5year Results of Viabahn Stent-Graft for Complex Femoropopliteal Lesions: Technical Tips, Advantage and Limitations

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COI Disclosure

Speaker name :

Osamu Iida, MD

I have the following potential conflicts of interest to report:

- ■ Consulting: Boston Scientific, Canon, NIPRO, Terumo
- □ Employment in industry
- □ Stockholder of a healthcare company
- □ Owner of a healthcare company
- ■ Other(s) Honoraria : Medtronic, Boston Scientific, Gore, Terumo, NIPRO, Canon
- □ I do not have any potential conflict of interest

Study Design and Objectives

Purpose

To confirm device efficacy and safety in the clinical setting after the launch of the GORE® VIABAHN® Endoprosthesis for the treatment of symptomatic peripheral arterial disease in the superficial femoral arteries (SFA)

Design

Prospective, multicenter, post-market surveillance study

64 Sites in Japan

321 Subject

5-year Follow-Up.

Methods

Enrollment Period: August 2016 – July 2017

Pre-specified follow-up: 1 month; 1, 2, 3, 4, 5 years

Expected Target Patients: SFA lesions ≥10cm in length with reference vessel diameters ranging from 4.0 to 7.5mm

Primary, Primary-assisted, and Secondary Patency

Limb salvage: Absence of major amputation

Freedom from target lesion revascularization

Clinical improvement: ABI, Rutherford relative to baseline

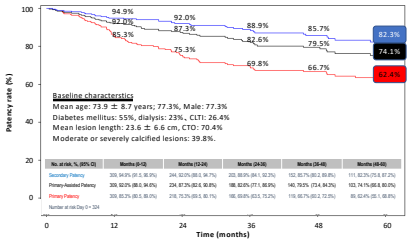
Device safety:

Device- or procedure-related serious adverse events and stent fracture

Procedural Characteristics

Procedural Characteristic	N=324
Target lesions fully covered by VIABAHN	314 (96.9)
Number of devices	562
Device diameter, mm	
5	190 (33.8)
6	289 (51.4)
7	74 (13.2)
8	9 (1.6)
Device length, cm	
2.5	4 (0.7)
5	47 (8.4)
10	107 (19.0)
15	204 (36.3)
25	200 (35.6)

Patency

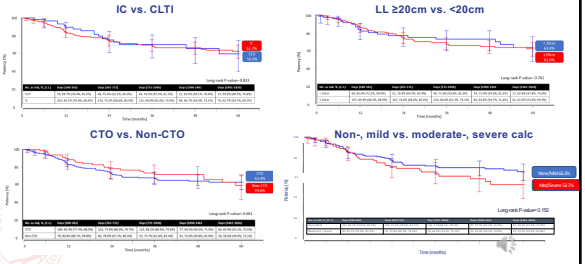


Uni- and Multivariate Analyses

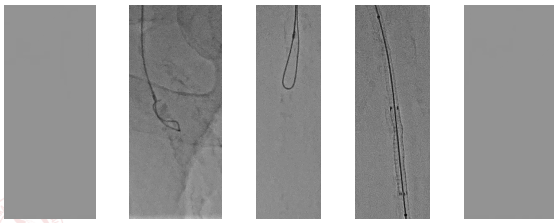
No association with loss of primary patency

Model term	Univariate (log-rank test)	Multivariate (likelihood ratio test)
Lesion length (≥20 cm vs. <20 cm)	0.761	0.871
Calcification (Mild/None vs. Moderate/Severe)	0.152	0.442
Run off (0 vs. 1 vs. 2 vs. 3 vessels)	0.169	-
Hemodialysis (Yes vs. No)	0.075	0.194
Rutherford (CLTI vs. IC)	0.823	0.587
TASC (A/B vs. C/D)	0.605	0.681
Sex (Male vs. Female)	0.439	0.405
Diabetes (Yes vs. No)	0.506	0.516
Proximal vessel diameter (≤5 mm vs. ≥6 mm)	-	0.598
Chronic Total Occlusion	0.601	-

Patency stratified by risk factors

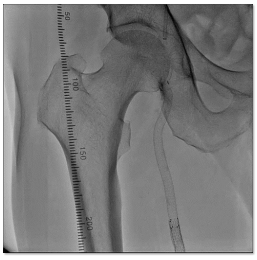


Technical tips of Viabahn stentgraft treatment
-Pave and crack technique for severely calcified FP lesion-



Pave and crack technique is nowadays a standard endovascular strategy for the Tx of severely calcified FP lesion.

Main concern of Viabahn stentgraft: stent thrombosis



How to prevent acute thrombotic occlusion (ATO)?
-Incidence of ATO and its predictors after contemporary FP-EVT-

ATO study design: single center and retrospective analysis

Study subjects: 763 limbs (CLTI: 44%, TASC C/D: 73%, involving popliteal artery: 44%) in 644 patients (age: 75 ± 9 years, HD: 34%)

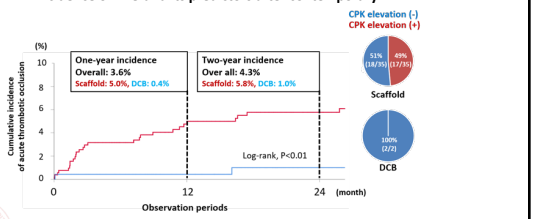
Outcome measure: acute thrombotic occlusion (ATO)

* Definition of ATO: the case with acute onset (<2 weeks) of claudication and/or signs of CLTI in combination with angiographic evidence as well as evidence of occlusive thrombus formation within the stented segment (±5 mm proximal and distal to a stent edge) of the FP lesion.

DCB (drug-coated balloon) n=235 | DCS (drug-coated stent) n=220 | DES (drug-eluting stent) n=150 | SG (stent graft), n=158

How to prevent acute thrombotic occlusion (ATO)?

-Incidence of ATO and its predictors after contemporary FP-EVT-



Overall 12- and 24-month incidence of ATO was significantly higher in the scaffold group than in the DCB group (12-month: 5.0±1.0% vs. 0.4±0.4% at 12-month and 5.8±1.1% vs. 1.0±0.7% at 24-month, respectively; P<.01).

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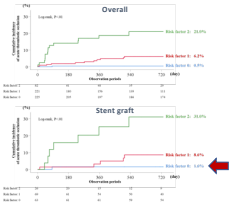
How to prevent acute thrombotic occlusion (ATO)?

-Incidence of ATO and its predictors after contemporary FP-EVT-

Univariable and multivariable analysis for ATO predictors in scaffold group

	Univariable analysis		Multivariable analysis	
	Hazard ratio (95% CI)	P-value	Hazard ratio (95% CI)	P-value
Female gender	0.91 [0.39–2.16]	.84		
Hemodialysis	**3.75 [1.71–8.19]**	**<.01**	**2.63 [1.13–6.09]**	**.02**
CLTI	3.32 [1.49–7.40]	<.01	1.94 [0.86–4.37]	.11
DAPT	1.08 [0.26-4.57]	.92		
TASC II C/D	10.92 [1.48–80.45]	.02	5.98 [0.79–45.06]	.08
Involving popliteal lesion	**13.99 [4.21–46.50]**	**<.01**	**8.22 [2.43–27.84]**	**<.01**
Lesion length	1.04 [0.99–1.08]	.07		
Vessel diameter	0.42 [0.17–1.06]	.07		
PACSS grade 4	2.77 [1.30–5.90]	<.01	1.53 [0.68–3.43]	.30
Stent graft use	2.01 [0.94-4.27]	.07		



The stentgraft was safely used in patients without those risk factors of acute thrombotic occlusion, but a non-scaffolding strategy, including surgical bypass therapy, should be considered for patients with more risk factors.

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Take Home Message

- ✓ **Japan PMS of the Viabahn stent graft study** demonstrated the VIABAHN® Device was associated with high primary patency and fTLR rates through 5-years. Patency outcomes were consistent across varying baseline patient and lesion characteristics.
- ✓ **Retrospective study** reveled that the Viabahn stent graft was safely used in patients without risk factors of acute thrombotic occlusion(dialysis and popliteal lesions) .