VASCUPEDIA

i-MEET NEXT GENERATION
Multidisciplinary European Endovascular Therapy

In-stent stenosis in the SFA needs prolonged paclitaxel elution

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Case

- 68y old, male
- CAD, CABG, DM-2, HCL
- BMI: 34
- PAD R4 (symptoms onset about 1 month)
- BMS (Everflex, Medtronic) SFA-3 (2016)
- ABI 0.53

Treatment strategies (CE-certified*)

Chemical block

- Drug-coated balloons (±debulking)

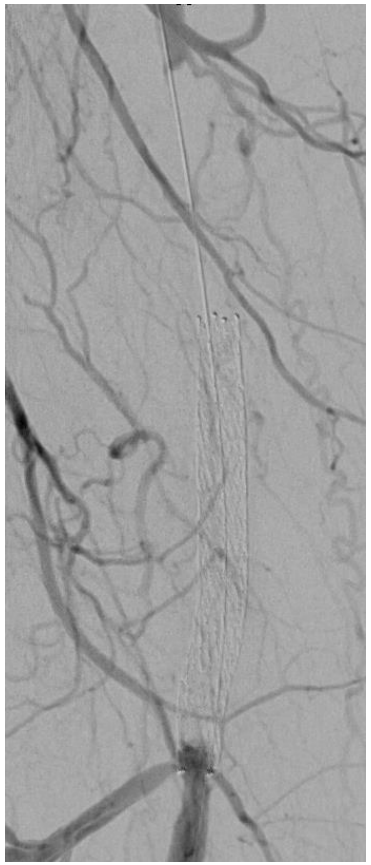
Mechanical block

- Covered stents

Chemical + ‚partially' mechanical block

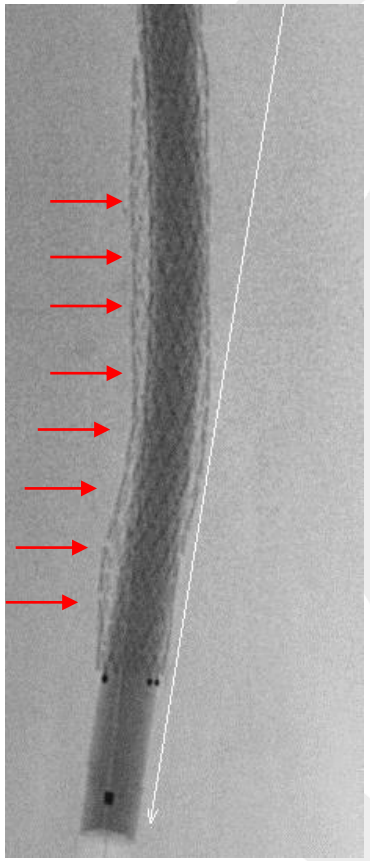
- Drug-coated stents
- Drug-eluting stents

The challenges of in-stent restenosis



Thrombotic material
(TOSAKA III)

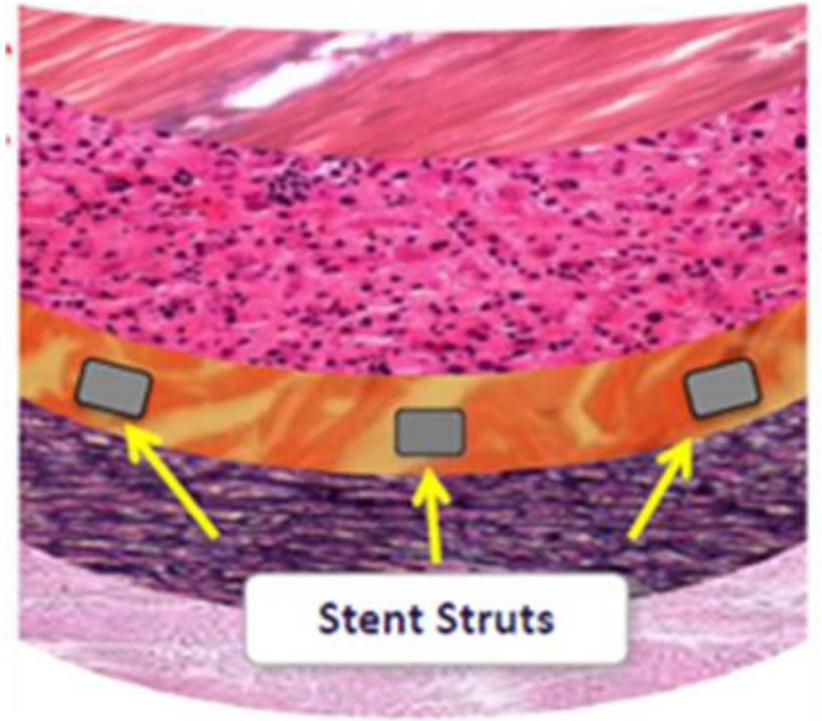
Recoil (spongy intimal layer)
(Post thrombectomy)



Drug-delivery?

Histological findings of ISR

- ISR lesions differ significantly from de novo atherosclerotic lesions
- ISR lesions consist primarily of collagen and smooth muscle cells
- **Innermost intimal layer**: dense smooth muscle cell tissue
- **Outermost intimal layer**: cell-poor scaffold or “sponge” comprised of collagen (RECOIL RISK!)
- **Outermost intimal layer is the largest volume constituent of an in-stent restenotic lesion**



Inoue S, et al J Vasc Surg 2002;35:672-678
Iida O, et al Catheter Cardiovasc Interv 2011;78:611-617

Case

- Access: Right CFA
- Support catheter
  - ➢QuickCross (Philips)
- Control for stent fracture
- Thrombectomy
  - ➢Rotarex (Straub Medical)
  - ➢8F

Rotarex for in-stent occlusions

Rofo. 2011 Oct;183(10):939-44. doi: 10.1055/s-0031-1281634. Epub 2011 Sep 5.

[Treatment of in-stent reocclusions of femoropopliteal arteries with mechanical rotational catheters].

Wissgott C[1], Kamusella P, Andresen R.

Author information

Abstract

PURPOSE: The main problem with the treatment of arterial stenoses by percutaneous transluminal angioplasty (PTA) or stent implantation is the relatively high restenosis rate. The objective of this prospective single-center study was to evaluate a mechanical rotational catheter (Straub Rotarex®) for its safety and efficacy in the treatment of in-stent reocclusions.

MATERIALS AND METHODS: 78 patients with a mean age of 64.2 ± 8.3 years (42 - 85) were treated by means of the Rotarex® catheter. All patients had in-stent reocclusions of the femoropopliteal arteries. The preinterventional Rutherford stage was on average 3.36 (2 - 5). The mean lesion length was 14.7 cm (6 - 30 cm). The ankle-brachial index (ABI) was determined prior to and after the intervention, as well as after 12 months. An additional follow-up was performed using color-coded duplex sonography.

RESULTS: The technical success rate was 97.4 % (76 / 78). In 52 / 76 patients (68.4 %), adjunctive balloon dilation was performed, and 8 / 76 (10.5 %) patients required a stent implantation. Clinically, there was an increase in the ankle-brachial index from 0.61 ± 0.17 to 0.85 ± 0.15 post-interventionally. After 12 months, it was 0.78 ± 0.16, and the average Rutherford stage fell to 1.65 (1 - 3). During the follow-up observation period, there were 14 (18.4 %) restenoses. Two dissections after Rotarex were recorded as peri-interventional complications. No distal embolizations were observed. There were no amputations or deaths during the entire period of the study.

CONCLUSION: The recanalization of in-stent reocclusions of femoropopliteal arteries using the Rotarex® system is safe and effective. The low rate of restenosis at 12 months appears to be promising.

PMID: 21894597 DOI: 10.1055/s-0031-1281634

[Indexed for MEDLINE]

Patency rate @ 1 year:

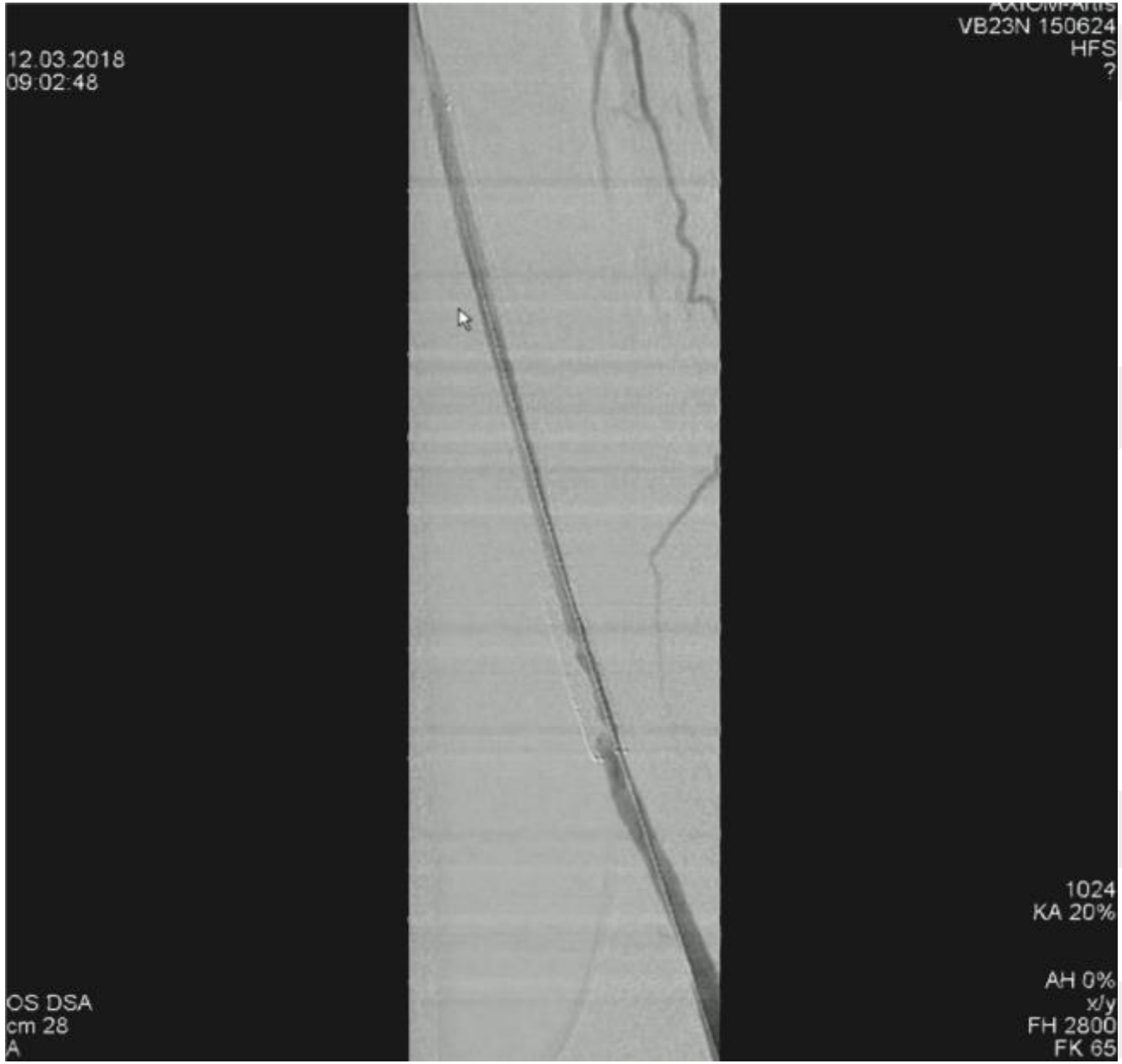
86%

Case

- Access: Right CFA
- Support catheter
  - QuickCross (Philips)
- Control for stent fracture
- Thrombectomy
  - Rotarex (Straub Medical)
  - 8F

Case

- Access: Right CFA
- Support catheter
  - ➢QuickCross (Philips)
- Control for stent fracture
- Thrombectomy
  - ➢Rotarex (Straub Medical)
  - ➢8F



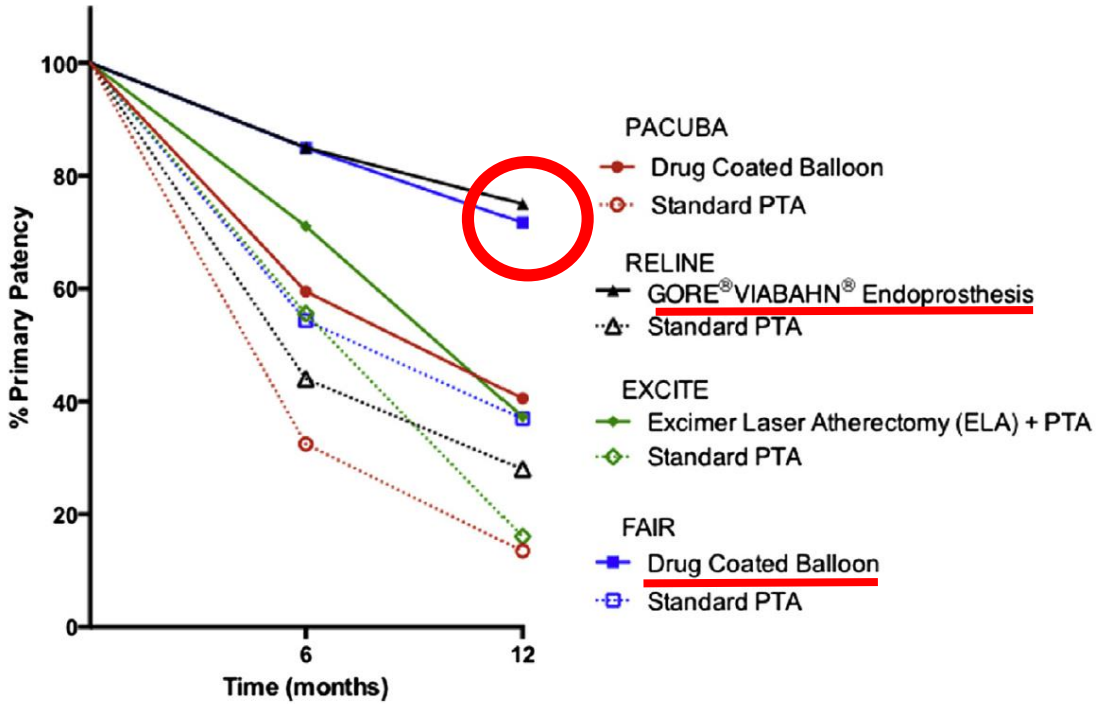
Current evidence

Overview of RCTs until 2016

TABLE 1 Results From 4 Randomized Trials (PACUBA, FAIR, RELINE, EXCITE-ISR) for Superficial Femoral Artery In-Stent Restenosis

Trial	Treatment Arms	N	Mean Lesion Length (cm)	Tosaka III (Occlusions)	TLR 6 Months	TLR 12 Months
PACUBA	DCB	35	17.3	31%	12%	51%
	PTA	39	18.4	28%	16%	78%
FAIR	DCB	62	8.2	24%	4%	9%
	PTA	57	8.1	33%	19%	47%
RELINE	Viabahn	39	17.3	23%	5%	20%
	PTA	44	19.0	25%	35%	58%
EXCITE-ISR	ELA + PTA	169	19.6	31%	20%	57%
	PTA	81	19.3	37%	36%	72%

DCB = drug-coated balloon; ELA = excimer laser atherectomy; PTA = percutaneous transluminal angioplasty; TLR = target lesion revascularization.



Gray B, Buchan J. JACC Cardiovasc Interv 2016:9(13):1393-6

Current evidence

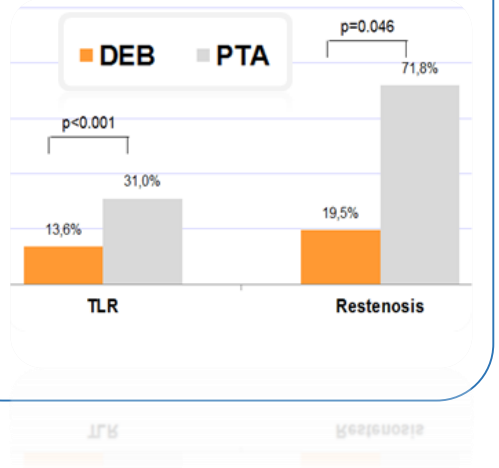
DEBATE-ISR

DEBATE ISR [2]

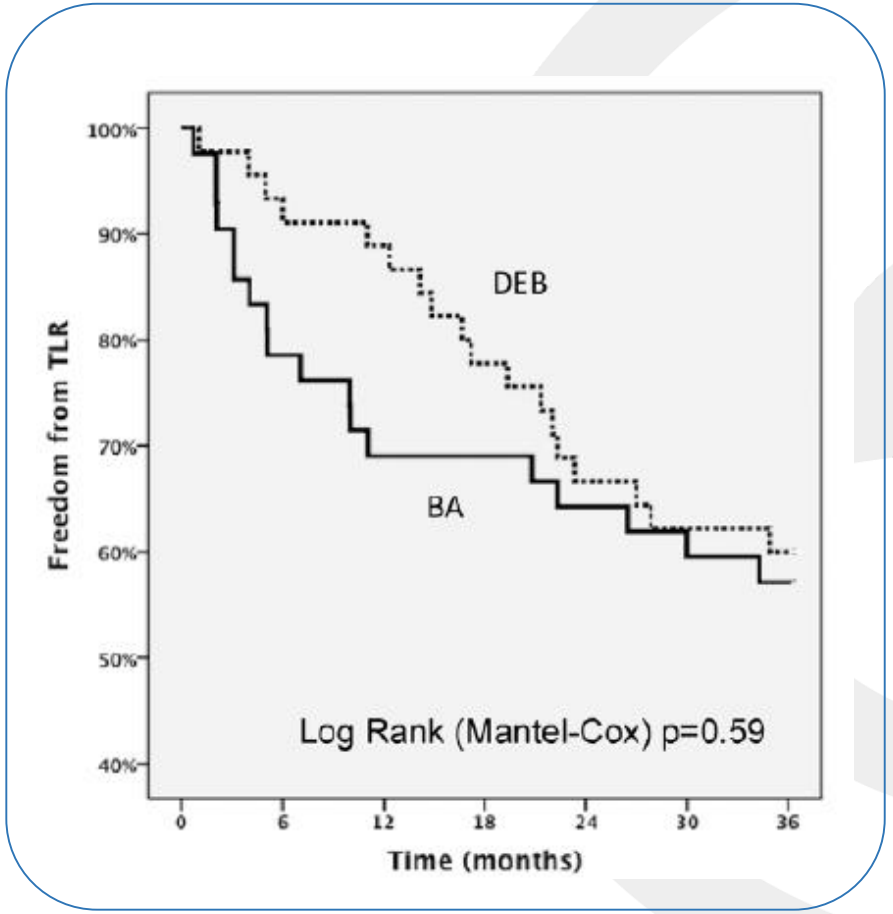
N= 44

100% DM, 75% CLI

ISR length = 13.2 cm



@ 3 years



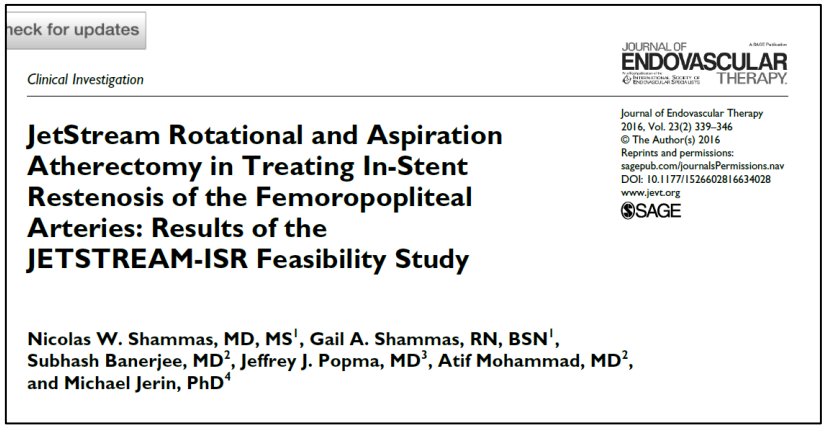
1. Liistro F, Angioli P, Porto I, Ricci L, Ducci K, Grotti S, Falsini G, Ventoruzzo G, Turini F, Bellandi G, Bolognese L. Paclitaxel-eluting balloon vs. standard angioplasty to reduce recurrent restenosis in diabetic patients with in-stent restenosis of the superficial femoral and proximal popliteal arteries: the DEBATE-ISR study. J Endovasc Ther. 2014 Feb;21(1):1-8

Current evidence

Other published studies

Study/first author	Devices	Follow-up	F-TLR	Primary patency
Zilver PTX	DES	1 year	81%	79%
Werner et al	Brachytherapy	1 year	NS	80%
Dick et al	Cutting balloon PTA	6 months	59% 64%	35% 27%
Shammas et al Trentmann et al Zeller et al	Directional atherectomy	1 year	66% NS 53%	NS 25% 54%
Laird et al	Laser atherectomy + heparin-coated stent	1 year	83%	48%
Van den Berg et al	Laser atherectomy + DCB	18 months	86%	86%
PLAISIR study	DCB	1 year	90%	84%

JETSTREAM-ISR study



heck for updates

Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY

JetStream Rotational and Aspiration Atherectomy in Treating In-Stent Restenosis of the Femoropopliteal Arteries: Results of the JETSTREAM-ISR Feasibility Study

Journal of Endovascular Therapy
2016, Vol. 23(2) 339–346

DOI: 10.1177/1526602816634028
www.jevt.org
SAGE

Nicolas W. Shammas, MD, MS[1], Gail A. Shammas, RN, BSN[1], Subhash Banerjee, MD[2], Jeffrey J. Popma, MD[3], Atif Mohammad, MD[2], and Michael Jerin, PhD[4]

9% embolization rate
9% bail-out stent rate

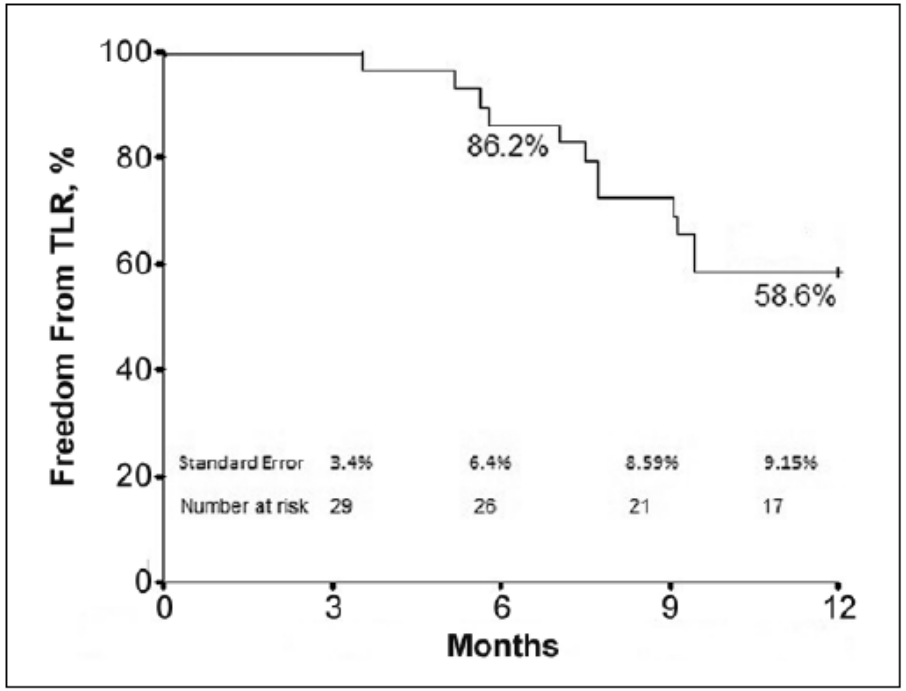


Figure 1. Kaplan-Meier plot (censored for death and loss of follow-up) for freedom from target lesion revascularization (TLR) in limbs treated for femoropopliteal in-stent restenosis using the JetStream XC atherectomy device.

Eluvia stent in complex lesions

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1-Year All-Comers Analysis of the Eluvia Drug-Eluting Stent for Long Femoropopliteal Lesions After Suboptimal Angioplasty

Theodosios Bisdas, MD, Efthymios Beropoulis, MD, Angeliki Argyriou, MD, Giovanni Torsello, MD, Konstantinos Stavroulakis, MD

FIGURE 2 Clinical Improvement in Rutherford Class Between Baseline and Last Follow-Up

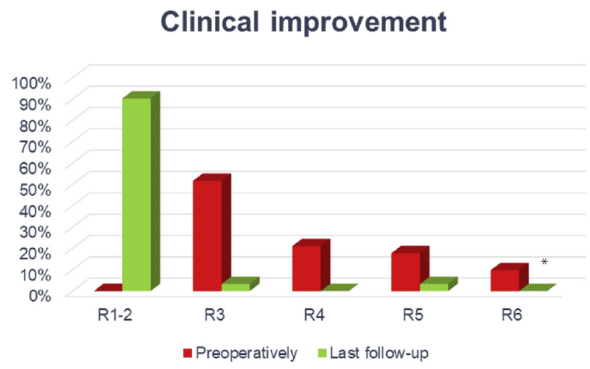
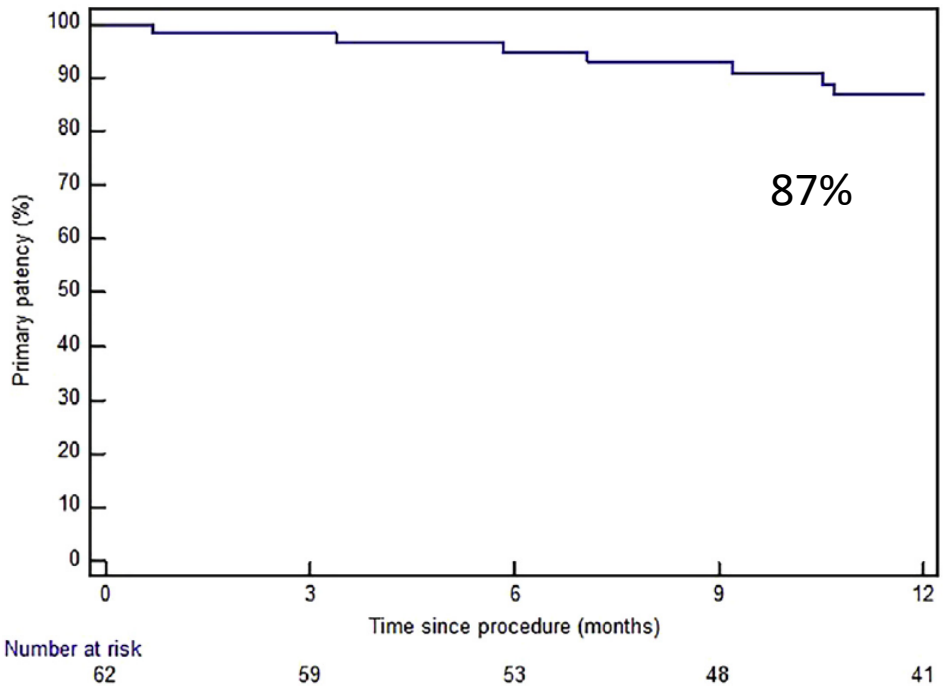


FIGURE 1 Primary Patency at 12 Months



Case

- DES implantation
  Eluvia, Boston Scientific

Case

- DES implantation
  Eluvia, Boston Scientific

Case

- Non-compliant balloon catheter

  (Mustang. Boston Scientific)

Case

- Control angiography

Conclusions

VASCUPEDIA

Topic of July

In-stent restenosis in the SFA

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