My approach to a AAA with "no neck"

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University of Barcelona

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Disclosures

Consultant/Advisor/Research

- Terumo-Aortic
- Medtronic
- iVascular
- Bayer
- MSD
- Ferrer
- Jotec/Cryolife

Proctor

- Terumo-Aortic
- Cook
- Medtronic
- W.L. Gore
- Cardinal/Cordis
- Jotec/Cryolife
- Lombard-Micropore

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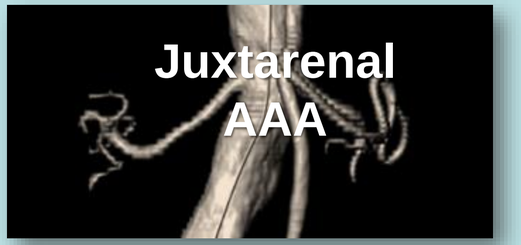
75-years old male patient

- Arterial Hypertension
- Dyslipidaemia
- Sever COPD
- ADK of rectum-Colostomy
- Incidental Diagnosis of JUXTARENAL AAA 62mm

My Algorithm



Low medical risk

Open repair

High medical risk

Suitable for fEVAR

fEVAR

Unsuitable for fEVAR (anatomic or urgent repair)

ChEVAR

Unsuitable for fEVAR or/and ChEVAR

Unfit for any intervention

Do nothing

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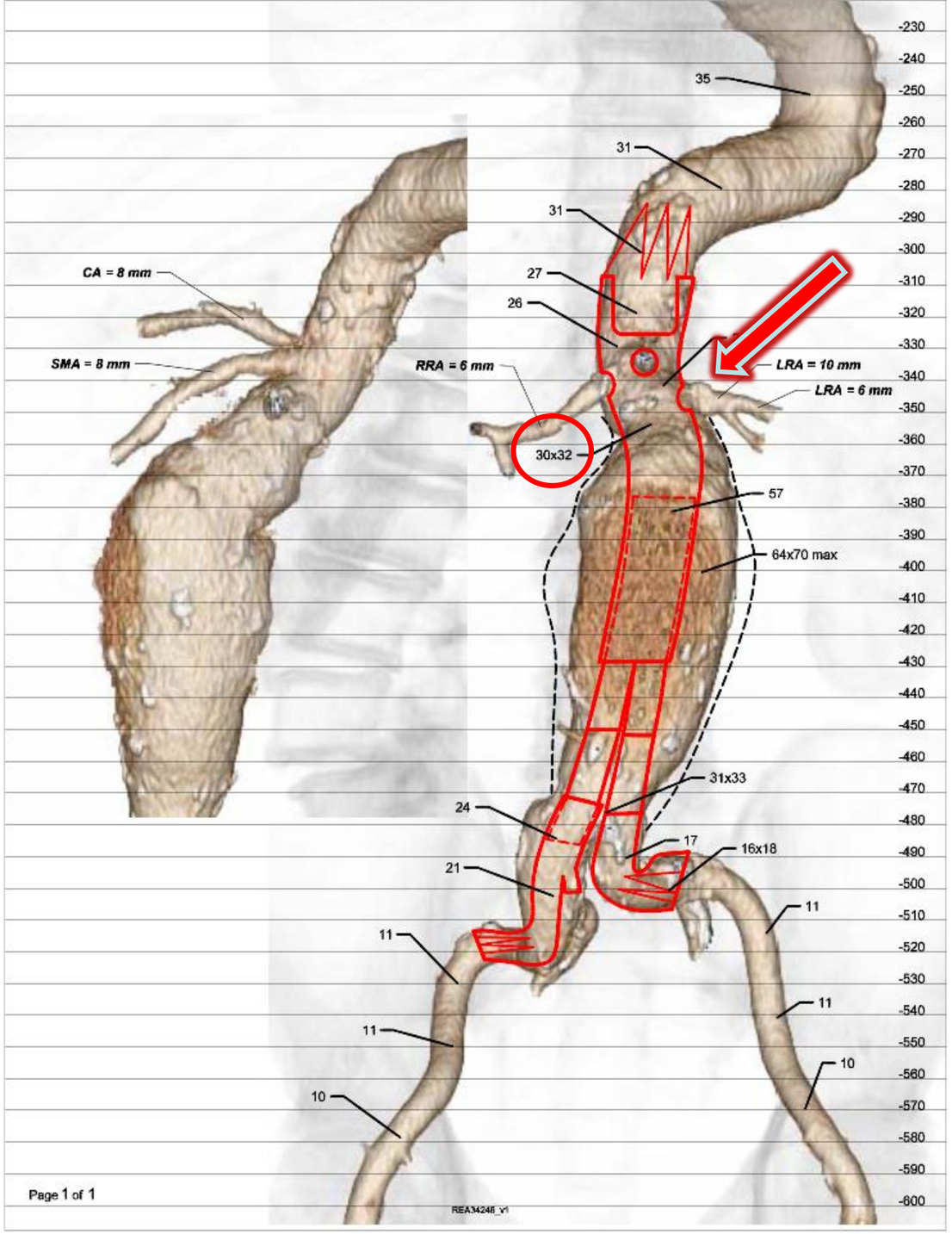
Planning



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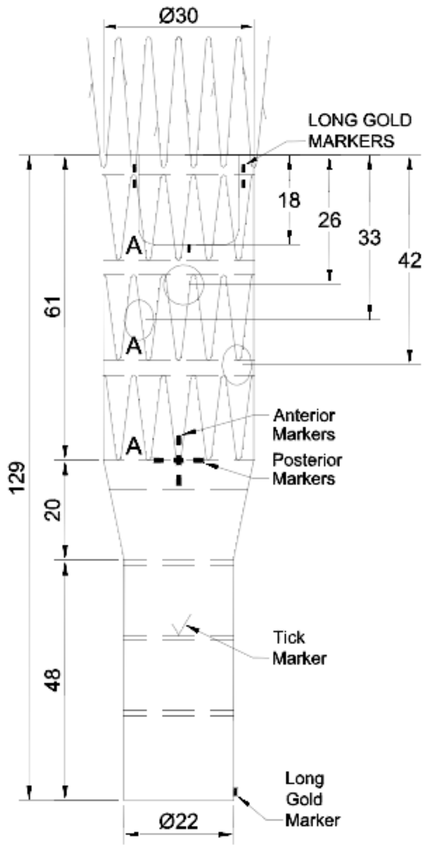
Planning

REA34244_v1 | **NON STANDARD DEVICE REQUEST - PROPRIETARY COOK MEDICAL** | **VERSION 1**

Device: FENESTRATED-PARARENAL-DEVICE
Component: AAA-REINFORCED-FEN-PROX



REINFORCED SCALLOP #1
WIDTH: 20mm
HEIGHT: 18 mm
CLOCK: 12:30
IVD: 25mm

REINFORCED LARGE FENESTRATION #1
Strut Free
DIAMETER: 8mm
DIST FROM PROX EDGE: 26mm
CLOCK: 12:15
IVD: 24mm

REINFORCED SMALL FENESTRATION #1
WIDTH: 6mm
HEIGHT: 8mm
DIST FROM PROX EDGE: 33mm
CLOCK: 10:15
IVD: 27mm

REINFORCED SMALL FENESTRATION #2
WIDTH: 6mm
HEIGHT: 8mm
DIST FROM PROX EDGE: 42mm
CLOCK: 2:30
IVD: 28mm

- SINGLE DIAMETER REDUCING TIES

Plus:

AAA-BIFURCATED-GRAFT
(As per ZFEN-D-12-28-76)

Ipsilateral Leg
ZSLE-20-39-ZT

ZSLE-20-56-ZT

Contralateral Leg
ZSLE-16-39-ZT

ZBIS-12-45-41

Please note the following: 1. By signing this graft plan you are confirming that the patient has consented to the provision of their personal information to Cook Medical. The patient understands that in order to plan and manufacture the requested device, Cook Medical may share his/her personal information with other Cook Group companies in the United States, Australia, Denmark, United Kingdom and Ireland and has consented to his/her personal information being so shared. **2.** You are confirming that all clinically important features (eg. fenestration size / orientation, gold marker placement, sealing stents) are included in this graft design prior to your approval. **3.** Unsigned plans or alterations may lead to a delay in the supply of this device. Please sign and date each page. If you wish to alter any part of this plan please initial and date each change.

Sheath Size:	20FR FLEXOR	Patient ID:	E No.:
O.D.:	7.7mm	Doctor: Prof. Riambau	Date of Procedure:
Sheath Length:	50cm	Hospital: Hospital Clinico Barcelona- Spain	
PUS-JSH	Drawn - Plan Date: 11-Jul-16	Drs Signature:	Date:
Not to scale	All Dimensions shown are in mm		

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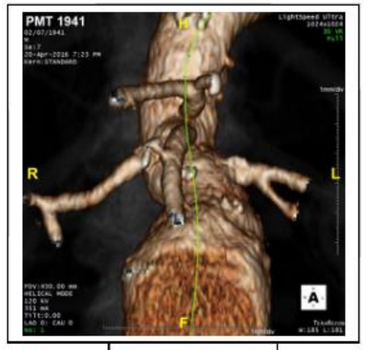
Planning

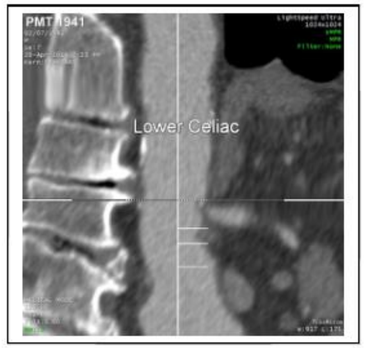
ZENITH ENDOVASCULAR PLANNING
FENESTRATION WORK-UP

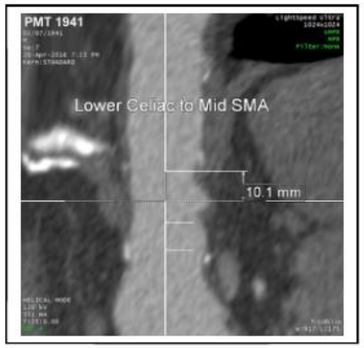
DR: Prof. Riambau

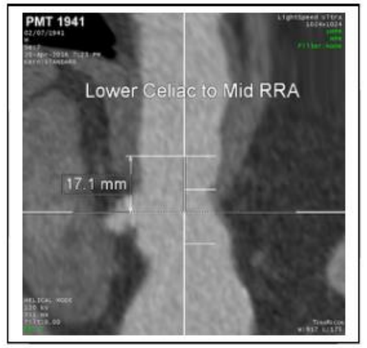


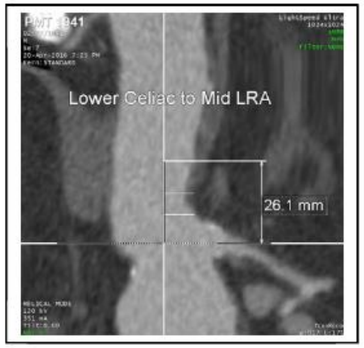
AP

LATERAL









Reference Point Zero = Lower margin of Celiac Trunk

Distance to middle of SMA = 10mm
Distance to middle of Rt. Renal artery = 17mm
Distance to middle of Lt. Renal artery = 26mm

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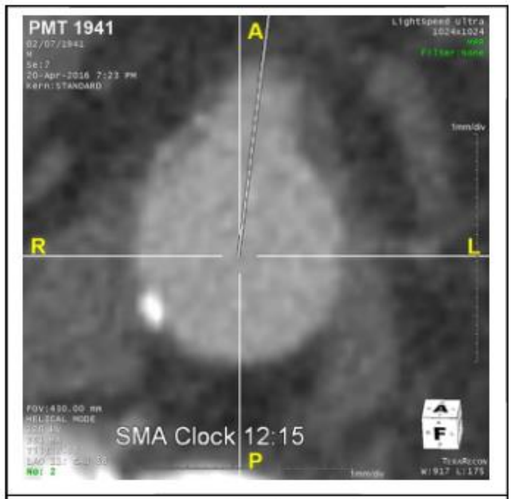
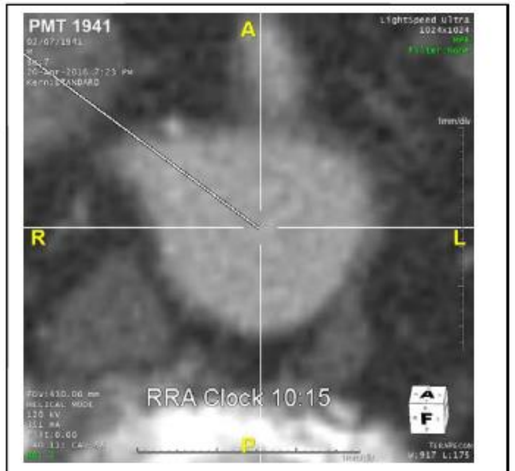
ZENITH ENDOVASCULAR PLANNING
FENESTRATION WORK-UP

DR: Prof Riambau

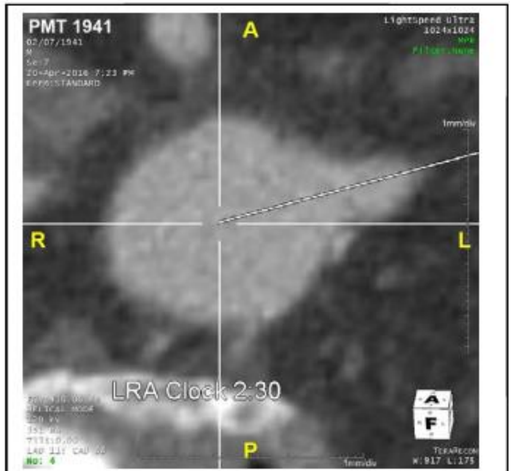
Celiac Trunk
O'clock = 12:30



SMA
O'clock = 12:15



Rt. Renal Artery
O'clock = 10:15



Lt. Renal Artery
O'clock = 2:30

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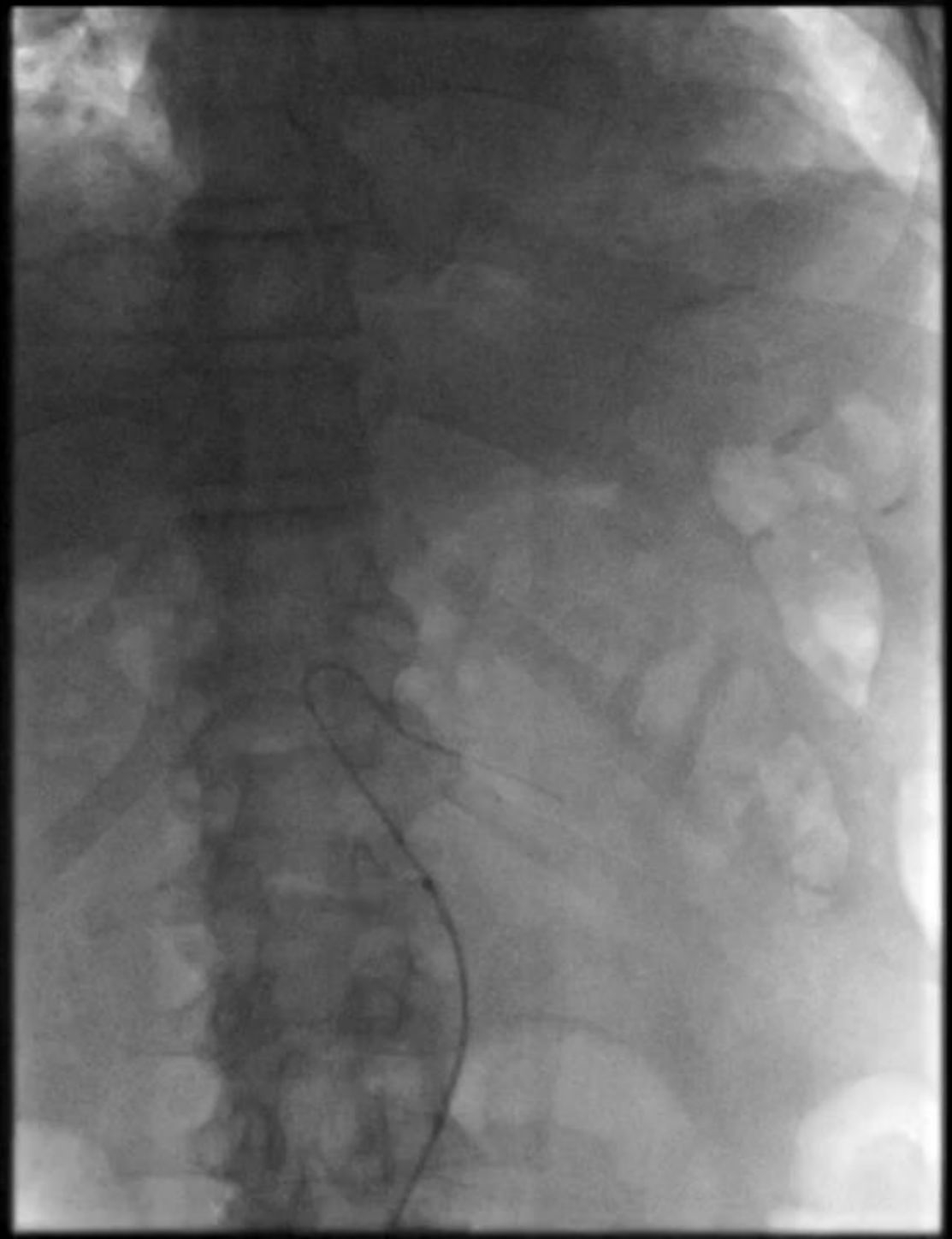
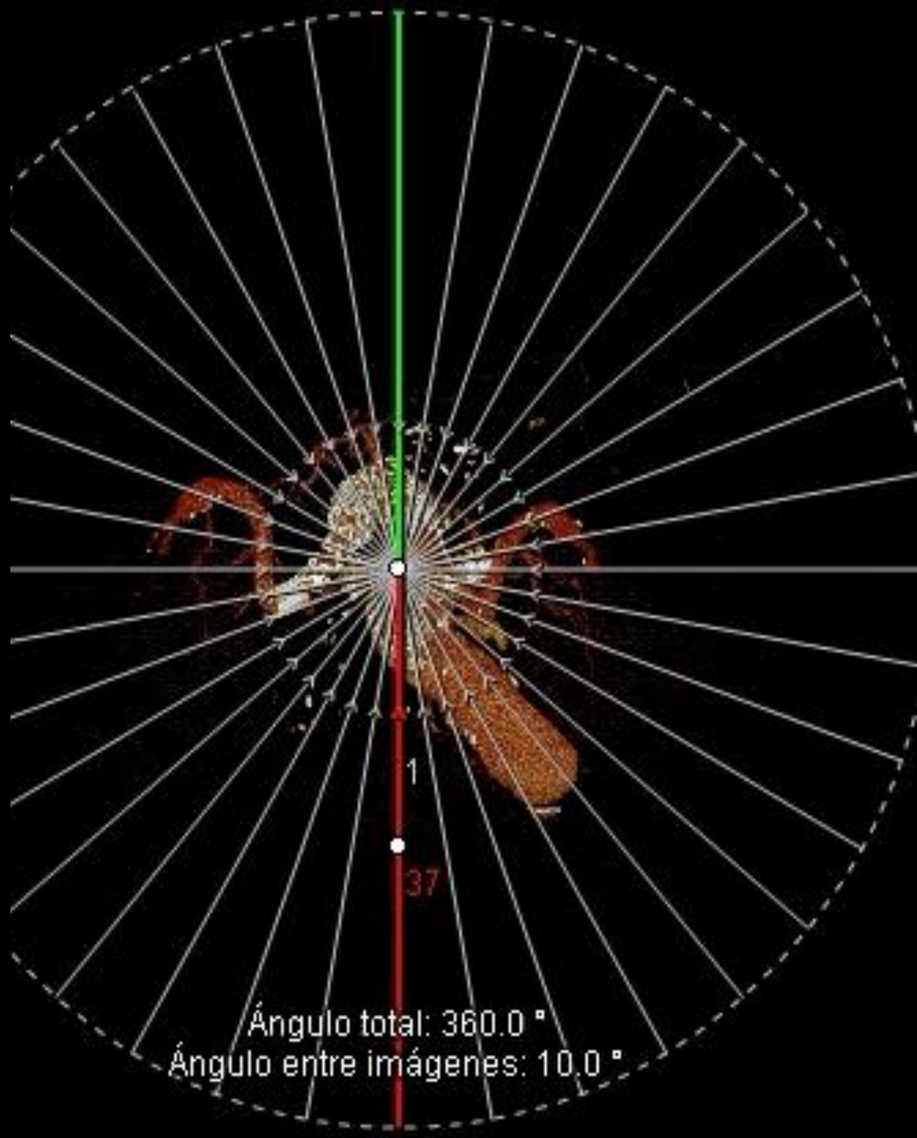
Interventional Procedure



Post operative CT
@ 30 days



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Clinical Data

Author Reference	n of pts (branches)	Technical success	Mortality 30-day	Dialysis	Branch Patency	Freedom 2ry Reintervention
Anderson J et al J Vasc Surg 2001	13 (33)	100%	0	0	0	0
Halak et al J Vasc Surg 2007	17 (42)	98%	0	0	95%	88%@2y
Muhs et al J Vasc Surg 2006	38 (87)	94%	2.6%	0	92%	88%@4y
O'Neil et al Eur JVES 2006	119 (302)	91%	1%	3%	97%	-
Semmens et al J Vasc Surg 2006	58 (143)	91%	3.4%	0	-	-
Ziegler et al J Vasc Surg 2007	63 (132)	97%	1.6%	1%	92%	75%@6y
Scurr Br J Surg 2008	45 (127)	100%	2.2%	0	97%	-
Bicknell et al Eur JVES 2008	15 (40)	98%	0	0	-	-
Kristnundsoon et J End Ther 2008	54 (134)	-	3.7%	0	96%	-
Greenberg et al J Vasc Surg 2010	30 (77)	100%	0	0	98%	89%@2y
Verhoeven et al Eur JVES 2010	100 (275)	100%	1%	2%	93%	91%@2y
Haulon et al Ann Surg 2010	80 (237)	100%	2.5%	1.5%	98%	85%@1y
Total	503/1629	98%	1.3%	0.3%	97%	83%

ZFEN Clinical Data

Results of the United States multicenter prospective study evaluating the Zenith fenestrated endovascular graft for treatment of juxtarenal

"Repair of Juxtarenal AAAs with Zenith Fenestrated…is Safe and Effective."

Philadelphia, Pa; and West Lafayette, Ind

Objective: This study reports the results of a prospective, multicenter trial designed to evaluate the safety and effectiveness of the Zenith fenestrated endovascular graft (Cook Medical, Bloomington, Ind) for treatment of juxtarenal abdominal aortic aneu

Methods: Six… 2005 to 20… analysis of … included clinical examination, laboratory studies, mesenteric-renal duplex u… radiography, and computed tomography imaging at hospital discharge and at 1 month, 6 months, a… d yearly thereafter up to 5 years.

Results: There were 54 male and 13 female patients with a mean age of 74 ± 8 years enrolled… aneurysm diameter was 60 ± 10 mm. A total of 178 visceral arteries required incorporation with small fenestrations … 18, scallops in 51, and large fe… ns in nine. Of these, all 118 small fenestrations (100%), eight of the scallops (16%), and one of the … s (11%) were aligned by stents. Technical success was 100%. There was one postoperative death within … ruptures or conversions were noted during … had migration ≥10 mm with no endoleak, … targeted by a fenestration, there were four … ed secondary interventions for renal artery … endoleak in one patient. At 5 years, patient … primary and secondary patency of targeted … ioration was 91% ± 5%, and freedom from secondary interventions was 63% ± 9%.

Conclusions: This prospective study demonstrates that endovascular repair of juxtarenal AAAs with the Zenith fenestrated AAA stent graft is safe and effective. Mortality and morbidity are low in properly selected patients treated in centers with experience in these procedures. (J Vasc Surg 2014;60:1420-8.)

100% Technical Success

1 Patient Reported with Type 1a Endoleak at 3 Years

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Late Outcomes

Mean follow-up: 37 ± 17 months (range, 3-65 months)

- 4 late deaths not related to aneurysm
- 9 late major adverse events not related to aneurysm
- No late ruptures, conversion to open repair, or dialysis
- No type III endoleak, only 1 case of type I endoleak
  - Renal outcomes
    3 patients with renal function deterioration (serum creatinine rise to >2 mg/dL and >30% from baseline, detected on two or more follow-up tests)
    4 renal stent occlusions (3% of targeted renal arteries)
    12 renal stent stenoses (9% of targeted renal arteries)
- **Re-interventions** were needed in 15 patients **(22%)**
  11 for renal stenosis/occlusion
  4 for endoleak (3 for type II endoleak; 1 for type I endoleak)

Oderich GS, et al. J Vasc Surg. 2014;60(6):1420

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Patency of Targeted Renal Arteries

Patency measures (defined *a posteriori*):

- **Primary patency:** uninterrupted patency from index procedure until occlusion or reintervention for renal stent stenosis
- **Secondary patency:** time to occlusion treated by surgical bypass or not suitable to endovascular salvage

Oderich GS, et al. J Vasc Surg. 2014;60(6):1420

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Twelve-year results of fenestrated endografts for juxtarenal and group IV thoracoabdominal aneurysms

Tara M. Mastracci, MD, Matthew J. Eagleton, MD, Yuki Kuramochi, BScN, Shona Bathurst, and Katherine Wolski, MPH, *Cleveland, Ohio*

Objective: The practice of using fenestrated endografts to treat juxtarenal and group IV thoracoabdominal aortic aneurysms (TAAAs) has become more accepted, but long-term outcomes are still unknown. We report long-term survival, complications, and branch-related outcomes from a single-center experience.

Methods: The study included consecutive patients enrolled prospectively into a physician-sponsored investigational device exemption classified as undergoing group IV TAAA or juxtarenal aneurysm repair by the treating surgeon using fenestrated endografts. Device morphology was used to subclassify this group of patients. Long-term survival and a composite outcome of secondary intervention, branch occlusion, stent migration, endoleak, aneurysm growth, or spinal cord injury were calculated. Descriptive analysis of branch-related outcomes and need for any reintervention was performed. Univariate and multivariate analysis of mortality and the composite outcome was performed to determine associative risks.

Results: Long-term survival for patients with juxtarenal and group IV TAAA aneurysms treated with fenestrated stent grafts was 20% at 8 years. Multivariate analysis showed long-term survival for this patient population was negatively associated with increasing age, congestive heart failure, cancer, and previous aneurysm repair. The risk of spinal cord ischemia (SCI) in this group was 1.2% and of aortic-related mortality was 2%. The risk of a spinal event increased with coverage above the celiac artery (52 mm of coverage above the celiac artery in patients with SCI vs 33 mm without SCI; $P = .099$). More complex device configurations were more likely to require an increased rate of reinterventions, and patients with celiac fenestrations were more likely to experience celiac occlusion over time (3.5% vs 0.5%; $P = .019$). However, less complex designs were complicated by an increased risk of type I endoleak over time (10.4% for renal fenestrations only vs 1.9% for others; $P < .01$). As experience evolved, there was a trend to increase the number of fenestrations in devices treating the same anatomy.

Conclusions: The use of fenestrated devices to treat juxtarenal and group IV TAAA is safe and effective in long-term follow-up. Mortality in this patient population is largely not aortic-related. Devices designed for fenestrated repair of juxtarenal and group IV thoracoabdominal aneurysms within a physician sponsored investigational device exemption have changed over time. Further research is needed to determine the best configuration to treat aneurysms requiring coverage proximal to the celiac artery. (J Vasc Surg 2015;61:355-64.)

610 patients
Mean FU 8 years

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Patient survival

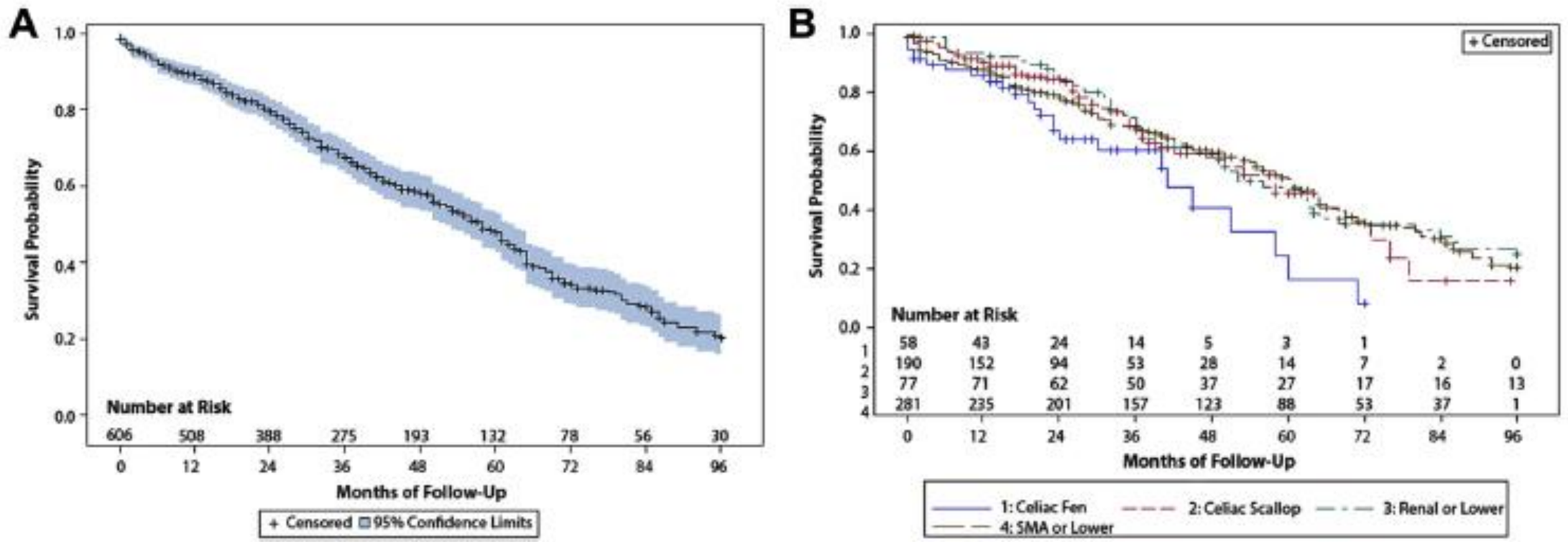

Fig 1. Survival for patients with juxtarenal and group IV aneurysms treated with (**A**) fenestrated (*Fen*) endograft and (**B**) by device morphology. *SMA*, Superior mesenteric artery.

Mastracci T, et al , JVS 2015

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Composite endpoint

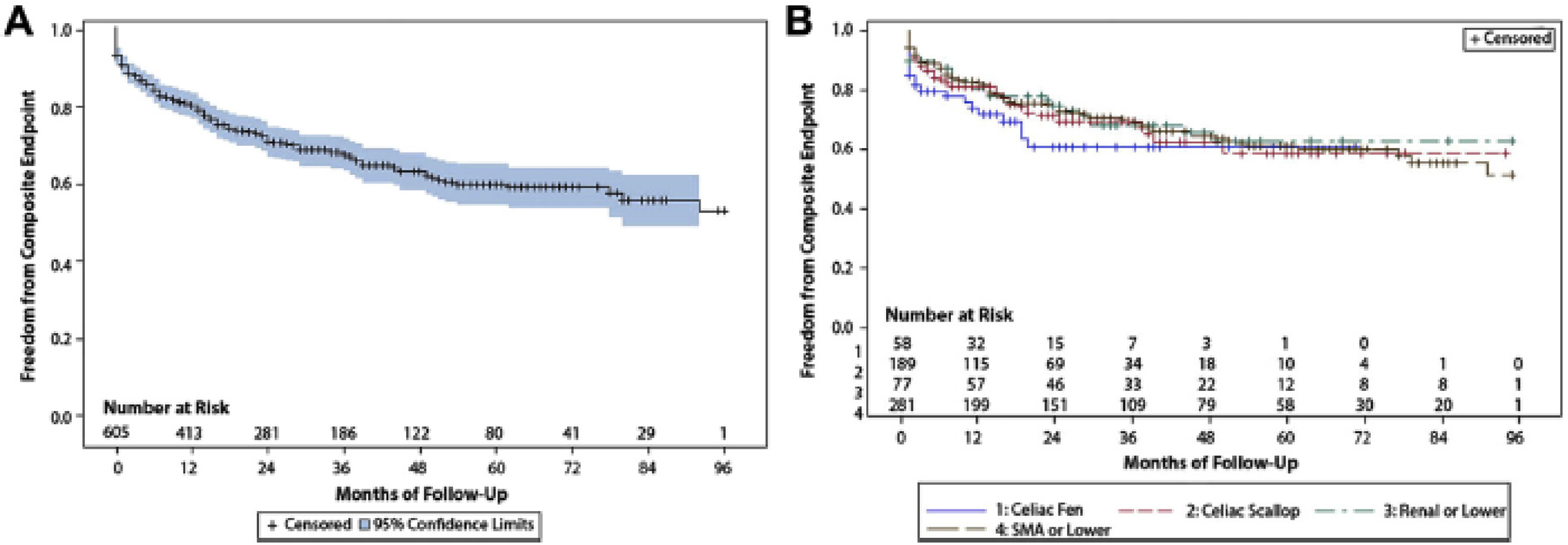

Fig 2. Composite end point in (**A**) all patients and (**B**) by device design. *Fen*, Fenestrated.

Mastracci T, et al , JVS 2015

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