Are low profile devices for EVAR and TEVAR improving or worsening outcomes

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Veith Symposium 2024

COI Disclosure

Speaker name :

Naoki Fujimura, MD, PhD

I have the following potential conflicts of interest to report:

- ■ Consulting: Cook Medical, and Endologix
- □ Employment in industry
- □ Stockholder of a healthcare company
- □ Owner of a healthcare company
- ■ Honorarium: BD, Boston Scientific, Canon, Cook Medical, Cordis, Japan Lifeline, Medtronic, Terumo, and WL Gore.
- □ I do not have any potential conflict of interest

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What can low profile EVAR and TEVAR devices do???

Pros

Helps treat more patients with EVAR and TEVAR

Cons

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What can low profile EVAR and TEVAR devices do???

Pros

Helps treat more patients with EVAR and TEVAR

Cons

possibility of losing structural integrity

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Possibility of losing structural integrity

A preliminary analysis of late structural failures of the Navion stent graft in the treatment of descending thoracic aortic aneurysms

Fabio Verzini, MD, PhD, FEBVS,[a] Enrico Cieri, MD, PhD,[b] Andrea Kahlberg, MD,[c] Yaron Sternbach, MD,[d] Robin Heijmen, MD, PhD,[e] Kenneth Ouriel, MD,[f] Sam Robaina, MS,[g] and Ali Azizzadeh, MD, FACS,[h] *Turin, Perugia, and Milan, Italy; Albany and New York, NY; Nieuwegein, The Netherlands; and Santa Rosa and Los Angeles, Calif*

ABSTRACT

Objective: Patients in the Valiant Evo U.S. and international clinical trials had positive short-term outcomes; however, late structural failures, including type IIIb endoleaks have been recently discovered. Type IIIb endoleaks are serious adverse events because the repressurization of the aneurysm sac increases the risk of rupture. The purpose of the present study was to detail the imaging patterns associated with the structural failures with the aim of increasing awareness of failing graft presentation, early recognition, and prompt treatment.

Methods: The Valiant Evo clinical trial was a prospective, single-arm investigation of a thoracic stent graft system. With the recent late structural failures, sites were requested to submit all available imaging studies to date to allow the core laboratory to assess for structural failures such as type IIIb endoleaks, stent ring fractures, and stent ring enlargement. Of the 100 patients originally enrolled in the trial from 2016 to 2018, the core laboratory assessed the imaging studies performed at ≥1 year for 83 patients.

Results: No structural failures of the graft were reported through 1 year of follow-up. At 1 to 4 years, graft structural failures were detected in 11 patients with descending thoracic aortic aneurysms. Of the 11 patients, 5 had a type IIIb endoleak. Four of the five had imaging findings showing stent fractures consistent with the location of the graft seam and one had a type IIIb endoleak attributed to calcium erosion with no stent fracture or ring enlargement. Of the four patients with stent fracture in line with the graft seam, three underwent a relining procedure that successfully excluded the type IIIb endoleak. One of these three patients died 4 days later of suspected thoracic aortic rupture because the distal thoracic endovascular aortic repair extension had been landed in a previously dissected and fragile section of the aorta. The remaining six patients had had stent ring enlargement. One of the six patients had had persistent aneurysm expansion from the time of implantation onward and had died of unknown causes. The remaining five patients have continued to be monitored.

Conclusions: In the present preliminary analysis, the imaging patterns associated with type IIIb endoleaks, stent fractures, and stent ring enlargement appear to be related to the loss of seam integrity or detachment of the stent rings from the surface of the graft material. The imaging patterns we have detailed should be closely monitored using computed tomography angiography surveillance to allow structural failures to be promptly identified and treated. (J Vasc Surg 2021;74:1125-34.)

Keywords: Endoleak; Stent graft fracture; TEVAR; Thoracic aneurysm; Thoracic endovascular aortic repair; Thoracic stent graft; Type IIIb endoleak

Increased incidence of type 3b endoleak leading to recall…

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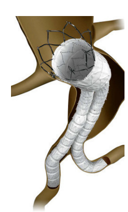
Possibility of losing structural integrity for EVAR devices



Able to treat more patients
=
Used in "tough" iliac anatomy

Low profile EVAR devices can lead to limb complications !!

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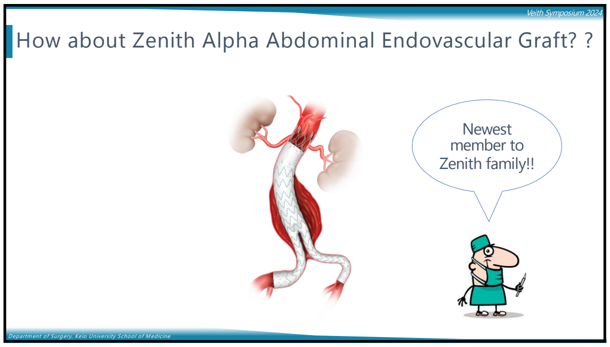
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How about Zenith Alpha Abdominal Endovascular Graft? ?
Newest member to Zenith family!!
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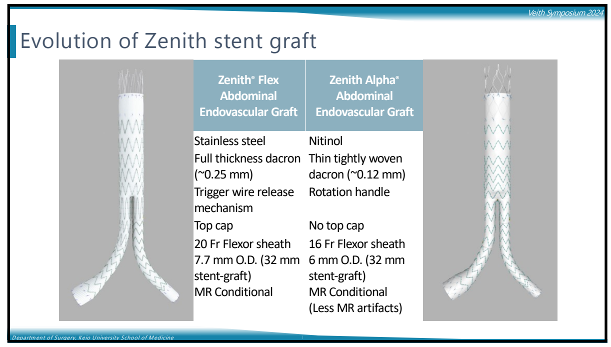
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Evolution of Zenith stent graft
Zenith® Flex Abdominal Endovascular Graft
Zenith Alpha® Abdominal Endovascular Graft
Stainless steel
Nitinol
Full thickness dacron (~0.25 mm)
Thin tightly woven dacron (~0.12 mm)
Trigger wire release mechanism
Rotation handle
Top cap
No top cap
20 Fr Flexor sheath
16 Fr Flexor sheath
7.7 mm O.D. (32 mm stent-graft)
6 mm O.D. (32 mm stent-graft)
MR Conditional
MR Conditional (Less MR artifacts)
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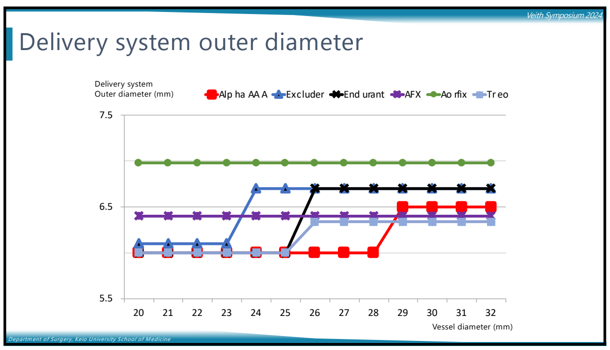
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Delivery system outer diameter
Delivery system Outer diameter (mm)
Alp ha AA A
Excluder
End urant
AFX
Ao rfix
Tr eo
7.5
6.5
5.5
20 21 22 23 24 25 26 27 28 29 30 31 32
Vessel diameter (mm)
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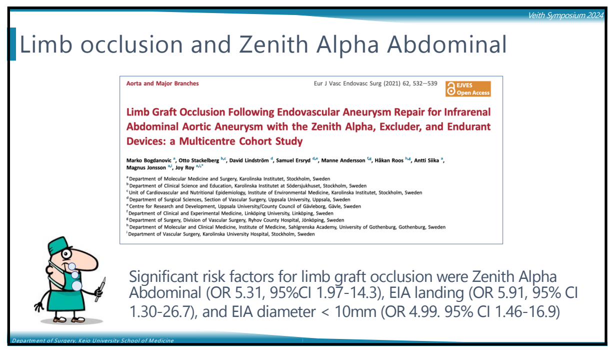
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Limb occlusion and Zenith Alpha Abdominal
Aorta and Major Branches
Eur J Vasc Endovasc Surg (2021) 62, 532–539
EJVES Open Access
Limb Graft Occlusion Following Endovascular Aneurysm Repair for Infrarenal Abdominal Aortic Aneurysm with the Zenith Alpha, Excluder, and Endurant Devices: a Multicentre Cohort Study
Marko Bogdanovic [a], Otto Stackelberg [b,c], David Lindström [d], Samuel Ersryd [d,e], Manne Andersson [f,g], Håkan Roos [h,g], Antti Siika [a], Magnus Jonsson [a,i], Joy Roy [a,i,*]
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[b] Department of Clinical Science and Education, Karolinska Institutet at Södersjukhuset, Stockholm, Sweden
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[d] Department of Surgical Sciences, Section of Vascular Surgery, Uppsala University, Uppsala, Sweden
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[h] Department of Molecular and Clinical Medicine, Institute of Medicine, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden
[i] Department of Vascular Surgery, Karolinska University Hospital, Stockholm, Sweden
Significant risk factors for limb graft occlusion were Zenith Alpha Abdominal (OR 5.31, 95%CI 1.97-14.3), EIA landing (OR 5.91, 95% CI 1.30-26.7), and EIA diameter < 10mm (OR 4.99. 95% CI 1.46-16.9)
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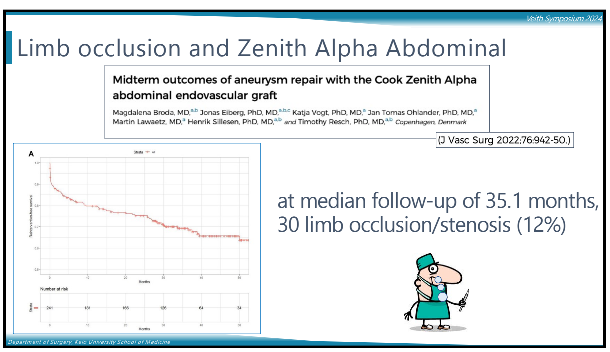
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Limb occlusion and Zenith Alpha Abdominal
Midterm outcomes of aneurysm repair with the Cook Zenith Alpha abdominal endovascular graft
Magdalena Broda, MD,[a,b] Jonas Eiberg, PhD, MD,[a,b,c] Katja Vogt, PhD, MD,[a] Jan Tomas Ohlander, PhD, MD,[a] Martin Lawaetz, MD,[a] Henrik Sillesen, PhD, MD,[a,b] and Timothy Resch, PhD, MD,[a,b] Copenhagen, Denmark
(J Vasc Surg 2022;76:942-50.)
A
Strata All
Number at risk
Months
at median follow-up of 35.1 months, 30 limb occlusion/stenosis (12%)
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JUSTICE Registry
(Japanese prospective multicenter study to evaluate Zenith Alpha Abdominal stentgraft for abdominal aortic aneurysm)
From July, 2020 to October, 2021
23 Japanese hospitals
147 patients enrolled!!
Prospective observational study with core lab analysis
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JUSTICE registry 12 months results

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12 months results from JUSTICE registry

ENDOVASCULAR THERAPY

Clinical Investigation

Early Clinical Results From the Japanese Prospective Multicenter Study to Evaluate Zenith Alpha Abdominal Stent Graft for Abdominal Aortic Aneurysm (JUSTICE) Registry Demonstrate Acceptable Limb Patency at 12 Months

Naoki Fujimura, MD, PhD, Shigeo Ichihashi, MD, PhD, Tsuyoshi Shibata, MD, PhD, Hitoshi Matsumura, MD, PhD, Michiko Watanabe, MD, PhD, Noriyasu Morikage, MD, PhD, Yoshihiko Kurimoto, MD, PhD, Hiroshi Banno, MD, PhD, Hidetoshi Uchiyama, MD, and Hideaki Obara, MD, PhD

Abstract

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JUSTICE registry 12 months results

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As long as it is used cautiously, low profile Zenith Alpha Abdominal can achieve,,,

Only 1 type 1a endoleak

12 months freedom from late complications: 93.5%

12 months aneurysm sac regression: 30.1%

5 limb events (3.4%)

High incidence of type 2 endoleak (35.2%) ??

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Patients' demographics and characteristics

Variable	Number of patients (%) (N = 147)
Age[a]	76.5 ± 7.7
Male	124 (84.4%)
AAA diameter[a] (cm)	52.4 ± 9.2
Hypertension	118 (80.3%)
Diabetes mellitus	36 (24.5%)
Chronic kidney disease (eGFR < 59 ml/min)	57 (38.8%)
Coronary artery disease	49 (33.3%)
Cerebrovascular disease	26 (17.7%)
Chronic obstructive pulmonary disease	41 (27.9%)
History of smoking[b]	121 (82.3%)
ASA>3	55 (37.4%)
Antiplatelet therapy	63 (42.9%)
Anticoagulant therapy	23 (15.6%)

•Continuous data are shown as the mean ± standard deviation.
•Includes current and former smokers.

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Anatomical characteristics

Variable	Num. of patients (%) N = 147
Outside IFU	76 (51.7%)
Proximal neck diameter[a] (mm)	22.8 ± 3.1
Proximal neck length[a] (mm)	39.9 ± 15.5
Proximal neck angle[a] (°)	32.7 ± 21.4
Suprarenal aorta angle[a] (°)	21.0 ± 15.8
Right CIA maximum diameter[a] (mm)	18.2 ± 6.8
Left CIA maximum diameter[a] (mm)	16.8 ± 3.9
Right CIA length	39.0 ± 15.2
Left CIA length	42.4 ± 17.0
Right EIA minimum diameter[a] (mm)	6.3 ± 1.4
Left EIA minimum diameter[a] (mm)	6.4 ± 1.3
Shaggy aorta	15 (10.2%)
Proximal neck calcification and thrombus	27 (18.8%)

Variable	Num. of pts (%) N = 147
IFU violation	76 (51.7%)
Proximal neck related	53 (36.1%)
Poor access (bil < 6 mm)	27 (18.4%)
Bilateral IIA embolization	8 (5.4%)

Continuous data are shown as the mean ± standard deviation

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Operative results

Variable		Num. of patients (%) N = 147
Operative time[a] (min)		140.9 ± 48.8
Percutaneous approach		68 (46.3%)
Hypogastric embolization		35 (23.8%)
Blood transfusion		11 (7.5%)
Intraoperative endoleaks	Type 1 / 3	1 (0.7%)
	Type 2	22 (15.0%)
	Type 4	38 (25.9%)
Intraoperative complications[b]		6 (4.1%)
Intraoperative additional treatments		62 (42.2%)

a. Continuous data are shown as the mean ± standard deviation.

b. Intraoperative complications include 1 unintentional RA coverage, 1 unintentional IIA coverage, 2 EIA dissections, 1 CFA injury, and 1 distal embolization.

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Intraoperative additional treatments

Variable	Number of patients N = 147
IMA embolization	37 (25.2%)
EIA bare nitinol stent placement	19 (12.9%)
LA embolization	14 (9.5%)
Aneurysm sac embolization using NBCA	8 (5.4%)
Distal limb extension[a]	6 (4.1%)
Proximal cuff extension	2 (1.4%)
CFA balloon angioplasty	1 (0.7%)
Renal artery stenting	1 (0.7%)
Kilt technique	1 (0.7%)

CFA, common femoral artery, EIA, external iliac artery, IMA, Inferior mesenteric artery, LA, lumbar artery, NBCA, n-butyl-2-cyanoacrylate

a. Unplanned extension to treat type 1a or 1b endoleak.

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24-months post operative results

Variable		Number of patients N = 147
Late complications[a]		19 (12.9%)
Endoleaks[b]	Type 1a	1 (0.7%)
	Type 1b	0 (0.0%)
	Type 2	52 (35.4%)
	Type 3	0 (0.0%)
	Type 5	3 (2.0%)
Aneurysm sac size change (> 5mm)[c]	Growth	8 (5.4%)
	Regression	51 (34.7%)
Mortality[d]		18 (12.2%)

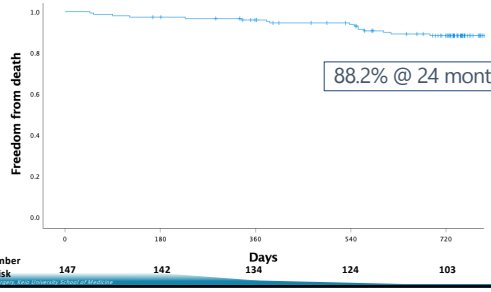
a. Late complications defined as any aneurysm related event and reinterventions > 30 days, which include 4 limb occlusions, 3 limb stenoses, 1 graft infection, 4 sac enlargements (1 type 2 and 3 type 5), and 7 reinterventions (1 type 1a and 6 type 2 endoleak).

b. Endoleaks in 146 patients with at least 1 CT scan postoperatively.

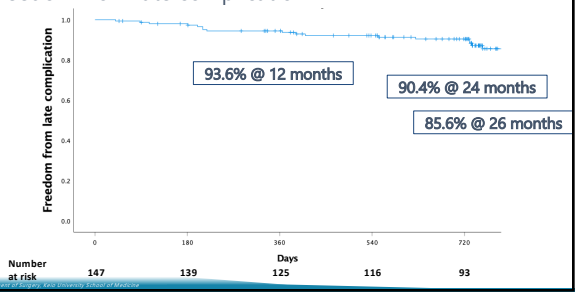
c. CTs were evaluated in 133 patients at 12 months and 116 patients at 24 months.

d. 1 Death due to graft infection and 17 deaths unrelated to the aneurysm

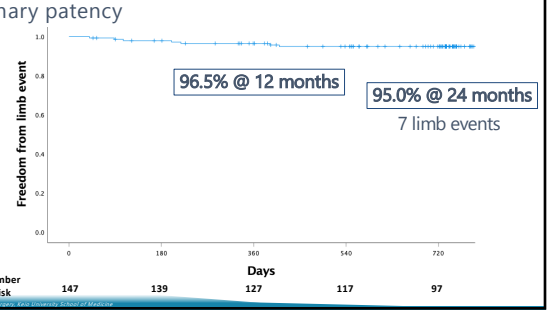
Overall survival



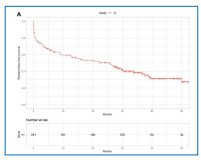
Freedom from late complication



Primary patency

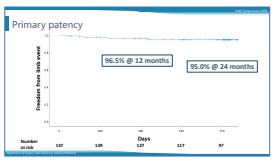


Comparison with other studies



Midterm outcomes of aneurysm repair with the Cook Zenith Alpha abdominal endovascular graft

12% limb occlusion @ 35months



JUSTICE registry

4.7% limb occlusion @ 24 months

Problem with EVAR with low profile device

Used frequently in poor access patients

right limb

- min EIA diameter: 6.3 ± 1.4 mm
- double iliac sign: 45 (30.6%)
- severe calcification: 25 (17.0%)
- rt EIA extension: 27 (18.4%)

left limb

- min EIA diameter: 6.4 ± 1.2 mm
- double iliac sign: 43 (29.3%)
- severe calcification: 30 (20.4%)
- lt EIA extension: 22 (15.0%)

Take home message from JUSTICE registry 24 months results

Only 1 type 1a endoleak

24 months freedom from late complications: 90.4%

24 months aneurysm sac regression: 34.7%

7 limb events (4.7 %)

High incidence of type 2 endoleak (35.4%) ??

At the moment, Alpha AAA seems to be a good solution for patients with challenging iliac anatomy, however, we need to keep an eye on its limb patency

Thank you for your attention !!

25-27 APRIL 2025
GRAND FRONT OSAKA, JAP

Osamu Iida
Masahiko Fujihara

Far Together