The Dream of EVAR Is Not Over!
EVAR Is Getting Better

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Open Versus Endovascular Stent Graft Repair of Abdominal Aortic Aneurysms

A Meta-Analysis of Randomized Trials

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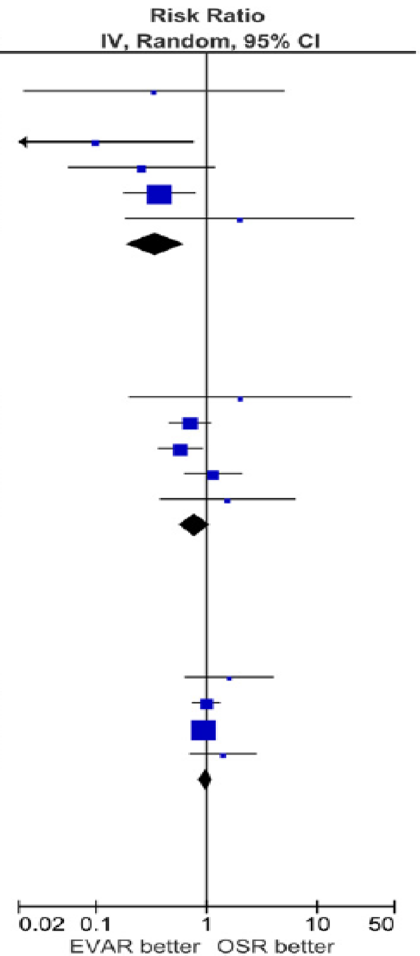
Table 1. Trial Description and Quality Assessment

Trial (Ref. #)	Year	Study Location	Institutions, n	Subjects Randomized, N	Study Period	Max Follow-Up Time, yrs	Mean/Median Follow-Up Time, yrs	Adequate Sequence Generation	Clear Inclusion/ Exclusion Criteria
ACE (12)	2011	France	25	306	2003–2009	4.80	3.00	Yes	Clear
DREAM (13,14,19)	2004, 2005, 2010	Netherlands	25	351	2000–2009	8.20	6.40	Yes	Clear
EVAR-1 (11,15,16)	2004, 2005, 2010	United Kingdom	37	1,252	1999–2009	10.00	6.00	Yes	Clear
OVER (17)	2009	United States	42	881	2002–2008	2.00	1.80	Yes	Clear
Soulez et al. (20)	2005	Canada	1	40	1998–2002	4.00	2.30	Yes	Clear
Lottman et al. (18)	2004	Netherlands	2	76	1996–1999	0.25	0.25	Yes	Clear

ACE = ACE [Carotid Endarterectomy] trial; DREAM = Dutch Randomized Endovascular Aneurysm Management trial; EVAR-1 = United Kingdom Endovascular Aneurysm Repair 1 trial; OVER = Open Versus Endovascular Repair trial.

All-cause Mortality

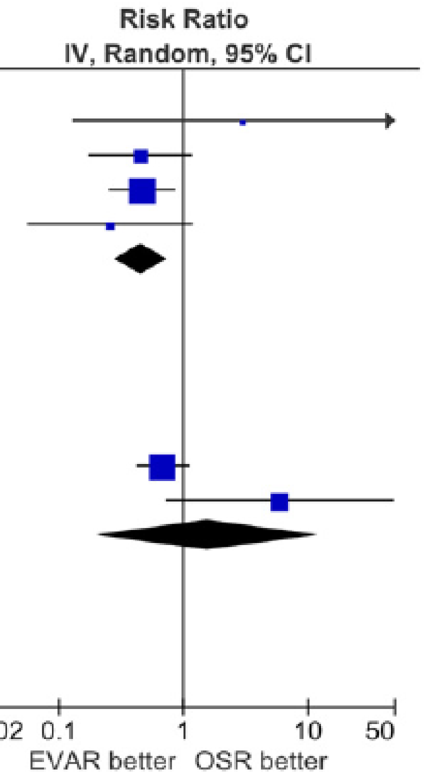
Study or Subgroup	EVAR Events	EVAR Total	Open Repair Events	Open Repair Total	Weight	Risk Ratio IV, Random, 95% CI	Year
Panel (A) Short-term mortality							
Lottman	1	57	1	19	5.0%	0.33 [0.02, 5.07]	2004
Soulez	0	20	0	20		Not estimable	2005
OVER	1	444	10	437	8.7%	0.10 [0.01, 0.77]	2009
DREAM	2	173	8	178	15.6%	0.26 [0.06, 1.19]	2010
EVAR1	9	543	24	539	64.2%	0.37 [0.17, 0.79]	2010
ACE trial	2	150	1	149	6.4%	1.99 [0.18, 21.68]	2011
Subtotal (95% CI)		**1387**		**1342**	**100.0%**	**0.35 [0.19, 0.64]**	
Total events	15		44				
Heterogeneity: Tau² = 0.00; Chi² = 3.68, df = 4 (P = 0.45); I² = 0%							
Test for overall effect: Z = 3.42 (P = 0.0006)							
Panel (B) Intermediate-term mortality							
Soulez	2	20	1	20	1.9%	2.00 [0.20, 20.33]	2005
OVER	31	444	43	437	36.5%	0.71 [0.46, 1.10]	2009
EVAR1	26	626	45	626	33.5%	0.58 [0.36, 0.92]	2010
DREAM	20	173	18	178	23.1%	1.14 [0.63, 2.09]	2010
ACE trial	5	150	3	139	5.0%	1.54 [0.38, 6.34]	2011
Subtotal (95% CI)		**1413**		**1400**	**100.0%**	**0.78 [0.57, 1.08]**	
Total events	84		110				
Heterogeneity: Tau² = 0.02; Chi² = 4.81, df = 4 (P = 0.31); I² = 17%							
Test for overall effect: Z = 1.48 (P = 0.14)							
Panel (C) Long-Term mortality							
Soulez	8	20	5	20	2.8%	1.60 [0.63, 4.05]	2005
DREAM	58	173	60	178	27.7%	0.99 [0.74, 1.33]	2010
EVAR1	151	626	161	626	64.7%	0.94 [0.77, 1.14]	2010
ACE trial	17	150	12	149	4.8%	1.41 [0.70, 2.84]	2011
Subtotal (95% CI)		**969**		**973**	**100.0%**	**0.99 [0.85, 1.15]**	
Total events	234		238				
Heterogeneity: Tau² = 0.00; Chi² = 2.29, df = 3 (P = 0.52); I² = 0%							
Test for overall effect: Z = 0.17 (P = 0.87)							



Dangas G, J Am Coll Cardiol Intv 2012;5:1071

Aneurysm-related Mortality

Study or Subgroup	EVAR Events	EVAR Total	Open Repair Events	Open Repair Total	Weight	Risk Ratio IV, Random, 95% CI	Year
Panel (A) Intermediate-term AAA-related mortality							
Soulez	1	20	0	20	2.4%	3.00 [0.13, 69.52]	2005
OVER	6	444	13	437	26.1%	0.45 [0.17, 1.18]	2009
EVAR1	14	626	30	626	61.4%	0.47 [0.25, 0.87]	2010
DREAM	2	173	8	178	10.2%	0.26 [0.06, 1.19]	2010
Subtotal (95% CI)		**1263**		**1261**	**100.0%**	**0.46 [0.28, 0.74]**	
Total events	23		51				
Heterogeneity: Tau² = 0.00; Chi² = 1.92, df = 3 (P = 0.59); I² = 0%							
Test for overall effect: Z = 3.14 (P = 0.002)							
Panel (B) Long-term AAA-related mortality							
EVAR1	26	626	38	626	61.7%	0.68 [0.42, 1.11]	2010
ACE trial	6	150	1	149	38.3%	5.96 [0.73, 48.91]	2011
Subtotal (95% CI)		**776**		**775**	**100.0%**	**1.57 [0.20, 12.35]**	
Total events	32		39				
Heterogeneity: Tau² = 1.74; Chi² = 3.86, df = 1 (P = 0.05); I² = 74%							
Test for overall effect: Z = 0.43 (P = 0.67)							

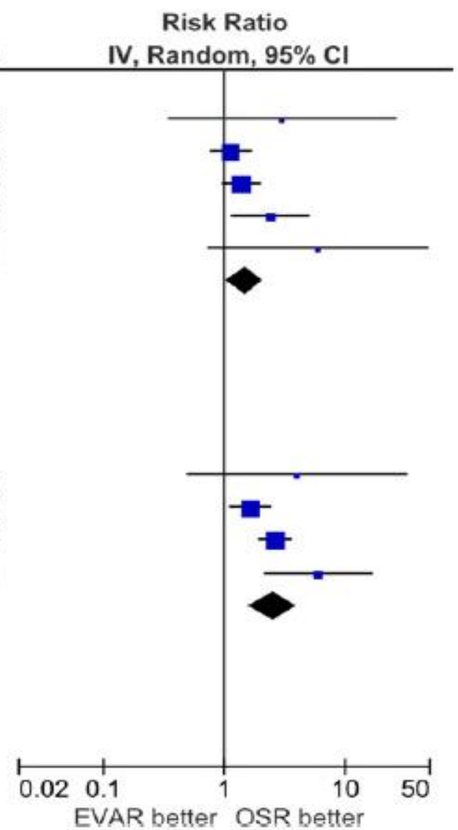


Dangas G, *J Am Coll Cardiol Intv* 2012;5:1071

Reintervention Rates

≤2yrs

Study or Subgroup	EVAR Events	EVAR Total	OSR Events	OSR Total	Weight	Risk Ratio IV, Random, 95% CI	Year
Panel (A) Intermediate-term reintervention rate							
Soulez	3	20	1	20	2.4%	3.00 [0.34, 26.45]	2005
OVER	46	444	40	437	38.0%	1.13 [0.76, 1.69]	2009
EVAR1	66	626	40	525	40.9%	1.38 [0.95, 2.01]	2010
DREAM	21	173	9	178	16.3%	2.40 [1.13, 5.09]	2010
ACE trial	6	150	1	149	2.5%	5.96 [0.73, 48.91]	2011
Subtotal (95% CI)		**1413**		**1309**	**100.0%**	**1.48 [1.06, 2.08]**	
Total events	142		91				
Heterogeneity: Tau² = 0.04; Chi² = 5.34, df = 4 (P = 0.25); I² = 25%							
Test for overall effect: Z = 2.27 (P = 0.02)							
Panel (B) Long-term reintervention rate							
Soulez	4	20	1	20	4.6%	4.00 [0.49, 32.72]	2005
DREAM	48	173	30	178	38.0%	1.65 [1.10, 2.47]	2010
EVAR1	121	626	46	626	42.6%	2.63 [1.91, 3.63]	2010
ACE trial	24	150	4	149	14.8%	5.96 [2.12, 16.76]	2011
Subtotal (95% CI)		**969**		**973**	**100.0%**	**2.53 [1.58, 4.05]**	
Total events	197		81				
Heterogeneity: Tau² = 0.11; Chi² = 6.79, df = 3 (P = 0.08); I² = 56%							
Test for overall effect: Z = 3.88 (P = 0.0001)							



Dangas G, J Am Coll Cardiol Intv 2012;5:1071

Real World: Medicare data

Comparison of Long-term Survival After Open vs Endovascular Repair of Intact Abdominal Aortic Aneurysm Among Medicare Beneficiaries

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Julie A. Freischlag, MD

Context Endovascular repair of abdominal aortic aneurysm (AAA) compared with open repair increases perioperative survival, but it is not known if it increases long-term survival.

Objective To compare long-term outcomes after open vs endovascular repair of AAA.

Design, Setting, and Patients Retrospective analysis of patients 65 years or older in the Medicare Standard Analytic File, 2003-2007, who underwent isolated repair of intact AAA. Cause of death was determined from the National Death Index.

Main Outcome Measures The primary outcome was all-cause mortality. Secondary outcomes were AAA-related mortality, hospital length of stay, 1-year readmission, repeat AAA repair, incisional hernia repair, and lower extremity amputation.

Results Of 4529 included patients, 703 were classified as having undergone open repair and 3826 as having undergone endovascular repair. Mean and median follow-up times were 2.6 (SD, 1.5) and 2.5 (interquartile range, 2.4) years, respectively. In unadjusted analysis, both all-cause mortality (173 vs 752; 89 vs 76/1000 person-years, $P=.04$) and AAA-specific mortality (22 vs 28; 11.3 vs 2.8/1000 person-years, $P<.001$) were higher after open vs endovascular repair. After adjusting for emergency admission, age, calendar year, sex, race, and comorbidities, there was a higher risk of both all-cause mortality (hazard ratio [HR], 1.24 [95% CI, 1.05-1.47]; $P=.01$) and AAA-related mortality (HR, 4.37 [95% CI, 2.51-7.66]; $P<.001$) after open vs endovascular repair. The adjusted hospital length of stay was, on average, 6.5 days (95% CI, 6.0-7.0 days, $P<.001$) longer after open repair (mean, 10.4 days), compared with endovascular repair (mean, 3.6 days). Incidence of incisional hernia repair was higher after open AAA repair (19 vs 23; 12 vs 3 per 1000 person-years; adjusted HR, 4.45 [95% CI, 2.37-8.34, $P<.001$]), whereas the incidence of 1-year readmission (188 vs 1070; 274 vs 376/1000 person-years; adjusted HR, 0.96 [95% CI, 0.85-1.09, $P=.52$]), repeat AAA repair (15 vs 93; 9.7 vs 12.3/1000 person-years; adjusted HR, 0.80 [95% CI, 0.46-1.38, $P=.42$]), and lower extremity amputation (3 vs 25; 1.9 vs 3.3/1000 person-years; adjusted HR, 0.55 [95% CI, 0.16-1.86, $P=.34$]) did not differ by repair type.

Conclusion Among older patients with isolated intact AAA, use of open repair compared with endovascular repair was associated with increased risk of all-cause mortality and AAA-related mortality.

JAMA. 2012;307(15):1621-1628 www.jama.com

Endovascular repair of abdominal aortic aneurysm (AAA), initially introduced as an option for high-risk patients,[1] has surpassed open surgery as the most common technique for elective management of AAA among Medicare beneficiaries in the United States.[2] In randomized clinical trials (RCTs), endovascular AAA repair has been shown to decrease 30-day and in-hospital mortality,[3,4] blood transfusion requirements, duration of mechanical ventilation, and intensive care unit and hospital length of stay after repair.[4] However, RCTs have failed to demonstrate a long-term survival advantage of endovascular compared with open repair.[3-5] Furthermore, compared with open repair, endovascular repair incurs higher costs[3] and a need for long-term surveillance because of a 25% to 40% late complication rate,[6,7] leading to ongoing controversy over the elective use of endovascular repair, especially in healthy patients with anticipated long-term survival.

Although clinical trials have failed to demonstrate a long-term mortality difference between open and endovascular repair, certain characteristics of RCTs limit the applicability of their results in clinical practice. In RCTs, repair of AAA is usually performed at high-volume centers by vascular surgeons experienced in endovascular technique. Participants in RCTs comparing endovascular with open AAA repair have, on average, fewer and less severe comorbidities and are more likely to be male than patients encountered in clinical practice.[8] Most impor-

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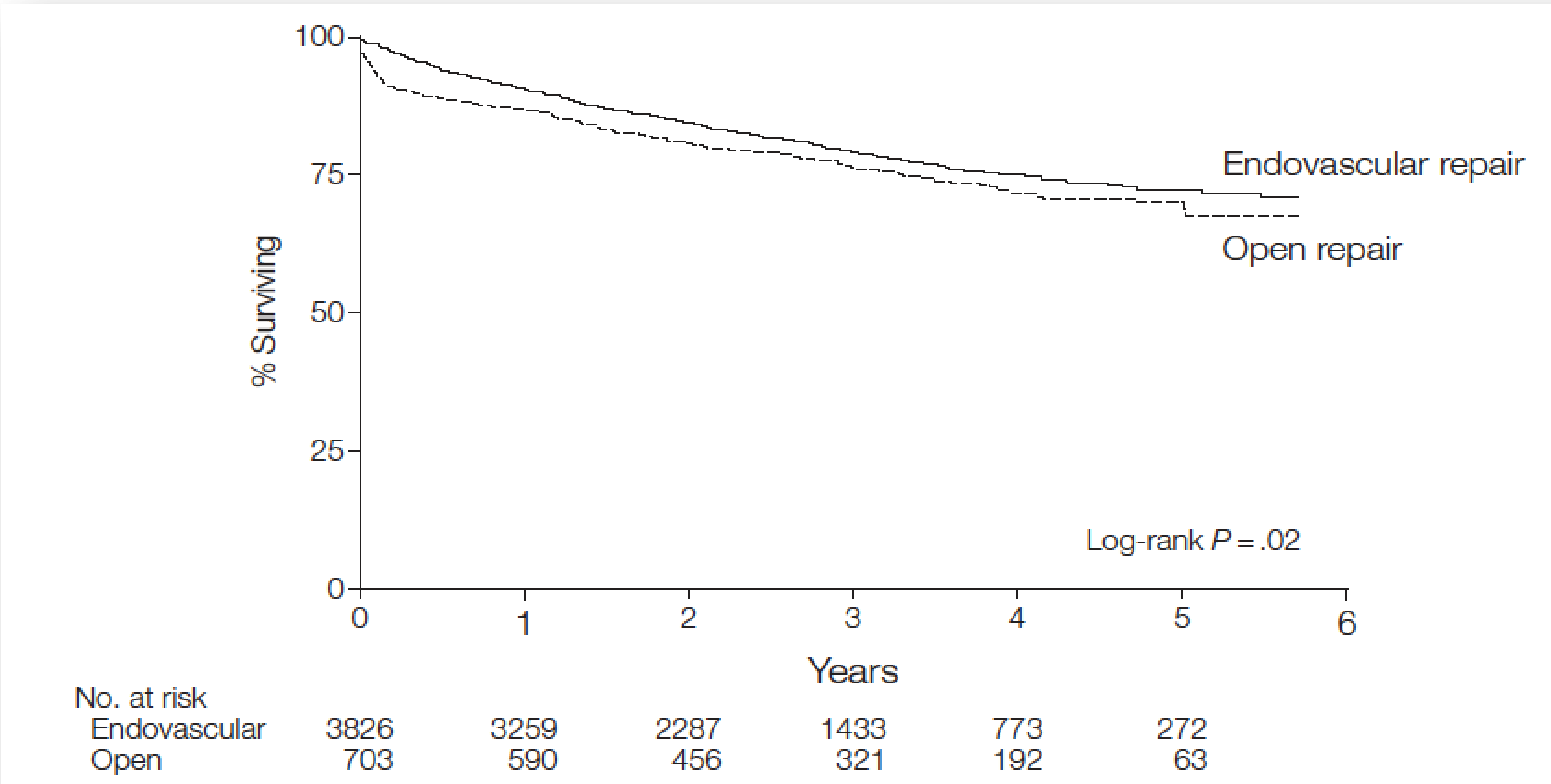
Table 1. Baseline Patient Characteristics, by Repair Type

Characteristic	No. (%) Open Repair (n = 703)	No. (%) Endovascular Repair (n = 3826)	*P* Value
Sex			
Men	498 (70.8)	3057 (79.9)	<.001
Women	205 (29.2)	768 (20.1)	
Race			
White	660 (93.9)	3602 (94.2)	.06
Black	32 (4.6)	113 (3.0)	
Other	11 (1.5)	111 (2.8)	
Age, mean (SD)	75.2 (5.7)	76.4 (6.3)	<.001
Year of surgery			
2003	143 (20.4)	558 (14.6)	<.001
2004	183 (26.0)	718 (18.8)	
2005	164 (23.3)	804 (21.0)	
2006	128 (18.2)	922 (24.1)	
2007	85 (12.1)	823 (21.5)	
Emergency admission	64 (23.3)	562 (14.7)	<.001
No. of CCS categories, mean (SD)	4.6 (4.01)	5.0 (3.78)	.003
Comorbidity[a]			
Diabetes mellitus	105 (14.9)	719 (18.8)	.02
Essential hypertension	379 (53.9)	2261 (59.1)	.01
Chronic renal failure	29 (4.1)	116 (3.0)	.13
Congestive heart failure	93 (13.2)	472 (12.3)	.51
COPD	177 (25.2)	929 (24.3)	.61

Jackson RS, JAMA. 2012;307:1621

Survival After Open vs Endovascular Repair of AAA



Jackson RS, JAMA. 2012;307:1621

Overall and Cause-Specific Mortality

Mortality rate per 1000 Person-Years of Follow-up

Mortality	No. (Unadjusted No. of Deaths): Overall Mortality[a] – Endovascular Repair (n = 3825)	Overall Mortality[a] – Open Repair (n = 703)	Overall Mortality[a] – *P* Value	Overall Mortality Excluding 30-d Mortalities[b] – Endovascular Repair (n = 3778)	Overall Mortality Excluding 30-d Mortalities[b] – Open Repair (n = 662)	Overall Mortality Excluding 30-d Mortalities[b] – *P* Value
Overall	76 (752)	89 (173)	.04	71 (705)	68 (132)	.30
Aneurysm-related						
Abdominal aortic aneurysm	2.8 (28)	11.3 (22)	<.001	2.2 (22)	3.1 (6)	.36
Thoracic/thoracoabdominal aortic aneurysm	0.5 (5)	0	.52	0.5 (5)	0	.52
Aortic aneurysm, unspecified	1.4 (14)	2.6 (5)	.19	1.0 (10)	0.5 (1)	.57
Aneurysm, other	0.2 (2)	1.0 (2)	.52	0.2 (2)	0	.55
Cardiovascular						
Coronary artery disease	15.1 (149)	13.3 (26)	.67	13.6 (134)	11.3 (22)	.49
Heart failure	2.2 (22)	4.6 (9)	.04	2.2 (22)	3.6 (7)	.20
Other cardiovascular disease	8.7 (86)	5.6 (28)	<.001	7.7 (76)	10.3 (20)	.04
Cancer	18.4 (182)	15.9 (31)	.47	18.5 (182)	15.9 (1)	.47
COPD	6.1 (60)	5.1 (10)	.66	5.8 (58)	4.1 (8)	.34
Other	19.4 (192)	20.0 (39)	.75	18.5 (183)	19.0 (7)	.79

Abbreviation: COPD, chronic obstructive pulmonary disease.
[a] The endovascular repair group included 9874 person-years of follow-up (84.5% of total); the open repair group included 1948 person-years (15.5% of total).
[b] The endovascular repair group included 9873 person-years of follow-up (85.1% of total); the open repair group included 1946 person-years (14.9% of total).

Jackson RS, JAMA. 2012;307:1621

Numbers of Events for Open and Endovascular Repair

Outcome	Unadjusted: No. of Events: Endovascular Repair (n = 3826)	Open Repair (n = 703)	P Value[a]	Adjusted: HR (95% CI) for Open vs Endovascular Repair	P Value
All-cause mortality					
Overall	752	173	.04	1.24 (1.05-1.47)	.01
Within <1 mo of surgery	47	41	<.001	5.54 (3.47-8.82)	<.001
≥1 mo after surgery	705	132	.08	1.01 (0.84-1.22)	.91
AAA-related mortality					
Overall	28	22	<.001	4.37 (2.51-7.66)	<.001
Within <1 mo of surgery	6	21	<.001	16.99 (4.62-62.54)	<.001
≥1 mo after surgery	22	6	.36	1.35 (0.44-4.11)	.60
1-year readmission	1070	188	.50	0.96 (0.85-1.09)	.52
Repeat AAA repair	93	15	.20	0.80 (0.46-1.38)	.42
Incisional hernia repair	23	19	<.001	4.45 (2.37-8.34)	<.001
Lower extremity amputation	25	3	.20	0.55 (0.16-1.86)	.34

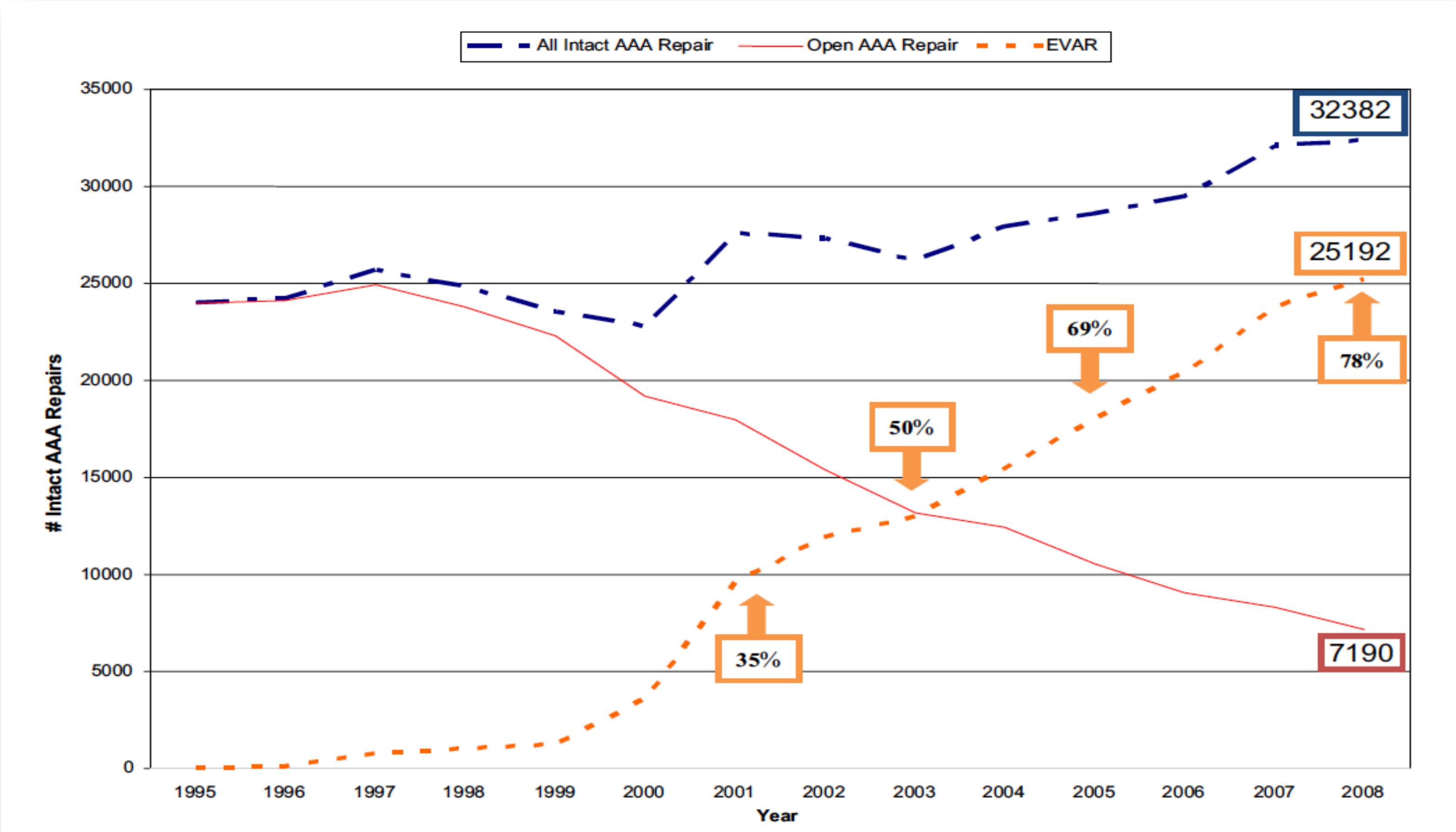
Jackson RS, JAMA. 2012;307:1621

Diagnosis Associated With Repeat Repair

Diagnosis (*ICD-9* Codes)	No. (%) Open Repair (n = 15)	No. (%) Endovascular Repair (n = 93)	*P* Value
Mechanical complication of vascular graft (996.1, 996.59)	0	36 (38.7)	.003
Graft infection (996.60)	0	2 (2.2)	.57
Graft rupture (441.3, 441.5)	0	6 (6.5)	.31
Aortic atherosclerosis (440.0) or graft atherosclerosis (996.74)	0	11 (11.8)	.16
Embolization to lower extremities (444.2, 444.22)	1 (6.7)	4 (4.3)	.69

Jackson RS, JAMA. 2012;307:1621

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



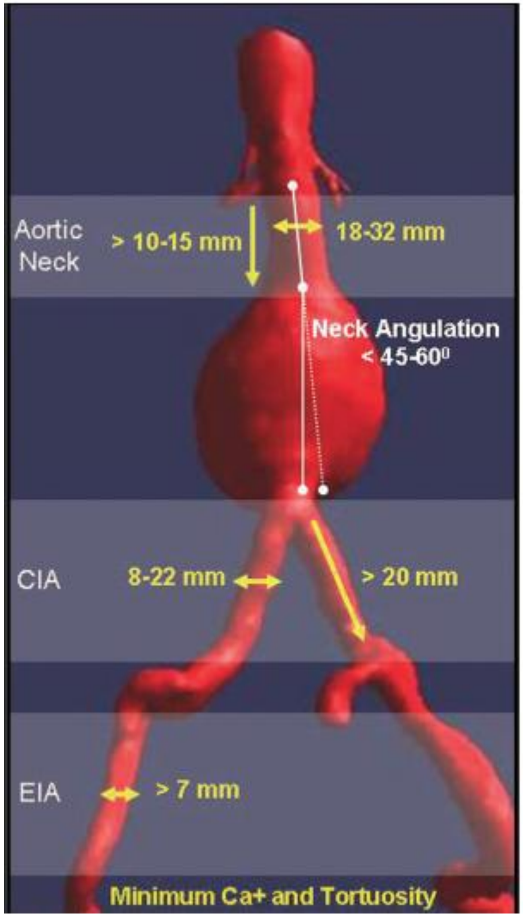
Sachs T, J Vasc Surg 2011;54:881

Mortality Rates: EVAR vs. Open Techniques in the Medicare Population

 Sachs T, J Vasc Surg 2011;54:

Suitable AAA Morphology for EVAR

- Aortic neck
  - Diameter: 18~32 mm
  - Length: >10~15 mm
  - Shape: straight, non-conical
  - Angulation <45~60°
  - Minimal thrombus or calcification
- CIA
  - Length: >20 mm
  - Diameter: 8 ~ 22 mm
- EIA
  - Diamter: > 7 mm
  - minimal Ca. & tortuosity



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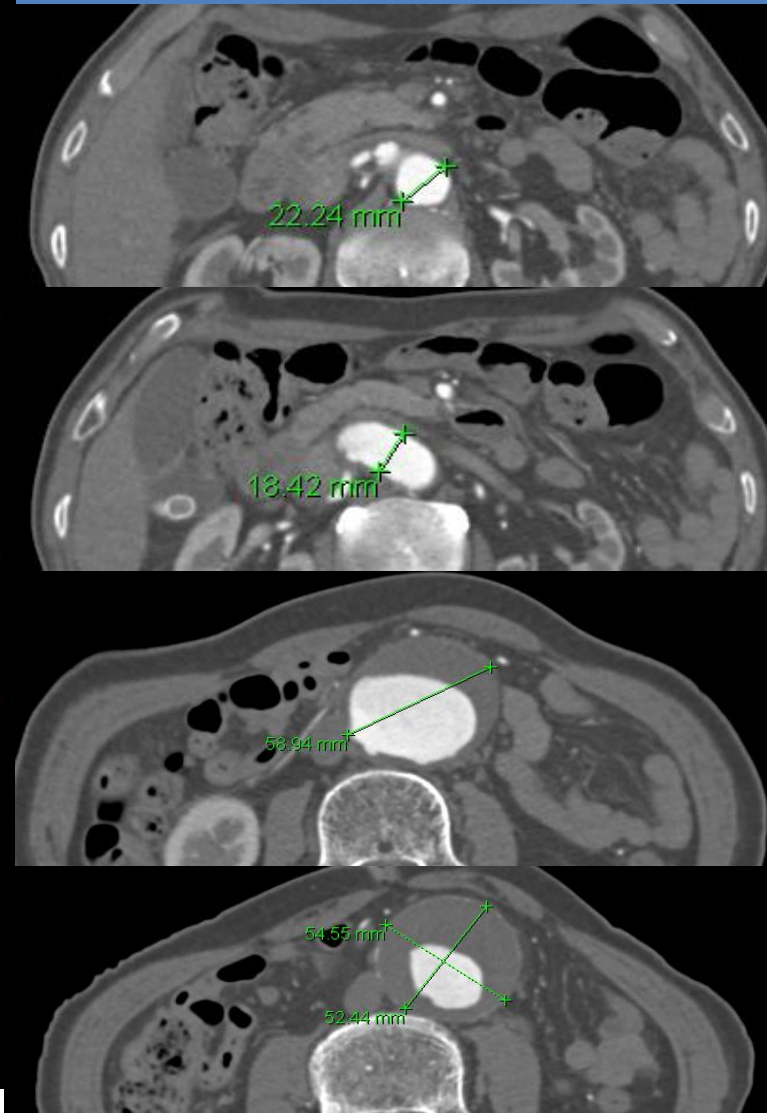

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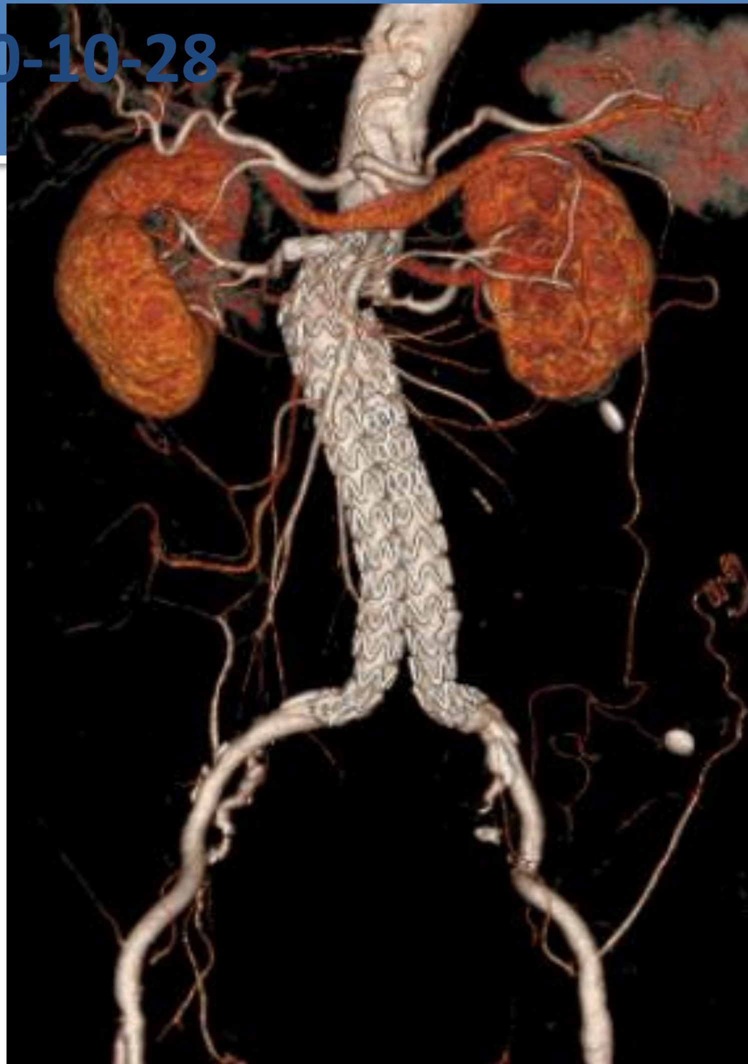
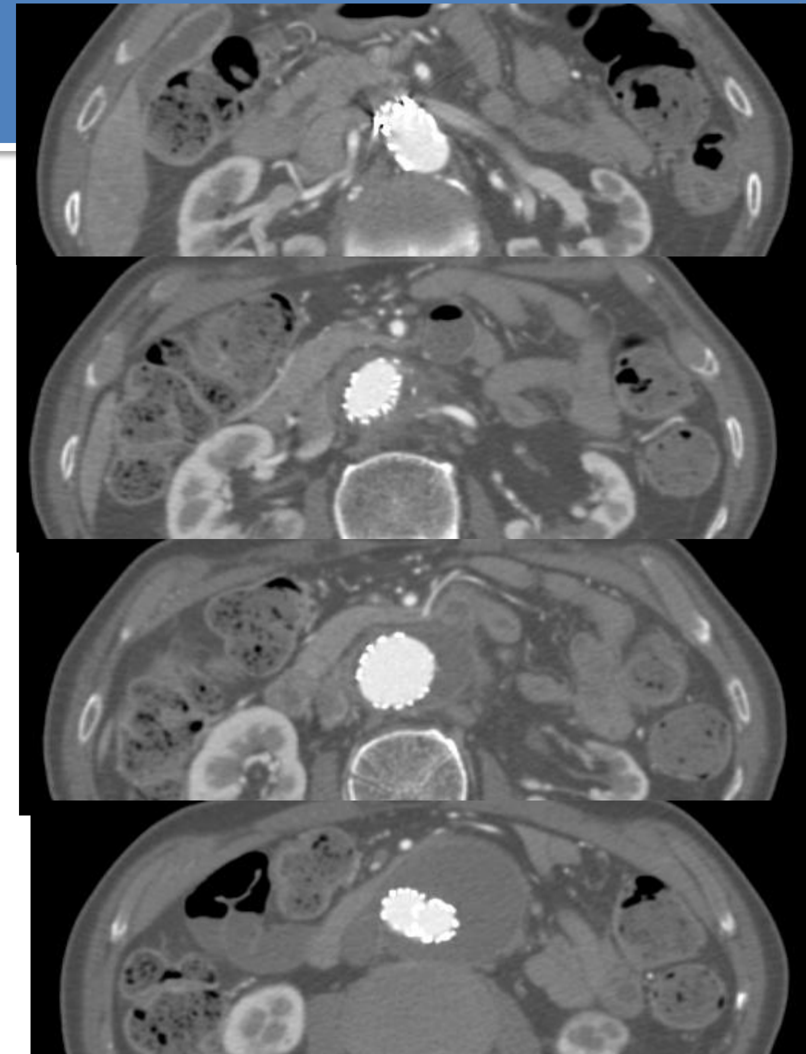
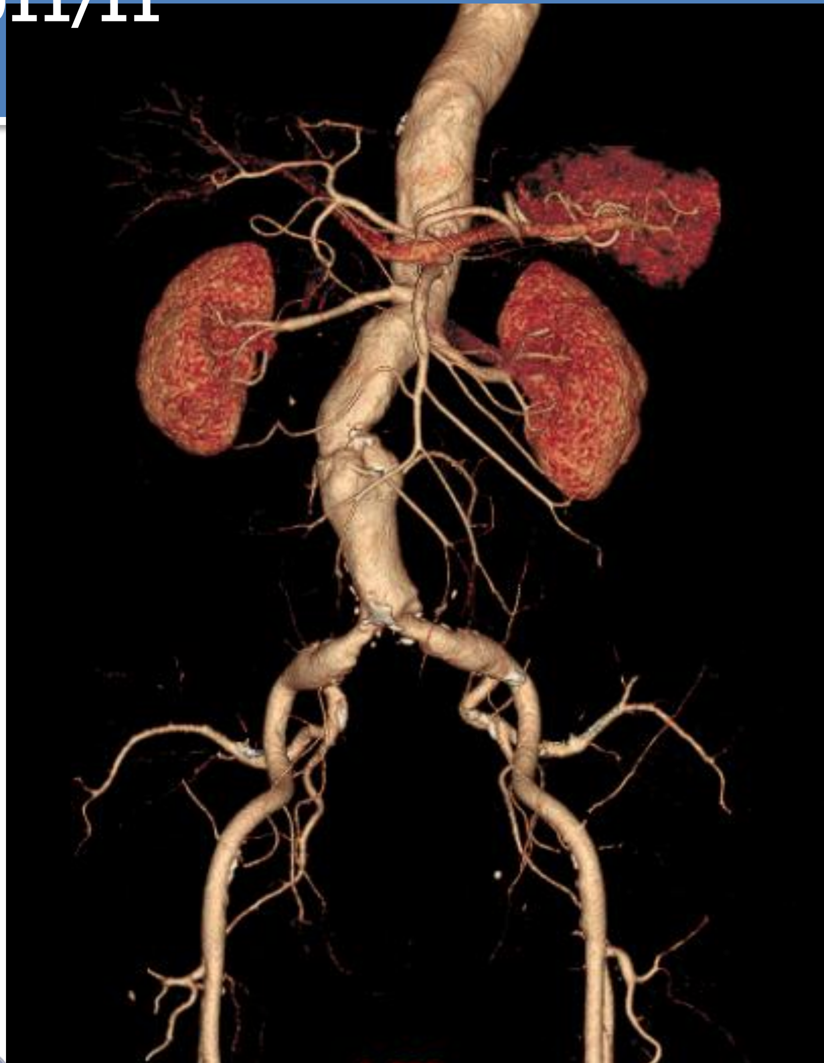
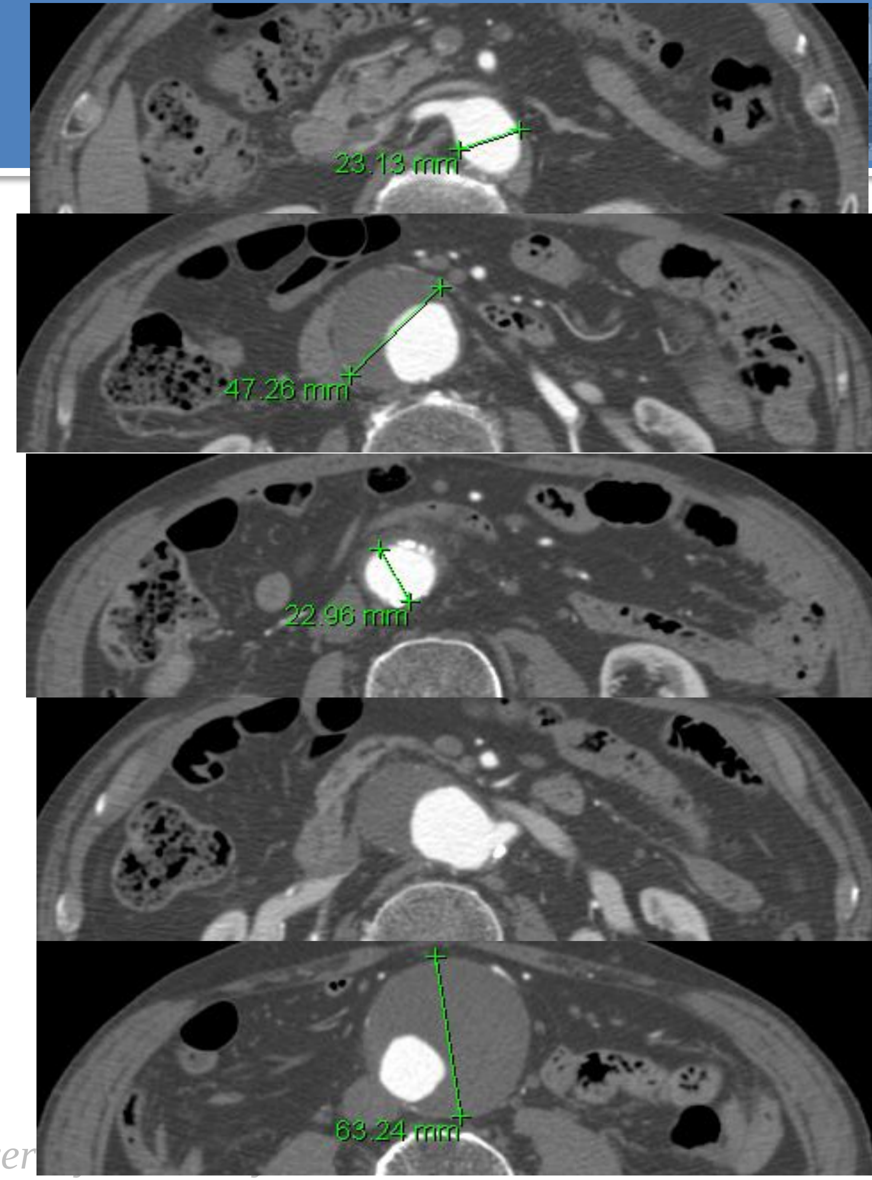


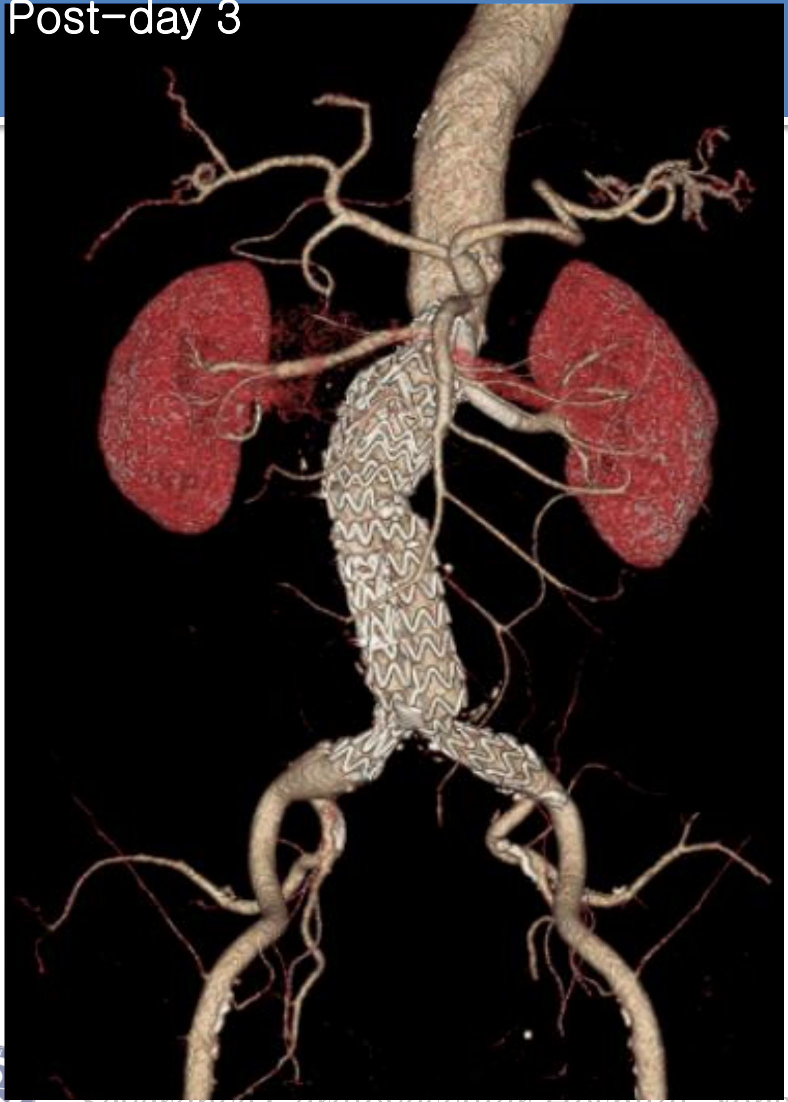


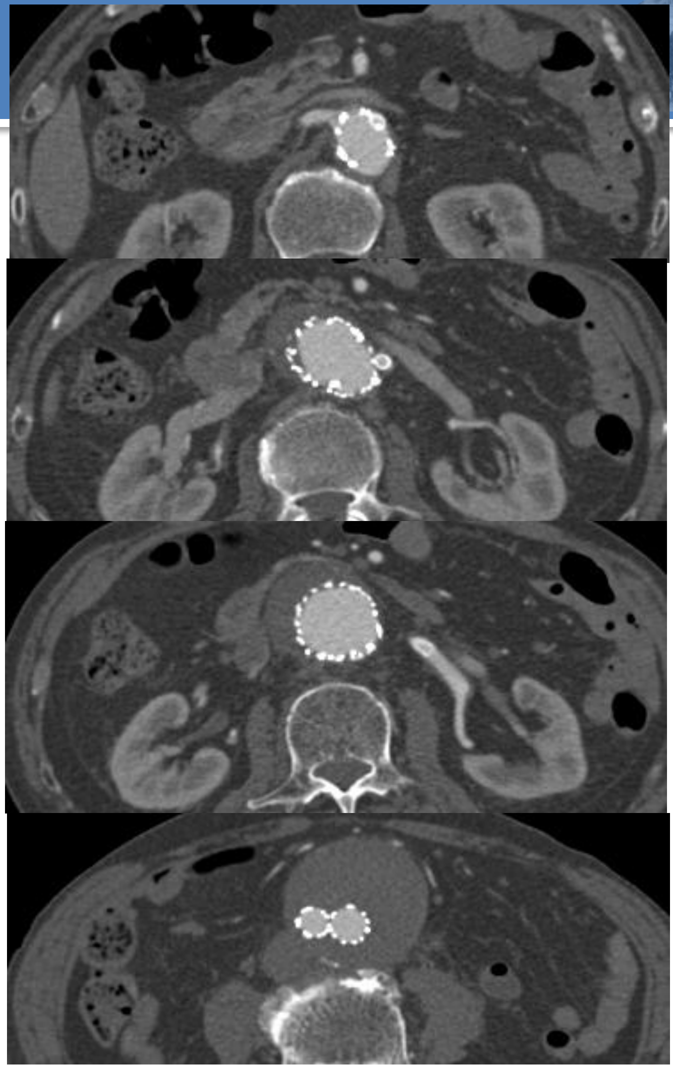
2011/11





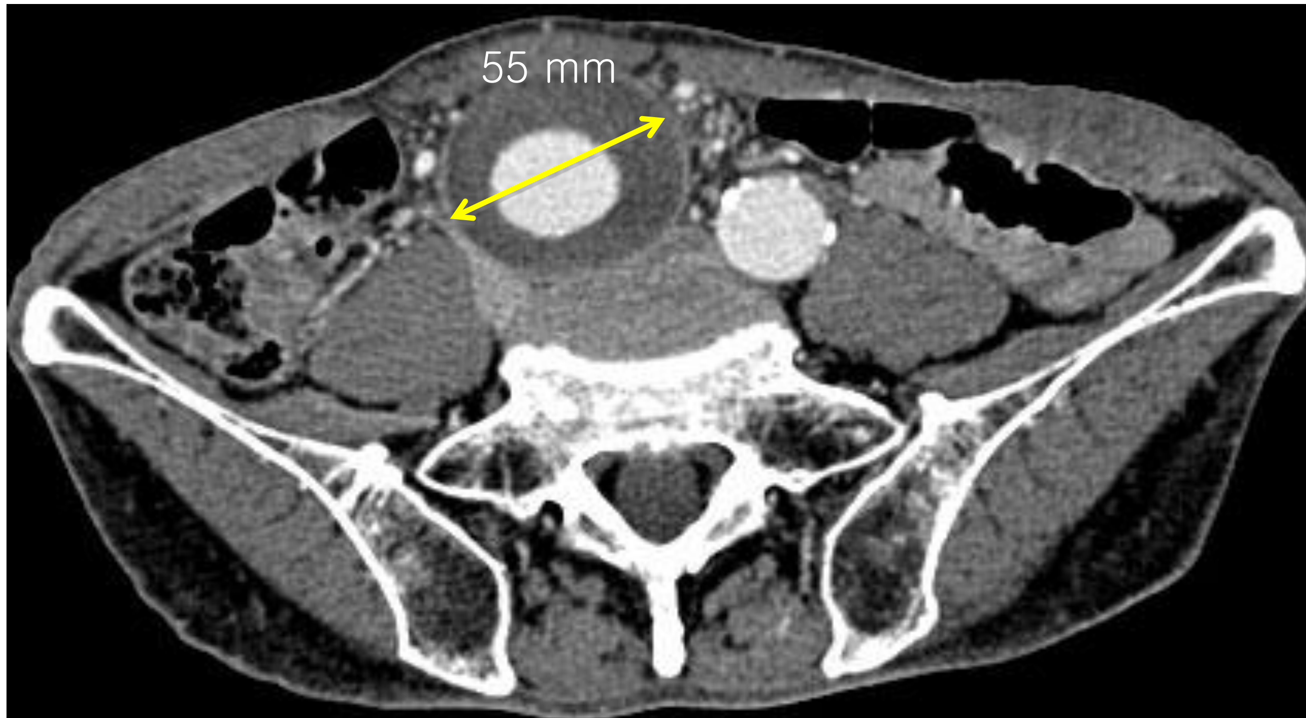
Post-day 3



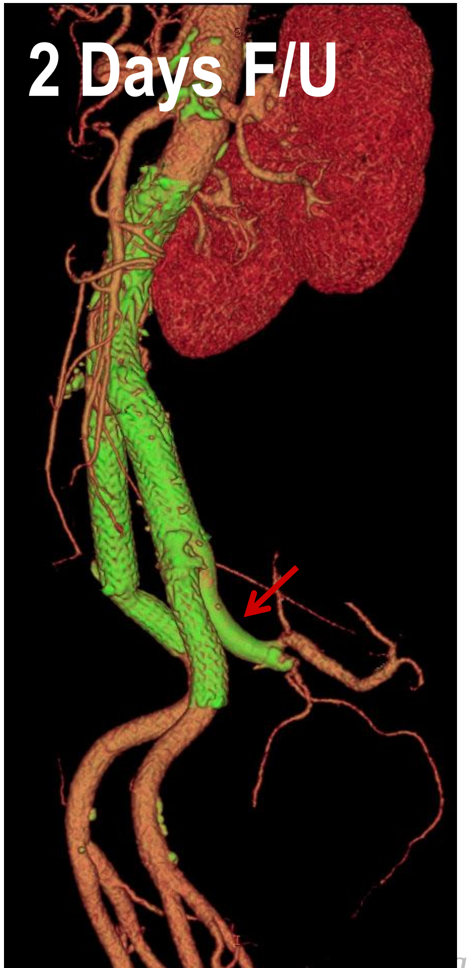


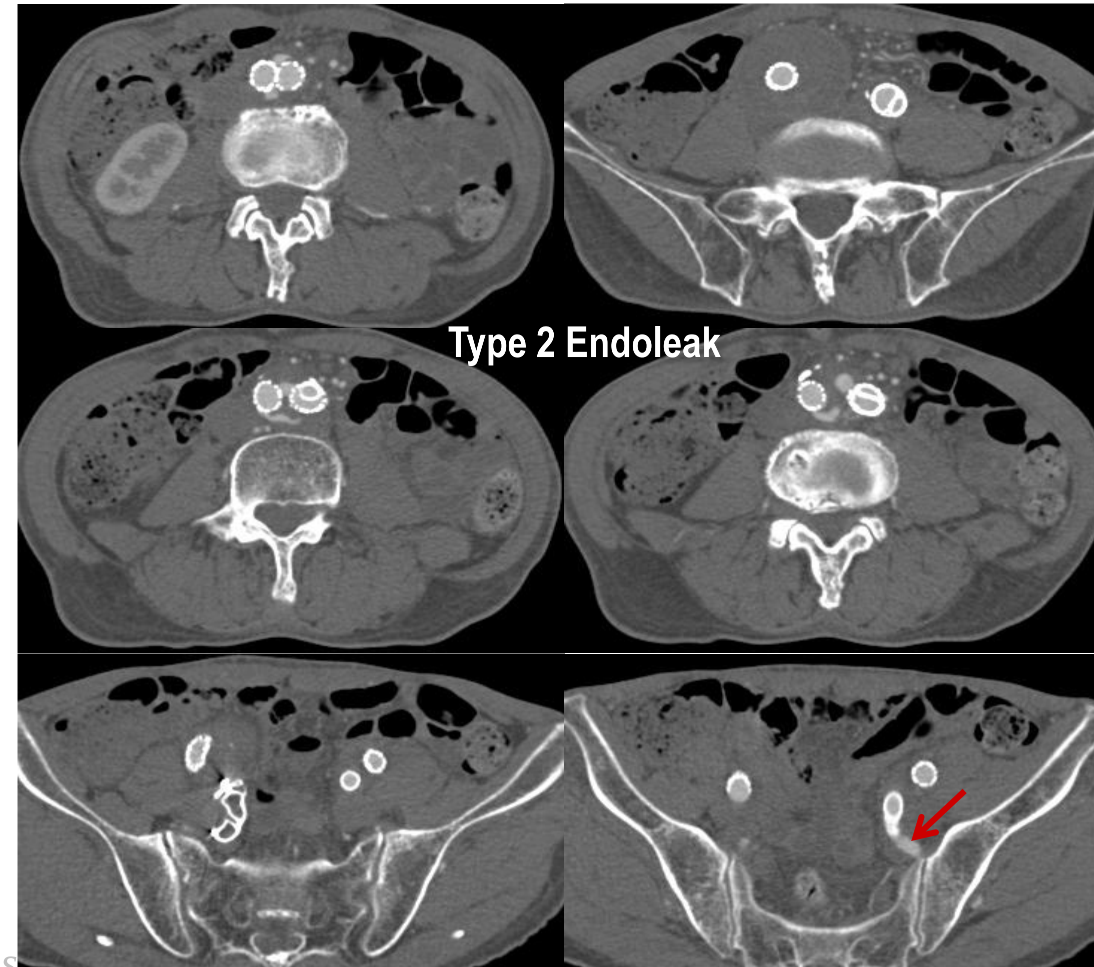
eral CIA Aneurysm

M / 76 JTH (#7461138)



Bilateral CIA Aneurysm





Limitations of Current Devices

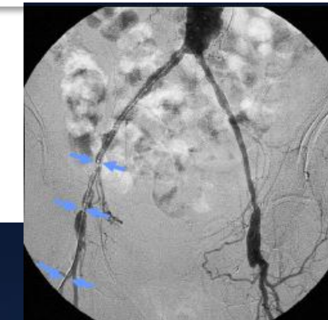
Limitations

- Hostile neck
- Inability of reposition
- Large device profile
- Endoleak
- Juxta- or suprarenal AAA

Required Improvement

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

Current Delivery System Profiles



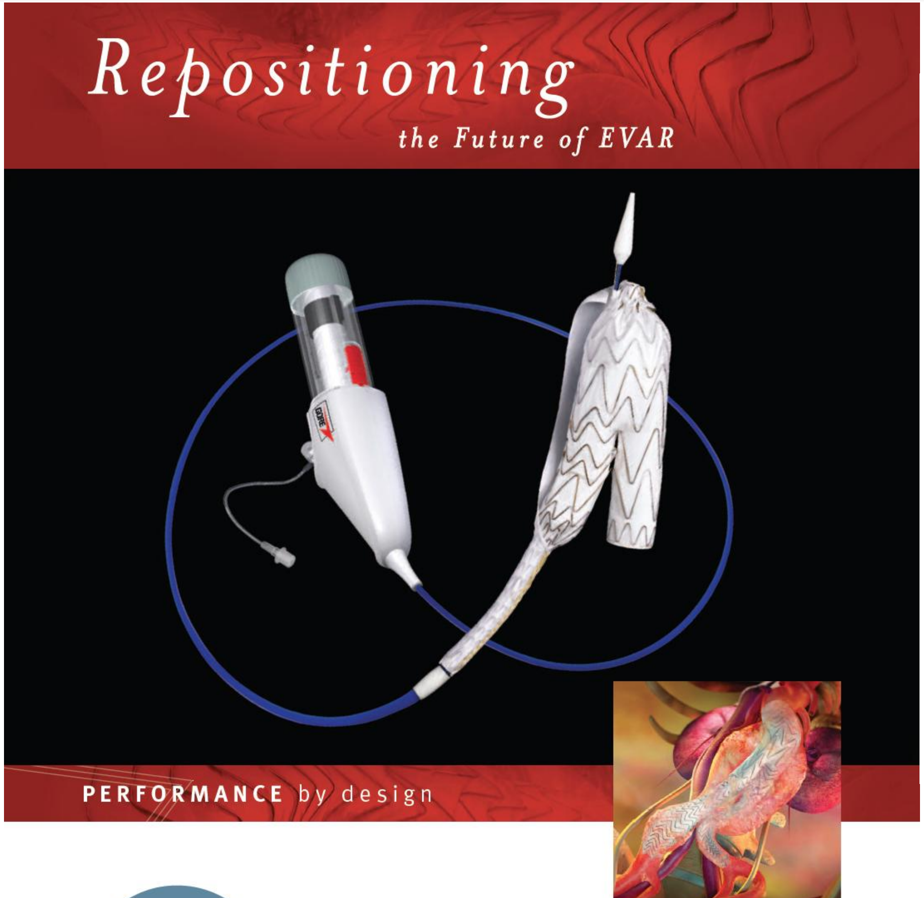
Outer diameters

ENDURANT	EXCLUDER®	TALENT AAA	ZENITH®
20Fr	20.4Fr	22Fr	24Fr

≈7mm access vessel required

6-19% of EVAR candidates are excluded due to small, tortuous and/or calcified access vessels

Excluder & C3 Delivery System (Gore)



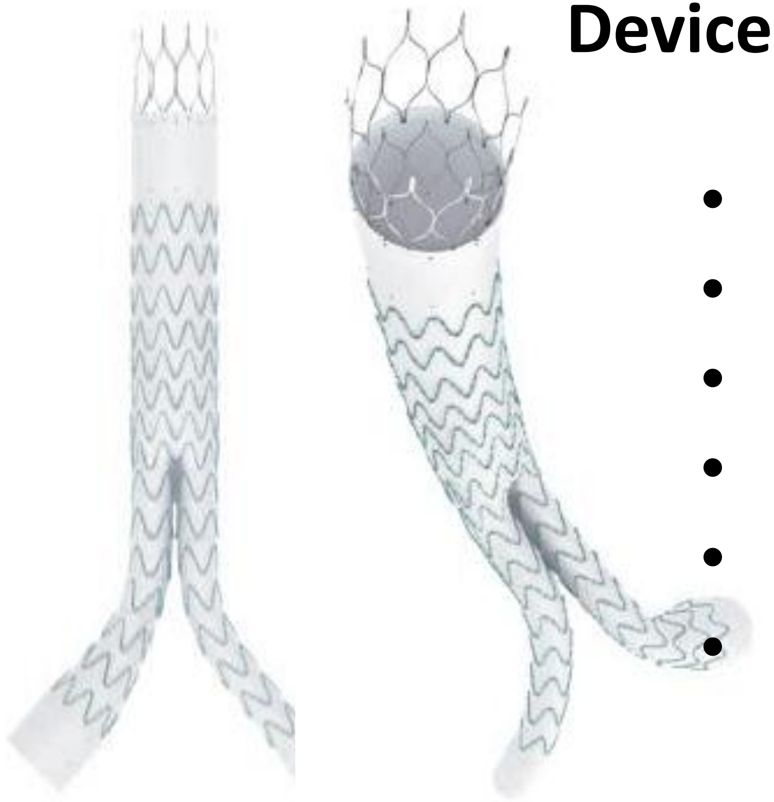
35 mm Trunk-Ipsilateral Legs

- Expands aortic neck diameter treatment range to 19–32 mm*
- 18 Fr low profile design
- 36 mm Aortic Extender also available

23 and 27 mm Contralateral Legs

- Expands iliac diameter treatment range to 8–25 mm
- 14–15 Fr introducer sheath compatible
- Available in 10, 12 and 14 cm lengths

Zenith Low Profile (Cook)



Device profile: 18-22 Fr ID => 16Fr ID

- *Nitinol instead of Stainless*
- *New suprarenal stent design*
- *New capless constraint*
- *New Stent configuration*
- *Woven polyester fabric*
- *New Dilator tip and Cannula*

Ovation (Trivascular)

CE Mark Approved
August 2010

14F OD Aortic Body
13F OD Iliac Limbs

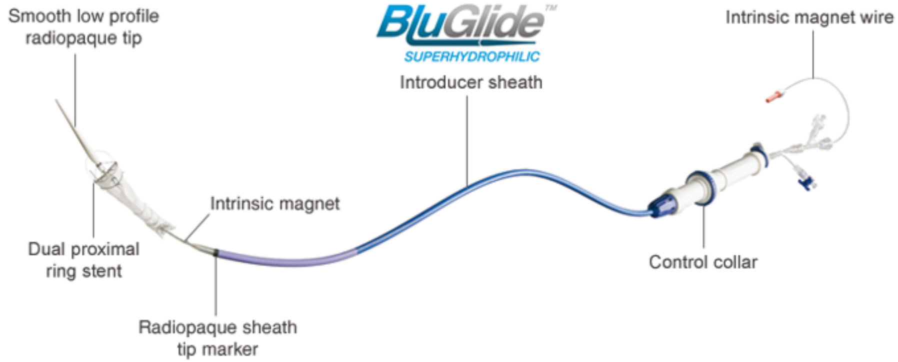
- Tri-modular design
- Suprarenal stent with integral anchors
- Inflatable sealing rings
- Low viscosity, radiopaque biocompatible fill polymer
- Kink resistant iliac limbs
- Hydrophilic catheter coating

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



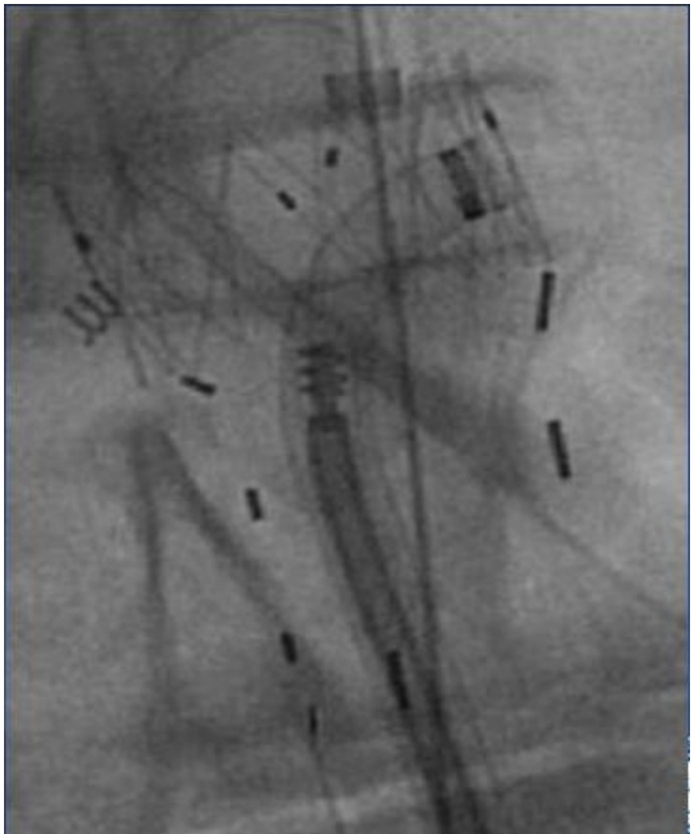
Newer Divices Profiles

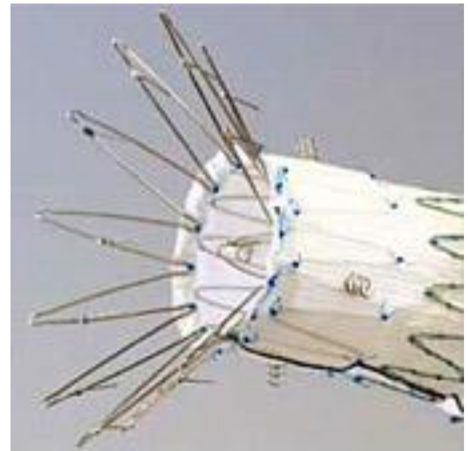
Company	Device	Profile	Neck Length	Neck Diameter	Iliac Diameter
Endologix	AFX	19F	15mm	32mm	23mm
Medtronic	Endurant	18F - 20F	10mm	32mm	23mm
Cook	Zenith LP	16F - 18F	15mm	32mm	23mm
Gore	C3	18F - 20F	15mm	29mm	23mm
Trivascular	Ovation	14F - 15F	7mm	32mm	23mm
Endologix	Nellix*	17F - 18F	5mm	34mm	35mm
JNJ	Incraft	14F	15mm	32mm	23mm
Terumo	Anaconda	21F - 23F	15mm	32mm	23mm

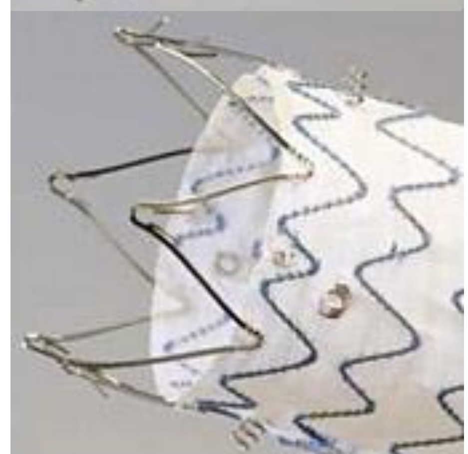
Nellix (Endologix)

- Dual balloon expandable endoframes
- Polymer filled endobags
- => obliterate aneurysm sac, provide support and eliminate endoleak space
- Fixation is not dependent on proximal neck and iliac arteries
- Common iliac aneuryms are treated with preservation of internal iliac

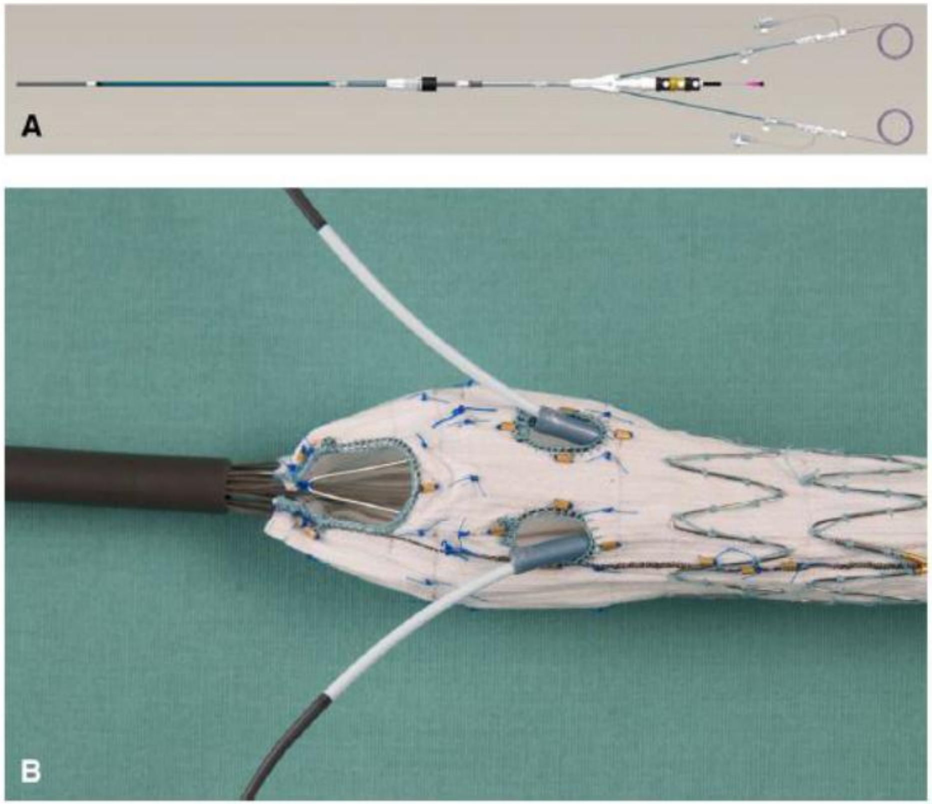
EndoStples (Aptus)

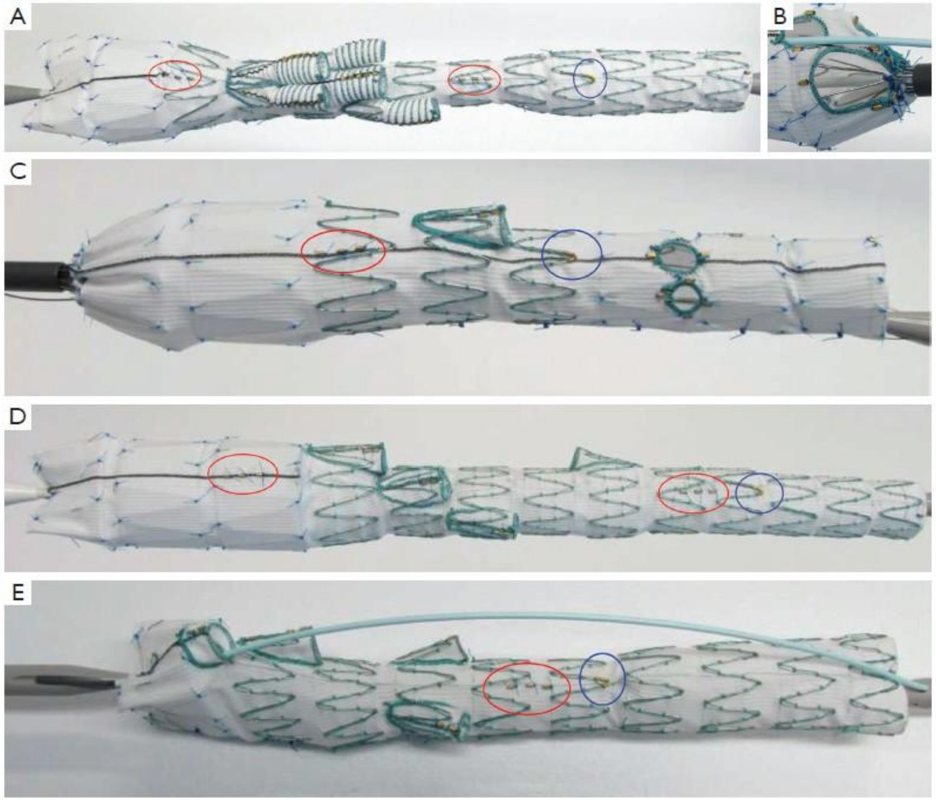






Fenestrated/Branched Stent Grafts (Cook)





Conclusion

- EVAR for AAA is achieved with relatively high success rate.
- EVAR is associated with relatively low peri-procedural mortality and morbidity rates.
- Currently, EVAR is indicated only for AAA with suitable anatomic criteria.
- However, newer devices will expand application of EVAR in AAA patients with complex anatomy

What is Better?

✓EVAR

vs.