### 2023 MID-ATLANTIC CONFERENCE 11th ANNUAL CURRENT CONCEPTS IN VASCULAR THERAPIES



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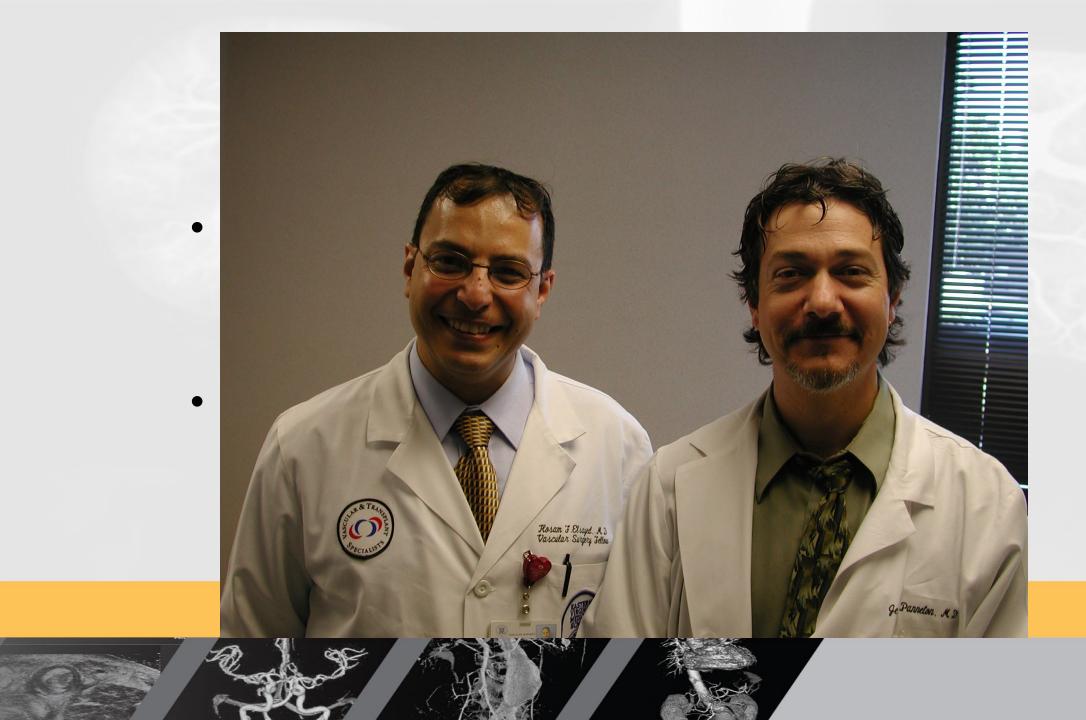


### 2023 MID-ATLANTIC CONFERENCE 11th ANNUAL CURRENT CONCEPTS IN VASCULAR THERAPIES



Open Thoracoabdominal Surgery. Every Procedure: Endovascular Surgery Will Remain Experimental

Hosam F El Sayed, MBBCh, PhD Sentara Vascular Specialists April 22, 2023



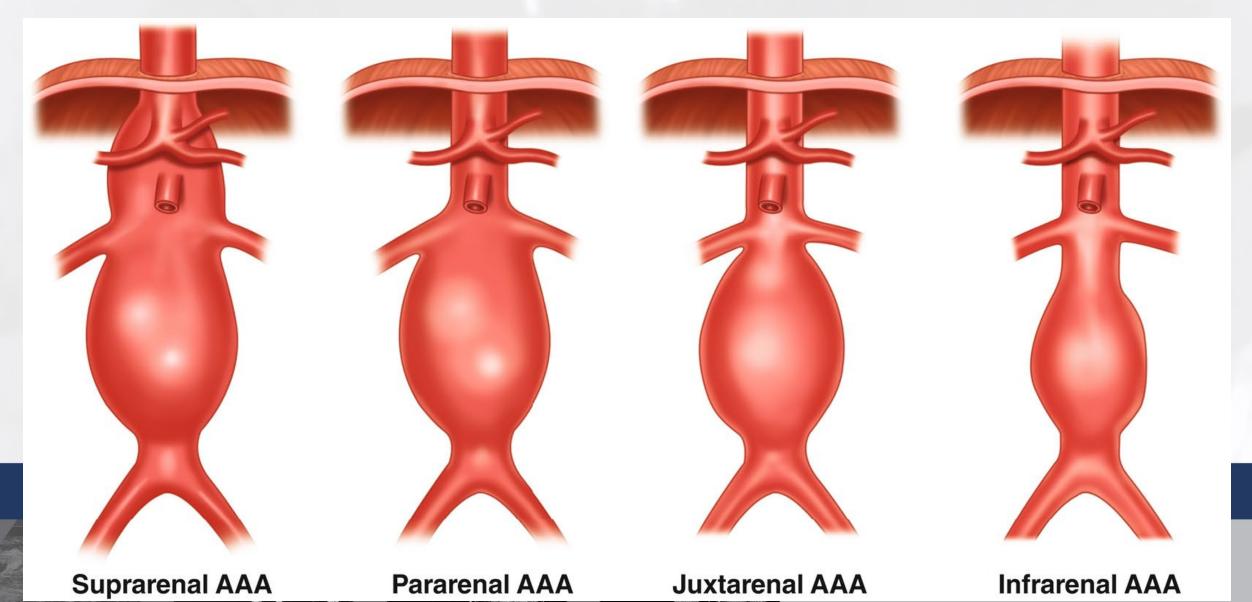
## Disclosures

- Vascular Surgeon
- Do not believe that there is a one size fits all therapy for complex aortic aneurysms
- The decision on which therapy modality chosen depends on
  - Factors related to the aneurysm itself
  - Factors related to the patient
  - Factors related to the treatment team and facility



TAAA II III IV I v interspace 6th. Ser.

### Juxta-renal



### **Treatment Requirements**

• Effective

• Safe

• Can be performed for most or all cases

• Durable



## **Repair Options**

• Open Surgical Repair

• Endovascular Repair

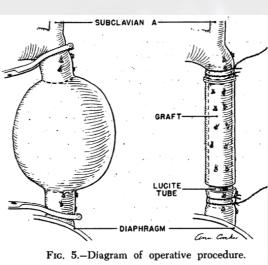
• Hybrid repair (Debranching)



### The First Reported Open TAAA Repair

The **first successful** resection of a descending aortic aneurysm was performed by Conrad and Hartley in **1951** 





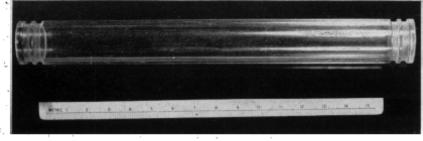
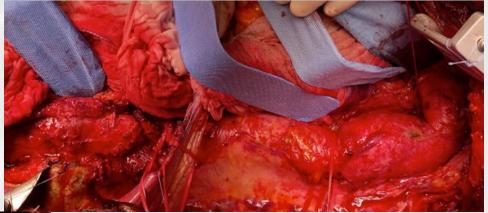


FIG. 4.-Lucite tube used to conduct blood through the graft during the suturing.

#### Annals of Surgery 1951; 134 743-52



• Effective?







• Safe?



- Safe? (This is the culprit)
  - Most complex surgery in our profession
  - Needs an experienced surgeon
  - It is a team sport (Surgeon, OR staff, Anesthesia, ICU, etc)
  - It is not a case for the occasional aortic surgeon or institution that is not experienced in doing it



### • Safe?

- It is quoted that the mortality after open repair can reach
  26% with major morbidity up to 50%. (Barbato et al, JVS, 2007)
- National mortality rate after open repair is historically 22%. (Cowan et al, JVS, 2003)
- This is far from the truth when performed under optimum conditions
- Centers of Excellence in this field report very reasonable mortality rate in the single digits between 2.3% and 9% depending on the type of aneurysm repaired (Konstantinos et al, JVS, 2018)



# Open repair of thoracoabdominal aortic aneurysms in experienced centers

Konstantinos G. Moulakakis, MD,<sup>a</sup> Georgios Karaolanis, MD,<sup>b</sup> Constantine N. Antonopoulos, MD,<sup>a</sup> John Kakisis, MD,<sup>a</sup> Christos Klonaris, MD,<sup>b</sup> Ourania Preventza, MD, FACS,<sup>c,d,e</sup> Joseph S. Coselli, MD,<sup>c,d,e</sup> and George Geroulakos, MD,<sup>a</sup> Athens, Greece; and Houston, Tex

#### ABSTRACT

**Objective:** We performed a systematic review and meta-analysis aiming to assess the mortality and morbidity of all published case series on thoracoabdominal aortic aneurysms (TAAAs) in experienced centers treated with open repair.

**Methods:** A systematic search of the literature published until April 2017 was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Separate meta-analyses were conducted for overall in-hospital mortality for TAAA, mortality according to the type of TAAA, spinal cord ischemia, paraplegia and paraparesis, cardiac events, stroke, acute kidney failure, and bowel ischemia. A metaregression analysis was performed with volume of the center, percentage of ruptured cases among the series, length of in-hospital stay, and publication year as covariates.

**Results:** A total of 30 articles were included in the meta-analysis, corresponding to a total of 9963 patients who underwent open repair for TAAAs (543 ruptured). The pooled mortality rate among all studies was 11.26% (95% confidence interval [CI], 9.56-13.09). Mortality was 6.97% (95% CI, 3.75-10.90), 10.32% (95% CI, 7.39-13.63), 8.02% (95% CI, 6.37-9.81), and 7.20% (95% CI, 4.19-10.84) for Crawford types I, II, III, and IV, respectively. Pooled spinal cord ischemia rate was estimated at 8.26% (95% CI, 6.95-9.67), whereas paraparesis and paraplegia rates were 3.61% (95% CI, 2.25-5.25) and 5% (95% CI, 4.36-5.68), respectively. We estimated a pooled cardiac event rate of 4.41% (95% CI, 1.84-7.95) and a stroke rate of 3.11% (95% CI, 2.36-3.94), whereas the need for permanent dialysis rate was 7.92% (95% CI, 5.34-10.92). Respiratory complications after surgery were as high as 23.01% (95% CI, 14.73-32.49). Metaregression analysis evidenced a statistically significant inverse association between mortality and the volume of cases performed in the vascular center (t = -2.00; P = .005). Interestingly, a more recent year of study publication tended to be associated with decreased in-hospital mortality (t = -1.35; P = .19).



**Conclusions:** Our study showed that despite the advances in open surgical techniques, the morbidity and mortality of the technique continue to remain considerable. Despite the focus on mortality and spinal cord ischemia, respiratory complications, permanent postoperative renal dialysis, stroke rate, and cardiac events also affect the outcome. The estimated trend of lower mortality in high-volume centers suggests that perhaps this type of service should be provided in a few reference centers that have an established record and experience in the management of these

### Pooled Mortality and Morbidity

			Heterogeneity	Publication bias
Outcome	No. of studies	Pooled rates, % (95% CIs)	ř (%), P value	Egger test (tau), P value
Mortality (in-hospital, all Crawford types)	30	11.26 (9.56-13.09)	82.8, .01	2.48, .02
Mortality (Crawford type I)	11	6.97 (3.75-10.90)	61.0, .01	1.24, .25
Mortality (Crawford type II)	12	10.32 (7.39-13.63)	65.8, .01	1.16, .27
Mortality (Crawford type II)	10	8.02 (6.37-9.81)	0.0, .45	1.32, .23
Mortality (Crawford type IV)	9	7.20 (4.19-10.84)	55.6, .02	1.49, .18
Cardiac events	10	4.41 (1.84-7.95)	96.4, .01	0.45, .66
Need for permanent dialysis	13	7.92 (5.34-10.92)	84.5, .01	0.42, .68
Reintervention due to hemorrhage	14	6.36 (3.78-9.50)	94.2, .01	0.90, .38
Stroke	13	3.11 (2.36-3.94)	52.9, .01	1.14, .27
Acute kidney injury	21	11.65 (8.78-14.68)	93.4, .01	0.12, .91
Bowel ischemia	5	1.72 (0.81-2.92)	72.9, .01	3.79, .03
Paraparesis	14	3.61 (2.25-5.25)	86.8, .01	-1.11, .29
Paraplegia	23	5.00 (4.36-5.68)	23.6, .15	0.95, .35
Respiratory complications	16	23.01 (14.73-32.49)	98.5, .01	-1.03, .32
Spinal cord ischemia	28	8.26 (6.95-9.67)	76.0, .01	-1.67, .11



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#### **Outcomes of 3309 thoracoabdominal aortic aneurysm repairs**

Joseph S. Coselli, MD,<sup>a,d,e</sup> Scott A. LeMaire, MD,<sup>a,b,c,d,e</sup> Ourania Preventza, MD,<sup>a,d,e</sup> Kim I. de la Cruz, MD,<sup>a,d,e</sup> Denton A. Cooley, MD,<sup>d</sup> Matt D. Price, MS,<sup>a,d</sup> Alan P. Stolz, MEd,<sup>a,d</sup> Susan Y. Green, MPH,<sup>a,d</sup> Courtney N. Arredondo, MSPH,<sup>b</sup> and Todd K. Rosengart, MD<sup>a,c,d,e</sup>

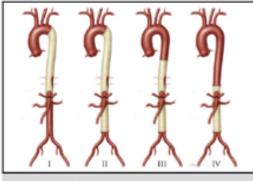
#### ABSTRACT

**Objective:** Since the pioneering era of E. Stanley Crawford, our multimodal strategy for thoracoabdominal aortic aneurysm repair has evolved. We describe our approximately 3-decade single-practice experience regarding 3309 thoracoabdominal aortic aneurysm repairs and identify predictors of early death and other adverse postoperative outcomes.

**Methods:** We analyzed retrospective (1986-2006) and prospective data (2006-2014) obtained from patients (2043 male; median age, 67 [59-73] years) who underwent 914 Crawford extent I, 1066 extent II, 660 extent III, and 669 extent IV thoracoabdominal aortic aneurysm repairs, of which 723 (21.8%) were urgent or emergency. Repairs were performed to treat degenerative aneurysm (64.2%) or aortic dissection (35.8%). The outcomes examined included operative death (ie, 30-day or in-hospital death) and permanent stroke, paraplegia, paraparesis, and renal failure necessitating dialysis, as well as adverse event, a composite of these outcomes.

**Results:** There were 249 operative deaths (7.5%). Permanent paraplegia and paraparesis occurred after 97 (2.9%) and 81 (2.4%) repairs, respectively. Of 189 patients (5.7%) with permanent renal failure, 107 died in the hospital. Permanent stroke was relatively uncommon (n = 74; 2.2%). The rate of the composite adverse event (n = 478; 14.4%) was highest after extent H repair (n = 203; 19.0%) and lowest after extent IV repair (n = 67; 10.2%; P < .0001). Estimated postoperative survival was 83.5% ± 0.7% at 1 year, 63.6% ± 0.9% at 5 years, 36.8% ± 1.0% at 10 years, and 18.3% ± 0.9% at 15 years.

**Conclusions:** Repairing thoracoabdominal aortic aneurysms poses substantial risks, particularly when the entire thoracoabdominal aorta (extent II) is replaced. Nonetheless, our data suggest that thoracoabdominal aortic aneurysm repair, when performed at an experienced center, can produce respectable outcomes. (J Thorac Cardiovasc Surg 2016;151:1323-38)



Outcomes of TAAA repair differ by Crawford extent.

#### Central Message

Open TAAA repair produces respectable outcomes, but there is clearly room for improvement. Outcome differs by repair extent.

#### Perspective

We present the results of 3309 open TAAA repairs to elucidate operative risk. These repairs require interrupting blood flow to vital organs, which incurs the risk of postoperative paraplegia, renal failure, and other complications. Our data suggest that open TAAA repair performed at an experienced center can produce respectable outcomes, but further improvement is needed.

See Editorial Commentary page 1339.

See Editorial page 1232.

- Mortality 7.5%
- Paraparesis 2.9%
- Paraplegia 2.4%
- Stroke 2.2%
- Renal failure 5.7%
- Total major morbidity of 14.4%



- Can be performed for all types of cases?
  - Yes
  - All anatomic variations can be repaired by open repair
  - Patients with CT disease have to be repaired by open repair
  - Does not matter if there is clot, tortuosity, calcification, etc



- Durable?
  - Yes
  - Over and over again studies have shown the durability of the technique
  - No need for intensive follow up
  - No need for long term repeated radiation and contrast exposure



## So, Should we do it on everyone?

- No
- THE PATIENT
  - Old age (>75 years)
  - Bad heart
  - Severe lung disease
  - Redo chest cases
- These are all independent risk factors for significant increase in morbidity and mortality of open repair.



# Endovascular Repair Available Options

 Dedicated devices for treating Thoracoabdominal aneurysms and aneurysms involving the visceral segment

- In the absence of dedicated devices:
  - Parallel grafts (Improvise)
  - Investigational devices (Fenestrated, branched endografts)
  - Physician modified devices (Fenestrations, cuffs, branches, etc)

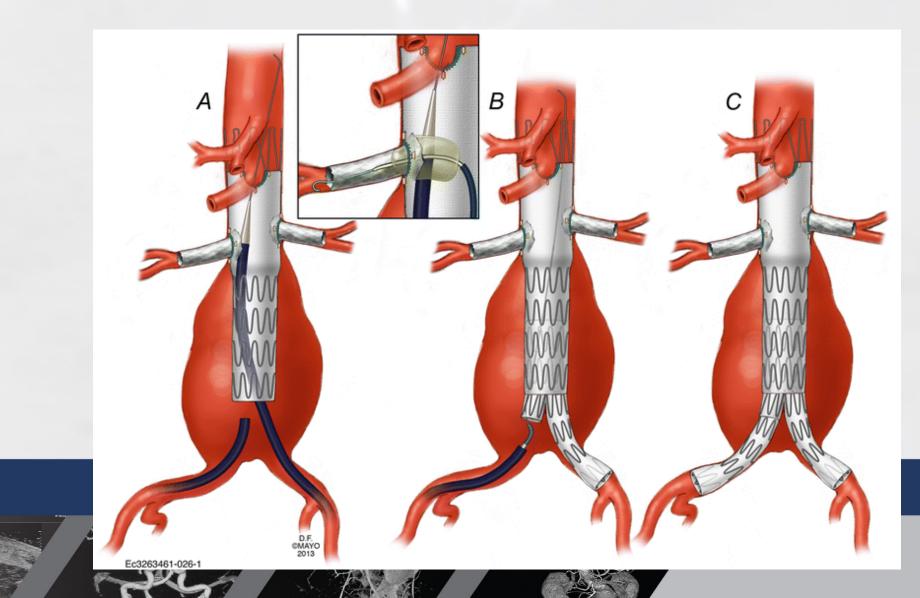


### **Dedicated Endovascular Devices**

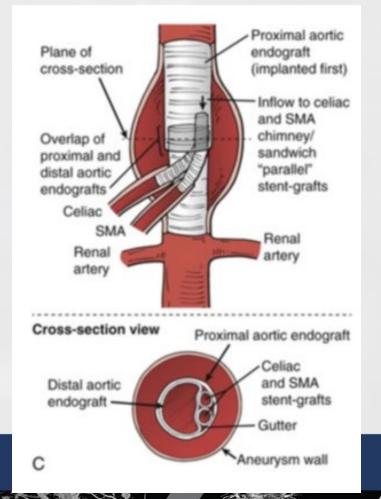
- We only have standard TEVAR devices
- We don't have commercial devices to deal with branches (Aortic arch, Visceral segment)
- The only approved and available device is the Cook fenestrated device for only juxta-renal aneurysms
- Maximum of 3 fenestrations
- Custom made (need 4-6 weeks to order)

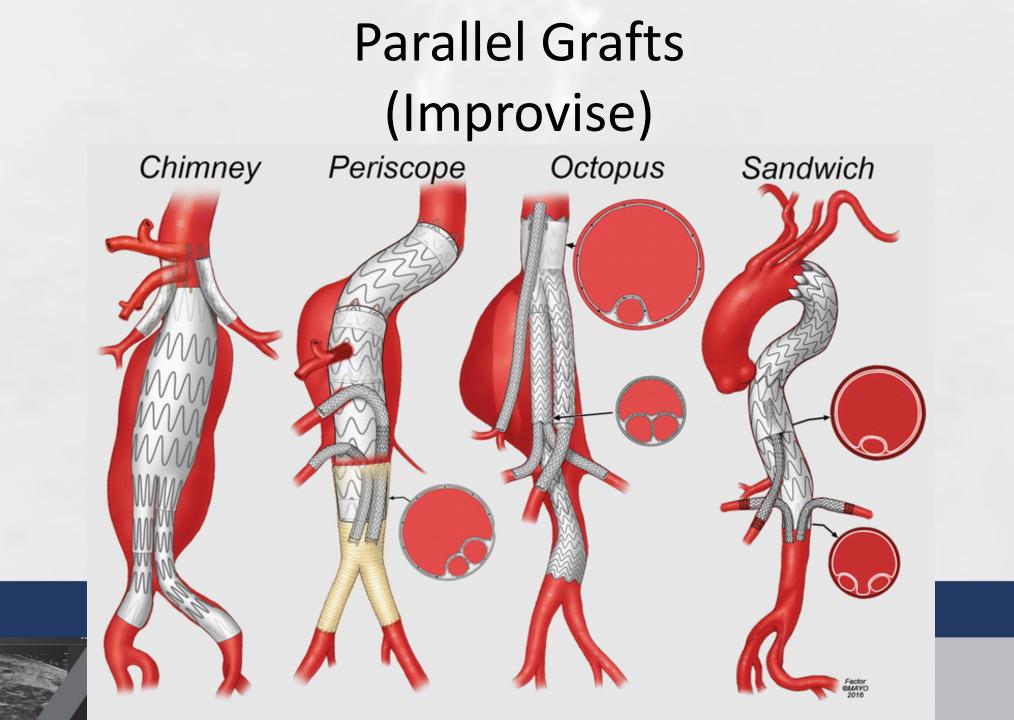


### **Cook Z-Fen Fenestrated Device**



# Parallel Grafts (Improvise)





### **Investigational Arch Devices**

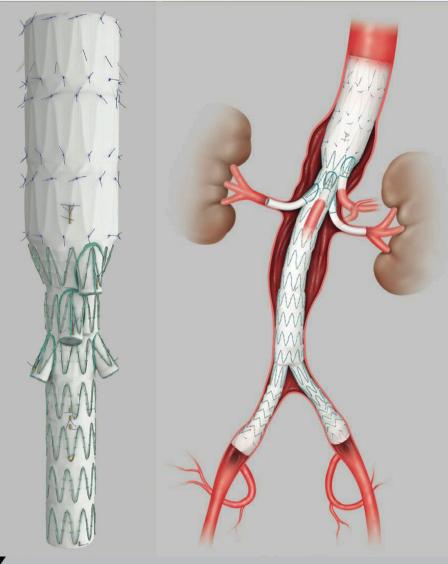




# Investigational Thoracoabdominal Branched Devices







## **Physician Modified Devices**

• Can be extremely complex procedures

• No quality control

• Significant regulatory and legal implications



### Endovascular Repair

### • Effective?

- Yes
- They have over 95% technical success rate for the properly selected patients for the device.
  - Greenberg et al, J Thorac Cardiovasc Surg, 2010 (100%)
  - Verhoeven et al, EJVS, 2006 (97%)
  - Ziegler et al, J Endovasc Ther, 2007 (94%)



### Endovascular Repair

- Safe?
  - This is where it shines
  - Definitely procedure related morbidity and mortality of endovascular repair is less compared to open repair



Author	Year	Aneurysm type	Ν	Vessel	Technical success	30 day mortality %	Dialysis %	Endoleaks %	Branch patency %	Follow up (months)
Greenberg et al	2004	JRA	32	83	100	3.1	3.1	6.5	98	9.2
Greenberg et al	2004	JRA	22	58	100	00	4.5	9		6
O'Neil et al	2006	JRA	119	302	100	0.8	3.4	25	92	19
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- Can be performed for all types of cases?
  - Absolutely not!!!
  - Not for CTD
  - Not for Shaggy aorta
  - Extreme tortuosity
  - Let us take a look at the IFUs of the currently available investigational devices



- IFU suitability and challenges
  - Adequate iliac access
  - Adequate upper extremity access
  - Adequate neck for no-thoracic component approach
  - Aortic neck angle
  - Adequate landing zone
  - Visceral vessels configuration and anatomy
  - Aortic lumen



 Anatomical suitability and challenges with an off-the-shelf branched endoprosthesis - analysis of CT scans of 500 patients

L Bertoglio, et al, CX Symposium 2019

- Studied the suitability of the cases for using t-branch or TAMBE device according to the IFU
- Only 50-70% of cases were suitable for the available device design.



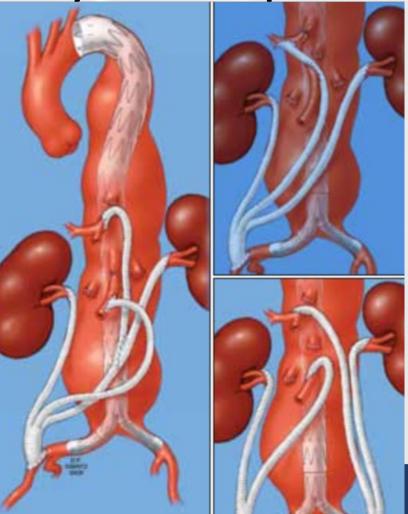
#### • Durable?

- We do not know
- There are no long term data to support the durability of the repair.
- The devices are more complex, more pieces, more connections, more chance of failure over time.
- The aorta is a living organ that changes with time and can contribute to progressive failures. (Lessons from EVAR)



Author	Year	Aneurysm type	Ν	Vessel	Technical success	30 day mortality %	Dialysis %	Endoleaks %	Branch patency %	For ow up (months)
Greenberg et al	2004	JRA	32	83	100	3.1	3.1	6.5	98	9.2
Greenberg et al	2004	JRA	22	58	100	00	4.5	9		6
O'Neil et al	2006	JRA	119	302	100	0.8	3.4	25	92	19
Semmens et al	2006	JRA, SRA	58	116	91	3.4	00	7	95	24
Muhs et al	2006	JRA, SRA	38	87	94	2.6	00	24	92	25
Ziegler et al	2007	JRA, SRA	63	122	97	1.5	1.5	19	92	23
Scurr et al	2008	JRA	45	117		2	00	00	97	24
Beck et al	2009	JRA	18	56	100	00			95	23
Greenberg et al	2009	JRA	30	54	100	00	3.7	60	94	24
Amiot et al	2010	JRA, SRA	134	403	99	2	4.5	18	97	15
Haulon et al	2010	JRA, SRA	80	237	99	2.5	4	11	95	10
Verhoeven et al	2010	JRA	100	275	99	1	2		94	24
Tambyraja et al	2011	JRA	29	79		00	00	21		20
GLOBALSTAR Collaborators	2012	JRA, SRA	318	889	75	3.5		16	99	21
Starnes et al	2012	JRA	47	82	98	2		13		20

## Hybrid Repair



#### Hybrid Repair

• The idea was to have the durable open repair combined with the lower risk of endovascular repair.

• Ended up getting the worst of both worlds.

• Only indicated in very few situations



### Conclusion

- Open repair is effective, safe in the proper hands, can be performed in all pathologies.
- It is durable and should be the first choice for repair of thoracoabdominal aneurysms.
- Endovascular repair is currently experimental and CAN be used in high-risk patients who cannot withstand open repair or when open repair experience is lacking.



- This stance can change over time with
  - Having dedicated off the shelf devices that are available for these complex pathologies.
  - Improving imaging modalities with reduction of radiation exposure over time.
  - Long term results that support the use of endovascular techniques
- Until then, open repair should be the primary modality of treatment.



#### Don't Think There is a Debate about That at all

• Open Thoracoabdominal repair: Every Procedure

 Endovascular Thoracoabdominal repair: Will remain Experimental



#### Don't Think There is a Debate about That at all

• Open Thoracoabdominal repair: Most Procedures

 Endovascular Thoracoabdominal repair: Will remain Experimental



#### Don't Think There is a Debate about That at all

• Open Thoracoabdominal repair: Most Procedures

 Endovascular Thoracoabdominal repair: Will remain Experimental for the time being









# Thank You

