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Eluvia Meta-Analysis

Performance of stenting in femoropopliteal disease: systematic review and meta-analysis of proportions.

OBJECTIVE

Systematically evaluate and analyze outcomes of four common stent types in femoropopliteal artery disease.

STUDY DESIGN

- Systematic literature review and meta-analysis of proportions
- Pooled proportions estimated with random-intercept logistic regression model
- Knapp-Hartung adjustments to calculate the 95% confidence interval around the pooled effect

INCLUSION CRITERIA

- PubMed search January 1, 2009 – July 1, 2024
- Studies of patients treated for SFA lesions or PAD treated with a vascular stent of interest ≥ 50 patients

STUDY SELECTION

- 142 articles
- 52,017 patients
- 27.5% core lab adjudication

STENT TYPES ANALYZED

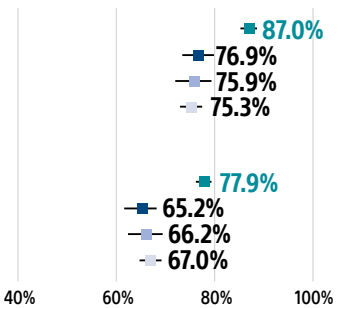
1. **Boston Scientific Eluvia™ Drug-Eluting Stent** (PB-PES: polymer-based paclitaxel eluting stent)
2. **Cook Zilver™ PTX** (PF-PCS: polymer-free paclitaxel-coated stent)
3. **GORE® Viabahn® covered vascular stent graft** (CVS)
4. **Bare Metal Stents: self-expanding nitinol stents, including interwoven stent** (BMS)

Eluvia DES demonstrated consistently greater primary patency and TLR outcomes compared to all other stent types.

Eluvia DES demonstrated consistently greater primary patency and TLR outcomes at 12 and 24 months, compared with Zilver PTX, Viabahn covered stent and self expanding nitinol stents (including interwoven stents) with no difference in mortality rates.

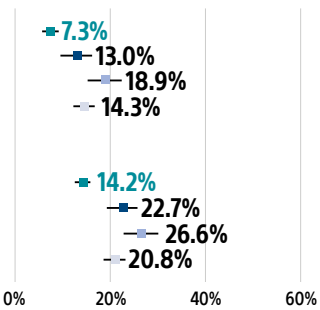
PRIMARY PATENCY

Stent Type	Studies (N)	Population (N)	Pooled Proportions with 95% Confidence Intervals
12 months			
Eluvia DES	17	3063	87.0%
Zilver PTX	34	5209	76.9%
Viabahn	13	1135	75.9%
BMS	93	18,437	75.3%
24 months			
Eluvia DES	9	2065	77.9%
Zilver PTX	17	2344	65.2%
Viabahn	10	913	66.2%
BMS	60	12,334	67.0%



TARGET LESION REVASCULARIZATION

Stent Type	Studies (N)	Population (N)	Pooled Proportions with 95% Confidence Intervals
12 months			
Eluvia DES	14	2892	7.3%
Zilver PTX	24	4740	13.0%
Viabahn	6	619	18.9%
BMS	59	10,138	14.3%
24 months			
Eluvia DES	8	1864	14.2%
Zilver PTX	12	2648	22.7%
Viabahn	5	571	26.6%
BMS	38	5754	20.8%

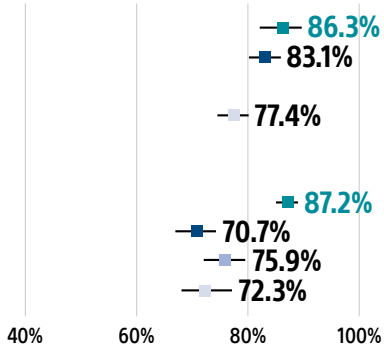


Eluvia DES is the definitive treatment choice for long, complex lesions.

In contrast to comparative stents, Eluvia DES primary patency rates did not decline in long lesions (mean length ≥ 150mm) at 12 and 24 months and remained higher when compared to patency rates of all other stent types.

12-MONTH PRIMARY PATENCY
Short & Long Lesions

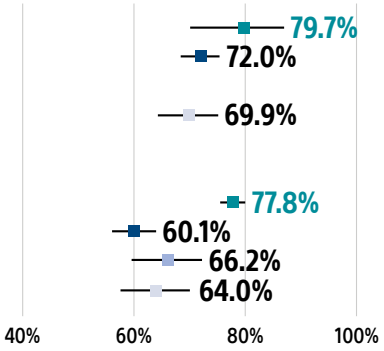
Stent Type	Studies (N)	Population (N)	Pooled Proportions with 95% Confidence Intervals
Short (<150 mm mean length)			
Eluvia DES	5	838	86.3%
Zilver PTX	15	3063	83.1%
Viabahn*	–	–	
BMS	53	11,451	77.4%
Long (≥150 mm mean length)			
Eluvia DES	12	2225	87.2%
Zilver PTX	18	2126	70.7%
Viabahn	13	1135	75.9%
BMS	36	5091	72.3%



*No Viabahn studies in the "short" lesion category.

24-MONTH PRIMARY PATENCY
Short & Long Lesions

Stent Type	Studies (N)	Population (N)	Pooled Proportions with 95% Confidence Intervals
Short (<150 mm mean length)			
Eluvia DES	2	128	79.7%
Zilver PTX	7	1412	72.0%
Viabahn*	–	–	
BMS	30	7554	69.9%
Long (≥150 mm mean length)			
Eluvia DES	7	1937	77.8%
Zilver PTX	10	932	60.1%
Viabahn	10	913	66.2%
BMS	27	4361	64.0%



*No Viabahn studies in the "short" lesion category.

No decline in Eluvia performance between short and long lesion length groups

More pronounced difference between Eluvia and other stent types for long lesions

1. Holden, A. Performance of Stenting in Femoropopliteal Disease: Systematic Literature Review and Meta-analysis of Proportions. Presented at Charing Cross 2025.

ELUVIA Drug-Eluting Vascular Stent System

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE/INDICATIONS FOR USE** The ELUVIA Drug-Eluting Vascular Stent System is indicated for improving luminal diameter in the treatment of symptomatic de-novo or restenotic lesions in the native superficial femoral artery (SFA) and/or proximal popliteal artery with reference vessel diameters (RVD) ranging from 4.0 mm - 6.0 mm and total lesion lengths up to 190 mm. **CONTRAINDICATIONS** • Women who are pregnant, breastfeeding, or plan to become pregnant in the next 5 years should not receive an ELUVIA Drug-Eluting Stent. It is unknown whether paclitaxel will be excreted in human milk, and there is a potential for adverse reaction in nursing infants from paclitaxel exposure. • Patients who cannot receive recommended anti-platelet and/or anti-coagulant therapy. • Patients judged to have a lesion that prevents proper placement of the stent or stent delivery system. **WARNINGS** Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative. For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy. Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications. STERILE – DO NOT RESTERILIZE – SINGLE USE ONLY • The delivery system is not designed for use with power injection systems. • Only advance the stent delivery system over a guidewire. • The stent delivery system is not intended for arterial blood monitoring. • In the event of complications such as infection, pseudoaneurysm or fistula formation, surgical removal of the stent may be required. • Do not remove the thumbwheel lock prior to deployment. Premature removal of the thumbwheel lock may result in an unintended deployment of the stent • It is strongly advised that the treating physician follow the Inter-Society Consensus (TASC II) Guidelines recommendations (or other applicable country guidelines) for antiplatelet therapy pre-procedure to reduce the risk of thrombosis. Post-procedure dual antiplatelet therapy is required for a minimum of 60 days **PRECAUTIONS** • Stenting across a bifurcation or side branch could compromise future diagnostic or therapeutic procedures. • The stent is not designed for repositioning. • Once the stent is partially deployed, it cannot be "recaptured" or "reconstrained" using the stent delivery system. • The stent may cause embolization from the site of the implant down the arterial lumen. • This product should not be used in patients with uncorrected bleeding disorders or patients who cannot receive anticoagulation or antiplatelet aggregation therapy. • Persons with a known hypersensitivity to paclitaxel (or structurally-related compounds), to the polymer or its individual components (see details in Primer Polymer and Drug Matrix Copolymer Carrier section), nickel, or titanium may suffer an allergic response to this implant. • Persons with poor kidney function may not be good candidates for stenting procedures. **POTENTIAL ADVERSE EVENTS** Potential adverse events which may be associated with the use of a peripheral stent include but are not limited to: • Allergic reaction (to drug/polymer, contrast, device or other) • Amputation • Arterial aneurysm • Arteriovenous fistula • Death • Embolization (air, plaque, thrombus, device, tissue, or other) • Hematoma • Hemorrhage (bleeding) • Infection/Sepsis • Ischemia • Need for urgent intervention or surgery • Pseudoaneurysm formation • Renal insufficiency or failure • Restenosis of stented artery • Thrombosis/thrombus • Transient hemodynamic instability (hypotensive/hypertensive episodes) • Vasospasm • Vessel injury, including perforation, trauma, rupture and dissection • Vessel occlusion Probable adverse events not captured above that may be unique to the paclitaxel drug coating: • Allergic/immunologic reaction to drug (paclitaxel or structurally-related compounds) or the polymer stent coating (or its individual components) • Alopecia • Anemia • Gastrointestinal symptoms • Hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia) • Hepatic enzyme changes • Histologic changes in vessel wall, including inflammation, cellular damage or necrosis • Myalgia/Arthralgia • Peripheral neuropathy There may be other potential adverse events that are unforeseen at this time. **92306016 D.4**

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