EndoAnchors to prevent or fix type I endoleaks: Mid-term results of the Global ANCHOR Registry

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Disclosures

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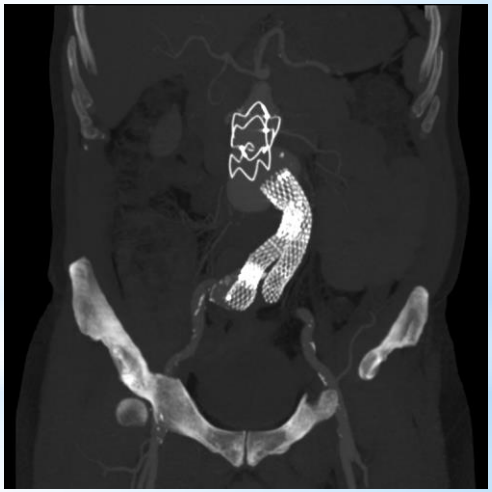
Without EndoAnchors, What Are Our Treatment Options?

* *When* they can be placed, Cuff/Palmaz do not always work
  * Greater radial force may not resolve focal issue
  * Additional components place greater dilating force on a diseased aorta
* Limited viable options for treating type I endoleak in short necks
  * Coils/Onyx require precise ID of leak paths, carry non-target embolization risk
  * Patient may be unfit for more complex procedures
* How do we **prevent** further disease progression & complications?
  * Cuffs, Palmaz, Coils, Onyx cannot resist neck dilatation



What New Capabilities Can We Achieve With EndoAnchors?

* **Target** and *close* type I endoleak paths
  * Analogous to an *interrupted suture*
  * Customize placement to anatomy
* Provide an adjunctive treatment where options can be limited
  * Such as short, hostile infra-renal necks
* Augment seal strength without increasing seal area
  * Potentially avoid more complex procedures or covering vessels

EndoAnchors do not inhibit other adjunctive or future options

>4,000 PATIENTS TREATED, >23,000 ENDOANCHORS IMPLANTED TO-DATE

PROPHYLAXIS

Hostile Anatomy

Overcoming concerns for implant stability

- Challenging neck anatomies (e.g. wide, short, conical, angulated)
- Difficult landing (e.g. birdbeaking, close to branched vessels)

Normal Anatomy

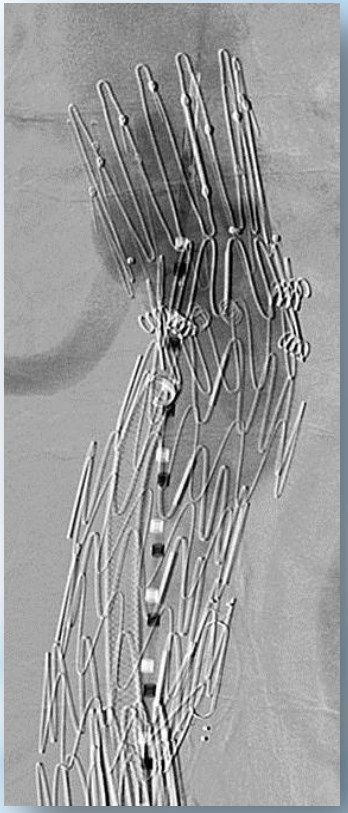
Mitigating risk of re-interventions

- Severe comorbidities that preclude safe re-intervention
- Patients potentially lost during F/U
- Long remaining life expectancy (young pts)

TREATMENT

Resolve proximal seal failures

- Targeted sealing of acute type I endoleaks
- Targeted sealing of late type I endoleaks
- Augmented stability in migrated grafts



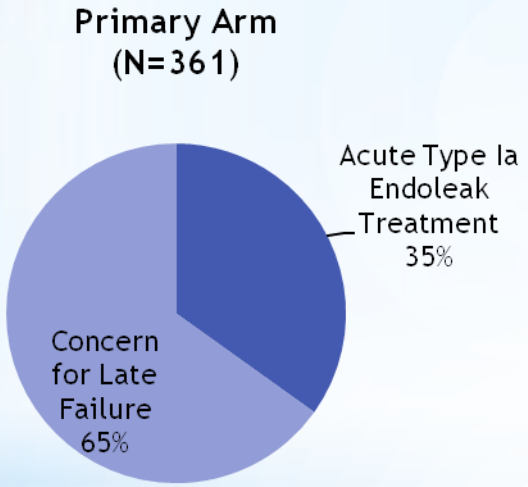
Case image from Gandhi RT, Katzen BT Treating a Type 1A Endoleak Using EndoAnchors. Endovascular Today March 2012 23:26.

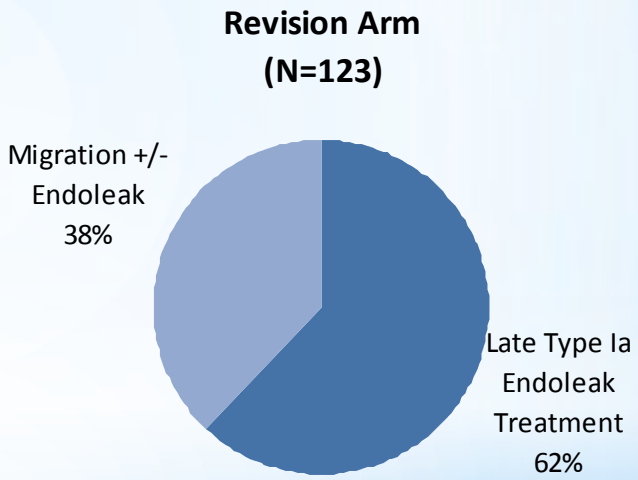
ANCHOR Registry: A Study of the *Real-World* Usage & Outcomes of the Heli-FX EndoAnchor System

Registry Design	**Prospective, observational, international, multi-center, dual-arm**
Current Enrollment	505 patients as of 31 Dec 2014 36 US Sites, 17 European Sites

Treatment Arms	"Primary" – Up to 1000 pts
	"Revision" – Up to 1000 pts
Duration	5 Years
Follow-up	Per Standard of Care at each center & investigator discretion

Indicated Reasons for EndoAnchoring in ANCHOR: *Complications and Concerns for Failure*





- **48.6% → prophylaxis** (n=235)
- **51.4% → treatment** (n=249): **Acute + Late Type Ia Endoleaks, Migration +/- Endoleak**

Median # EndoAnchors Implanted	
Primary Arm:	6
Revision Arm:	7
Combined:	7

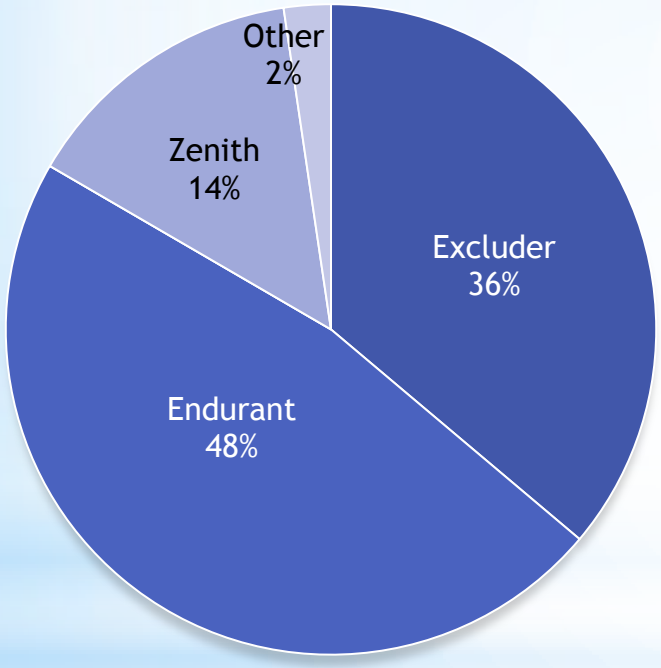
Majority Proximal Necks in ANCHOR are **Hostile**
per Corelab

Proximal Neck Anatomical Characteristics	Primary N = 237	Revision N = 92
Max Aneurysm Diameter [mean]	56 mm	69 mm
Neck Length [mean]	17 mm	14 mm
Neck Length ≤10mm	**88/237 (37.1%)**	**45/92 (48.9%)**
Necks Length ≤15mm	**127/237 (53.6%)**	**60/92 (65.2%)**
Neck Diameter [mean]	26 mm	30 mm
Conical Neck (10% increase over 10mm)	**36.7%**	**48.9%**
Neck Thrombus [mean thickness over circumference]	0.7 mm	1.0 mm
Neck Calcium [mean thickness over circumference]	1.2 mm	0.3 mm
Hostile Neck*	**91.6%**	**84.8%**

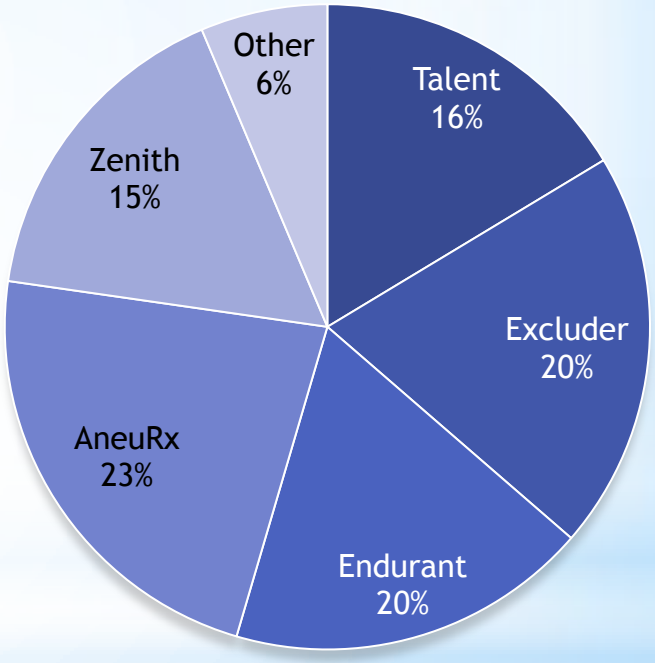
*Hostile neck defined by neck diameter >28mm, length <10mm, angulation >60°, thrombus or calcium over >180 degrees of circumference

All Major Endografts Have Required EndoAnchors
to Treat Complications and Address Concerns

Primary Arm n=361 (75%)



Revision Arm n=123 (25%)

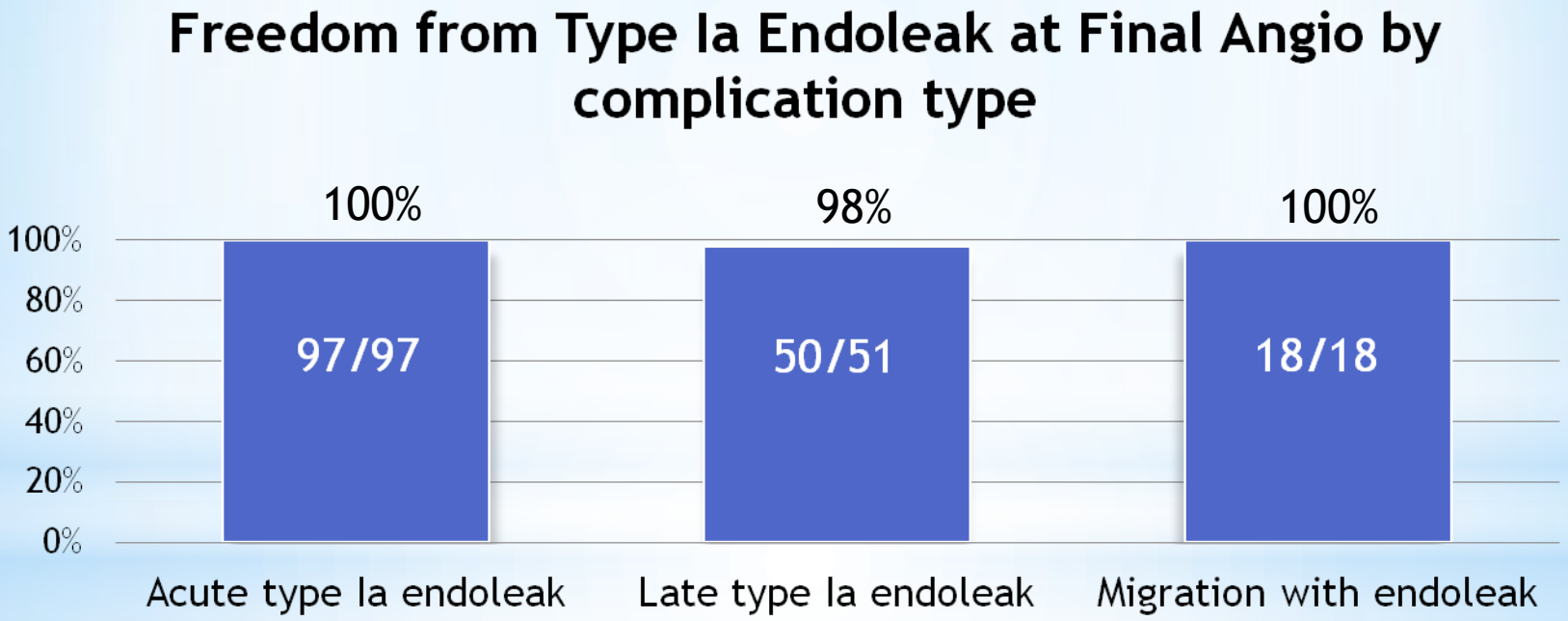


Low Proximal Seal-Related Events
in Midterm Follow-Up *Despite Hostile Neck Anatomy*

	Primary		Revision	
	Mean ± SD	Min - Max	Mean ± SD	Min - Max
Length of clinical follow-up	14.9± 7.7 months	0.0 – 33.2 months	15.0 ± 7.9 months	1 – 32.0 months
Rupture post-repair	0/361 (0.0%)		0/123 (0.0%)	
Aneurysm-related reinterventions	16/361 (4.4%)		21/123 (17.1%)	
Proximal-seal related re-interventions[1]	***3/361 (0.8%)***		***10/123* (8.1%)***	
Aneurysm-related deaths	4/361** (1.1%)		0/123 (0.0%)	

[1]Includes total re-interventions for type Ia endoleaks, type III endoleaks and graft migrations
*10 patients with 16 re-interventions. 2 patients with multiple revisions: 1 with 4, another with 2
**Site reported cause of death: left sided ischemic bowel, respiratory failure, MOF

High Success Treating Type Ia Complications *Despite Hostile Neck Anatomy*

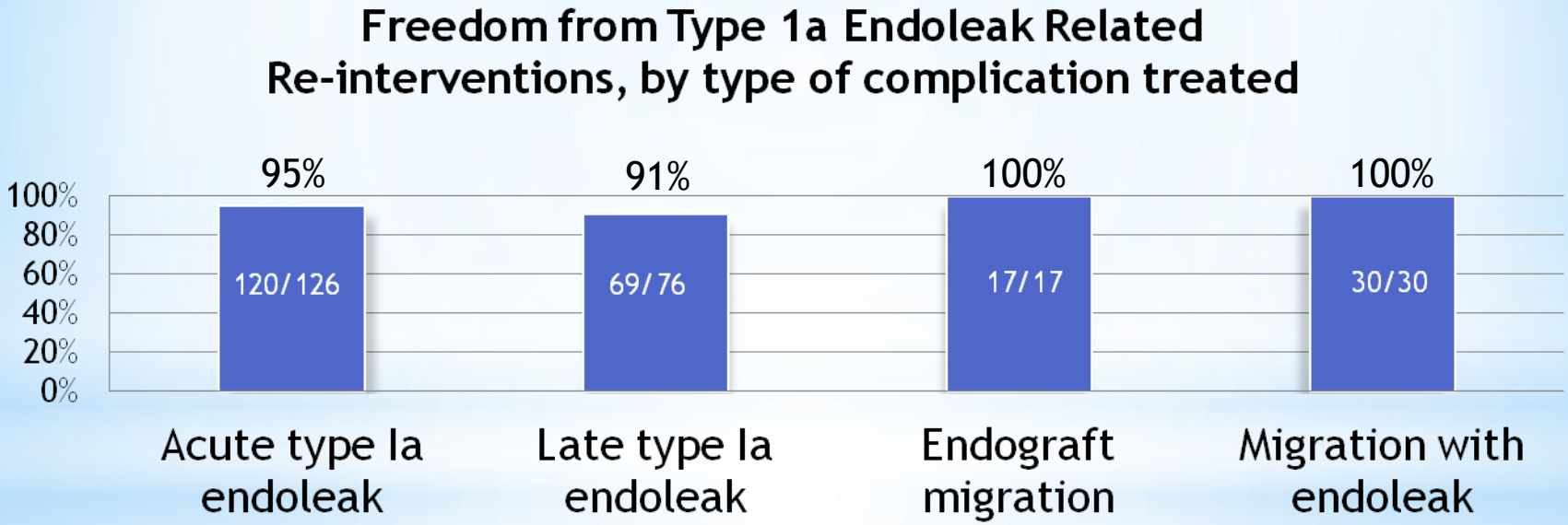


Based on Corelab,

99.3% of proximal necks meet criteria for hostile*

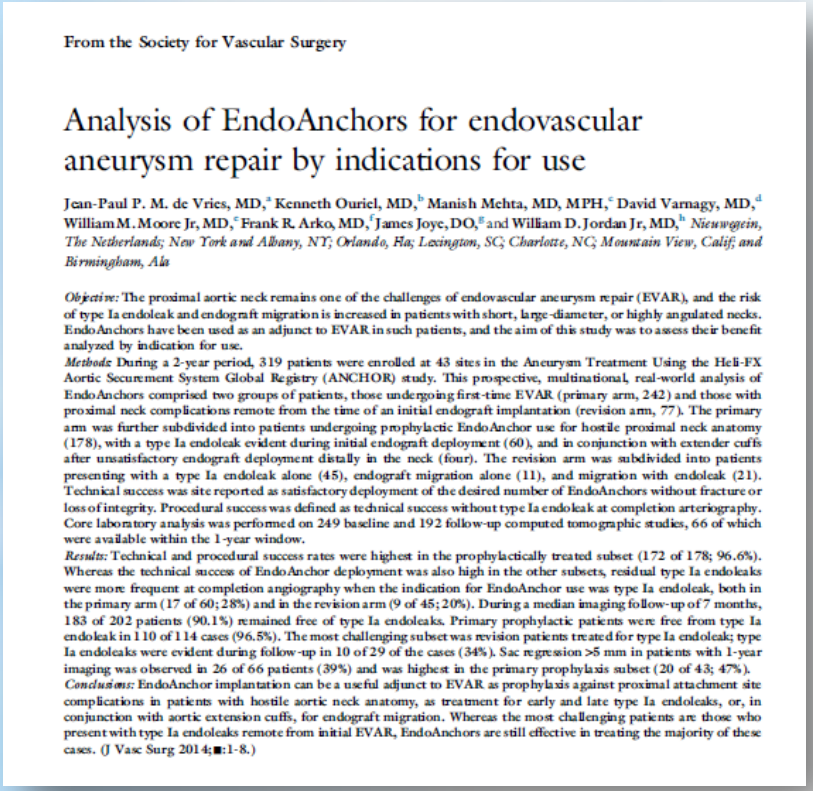
*Hostile necks are based on CT images available for Corelab analysis and presence of type Ia endoleaks are based on site reported angio results.
Defined by neck diameter >28mm, length <10mm, angulation >60°, thrombus or calcium over >180 degrees of circumference

Low Proximal Seal Re-Interventions in F/U
Despite Hostile Neck Anatomy



Mean follow-up (CT-scans): 15 ± 8 months

Recent Published Article in JVS:
As Prophylaxis, Strong Outcomes in ANCHOR



From the Society for Vascular Surgery

Analysis of EndoAnchors for endovascular aneurysm repair by indications for use

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Objective: The proximal aortic neck remains one of the challenges of endovascular aneurysm repair (EVAR), and the risk of type Ia endoleak and endograft migration is increased in patients with short, large-diameter, or highly angulated necks. EndoAnchors have been used as an adjunct to EVAR in such patients, and the aim of this study was to assess their benefit analyzed by indication for use.

Methods: During a 2-year period, 319 patients were enrolled at 43 sites in the Aneurysm Treatment Using the Heli-FX Aortic Securement System Global Registry (ANCHOR) study. This prospective, multinational, real-world analysis of EndoAnchors comprised two groups of patients, those undergoing first-time EVAR (primary arm, 242) and those with proximal neck complications remote from the time of an initial endograft implantation (revision arm, 77). The primary arm was further subdivided into patients undergoing prophylactic EndoAnchor use for hostile proximal neck anatomy (178), with a type Ia endoleak evident during initial endograft deployment (60), and in conjunction with extender cuffs after unsatisfactory endograft deployment distally in the neck (four). The revision arm was subdivided into patients presenting with a type Ia endoleak alone (45), endograft migration alone (11), and migration with endoleak (21). Technical success was site reported as satisfactory deployment of the desired number of EndoAnchors without fracture or loss of integrity. Procedural success was defined as technical success without type Ia endoleak at completion arteriography. Core laboratory analysis was performed on 249 baseline and 192 follow-up computed tomographic studies, 66 of which were available within the 1-year window.

Results: Technical and procedural success rates were highest in the prophylactically treated subset (172 of 178; 96.6%). Whereas the technical success of EndoAnchor deployment was also high in the other subsets, residual type Ia endoleaks were more frequent at completion angiography when the indication for EndoAnchor use was type Ia endoleak, both in the primary arm (17 of 60; 28%) and in the revision arm (9 of 45; 20%). During a median imaging follow-up of 7 months, 183 of 202 patients (90.1%) remained free of type Ia endoleaks. Primary prophylactic patients were free from type Ia endoleak in 110 of 114 cases (96.5%). The most challenging subset was revision patients treated for type Ia endoleak; type Ia endoleaks were evident during follow-up in 10 of 29 of the cases (34%). Sac regression >5 mm in patients with 1-year imaging was observed in 26 of 66 patients (39%) and was highest in the primary prophylaxis subset (20 of 43; 47%).

Conclusions: EndoAnchor implantation can be a useful adjunct to EVAR as prophylaxis against proximal attachment site complications in patients with hostile aortic neck anatomy, as treatment for early and late type Ia endoleaks, or, in conjunction with aortic extension cuffs, for endograft migration. Whereas the most challenging patients are those who present with type Ia endoleaks remote from initial EVAR, EndoAnchors are still effective in treating the majority of these cases. (J Vasc Surg 2014;■:1-8.)

- Strong acute results in majority hostile neck anatomy
  - ***Zero*** type I endoleaks (0/178) at final angio
- Favorable follow-up (mean 7-month)
  - ***Zero*** re-interventions for type Ia endoleak or endograft migration (0/186)
  - High early sac regression, 47% (20/43)

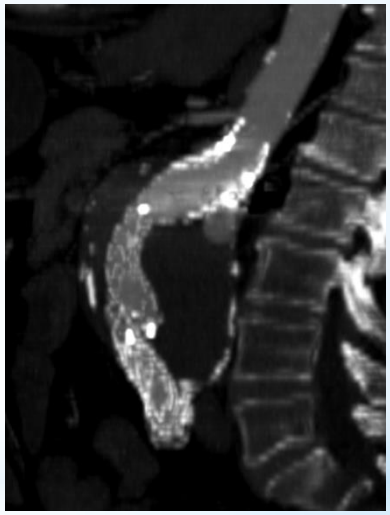
What We've Learned to Further Improve Outcomes

Lack of EndoAnchor penetration in aortic tissue may increase risk of developing/re-developing type I endoleaks

CoreLab assessment of etiology of residual type 1A after EndoAnchor placement (N =17)

Reason for persistent type 1a endoleak	Number of cases
Calcified Rim	5
Gap between graft and aortic wall	6
EndoAnchor deployed above graft fabric	3
EndoAnchor deployed in aneurysm sac	4
EndoAnchor not oriented perpendicular to graft wall	2

4 subjects had two reasons identified for persistent type 1a endoleak



Can It Fix Type I Endoleaks and Graft Migration: Can It Be Proven?

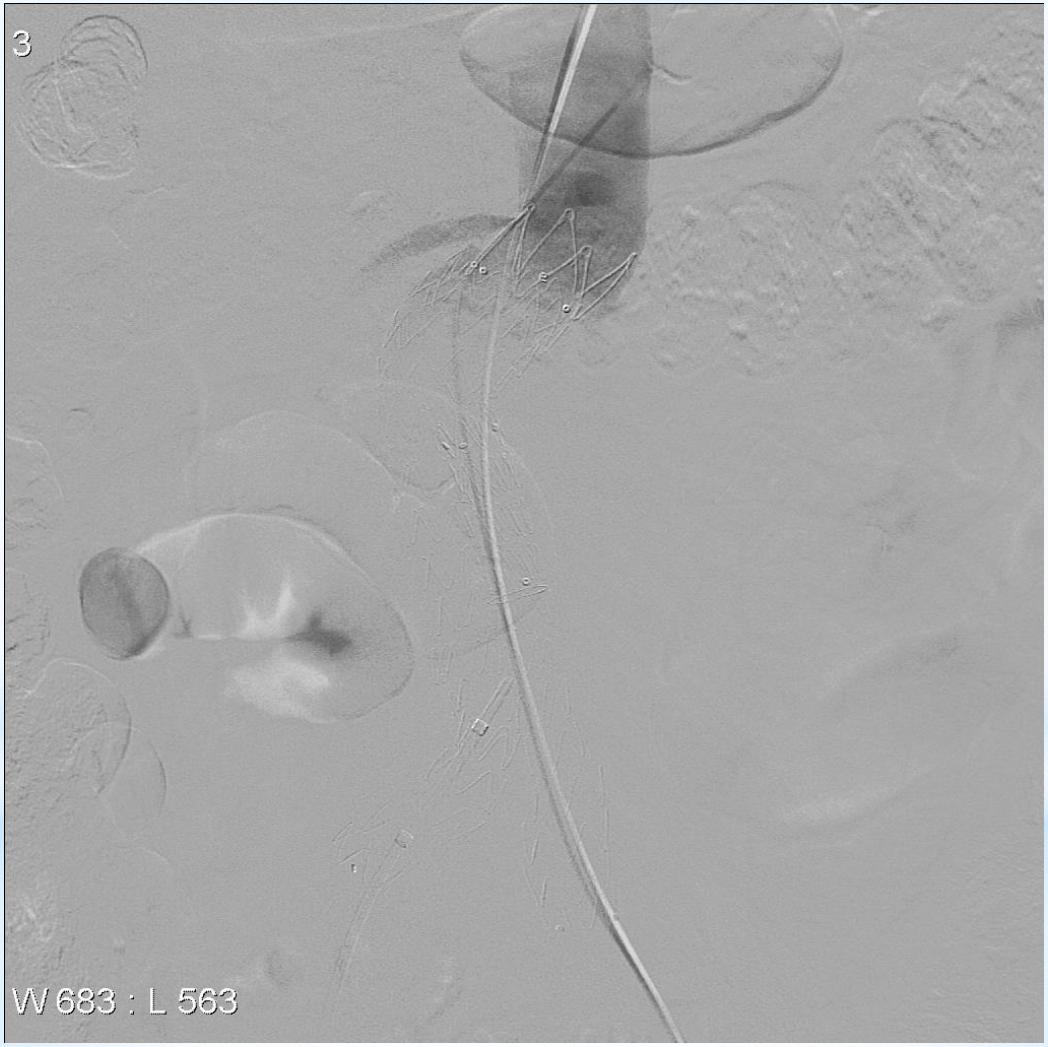
What we've learned…

* EndoAnchors can be a powerful tool in fixing complications
  * High success in treating type Ia endoleaks (>90%)
  * Zero re-interventions for endograft migration in f/u
* Can enable viable treatment, especially when options are limited
* High seal integrity despite high-risk neck anatomy
* Maturing follow-up data are in-process

Site Name	Total Enrolled	% of Total
University of Alabama	43	8.9%
St. Antonius Hospital	34	7.0%
El Camino Hospital	16	3.3%
Technical University Munich	11	2.3%
University Medical Center Utrecht	1	0.2%
Carolinas Health Care System	32	6.6%
William Beaumont Hospital	6	1.2%
Scott & White Medical Center	9	1.9%
Maasstad Medical Hospital Rotterdam	5	1.0%
University of Siena	2	0.4%
Malmo University Hospital	1	0.2%
Thorax Institute Hospital Clinic	4	0.8%
Park Hospital Leipzig	3	0.6%
NYU School of Medicine	1	0.2%
Cleveland Clinic	6	1.2%
Central Arkansas Veterans Health System (CAVHS)	2	0.4%
University of North Carolina	2	0.4%
St. Bonifatius Hospital	4	0.8%
St. Franziskus-Hospital GmbH Munster	7	1.4%
Dartmouth-Hitchcock Medical Center	5	1.0%
Sentara Heart Hospital - Norfolk	15	3.1%
Carolina Vascular-Mission Hospital	16	3.3%
Southern Illnois University School of Medicine	1	0.2%
Washington University School of Medicine	9	1.9%
Baptist Hospital	4	0.8%
Montefiore Medical Center	3	0.6%
Duke University Medical Center	6	1.2%

Site Name	Total Enrolled	% of Total
Vanderbilt University Medical Center	9	1.9%
Arizona Heart	2	0.4%
Beth Israel Deaconess Medical Center (BIDMC)	2	0.4%
Hawaii Permanente Medical Group	11	2.3%
Harbor - UCLA Medical Center	1	0.2%
Albany Medical Center	74	15.3%
Deutsches Herzzentrum Berlin	5	1.0%
Michigan Vascular Center	10	2.1%
Florida Hospital	25	5.2%
Lexington Medical Center	30	6.2%
Imperial College London	8	1.7%
University of South Florida	3	0.6%
Yale	7	1.4%
Baptist Memphis	4	0.8%
Johns Hopkins	6	1.2%
HeartCare Peoria	3	0.6%
Mount Sinai	3	0.6%
NorthShore University	1	0.2%
University of Heidelberg	7	1.4%
LMU Munich	2	0.4%
Klinikum Nürnberg	3	0.6%
Klinikum Ludwigsburg	1	0.2%
Rijnstate Hospital	7	1.4%
PinnacleHealth	3	0.6%
Loma Linda VA	4	0.8%
SUNY Stony Brook	5	1.0%
Total	484	100%

Case Examples



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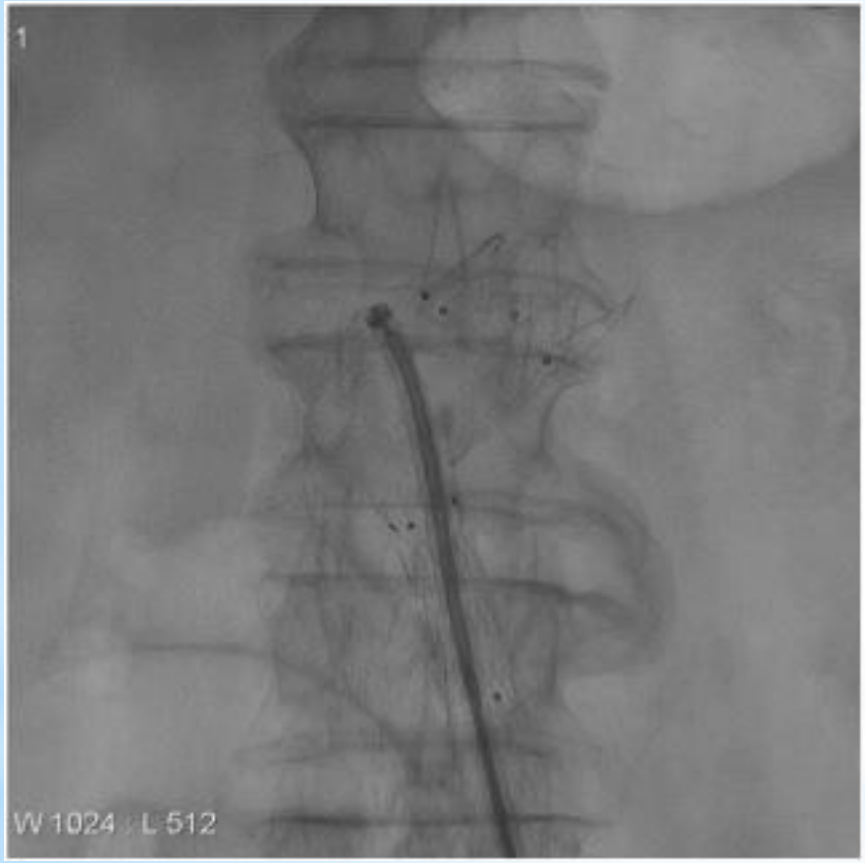

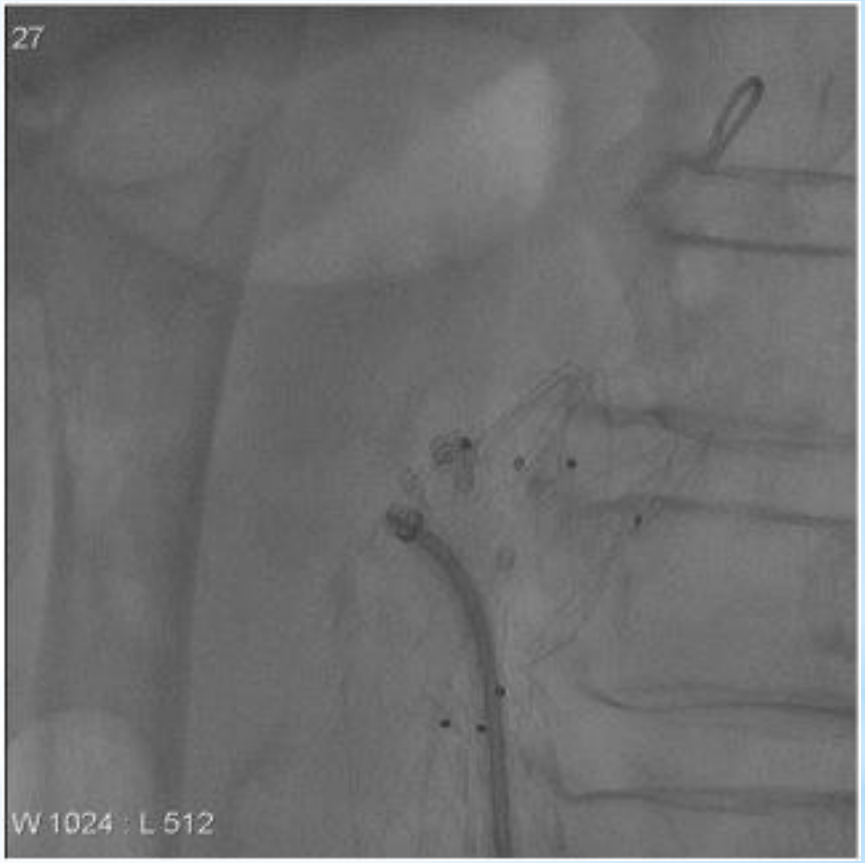

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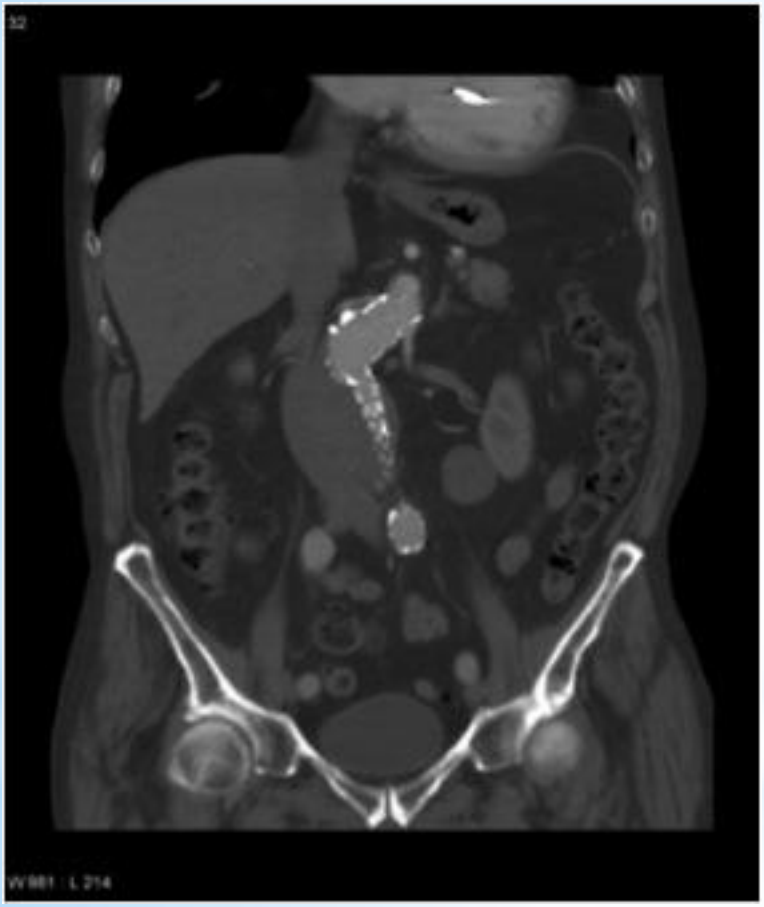

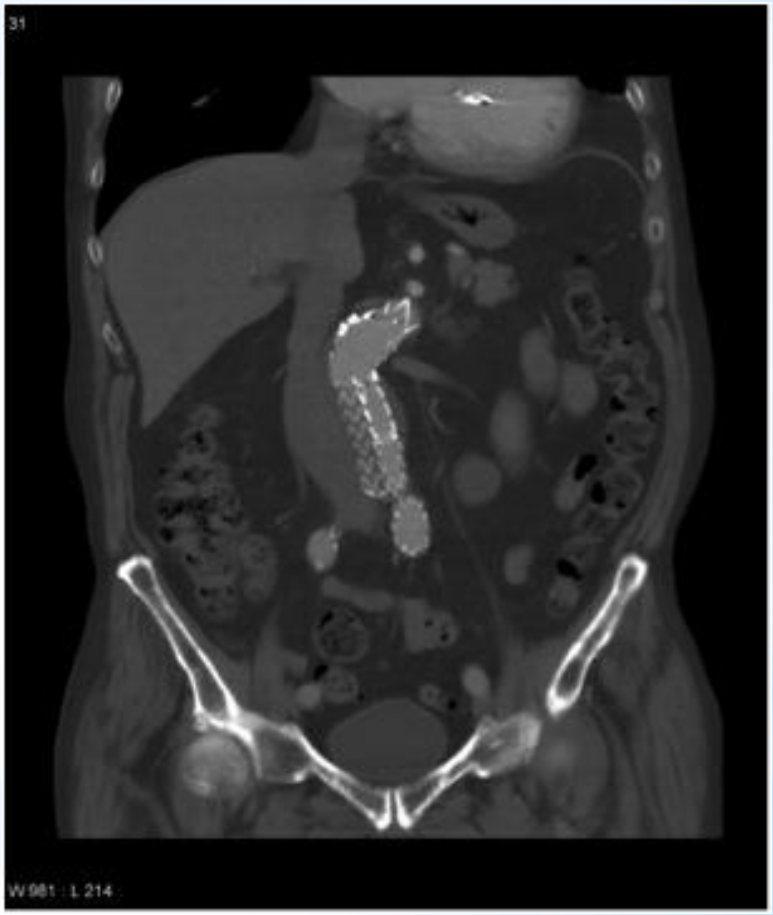

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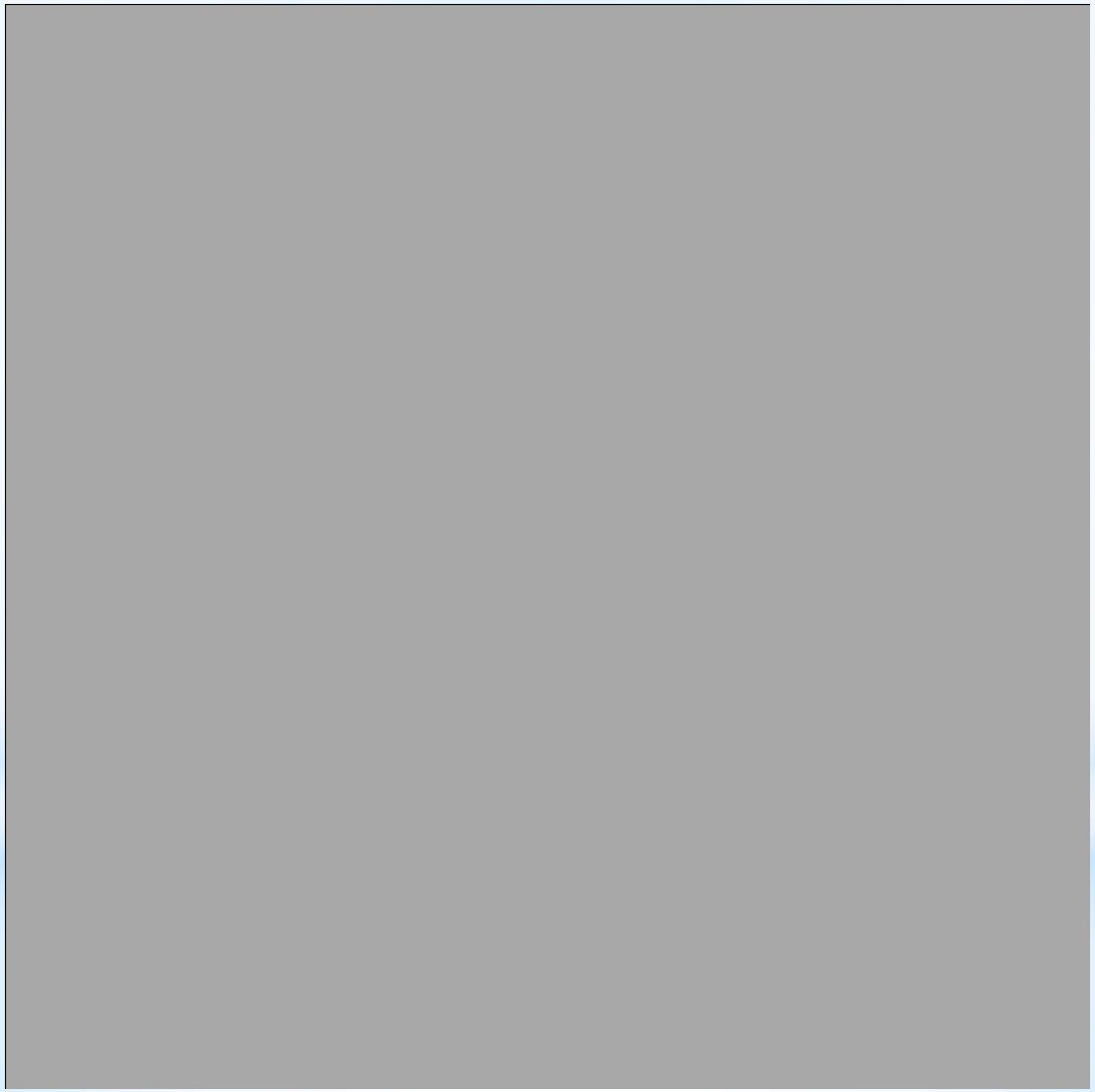

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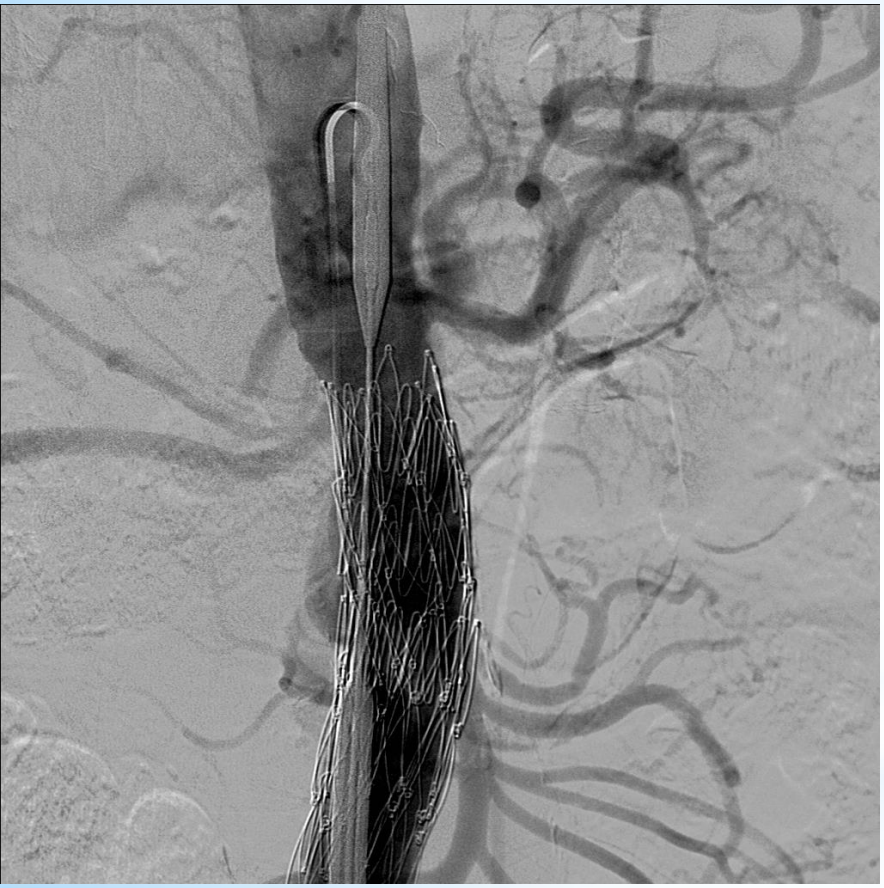

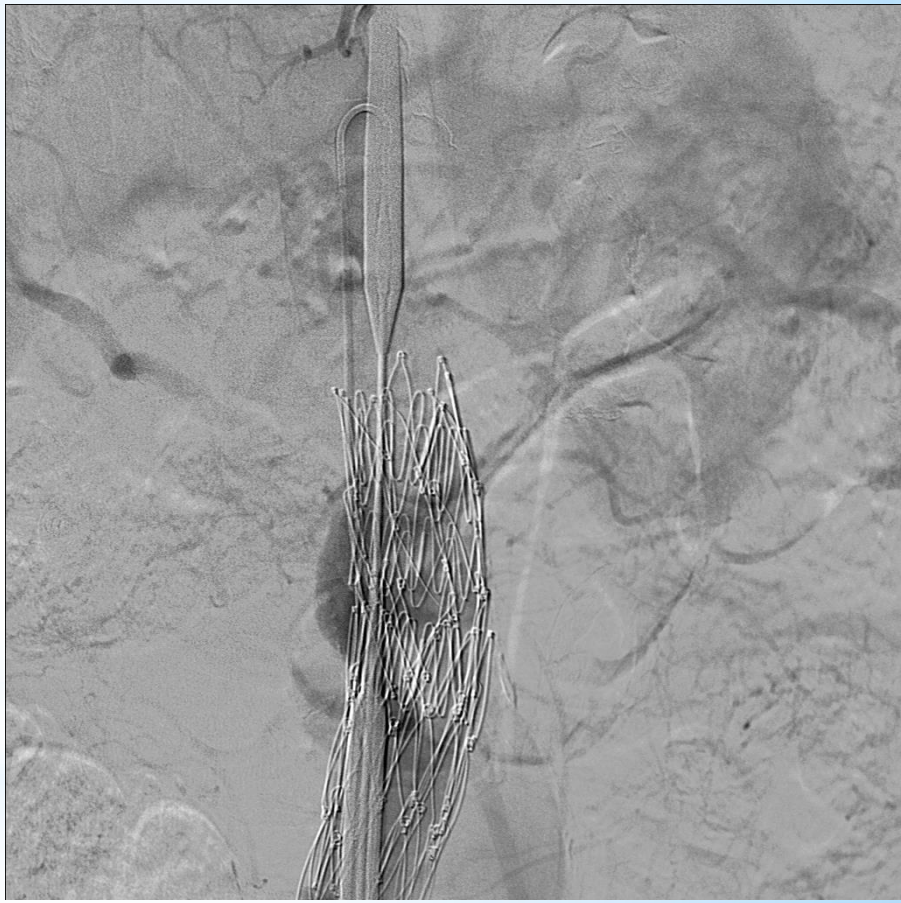

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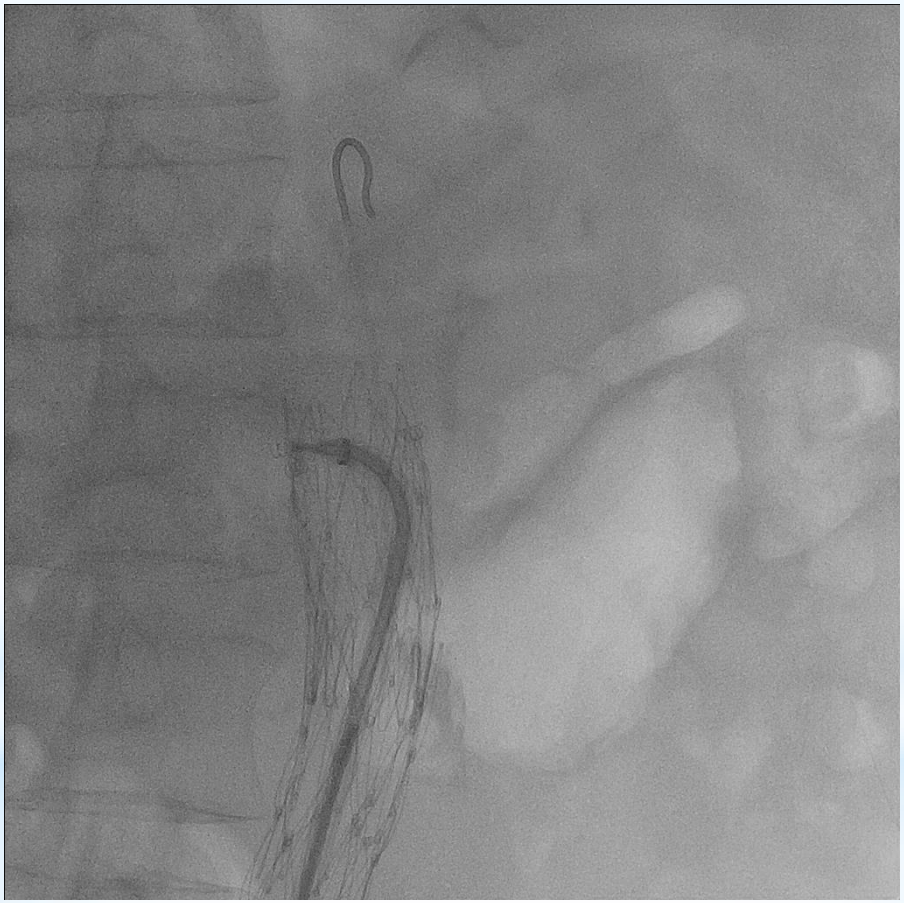

Case Examples