

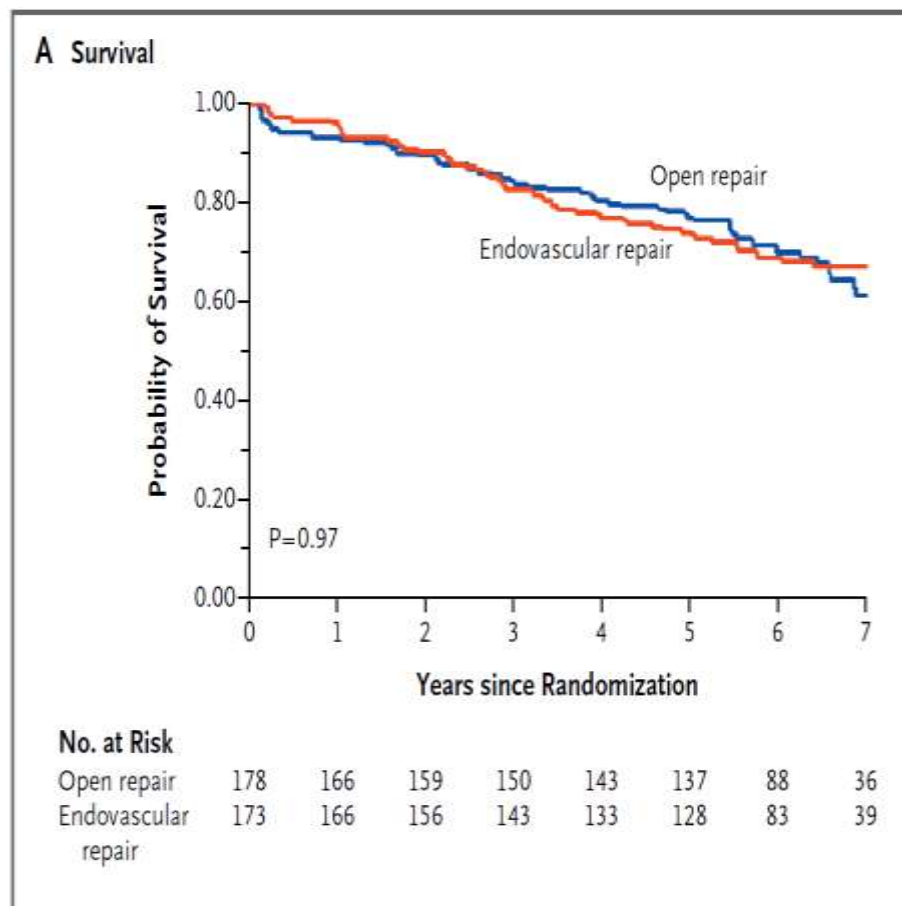
Evolution in AAA Endograft Devices, Technique, and Outcomes

Woong Chol Kang M.D.

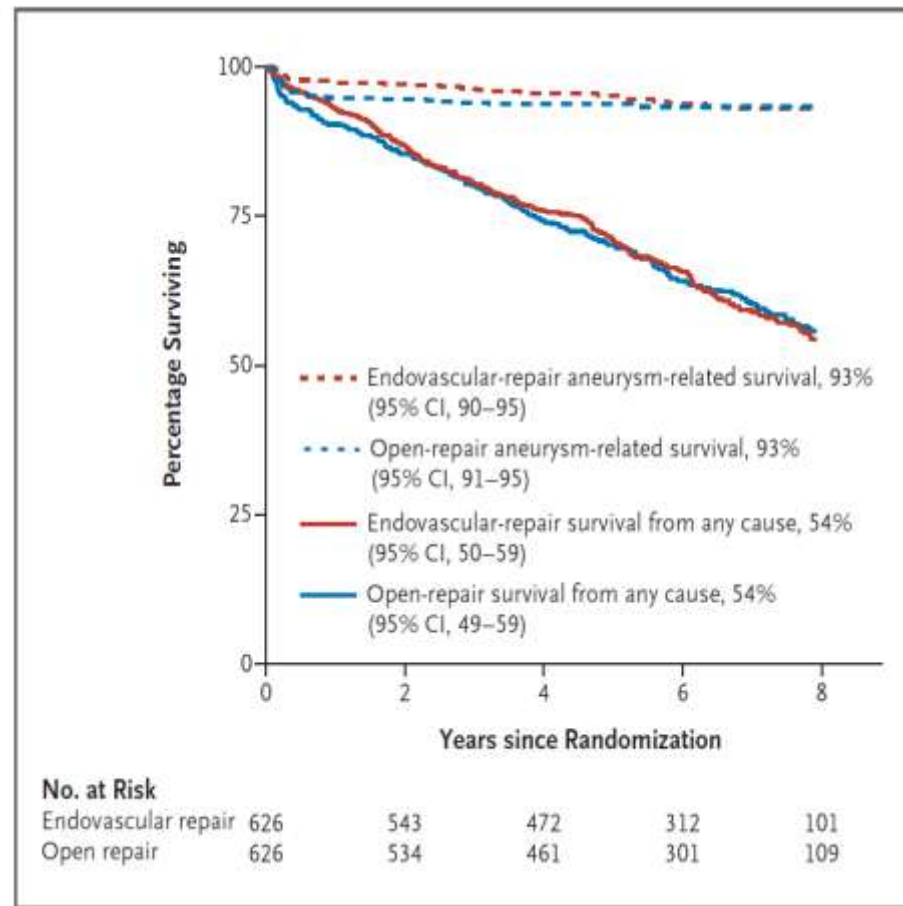
Gil Hospital, Gachon University, Incheon, Korea



EVAR vs. Open repair for AAA



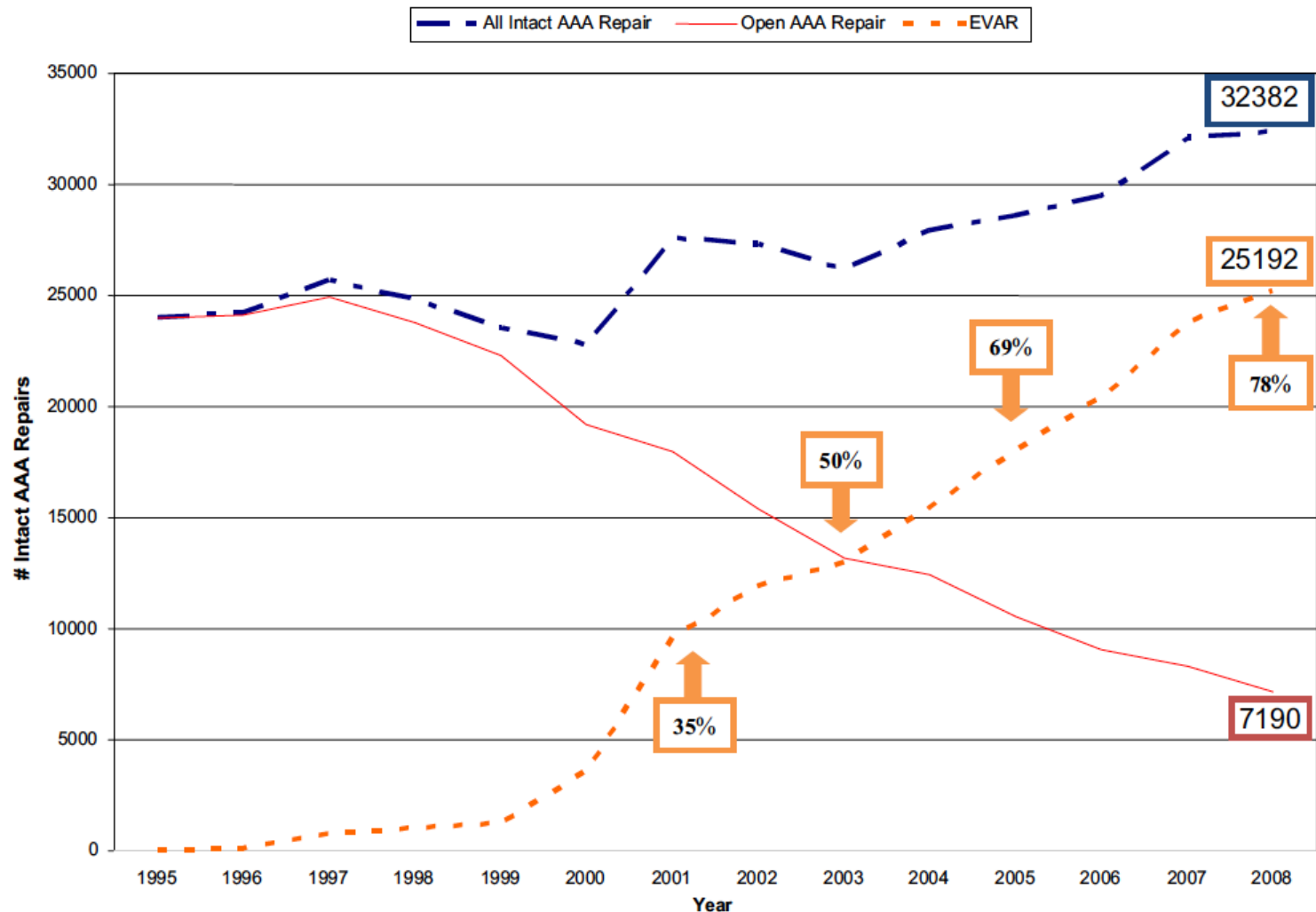
DREAM



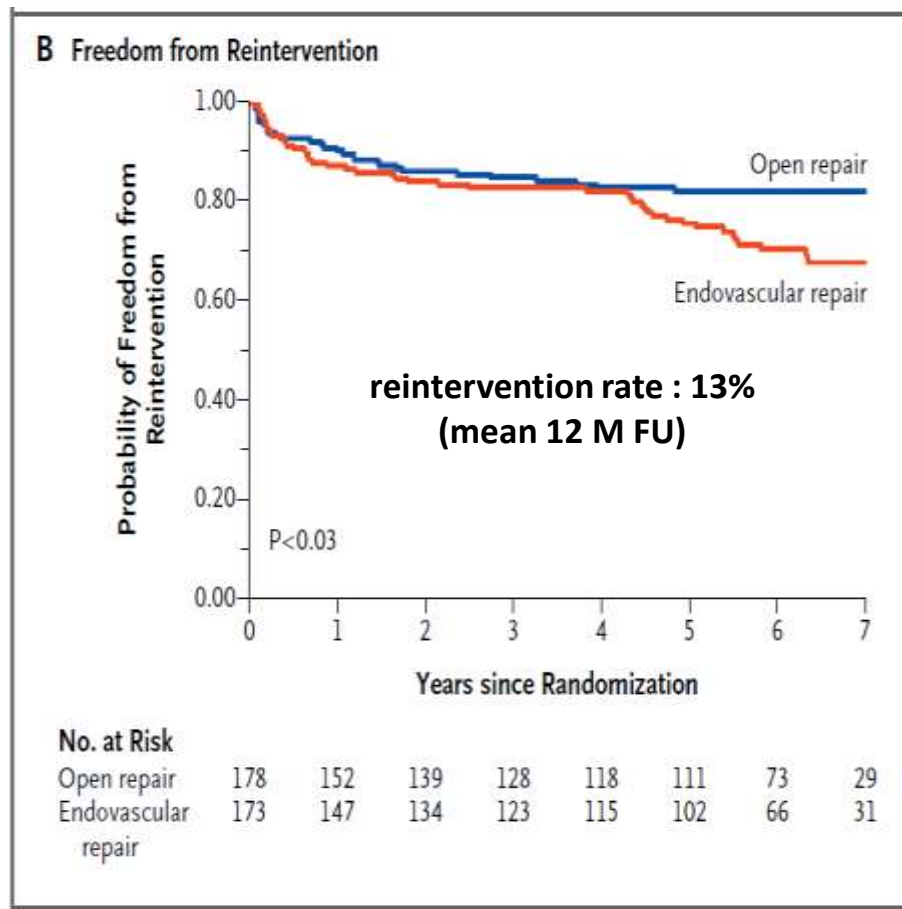
EVAR-1

Low perioperative morbidity/mortality, hospital stay/ its associated costs

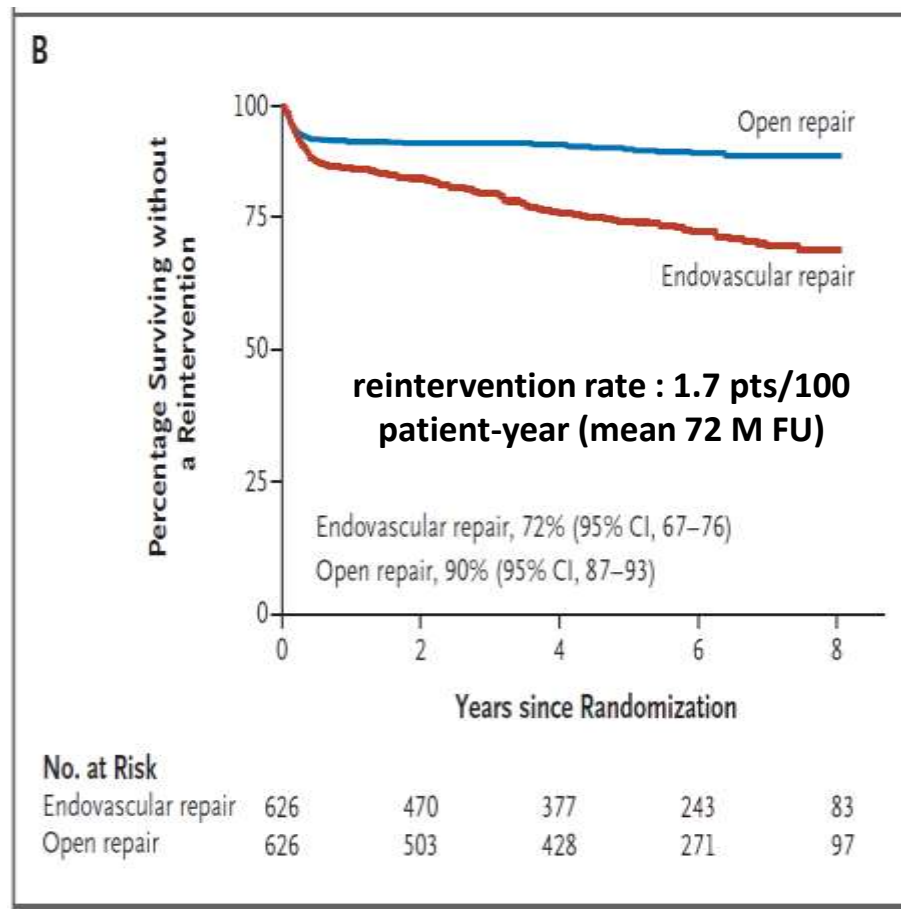
The Number of Open and Endovascular AAA Repairs in the US Medicare Population



Reintervention after EVAR



DREAM



EVAR-1

Reintervention rate : 3.7%/year (meta-analysis)

Currently Available Devices in Korea



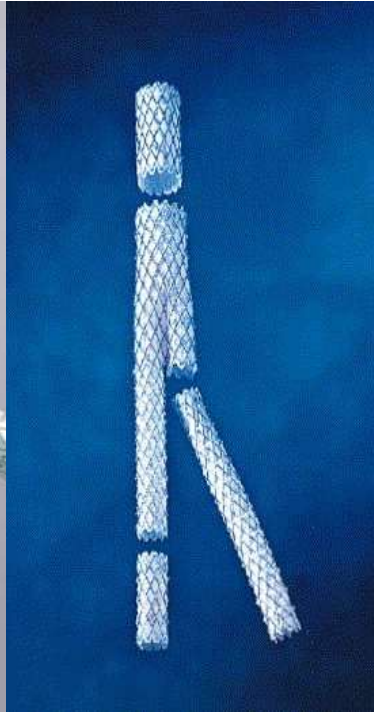
Seal,
S&G



**Zenith Flex,
Cook**



**Excluder,
Gore**



**2002
Aneurix,
Medtronic**

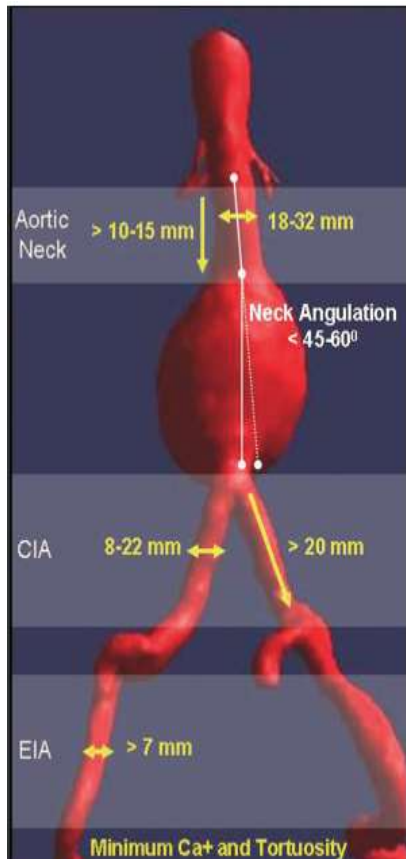


**2008
Talent,
Medtronic**



**2010
Endurant,
Medtronic**

Minimal requirement for standard EVAR



Proximal aortic neck

Neck diameter >17 mm, <32 mm

Angle between the suprarenal aorta and the juxtarenal aorta <60°

Angle between the juxtarenal aorta and the long axis of the aneurysm sac <60-90°

Neck length >10 mm

Neck thrombus covering <50% of the proximal neck circumference

Neck dilated <3 mm within 10 mm of the most caudal renal artery

Focal neck enlargement <3 mm within 15 mm from the most caudal renal artery

Neck calcification <50% of the proximal neck circumference

Aortic bifurcation

Aortic bifurcation diameter >20 mm in case of a bifurcated graft

Iliac artery

Iliac luminal diameter >7 mm

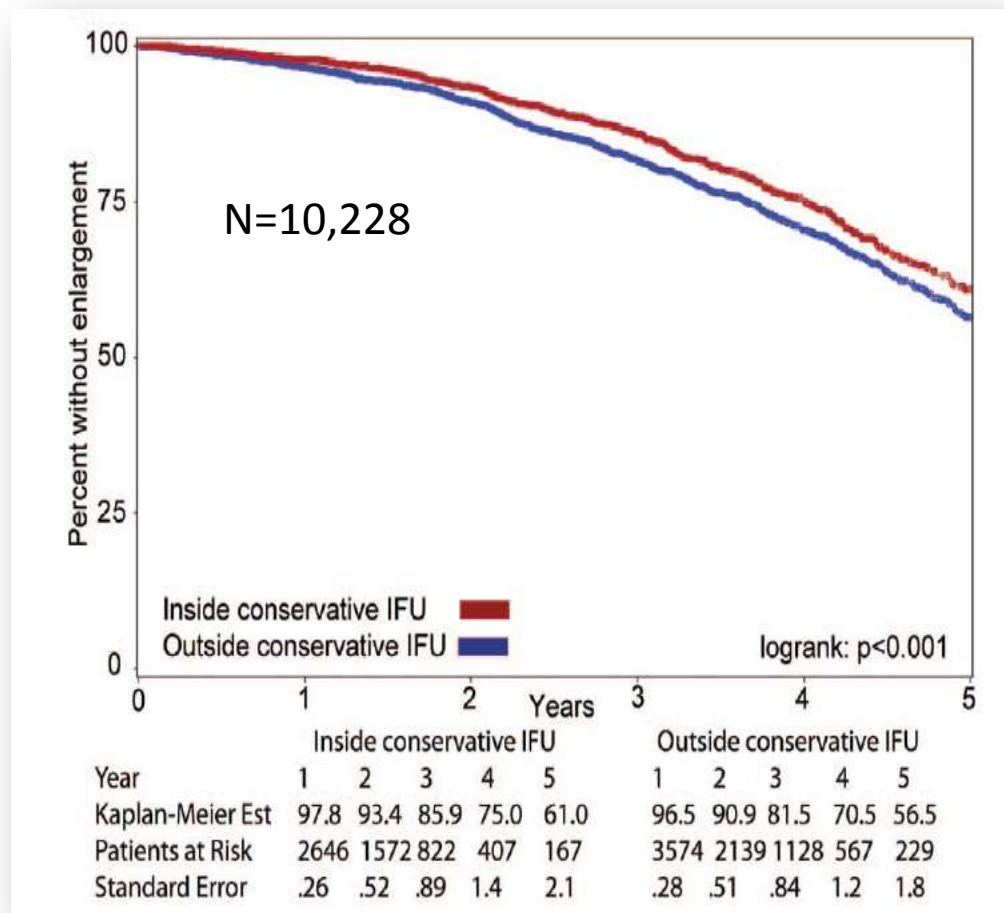
Angle between the long axis of the aneurysm and the iliac axis <60°

Iliac calcification: non extensively circumferential

Iliac neck diameter <22 mm

Iliac neck length >15 mm

AAA Enlargement after EVAR



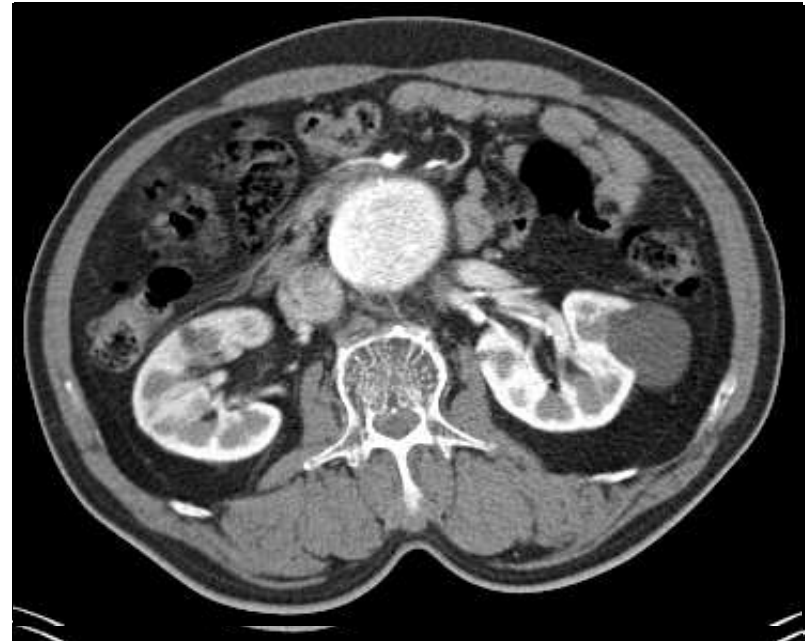
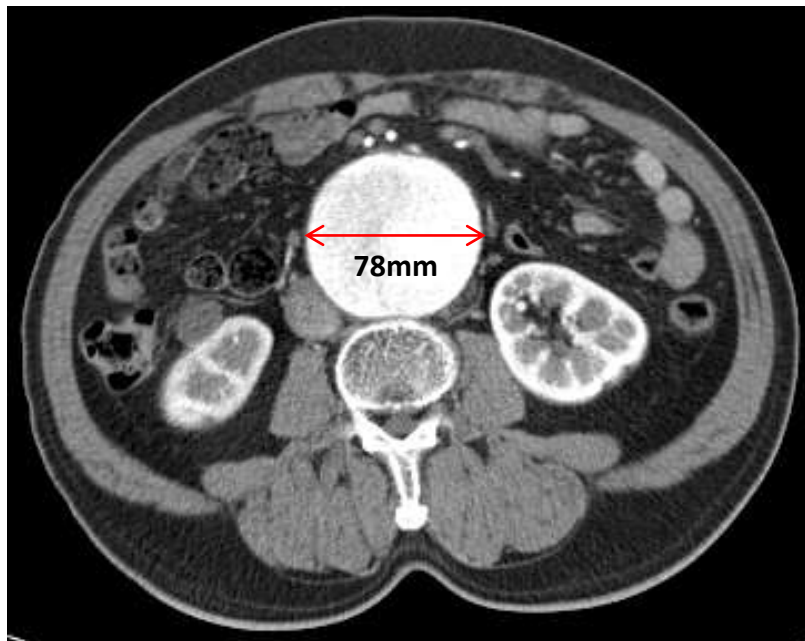
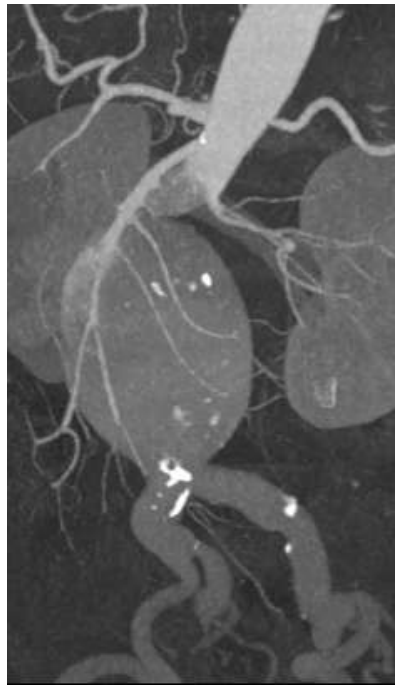
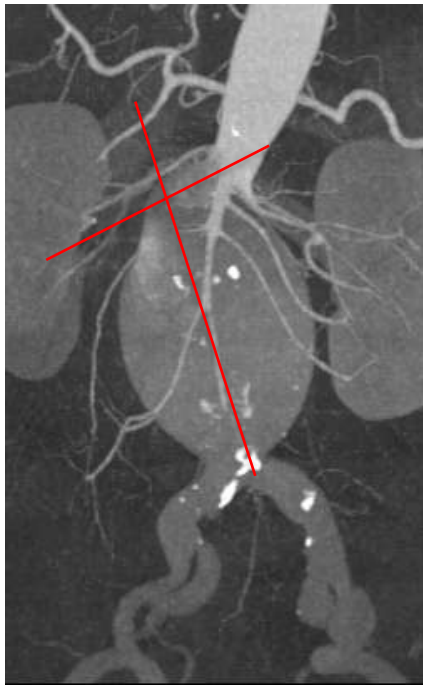
- Only **42%** of patients had anatomy that met the most conservative device IFU
- **Sixty-nine percent** met the most liberal device IFU.
- The 5-year post-EVAR rate of sac enlargement was **41%**

Table 5. Determinants of Aortic Aneurysm Sac Enlargement Identified on Multivariable Cox Proportional Hazards Analysis

Covariates	Hazard Ratio (95% Confidence Interval)	P
Age, y		
<60	Reference	
60–69	0.80 (0.60–1.05)	0.11
70–79	0.87 (0.67–1.14)	0.31
≥80	1.32 (1.03–1.75)	0.05
Female	0.96 (0.82–1.13)	0.64
AAA diameter		
Maximum AAA diameter		
≥55 mm	0.97 (0.86–1.10)	0.62
Aortic neck length, mm		
>15	Reference	
10–15	0.87 (0.71–1.07)	0.19
<10	0.94 (0.77–1.15)	0.53
Aortic neck diameter		
Diameter at lowest renal artery		
<28 mm	Reference	
Diameter at lowest renal artery 28–32 mm	1.80 (1.44–2.23)	<0.0001
Diameter at lowest renal artery >32 mm	2.07 (1.46–2.92)	<0.0001
Conical neck	1.17 (0.97–1.42)	0.10
Aortic neck angle, °		
<45	Reference	
45–60	1.04 (0.90–1.21)	0.58
>60	1.96 (1.63–2.37)	<0.0001
Iliac diameter		
Both common iliac arteries		
≤20 mm	Reference	
Only 1 common iliac arteries >20 mm	1.46 (1.21–1.76)	<0.0001
Both common iliac arteries >20 mm	1.31 (0.99–1.74)	0.06
Endoleak during follow-up	2.70 (2.40–3.04)	<0.0001

M/65

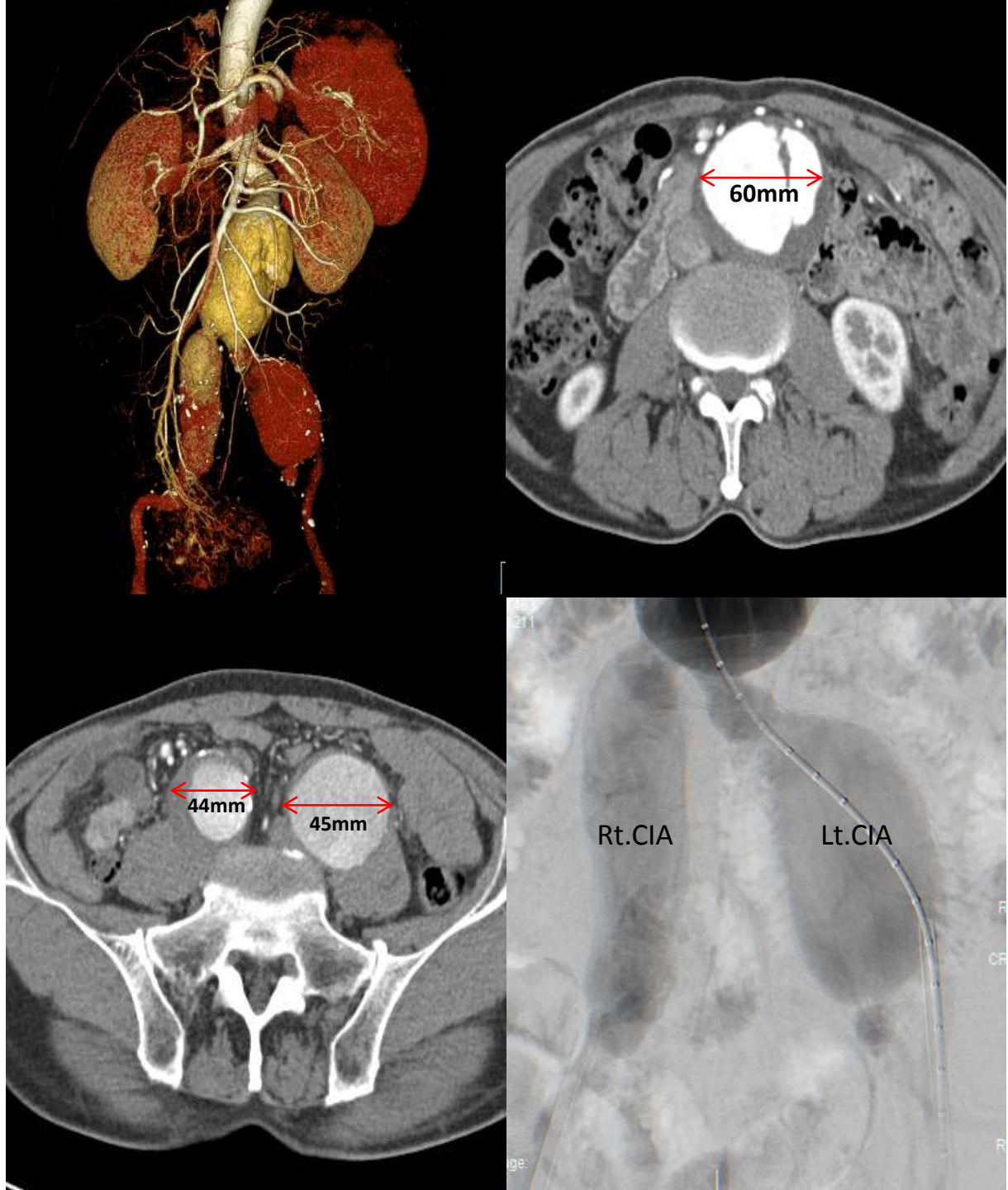
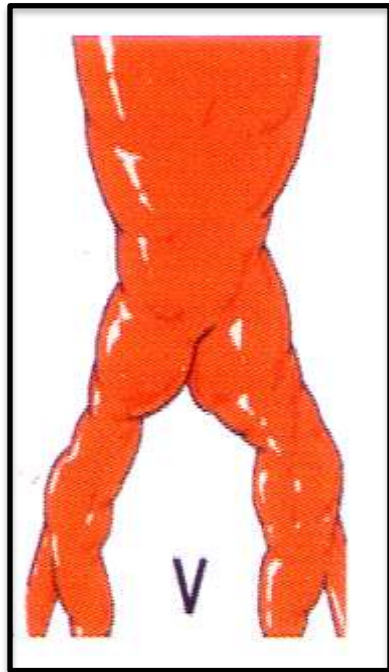
HTN, DM



M/73

HTN

**Old MI, s/p PCI
at LAD**



Limitations of Current Devices

Limitations

- Hostile neck
- Inability of reposition
- Large device profile
- Inadequate sealing
- Juxta- or suprarenal AAA
- AAA with Iliac involvement



Required Improvement

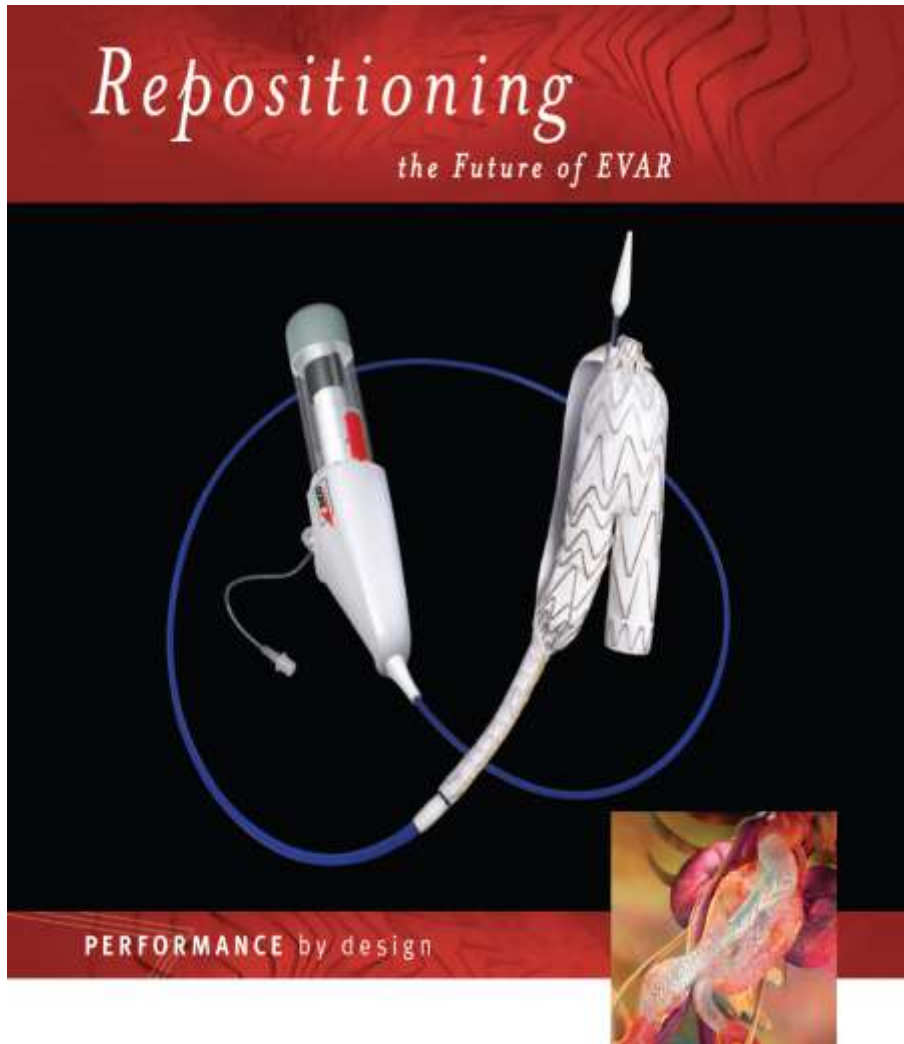
- Flexibility and conformability
- Controllable deployment
- Migration resistance
- Low profile
- Long-term durability
- Fenestrated/branched endograft

New generation of endograft with main features

Type of anatomic fixation and devices	Stent - main graft material	Main body delivery sheath (size)	Re-positioning mechanism	Special characteristics/features
Suprarenal fixation				
<i>Endurant</i> ®	Nitinol-polyester	18-20F (OD) ³	No	Low profile, tip capture mechanism
<i>Incraft</i> ®	Nitinol-polyester	13 and 15F	Yes	Ultra-low profile, in-situ length adjustment, repositionable, active locking mechanism
<i>Ovation</i> ®	Nitinol-PTFE	14-15F	No	Ultra-low profile, inflatable rings for sealing, no radial force
<i>Zenith LP</i> ®	Nitinol-polyester	16-17F	No	Low profile, long main body, COOK Medical ARC technology
Infrarenal fixation				
<i>AFX</i> ®	Cobalt chromium-STRATA ¹	17F	No	Anatomical fixation at the aortoiliac bifurcation, STRATA material, dual seal mechanism
<i>Anaconda One-Lok</i> ®	Nitinol-polyester/tantalum	20-23F (OD)	Yes	Repositionable, preloaded wire and magnet system
<i>Aptus</i> ™	Nitinol-polyester	16-18F	No	EndoStaples, polyester without stents in the main body
<i>Aorfix</i> ®	Nitinol-polyester	22F	No	Coil design, closely aligned nitinol wires in the proximal part, treats neck angles $\geq 90^\circ$
<i>C3-Excluder</i> ®	Nitinol-ePTFE	18-20F	Yes	Three-step deployment system, repositionable
<i>Nellix</i> ®	Cobalt chromium-PEG-endobags ²	17F	No	EVAS system (balloon-expandable endoframes surrounded by endobag filled with polyethylene glycol)
Supra- and infrarenal fixation				
<i>Treovance</i> ®	Nitinol-polyester	18-19F	Yes	Both supra- and infrarenal fixation, Navitel® delivery sheath, repositionable

¹multilayer ePTFE, ²balloon –expandable endoframes surrounded by an endobag filled with an in-situ curing polymer, ³outer diameter

Excluder & C3 Delivery System (Gore)



- Allows the proximal end of the endograft to be reconstrained after insertion
- Be rotated or moved cranially or caudally.
- Facilitate contralateral limb cannulation and placement of the endograft closer to the lowest renal artery
- Decreasing the risk of inadequate sealing and consequent graft migration and endoleaks.

C3 Delivery System

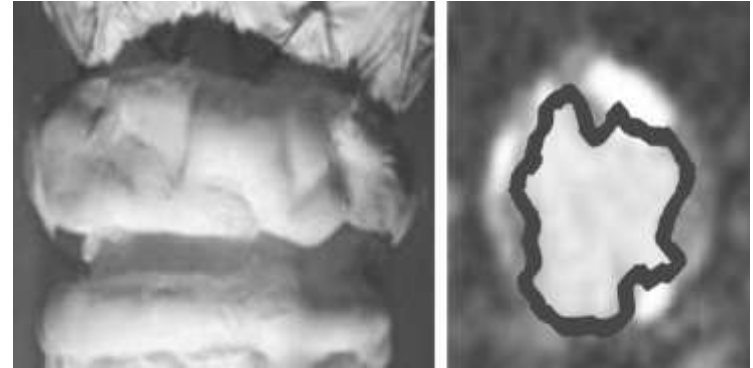
- EVAR with unfavorable neck anatomy using the Excluder endoprosthesis on the **traditional deployment system** or the **C3 repositionable system**.
- Of all **77** patients, 44 (57%) patients had unfavorable neck anatomy defined as proximal aortic neck length of <15 mm, neck diameter of >28 mm, neck angulation of >60, circumferential thrombus of >50% or calcification at the proximal seal zone, or a “reverse taper” on CT angiography.
- Of the 44 patients, 24 patients received the C3 Excluder and 20 received the traditional Excluder

Endoleaks	C3 Excluder (n = 24)	Traditional Excluder (n = 20)	P value
Proximal type I endoleaks	<u>6 (25%)</u>	<u>12 (60%)</u>	<u>0.03^a</u>
Distal type I endoleaks	1 (4.2%)	1 (5%)	1.0
Type II endoleaks	4 (16.7%)	5 (25%)	0.71
Proximal extensions used	<u>3 (12.5%)</u>	<u>13 (65%)</u>	<u>0.0005^a</u>

Ovation (Trivascular)

14F OD Aortic Body

13F OD Iliac Limbs



- **Tri-modular design**
- Suprarenal stent with integral anchors
- **Inflatable sealing rings**
 - inflated with a low-viscosity radiopaque polymer during stent- graft deployment
 - reveals the high conformability to irregular surfaces
- Kink resistant iliac limbs
- Hydrophilic catheter coating



Ovation for AAA: 2 year Outcome

- Prospective, multicenter, single-arm trial was conducted at 36 sites in the United States, Germany, and Chile to evaluate the safety and effectiveness of the **Ovation stent graft**.
- From November 2009 to May 2011, **161** patients (88% males; mean age, 73 ± 8 years) with AAAs (mean diameter, 54 ± 9 mm) were treated with the Ovation stent graft.

Safety	0-30 Days	1 Year	2 Years
Major Adverse Events	0%	3.2%	NR
Device Related MAEs	0%	0%	NR
Effectiveness	30 Days	365 Days	2 Years
Freedom from Type I and III Endoleaks	100%	100%	100%
Freedom from Migration	100%	100%	100%
Freedom from Rupture & Conversion	100%	100%	100%
Freedom from AAA Enlargement	100%	100%	95.9%

Anaconda (Vascutek, Terumo)



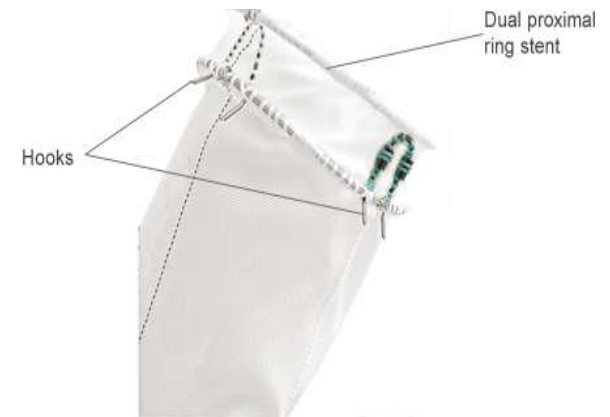
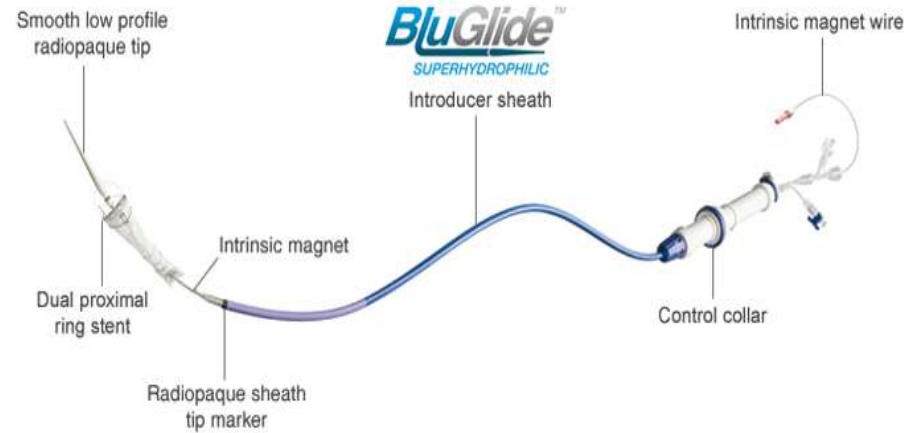
- **Modular type:**
 - Avoid mechanical coupling of perirenal aorta to iliacs
 - Avoid longitudinal rigidity
 - Enhance radial support
- Transmural Hooks
- Advanced deployment methodology:
 - **Repositionalbe**
 - **Contralateral limb: magnet assisted cannulation**

Repositionable

Deployed

Collapsed

Re-deployed



Fully repositioned by use of the **control collar** of the delivery system handle

Contralateral Limb

Magnet assisted cannulation



A **magnet system** that uses a preloaded magnet wire to assist in the cannulation and deployment of the contralateral iliac leg.

EndoStaples (Aptus)

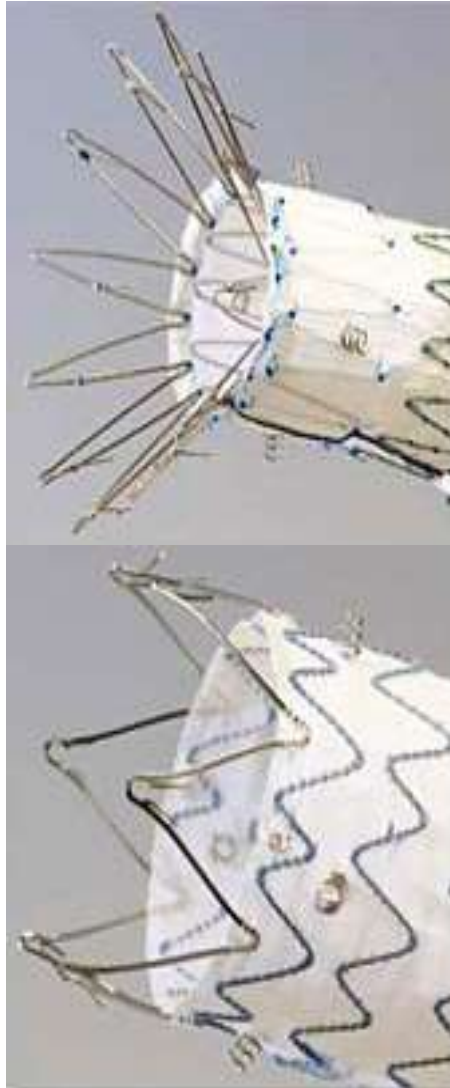
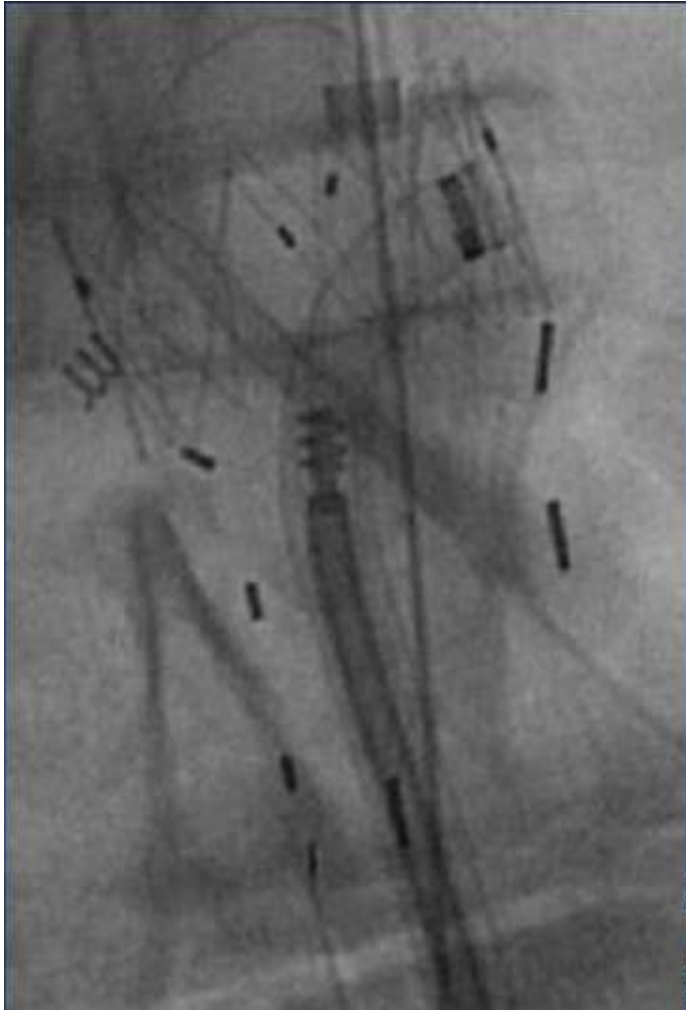


Helical screw (4 mm depth)

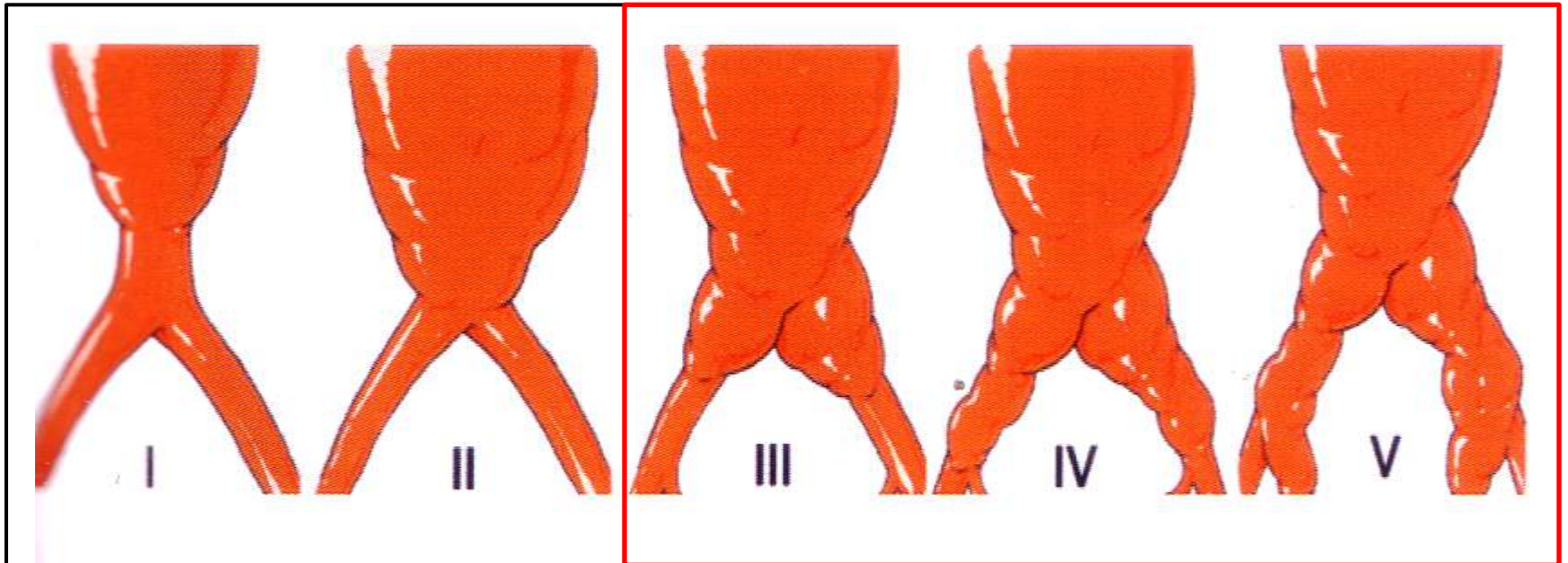


- Prevents migration and limits proximal neck dilation
- Augments proximal seal in challenging anatomy
- Four endostaples is the minimum in most cases (anterior, posterior, and lateral);

EndoStaples (Aptus)

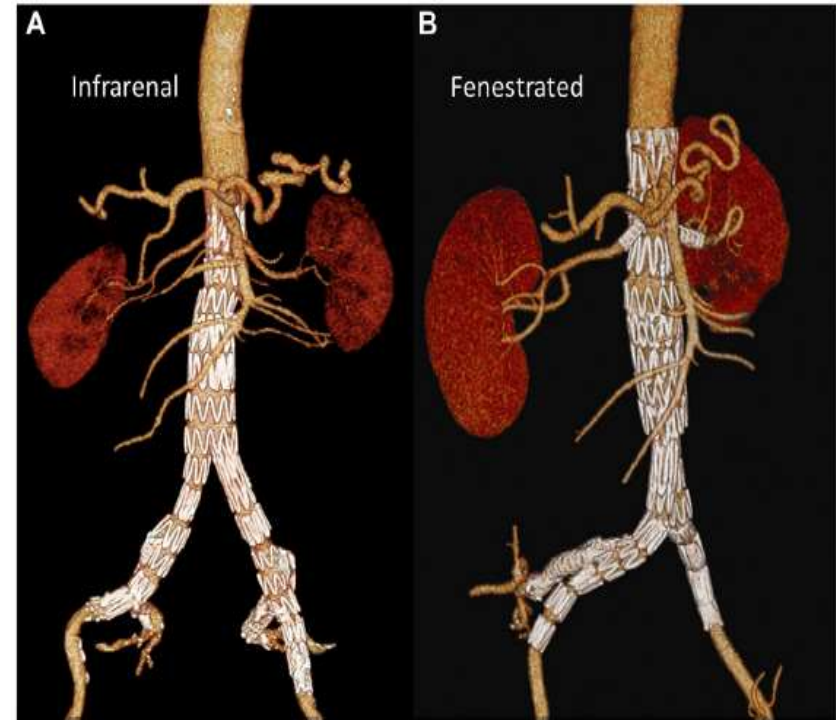
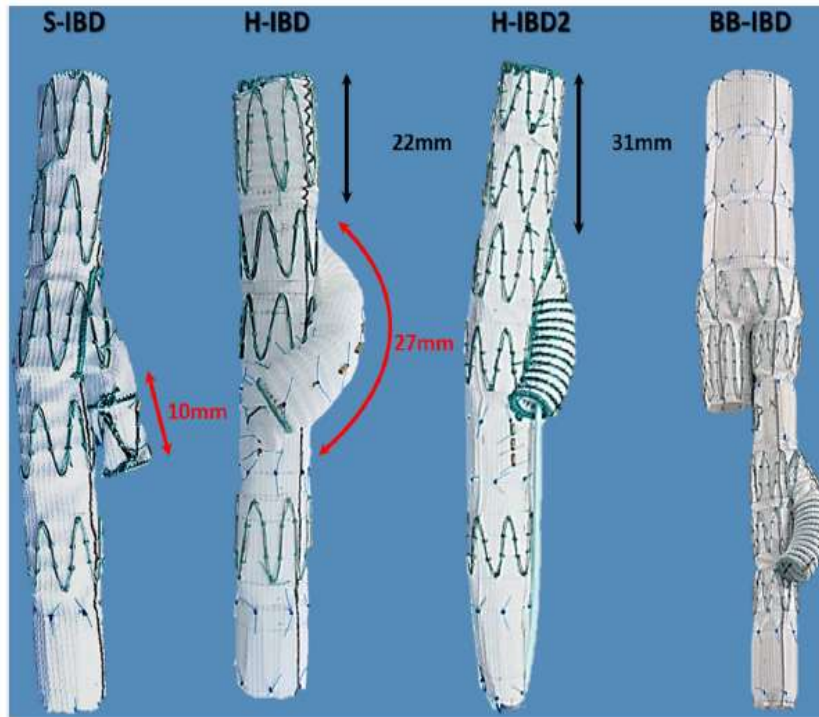


Aneurysmal Extension to Iliac Arteries



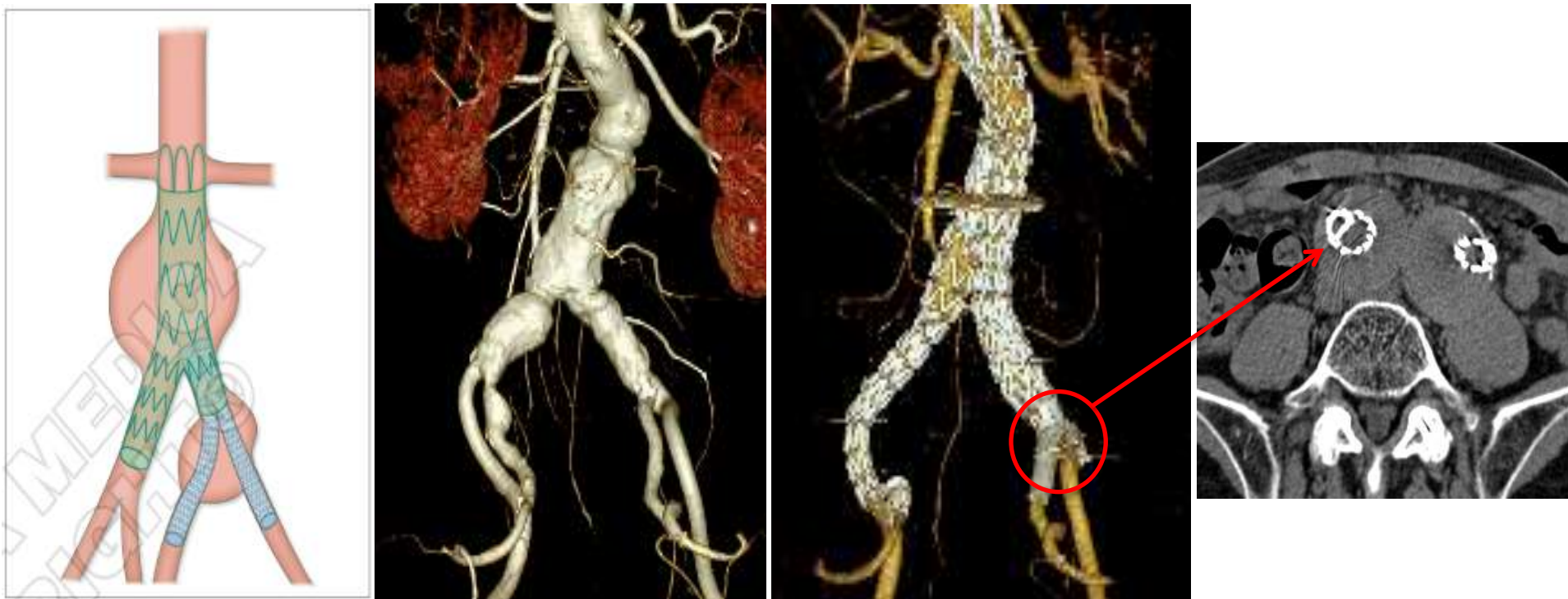
AAA accompanied by CIA aneurysm, found in 20% to 30% of AAA

Endovascular repair of aortoiliac aneurysm with IBD



- **IBDs** are specific endografts designed to preserve flow to the **IIA** in patients with aortoiliac aneurysms.
- **IBDs** showed satisfactory medium-term results with **high patency** and **low reintervention rates**.

Sandwich technique for involving CIA aneurysm



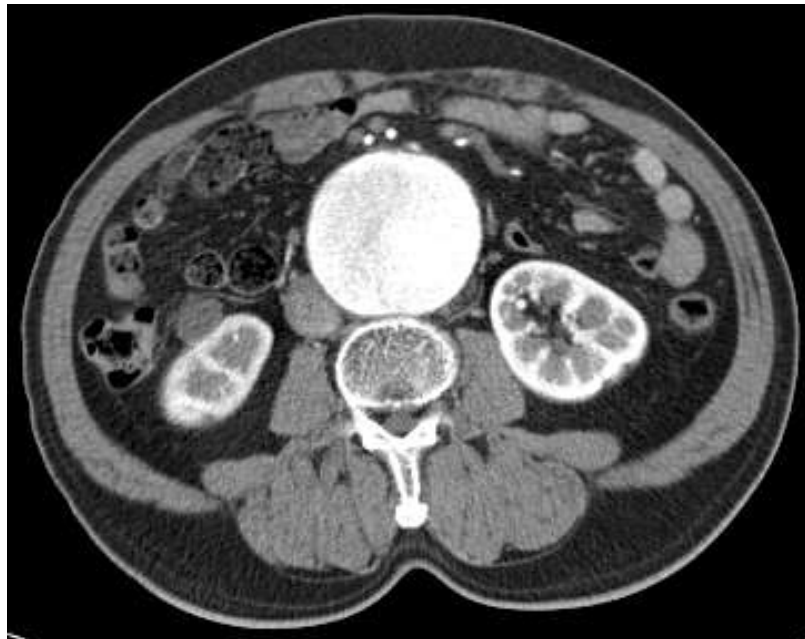
Courtesy of Dr. Geisbusch

This technique could be used EVAR for complex aortoiliac aneurysms in a safe, easy to perform, and cost-effective manner

M/65

HTN

DM

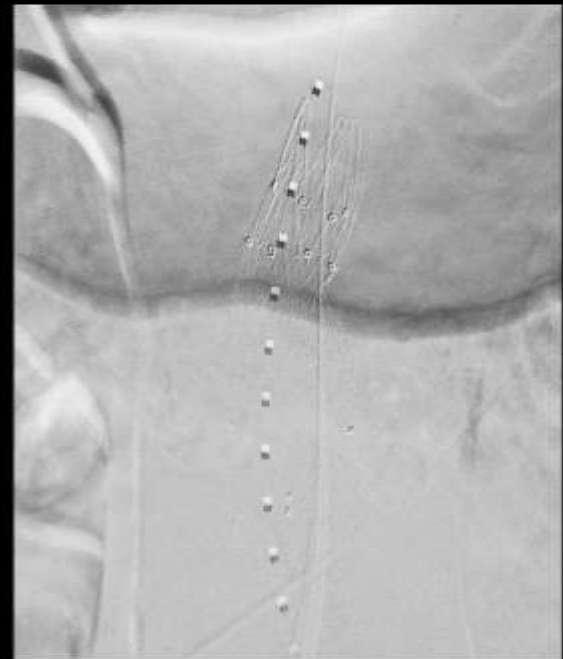
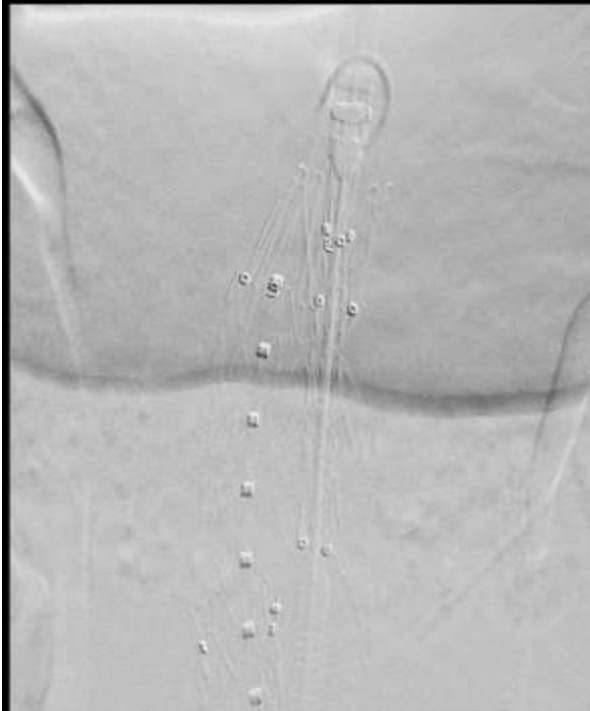


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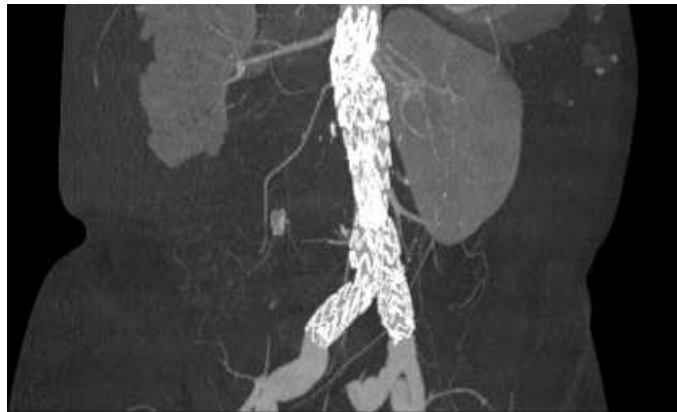
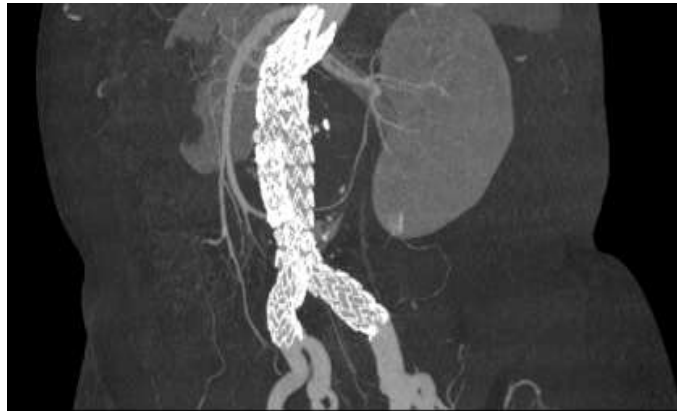
Main body: Endurant

28 x 166 mm

Cuff : Endurant 28 x 64
mm



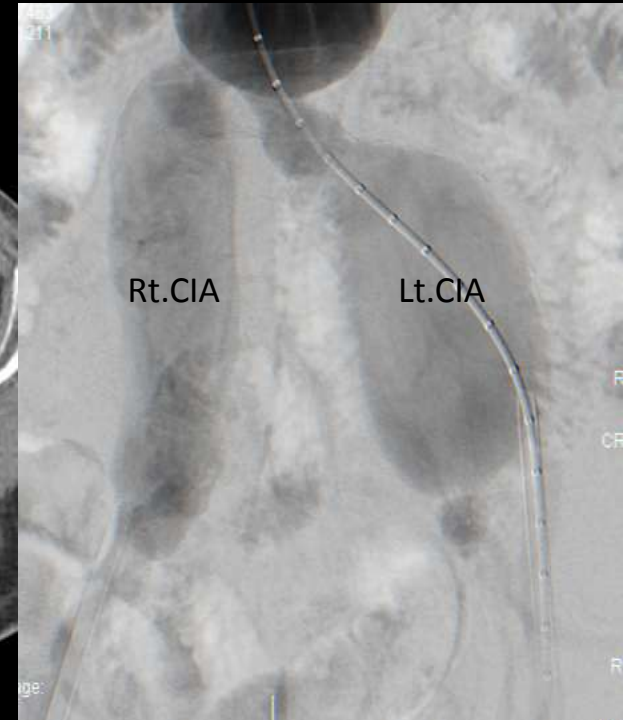
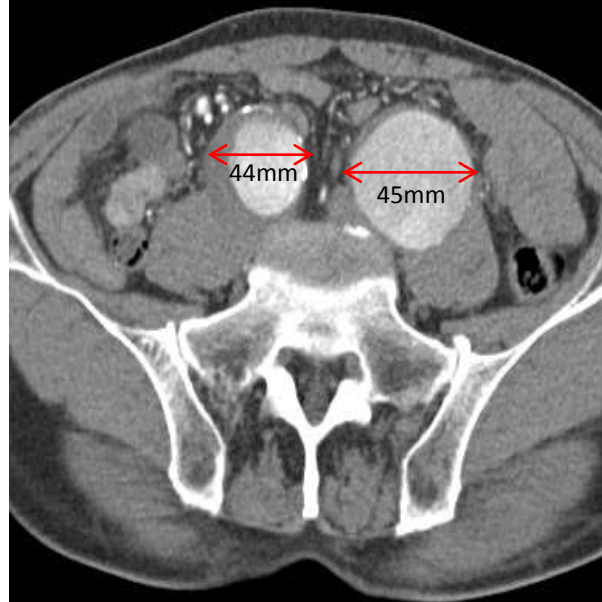
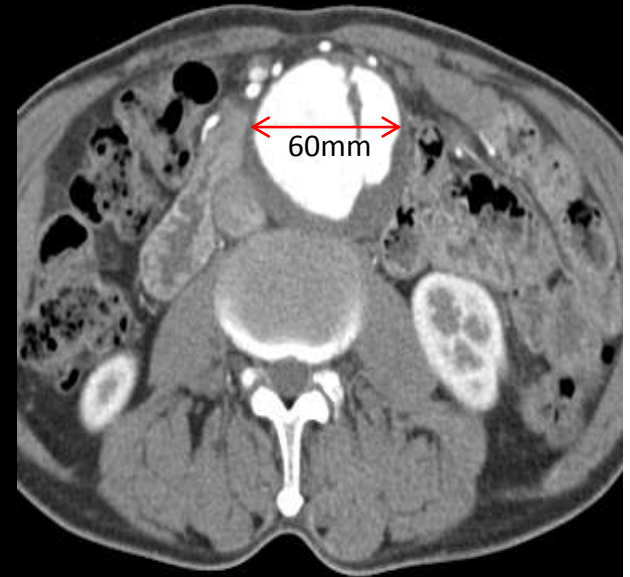
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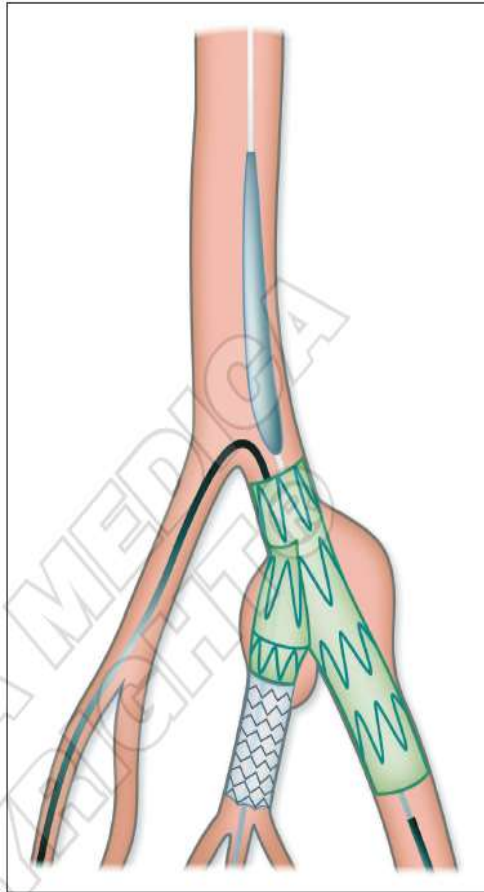
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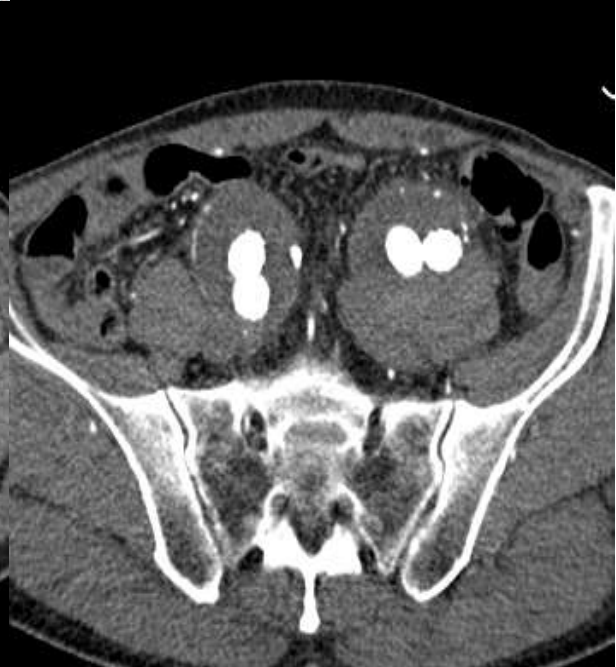
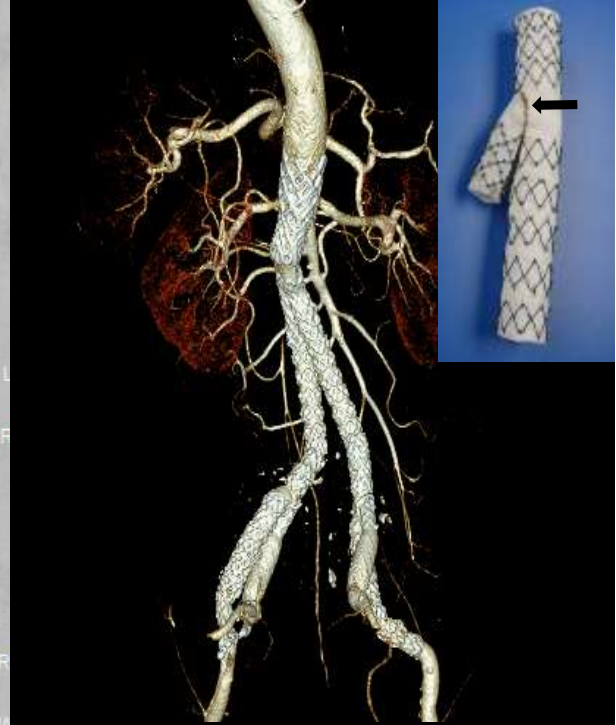
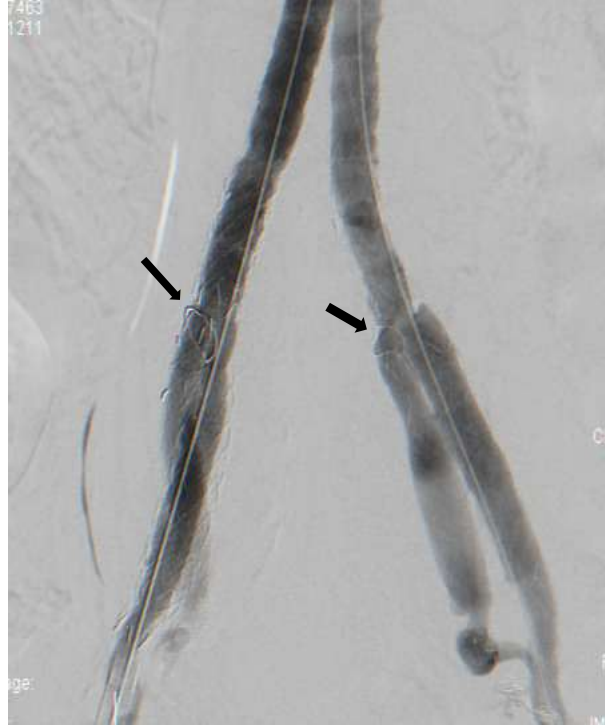
**Old MI, s/p
PCI at LAD**



M/73



Courtesy of Dr. Geisbusch



Conclusions

- Next generation devices are transforming to solve unmet clinical need with current devices.
- More flexible devices with lower profile are available.
- New devices may eliminate endoleaks by aneurysm sealing
- Branched/fenestrated endografts or IBD may enable EVAR in juxta/suprarenal AAA or involving iliac artery.
- However, efficacy and safety of newer devices needed to be validated in larger clinical trials.

Thank you for your attention!