



When Are Polymer Based Paclitaxel Eluting Stents (Eluvia®, Boston Scientific) Superior To Other Endo Treatments For Lower Extremity Lesions

Y. Gouëffic, MD, PhD
*Department of vascular and endovascular surgery
 Groupe Hospitalier Paris Saint Joseph, Paris, France.*







Disclosures

Y. Gouëffic reports:

- Research funding from General Electric, WL Gore, Sensom
- Personal fees and grants from Abbott, BD, Biotronik, Boston Scientific, Cook, General Electric, Medtronic, Penumbra, WL Gore (medical advisory board, educational course, speaking)

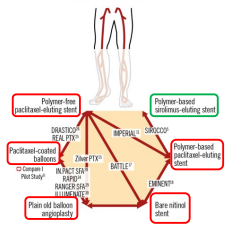
No Association Between Paclitaxel-Coated Device Exposure and Risk of Death (RWD and Pooled Data)




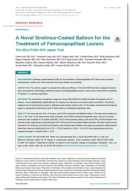


Prakish, Lancet, 2023; Wargny, JACC, 2024

Main Head-to-Head Comparisons were Provided by Paclitaxel Devices

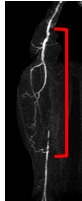






Gouëffic, Brodman, Deboise, Nordandig, Duboisq Lebas, EurIntervention, 2024 Steiner, JACC Interv, 2022 Iida, JACC Interv, 2024

TASC A-B versus TASC C-D lesions



< 15 cm

Define the approach

Cross the lesion

Vessel preparation

Treatment

Reijnen, JACC 2017; Bosiers J Endovasc Surg 2020; Einmann JACC 2019 Duboisq M, Gouëffic Y, Medicina (Kaunas), 2022

TASC A-B Lesions (<15-cm)

DCB reduced late lumen loss, binary restenosis, and TLR compared with POBA alone in the treatment of femoropopliteal disease.

RCTs compared DCB with POBA alone

POBA is not the standard of care anymore

No head to head comparison between DCB and BMS or DES

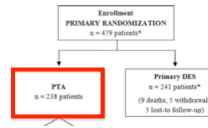
Leaving nothing behind is not based on evidence

Caradu, J Vasc Surg, 2019, Tepe, Circulation, 2014; Rosenfield, NEJM, 2015; Schroeder, Circulation, 2017

Regarding Non Polymer Paclitaxel Eluting Stent

Zilver® PTX® RCT
Zilver PTX vs POBA (n=474)

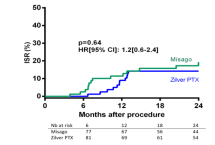
Designed to compare ZILVER® PTX® vs uncoated PTA for femoropopliteal lesions



Dake, Circ Cardiovasc Interv, 2011

BATTLE RCT
Zilver PTX vs MISAGO (n=171)

ZILVER® PTX® failed to show superiority in comparison to MISAGO®



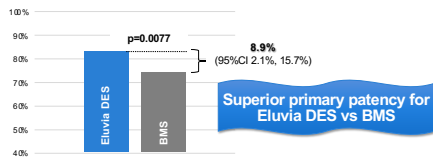
Gouëffec, JACC Interv, 2020

EMINENT Effectiveness | Primary Patency

Primary Endpoint

Statistically significantly greater primary patency in patients treated with Eluvia DES vs BMS

83.2% [337/405] vs 74.3% [165/222]; p=0.0077



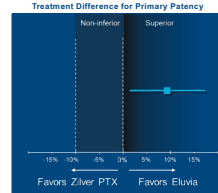
Intention to treat. Primary patency defined as core-lab assessed duplex ultrasound peak systolic velocity ratio (PSVR) ≤ 2.4 at 12 months in the absence of clinically-driven TLR or bypass of the target lesion.

Gouëffec, Circulation, In press

IMPERIAL- Effectiveness: Primary Patency at 12 Months Pre-specified superiority analysis on primary endpoint

Eluvia (N=309)	Zilver PTX (N=156)	Δ (95% CI)	p value
86.8% (243/280)	77.5% (110/142)	9.3% (1.4%, 17.3%)	0.0144

Superior primary patency for Eluvia vs Zilver PTX



IMPERIAL Trial: A global, randomised, controlled, multicentre trial with 2:1 randomisation of the Eluvia® Drug-Eluting Stent against Core Medical's Zilver® PTX® Stent, single-drug, non-elutively design independent core lab adjudication. Superiority measured as both the primary and secondary endpoints. 12-month Primary Patency (PP) in the Eluvia group was 86.8% (95% CI 83.2-90.4) versus 77.5% (95% CI 73.8-81.2) in the Zilver PTX group (p=0.0144). Primary patency defined as duplex ultrasound PSVR ≤ 2.4 at 12 months in the absence of clinically-driven target lesion re-intervention or bypass of the target lesion, as assessed by the Core Lab.

Gray, Lancet, 2018

TASC C-D Lesions (≥15-cm)

BEST SFA

Study Design

OBJECTIVES

To compare a stent-avoiding (SA) vs a stent-preferred (SP) strategy, promoting optimal lesion preparation and the use of drug-eluting technologies in both arms.

DESIGN

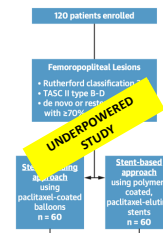
Prospective, randomized (1:1), multicenter, pilot study (no formal sample size calculation or hypothesis testing was performed).

POPULATION

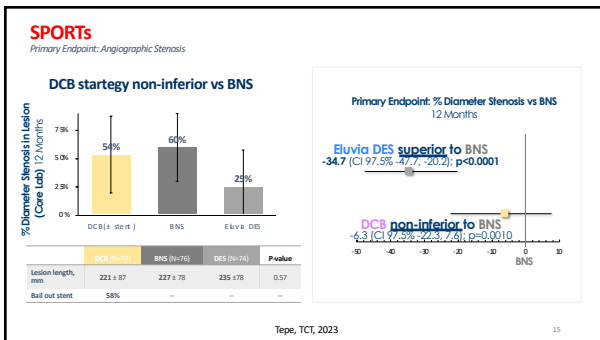
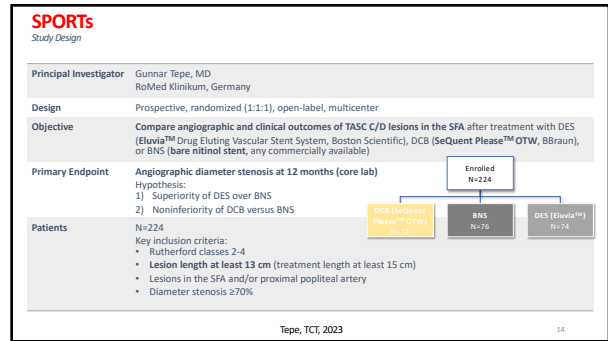
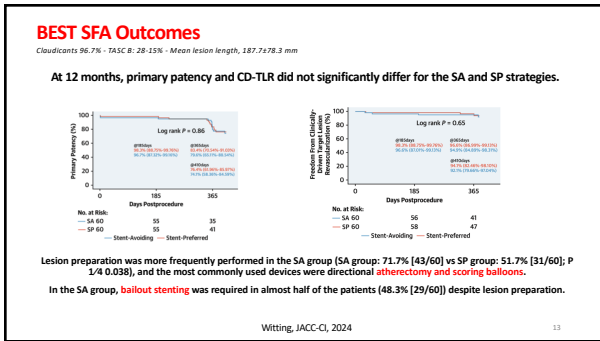
Patients with symptomatic complex femoropopliteal lesions (Rutherford 2-4).

STENT-AVOIDING/STENT PREFERRED

Paclitaxel-coated balloons/polymer-coated paclitaxel-eluting stents. Lesion preparation was at the operators' discretion.



Witting, JACC-CI, 2024



Take Home Message

For short femoropopliteal lesions,
Eluvia DES shows superior 1-year primary patency compared with bare metal stents and non polymer paclitaxel eluting stent.

For long femoropopliteal lesions,
Eluvia DES shows superior 1-year primary patency compared with bare metal stents and paclitaxel coated balloon.

When Are Polymer Based Paclitaxel Eluting Stents (Eluvia®, Boston Scientific) Superior To Other Endo Treatments For Lower Extremity Lesions

Y. Gouëffic, MD, PhD
 Department of vascular and endovascular surgery
 Groupe Hospitalier Paris Saint Joseph, Paris, France.

HÔPITAUX Paris
 Saint-Joseph
 Marie-Lannelongue

