Updated 5-Year Results Of The IMPERIAL RCT Head To Head Comparison Of The Eluvia DES (Boston Scientific) With The Zilver PTX DES (Cook): Both Are Safe And Effective - What Are The Differences ?

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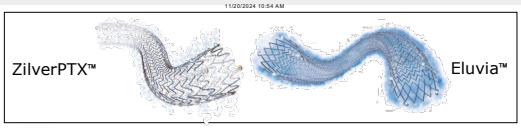

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Disclosure

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I have the following potential conflicts of interest to report:

- ☒ Consulting: Terumo, Alvimedica, Eurocor
- ☐ Employment in industry
- ☒ Stockholder of a healthcare company: Roche, Novartis, Johnson&Johnson, Novonordisk, Amgen, Chugai, Sandoz
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☐ I do not have any potential conflict of interest

Zilver PTX Clinical Evidence - Key Studies

- **Favorable 2-year outcomes** of the Zilver PTX randomized trial[1]
- **Durable superior 5-year primary patency** with polymer-free paclitaxel-coated stents (PF-DCS; Zilver PTX, Cook Corporation) compared with standard balloon angioplasty (lesion length: PF-DCS, 6.6 cm; standard balloon angioplasty, 6.3 cm)[2]
- Although the combination of scaffolding with antiproliferative treatment is assumed to be a good option, notably in long, occluded, and calcified lesions, a **subsequent multistudy model** of PF-DCS identified critical limb-threatening ischemia (CLTI), total occlusion, lesion length, prior intervention, and small reference vessel diameter as **predictors** of target lesion revascularization (**TLR**)[3]

1. Dake MD, et al. J Am Coll Cardiol. 2013 Jun 18;61(24):2417-2427.
2. Dake MD, et al. Circulation. 2016 Apr 12;133(15):1472-83.
3. Dake MD, et al. Cardiovasc Intervent Radiol. 2021;44:196-206.

Eluvia Clinical Evidence - Key Studies

MAJESTIC (2017)[1,2]	IMPERIAL RCT (2018)[3-5]	EMINENT (2022)[6]	Multiple Registries (2018-)[7-12]	SPORTS*	ELEGANCE Registry
• N =57 • Prospective, single arm • First-in-human demonstration of Eluvia DES performance	• N = 465 • RCT Eluvia vs Zilver PTX • **Eluvia demonstrated superior 1-year primary patency** • 5-year follow-up complete	• N = 775 • RCT Eluvia vs BMS • **Eluvia demonstrated superior 1-year primary patency**	• >1600 patients • **Demonstrated consistent Eluvia effectiveness in real-world settings and complex patient populations**	• Up to 222 patients • Eluvia vs DCB vs BMS • Enrollment complete (clinicaltrials.gov NCT03332264)	• Up to 5000 patients • Multicenter registry for RANGER DCB and Eluvia DES • Real-world evidence focused on under-represented minorities and women

1. Müller-Hülsbeck S, et al. J Endovasc Ther. 2014;21(5):701-707.
2. Müller-Hülsbeck S, Cardiovasc Intervent Radiol. 2017;40(12):1832-1838.
3. Gray WA, et al. Lancet. 2018;392(10157):1541-1551.
4. Müller-Hülsbeck S, et al. Cardiovasc Intervent Radiol. 2021;44(3):368-375.
5. Gray WA. CRT 2020. Washington DC.
6. Gouëffic Y, et al. Circulation. 2022;146(21):1564-1576.
7. Stavroulakis K, et al. JACC Cardiovasc Interv. 2021;14(4):492-701.
8. Tonello G. LINC 2023.
9. Holden A. LINC 2020.
10. Kum S. Vasc Med. 2021 Mar 18:1358863X20987894.
11. Ibba G, et al. JACC Cardiovasc Interv. 2022;15(4):430-438.
12. Lansink W. LINC 2023.

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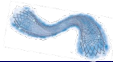

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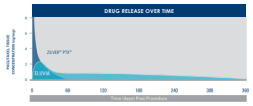
IMPERIAL RCT - Study Devices

	Eluvia™ DES Boston Scientific	Zilver® PTX® Cook Medical	
			
Stent Platform	Innova	Zilver Flex	
Material	Nitinol	Nitinol	
Polymer	Biostable Fluorinated Polymer Matrix (PROMUS polymer)	None	
Drug Dose Density	**Paclitaxel 0.167µg/mm²**	**Paclitaxel 3 µg/mm²**	
Deployment	Self-expanding	Self-expanding	
Sizes	Diameter: 6-7 mm; Length: 40-150 mm	Diameter: 6-8 mm; Length: 40-120 mm	

1st Difference

ELUVIA and ZILVER PTX - Drug Release

Restenosis predominantly occurred within a year following nitinol stenting in the SFA[1]



- Drug release from the Eluvia system is sustained over time >90% of drug is released at 1 year
- Drug release from the Zilver PTX is achieved at 60 days*

2nd Difference

1. Tepe, Cath and Cardiovasc Inte, 2011.
Based on pre-clinical PK analysis. Data on file at Boston Scientific. *Globe MD, et al. J Vasc Interv Radiol. 2011;22(5):603-610.

Safety - IMPERIAL RCT: 5 Years

no Difference

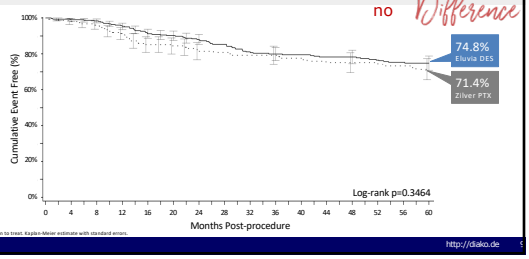
	Eluvia DES (N=309)	Zilver PTX (N=156)	P
All-cause Mortality[a]	**18.8%** (58/309)	**17.9%** (28/156)	0.8294
Target Limb Major Amputation	**3.4%** (8/232)	**2.6%** (3/114)	>0.99
Clinically-Driven TLR	**29.3%** (68/232)	**34.2%** (39/114)	0.3540

No significant differences in 5-year safety measures

[a]Crude rate including all vital status assessments regardless of CEC adjudication.

Freedom from CD-TLR - IMPERIAL RCT: 5 Years

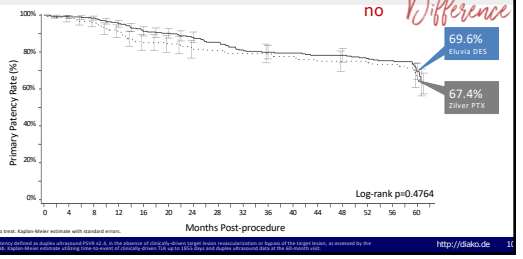
no Difference



Intention to treat. Kaplan-Meier estimate with standard errors.

Primary Patency - IMPERIAL RCT: 5 Years

no Difference



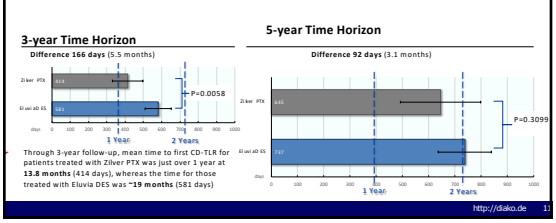
Intention to treat. Kaplan-Meier estimate with standard errors.

Primary patency defined as duplex ultrasound PSVR ≤2.4, in the absence of clinically-driven target lesion revascularization or bypass of the target lesion, as assessed by the DUS core lab. Kaplan-Meier estimate utilizing time-to-event of clinically-driven TLR up to 1854 days and duplex ultrasound data at the 60-month visit.

Time to CD-TLR - IMPERIAL RCT: 5 Years

no Difference

Mean Number of Days to First CD-TLR



Through 3-year follow-up, mean time to first CD-TLR for patients treated with Zilver PTX was just over 1 year at **13.8 months** (414 days), whereas the time for those treated with Eluvia DES was **~19 months** (581 days)

Polymer-based drug-eluting stent treatment extends the time to reintervention for patients with symptomatic femoropopliteal artery disease: clinical evidence and potential economic value RCT: 5 Years

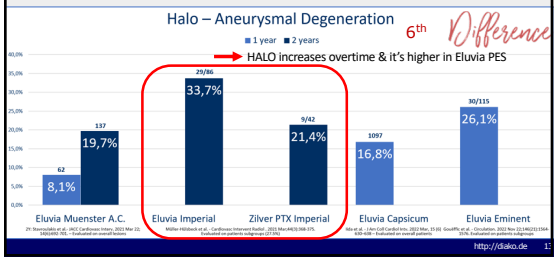
Journal of Comparative Effectiveness Research
J. Comp. Eff. Res. (2024) e240025

William A Gray[*,1,2], Yoshimitsu Soga[3], Masahiko Fujihara[4], Osamu Iida[5], Anvar Babaev[6], Daizo Kawasaki[7], Thomas Zeller[8,9], David O'Connor[6], Michael R Jaff[10], Anna M Chavez[10] & Stefan Müller-Hülsbeck[11]

- Simulated savings considering reinterventions occurring over 1 and 5 years following initial use of Eluvia over Zilver PTX were US $1,395,635 and US $1,531,795, respectively, when IMPERIAL CD-TLR rates were extrapolated to 1000 patients.

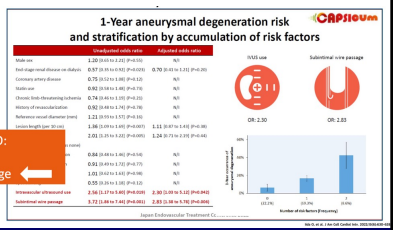
- Conclusion:
- IMPERIAL data suggest initial treatment with Eluvia extends the time patients spend without undergoing reintervention. **This extension may be associated with cost savings in relevant time frames.**

Paclitaxel release linked to HALO ?



Paclitaxel release linked to HALO ?

There was no evidence for an association of aneurysmal degeneration with restenosis (OR: 1.2; *P* = 0.61).

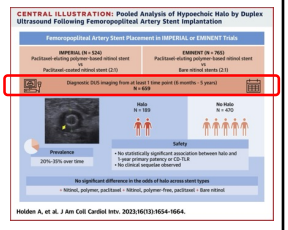


Factors impacting 1y HALO:
1) IVUS usage
2) subintimal wire passage

Hypoechoic Halo Imaging – Pooled analysis from IMPERIAL & EMINENT

- Hypoechoic peri-stent areas in duplex ultrasonography (DUS) (ie, "halo") noted following femoropopliteal artery stenting
  - Pooled analysis of Imperial & Eminent including Eluvia DES, Zilver PTX, BMS
  - Systematic DUS screening with core lab assessment

"…hypoechoic halo following a femoropopliteal stent procedure is a **common occurrence** associated with **all studied stent types**. The presence of a halo appears to be benign with **no associated clinical sequelae** or effect on target vessel revascularization rates within 1 year of stent implantation."



DES in complex lesions: IMPERIAL Long Lesion Sub-Study @ 5 Years

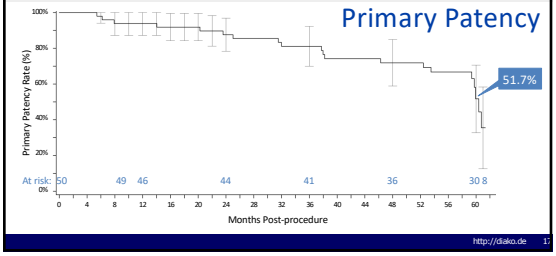
Golzar J, Soga Y, Babaev A, et al. J Endovasc Ther. 2020;27(2):296-303. doi:10.1177/1526602820901723

	Eluvia DES (N=50)
Age (years)	68.2 ± 8.9
Male	64.0%
Diabetes Mellitus	40.0%
Lesion length (mm)	162.8 ± 34.7
Occlusion	32.0%
Calcification	
Moderate	42.0%
Severe	28.0%

	Eluvia DES (N=309)
All-cause Mortality[a]	**26%** (13/50)
Target Limb Major Amputation	**0%** (0/35)
Clinically-Driven TLR	**42.9%** (15/35)

Mean time to first CD-TLR[b] was 876 days (~**29 months**; 95%CI 630, 1122 days)

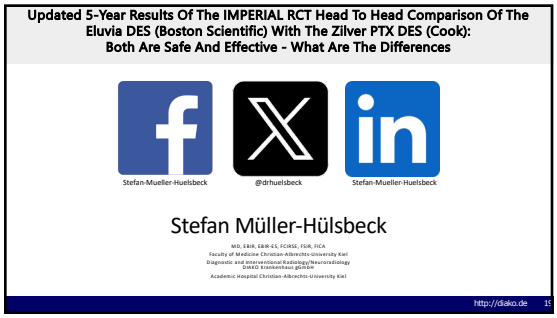
DES in complex lesions: IMPERIAL Long Lesion Sub-Study @ 5 Years



Summary & Conclusions

Eluvia DES & Zilver PTX DES: What Are The Differences ?

- Device: Polymer & drug dose density — 1st Difference
- Drug release over time — 2nd Difference
- HALO increases overtime & it's higher in Eluvia — 3rd Difference
- 5-year safety measures and PP (Eluvia 69.6% vs. Zilver PTX 67.4%) — NO Difference
- A halo appears to be benign with no associated clinical sequelae within the 1st year
- IMPERIAL data suggest treatment with Eluvia DES may delay the need for reintervention ! … this is associated with cost savings in relevant time frames.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