



# ENDOPROTESIS FENESTRADAS

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# DICLOSURES

- ◉ **Cook Medical:**

- Proctoring, educación
- Fondos directamente para división quirúrgica.

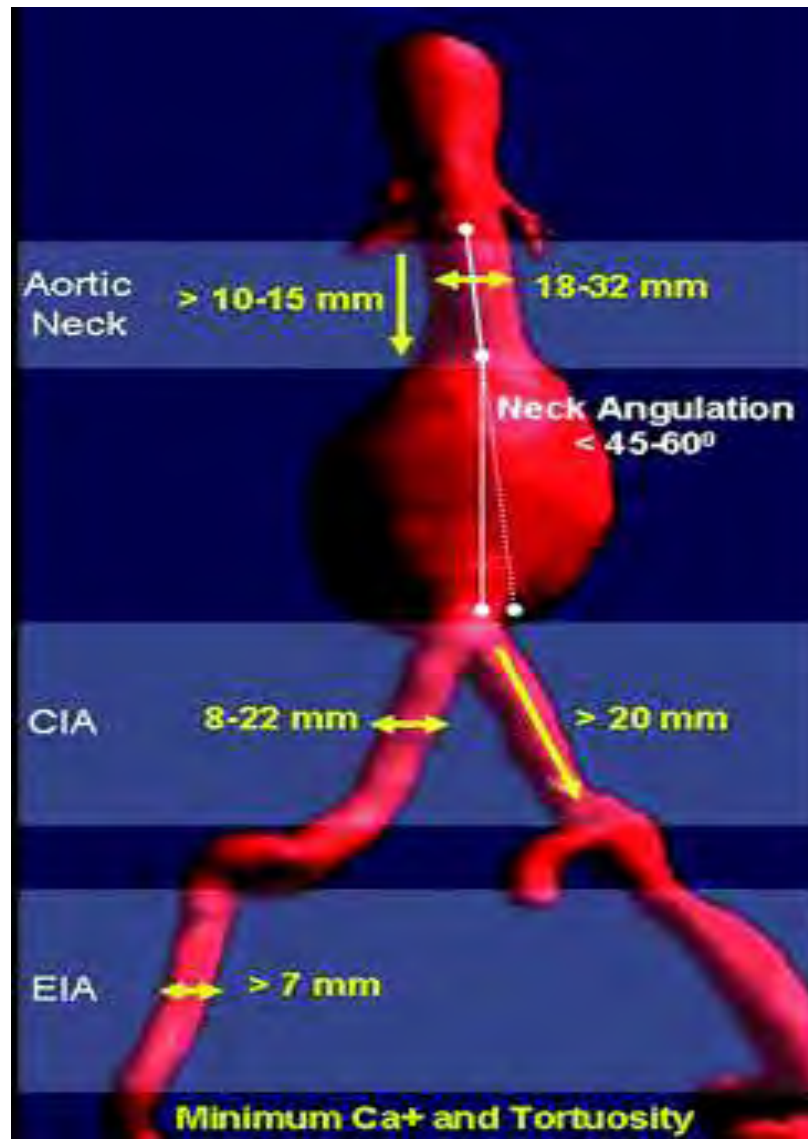
# AAA

- ◉ 70% de los AAA pueden ser tratados con prótesis infrarenales.
- ◉ Criterios de exclusión mayormente relacionados a anatomía del cuello y acceso iliaco
- ◉ Longitud del cuello es la mayor limitación para EVAR
  - *Sweet et al, 2011. Journal of Vascular Surgery*
- ◉ Peores resultados si no se ajustan a las indicaciones para uso(IFU)

# AAA

- ◉ Cirugía abierta para aneurismas pararenales con morbilidad y mortalidad elevada
- ◉ Morbilidad hasta del 60%
- ◉ Mortalidad hasta del 10%
- ◉ Residentes/fellows con menos oportunidades de aprender reparos abiertos complejos

AAA



# IFU COMPLIANCE STUDY

- ◉ Seguimiento a 10 años(1999-2008)
- ◉ M2S (dataset)
- ◉ 10,228 pacientes
- ◉ 41% crecimiento del saco
- ◉ Factores asociados: Edad>80, Angulación del cuello >60, diámetro del cuello(>28), aneurismas iliacos, Endofugas
  - ◉ *Schanzer A, et al; Circ 2011*

# IFU COMPLIANCE STUDY

- ⊙ Endoprotesis con criterios estrictos
  - 58.5 % por fuera del IFU
- ⊙ Endograft with liberal criteria
  - 31.1% por fuera del IFU

Resultados controversiales/casos no consecutivos/Registros no incluidos/bias

# ENDOPROTESIS FENESTRADAS

- ⦿ Elevan el área de sellamiento proximalmente(idealmente  $> 2$  cm)
- ⦿ Disminuye fallas a largo plazo de endoprotesis infrarenales
- ⦿ Disminuye morbilidad y mortalidad asociada a reparo suprarrenal abierto
- ⦿ Permite salvar reparos abiertos y endovasculares fallidos.



# ENDOPROTESIS FENESTRADAS

J Vasc Med Biol. 2012 Jun;24(6):238-46. doi: 10.1016/j.jvb.2011.10.032. Epub 2012 Jan 21.

## Pararenal aortic aneurysm repair using fenestrated endografts.

Linsen MA, Jangkind V, Nix D, Hoksbergen AW, Wisseink W.

### Author information

### Abstract

**OBJECTIVE:** We performed a systematic review of the current literature to analyze the immediate and follow-up results of fenestrated endovascular aortic aneurysm repair (F-EVAR) in patients with pararenal abdominal aortic aneurysms (AAAs).

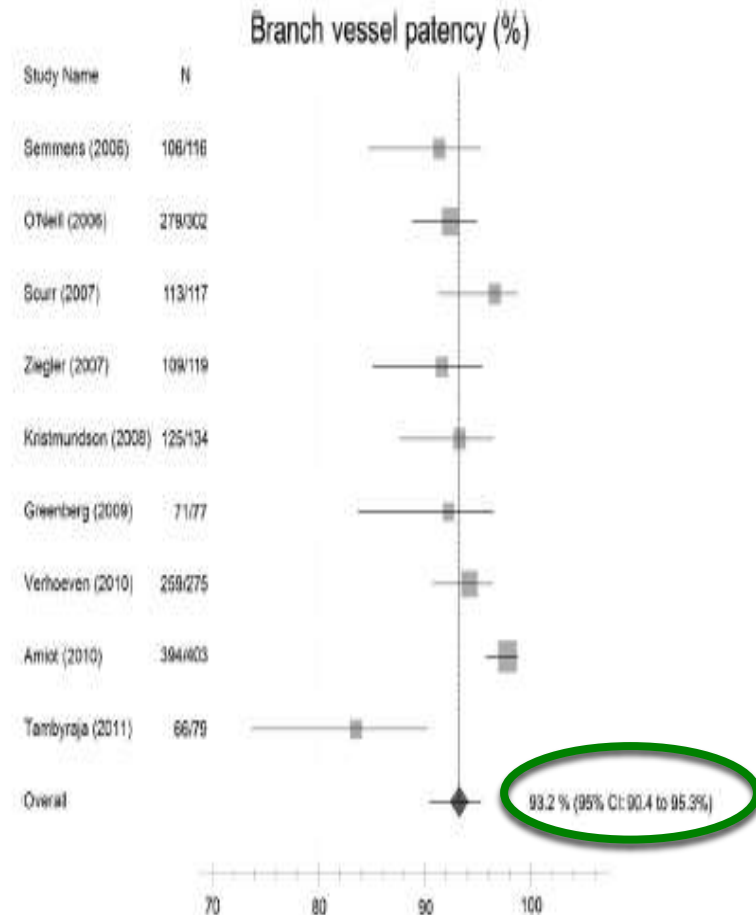
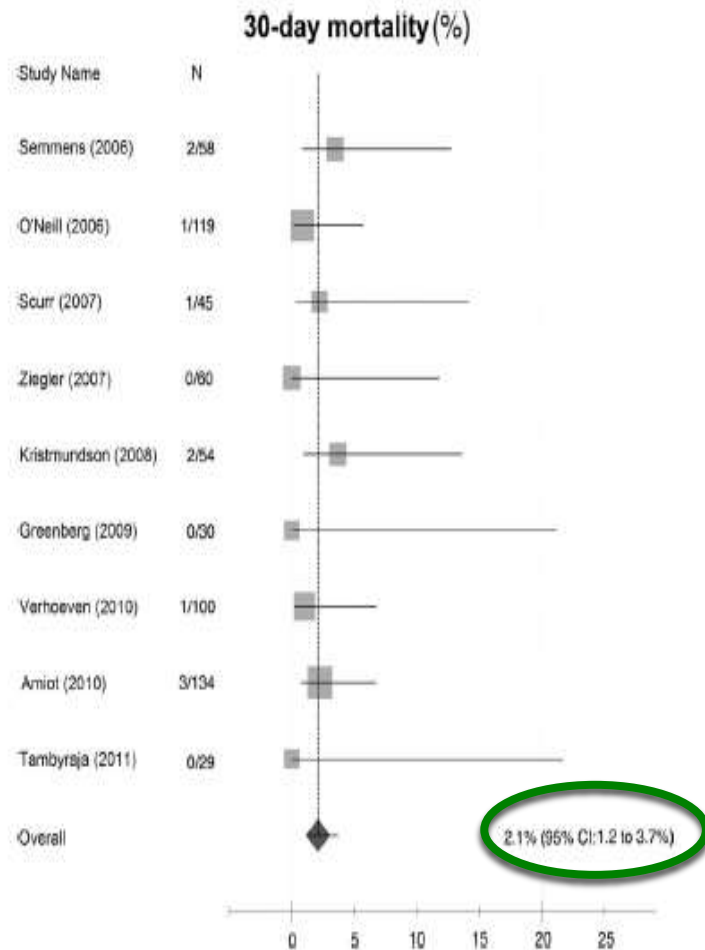
**METHODS:** The Medline, Embase, and Cochrane databases were searched to identify all studies reporting F-EVAR of pararenal AAAs published between January 2000 and May 2011. Two independent observers selected studies for inclusion, assessed the quality of the included studies, and performed the data extraction. Studies were selected based on specific predefined criteria. Outcomes were technical success (successfully completed procedure with endograft patency, preservation of target vessels, and no evidence of type I or III endoleak at postprocedural imaging), 30-day mortality, all-cause mortality, branch vessel patency, renal impairment, and secondary interventions. Between-study heterogeneity was calculated using  $I^2$  statistics. Pooled estimates were calculated using a fixed-effects ( $I^2 < 25\%$ ) or a random-effects ( $I^2 > 25\%$  to  $< 50\%$ ) model.

**RESULTS:** Nine studies were included reporting 629 patients who underwent F-EVAR for a pararenal AAA, of which 1622 target vessels were incorporated in an endograft design. Between-study heterogeneity was  $\leq 41\%$  for all outcomes. The pooled estimate (95% confidence interval [CI]) was 90.4% (87.7%-92.5%) for technical success, 2.1% (1.2%-3.7%) for 30-day mortality, and 16% (12.5%-20.4%) for all-cause mortality. Follow-up was 15 to 25 months. The pooled estimate (95% CI) during follow-up was 93.2% (90.4%-95.3%) for branch vessel patency, 22.2% (16%-30.1%) for renal impairment, and 17.8% (13.5%-22.6%) for secondary interventions.

**CONCLUSIONS:** Promising immediate and midterm results (up to 2 years) support F-EVAR as a feasible, safe, and effective treatment in a relatively high-risk cohort of patients with pararenal AAAs.

- Revision sistematica
- 2000-2011
- 9 estudios
- 629 pacientes

# ENDOPROTESIS FENESTRADAS



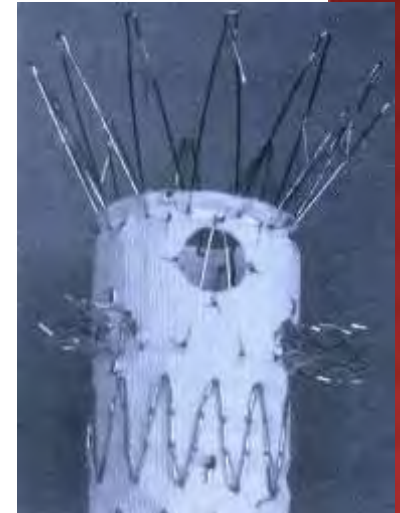
# FEVAR

- ⊙ Experiencia australiana(1997-2004)
- ⊙ 58 pacientes - Mortalidad 3.4%
- ⊙ 17 meses de seguimiento
  - Tratamiento exitoso- **95%**
  - Oclusion de ramas- 9.5%
    - ✓ Factores importantes: Angulación, renales múltiples, diámetros < 4mm, enfermedad oclusiva, No stents
    - ✓ Intervenciones secundarias- 24%

*Semmens JB et al., J Endovasc Ther 2006*

# FEVAR

- Cleveland Clinic (2001-2005)
- 119 pacientes - Mortalidad <1%
- 58% - 2 renales/AMS fenestraciones
- 302 arterias viscerales tratadas
- 19 meses de seguimiento
  - Endofuga a 30 dias- 10% (Tipo II)
  - Reestenosis de stents- 13 (5%)
  - Arterias renales ocluidas- 10/231 (4.3%)



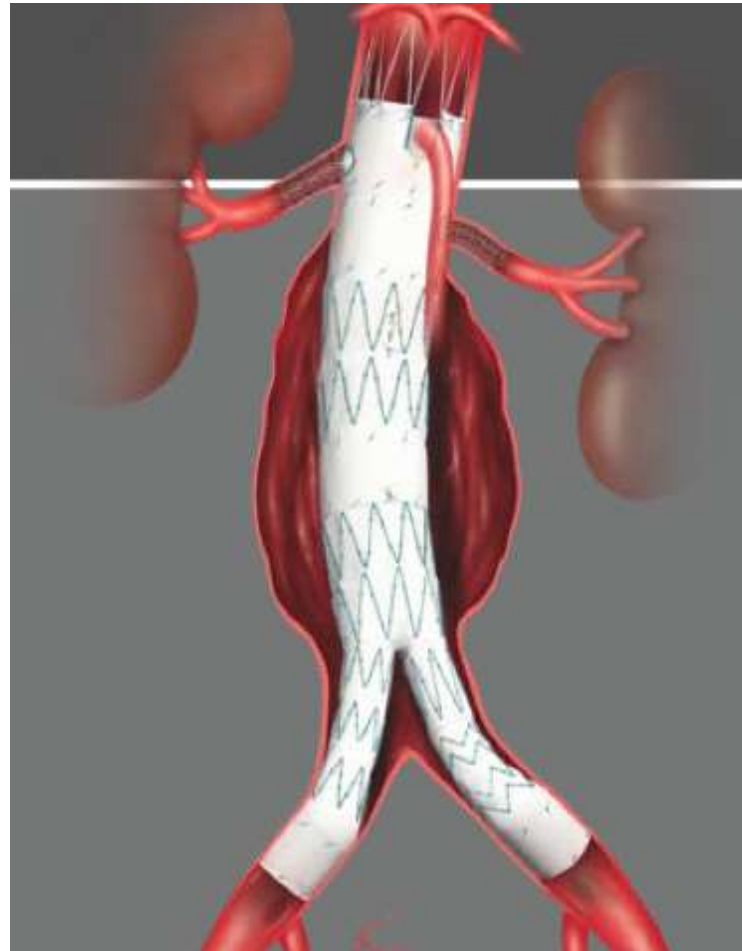
*O'Neill S et al., Eur J Vasc Endovasc Surg 2006*

# FEVAR

- ◉ Prótesis Z-FEN
- ◉ Resultados intermedios
- ◉ 5 centros
- ◉ 30 pacientes
- ◉ 77 arterias tratadas(100%)
- ◉ Sin mortalidad asociada(24 meses)
- ◉ 20% Endofuga tipo II
  - ◉ *Greenberg, et al: j Vasc Surg 2009*

# ZFEN

- Aprobada 4/2012 en USA
- Mas de 6000 casos en el mundo
- Dispositivo planificado
- 4 mm cuello infrarenal
- Lanzamiento controlado
- Entrenamiento de 2 días y casos con proctor



# Modificaciones

Escotaduras o  
scallops



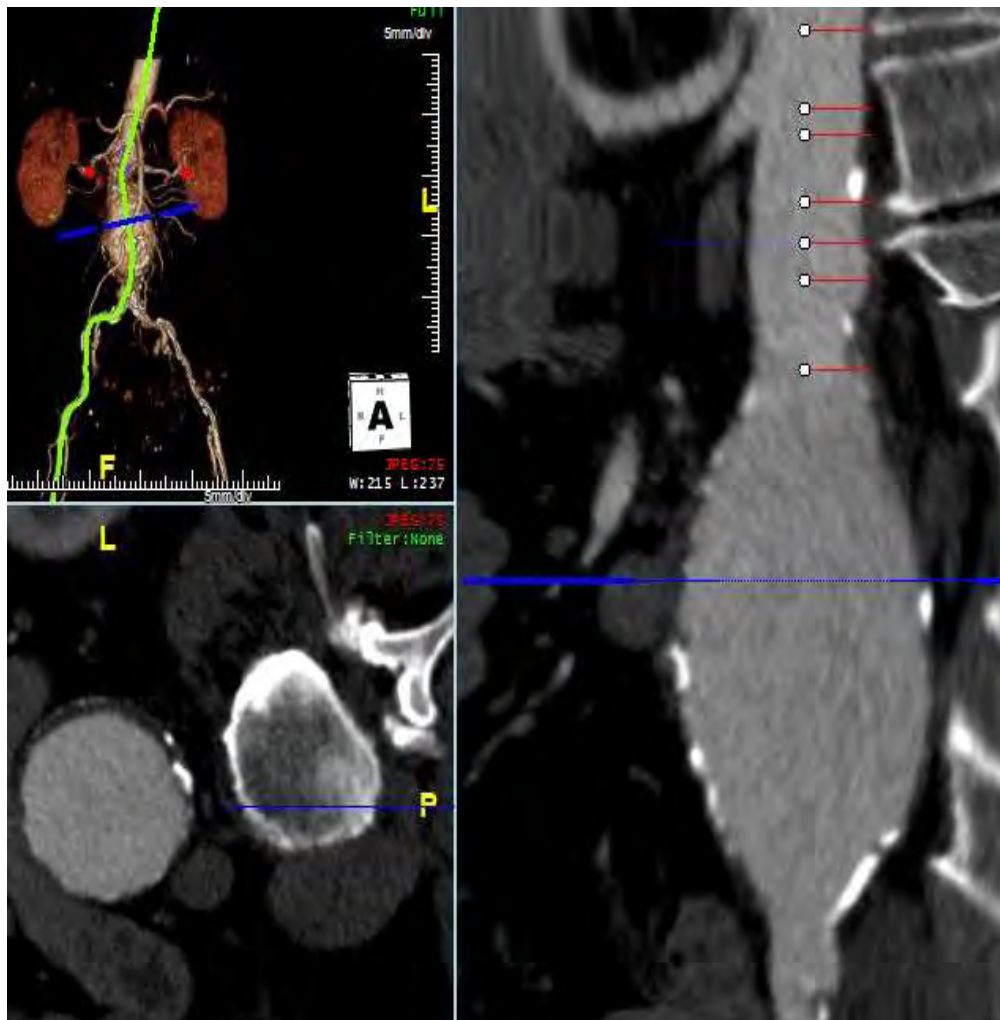
Fenestraciones  
pequeñas



Fenestraciones  
grandes



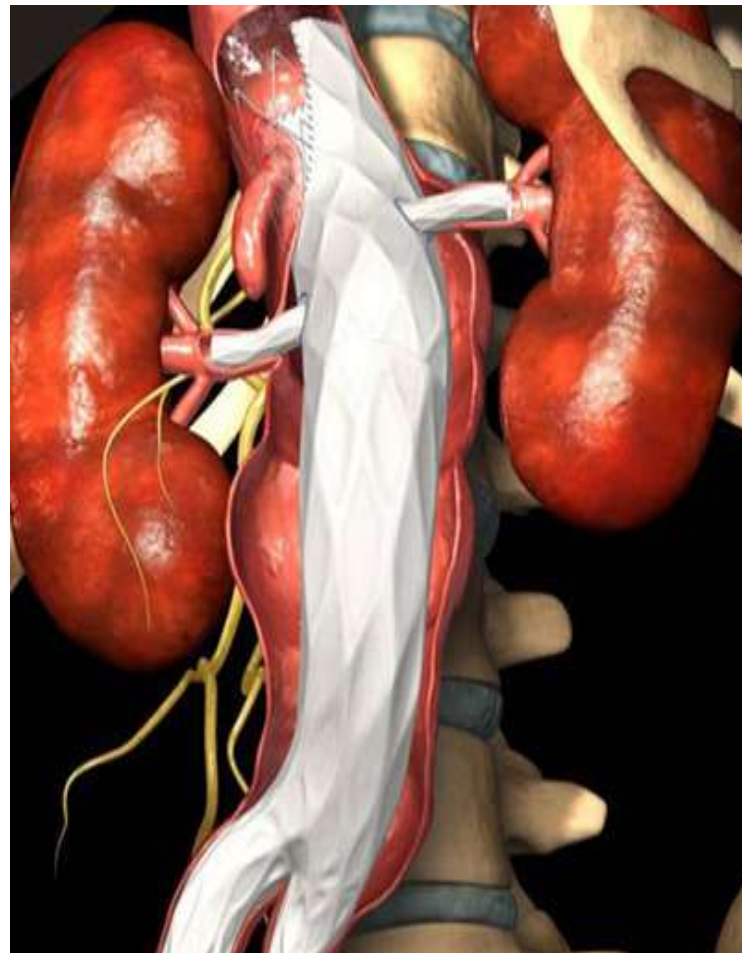
# TERARECON





# VENTANA

- ⦿ Primer diseño “off the shelf”
- ⦿ 15 mm cuello debajo de AMS
- ⦿ 5 Modelos diferentes



# VENTANA PILOT STUDY

- ◉ Dos centros, 15-pacientes
  - o Auckland, NZ; Santiago, Chile
  - o CCF Core Lab Patient Eligibility Determination o Enrollment Nov 2010 - Aug 2011
- ◉ Primary Endpoint: Tratamiento exitoso a 30 dias con protesis permeable
- ◉ Libre de endofuga tipo I/III (Core Lab)
  - o Seguridad: Major Adverse Events
- ◉ Seguimiento a 5 anos
  - *Holden A, Mertens R, Hill A, et al. J Vasc Surg 2013*

# VENTANA PILOT STUDY

Parameter	First 5 Patients	Last 10 Patients
Anesthesia, General/Regional, %	80% / 20%	80% / 20%
Time to Renal Artery Cannulation , min*	45 ± 20 →	31 ± 9.6
Fluoroscopy Time, min	59 ± 26 →	48 ± 11
Contrast Volume, mL	273 ± 104	216 ± 171
Blood Products, %	30%	40%
Endovascular Procedure Time, min	116 ± 40 →	90 ± 18
In-Hospital Mortality	0	0
Time to Hospital Discharge, days	3.4 ± 2.9	3.0 ± 1.7

# VENTANA

- Objetivo primario
- Tratamiento exitoso a 30 días: 93% (14/15)
- 100% procedimiento exitoso
- Oclusión rama iliaca, n=1 (6.7%)
  - Debido a acodamiento de la rama, no reconocido intraoperatoriamente. Solucionado día 26
- No endofugas tipo I o III
- Permeabilidad renal 100%

# VENTANA US TRIAL

J Vasc Surg. 2013 Jul 58(1):1-9. doi: 10.1016/j.jvs.2012.12.065. Epub 2013 Apr 12.

## Prospective, multicenter experience with the Ventana Fenestrated System for juxtarenal and pararenal aortic aneurysm endovascular repair.

Quilones-Baldrich WJ, Holden A, Meneses R, Thompson MM, Sawchuk AP, Bequermis JP, Eagleston M, Clair DG.

### Author information

#### Abstract

**OBJECTIVE:** This study assessed preliminary results of the Ventana Fenestrated System (Endologix, Irvine, Calif) as an off-the-shelf integrated device for juxtarenal aortic aneurysm (JAA) or pararenal aortic aneurysm (PAA) endovascular repair.

**METHODS:** From November 2010 to April 2012, seven centers enrolled 31 patients with JAAs or PAAs in an international clinical trial of the Ventana Fenestrated System. Clinical and laboratory evaluations were done pre-discharge and at 1 month, with continuing follow-up through 5 years. Core laboratory computed tomography imaging assessments were performed at 1 month and at each subsequent follow-up.

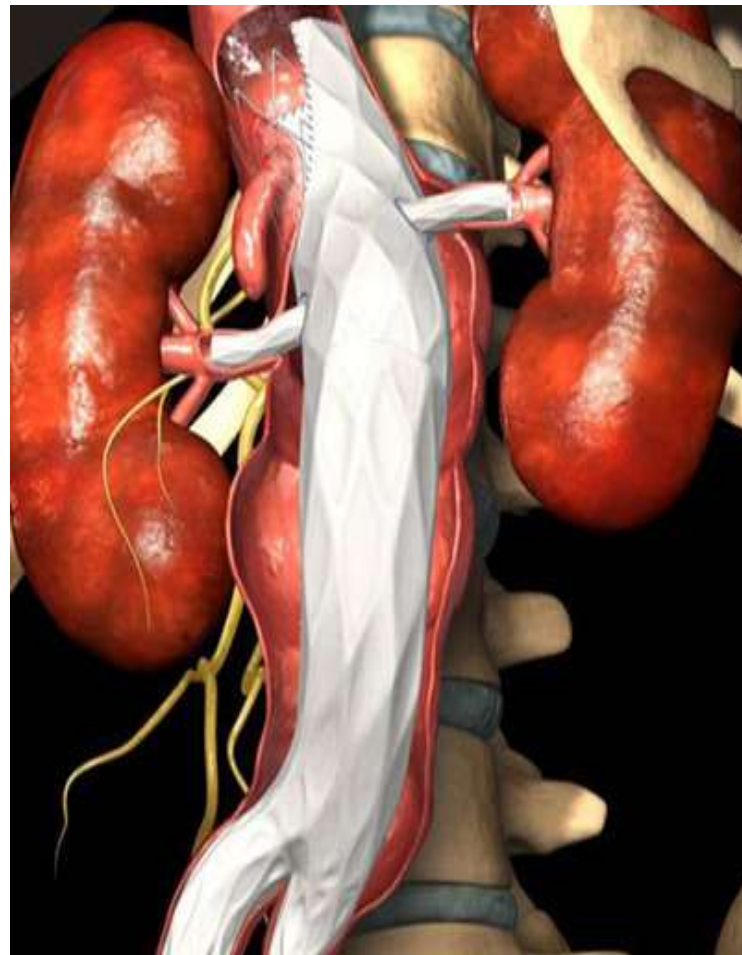
**RESULTS:** Patients (mean age, 73 years; 90% male) presented with mean aneurysm sac diameter of 6.0 cm. One patient with a short, reversed tapered infra-superior mesenteric artery (SMA) neck was enrolled under a protocol waiver. Among the 31 patients, one of five Ventana device models was used to preserve main renal arteries, the SMA, and celiac arteries; 20 patients (65%) received the same Ventana device (aligned fenestrations, 29-mm diameter). Median fluoroscopy and procedure times were 49 and 197 minutes, respectively; median hospital length of stay was 3.0 days. The 1-month clinical success rate was 94% (29 of 31), with no perioperative mortality. One intervention on day 26 was done to resolve limb kink/occlusion. A type IA endoleak and renal occlusion secondary to procedural device damage led to a reintervention on day 52 and dialysis at 5 months. During follow-up to 23 months, three non-aneurysm-related deaths occurred. No aneurysm rupture or conversion to open repair has occurred. One late migration with endoleak and covered renal stent fracture/occlusion occurred at 8 months in the patient with a short, reverse tapered infra-SMA neck performed under a protocol waiver, which was managed successfully with bilateral renal bypasses and endovascular repair of the endoleak. Another patient underwent late endovascular interventions to resolve bilateral renal stenosis.

**CONCLUSIONS:** The multicenter experience of the Ventana Fenestrated System supports its safety and early-term to midterm effectiveness for the endovascular repair of JAAs and PAAs. This off-the-shelf integrated system permits endovascular treatment of JAAs or PAAs; however, further expanded clinical experience and longer-term follow-up are needed to more fully assess this device system.

- 31 pacientes
- Fluoro: 49 min
- Éxito a 1 mes: 94% (29/31)
- 1 Endofuga IA
- 1 stent renal acodado
- Seguridad y eficacia tempranos prometedoros

# VENTANA

- ⦿ Resultados prometedores iniciales
- ⦿ Estudio en USA esta parado
- ⦿ Eventos renales



# ANACONDA

- ◉ Sistema planificado
- ◉ Reposicionable
- ◉ Experiencia clínica temprana
- ◉ Resultados iniciales promisorios
- ◉ No disponible en USA



# ANACONDA

- ◉ 2011
- ◉ Reporte inicial en 4 pacientes
- ◉ Buenos resultados clínicos
- ◉ Mas de 50 casos mundialmente

J Vasc Surg. 2011 Dec;54(6):1832-8. doi: 10.1016/j.jvs.2011.05.115. Epub 2011 Sep 29.

## **Initial experience with a new fenestrated stent graft.**

Bungay PM, Burfitt N, Sriharan K, Muir L, Khan SL, De Nunzio MC, Lingam K, Huw Davies A.

### Author information

#### Abstract

**OBJECTIVES:** The Anaconda fenestrated stent graft (Vascutek, Inchinnan, United Kingdom) is a new device that can easily be repositioned during deployment. This study evaluated its feasibility for treating abdominal aortic aneurysms with inadequate infrarenal sealing zones.

**METHODS:** Patients undergoing stent graft placement at two institutions in the United Kingdom were recruited.

**RESULTS:** A total of 12 visceral vessels were accommodated with 8 fenestrations for renal arteries and 4 superior mesenteric artery valleys/scallops in 4 patients. One type Ib endoleak was identified at the 1-month follow-up and successfully treated.

**CONCLUSIONS:** The Anaconda fenestrated stent graft device can be used for the repair of abdominal aortic aneurysms with hostile anatomy and has acceptable immediate and short-term results.

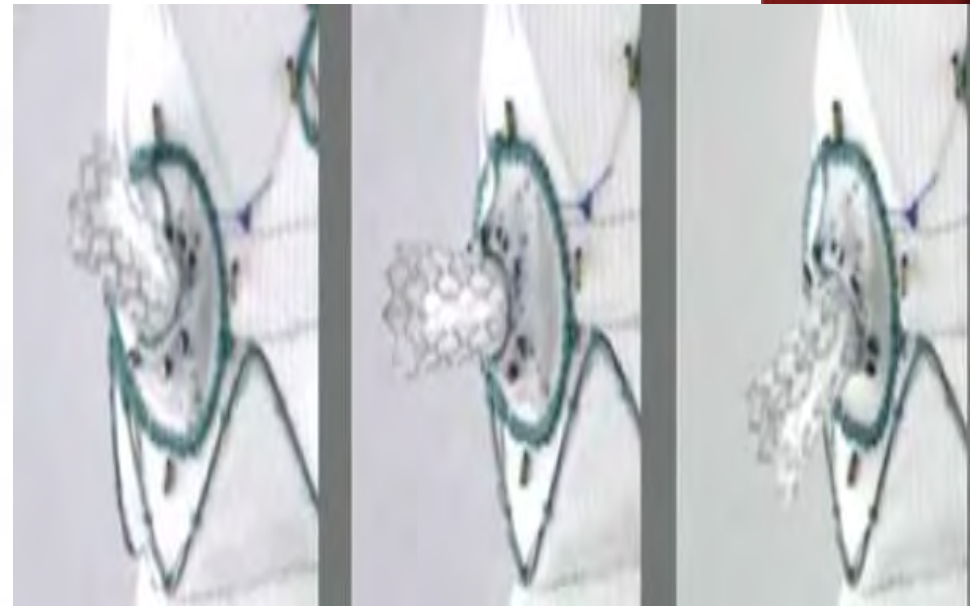
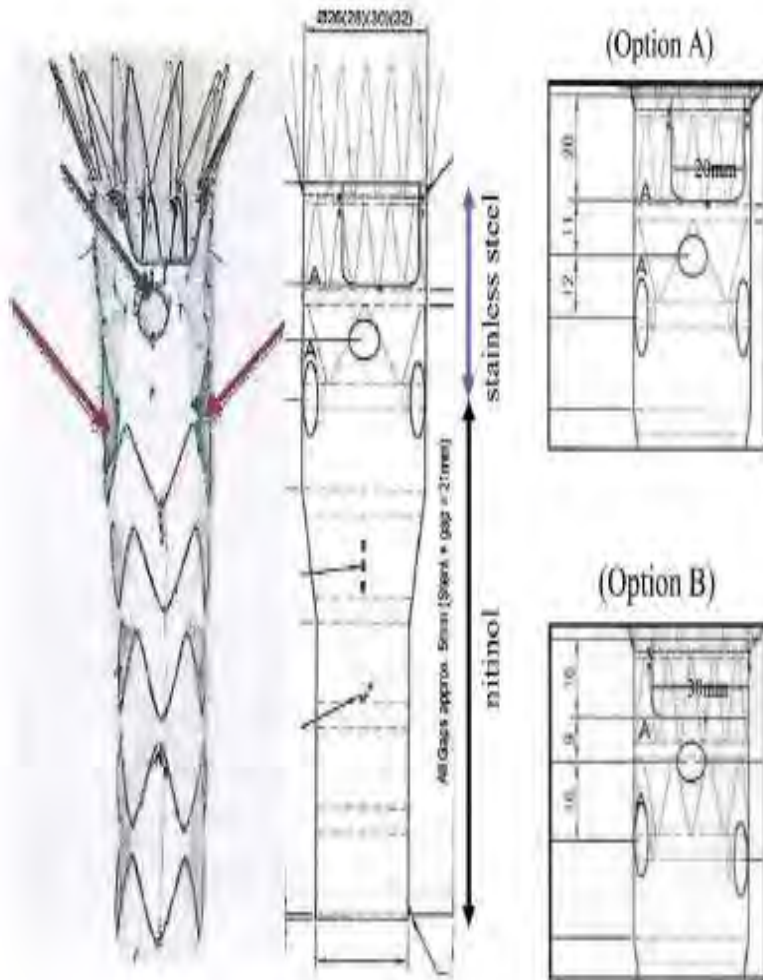


# PARARENAL BRANCH



- ◉ US feasibility study
- ◉ 9 centros
- ◉ 30 pacientes
- ◉ Evalúa seguridad/eficacia
- ◉ 0 mm infra AMS
- ◉ Scallop AC
- ◉ Fenestración AMS
- ◉ Fenestraciones en pivot para renales

# PARARENAL BRANCH



# PARARENAL BRANCH



- ◉ Cleveland clinic
- ◉ Mayo Clinic
- ◉ Washington University in St Louis
- ◉ St. Anthony Hospital
- ◉ University of Florida
- ◉ UT Southwestern
- ◉ University of Massachusetts
- ◉ Indiana University

# PARARENAL BRANCH

*J Vasc Surg.* 2013 Aug;58(2):291-300. doi: 10.1016/j.jvs.2012.12.087. Epub 2013 Apr 20.

## Zenith p-branch standard fenestrated endovascular graft for juxtarenal abdominal aortic aneurysms.

Kitadawa A, Greenberg RK, Esqleton MJ, Mastracci TM.

### Author information

#### Abstract

**OBJECTIVE:** This article reports the early clinical outcomes and experiences of Zenith pivot branch device (p-branch) standard fenestrated endovascular graft (Cook, Bloomington, Ind) for treating juxtarenal abdominal aortic aneurysm (AAA) originating below the superior mesenteric artery (SMA).

**METHODS:** A physician-sponsored investigational device exemption study was used to assess enrolled elective and emergency patients from August 2011 to September 2012 for treatment with an off-the-shelf Zenith p-branch device. Patients were included provided an anatomic seal could be established 4 mm below the SMA and the renal geometry fit the protocol based on reconstructed computed tomography data. The celiac artery was addressed with a scallop and the SMA with an 8-mm fenestration. The renal fenestrations were constructed as a modified design to allow a range of renal locations (7.5 mm radially from the center of the fenestration) to be acceptably treated with a single configuration. Two anatomic configurations were created for renal arteries (origins at the same level, or disparate renal arteries with left lower than right). Outcomes are reported in coherence with endovascular reporting standards documents.

**RESULTS:** The study enrolled 16 patients (94% men; median age, 75 years [range, 59-87 years]) with a mean aneurysm size of 61 mm (range, 52-82 mm). Two were treated for aneurysm rupture. Technical success was achieved in all patients. The median fluoroscopy time was 62 minutes (range, 38-105 minutes), and the amount of contrast media was 69 mL (range, 31-121 mL). There were no aortic-related deaths, aneurysm ruptures, open surgical conversion, or type I/III endoleaks. One right renal artery occluded during follow-up in the setting of a conically shaped visceral aortic segment and was successfully treated with endovascular recanalization.

**CONCLUSIONS:** The use of the p-branch device for aneurysms originating infra-SMA is associated with a high rate of technical success and minimal problems during the short follow-up duration. The off-the-shelf design allows for the treatment of ruptures and other urgent situations. Additional patients and more follow-up will be required to further define the risks and benefits of such a treatment strategy.

- Off the shelf
- 16 pacientes
- 100% éxito técnico
- Fluoro: 62 min
- Contraste: 69 ml
- LOS: 5 dias
- Un evento renal en seguimiento, tratado endovascularmente.

# EXPERIENCIA INDIANA UNIVERSITY

- ◉ 10/2012-10/2014
- ◉ ZFEN Custom device
- ◉ >60 procedimientos
- ◉ Top 3 en experiencia con ZFEN

# EXPERIENCIA INDIANA UNIVERSITY

Age	73.8
Male	79%
BMI	27.8
Aneurysm size	62 mm (46-89)
EBL	567 ml
Fluoro time	59.9 min (26.4-121.5)
Contrast:	104 ml (53-242)
Technical success	97% (32/33)

# EXPERIENCIA INDIANA UNIVERSITY

	FIRST 20 PATIENTS	LAST 15 PATIENTS
BMI	26.1	28.1
Fluoro time	63.4 min	48.5 min
Contrast	115 ml	85 ml
EBL	497 ml	540 ml
Technical success	95%	100%

# EXPERIENCIA INDIANA UNIVERSITY

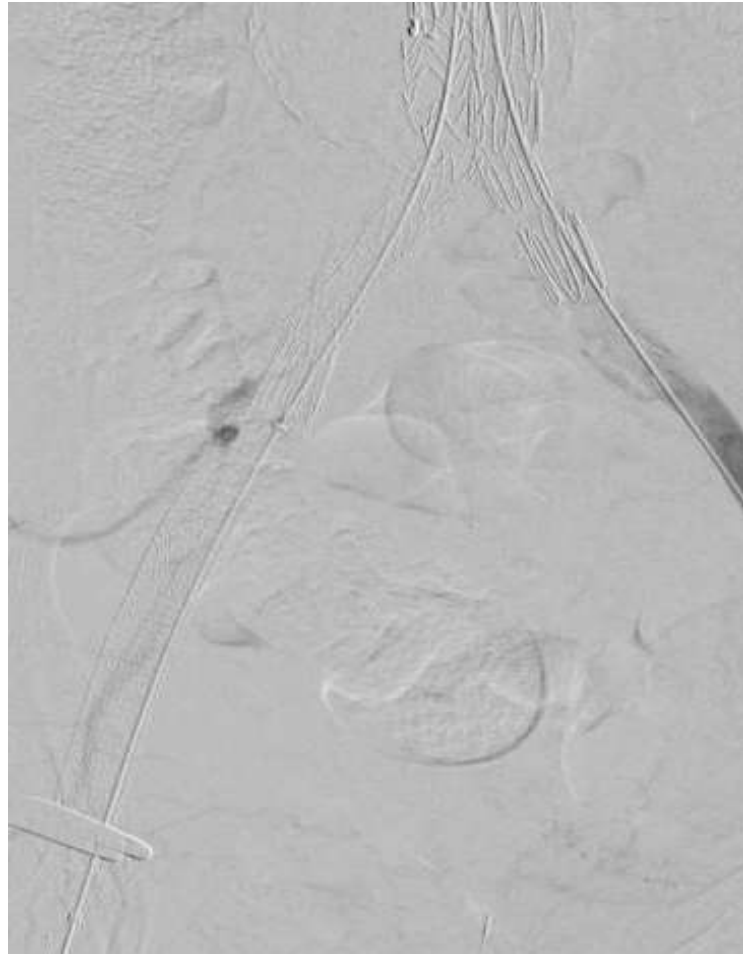
LOS	3.3 Days (20 patients 1-2 days)
30 day mortality	3%
Renal failure requiring HD	3%
Major endoleak 30 days	3% (Type III left renal stent)



# DIFICULTADES

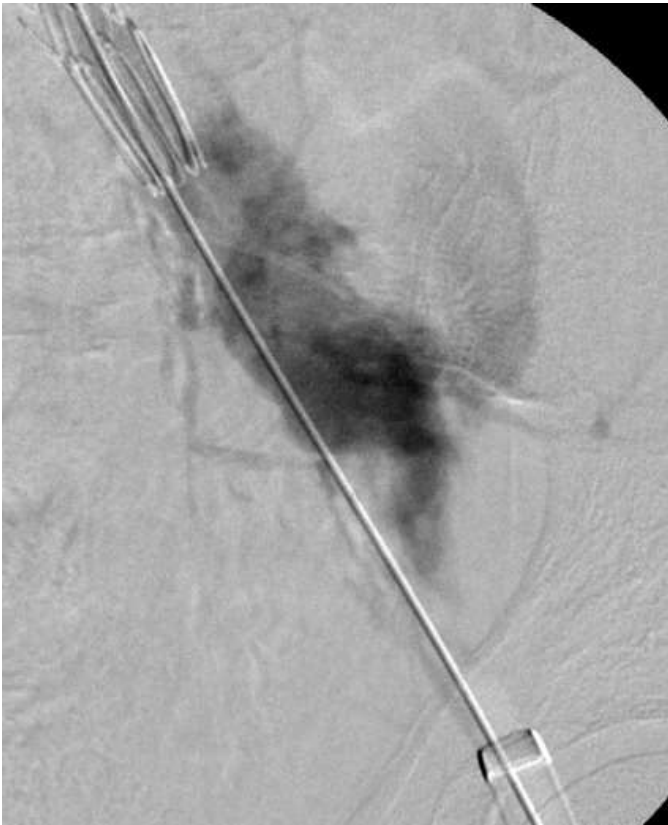
- **Accesos iliacos siguen siendo limitantes**
  - Introdutores largos bilaterales requeridos
  - Tortuosidad severa hace orientación de la prótesis mas complicada
  - Calcificación es un obstáculo para manipulación del dispositivo
- **2 pacientes con rotura iliaca al remover introductores.**
  - Considerar uso de conductos mas tempranamente.

# ROTURA ILIACA





# ILIAC RUPTURE



# DIFICULTADES

## ⊙ Anatomía arterial

- Anatomía aberrante
- Renales múltiples/accesorias
- Arterias pequeñas(<4mm)/enfermas
- Bifurcaciones tempranas

# DIFICULTADES

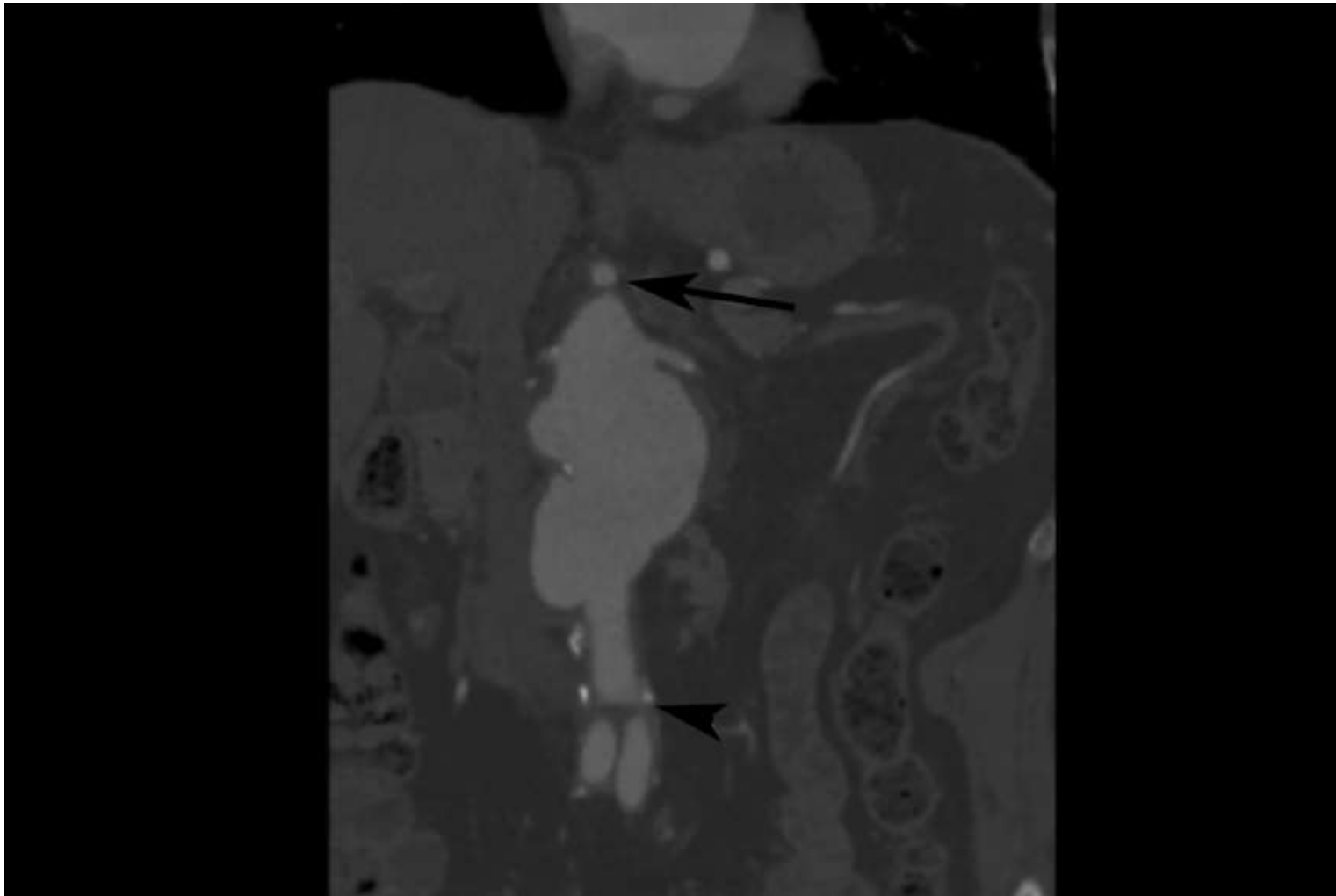
## ⊙ Reparación abierta previa

- Distancia a bifurcación de injerto usualmente corta

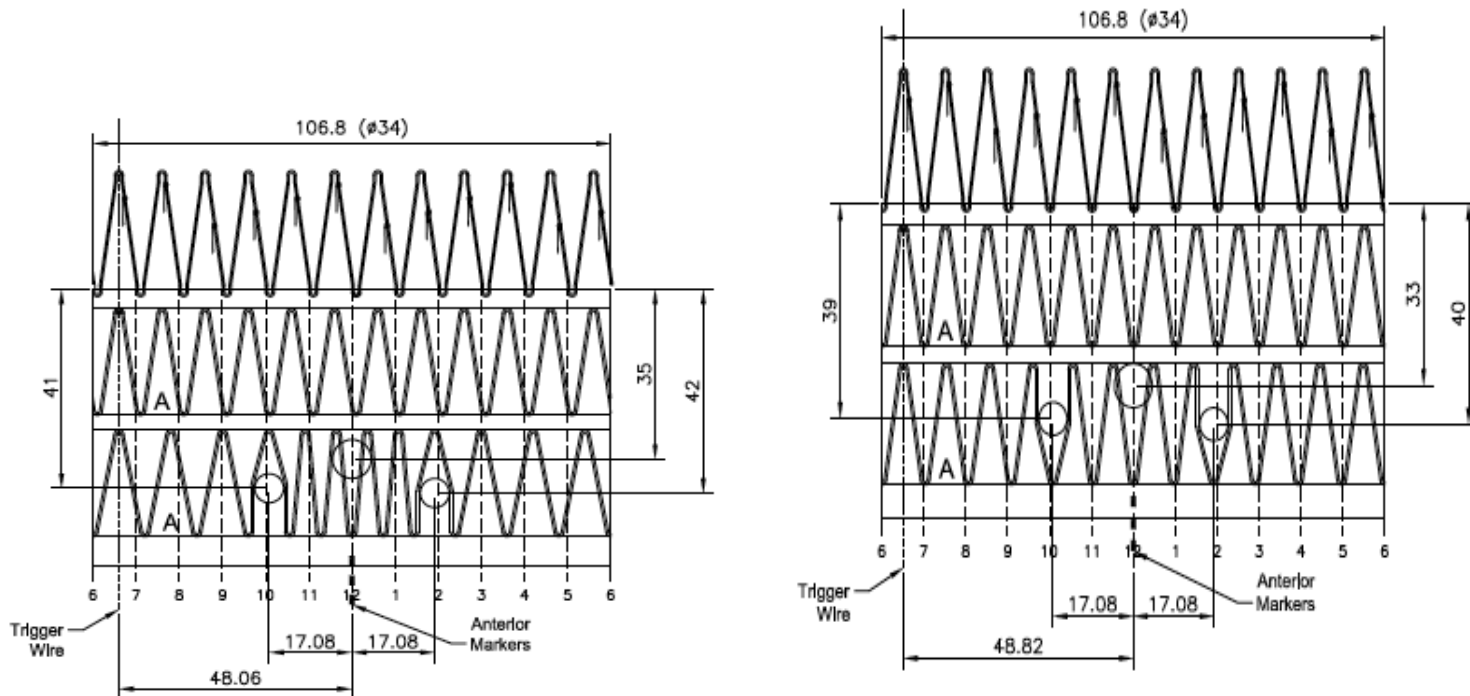
## ⊙ EVAR previo

- Dispositivos con corta distancia a bifurcación
- Fijación suprarrenal de dispositivos puede interferir con origen arterial

# REPARO ABIERTO PREVIO



# REPARO ABIERTO PREVIO

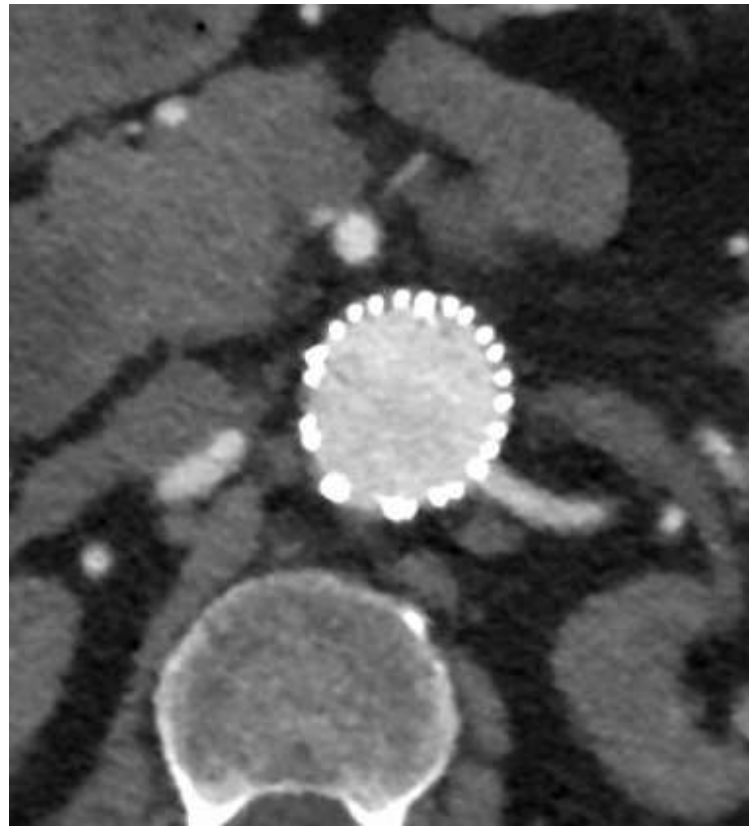
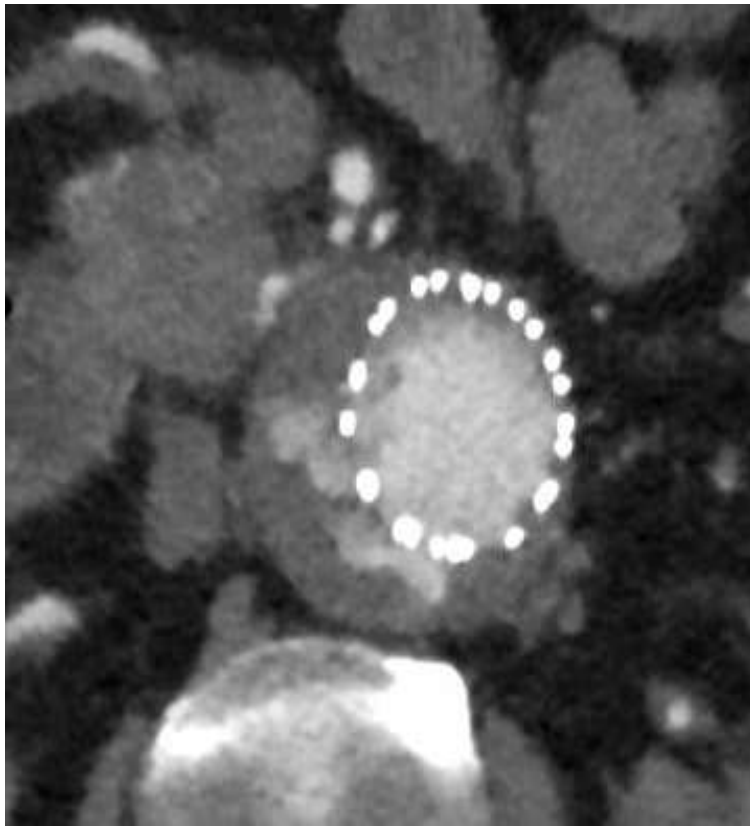




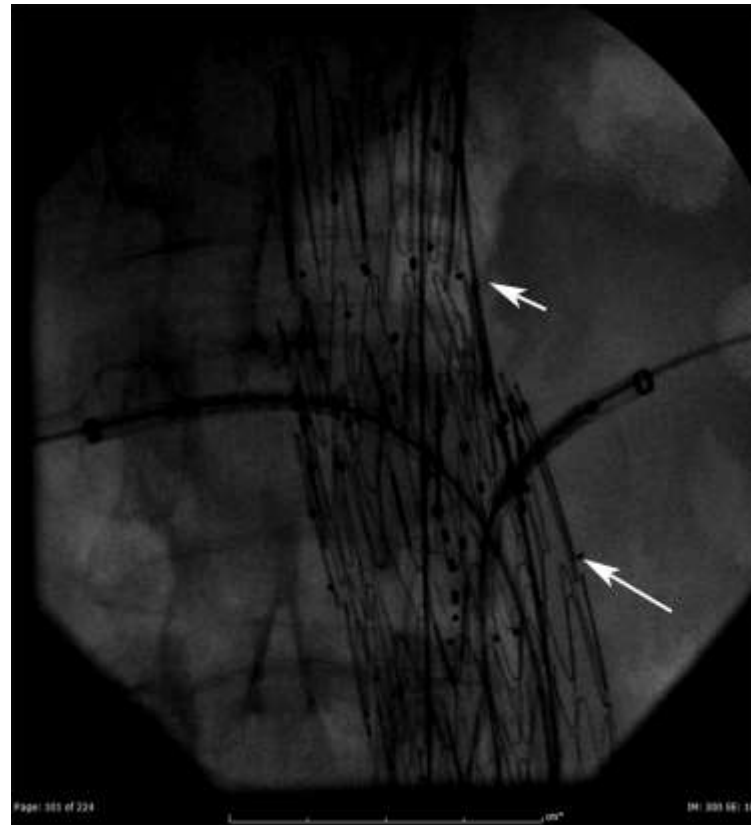
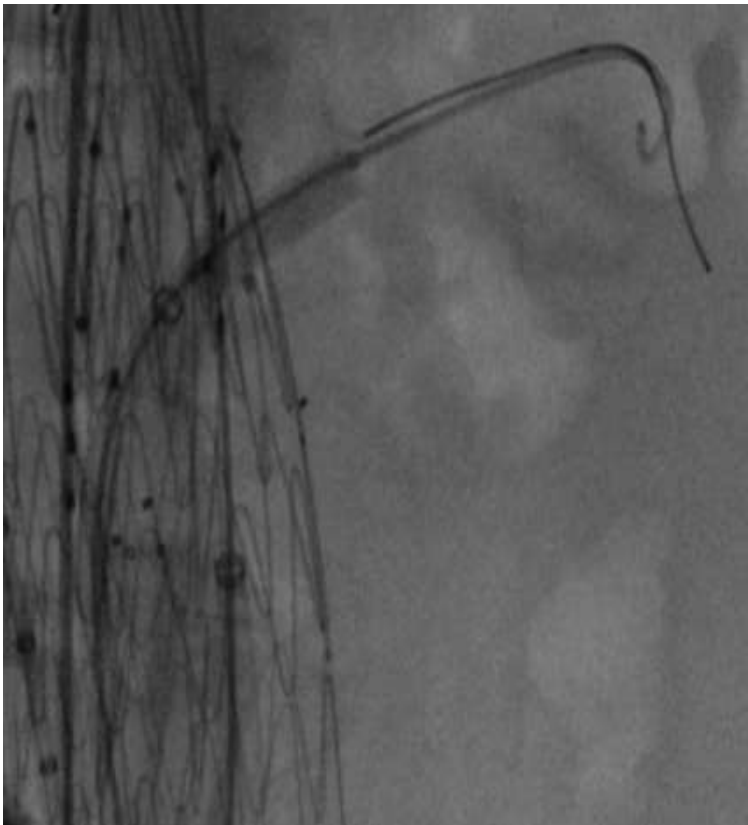
# REPARO ABIERTO PREVIO



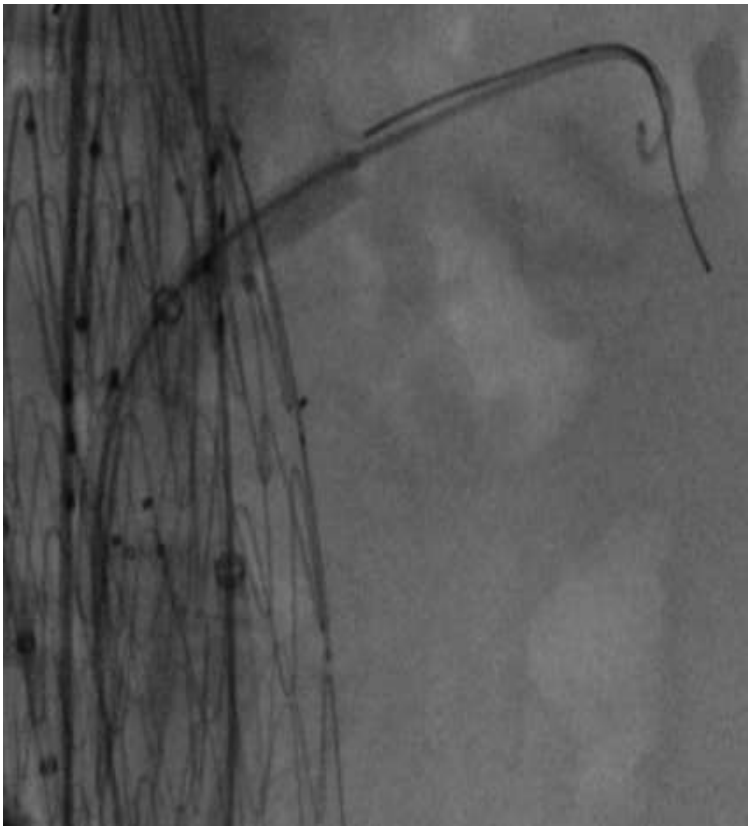
# EVAR PREVIO



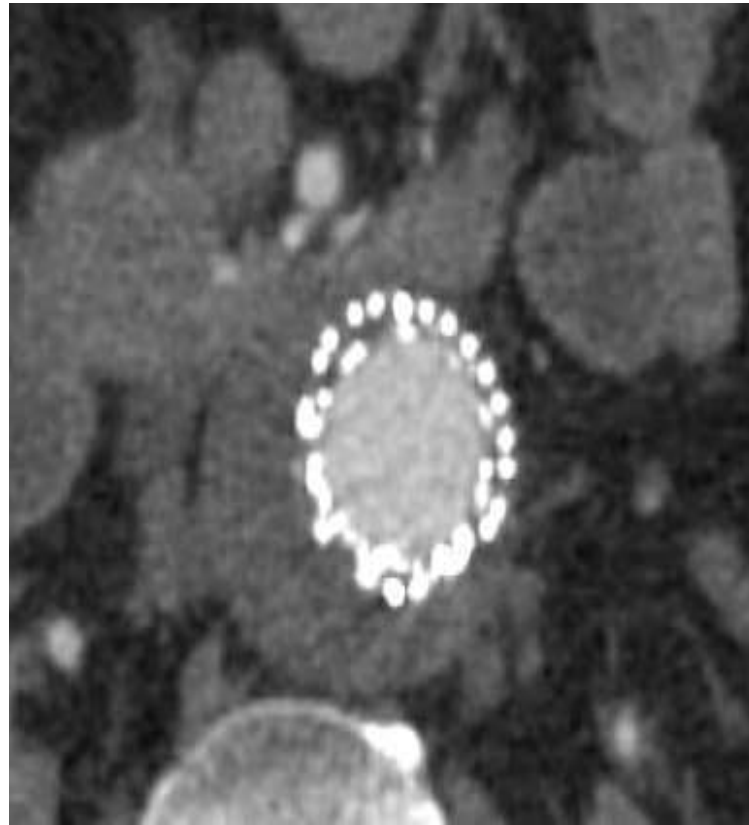
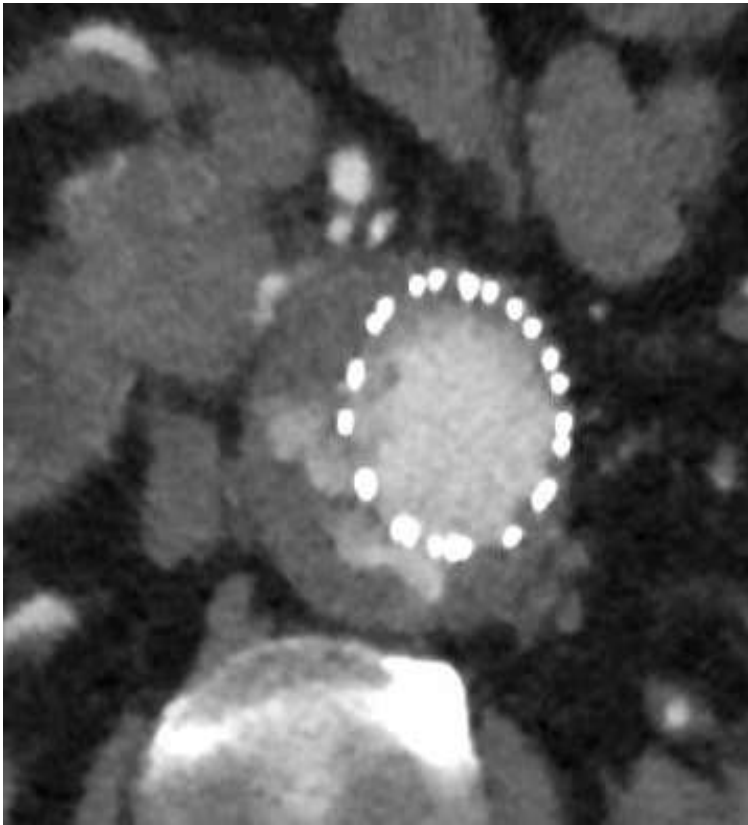
# EVAR PREVIO



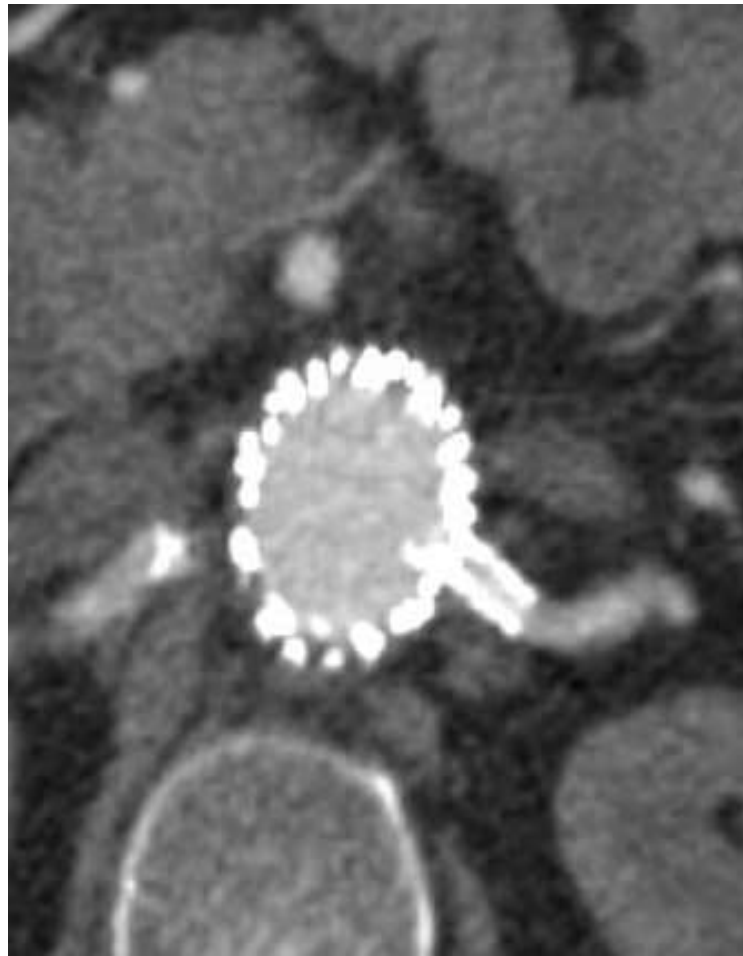
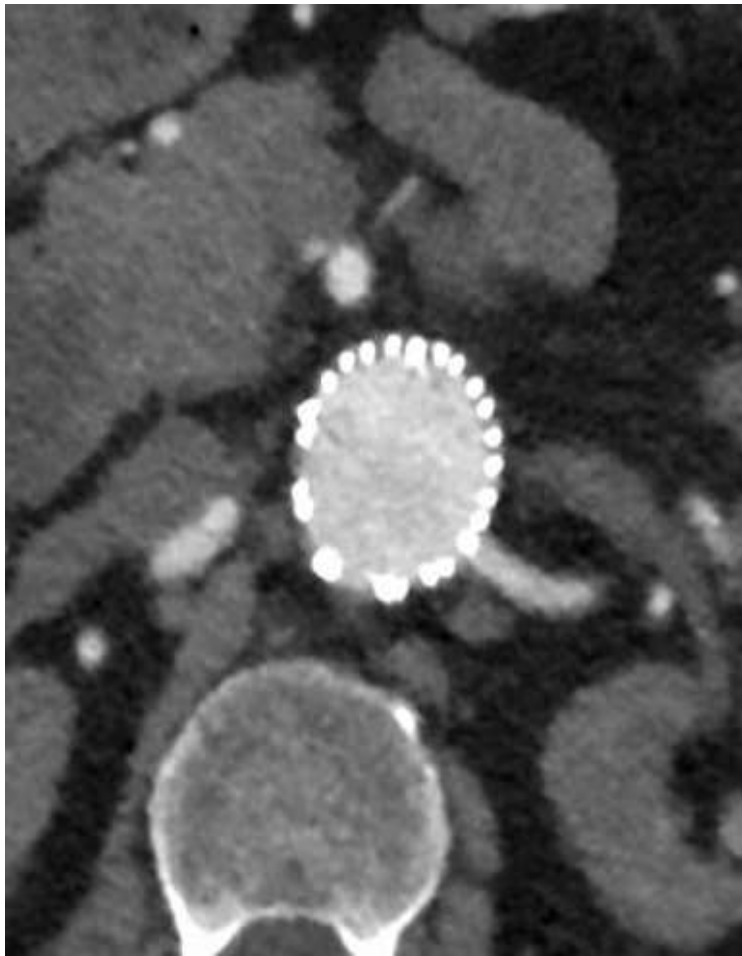
# EVAR PREVIO



# EVAR PREVIO



# EVAR PREVIO



# CONCLUSIONES

- ◉ Técnicas/dispositivos nuevos para el manejo de aneurismas juxta y pararenasls están avanzando rápidamente
- ◉ Aumentado la cantidad de pacientes que se les puede ofrecer tratamiento
- ◉ Resultados promisorios
- ◉ Ausencia de estudios randomizados, comparando con cirugía abierta.
- ◉ Procedimientos complicados, donde a mayor experiencia, mejores resultados

# CONCLUSIONES

- ◉ Dispositivos “Off the shelf” nos permitirán tratar pacientes mas rápidamente
- ◉ Dispositivos planificados(“custom”) van a seguir siendo usados.
- ◉ Perfil de los dispositivos, asociado a tortuosidad y angulación aortica e iliaca seguirán siendo un obstáculo.
- ◉ Usar dispositivos con cuidado, con maximización del área de sellado, para prevenir complicaciones tardías.



# GRACIAS

