ESAR and FEVAR: How can evidence support tailored treatment of hostile neck AAA's

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

☒ Consulting

☐ Employment in industry

☐ Stockholder of a healthcare company

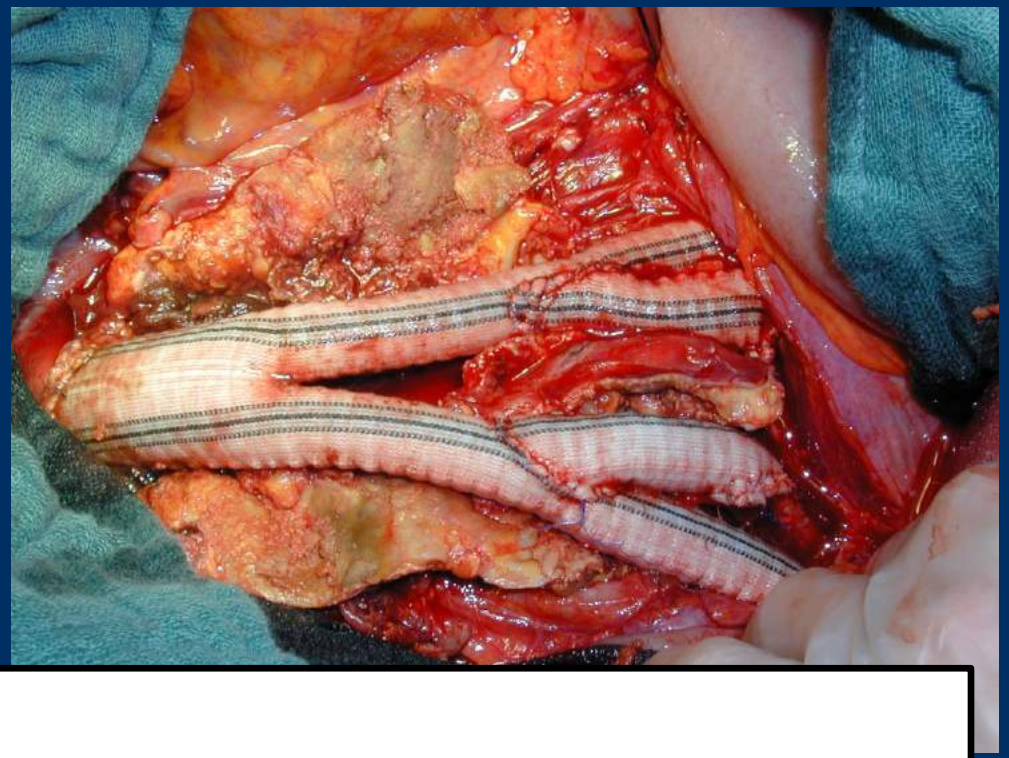
☐ Owner of a healthcare company

☐ Other(s)

☐ Sokrates is a study sponsored by Medtronic

Aneurysm with short neck: open repair

Open Surgery



- 30-day mortality >3.6%
- High morbidity (myocardial infarction, impaired renal function, abdominal wall hernias, small bowel obstruction)

Patient with AAA after multiple abdominal operations

Fenestrated Stent Grafts

- We use FEVAR as custom-made devices since 2001 to create a suitable neck for adequate graft fixation
- Designed for endovascular repair of AAA having morphology unsuitable for endovascular repair with other stent graft

Meta-Analysis

35 studies, OR : FEVAR = 1575 : 751

Open repair versus fenestrated endovascular aneurysm repair of juxtarenal aneurysms

Rohini Rao, BSc, Tristan R. A. Lane, MRCS, Ian J. Franklin, FRCS(Gen Surg), and
Alun H. Davies, DM, FRCS, *London, United Kingdom*

Background: Open repair is the gold standard management for juxtarenal aneurysms. Fenestrated endovascular aneurysm repair (FEVAR) is indicated for high-risk patients. The long-term outcomes of FEVAR are largely unknown, and there is no Level I comparative evidence. This systematic review and meta-analysis of case series compares elective juxtarenal aneurysm surgery by open repair and FEVAR.

Methods: A systematic literature search was conducted for all published studies on elective repair of juxtarenal aneurysms by FEVAR and open repair. The MEDLINE, EMBASE, and Cochrane databases were searched from 1947 to April 2013. The exclusion criteria were case series of <10 patients or ruptured aneurysms. The primary outcomes were perioperative mortality and postoperative renal insufficiency. The secondary outcomes were secondary reinterventions and long-term survival.

Results: We identified 35 case series with data on 2326 patients. Perioperative mortality was 4.1% in open repair and

Conclusions: FEVAR and open repair have similar short-term outcomes but have diverging long-term outcomes that may be secondary to the selection bias of FEVAR being offered to high-risk patients. FEVAR is a favorable option in high-risk patients, and open repair remains viable as the gold standard. (J Vasc Surg 2014;■:1-14.)

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R. Rao, *et al.* J Vasc Surg 2014

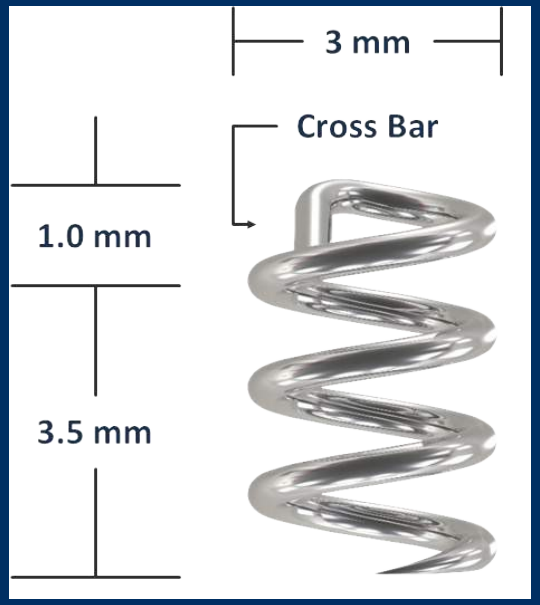
Long-term outcomes after FEVAR

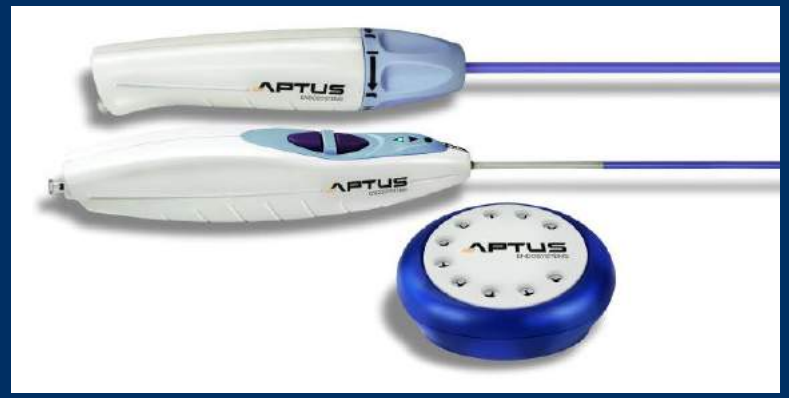
- 94 patients (2007-2011). Median FU 89 months
- 37 (39.4%) required 70 reinterventions
- Five patients (5.3%) died of aneurysm-related causes
- Survival 95.7% at 1 year, 87.1% at 3 years, and 71.0% at 5 years
- GFR decrease from 59.2 mL/min/1.73 m^2 preoperatively to 50.0

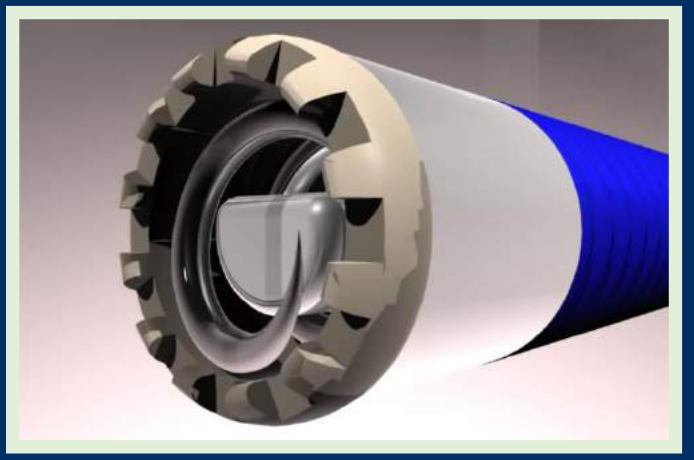
Sveinsson M. JVS 2022 75:1164. Long-term outcomes after fenestrated endovascular aortic repair for juxtarenal aortic aneurysms

Endovascular Suture Heli-Fx Endo-Anchors

ESAR: EndoSuture Aneurysm Repair







LINC

Endosuture Aneurysm Repair (ESAR) for infrarenal neck between 4mm and 10mm

(Arko F. JVS 2019)

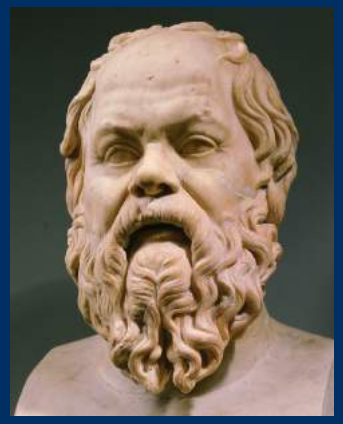
Primary Outcomes	Short Neck
Technical Success Rate at Index Procedure[1]:	88.6% (62/70)
Type Ia Endoleak at 1-month[4]	6.8% (4/59)
Type Ia Endoleak at 1-year[4]	1.9% (1/53)
Secondary Procedures through 1 year	4.7% (3/64)
Conversion to Open Surgical Repair through 12 months	0.0% (0/64)
Other Secondary Open Surgical Procedures through 12 months	1.6% (1/64)

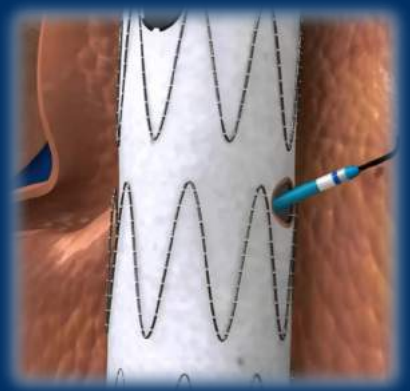
ESAR for short infrarenal neck - possible advantages -

- less technically demanding (widening applicability)
- Less fluoroscopy time and amount of contrast medium
- Less procedure length
- Devices are available off-the-shelf (particularly important in urgent or emergent clinical situations)
- Lack of renal artery manipulation and stenting, minimizing the potential for early and late renal impairment
- Less secondary procedures for branch instability

SOCRATES (ESAR & FEVAR)- Study Objectives

To evaluate and compare the safety and performance of ***ESAR*** (Endurant + Heli-FX EndoAnchors) ***and FEVAR*** (Cook Zenith Fenestrated and Terumo Fenestrated Anacaonda) for the treatment of ***aortic abdominal aneurysms*** with a non-aneurysmal ***infrarenal aortic neck*** in the length of ***4-15mm*** and has a circumferential ***minimum sealing zone*** in length of ***8 mm***.



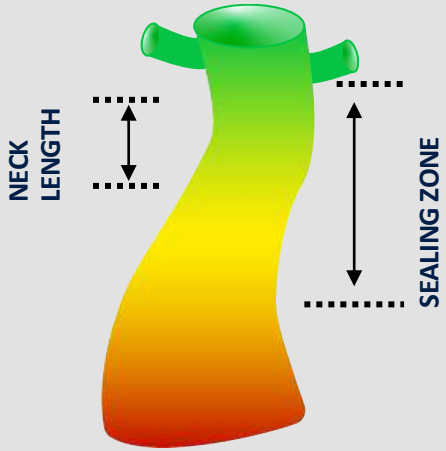


Neck length and Sealing zone

INFRARENAL NECK LENGTH

Length over which neck diameter remains within 10% of infrarenal diameter (Core Lab definition)

- Anatomy related
- NOT Stent Graft dependent



Diameter < 10% of infrarenal

Diameter > 10% of infrarenal or Neck > 28mm or infrarenal angle > 60° but graft apposition maintained

Diameter > 20% of infrarenal, no graft apposition

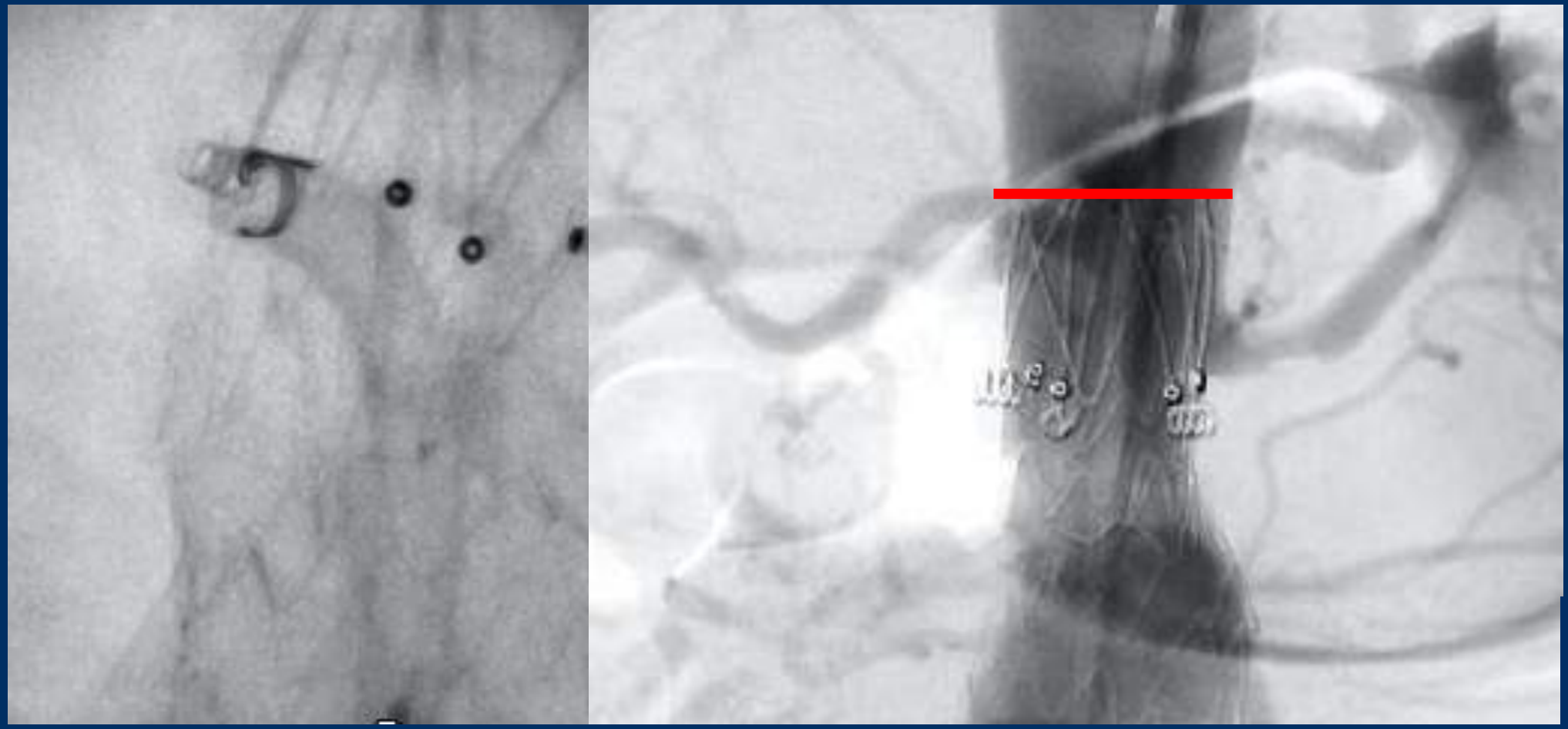
INFRARENAL SEALING ZONE

Length over which a correctly (per IFU) oversized stent graft is circumferentially apposed against the aortic wall

- Anatomy related
- Dependent on SG oversizing[1]
- Dependent on SG deployment accuracy[2]

1. Higheoversizing may result in a longer apposition area 2. potential sub-optimal disposition of the stent graft once implanted may not use all the theoretical sealing zoner

ESAR - EVAR with EndoAnchors



SOCRATES (ESAR & FEVAR)- Study Synopsis

Study Title	**ShOrt neCK AAA RAndomized Trial - ESAR and FEVAR: SOCRATES** Physician-initiated trial investigating ESAR (EVAR plus Heli-FX EndoAnchors) and FEVAR for the treatment of aortic aneurysms with short infrarenal aortic neck
Collaborator	FCRE (Foundation for Cardiovascular Research and Education), Munster, Germany
PI	Giovanni Torsello, Germany
Purpose	To prospectively evaluate and compare safety and performance of **ESAR** (Endurant & Heli-FX) and **FEVAR** (Cook Z-Fen and Terumo Anaconda) for treatment of AAA with non-aneurysmal infrarenal aortic sealing zone, proximal to the aneurysm, that is sufficiently healthy with **proximal neck length between 4-15 mm** and circumferential minimum sealing zone length of 8 mm
Study design	Prospective, multicenter, randomized (1:1), non-inferiority study
Sample size/ Sites	• **204** total subjects (1:1 randomization) • Up to 40 sites globally (**EU, US, and ANZ**)
Primary Endpoints	**Effectiveness:** Composite of technical success at index procedure, and freedom from type IA or type III endoleaks, freedom from aneurysm-related mortality, and freedom from secondary reinterventions through 12 months **Safety:** Freedom from MAEs (ACM, bowel ischemia, MI, respiratory failure, disabling stroke, access-related complications, procedural blood loss >1000cc, permanent paraplegia or paraparesis, renal complications) through 30 days Core Lab and Clinical Events Committee will be installed to assess selected endpoints and datapoints (both managed by FCRE)
Follow-up	1M, 1YR, 2YR, and 3YR

FEVAR = fenestrated endovascular aneurysm repair
ESAR = endosuture aneurysm repair

AAA= abdominal aortic aneurysm
ACM = all-cause mortality

Conclusions

- FEVAR is the gold standard therapy for pararenal AAA with no infrarenal seal zone, where taking the risk of renal and visceral artery manipulation is mandatory
- ESAR has the potential to treat challenging/hostile sealing zones without compromising outcomes (similar to EVAR in non-hostile anatomies)
- Understanding the right indications of each therapy is a shared responsability between Industry and physicians with the ultimate goal of improving patients outcomes
- Head to head comparison will clarify the role of ESAR and FEVAR in short neck