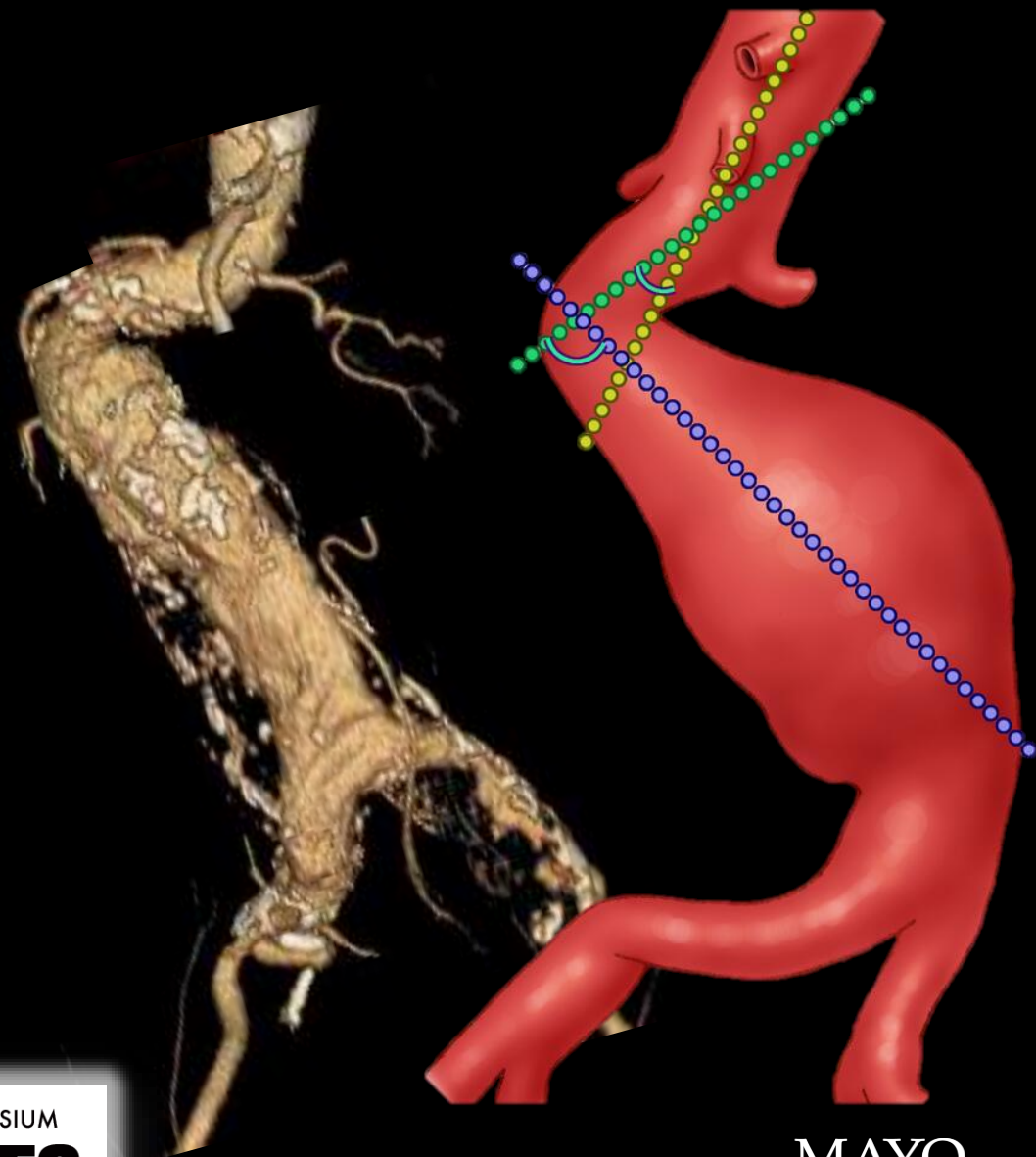


DEDICATED DEVICES FOR HIGHLY ANGULATED INFRARENAL NECKS - LIFE SAVER OR MARKETING GIMMICK?

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THE 26TH INTERNATIONAL EXPERTS SYMPOSIUM
CRITICAL ISSUES
IN AORTIC ENDOGRAFTING



DISCLOSURES

- WL Gore, Cook Medical
 - Research funding, consulting
- Medtronic, Cook Medical
 - Aortic advisory board
- All fees paid to Mayo Clinic

Tack så mycket!



IDEAL ANATOMY



Most AAA devices designed for relatively straight, uniform proximal necks

Angulation $< 60^\circ$ typical

Complete wall apposition and seal are often unattainable in highly angulated necks, resulting in higher rates of type IA endoleaks

RATIONALE?

- 10228 patients
- 59% treated with < 55-mm
- **42% performed off-IFU**
- 69% within "liberal" IFU
- 41% had sac enlargement/5-years
- **Independent predictors**
 - Age >80
 - Neck diameter >28
 - **Neck angle >60**
 - CIA diameter >20

Schanzer et al. *Circulation* 2011 / *Tsilimparis N JVS* 2015 / *Hobo R JEVT* 2007

Vascular Medicine

Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair

Andres Schanzer, MD; Roy K. Greenberg, MD; Nathanael Hevelone, MPH; William P. Robinson, MD; Mohammad H. Eslami, MD; Robert J. Goldberg, PhD; Louis Messina, MD

Background—The majority of infrarenal abdominal aortic aneurysm (AAA) repairs in the United States are performed with endovascular methods. Baseline aortoiliac arterial anatomic characteristics are fundamental criteria for appropriate patient selection for endovascular aortic repair (EVAR) and key determinants of long-term success. We evaluated compliance with anatomic guidelines for EVAR and the relationship between baseline aortoiliac arterial anatomy and post-EVAR AAA sac enlargement.

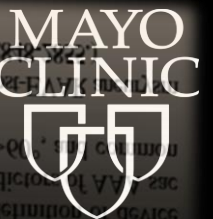
Methods and Results—Patients with pre-EVAR and at least 1 post-EVAR computed tomography scan were identified from the M2S, Inc. imaging database (1999 to 2008). Preoperative baseline aortoiliac anatomic characteristics were reviewed for each patient. Data relating to the specific AAA endovascular device implanted were not available. Therefore, morphological measurements were compared with the most liberal and the most conservative published anatomic guidelines as stated in each manufacturer's instructions for use. The primary study outcome was post-EVAR AAA sac enlargement (>5-mm diameter increase). In 10 228 patients undergoing EVAR, 59% had a maximum AAA diameter below the 55-mm threshold at which intervention is recommended over surveillance. Only 42% of patients had anatomy that met the most conservative definition of device instructions for use; 69% met the most liberal definition of device instructions for use. The 5-year post-EVAR rate of AAA sac enlargement was 41%. Independent predictors of AAA sac enlargement included endoleak, age ≥ 80 years, aortic neck diameter ≥ 28 mm, aortic neck angle $> 60^\circ$, and common iliac artery diameter > 20 mm.

Conclusion—In this multicenter observational study, compliance with EVAR device guidelines was low and post-EVAR aneurysm sac enlargement was high, raising concern for long-term risk of aneurysm rupture. (*Circulation*. 2011;123:2848-2855.)

Key Words: abdominal aortic aneurysm ■ endovascular procedures ■ graft

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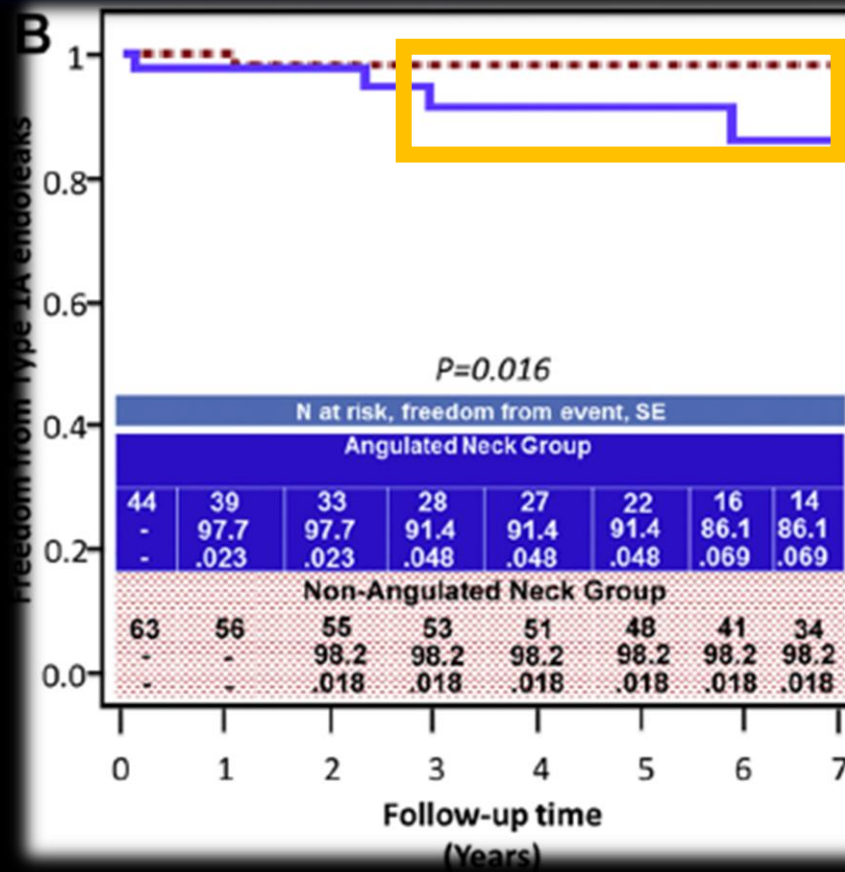


Long-term outcomes of standard endovascular aneurysm repair in patients with severe neck angulation

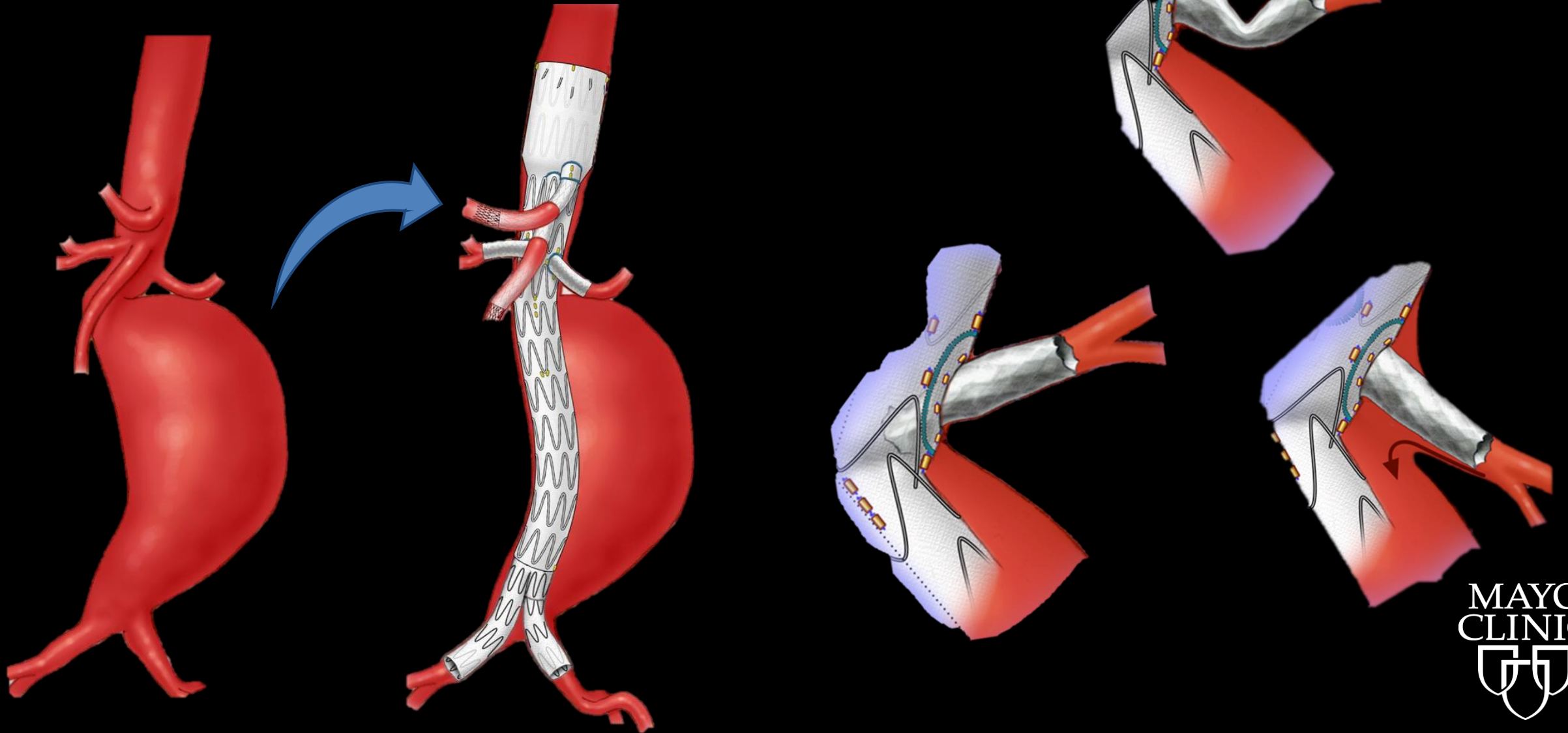
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Nelson F. G. Oliveira, MD,^{a,b} Frederico Bastos Gonçalves, MD, PhD,^{a,c} Sanne E. Hoeks, PhD,^d Marie Josee van Rijn, MD, PhD,^a Klaas Ultee, PhD,^a José Pedro Pinto, MD,^{a,e} Sander Ten Raa, MD, PhD,^a Joost A. van Herwaarden, MD, PhD,^f Jean-Paul P. M. de Vries, MD, PhD,^g and Hence J. M. Verhagen, MD, PhD,^a Rotterdam, Utrecht, and Nieuwegein, The Netherlands; and Azores, Lisbon, and Porto, Portugal

- Exclusively patients with high angulation (45) compared to matched controls (65)
- All patients treated with Endurant SG
- **Freedom from EL1A was 86% x 96% at 7 Y**
- Primary clinical success 41% x 57%
- Long term mortality not affected
- **Only 20% of patients with EL1A suitable for endovascular conversion**



WHAT ABOUT FB-EVAR?



Effect of aortic angulation on the outcomes of fenestrated-branched endovascular aortic repair

Francesco Squizzato, MD, Gustavo S. Oderich, MD, Parvathi Balachandran, MS, Emanuel R. Tenorio, PhD, Bernardo C. Mendes, MD, and Randall R. De Martino, MD, MS, Rochester, Minn

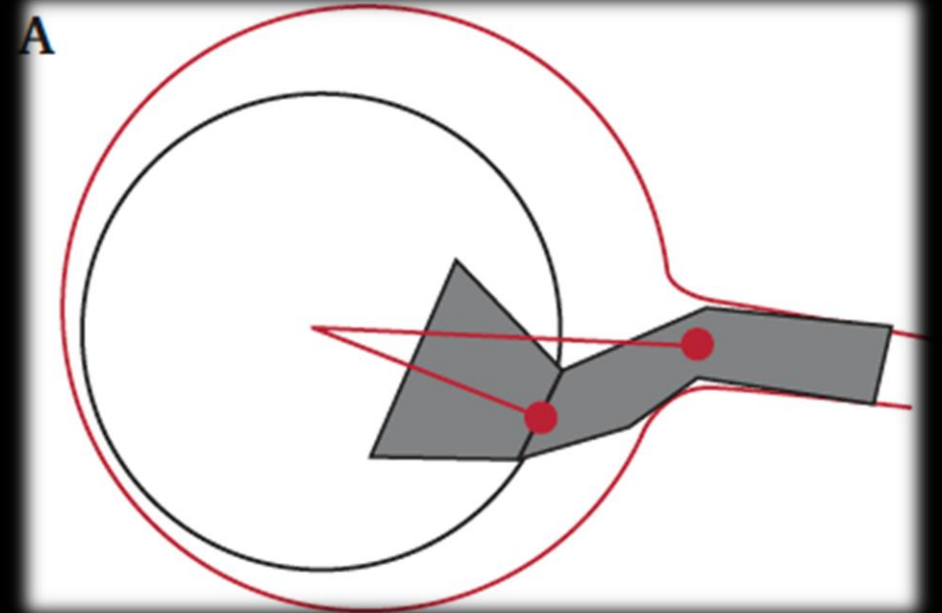
- 298 patients (196 TAAA) / FU 42 months
- Supraceliac, suprarenal, infrarenal necks evaluated
- Technical success similar
- Operative, fluoroscopy times greater with any angulation
- Freedom from TVI was significantly lower in patients with $>45^\circ$ supraceliac angle, similar in others



Clinical Impact and Determinants of Fenestration to Target Vessel Misalignment in Fenestrated Endovascular Aortic Repair

Francesco Squizzato^{*}, Michele Piazza, Edoardo Forcella, Sofia Coppadoro, Franco Grego, Michele Antonello

- 60 patients (80% JRAAA/PRAAA)
- Misalignment $>15^\circ$ horizontally associated with TVI (OR 5.19)
- **Pararenal angle $>45^\circ$** , fen gap $>5\text{mm}$, high profile/tortuous access independently associated with misalignment



THE "IDEAL" DEVICE?

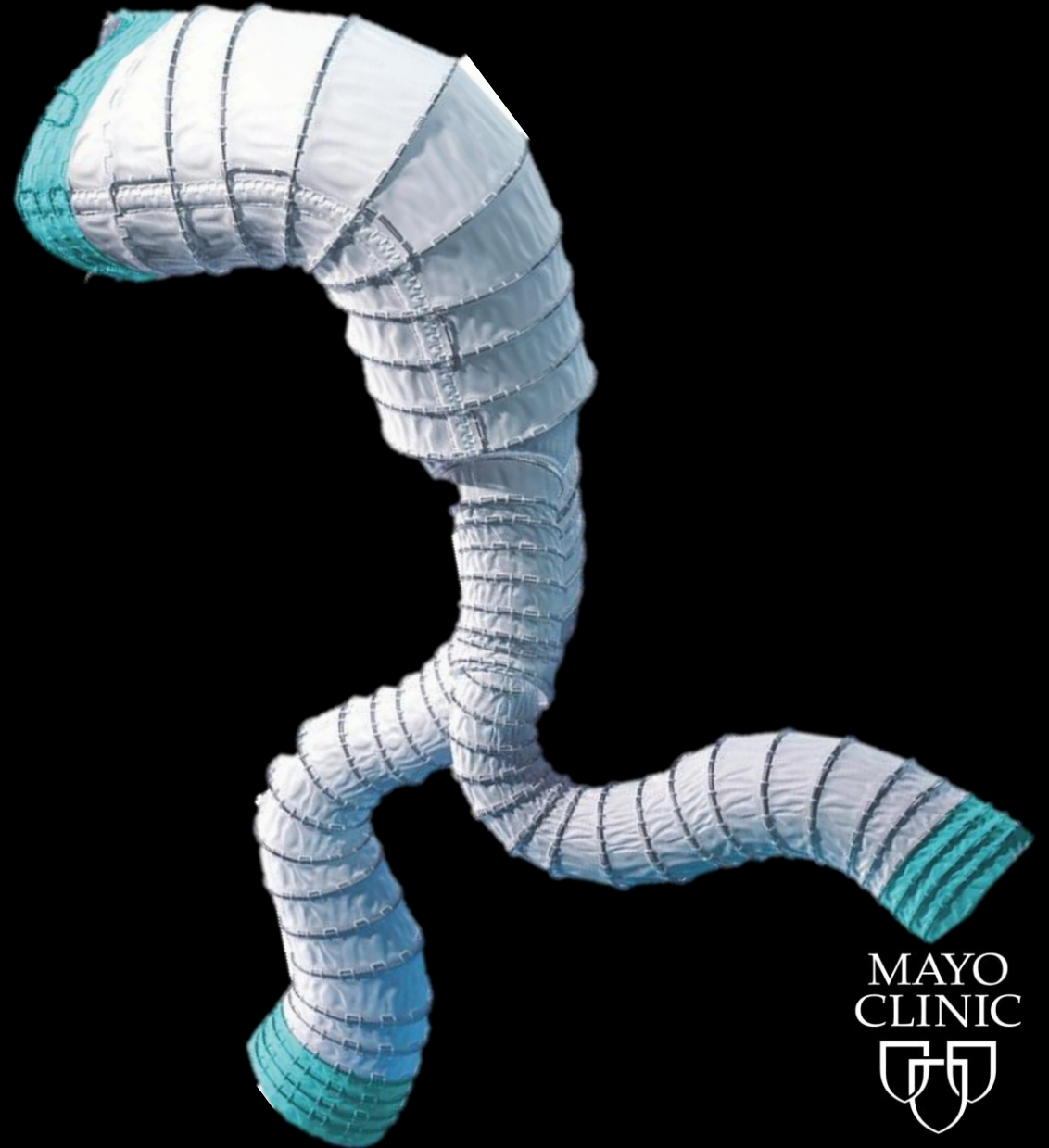
- Highly flexible and adaptable
- Reliable active proximal fixation
- Long-term (>5 years) results consistent
- Unlikely to have suprarenal fixation
- *Relative ease for late endovascular conversion*



DEDICATED DEVICES

Lombard AORFIX

- “Fishmouth” proximal graft
- Four hooks for proximal fixation
- Independent stents for flexibility
- Sealing in the proximal 8 mm
- FDA approved 2015 / CE Mark 2013



Five-year outcomes of the PYTHAGORAS U.S. clinical trial of the Aorfix endograft for endovascular aneurysm repair in patients with highly angulated aortic necks

Mahmoud B. Malas, MD, MHS,^a Caitlin W. Hicks, MD, MS,^a William D. Jordan Jr, MD,^b Kim J. Hodgson, MD,^c Joseph L. Mills Sr, MD,^d Michel S. Makaroun, MD,^e Michael Belkin, MD,^f and Mark F. Fillinger, MD,^g for the PYTHAGORAS Investigators, *Baltimore, Md; Atlanta, Ga; Springfield, Ill; Houston, Tex; Pittsburgh, Pa; Boston, Mass; and Lebanon, NH*

- Prospective sponsored trial, **5Y follow-up**
- 218 patients, 151 highly angulated neck (>60°)
- Similar EL1A, migration, sac expansion
- Similar freedom from aneurysm related mortality, rupture, secondary interventions
- **Neck-related or EL1A specific reinterventions not individually reported**
- **23% stent fractures in fixation zone**

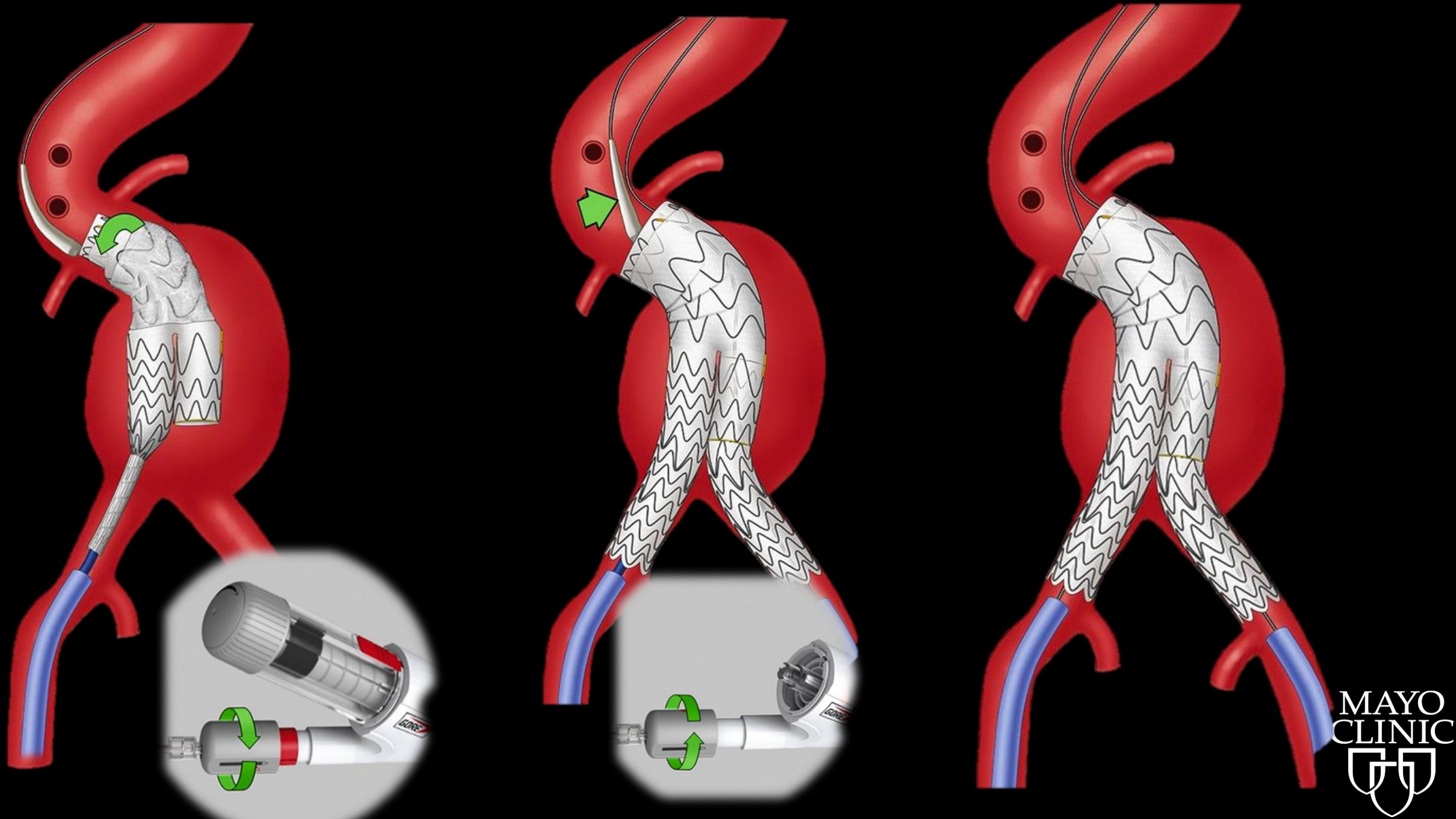


DEDICATED DEVICES

Gore Conformable Excluder (CEXC)

- Individual stent rings
- Reconstraintment capability
- Secondary constraintment sleeve
- “Active Control”/ angulation feature
- Sealing in the proximal 10 mm
- FDA approved 2021 / CE Mark 2016





One-year results of the GORE EXCLUDER Conformable AAA Endoprosthesis system in the United States regulatory trial

Robert Rhee, MD,^a Gustavo Oderich, MD,^b Sukgu Han, MD,^c Chandler Long, MD,^d Patrick Muck, MD,^e Erin Moore, MD,^f and Jon Matsumura, MD,^g For the EXCC investigators, *Brooklyn, NY; Houston, TX; Los Angeles, CA; Durham, NC; Cincinnati, OH; Jacksonville, FL; and Madison, WI*

- Prospective sponsored trial
- 80 patients, **short neck arm**
 - Neck >10 mm, angulation <60°
 - High angulation arm not yet reported
- Technical success 100%, no EL1A at completion
- No MAE, no mortality
- No AAA related mortality, EL1A, ELIII, fractures
- **12-month follow-up**



Early outcomes of the Conformable endograft in severe neck angulation from the Triveneto Conformable Registry

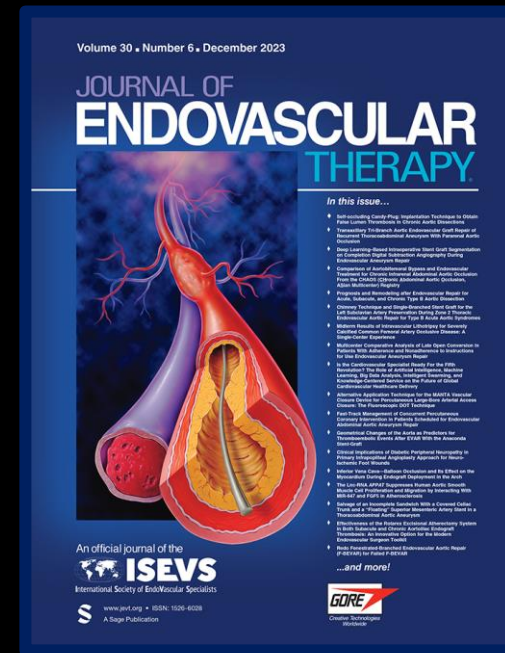
Stefano Bonvini, MD, PhD,^a Nicola Spadoni, MD,^a Paolo Frigatti, MD,^b Michele Antonello, MD,^c Sandro Irsara, MD,^d Gian Franco Veraldi, MD,^e Domenico Milite, MD,^f Edoardo Galeazzi, MD,^g Sandro Lepidi, MD,^h Reinhold Perkmann, MD,ⁱ and Sebastiano Tasselli, MD,^a on behalf of the TriCoRe Contributors, Trento, Udine, Padova, Belluno, Verona, Vicenza, Treviso, Bolzano, and Trieste, Italy

- Nine centers
- 56 patients, angulation 60-90°
- Technical success 100%, no EL1A at completion
- Two reinterventions (3%), one for EL1A
- Freedom from reintervention at 24 months – 92%
- Sac shrinkage 15 patients (26%) / stability 35 (62%)
- **Median follow-up 13-months**

Endovascular Treatment of Abdominal Aortic Aneurysm With Severe Angulation of Infrarenal Aortic Neck by Gore Conformable Endograft

Chiara Mascoli, MD, PhD¹, Gianluca Faggioli, Prof¹, Martina Goretti, MD¹, Enrico Gallitto, MD, PhD¹, Rodolfo Pini, MD, PhD¹, Antonino Maria Loggiacco, MD¹, Andrea Vacirca, MD¹, and Mauro Gargiulo, Prof¹

- 25 patients, angulation $>60^{\circ}$ (11 patients $>90^{\circ}$)
- Technical success 100%, no EL1A at completion
- No EL1A, ELIII or associated reinterventions
- No AAA related deaths
- Sac shrinkage or stability in 96%
- **Median follow-up 12-months**





Reality of vascular surgery...



CONCLUSION

- Pararenal and infrarenal aortic angulation is a clear predictor of failure for infrarenal EVAR and increase difficulty in FB-EVAR
- Dedicated devices have potential but data is still somewhat limited, particularly long term for CEXC
- It is logical to assume that very long term follow up will reveal failure modes and require attention
- Patient selection on open x dedicated devices x FB-EVAR is critical



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