

# The use of aortic BeGrafts to treat aorto-iliac occlusive disease

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# Disclosures

- Research grant Cardionovum, BTG, Philips
- Consultant Medtronic, Endologix Inc
- Advisory board member Endologix Inc
- Speaking fee Bentley InnoMed

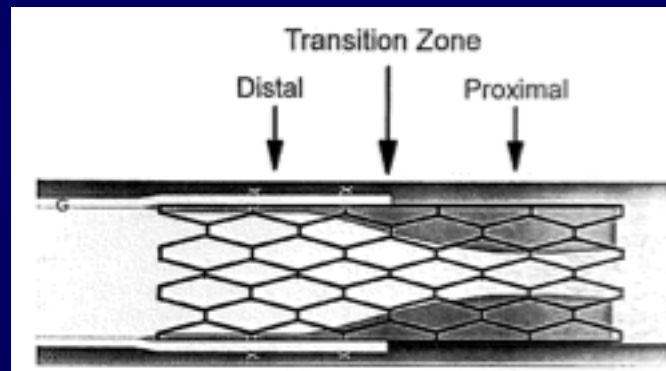


# First reports covered stents

## Effect of Polytetrafluoroethylene Covering of Palmaz Stents on the Development of Intimal Hyperplasia in Human Iliac Arteries<sup>1</sup>

JVIR 1996; 7:651-656

Marin ML, Veith FJ, et al.



- 12 long-segment iliac artery occlusions
- Covering at each Palmaz stent over  $\frac{1}{2}$  of its length
- Mean lumen  $\odot$  7.7 mm (cov) vs 6.7 mm ( P < .01)



# Experimental studies

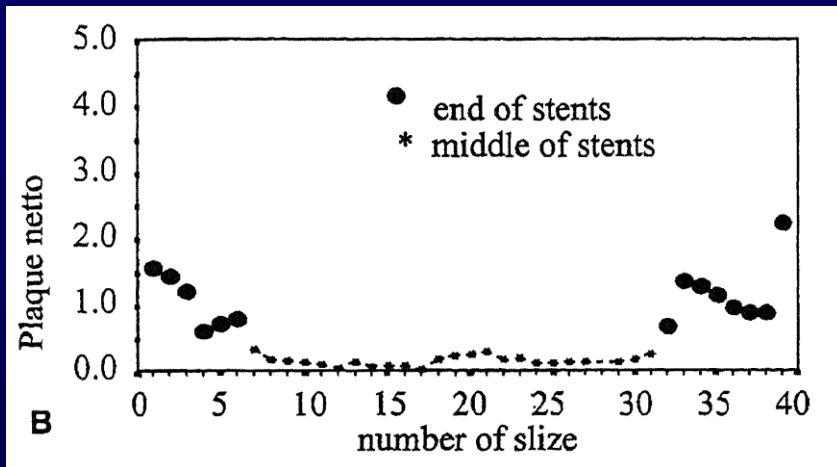
## Neointima Formation After Stent Implantation in an Experimental Model of Restenosis

Heart Disease 2002;4:18-25

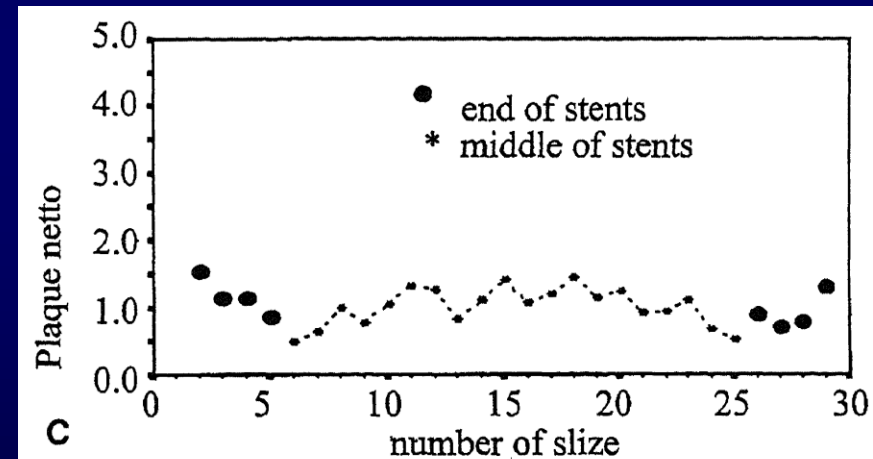
### Polytetrafluoroethylene-Covered Versus Uncovered Stainless Steel Stents

Peter B. Sick, MD,\* Oana Brosteanu, PhD,† Josef Niebauer, MD, PhD,\* Christoph Hehrlein, MD,‡ and Gerhard Schuler, MD\*

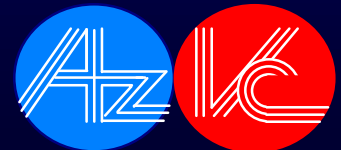
Covered



Uncovered



PTFE prevents intimal hyperplasia in the middle  
Hyperplasia migrates from ends towards middle



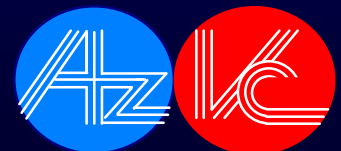
# Clinical Evidence *covered stents*

**Table 2 Results of studies reporting on the results of PTFE-covered stents for PAOD in the iliac artery**

Author, year	Type of study	Number	Type of stent	Freedom of binary restenosis	
				Covered	Uncovered
Sabri, 2010 [54]	Retrospective, comparative	26 covered 28 uncovered	Balloon-expandable	1 year: 92% 2 year: 92%,	1 year: 78%, 2 year: 62%
Lammer, 2000 [61]	Prospective	61	Self-expanding	6 month: 98%, 1 year: 91%	
Wiesinger, 2005 [62]	Prospective	60	Self-expanding	6 month: 94%, 1 year: 91%	
Bosiers, 2007 [63]	Prospective	91	Balloon-expandable	1 year: 91%	
Chang, 2008 [53]	Retrospective, comparative	71 covered 122 uncovered	Mostly self-expanding	5 year: 87%	5 year: 53%
Mwipatayi, 2011	Randomized controlled trial	83 covered 84 uncovered	Both	18 month: 92%	18 month: 75%

Bekken et al, Trials 2012; 13:215

- 1 RCT



## Clinical Evidence *covered stents*

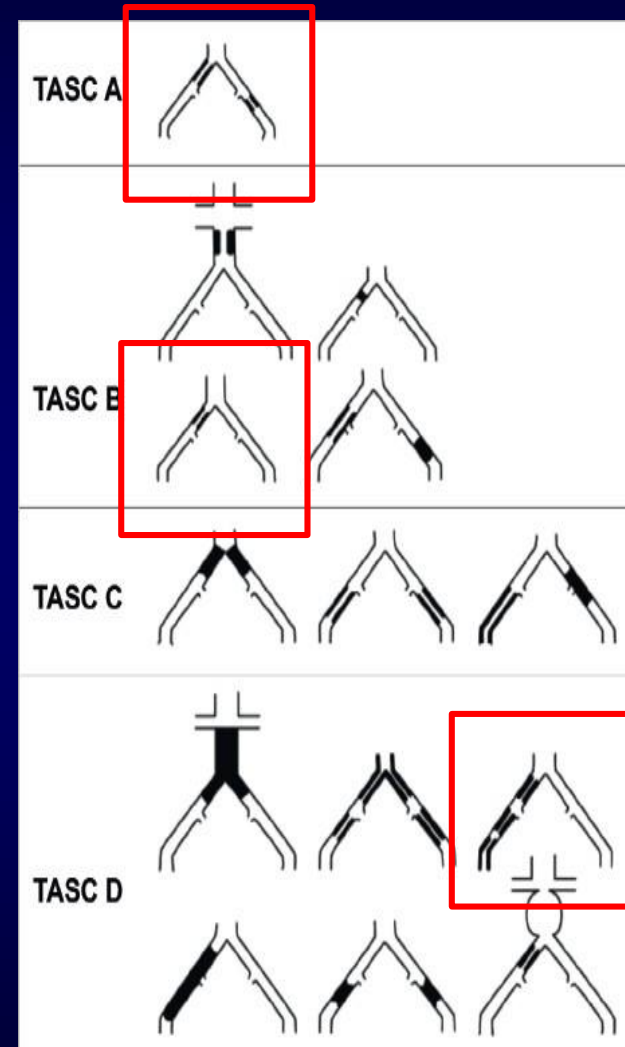
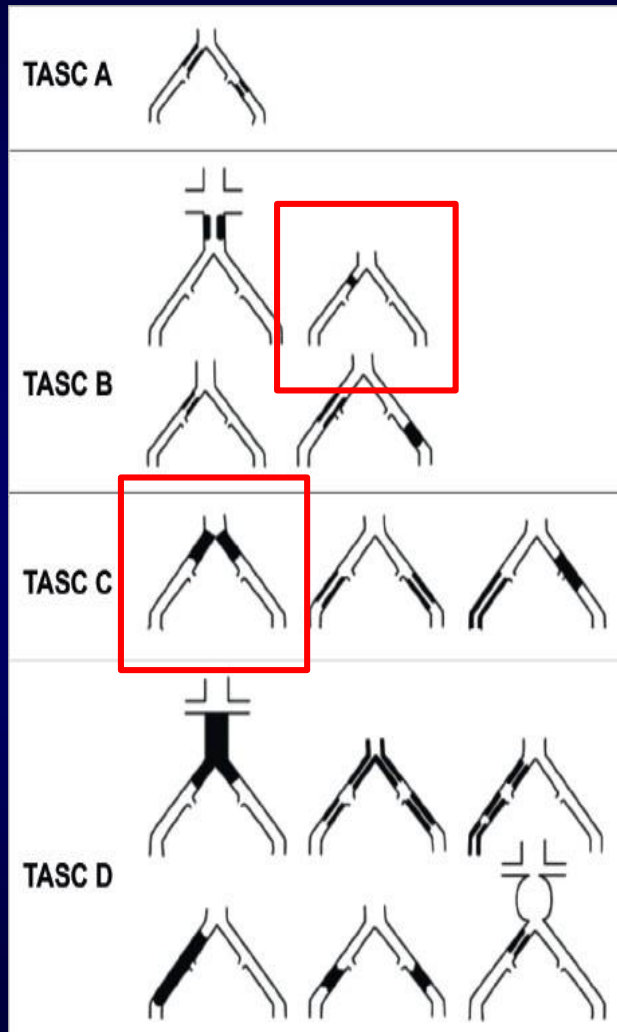
Durability of the balloon-expandable covered versus bare-metal stents in the Covered versus Balloon Expandable Stent Trial (COBEST) for the treatment of aortoiliac occlusive disease

Bibombe P. Mwipatayi, MMed (Surg), FCS (SA), FRACS,<sup>a,b</sup> Surabhi Sharma, MBBS,<sup>a</sup>  
Ali Daneshmand, MD,<sup>a</sup> Shannon D. Thomas, BMedSc, FRACS,<sup>c,d</sup> Vikram Vijayan, MRCS, FRCS,<sup>e</sup>  
Nishath Altaf, PhD, FRCS,<sup>a</sup> Marek Garbowski, MB BS, FRACS,<sup>f</sup> and Mark Jackson, MD, FRACS,<sup>g</sup> on  
behalf of the COBEST co-investigators,\* *Perth, Sydney, and Queensland, Australia; and Singapore*

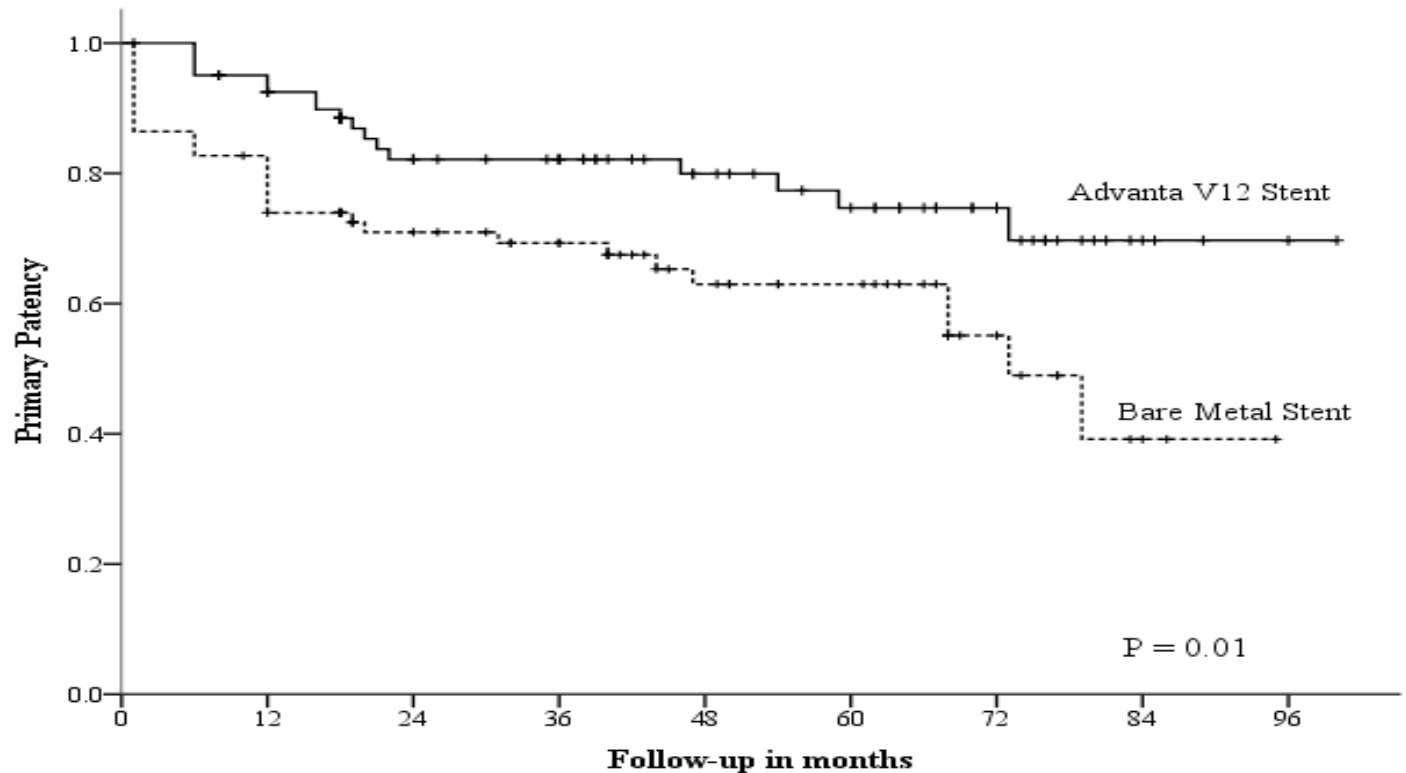
**J Vasc Surg 2016;64:83-94**



# TASC II (limitations)



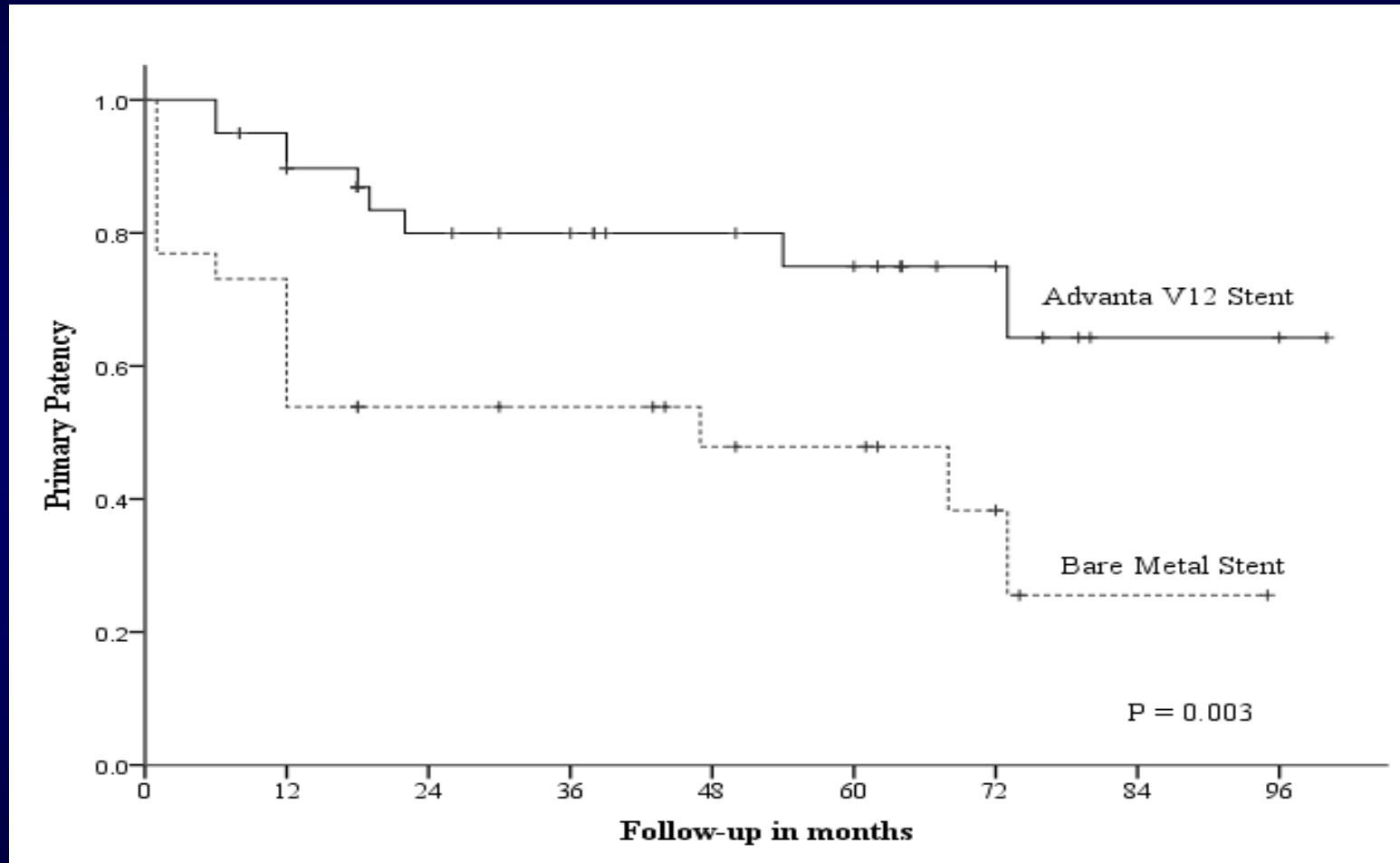
# Effectiveness: adjusted primary patency



Months	0	12	24	36	48	60	72	84	96
Advanta V12 Stent (n. at risk)	83	80	68	46	34	22	10	3	3
BMS (n. at risk)	85	80	69	45	33	21	9	2	2

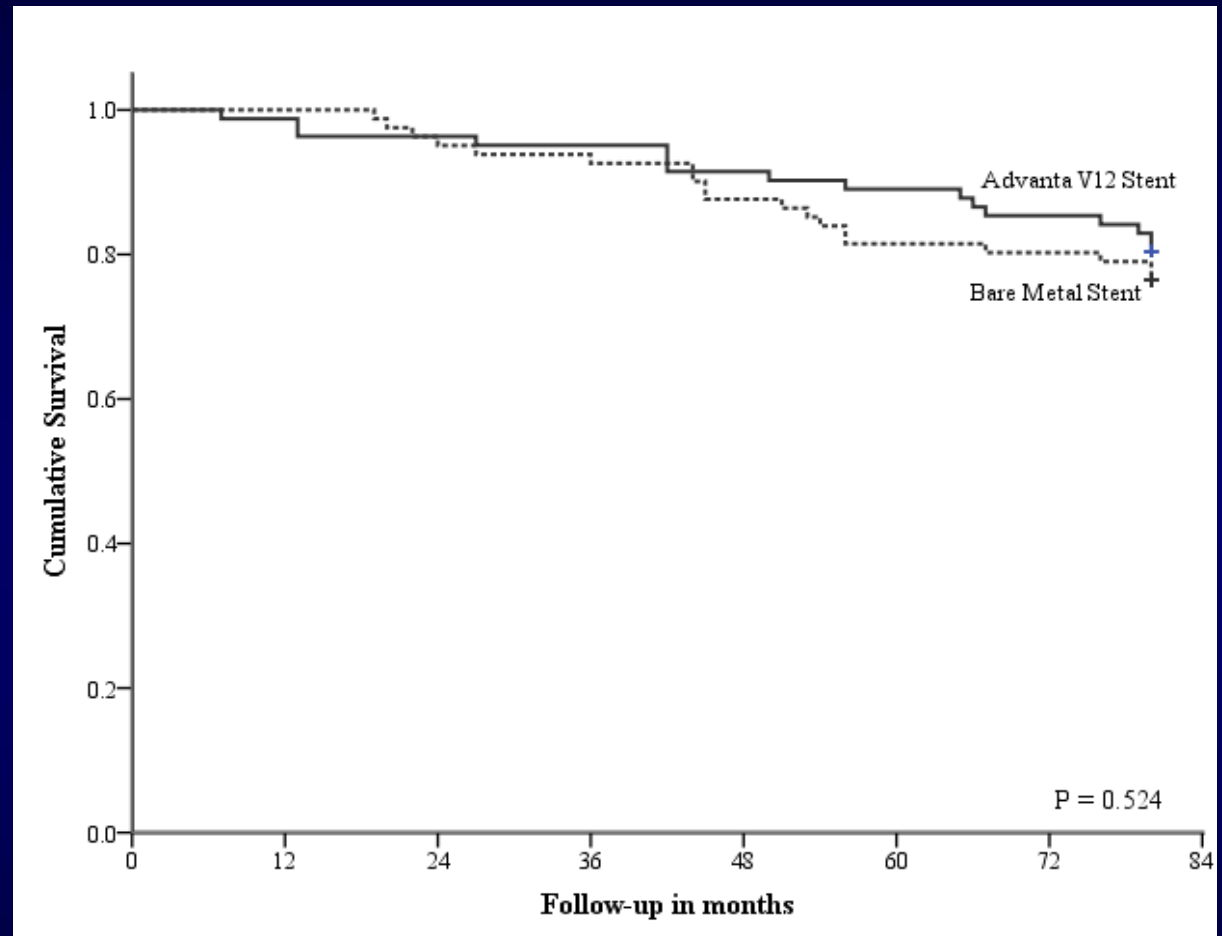


# Adjusted primary patency TASC C/D lesions



Months	0	12	24	36	48	60	72	84	96
Advanta V12 Stent (n. at risk)	40	35	23	20	17	14	7	2	1
BMS (n. at risk)	26	18	12	11	8	6	3	1	0

# Safety: adjusted mortality



Months	0	12	24	36	48	60	72	84	96
Advanta V12 Stent-cumulative event*-	0	12	16	16	16	16	16	16	16
BMS –cumulative event*	0	12	19	19	19	19	19	19	19

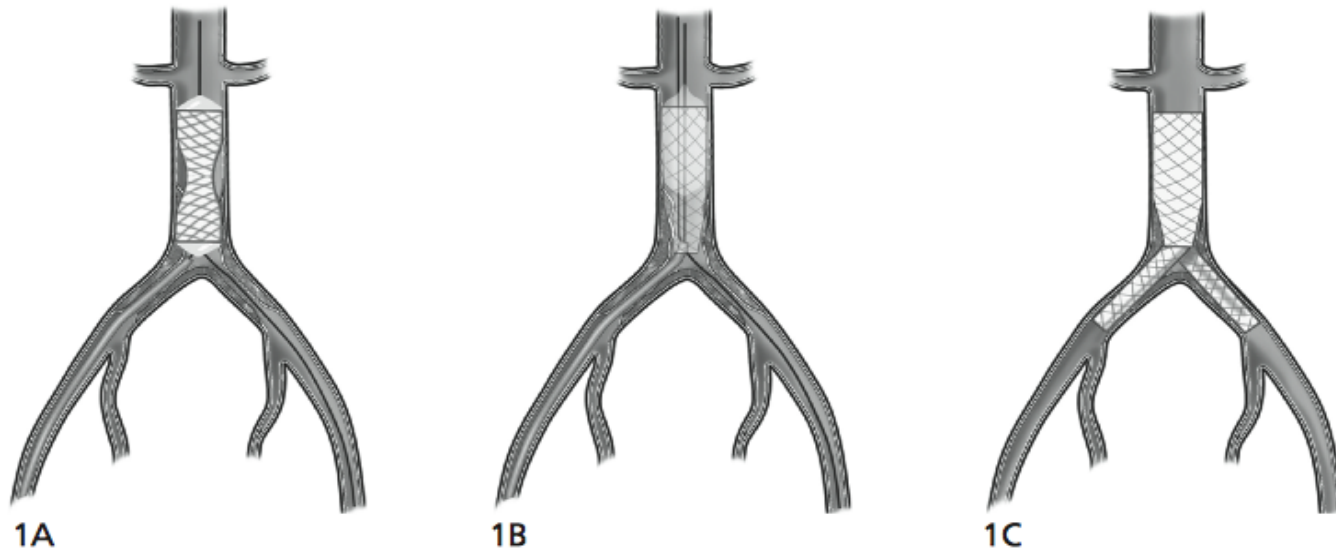
Need for improvement of endovascular configuration

# CERAB

Covered  
Endovascular  
Reconstruction of the  
Aortic  
Bifurcation



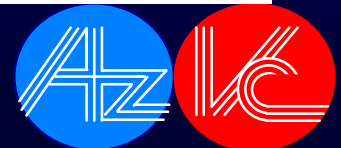
# CERAB: procedural steps



**Figure 1A** During the first step of the CERAB procedure a 12 mm balloon expandable stent is positioned and deployed 15-20 mm above the aortic bifurcation

**Figure 1B** During second step of the CERAB procedure the proximal part of the aortic covered stent is overdilated to adapt to the aortic wall

**Figure 1C** The CERAB configuration is completed by simultaneous inflation of two iliac covered stents in the conic segment, thereby moulding the first one around the latter two

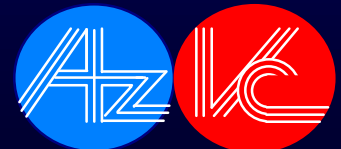
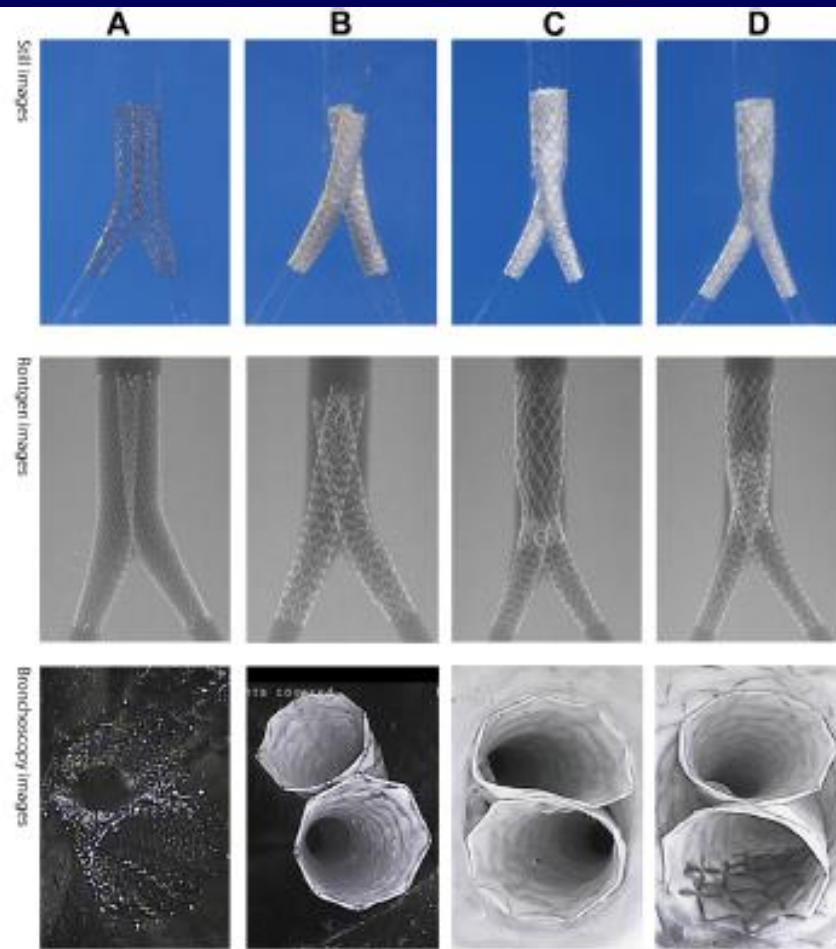


# CERAB: rationale

Geometrical consequences of kissing stents and the Covered Endovascular Reconstruction of the Aortic Bifurcation configuration in an in vitro model for endovascular reconstruction of aortic bifurcation

Erik Groot Jebbink, MSc,<sup>a,c</sup> Frederike A. B. Grimme, MD,<sup>a</sup> Peter C. J. M. Goverde, MD,<sup>d</sup>  
Jacques A. van Oostayen, MD,<sup>b</sup> Cornelis H. Slump, PhD,<sup>c</sup> and Michel M. P. J. Reijnen, MD, PhD,<sup>a</sup>  
*Arnhem and Enschede, The Netherlands; and Antwerp, Belgium*

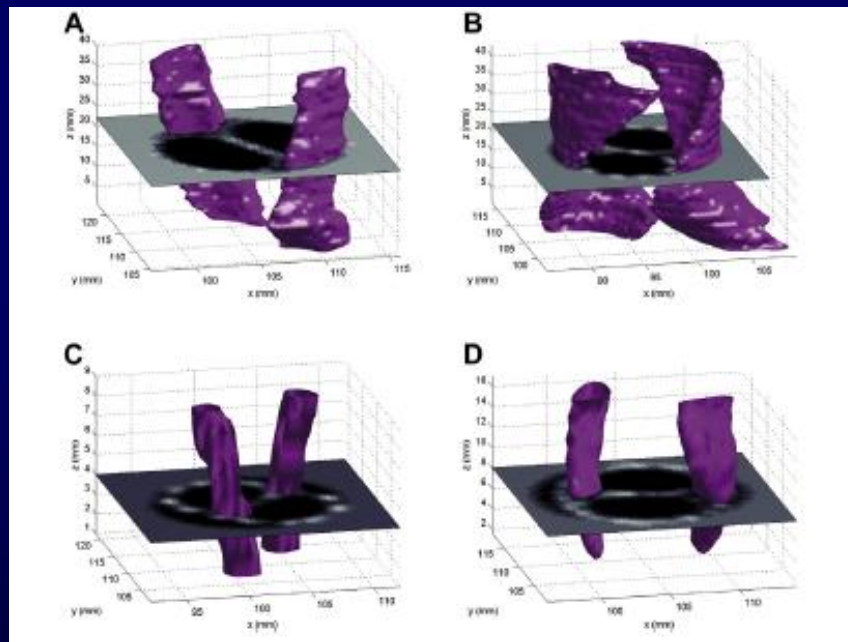
J Vasc Surg 2015;61:1306-11



# CERAB: rationale

**Table II.** Mean mismatch areas and volumes of the four different configurations

Configuration	Mismatch area, mm <sup>2</sup>						Mismatch volume, mm <sup>3</sup>		
	Prox. left	Prox. right	Prox. left + right	Mean left	Mean right	Mean left + right	Left	Right	Total
A, BMK stents	12.10	13.2	24.75	10.02	11.37	21.38	417.07	486.27	903.34
B, KC stents	27.64	30.43	56.68	26.1	27.4	53.48	1031.45	1121.85	2153.3
C, CERAB-1	2.3	1.74	4.04	1.45	1.66	3.11	14.06	16.19	30.25
D, CERAB-2	14.45	8.10	22.5	7.97	4.68	12.65	149.10	88.89	237.99



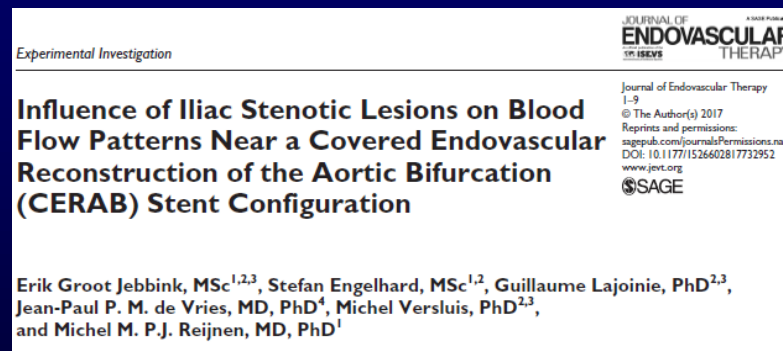
# CERAB vs Kissing stents

Anatomical and physiological reconstruction

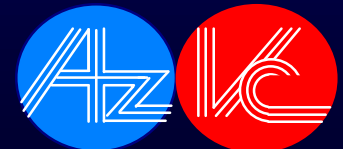
Decreased radial mismatch, associated with failure

Decreased flow perturbation and thrombus formation

(Potentially) increased patency



Sharafuddin, Ann Vasc Surg 2008;22:346-57  
Groot Jebbink, J Vasc Surg 2015;61:1306-11



# Possible BeGraft CERAB configurations



## Main body :

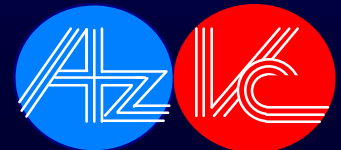
- BeGraft Aortic Bentley Bx
- Diameters: 12-24 mm (12 mm = 9 Fr)
- Can be postdilated up to max 28 mm
- Lengths: 19-59 mm

## Legs:

- BeGraft Bentley Bx
- Diameters: 6-10 mm ( 7 Fr)
- Lengths: 27 – 58 mm

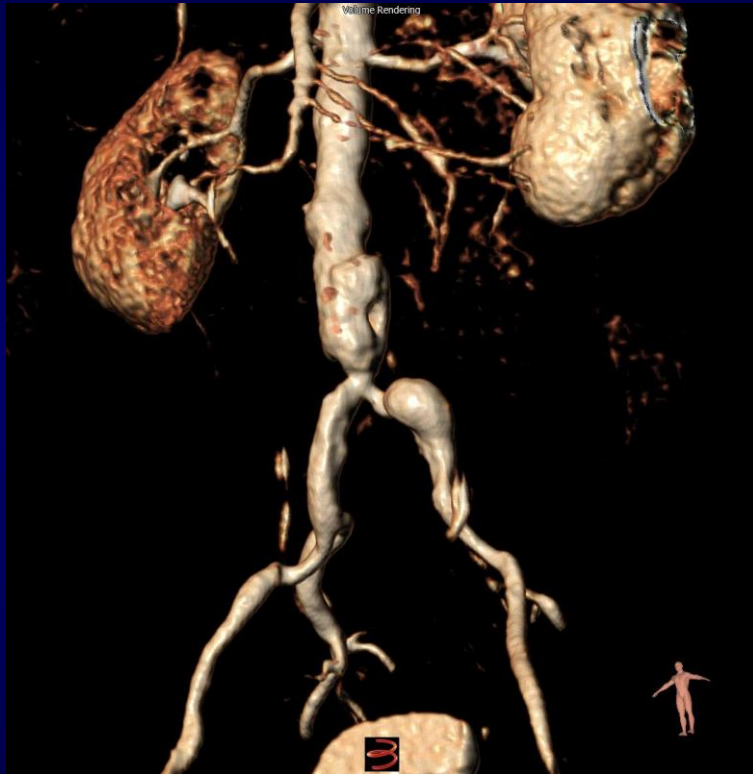
- Can be postdilated
- Less shortening

Courtesy of P. Goverde

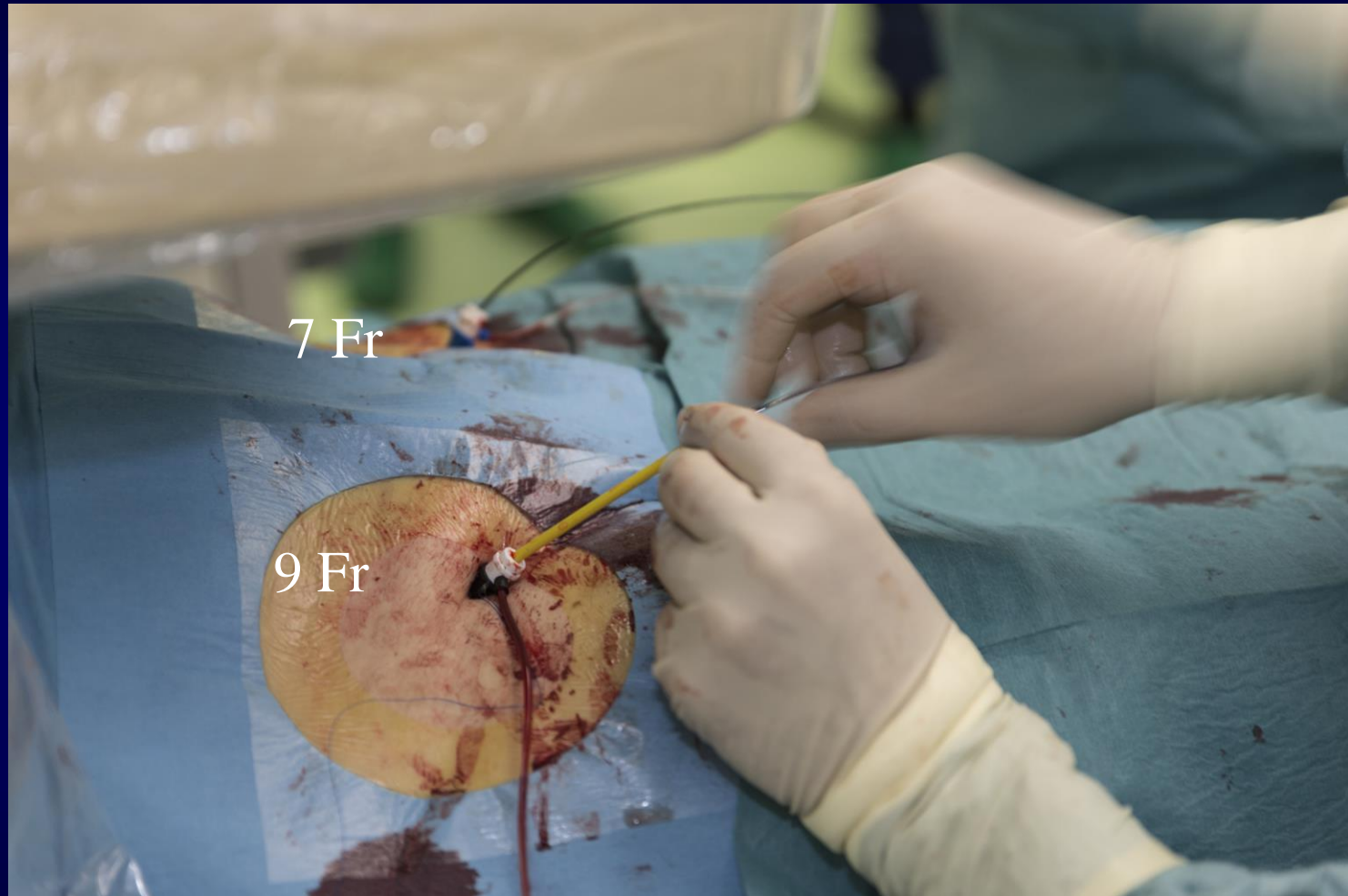




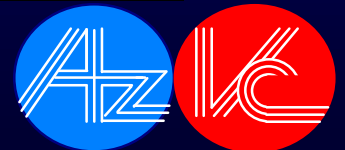
# CERAB step by step: *pre-procedural imaging (measurements)*



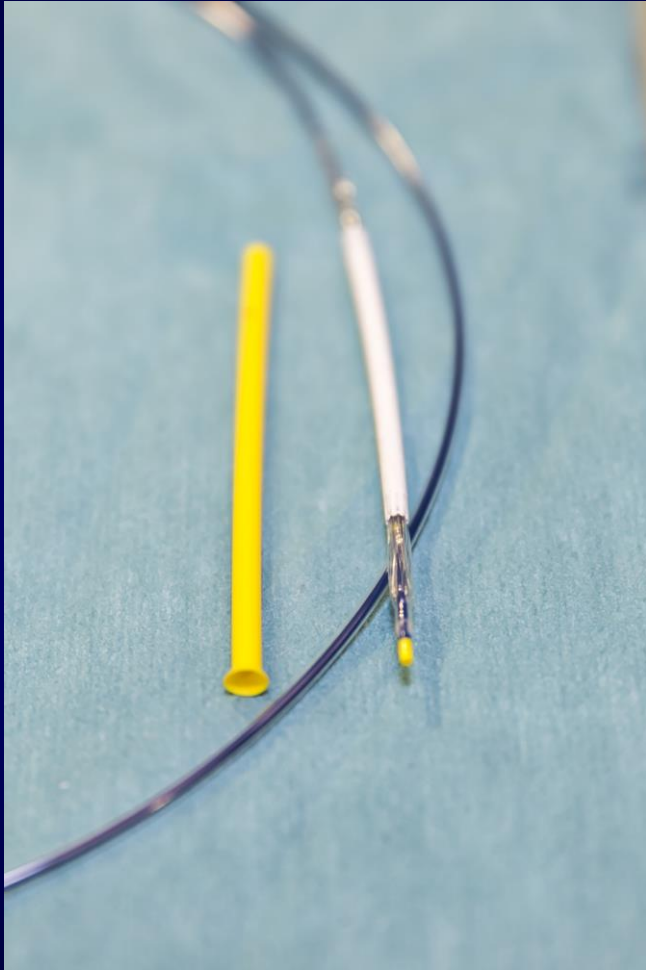
## CERAB step by step: access



## CERAB step by step: *length measurements*

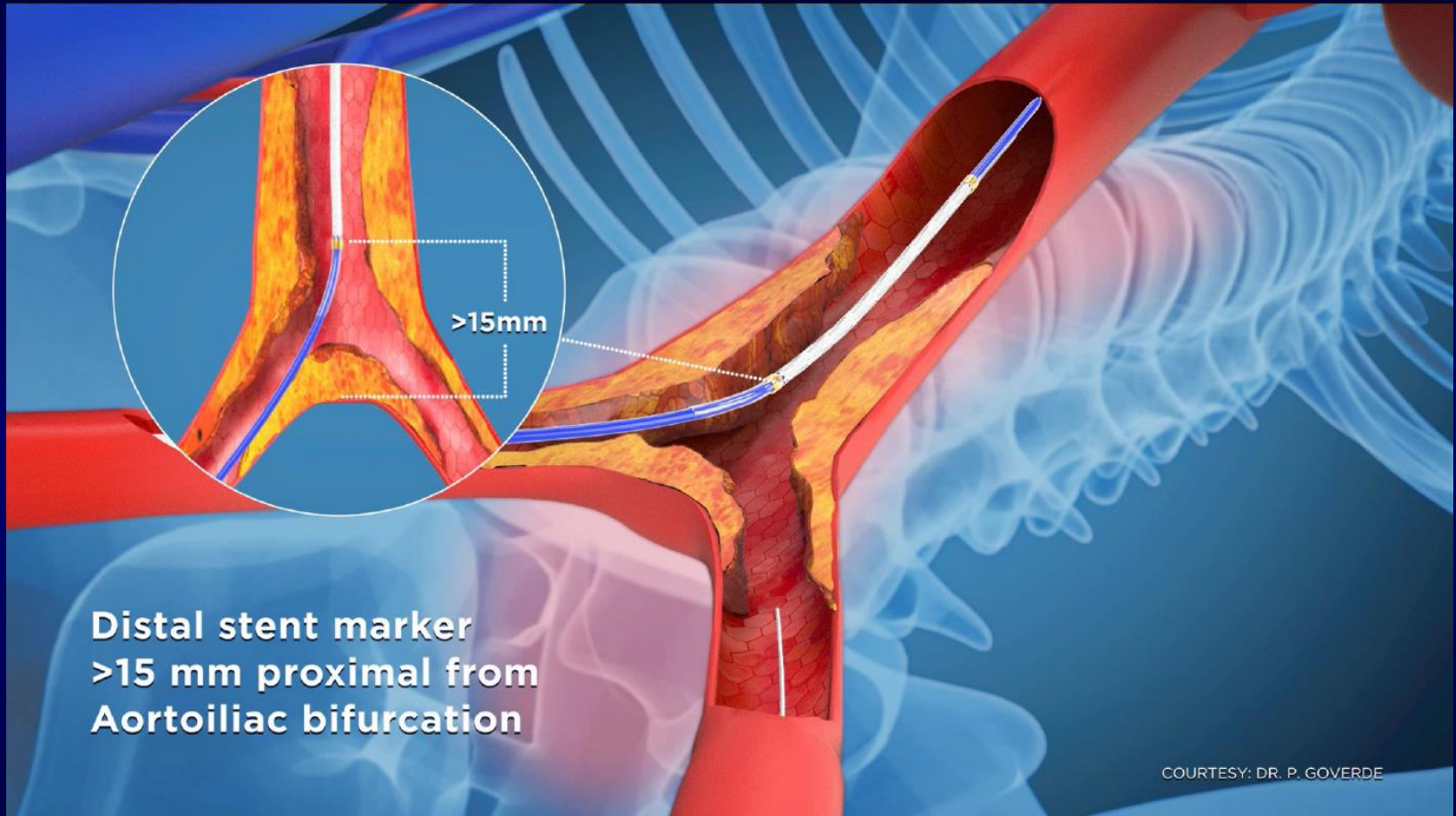


## CERAB step by step: *introduction 12 mm aortic BeGraft*

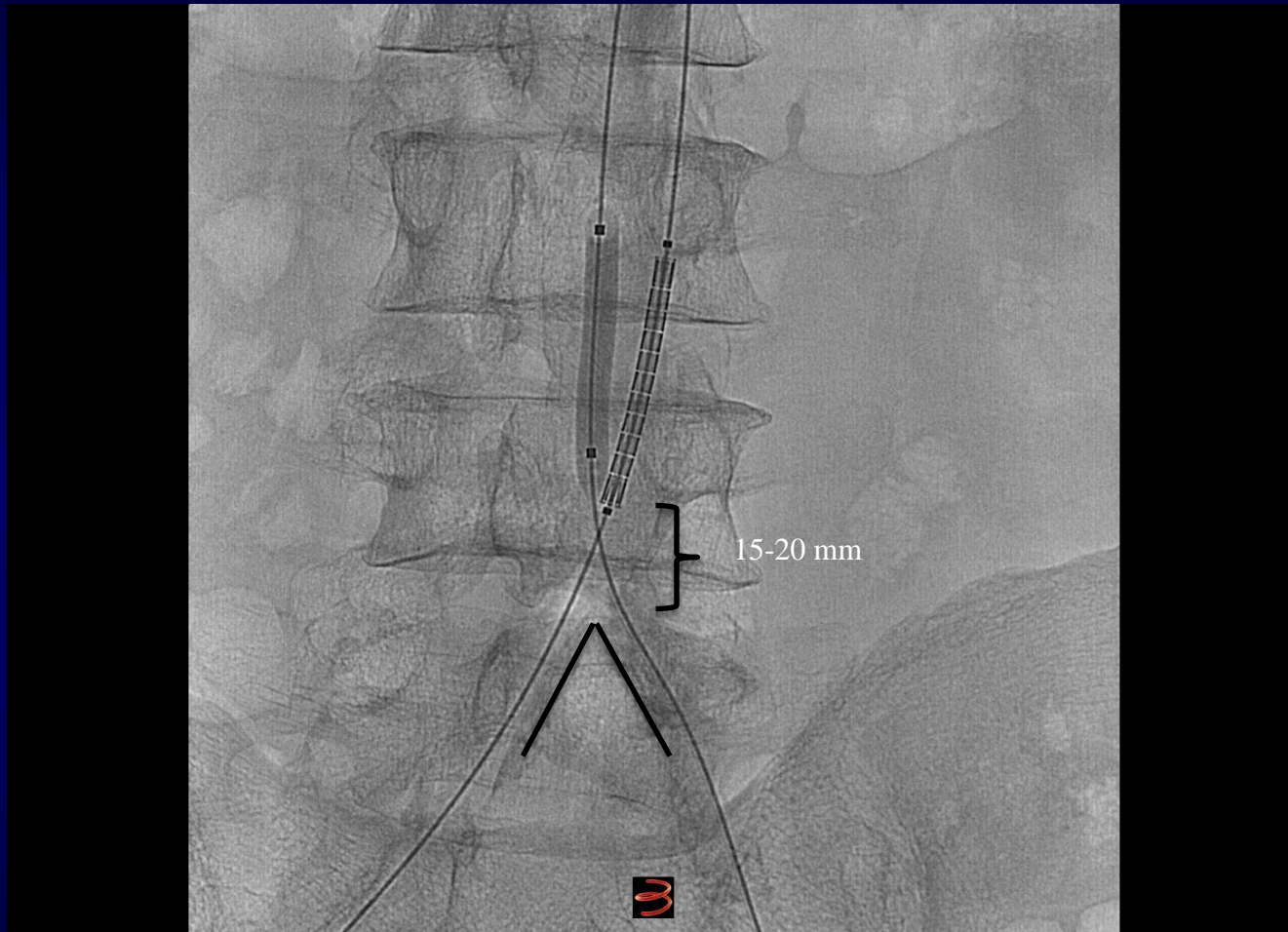




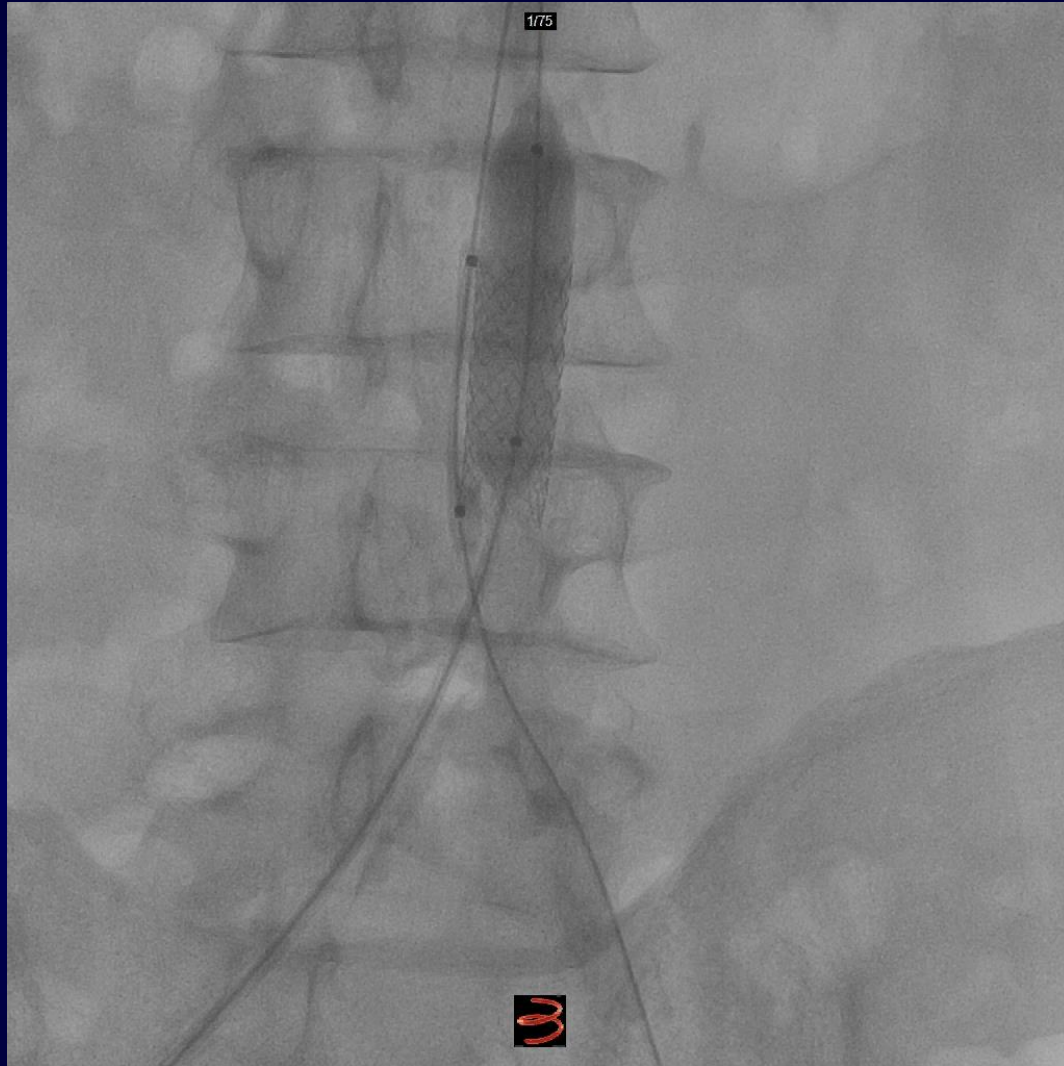
## CERAB step by step: *introduction 12 mm aortic BeGraft*



## CERAB step by step: *deployment 12 mm aortic BeGraft*

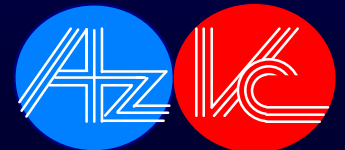
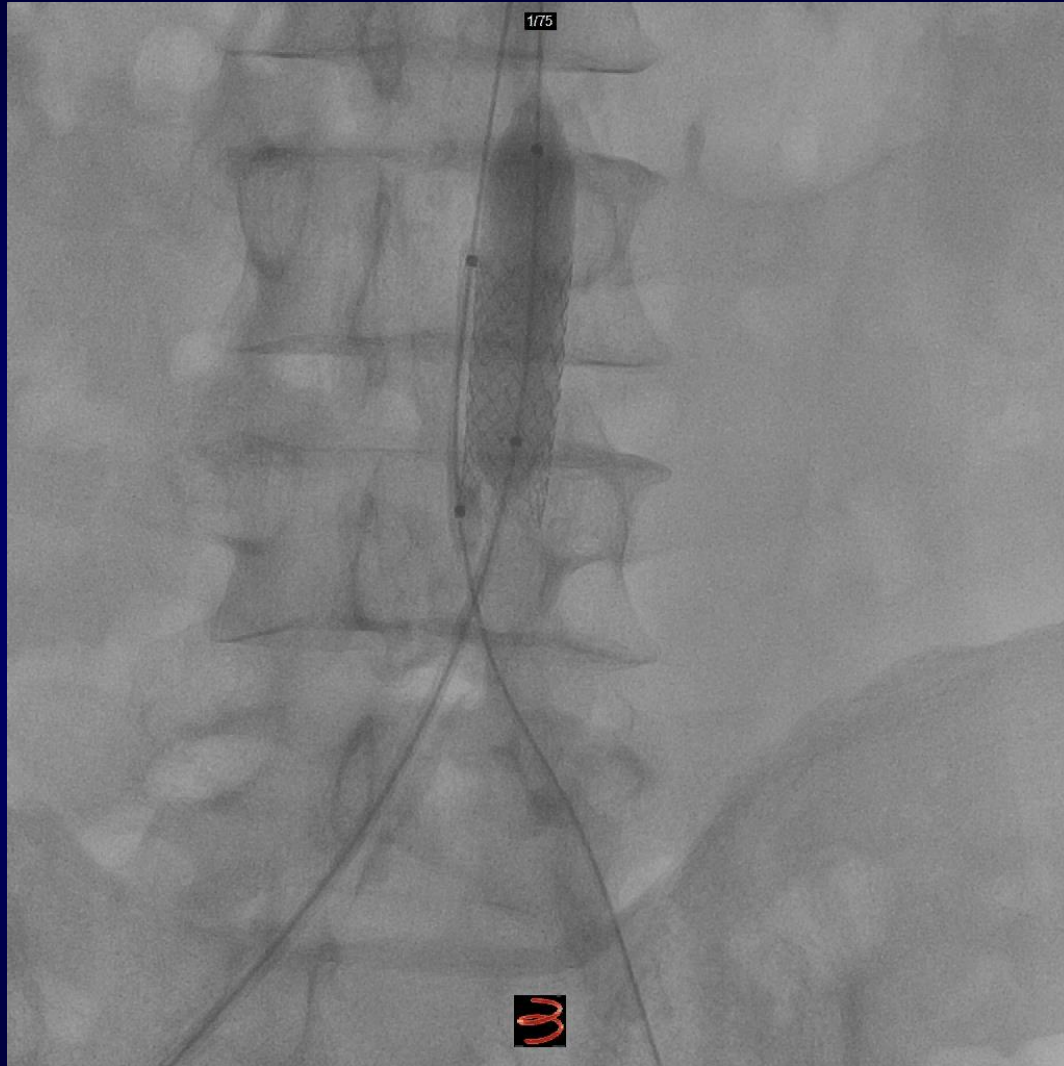


## CERAB step by step: *dilatation with XL balloon*



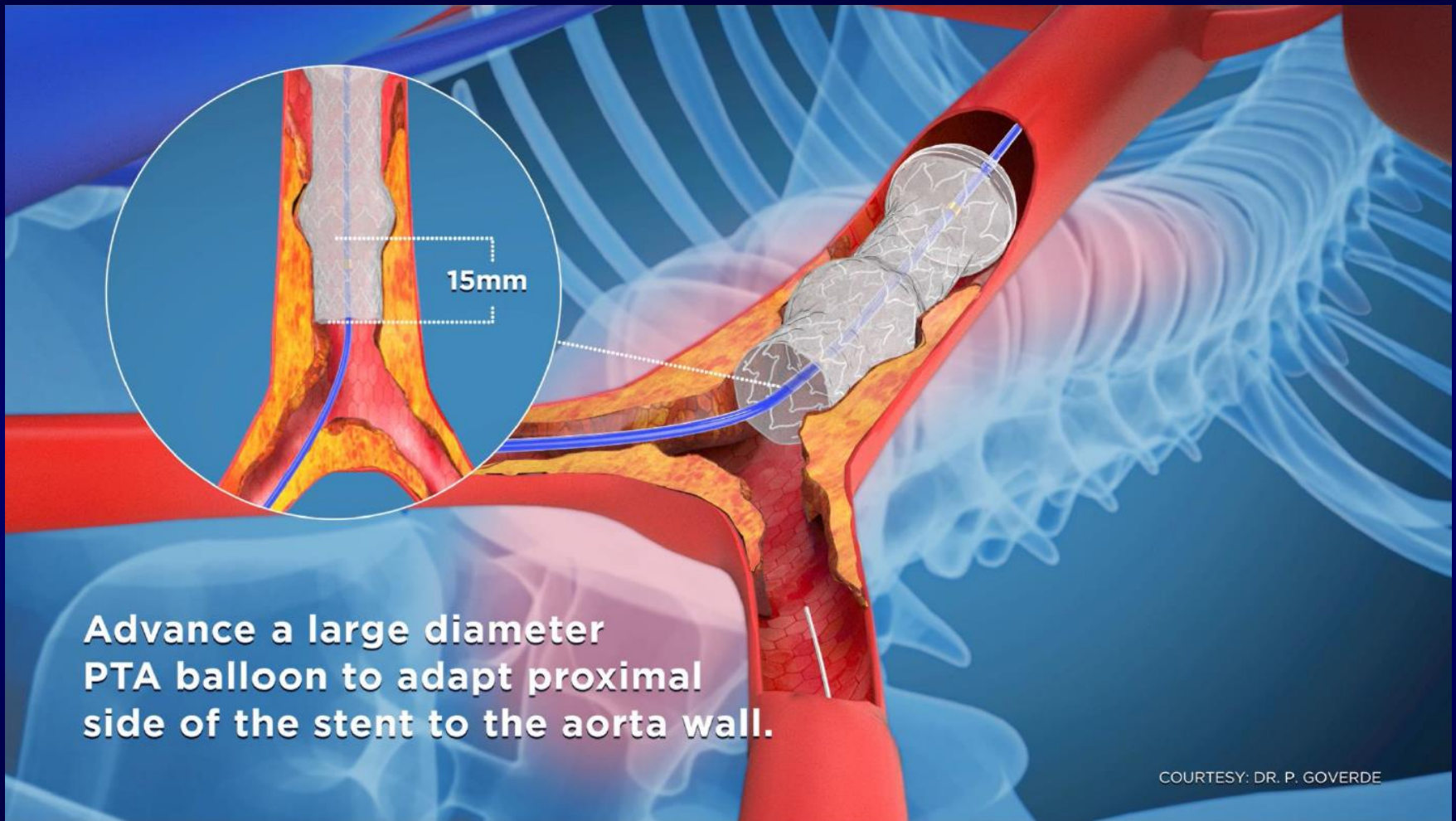


## CERAB step by step: *dilatation with XL balloon*



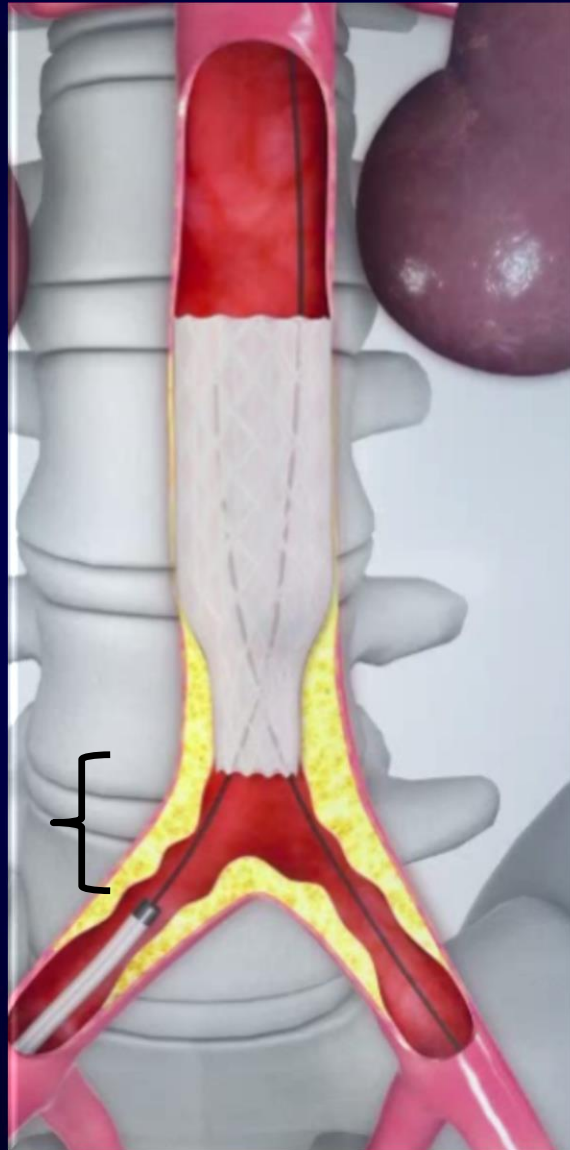


## CERAB step by step: *creation of conical distal part*

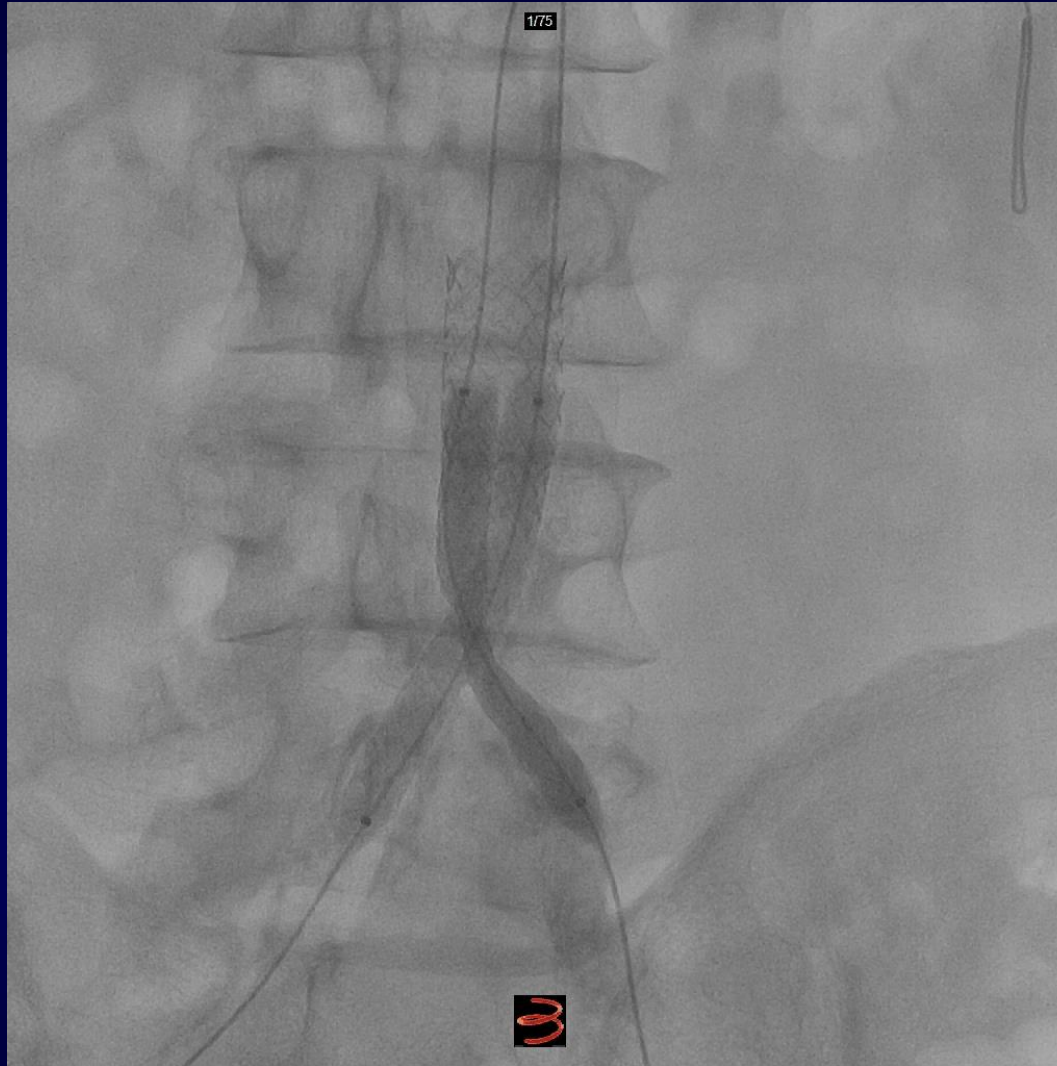


## CERAB step by step: *creation of conical distal part*

15-20 mm



## CERAB step by step: 2 *kissing distal BeGrafts*

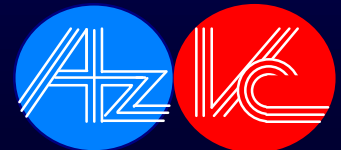
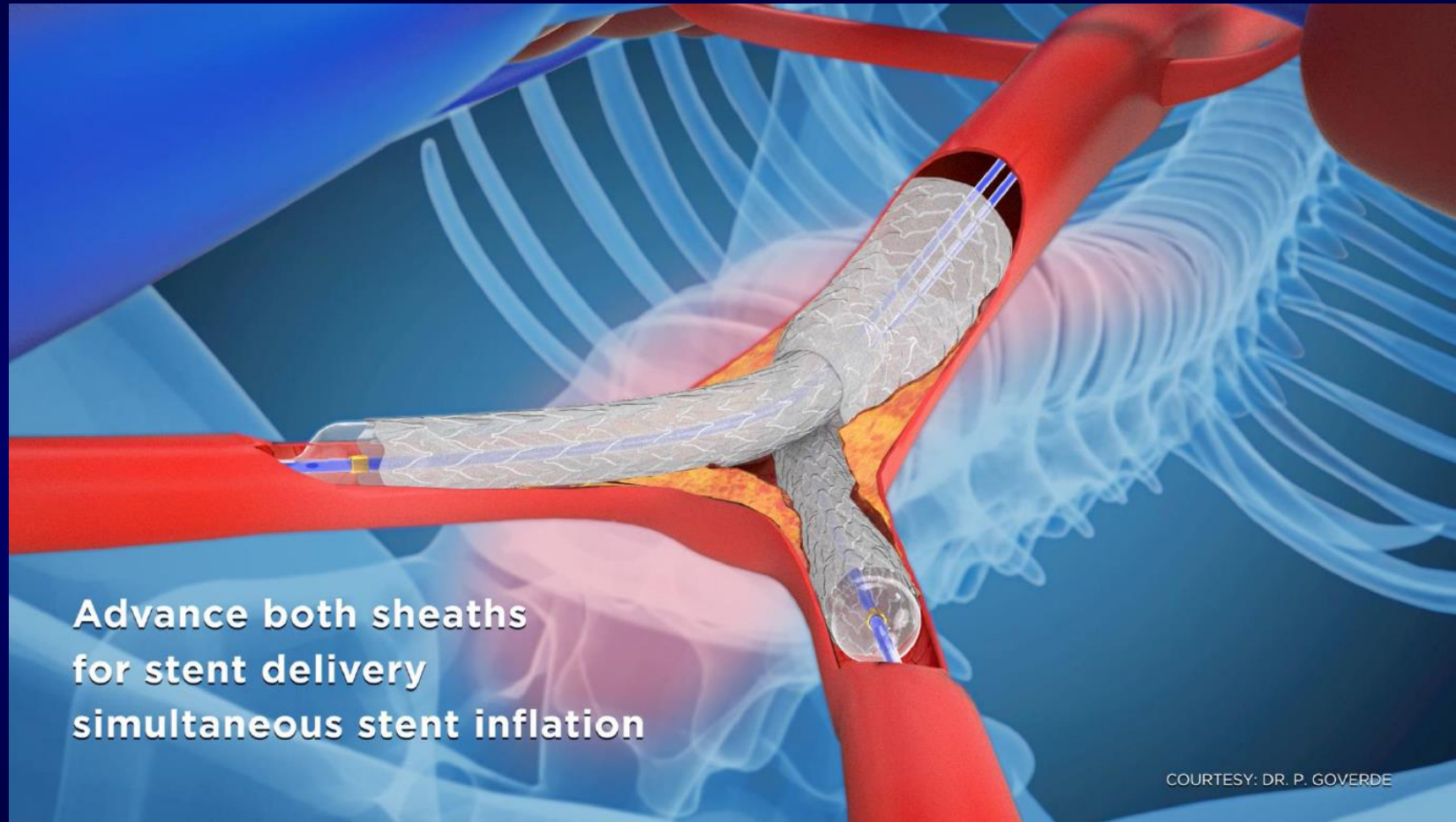


## CERAB step by step: 2 kissing distal BeGrafts

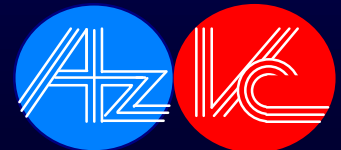
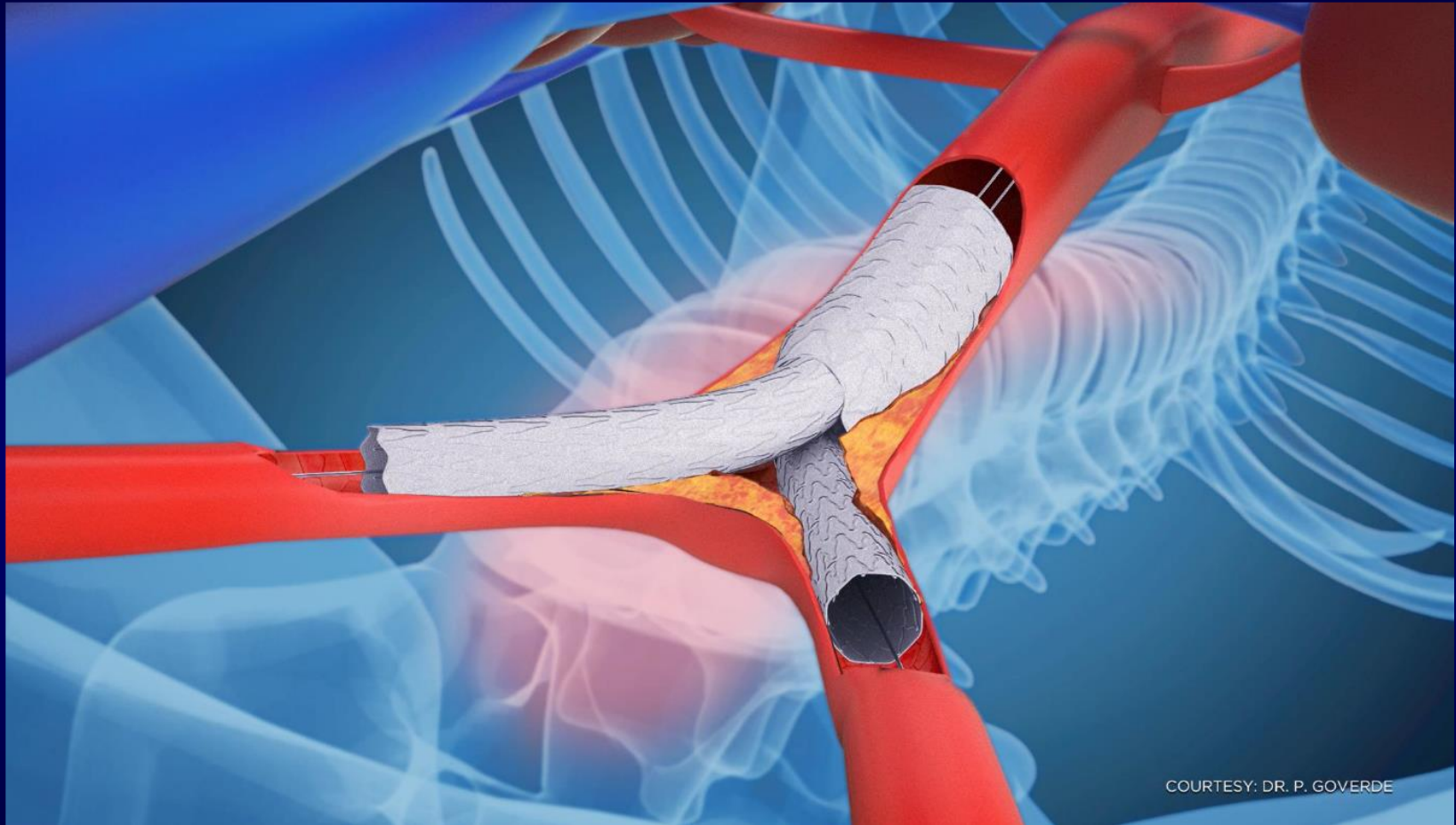




## CERAB step by step: 2 kissing distal BeGrafts



## CERAB step by step: 2 kissing distal BeGrafts



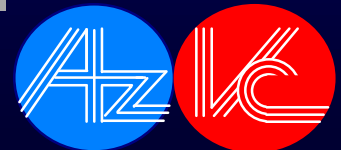
# CERAB step by step: *check in- and outflow*



# CERAB step by step: *check in- and outflow*

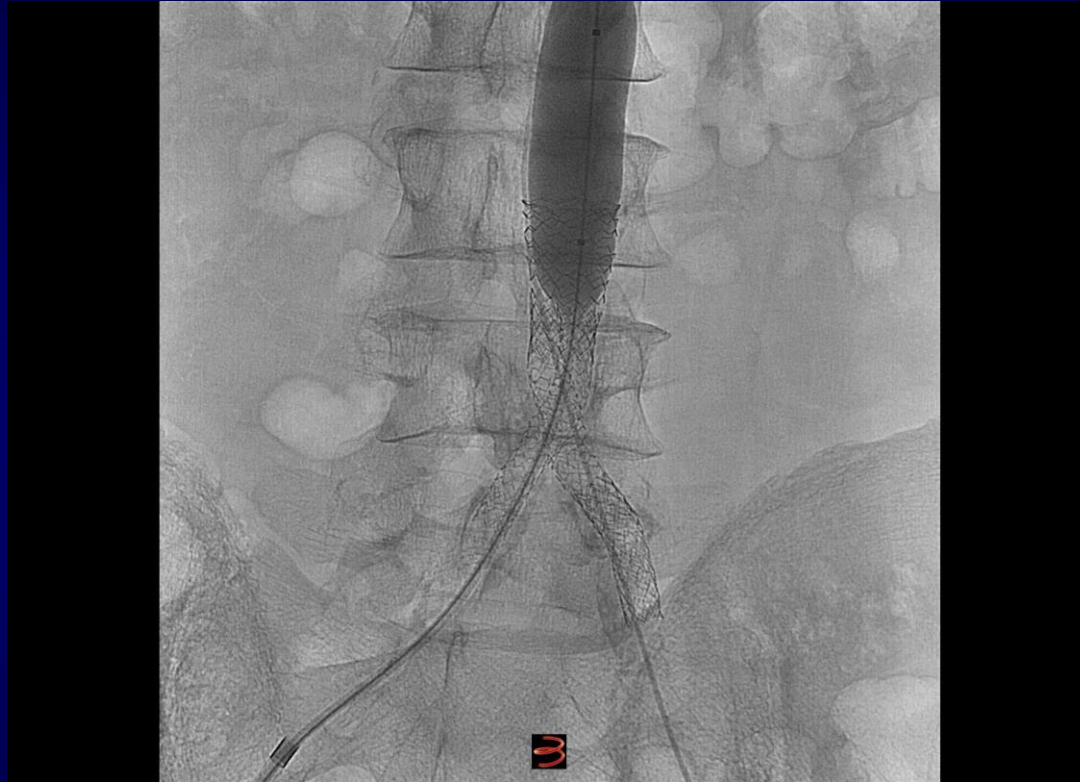


1/13





## CERAB step by step: *check in- and outflow*



# CERAB step by step: *check in- and outflow*

1/14



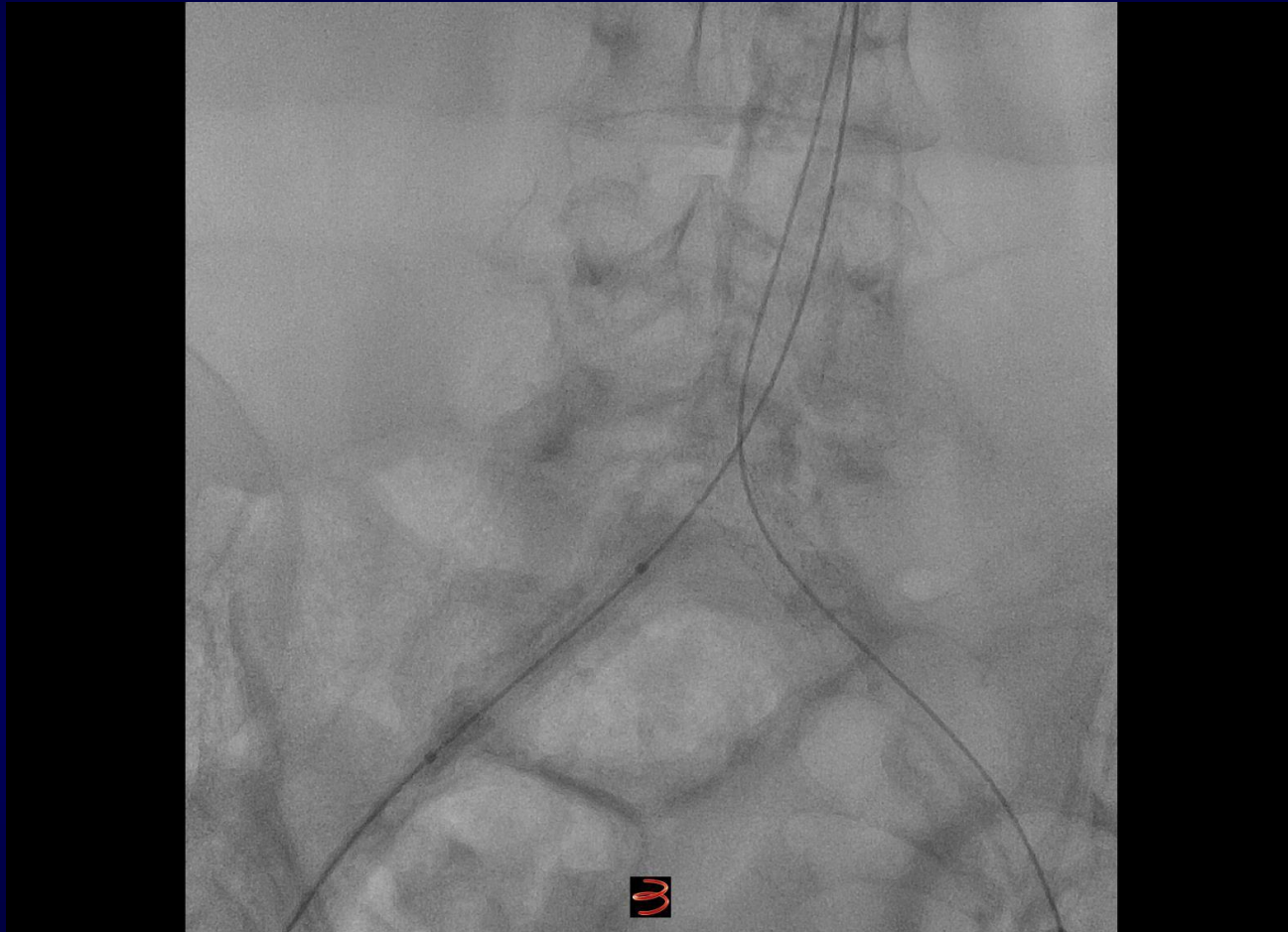
Pat #2



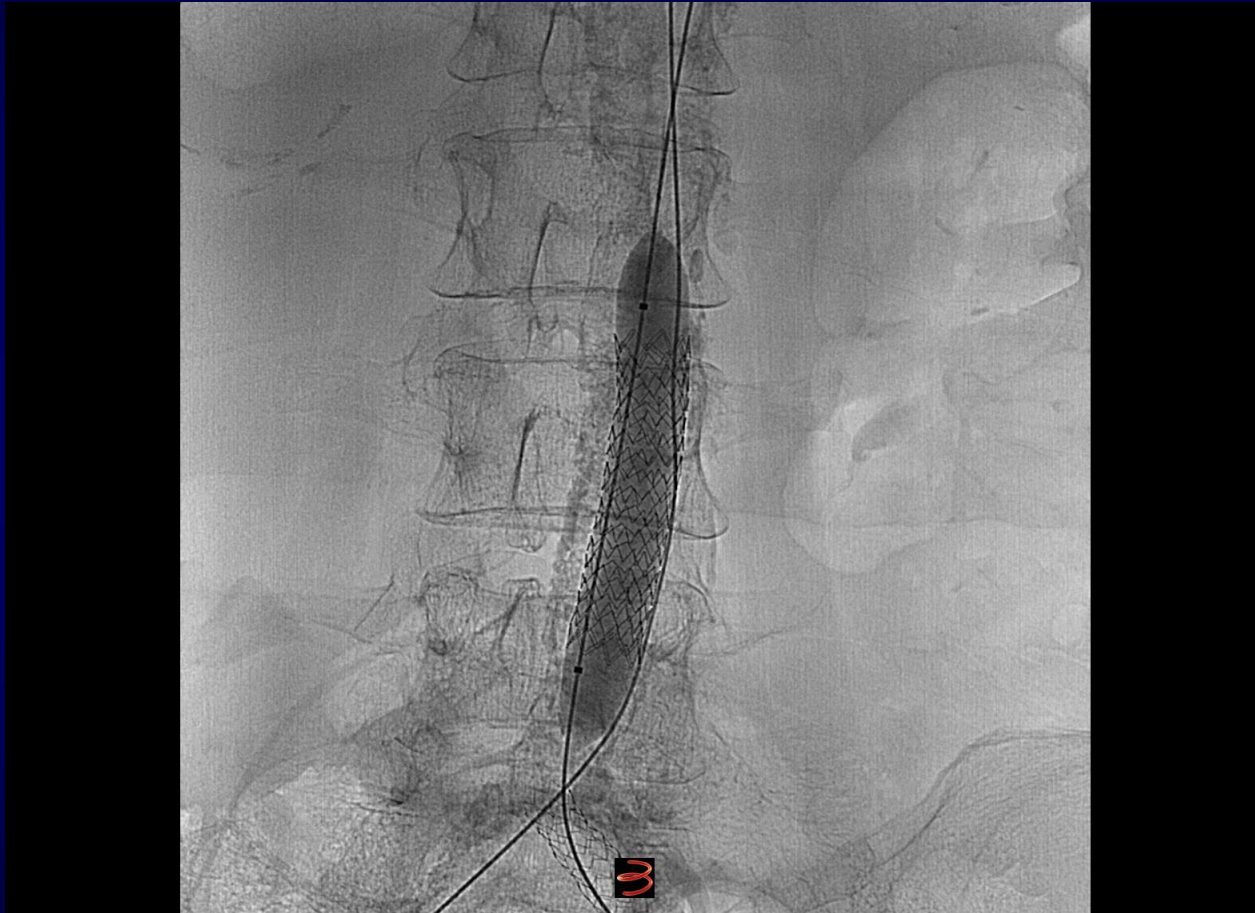
## Pat #2



# Predilatation / Recanalization



# Deployment 12 mm aortic BeGraft





# Deployment 12 mm aortic BeGraft



# Deployment 8 mm distal BeGrafts





# Completion DSA

1/13



# Pat #3

1/14



# Pat #3

1/14



## Editor's Choice — First Results of the Covered Endovascular Reconstruction of the Aortic Bifurcation (CERAB) Technique for Aortoiliac Occlusive Disease

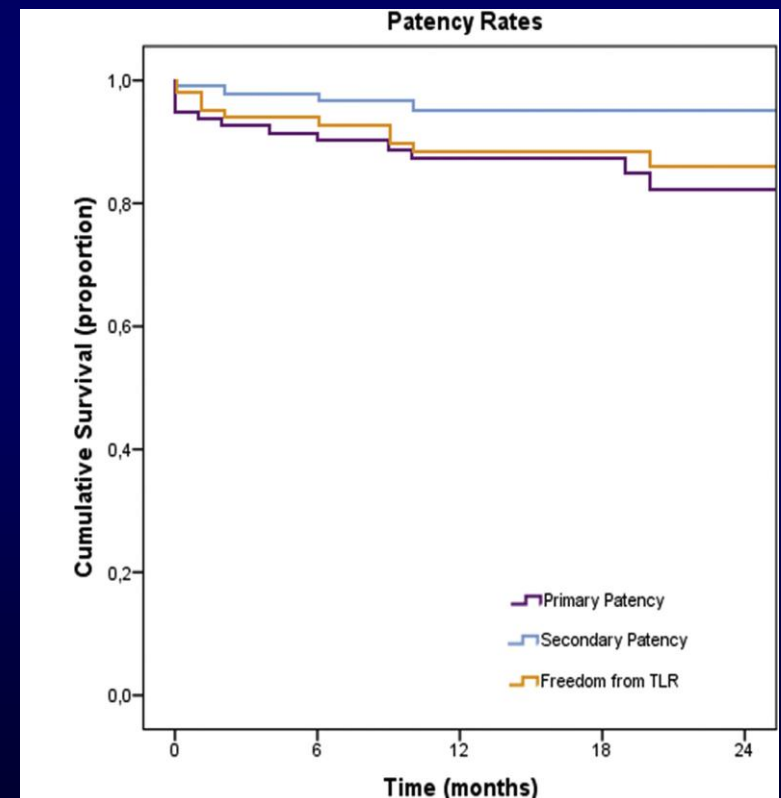
F.A.B. Grimme<sup>a</sup>, P.C.J.M. Goverde<sup>b</sup>, P.J.E.M. Verbruggen<sup>b</sup>, C.J. Zeebregts<sup>c</sup>, M.M.P.J. Reijnen<sup>a,\*</sup>

103 Patients

TASC D 88 patients (85.4%)

Primary patency 82.3% at 2 years

Secondary patency 95% at 2 years



# Initial Experience With Covered Endovascular Reconstruction of the Aortic Bifurcation in Conjunction With Chimney Grafts

Journal of Endovascular Therapy  
2017, Vol. 24(1) 19-24  
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sagepub.com/journalsPermissions.nav  
DOI: 10.1177/1526602816673824  
www.jevt.org  
SAGE

Martijn L. Dijkstra, MD<sup>1,2</sup>, Peter C. J. M. Goverde, MD, PhD<sup>3</sup>,  
Andrew Holden, MBChB, FRANZCR, EBIR<sup>4</sup>, Clark J. Zeebregts, MD, PhD<sup>2</sup>,  
and Michel M. P. J. Reijnen, MD, PhD<sup>1</sup>



14 patients, 15 chimney stentgrafts

100% technical success

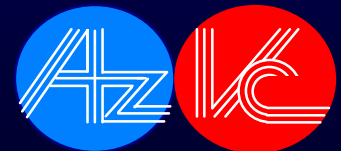
12 months FU: 1 occluded CERAB limb, 1 occluded IMA stentgraft



# Conclusions

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- Covered stents prevent neointimal hyperplasia (mainly in the middle)
- For extensive lesions (TASC C and D lesions), covered stents perform better than bare stents in terms of patency and clinical outcome results at long-term follow-up (COBEST).





# Conclusions

- CERAB configuration with covered BeGrafts better compared to kissing stents regarding hemodynamics
- Percutaneous procedure / wide variety diameters & lengths BeGrafts
- CERAB step by step procedure → good midterm outcomes
- Even chimney-CERAB is possible (limited data so far)

