



70TH ESCVS CONGRESS & 7TH IMAD MEETING

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70th ESCVS

International congress of the European Society
for Cardiovascular and Endovascular Surgery



7th IMAD meeting



What proves better: surgery or percutaneous atherectomy in extended femoro-popliteal lesions?

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DISCLOSURES

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INTRODUCTION

- Extended or long femoro-popliteal lesions belong to complex lesions, like chronic total occlusions (CTO), in-stent restenosis and heavy calcified diseases.
- Complex femoro-popliteal lesions are common in clinical routine.
- Endovascular treatment of complex lesions is associated with poorer outcomes.

Endovascular treatment of femoropopliteal arterial occlusive disease. Kerzmann A, Boesmans E, Holemans C, Quaniers J, Alexandrescu V, Defraigne JO. Rev Med Liege. 2020 Nov;75(11):717-723.

GUIDELINES

ESVS guidelines for extended femoro-popliteal

Recommendations on revascularization of femoro-popliteal occlusive lesions^c

Recommendations	Class ^a	Level ^b
An endovascular-first strategy is recommended in short (i.e. <25 cm) lesions. ^{302,303}	I	C
Primary stent implantation should be considered in short (i.e. <25 cm) lesions. ^{304,305}	IIa	A
Drug-eluting balloons may be considered in short (i.e. <25 cm) lesions. ^{77,306–310}	IIb	A
Drug-eluting stents may be considered for short (i.e. <25 cm) lesions. ^{302,303,311}	IIb	B
Drug-eluting balloons may be considered for the treatment of in-stent restenosis. ^{312,313}	IIb	B
In patients who are not at high risk for surgery, bypass surgery is indicated for long (i.e. ≥25 cm) superficial femoral artery lesions when an autologous vein is available and life expectancy is >2 years. ³¹⁴	I	B
The autologous saphenous vein is the conduit of choice for femoro-popliteal bypass. ^{284,315}	I	A
When above-the-knee bypass is indicated, the use of a prosthetic conduit should be considered in the absence of any autologous saphenous vein. ²⁸⁴	IIa	A
In patients unfit for surgery, endovascular therapy may be considered in long (i.e. ≥25 cm) femoro-popliteal lesions. ³¹²	IIb	C

^a Class of recommendation.

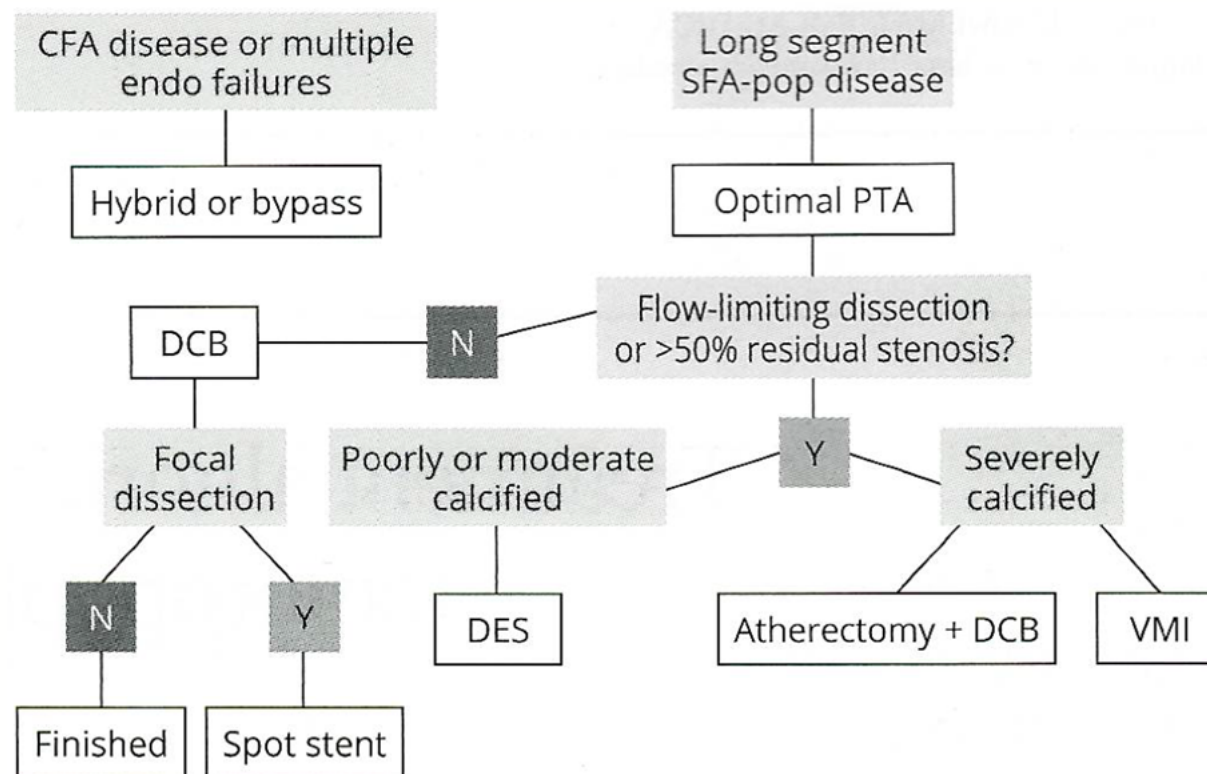
^b Level of evidence.

^c These recommendations apply for patients with intermittent claudication and severe chronic limb ischaemia.

2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS).
Aboyans V, Ricco JB, Bartelink MEL, Björck M, Brodmann M, Cohnert T, Collet JP, Czerny M, De Carlo M, Debus S, Espinola-Klein C, Kahan T, Kownator S, Mazzolai L, Naylor AR, Roffi M, Röther J, Sprynger M, Tendera M, Tepe G, Venermo M, Vlachopoulos C, Desormais I, Document Reviewers, Widimsky P, Kolh P, Agewall S, Bueno H, Coca A, De Borst GJ, Delgado V, Dick F, Erol C, Ferrini M, Kakkos S, Katus HA, Knuuti J, Lindholt J, Mattle H, Pieniazek P, Piepoli MF, Scheinert D, Sievert H, Simpson I, Sulzenko J, Tamargo J, Tokgozoglu L, Torbicki A, Tsakountakis N, Tuñón J, Vega de Ceniga M, Windecker S, Zamorano JL. Eur J Vasc Endovasc Surg. 2018 Mar;55(3):305-368.

GUIDELINES

- Surgery is only recommended in lesions longer than 25 cm in patients not at high operative risk
- Treatment algorithm :



Bosiers M. Treatment algorithm for long segment femoropopliteal disease. J Cardiovasc Surg. 2019;60(5):543-545.



VESSEL PREP

- Vessel preparation is essential to treat percutaneously femoro-popliteal lesions.
- low-trauma balloons
cutting and scoring balloons
atherectomy or debulking
lithotripsy

Bosiers M. Is vessel prep necessary before treating the superficial femoral artery? J Cardiovasc Surg. 2019 Oct;60(5):557-566.



VESSEL PREP

BEST-SFA - **B**est **E**ndovascular **S**trategy for complex lesions of the Superficial **F**emoral **A**rtery comparing a stent-avoiding versus stent-preferred approach

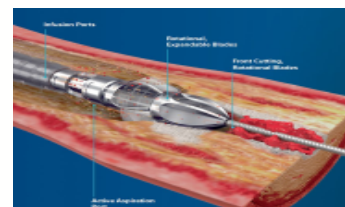
- Exploratory pilot study comparing strategies rather than single devices
- Randomized controlled pilot study comparing stent-avoiding (DCB) vs stent-preferred (DES) strategies encouraging vessel preparation
- 1 year follow-up ongoing (target Q3/2022)

ATHERECTOMY

- Goals :
 - lumen gain
 - vessel compliance
 - drug delivery
 - dissection and bailout stenting prevention

**the
intraluminal !**

- Types :
 - directional
 - hybrid
 - rotational
 - laser
 - orbital



**Wire has to cross
lesion**



PROOFS

- Dissections post atherectomy are grossly under-appreciated (4 to 6 times) on angiogram when compared to IVUS[†].
- The severity of the induced dissections is associated with lower primary patency and higher target lesion revascularization (TLR) rates[‡].

[†]Shammas NW, Torey JT, Shammas WJ, Jones-Miller S, Shammas GA. Intravascular Ultrasound Assessment and Correlation With Angiographic Findings Demonstrating Femoropopliteal Arterial Dissections Post Atherectomy: Results From the iDissection Study. J Invasive Cardiol. 2018 Jul;30(7):240-244.

[‡]Fujihara M, Takahara M, Sasaki S, et al. Angiographic dissection patterns and patency outcomes after balloon angioplasty for superficial femoral artery disease. J Endovasc Ther 2017;24:367-75.



PROOFS

- DCB angioplasty of femoropopliteal artery disease reduces reintervention rates through 5 years compared to percutaneous transluminal angioplasty (PTA).
- Real-world data from the IN.PACT Global study confirmed the 5-year safety and effectiveness of the IN.PACT™ Admiral™ DCB in complex lesions (in-stent restenosis, chronic total occlusions, long lesions).
- However, the use of DCBs alone in long, calcified lesions may be associated with vessel recoil or dissection requiring provisional stenting.
- The use of atherectomy to debulk calcified lesions prior to DCB treatment may facilitate drug diffusion into the vessel wall and provide better outcomes in complex atherosclerotic lesions.



PROOFS

- **Combination of Percutaneous Rotational Thrombectomy and Drug-Coated Balloon for Treatment of Femoropopliteal Artery Nonembolic Occlusion: 12-Month Follow-up**
Qi Wang, Ren-Ming Zhu, Hua-Liang Ren, Rui Leng, Wang-De Zhang, Chun-Min Li.
J Vasc Interv Radiol. 2020 Oct;31(10):1661-1667.
- **Jetstream Atherectomy System treatment of femoropopliteal arteries: Results of the post-market JET Registry**
William A Gray , Lawrence A Garcia, Ali Amin, Nicolas W Shammas, JET Registry Investigators.
Cardiovasc Revasc Med. 2018 Jul;19(5 Pt A):506-511.

SAFETY



PROOFS

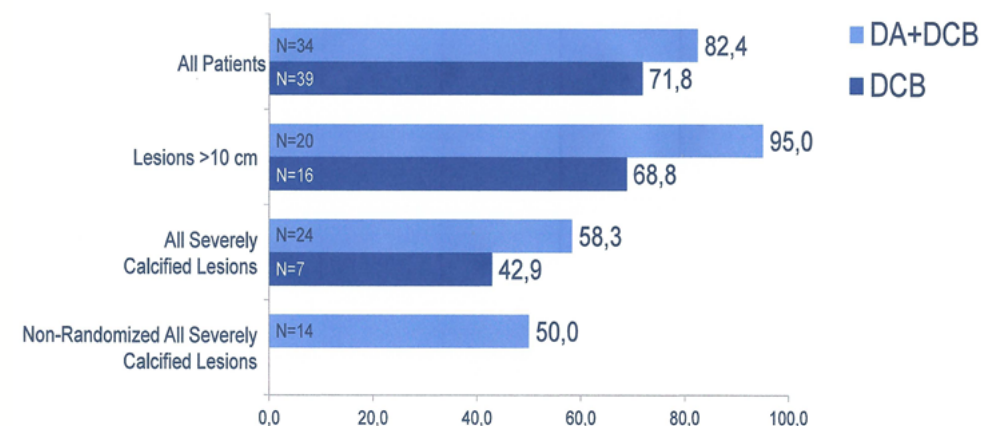
Directional Atherectomy Followed by a Paclitaxel-Coated Balloon to Inhibit Restenosis and Maintain Vessel Patency: Twelve-Month Results of the DEFINITIVE AR Study.

Zeller T, Langhoff R, Rocha-Singh KJ, Jaff MR, Blessing E, Amann-Vesti B, Krzanowski M, Peeters P, Scheinert D, Torsello G, Sixt S, Tepe G; DEFINITIVE AR Investigators.
Circ Cardiovasc Interv. 2017 ; [12-Month Angiographic Patency](#)

- Multicentre RCT
- 10 centres, 121 patients

Longer Lesions Treated in the DA+DCB Arms

Baseline Lesion Characteristics	Randomized		P Value	Severe Ca++
	DA+DCB (n=48)	DCB (n=54)		DA+DCB (n=19)
Lesion Length (cm)	11.2	9.7	0.05	11.9



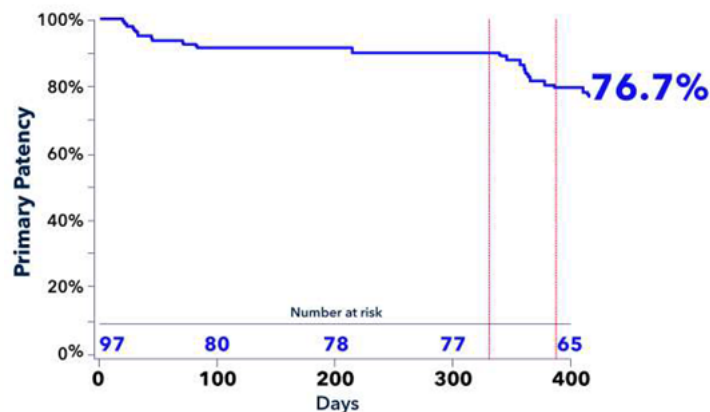
PROOFS

The REALITY study

Zeller T
LINC 2022

- Evaluation of HawkoneTM followed by DCB
- Prospective, non-randomized, single-arm study
- 13 centers, 102 patients
- Primary endpoints:
 - Effectiveness: Primary Patency at 12 months
 - Safety: Freedom from Major Adverse Events (MAE) through 30 days
- Results from a single-center prospective registry (V. Puttaswamy, LINC, 6th June 2022) support the longer-term sustainability of these results, with a 71.4% primary patency rate and 63.8% freedom from CD-TLR through 3 years

Key Lesion & Procedural Characteristics	DA+DCB (n=102)
Lesion Length (mm)	179.4 ± 81.4
Lesion Length ≥ 150mm	55.6%
CTO Length (mm)	226.0 ± 86.0
Provisional Stenting	8.8% (9/102)
Stenting for Perforations (cases)	3
Stenting for Dissection (cases)	5
Stenting for Embolization (cases)	1





PROOFS

A prospective randomized trial on endovascular recanalization with stenting versus remote endarterectomy for the superficial femoral artery total occlusive lesions.

Saaya S, Osipova O, Gostev A, Rabtsun A, Starodubtsev V, Cheban A, Ignatenko P, Karpenko A.
J Vasc Surg. 2022;76(1):158-64.

- Single-center prospective RCT
- 119 recanalization with stenting versus 119 remote endarterectomy
- Mean lesions length ≥ 250 mm in both groups
- All CTOs
- Cumulative primary patency rates 83% versus 82% at 1 year and 28% versus 46% at 4 years (p-value 0,04)
- Endovascular reintervention possible after remote endarterectomy



PROOFS

1-Year Results of a Multicenter Randomized Controlled Trial Comparing Heparin-Bonded Endoluminal to Femoropopliteal Bypass.

Reijnen MMPJ, van Walraven LA, Fritschy WM, Lensvelt MMA, Zeebregts CJ, Lemson MS, Wikkeling ORM, Smeets L, Holewijn S.
JACC Cardiovasc Interv. 2017 Nov 27;10(22):2320-2331.

- Multicenter prospective RCT
- 62 prosthetic surgical bypass versus 63 heparin-bonded endografts
- Mean lesions length 23 cm in both groups
- CTO 80% versus 75%
- Same patency rate
- Less morbidity and quicker improvements in quality of life



PROOFS

Nitinol Stent Versus Bypass in Long Femoropopliteal Lesions: 2-Year Results of a Randomized Controlled Trial.

Enzmann FK, Nierlich P, Aspalter M, Hitzl W, Dabernig W, Hölzenbein T, Ugurluoglu A, Seitelberger R, Linni K.
JACC Cardiovasc Interv. 2019 Dec 23;12(24):2541-2549.

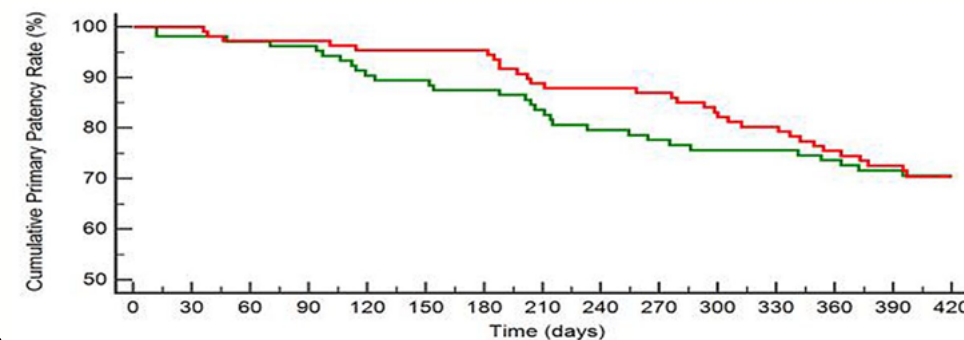
- Single-center prospective RCT
- 55 surgical bypass versus 55 self expandable stents
- Mean lesions length 27 cm
- 49% of chronic limb-threatening ischemia
- Same primary patency, limb salvage, survival and complications rates
- Clinical improvement was significantly better in the bypass group

PROOFS

ZILVERPASS Study: ZILVER PTX Stent vs Bypass Surgery in Femoropopliteal Lesions.

Bosiers M, Setacci C, De Donato G, Torsello G, Silveira PG, Deloose K, Scheinert D, Veroux P, Hendriks J, Maene L, Keirse K, Navarro T, Callaert J, Eckstein HH, Teßarek J, Giaquinta A, Wauters J.
J Endovasc Ther. 2020 Apr;27(2):287-295.

- Multicenter prospective RCT
- 220 DES versus 113 surgical bypass
- Results at 12 months
- Primary patency rate 74,5% versus 72,5%
- Lower complications rate and shorter hospital stays for DES group



		Baseline	30 days	6MFU	12MFU-D365	12MFU-D395	
ZILVER PTX	Tar	113	109	102	78	74	P = 0.8448
	%	100	100	95.40	74.50	71.60	
BYPASS	Tar	107	104	90	73	70	
	%	100	98.10	87.50	72.50	70.60	

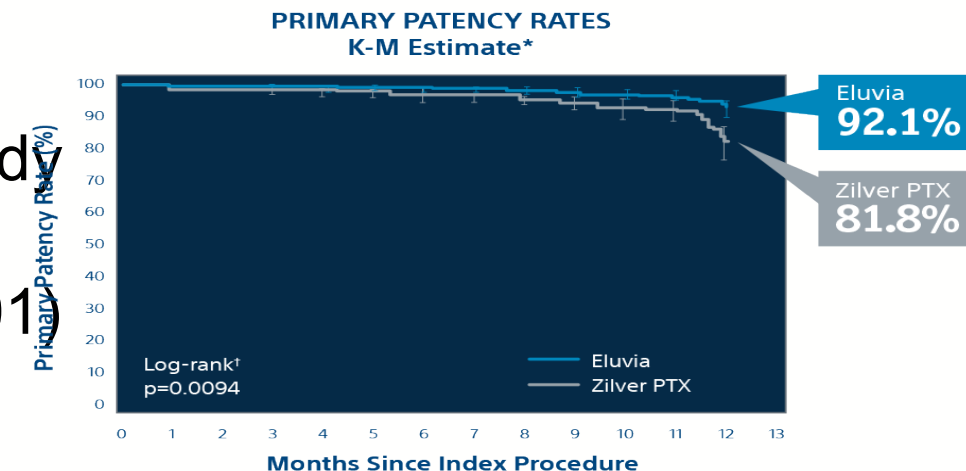
PROOFS

A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial.

Gray WA, Keirse K, Soga Y, Benko A, Babaev A, Yokoi Y, Schroeder H, Prem JT, Holden A, Popma J, Jaff MR, Diaz-Cartelle J, Müller-Hülsbeck S; IMPERIAL investigators.

Lancet. 2018 Oct 27;392(10157):1541-1551.

- Multicentre prospective randomized single-blind study
- 309 Eluvia versus 156 ZilverPTX
- Primary patency rate 86,8 versus 81,5 % ($p < 0,0001$)
- Same MAE and TLR rates

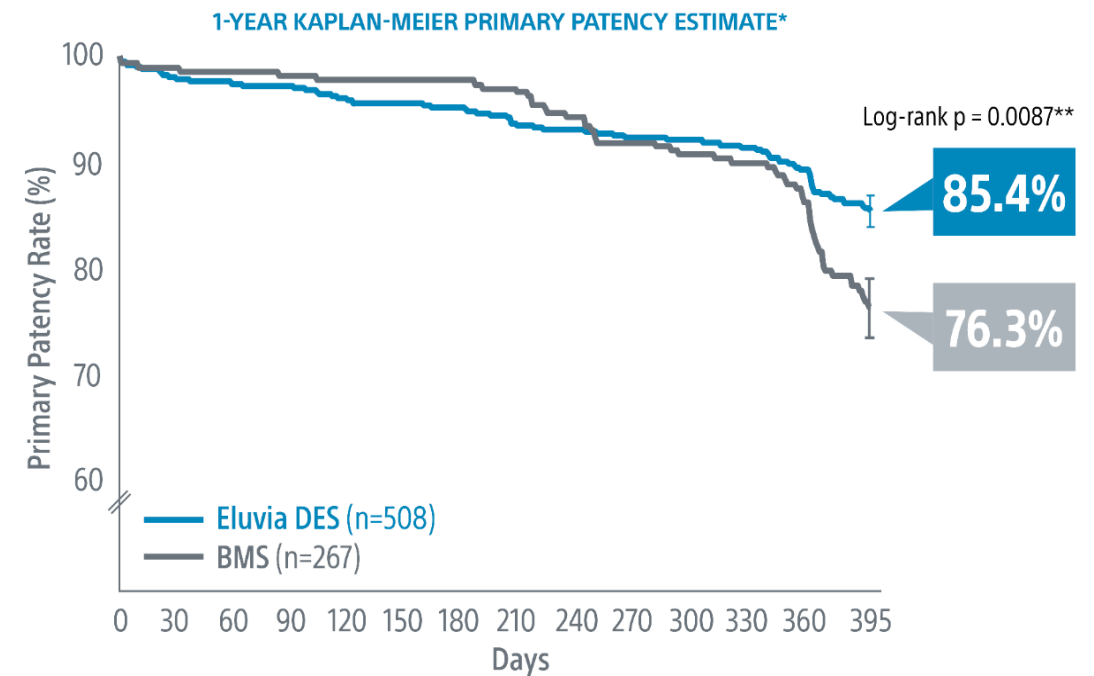


PROOFS

Eminent study

Goueffic Y
VIVA 2021

- Multicentre randomized controlled trial
- 267 bare metal stents versus 508 Eluvia
- at 1 year

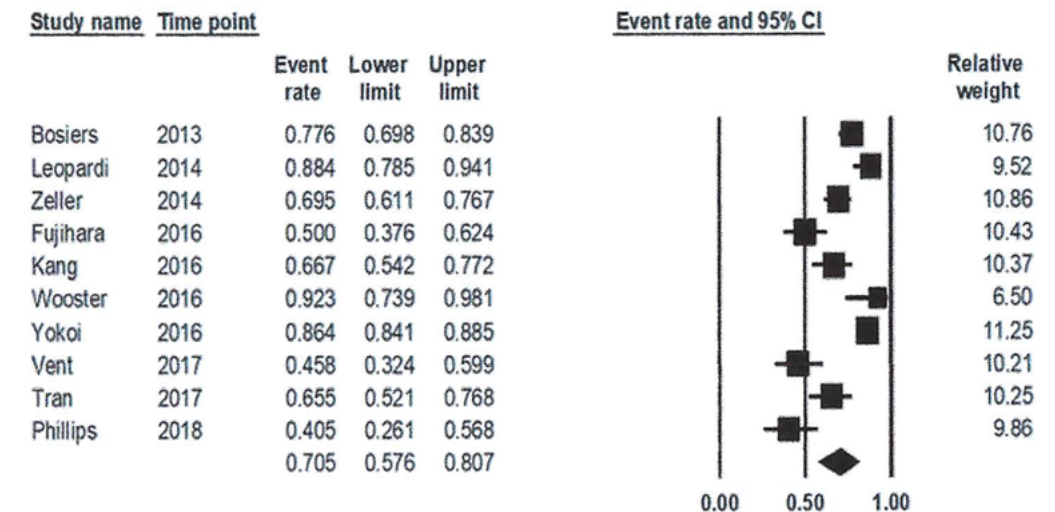


PROOFS

Drug-eluting stents for the treatment of complex femoro-popliteal disease: a systematic review and meta-analysis.

Katsogridakis E, Ballance L, Cawley O, Antoniou GA.
J Cardiovasc Surg. 2022 Jun;63(3):299-307.

- 10 articles, 1539 patients
- TASC C and D
- All Zilver PTX
- Primary patency rate 70,5% at 1 year
- Secondary patency rate 89,8% at 1 year





CONCLUSIONS

- **Endovascular** therapies work as well as open surgery to treat extended femoro-popliteal lesions.
- **Drug eluting** therapies seem to be the best treatment for femoro-popliteal lesions.
- Vessel **preparation** is essential.
- Atherectomy for femoro-popliteal lesions is **safe** if the wire stays **intraluminal**.
- Atherectomy **could enhance** primary patency and TLR rates for complex femoro-popliteal lesions.
- **Bypass surgery** indicated for CLTI patients with low operative risk and