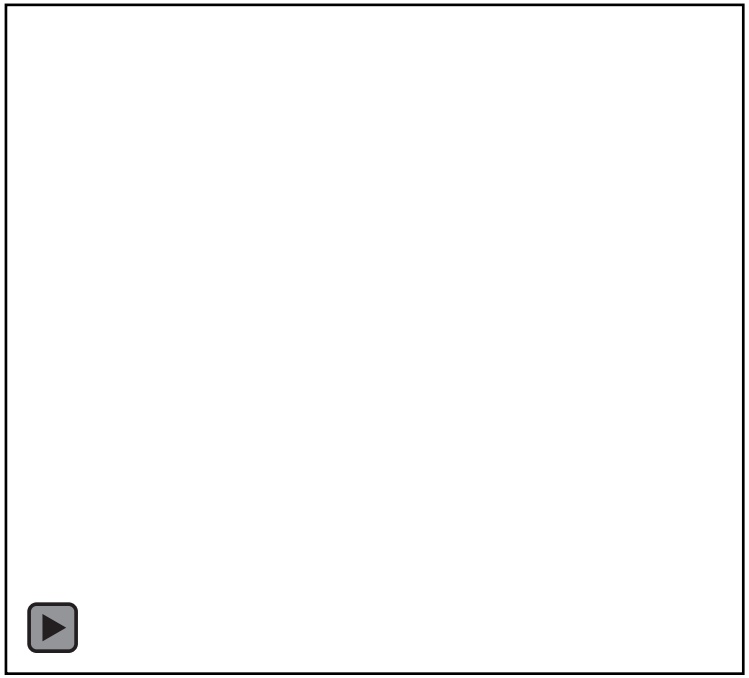
- 3-DAM were proposed as a strategy to eliminate those problems in a phantom aorta.

  Leotta DF et al J vasc surg 61 (6), pp. 1637–1641.

- The clinical use of 3-DAM is limited until this point.

  Huang J et al . Vascular 25 (4), pp. 442–446.

  Rynio P et al J Endovasc Ther. 2018Oct;25(5):554-558.

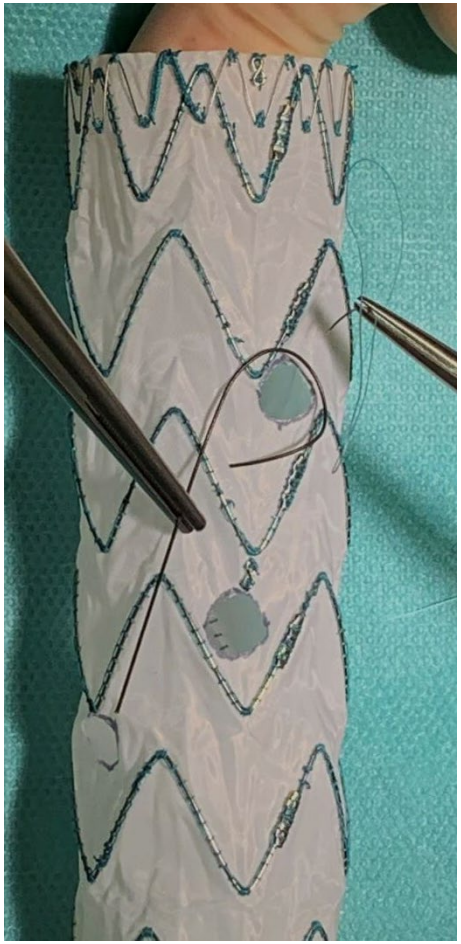




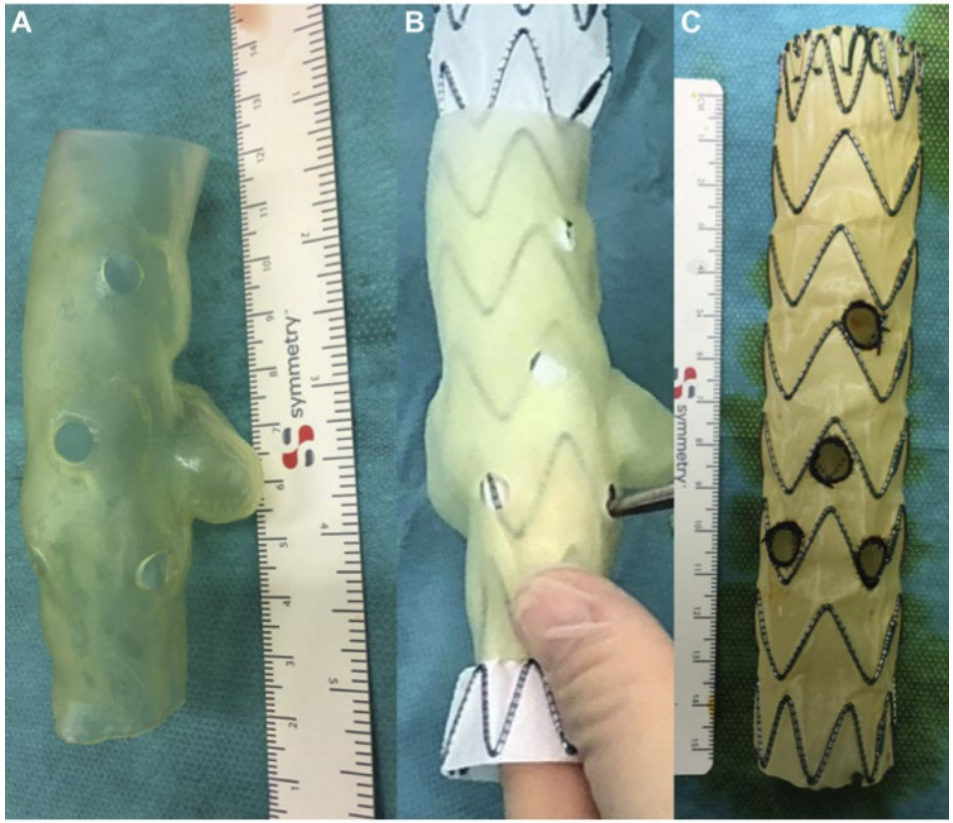
© Universitätsklinikum Leipzig AöR (2019): 3DAM, DCK, Branzan







Manufacturing of the PMSG since 2017



Three-dimensional printed aortic model. **(B)** Preparation of fenestrations. **(C)** Physician-modified stent graft.

Branzan D, et al .JACC Cardiovasc Interv. 2019 Apr 22;12(8):793-795.

3-D Aortic Models (3-DAM)

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- Printing time: 6h
- Sterilization: 1h steam pressure





Planning and Manufacturing of the PMSG: Fenestrations

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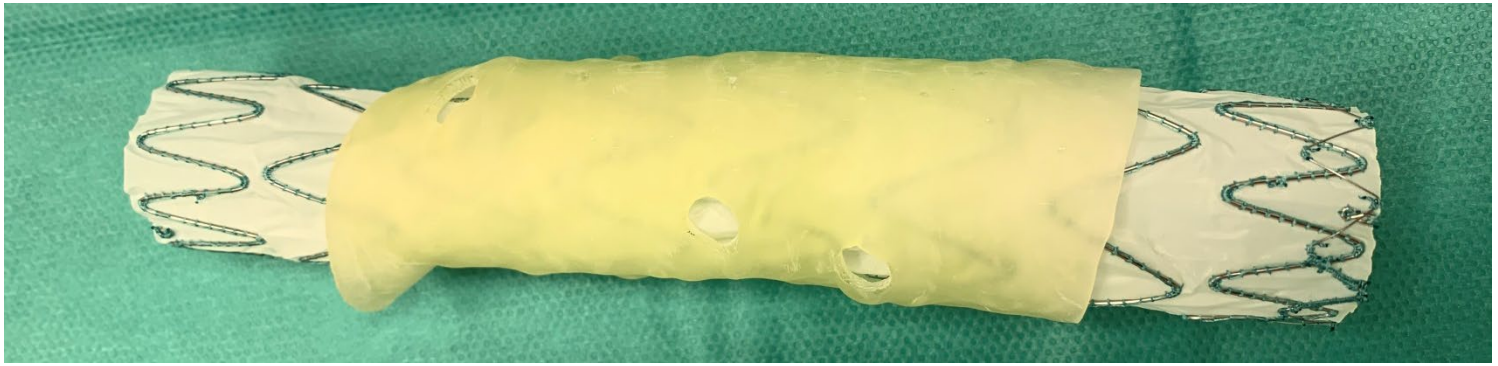

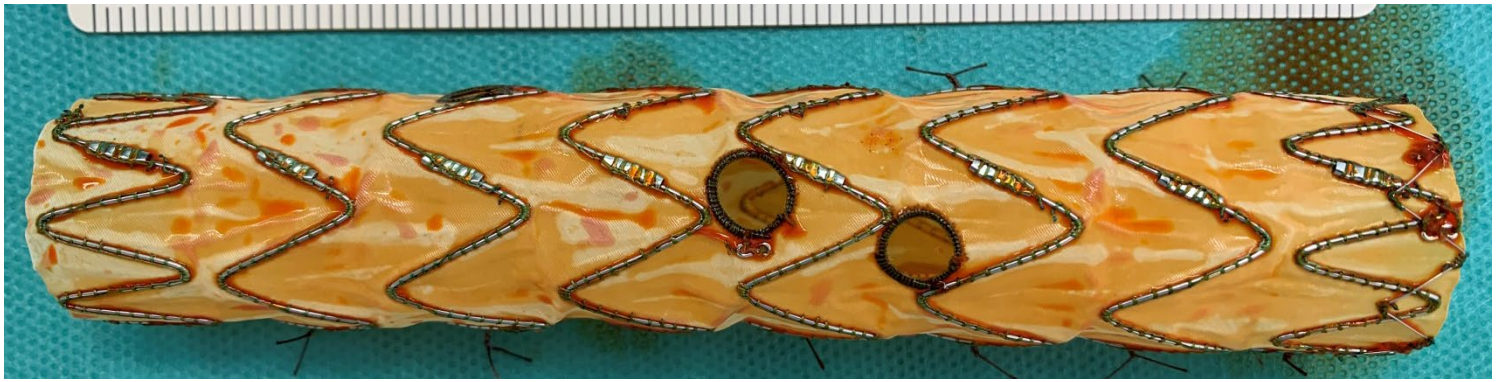

- **Valiant Captivia closed-web** thoracic Stentgraft (Medtronic, MN, USA)
- **Ethibond 6-0 sutures** (Ethicon Inc., Johnson and Johnson, USA)
- Radioopaque marker: Tip of a **V-18 guidance catheter** (Boston Scientific, MA, USA) for reinforcement of the fenestrations
- 10 min **Rifampicin solution**

Manufacturing of the PMSG: Reducing Ties

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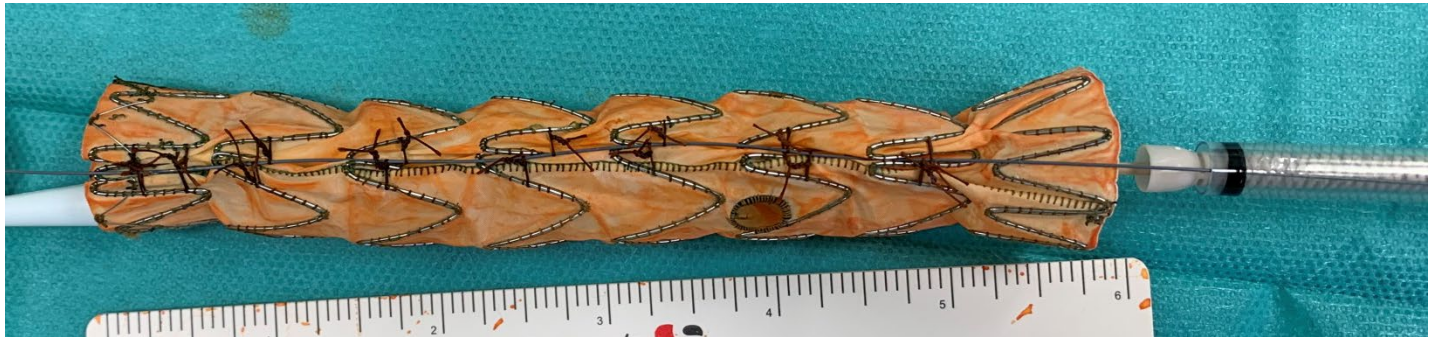

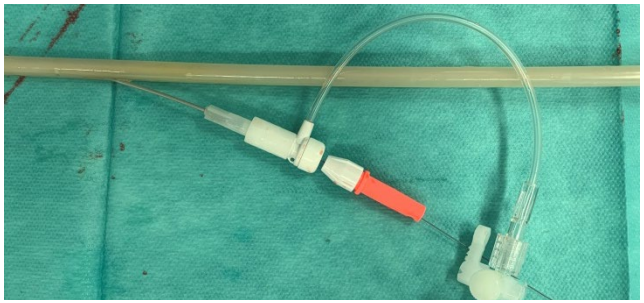

Manufacturing of the PMSG: Endoprothesis

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Variables			***N***
Modified Graft	Valiant Captivia Closed web		18
	Aorto uni Endurant		1
3DAM			12
Reducing Ties			3
Fenestrations			71
	4		16
	3		1
	2		2
Distal component	none		5
	tubular		1
	bifurcated		13
		Endurant	2
		Gore	11
Thoracic extension			2





Data under review

Manufacturing time of the PMSG

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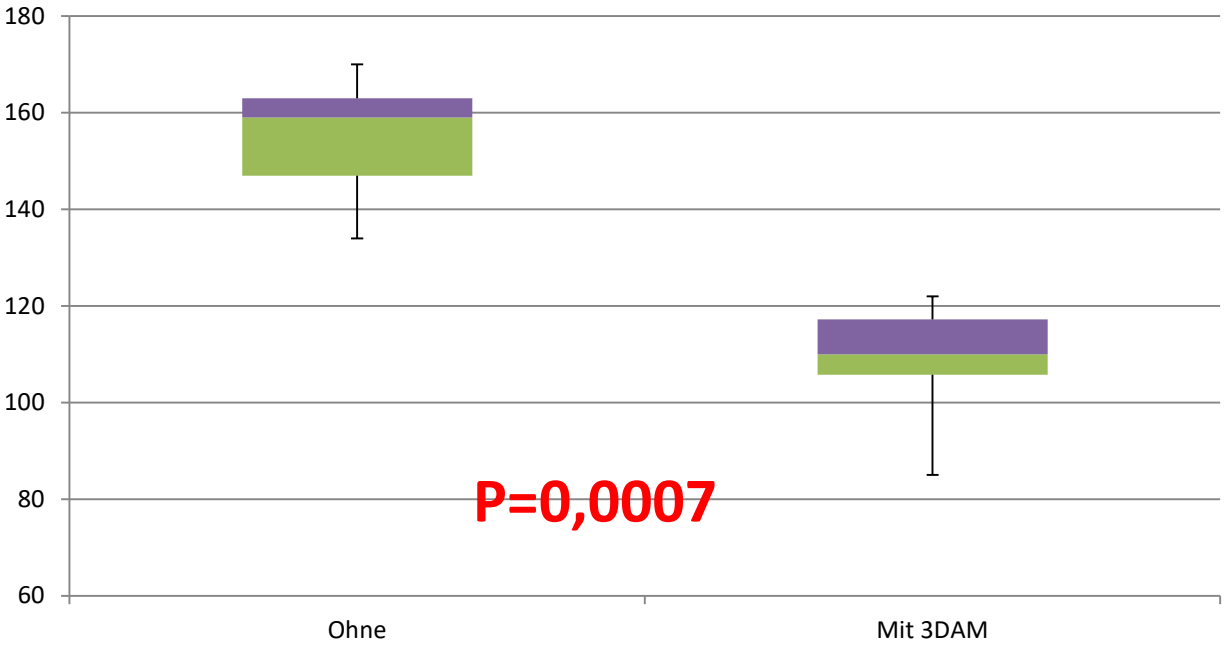
- Mean manufacturing time of the PMSG:
  - **Without 3DAM**: 154,6 ± 12,7min
  - **With 3DAM**: 109,6 ± 10,7min



Data under review

Implantation of the PMSG

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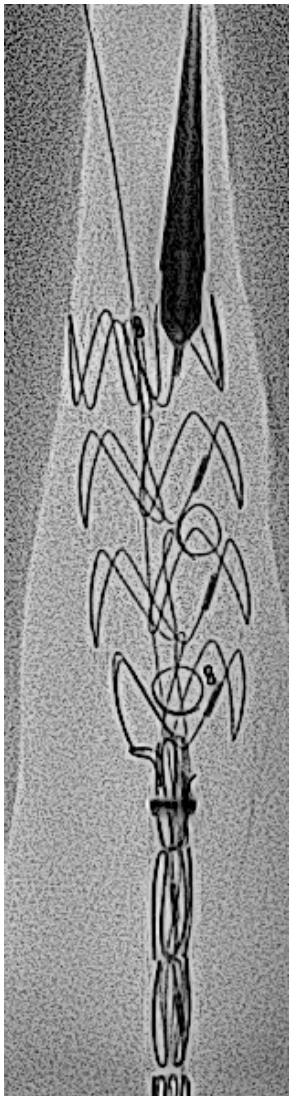

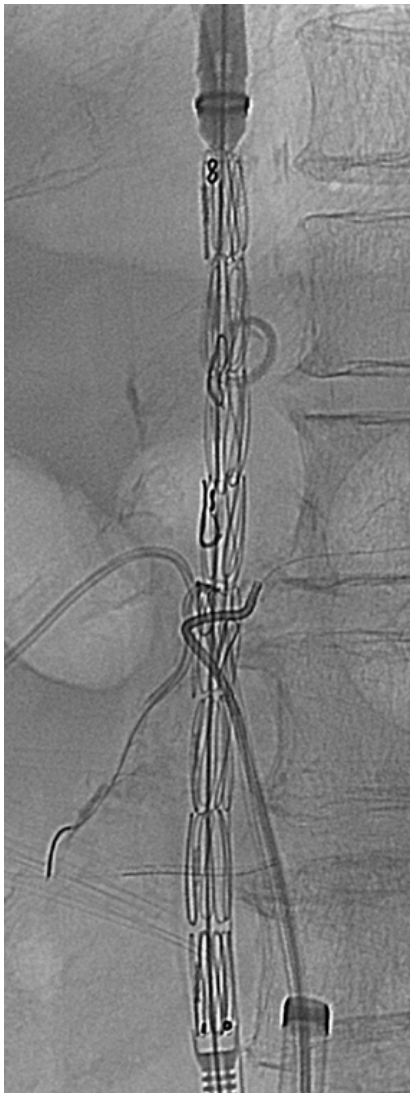



Implantation of the PMSG

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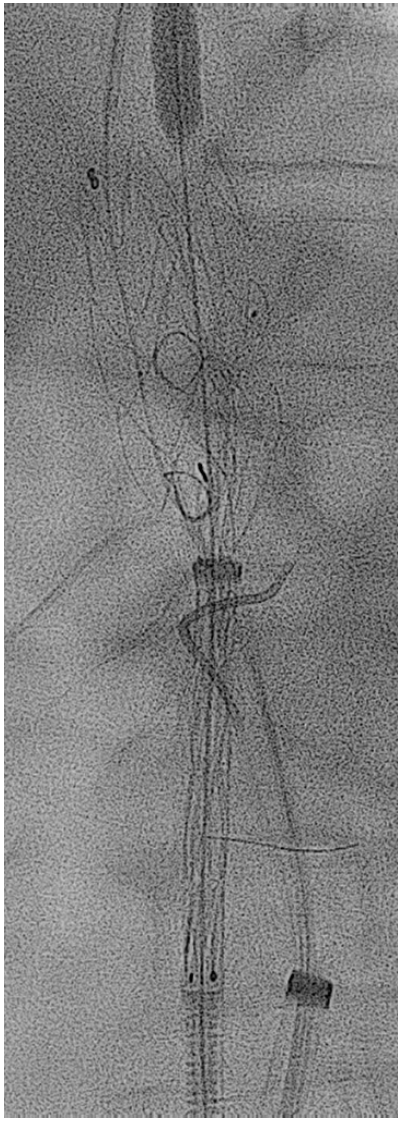
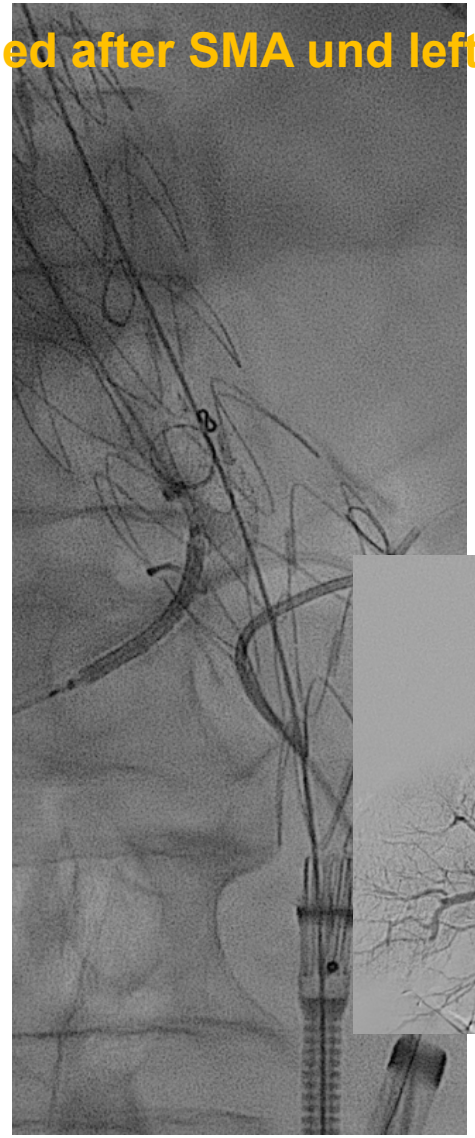
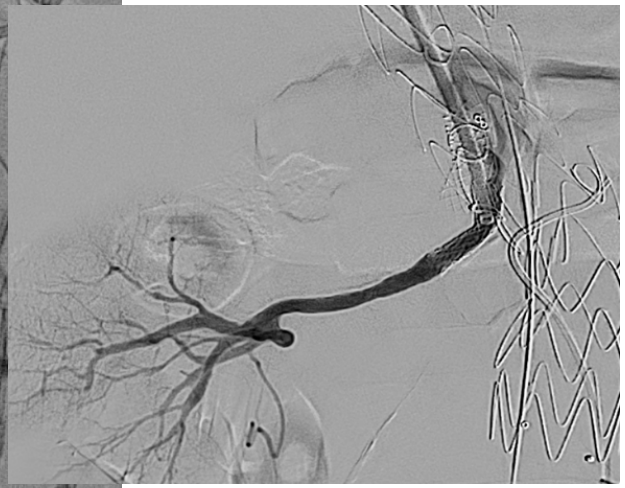


The PMSG was aligned after SMA und left RA in the aorta







Implantation of the PMSG

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Each Vessel was cannulated with a guiding catheter via the left brachial artery

Implantation of the PMSG

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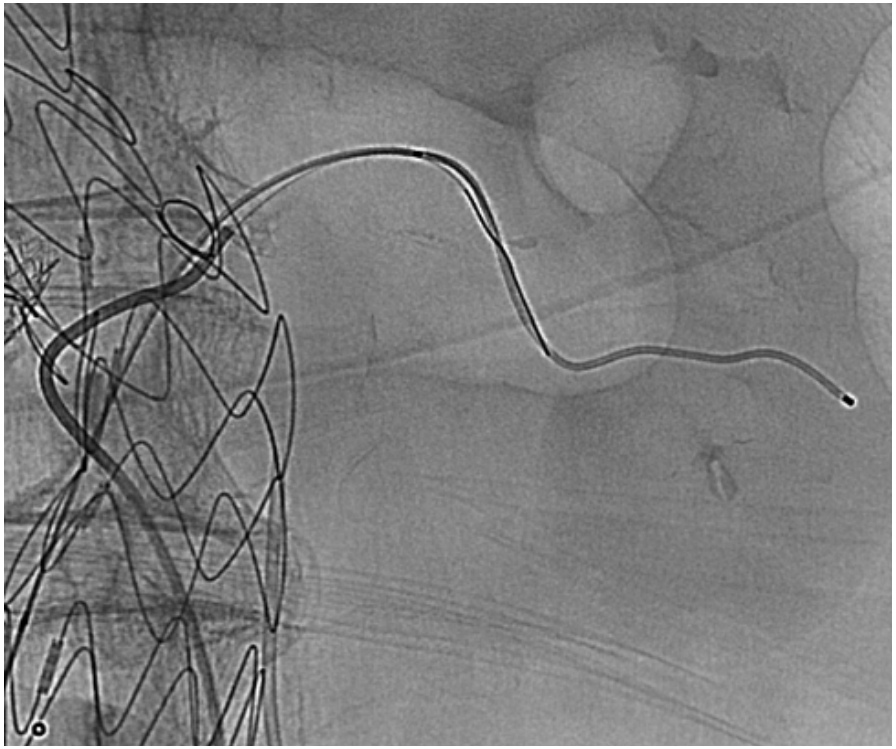



Balloon-expandable covered bridging stents were placed in the fenestrations and the corresponding target vessels

EVAR - Procedures

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Variables			***N***
General Anesthesia			19
Access	Percutaneous		17
	surgical	fem-fem coBP	1
		TEA CFA	1
Duration of Procedure (min)	Mean±SD		174,6±49,4
	Median (Range)		161 (79-269)
X Ray Time (min)	Mean±SD		54,7±18,6
	Median (Range)		55 (17-99)
CT			17
	Lifestream		5
	Begraft		9
	VBX		3
SMA			19
	Lifestream		5
	Begraft		12
	VBX		2
RA			35
	Lifestream		9
	Begraft		19
	VBX		7

Data under review

Results @ 30 days

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Variables		***N***
ICU Stay (days)	Mean±SD	2,8±3,7
	Median (Range)	1 (1-14)
Hospital Stay (days)	Mean±SD	17,3±10,4
	Median (Range)	15 (5-38)
Death		0
Stroke		0
SCI		2
Acute renal failure		1
Access complications		2
Endoleaks	Type Ia	1
	Type Ic	1
	Type II	1
Reintervention		2

→ Reversible
→ Reversible after RRA Recanalization
→ PSA A. brachialis, AFC Stenosis

→ Recanalization of RRA
→ Coiling of Aneurysm Sack

Data under review

Follow-up with CTA

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FIGURE 1 Paravisceral Penetrating Aortic Ulcer



Three-dimensional volume rendering reconstructions of computed tomographic angiography showing the penetrating aortic ulcer before **(A)** and after **(B)** treatment.

Branzan D, et al .JACC Cardiovasc Interv. 2019 Apr 22;12(8):793-795.

Follow-Up

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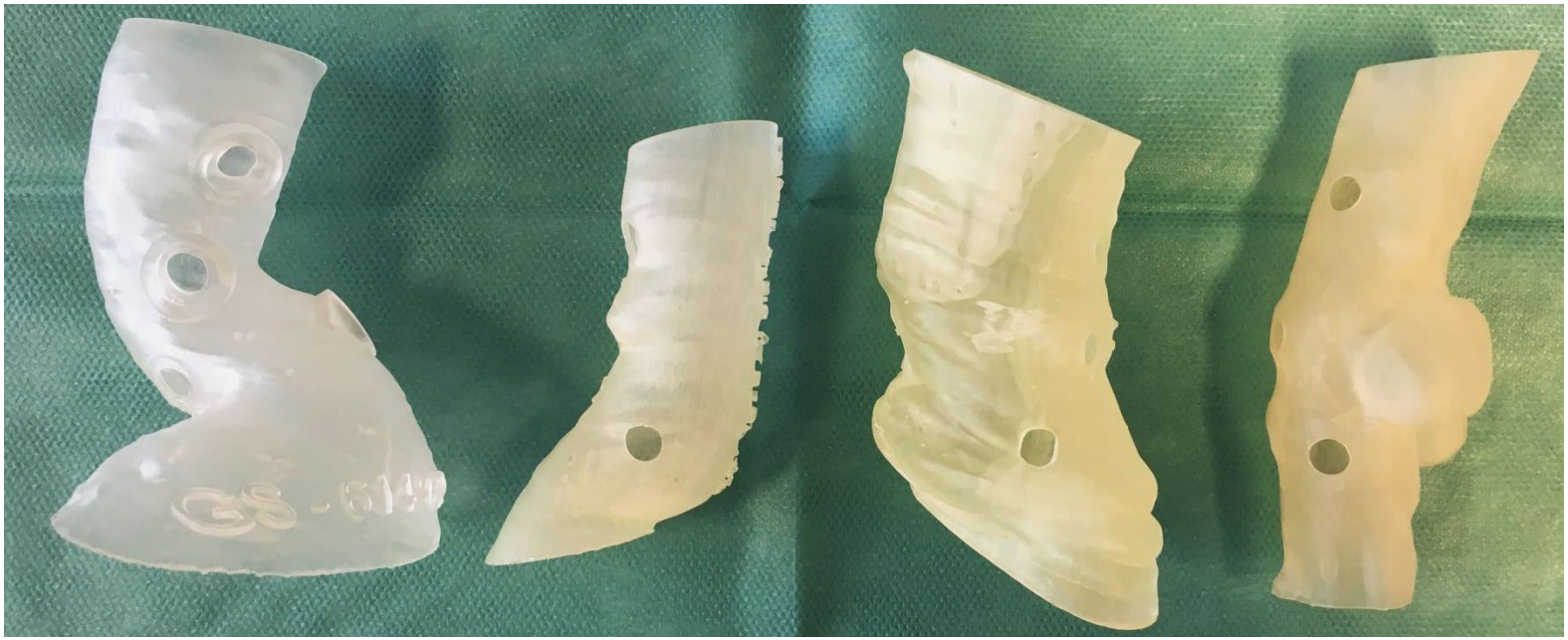
- Mean Follow-Up: 13,8 (1-45,3) Months
- Death: 1 @ 1Jahr
  - Due to Bone-TBC
- Endoleak:
  - Type Ic: 1
  - Type II: 1
- Reinterventions:
  - 1 renal Recanalisation @ 361. POT
  - 1 relining Lifestream @ 76. POT for EL Type Ic

Data under review

Conclusion

- 3-D printing allows the manufacturing of patient specific devices as treatement option for complex paravisceral aortic pathologies, leading to a significant reduction in planning and manufacturing time and potentially increasing the accuracy.



Thank you!





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