

FRONTIER IV – Results from a Fully Absorbable Large Hole Vascular Closure Device in Percutaneous Closure of Large Bore Femoral Punctures

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Background

The current approach to large diameter arterial closure is surgical repair or use of suture-based closure devices. Both techniques have serious limitations resulting in major vascular complications ranging from 5 - 15% as reported in literature.

The PerQseal® (Vivasure Medical Ltd) large hole closure system may offer a useful alternative to surgical or suture-based closure devices.

Objective

The FRONTIER IV study was designed to confirm safety and clinical performance of the PerQseal synthetic patch-based, fully absorbable large hole vascular closure device.

Methods

Design: 75-patient prospective, multi-centred, non-randomized study across 10 European centres.

Cohort: Patients undergoing a trans-femoral procedure using sheath sizes in the range of 12F to 20F.

Analysis conducted on all treated patients, without a roll-in cohort.

Post procedure follow-up assessments: At discharge, 1 and 3 months with ultrasound screening at 3 months.

Primary outcome: Incidence of (peri-procedure to 1-month post-procedure) major vascular complications as defined by VARC-2 criteria.

Secondary outcomes: Incidence of (peri-procedure to 1-month post-procedure) minor vascular complications and the device technical success rate.

Disclosures

Dr Arne Schwindt has no conflicts to disclose

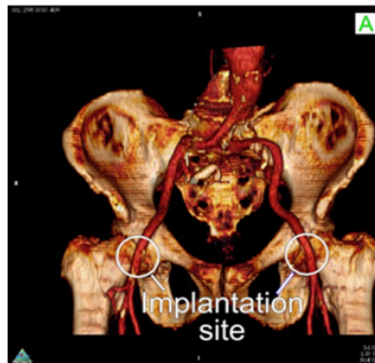
Results

- ▶ One (1%) major procedure related complication (SFA side-stick)
- ▶ Five (6%) minor device related complications (4 x haematoma / bleeding and 1 x pseudo-aneurysm)
- ▶ **No late minor or major device related vascular complications**
- ▶ **No clinically significant changes on ultrasound or CT-angiogram**
- ▶ **96% technical success**

Conclusions

- ▶ The **PerQseal** large bore closure device:
 - ▶ Is **Safe and Efficient** in closing arteriotomies up to 24F
 - ▶ Is **easy to use**
 - ▶ Has **excellent outcomes** from discharge through 1 and 3 month follow up
 - ▶ Provides a **compelling solution for fully percutaneous large hole closure** with reduced complexity and procedure times.

CFA CT Pre-Procedure



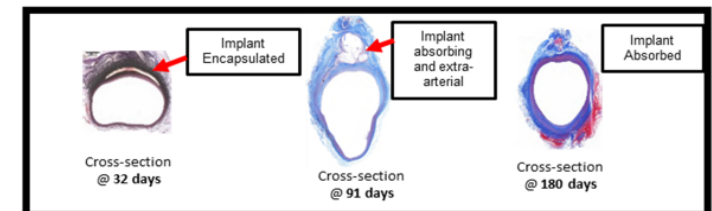
CFA CT 4 days Post-Procedure



Tables

BASELINE CHARACTERISTICS		CLOSURE PROCEDURES	
Patients (n)	75	TAVR (n / %)	41 / 49
Mean Age (years ± SD)	78.7 ± 8.0	EVAR (n / %)	40 / 48
Male gender (%)	61.3	TEVAR (n / %)	3 / 3
Mean Weight (kg ± SD)	80.8 ± 15.3	Total Closures (n)	84
Hypertension (%)	86.7	sheath size < 18F (n / %)	39 / 46
Diabetes mellitus (%)	29.3	sheath size ≥ 18F (n / %)	45 / 54
Peripheral vascular disease (%)	3.0	FOLLOW-UP	
Claudication (%)	1.3	Discharge (n)	74
Previous arterial access procedure in CFA (%)	4.3	1 Months (n)	71
		3 Months (n)	68

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