EVALUATING PROXIMAL AND DISTAL FIXATION ABILITY OF 8 ENDOGRAFTS USED IN EVAR

ΑΡΙΣΤΟΤΕΛΕΙΟ
ΠΑΝΕΠΙΣΤΗΜΙΟ
ΘΕΣΣΑΛΟΝΙΚΗΣ

ΝΟΣΟΚΟΜΕΙΟ
ΠΑΠΑΓΕΩΡΓΙΟΥ

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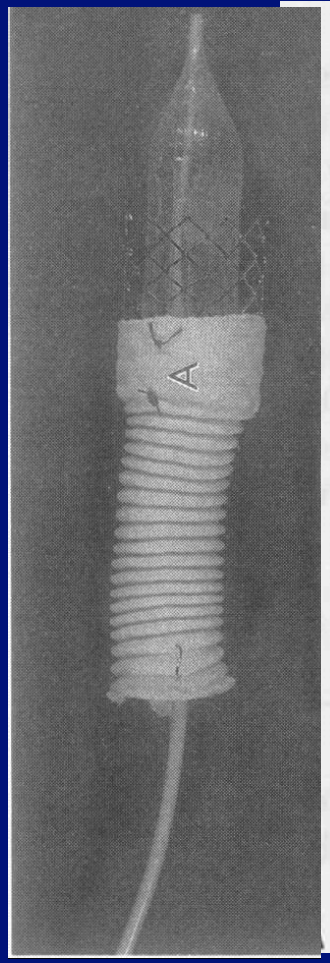
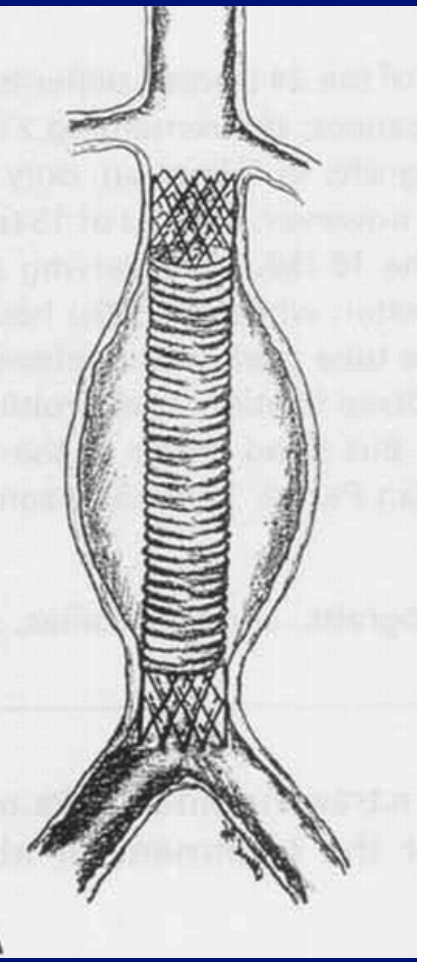
Associate in Interbalcan Medical Center

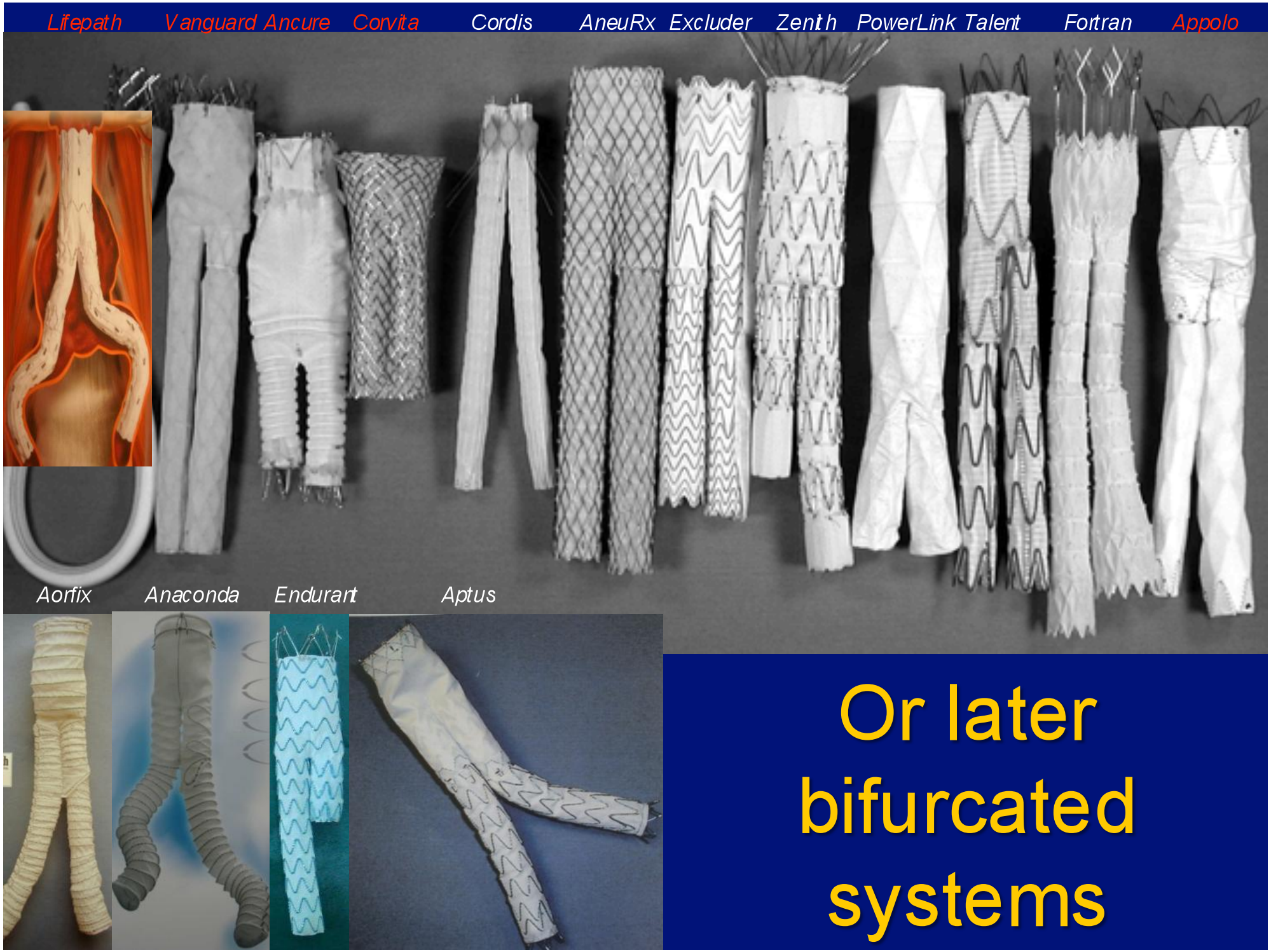
From the very beginning of EVAR introduction, with tube endografts,

Parodi 1990 (1)

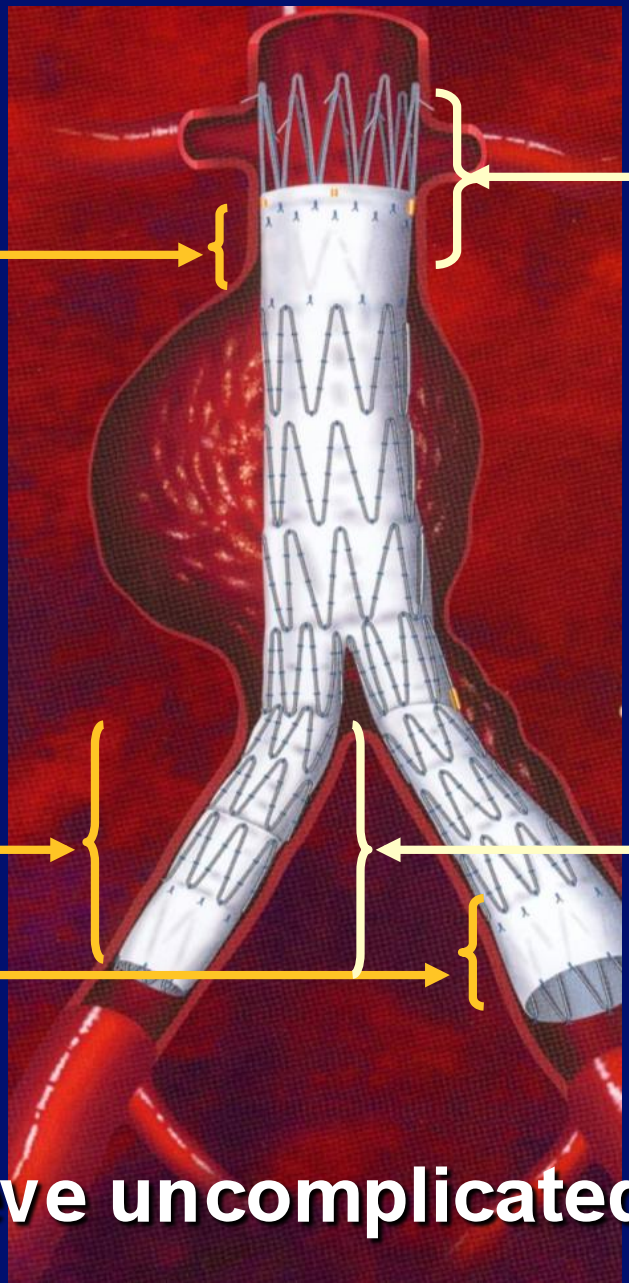




1. Parodi JC, Palmaz JC, Barone HD. **Transfemoral intraluminal graft implantation for AAA**. Ann Vasc Surg 1991; 5 :491-9
2. Parodi JC, Barone A, Piraino R, Schonholz. Endovascular treatment of abdominal aortic aneurysms: lessons learned. J Endovasc Surg 1997;4: 102-10


Lifepath
Vanguard Ancure
Corvita
Cordis
AneuRx
Excluder
Zenith
PowerLink
Talent
Fortran
Appolo
Aorfix
Anaconda
Endurant
Aptus
Or later bifurcated systems

It became clear that for durable sac exclusion, there should exist adequate



Sealing zones

Fixation zones

In order to achieve uncomplicated long-term results

Established Fixation Methods

Endografts

- Are not sewn
- Are not incorporated
- require continuous mechanical fixation in order to withstand pulsatile blood forces (1,2)

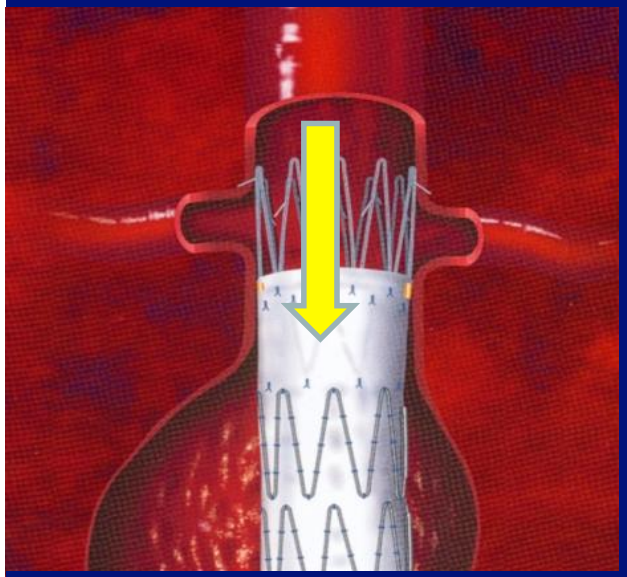
Suspension, SR, Hooks, Bards, Anchors

This is achieved by

- radial force :
  - Blood pressure,
  - oversizing producing friction
- columnar strength
- suspension (SR stent, barbs, hooks, anchors, pins, proximal stent frixion)

1. Malina M, et al. Endovascular healing is inadequate for fixation of Dacron stent grafts in human aorta ilial vessels. Eur J Vasc Endovasc Surg. 2000; 19: 5–11.
2. Zarins CK. Stent-Graft Migration: How Do We Know When We Have It and What Is Its Significance. JEVT 2004;11:364–365.

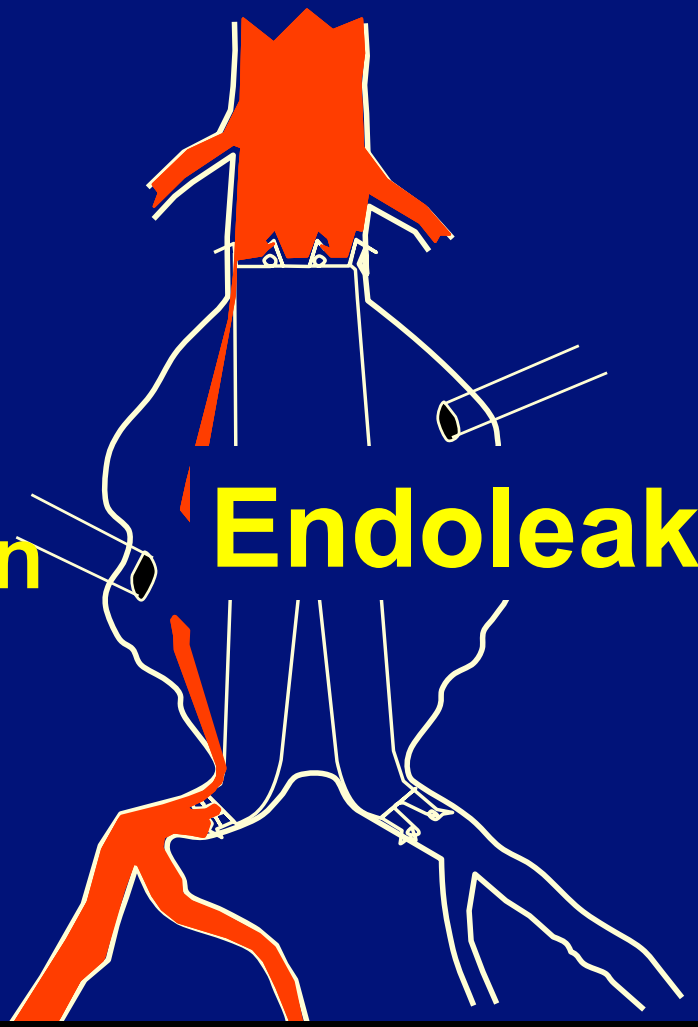
Loss of fixation - consequences



Migration

Sac re-pressurization

Rupture



Endoleak I

1. Greenberg RK, et al. Stentgraft migration: a reappraisal of analysis methods and proposed revised definition. J Endovasc Ther. 2004;11:353–363.
2. 1. Luis R. Leon, Jr and Heron E. Rodriguez. Aortic Endograft Migration. Perspectives in Vascular Surgery and Endovascular Therapy. 2005, Volume 17, Number 4, 363-373.
3. Conners MS, Sternbergh WC, Carter GS, Tonnessen BH, Yoselevitz M, Money SR, et al. Secondary procedures following endovascular aneurysm repair. J Vasc Surg. 2002;36:992–996.
4. Ivancev K, Malina M, Lindbland B, et al. Abdominal aortic aneurysms: Experience with the Ivancev-Malmo endovascular system for for aortomonoiliac stent graft. J Endov Surg. 1997; 4 :242-251.
5. Malina M, et al. Endovascular healing is inadequate for fixation of Dacron stent grafts in human aorta ilial vessels. Eur J Vasc Endovasc Surg. 2000; 19: 5–11.
6. Zarins CK. Stent-Graft Migration: How Do We Know When We Have It and What Is Its Significance. JEVT 2004;11:364–365.
7. Liffman K, Et al. Analytical Modeling and Numerical Simulation of Forces in an Endoluminal Graft. JEVT. 2001;8:358–371.
9. White G, et al. “Endoleak” a proposed new terminology to describe incomplete aneurysm exclusion by an endoluminal graft. J Endovasc Surg1996; 3 : 124–125.
10. Veith FJ, et al. Nature and significance of endoleaks and endotension: summary of opinions expressed at an international conference. J Vasc Surg 2002;35:1029-35.
11. Conners MS 3rd, et al. Endograft migration one to four years after endovascular abdominal aortic aneurysm repair with the AneuRx device: a cautionary note. J Vasc Surg, 2002; 36:476-484.
12. Luis R. Leon, et al. Aortic Endograft Migration. Perspectives in Vascular Surgery and Endovascular Therapy. 2005, Volume 17, Number 4, 363-373.

Migration - definition

- Endograft movement >10 mm in relation to fixed anatomic landmarks as SMA or renals (for proximal) and IIA for distal. (1)

- Immediate (2-4)
  - Rare
  - Perioperative or Within 30 days
  - Due to wrong indication for suitable anatomy /graft choice, or technical insufficiency

- Late (2-4)
  - More often
  - After 30 days, usually after the 1st year increasing frequency thereafter
  - Due to neck dilatation / remodeling, endoleak I, material fatigue

Main pathophysiology

- The continuous force applied by the pulsatile blood flow against the graft which is not incorporated to the aortic wall but needs permanent mechanical fixation (anchoring, suspension, radial force) to remain stable. (5,6)

1. Greenberg RK, et al. Stentgraft migration: a reappraisal of analysis methods and proposed revised definition. J Endovasc Ther. 2004;11:353–363.
2. 1. Luis R. Leon, Jr and Heron E. Rodriguez. Aortic Endograft Migration. Perspectives in Vascular Surgery and Endovascular Therapy. 2005, Volume 17, Number 4, 363-373.
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5. Malina M, et al. Endovascular healing is inadequate for fixation of Dacron stent grafts in human aorta ilial vessels. Eur J Vasc Endovasc Surg. 2000; 19: 5–11.
6. Zarins CK. Stent-Graft Migration: How Do We Know When We Have It and What Is Its Significance. JEVT 2004;11:364–365.

Purpose

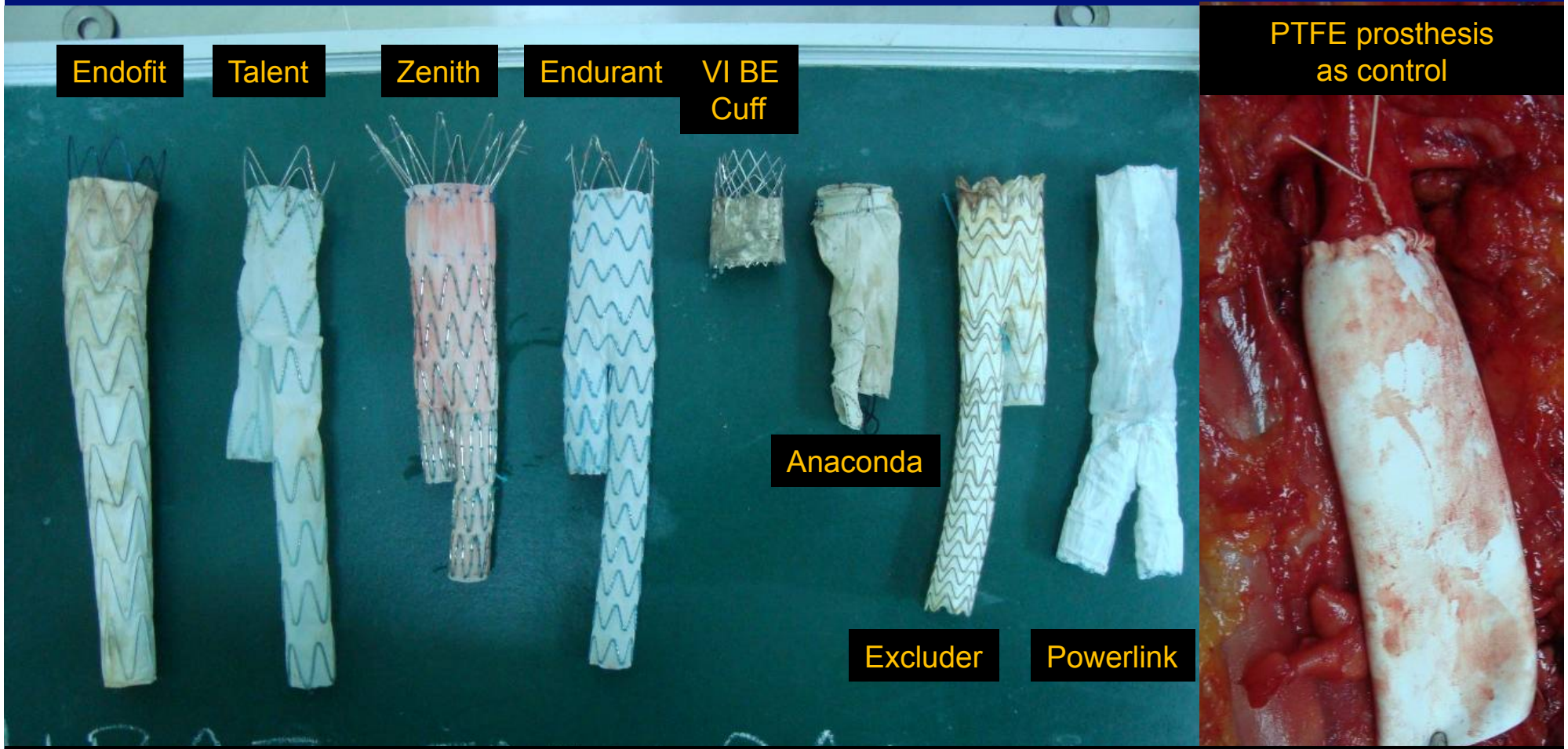
- evaluate the differences of proximal, distal and overall fixation mechanisms within 8 commercially available endografts

Validate various parameters that might influence fixation.

Melas N, Saratzis A, Saratzis N, Lazaridis J, Psaroulis D, Trygonis K, Kiskinis D. Aortic and iliac fixation of endografts for abdominal-aortic aneurysm repair in an experimental model using human cadaveric aortas.
Eur J Vasc Endovasc Surg. 2010 Oct;40(4):429-35.

Methods

- 20 human cadaveric aortas
- Mean proximal infrarenal aortic diameter 20,5 mm (range 19,2-21,9)

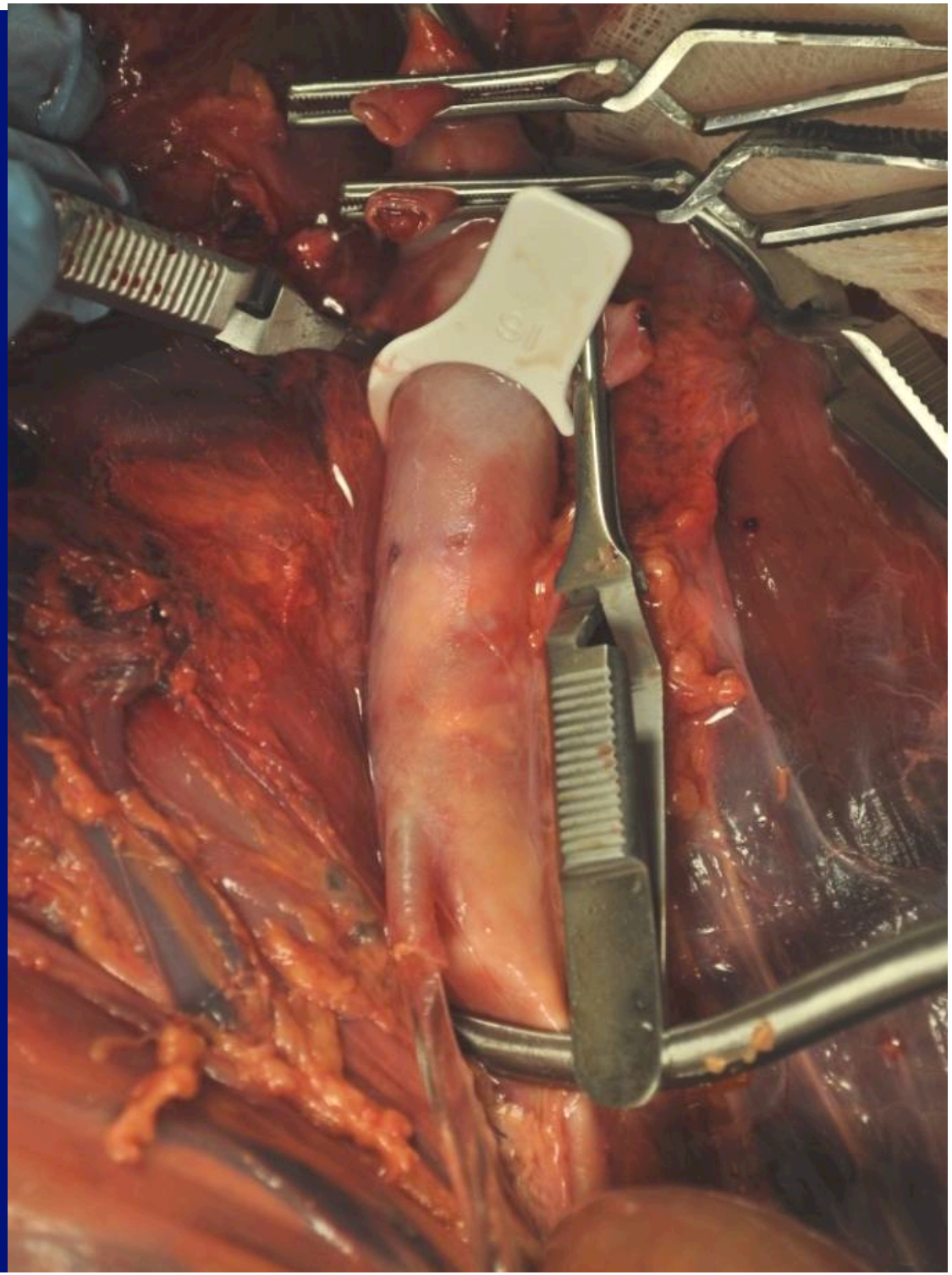


Validated Endografts

Methods

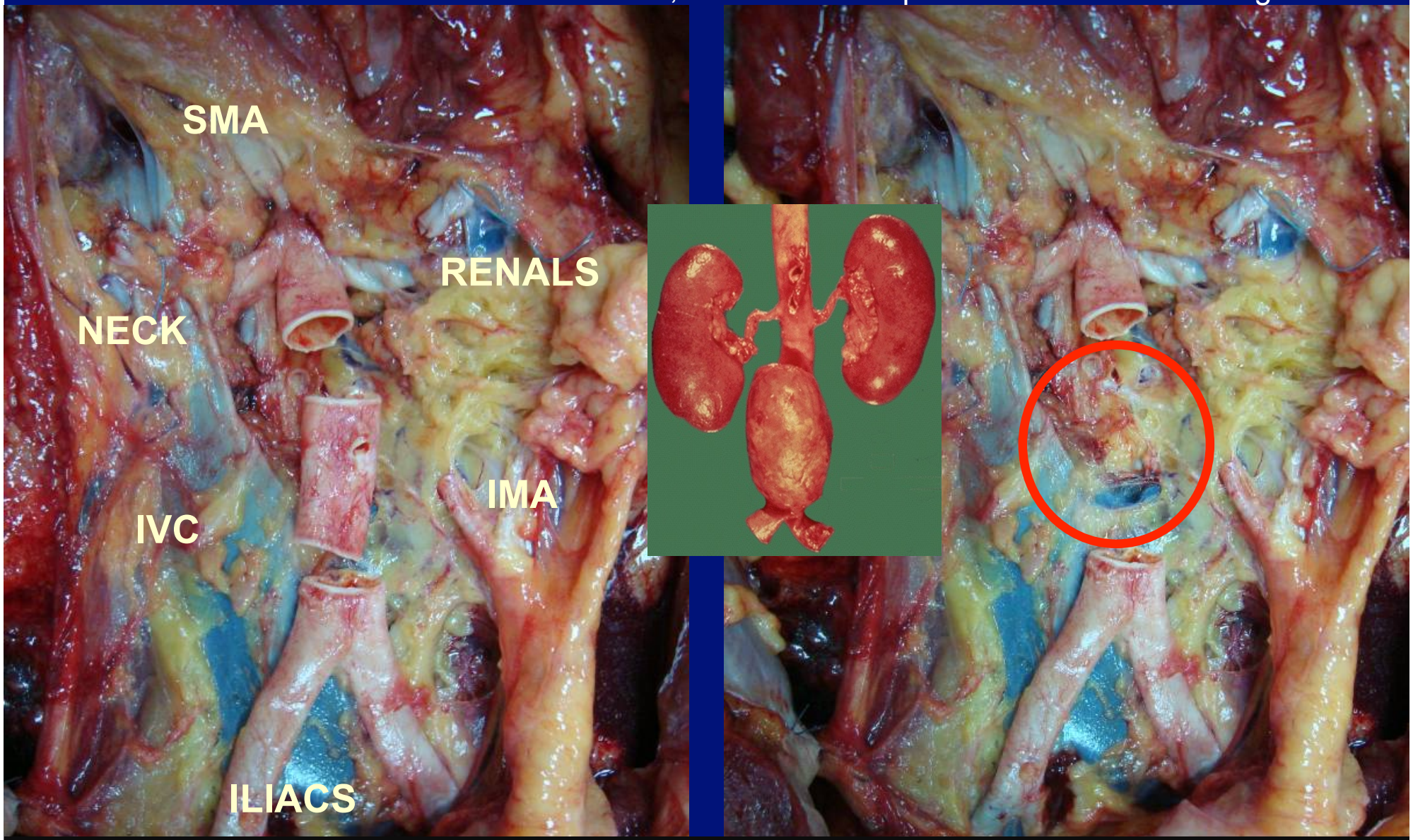
Cadaveric preperation

Abdominal aorta was exposed, and pressurization followed for OD measurement



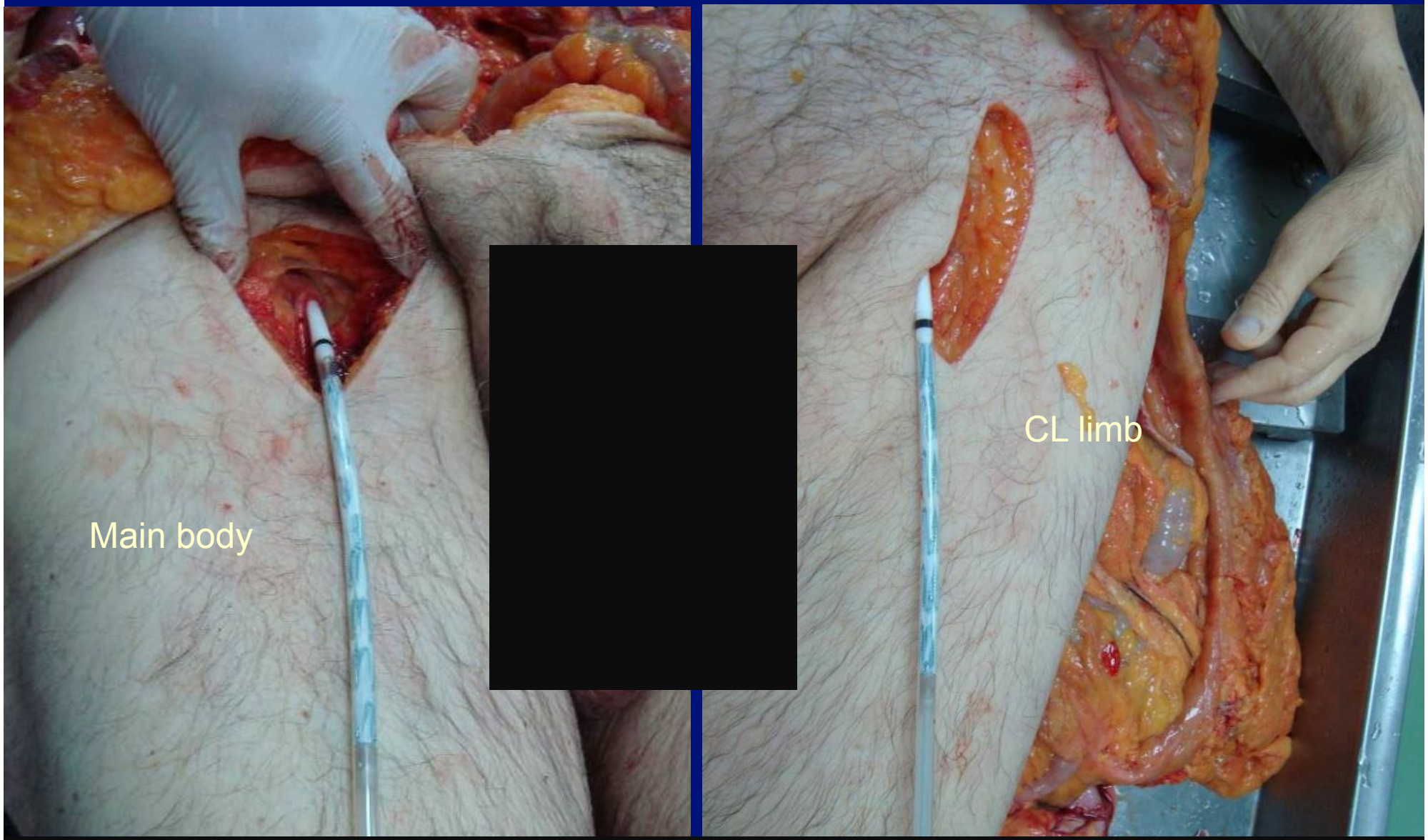
Methods

Aortas were surgically dissected from renals to iliac bifurcations, left in situ and transected 2 cm below the renals and above aortic bifurcation, to mimic AAAs' proximal and distal landing zones



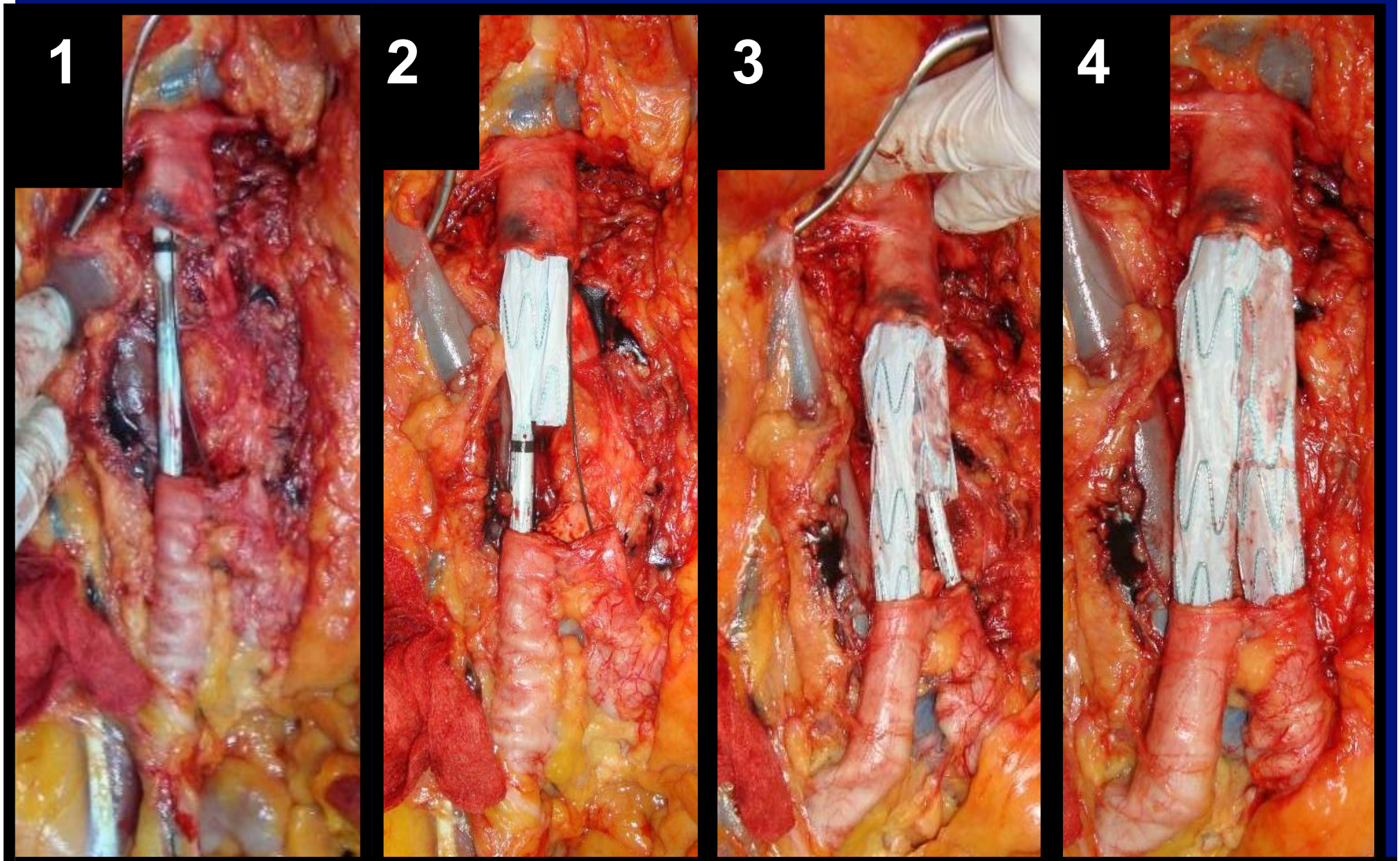
Aortoiliac dissection

Methods



Endografts were inserted

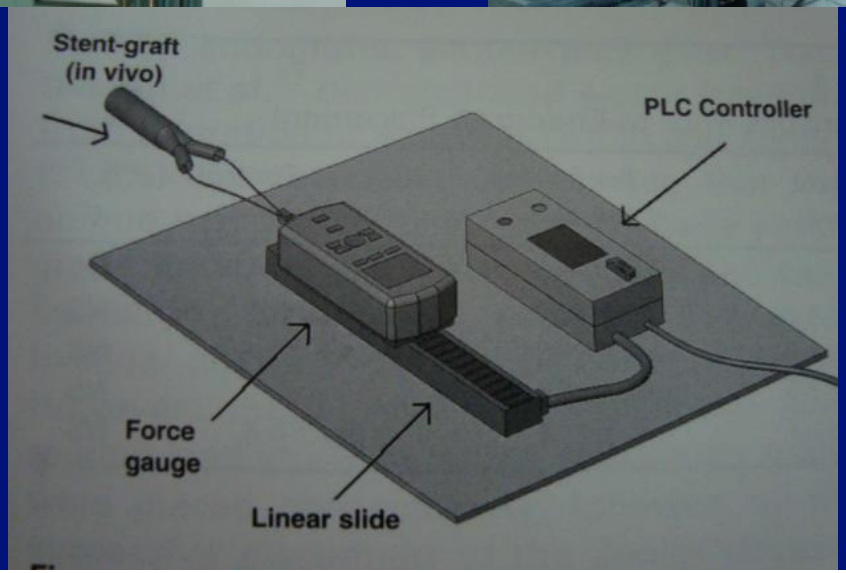
Methods

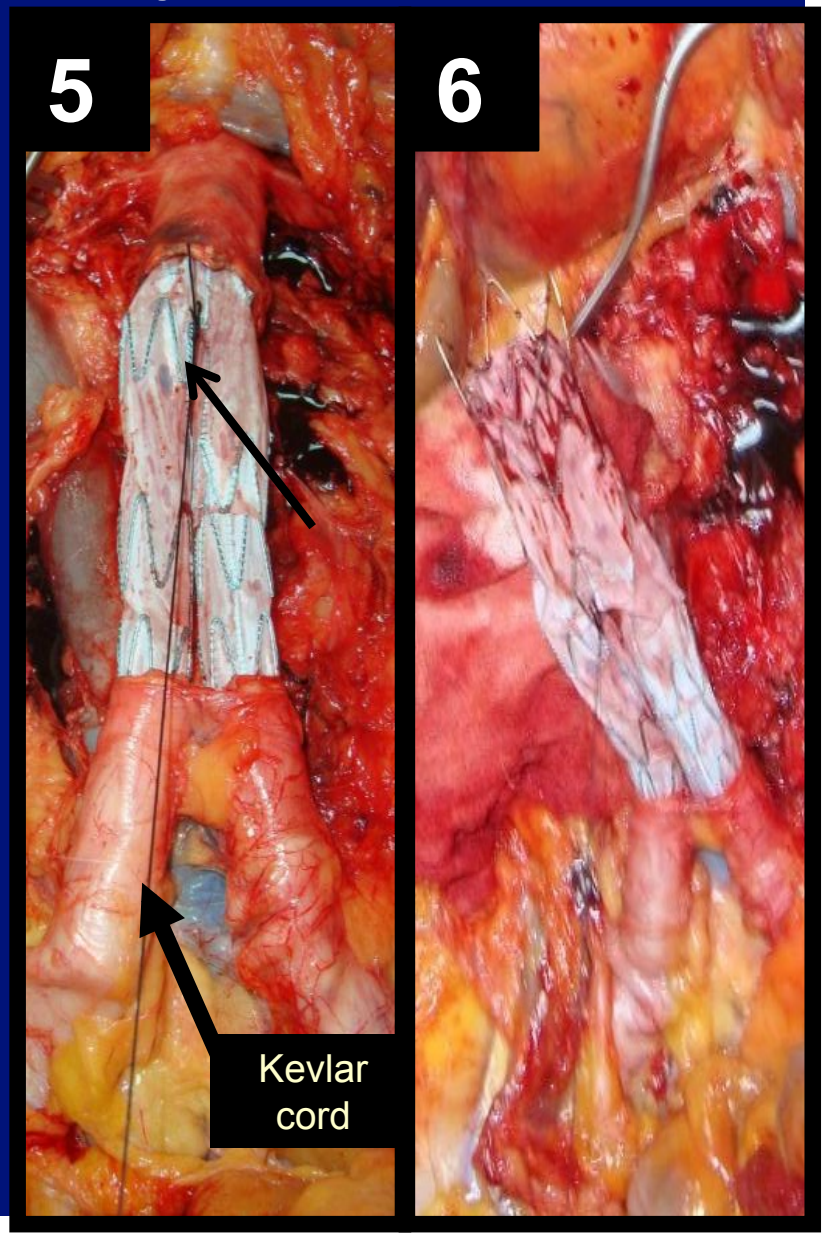


Deployed in the usual manner

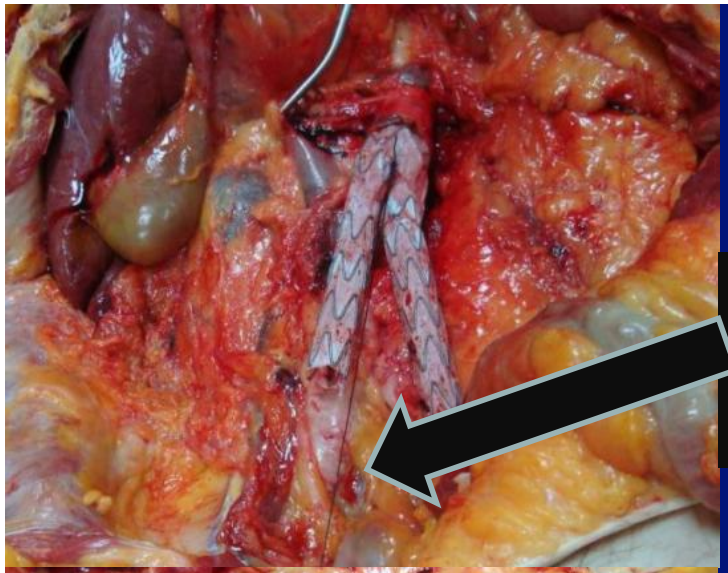
Methods

- Grafts were connected via a strong suture (kevlar cord) to a force gauge
- Caudal force was applied to the flow divider of each graft.

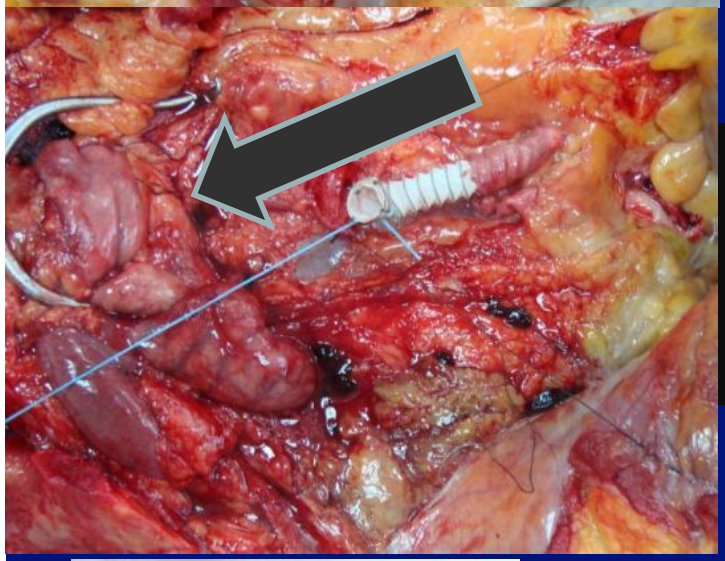




Methods



Recordings were repeated without iliac fixation

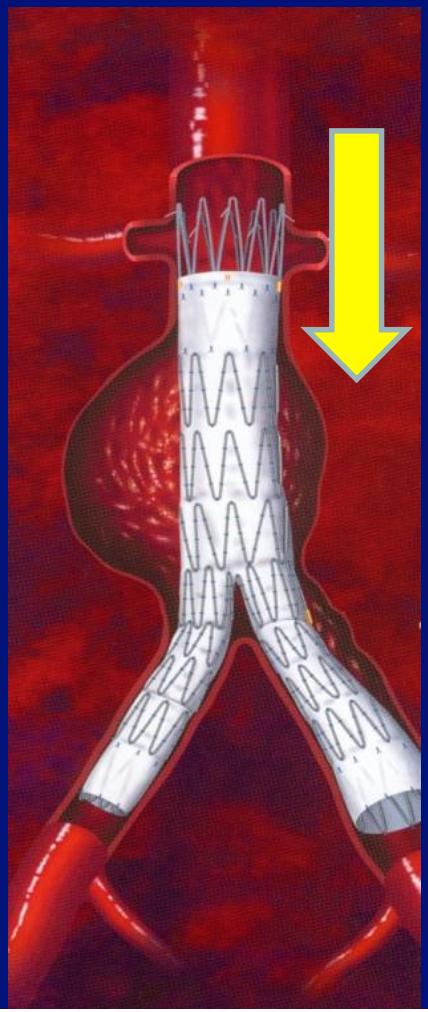


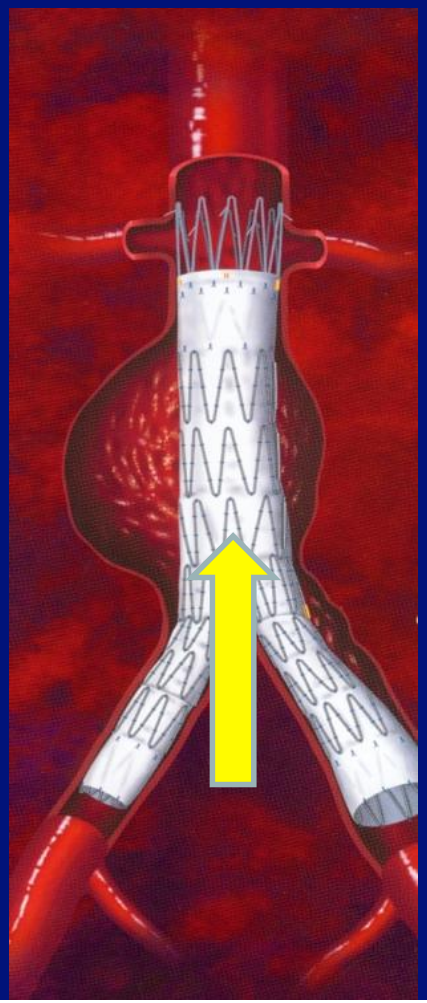
Similar protocol was applied for iliac limbs but the DF was cephalad

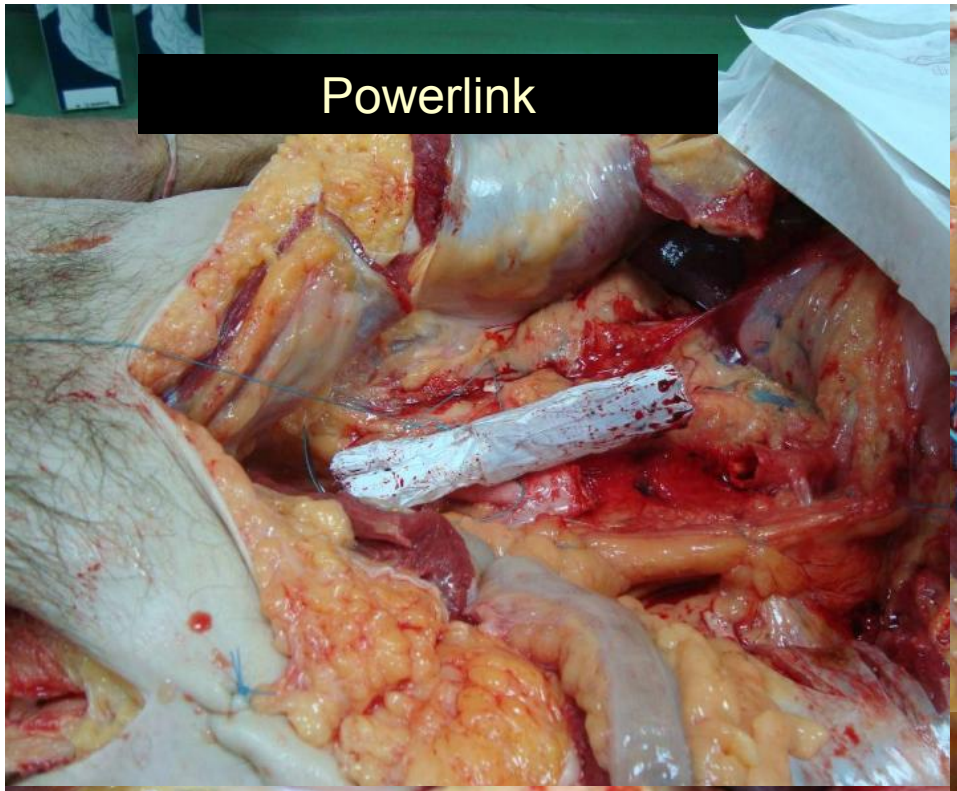
Recordings were repeated after molding balloon dilatation

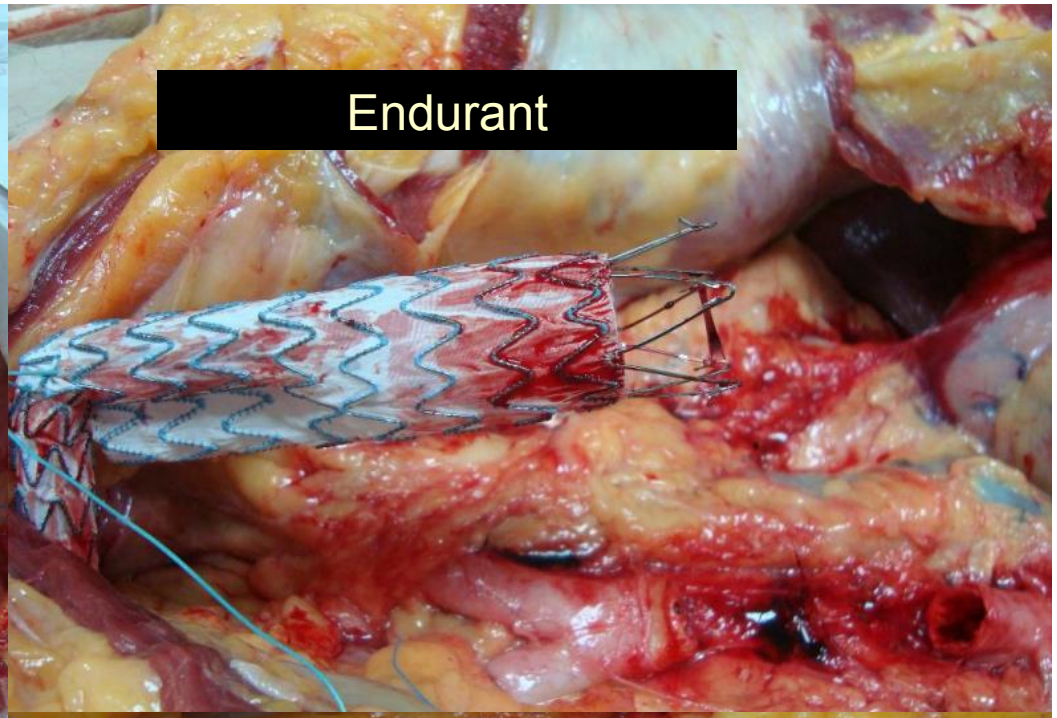
Methods

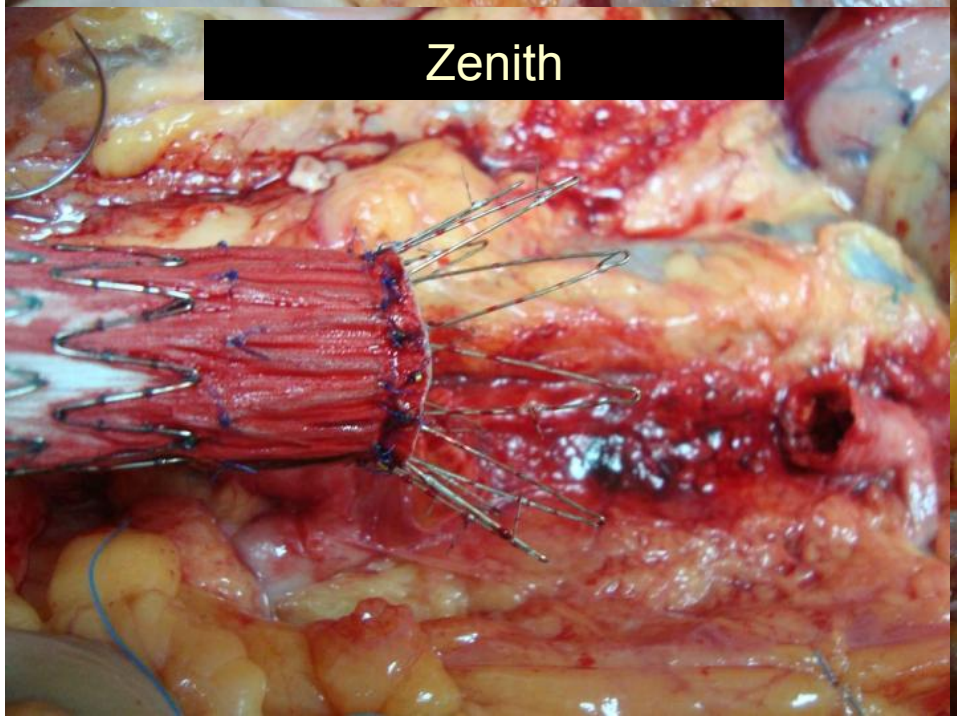
The pull out force recorded until dislocation from fixation zone was defined as displacement force (DF)

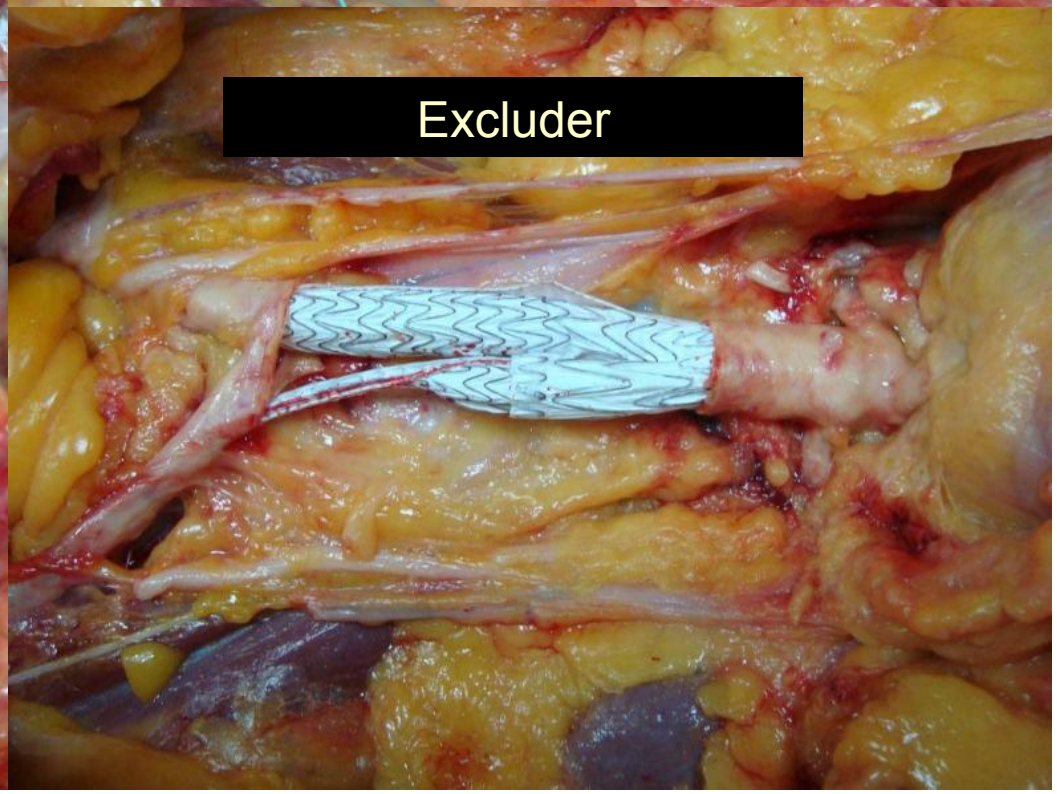


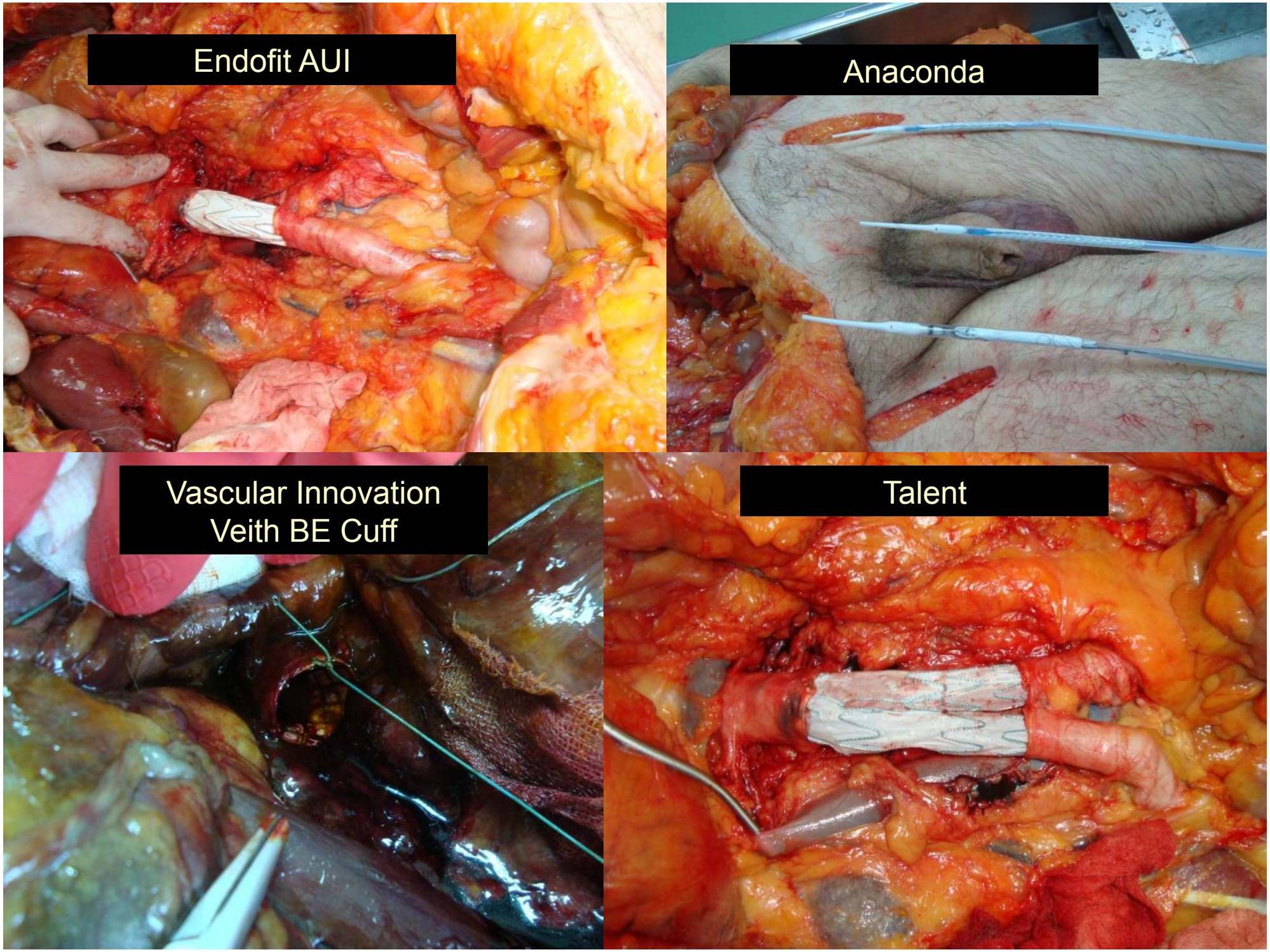



Powerlink


Endurant


Zenith


Excluder


Endofit AUI
Anaconda
Vascular Innovation
Veith BE Cuff
Talent

Results

Statistics

- Shapiro Wilk test ,Kolmogorov Smirnov test.

- Mann-Whitney U test (non parametric data)
- Student's T-test (parametric data).

- $p<0,05$ significant .

Results

We acuired 8 different categories

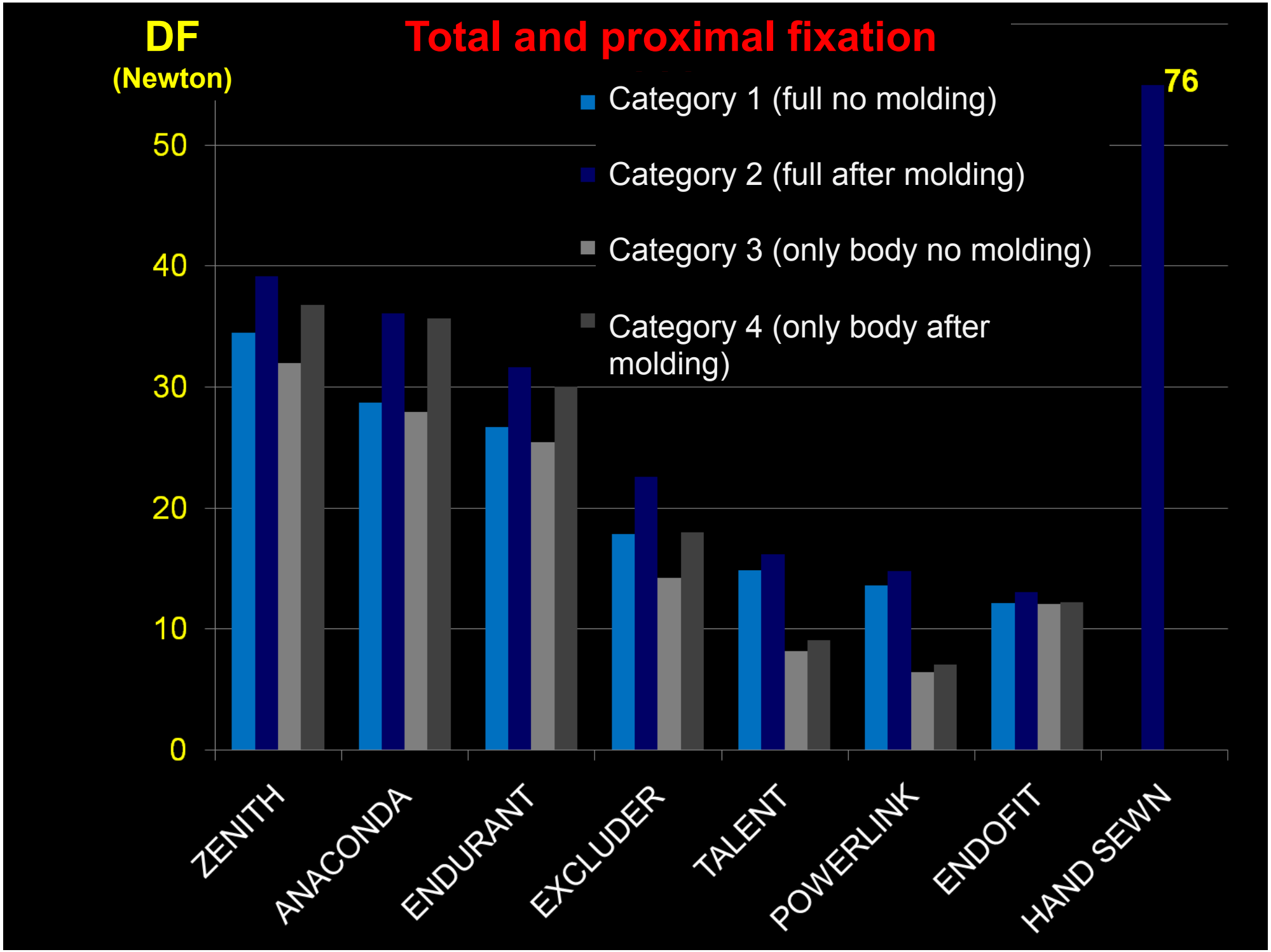
	TALENT	ANACONDA	EXCLUDER	ENDOFIT AUI	ZENITH	ENDURANT	POWERLINK	HAND SEWN
1) Endograft fully deployed without molding balloon	**14.90** (14.40-15.30)	**28.75** (26.50 - 31.05)	**17.90** (17.30-18.85)	**12.15** (11.00-13.40)	**34,50** (31.35-37.50)	**26.75** (24.60-28.70)	**13.65** (12.50-14.90)	---
2) Endograft fully deployed after molding balloon	**16.20** (15.70-16.65)	**3** (34.90-37.50)	(21.85-23.30)	(12.50-14.00)	(37.80-40.90)	**31.70** (29.50-34.05)	**14,80** (14.10-15.50)	**76.20** (66.40-79.00)
3) Only body deployed without molding balloon	**8.20** (7.05-9.25)	**27.95** (25.0	**14.30**	**12.10**	**32.05** 60)	**25.50** (23.95-27.05)	**6.50** (6.45-6.70)	---
4) Only body deployed after molding balloon	**9.10** (8.30-9.95)	**3** (34.65-36.80)	(16.80-18.30)	(11.20-13.05)	(34,70-38.75)	**30.10** (26.30-34.20)	**7.10** (7.00-7.25)	---
5) Iliac leg deployed 2 cm into iliac artery without molding balloon	**6.85** (6.40-7.30)	**8,90** (7.75-9.90)	**7,65** (7.20-8.10)	**6.75** (5.00-7.10)	**7.15** (6.80-7.50)	**7,30** (7.10-7.55)	**2,65** (2.60-3.50)	---
6) Iliac leg deployed 2 cm into iliac artery after molding balloon	**7.30** (7.00-7.55)	**9,85** (9.55-10.20)	**8.05** (7.30-8.75)	**7.10** (6.00-7.15)	**7.75** (7.25-8.20)	**7.85** (7.15-8.50)	**2,80** (2.70-3.60)	---
7) Iliac leg deployed 5 cm into iliac artery without molding balloon	**8.65** (7.55-9.80)	(12.15-14.10)	(9.45-10.40)	(8.05-9.10)	(7.55-10.60)	**9,05** (8.50-9.80)	**4,50** (4.35-4.95)	---
8) Iliac leg deployed 5 cm into iliac artery after molding balloon	**9.20** (8.00-10.50)	**14.50** (13.95-15.30)	**10.55** (10.10-10.90)	**9.00** (8.30-9.20)	**9.50** (8.05-11.10)	**9.60** (9.25-10.10)	**4.75** (4.55-5.50)	**60.40** (53.50-62.70)

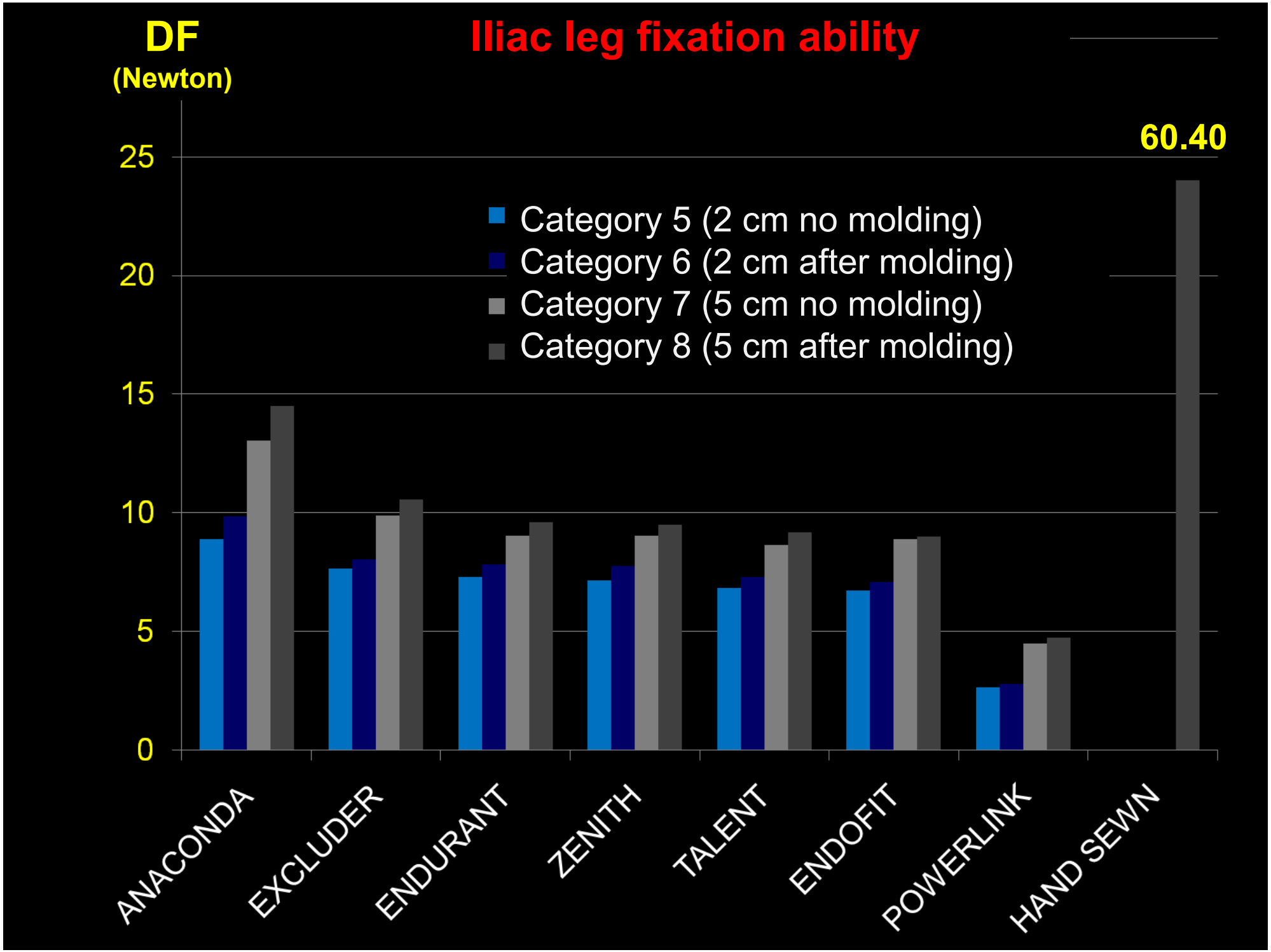
Validated Overall fixation against caudal migration

Validated Proximal fixation against caudal migration

Validated Distal fixation against cephalad migration

All values refer to DF (displacement force) in **Newton** after statistical analysis. (**Median - range**).


DF
(Newton)
Total and proximal fixation
Category 1 (full no molding)
Category 2 (full after molding)
Category 3 (only body no molding)
Category 4 (only body after molding)
76
50
40
30
20
10
0
ZENITH
ANACONDA
ENDURANT
EXCLUDER
TALENT
POWERLINK
ENDOFIT
HAND SEWN


DF
(Newton)
Iliac leg fixation ability
60.40
25
20
15
10
5
0
Category 5 (2 cm no molding)
Category 6 (2 cm after molding)
Category 7 (5 cm no molding)
Category 8 (5 cm after molding)
ANACONDA
EXCLUDER
ENDURANT
ZENITH
TALENT
ENDOFIT
POWERLINK
HAND SEWN

Maximum overall fixation ability (p=S)

	DF in Newton, median (range).							
	TALENT	ANACONDA	EXCLUDER	ENDOFIT AUI	ZENITH	ENDURANT	POWERLINK	HAND SEWN
2) Endograft fully deployed after molding balloon	**16.20** (15.70-16.65)	**36,10** (34.90-37.50)	**22.60** (21.85-23.30)	**13.10** (12.50-14.00)	**39.20** (37.80-40.90)	**31.70** (29.50-34.05)	**14,80** (14.10-15.50)	**76.20** (66.40-79.00)

Maximum distal fixation ability p=S

8) Iliac leg deployed 5 cm into iliac artery after molding balloon	**9.20** (8.00-10.50)	**14.50** (13.95-15.30)	**10.55** (10.10-10.90)	**9.00** (8.30-9.20)	**9.50** (8.05-11.10)	**9.60** (9.25-10.10)	**4.75** (4.55-5.50)	**60.40** (53.50-62.70)

All endografts / limbs showed the max. fixation when fully deployed and after molding balloon dilatation

The role of hooks / barbs

Categories 1-4	W/out hooks Talent, Endofit AUI and Powerlink	With hooks Anaconda, Excluder, Zenith and Endurant
Median	**12,3250**	**29,5750**
Minimum	6,45	13,40
Maximum	16,65	40,90
	P<0.0001	

endografts with hooks recorded higher fixation ability when compared with endografts without hooks and the difference was stat. significant

The role of SR stent

Categories 1-4	Suprarenal grafts Talent, Endofit AUI, Zenith, Endurant and extender cuff	Infrarenal grafts Anaconda, Excluder, and Powerlink
Median	**23,9500**	**17,9500**
Minimum	7,05	6,45
Maximum	40,90	37,50
	P=0.628 NS	

endografts with SR stent showed slightly increased fixation ability when compared with endografts with infrarenal fix. and the difference was insignificant

PTFE anastomosis

Proximal aortic

Category 2	All endografts (Talent, Anaconda, Excluder, Endofit AUI, Zenith, Endurant, Powerlink και Veith)	PTFE
Median	**22.60**	**76.20**
Minimum	12,50	66.40
Maximum	40,90	79.00
	P=0.001	

Distal iliac

Category 8	All limbs (Talent, Anaconda, Excluder, Endofit AUI, Zenith, Endurant, και Powerlink)	PTFE
Median	**9,5000**	**60,40**
Minimum	4,55	53,50
Maximum	15,30	62,70
	P=0.01	

HAND PTFE anastomosis recorded higher fixation ability when compared with all endografts or limbs and the difference was stat. significant

The role of molding balloon

In grafts with hooks / barbs balloon dilatation produced a stat. significant increase in fixation

Anaconda, Excluder, Zenith, Endurant	No dilatation	After dilatation
Median	27.7250	34.4750
Minimum	17.30	21.85
Maximum	37.50	40.90
	P=0.045	

In grafts without hooks / barbs balloon dilatation produced a stat. insignificant increase in fixation

Talent, Endofit AUI , Powerlink	No dilatation	After dilatation
Median	13.6500	14.8000
Minimum	11.00	12.50
Maximum	15.30	16.65
	P=0.133 NS	

The role of column strength

In grafts with column strength mechanisms (bar or unibody frame) complete deployment produced a stat. significant increase in fixation

Talent and Powerlink	Category 1 Fully deployed	Category 3 Proximal deployed
Median	**14.6500**	**6.8750**
Minimum	12.50	6.45
Maximum	15.30	9.25
	P=0.004	

In grafts without column strength mechanisms (bar or unibody frame) complete deployment produced a stat. insignificant increase in fixation

Anaconda, Excluder, Endofit, Zenith and Endurant	Category 1 Fully deployed	Category 3 Proximal deployed
Mean	**24.0200**	**22.3967**
SD	8.38983	8.25304
	P=0.597 NS	

Balloon expandable vs self expanding

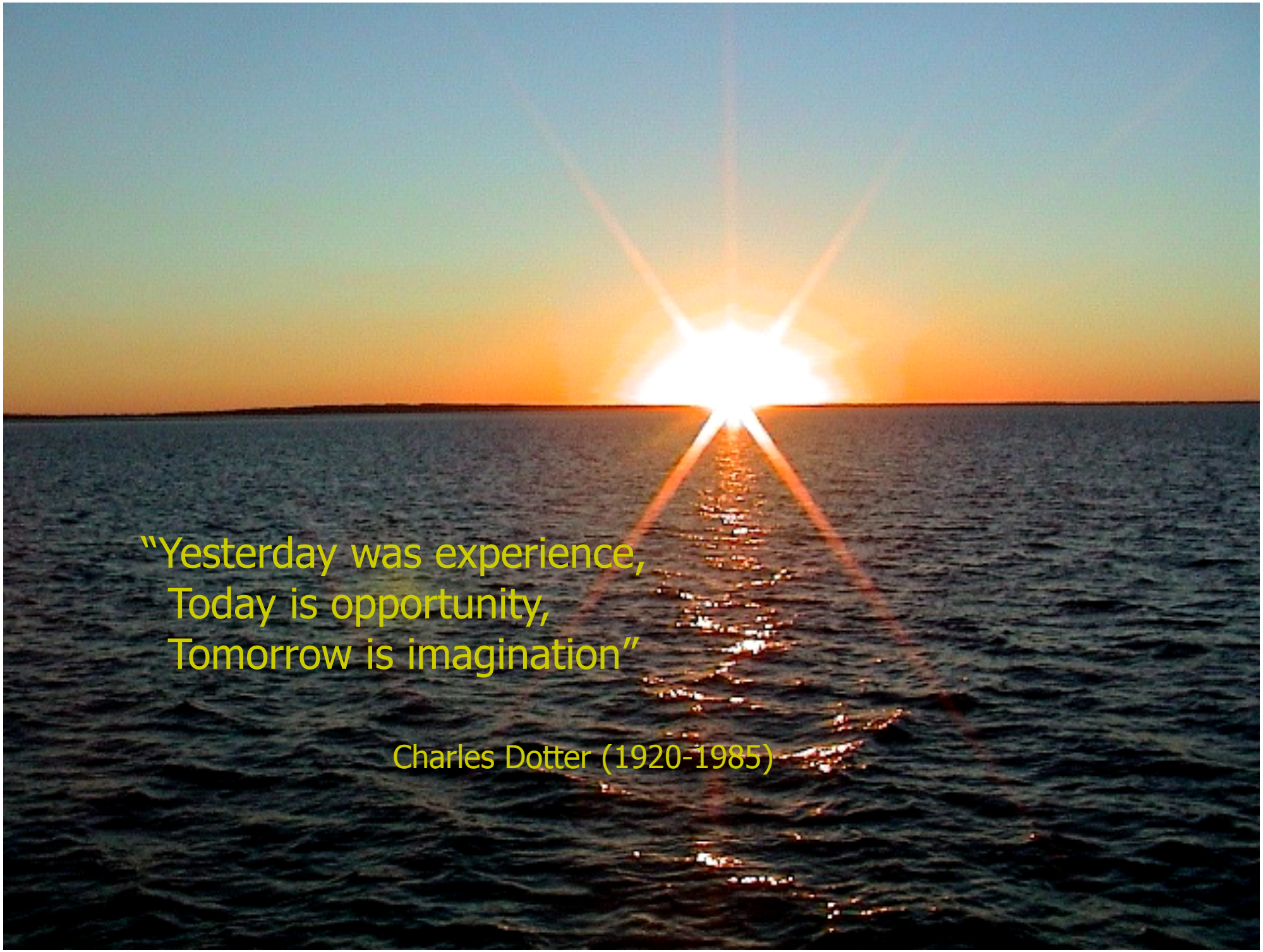
DF in Newton.		
Proximal aortic	BE	SE
Category 4 **Proximal deployed after balloon dilatation**	27.70	21.30 mean

DF in Newton.		
Distal iliac	BE	SE
Category 6 **Iliac leg deployed 2 cm into iliac artery after molding balloon**	12.45	7.25 mean
Category 8 **Iliac leg deployed 5 cm into iliac artery after molding balloon**	25,20	8.3 mean

BE stent showed a higher fixation ability compared with SE endografts or limbs

Conclusions

1. Each endograft bears a unique fixation system which is a mixture of many separate mechanical characteristics.
2. Hooks and barbs offer the best overall and proximal fixation.
3. Ring stents offer the best distal fixation.
4. Molding balloon dilatation increases fixation mostly for “hooked’ grafts.
5. Columnar support increases overall fixation.
6. Balloon expandable stent graft recorded high fixation ability.
7. PTFE anastomosis recorded the highest fixation.
8. Suprarenal stent slightly increases fixation.


"Yesterday was experience,
Today is opportunity,
Tomorrow is imagination"
Charles Dotter (1920-1985)