



REAL-World or REAL-Biased?

A Critical Review of REAL-DES

REAL-DES is a prospective, multicenter, observational study across 8 sites in Japan of Zilver PTX and Eluvia. The study is **small** (n=184 patients) with **no core lab adjudication or randomization**.

▶ A REAL SMALL STUDY...

REAL-DES¹⁻³
184 Patients | 8 Sites

Enrolled: 184 Patients

1 Year: 165 Patients

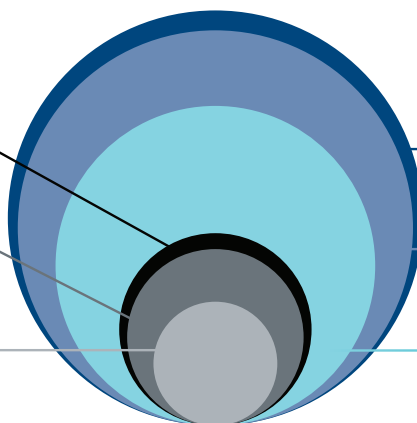
3 Years: 99 Patients

IMPERIAL RCT⁴⁻⁶
465 Patients | 64 Sites

Enrolled: 465 Patients

1 Year: 440 Patients

5 Years: 346 Patients

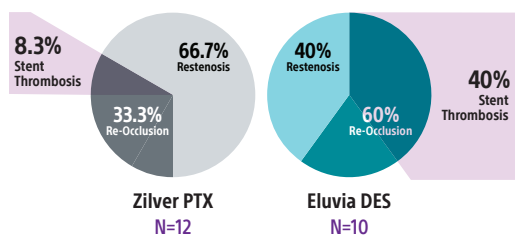


*Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

In REAL-DES, the type of restenosis was presented as a **percentage of reinterventions**, hiding the overall **LOW number of reintervention events**.

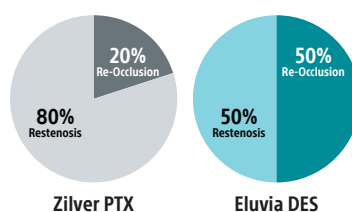
1 YEAR

N = Number of Reinterventions



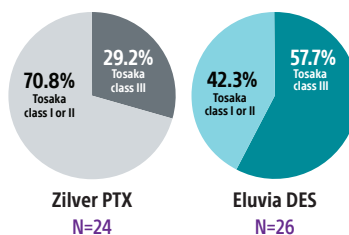
2 YEARS

Number of reinterventions not reported

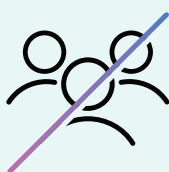


3 YEARS

N = Number of Reinterventions



▶ LACKING RIGOR...



No endpoints were core-lab adjudicated

- Primary patency
- Freedom from CD-TLR
- Type of restenosis



Determination of Tosaka class was based on duplex ultrasound, **a less accurate method** than angiography for determining the pattern of restenosis.

▶ WITH REAL BIAS...

In REAL-DES, a **non-randomized** study, stent selection (Zilver PTX vs. Eluvia) was determined by the operator. Additionally, there is **potential bias** in how Eluvia and Zilver PTX stents were sized.

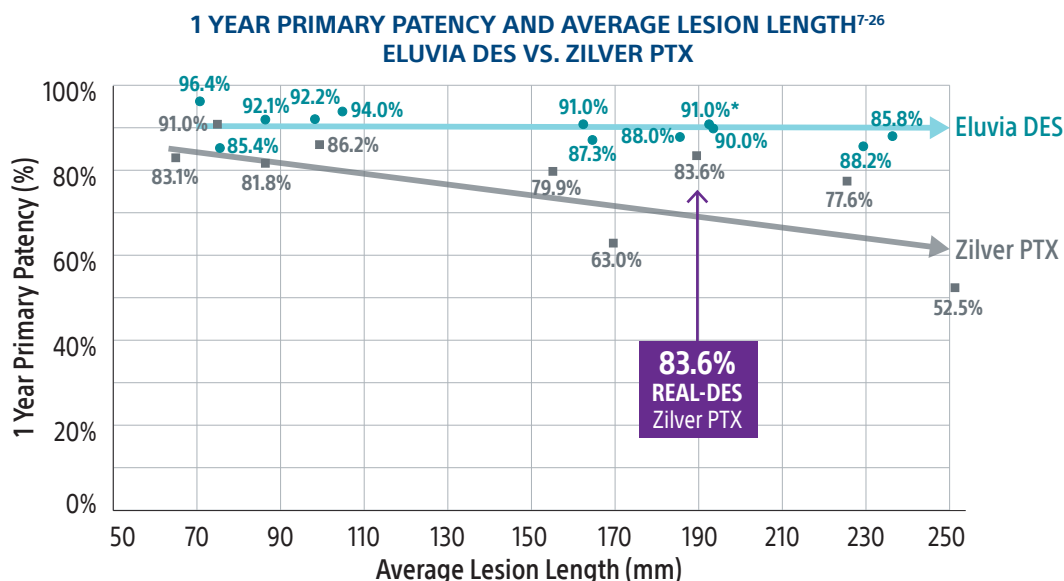
LESION CHARACTERISTICS AND TREATMENT DETAILS

Characteristic	Eluvia (n = 104)	Zilver PTX (n = 96)	P value
Target Vessel Diameter (mm)	5.0 ± 0.8	4.9 ± 0.8	0.82
Pre-dilatation Balloon Diameter (mm)	5.0 ± 0.9	5.3 ± 0.7	0.006
Mean DES Diameter	6.3 ± 0.4	6.9 ± 0.6	< 0.001

Despite **Eluvia patients having a larger average vessel diameter**, pre-dilatation balloon diameter and mean DES diameter were **significantly smaller** for the Eluvia group compared to Zilver PTX.

▶ REAL-DES RESULTS ARE AN ANOMALY FOR ZILVER PTX

REAL-DES **results diverge** from the body of clinical evidence established in the literature for Zilver PTX. Eluvia delivers incredibly consistent, near **90% 1-year primary patency** results across hundreds of patients studied in RCTs and thousands studied in real-world registries*.



ELUVIA 1 YEAR PRIMARY PATENCY

96.4%	MAJESTIC	87.3%	REAL-DES
85.4%	EMINENT RCT	88.0%	CAPSICUM
92.1%	IMPERIAL RCT	91.0%	DESAFINADO
92.2%	REGAL	90.0%	MÜNSTER
94.0%	AUCKLAND	88.2%	SPORTS
91.0%	IMPERIAL LL	85.8%	ULTIMATE

ZILVER PTX 1 YEAR PRIMARY PATENCY

83.1%	ZILVER PTX RCT	63.0%	ZEPHYR* Zilver PTX
91.0%	BATTLE Zilver PTX	83.6%	REAL-DES
81.8%	IMPERIAL ZPTX	77.6%	ZILVER PTX Single-Arm TASC C/D
86.2%	Zilver PTX Single-Arm Clinical Study	52.5%	STELLA-PTX Registry
79.9%	REAL-PTX ZPTX		

1. Shibata T, et al. J Endovasc Ther. 2025;32(2):490-497. 2. Shibata, T. Presented at JET 14 June 2024. 3. Shibata T, et al. Eur J Vasc Endovasc Surg. 2025 Mar 14:S1078-5884(25)00238-2. 4. Gray WA, LINC 2020. 5. Müller-Hulsbeck S, et al. Cardiovasc Intervent Radiol. 2021;44(3):368-375. doi:10.1007/s00270-020-02693-1. 6. Gray WA, et al. J Comp Eff Res. 2024. doi:10.57264/cer-2024-0025
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 *91% corresponds with the DESAFINADO "complete lesion coverage" subgroup.
 7. Müller-Hulsbeck S, et al. Cardiovasc Intervent Radiol. 2017;40(12):1832-1838. 8. Gouëffic Y, et al. Circulation. 2022;146(21):1564-1576. 9. Gray WA, LINC 2020. Lansink W, LINC 2023. 10. Holden A, LINC 2020. 11. Golzar J, et al. J Endovasc Ther. 2020;27(2):296-303. 12. Iida O, et al. Vasc Med. 2024. doi:10.1177/1358863X241228261. 13. Kum S, et al. Vasc Med. 2021;26(3):267-272. 14. Stavroulakis K, et al. JACC Cardiovasc Interv. 2021;14(6):692-701. 15. Ichihashi S, et al. Eur J Vasc Endovasc Surg. 2022;64(4):359-366. 16. Tepe, G. Charing Cross 2025.
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 17. Dake MD, et al. Circulation. 2016 Apr 12;133(15):1472-83. 18. Gouëffic Y, et al. JACC Cardiovasc Interv. 2020 Feb 24;13(4):447-457. 19. Gray WA, LINC, 2020. 20. Dake MD, et al. J Endovasc Ther 2011;18:613-23. 21. Bausback Y, et al. J Am Coll Cardiol. 2019 Feb 19;73(6):667-679. 22. Iida O, et al. JACC Cardiovasc Interv. 2015 Jul;8(8):1105-1112. 23. Bosiers M, J Cardiovasc Surg (Torino). 2013 Feb;54(1):115-22. 24. Davaine JM, et al. Eur J Vasc Endovasc Surg. 2015 Nov;50(5):631-7. 25. Shibata, T. REAL-DES: Zilver PTX vs. Eluvia for femoropopliteal disease in multicenter prospective study. Presented at JET 14 June 2024. 26. Gray WA, et al. Lancet. 2018;392(10157):1541-1551. doi:10.1016/S0140-6736(18)32262-12

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