The Light and Darkness of Fluoropolymer-Based Paclitaxel DES in the Treatment of Femoropopliteal lesions

Osaka Police Hospital Cardiovascular Division
Osamu Iida, MD, PhD, Osaka, Japan

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COI Disclosure

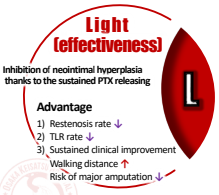
Speaker name :

Osamu Iida, MD

I have the following potential conflicts of interest to report:

- ■ Consulting: Boston Scientific, Canon, NIPRO, Terumo
- □ Employment in industry
- □ Stockholder of a healthcare company
- □ Owner of a healthcare company
- ■ Other(s) Honoraria: Medtronic, Boston Scientific, Gore, Terumo, NIPRO, Canon
- □ I do not have any potential conflict of interest

The Light and Darkness of FP-DES in the Treatment of FP lesions



	IMPERIAL trial (Lancet)[1]	CAPSICUM registry (JACC CI)[2]
Study design	Industry-initailted RCT, Core laboratory adjudicated trial (N=465, FP-DES: N=309, FP-DCS: N= 156)	Physician-initiated Single arm, Non-core laboratory adjudicated study (N=1204)
Frequency of CLTI and CTO	<5%/31%	35%/53%
Lesion length	87mm	86mm
1-year Primary patency	88.5%	87.1%

1 Gray WA, et al. Lancet. 2018;392:1541-1551. 2 Iida O, et al. JACC Cardiovasc Interv. 2022;15:630-638.

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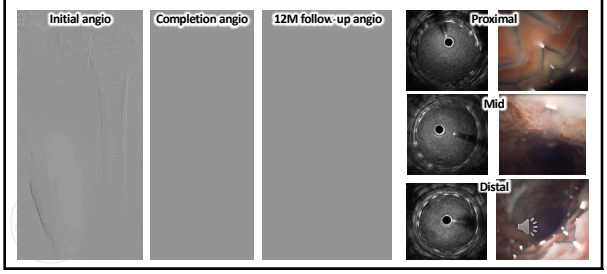
-Summary of 12-month Primary Patency on FP-DES-

	MAJESTIC[1] (n = 57)	IMPERIAL RCT[2] (n = 309)	IMPERIAL Japan[3] (n = 84)	IMPERIAL Long Lesions[4] (n = 50)	Münster Registry[7] (n = 62)	Auckland All-comers Registry[8] (N=51)	DESAFINADO Registry[9] (N=64)	CAPCISUM registry (N=1204)
Study Design	RCT, multicenter, global	RCT, multicenter, global	RCT, multicenter, Japan	Single arm, multicenter, global	Single center registry	Single center registry	Single center registry	Multicenter registry, Japan
12-M Primary Patency*	96%	92%	96%	91%	87%	94%	84%	87%
Lesion length (mm)	71	87	92	163	200	105	193	186
Severe Calcification	65%	40%	29%	28%	42%**	n/a	52	42
CTO	46%	31%	20%	32%	79%	52.9	48	53%
CLTI	4%	n/a	n/a	n/a	48%	52.9%	84%	35%

1. Müller Hülsbeck S, et al. J Endovasc Ther. 2016;23:701-7.
2. Gray WA, et al. Lancet. 2018 Oct 27;392(10157):1541-1551.
3. Soga Y, et al. Cardiovasc Intervent Radiol. 2020 Feb;43:215-222.
4. Goltzer J, et al. J Endovasc Ther. 2020;27:296-303.
5. Müller-Hülsbeck S, LINC 2019.
6. Vermassen F, CX 2019.
7. Bisdas T, et al. JACC Cardiovasc Interv. 2017;10(10):957-966.
8. Holden A, LINC 2020.
9. Kum S, et al. Vasc Med. 2021 Mar 18;1358863X20987894.
10. Iida O, et al. JACC Cardiovasc Interv. 2022;15:630-638.

12-month follow-up angiogram, IVUS and angioscopy evaluation

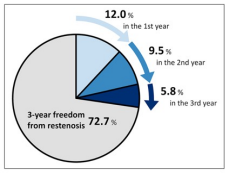
(70's yrs, DM, CHF [EF 26%], CLTI, TASC II D, LL: 30cm)



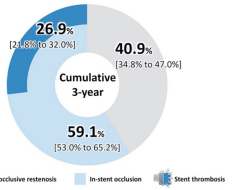
The Light and Darkness of FP-DES in the Treatment of FP lesions

-3-year incidence of restenosis after FP-DES implantation in the CAPSICUM study-

Annual Occurrence of ISR related to FP-DES



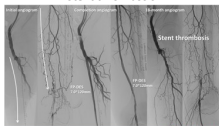
The Morphology of ISR related to FP-DES



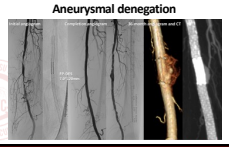
Iida O, et al. Vasc Med. 2024;29:182-188.

The Light and Darkness of FP-DES in the Treatment of FP lesions

Stent thrombosis



Aneurysmal denegation



Darkness (safety)

D

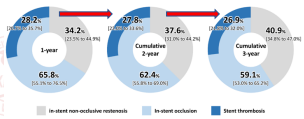
Delayed arterial healing due to the sustained PTX releasing

Disadvantage

1) Stent thrombosis ↑
2) Stent re- occlusion ↑
3) DAPT duration ↑
4) Aneurysmal degeneration ↑

The Light and Darkness of FP-DES in the Treatment of FP lesions

	The 1st year (a) = cumulative at 1 year	The 2nd year (b)	The 3rd year (c)	P value among (a), (b), and (c)	Cumulative at 2 years (a + b)	Cumulative at 3 years (a + b + c)
Restenosis	12.0% [10.1 to 13.9%]	9.5% [7.5 to 11.4%]	5.8% [4.4 to 7.2%]	(P<0.001)	21.5% [19.0 to 24.0%]	27.3% [24.6 to 30.0%]
Re-occlusion	7.9% [6.1 to 9.7%]	5.5% [4.0 to 7.0%]	2.7% [1.6 to 3.8%]	(P<0.001)	13.4% [11.2% to 15.6%]	16.1% [13.8% to 18.5%]
Stent thrombosis	3.4% [2.4 to 4.4%]	2.6% [1.6 to 3.6%]	1.4% [0.7 to 2.0%]	(P=0.007)	6.0% [4.5% to 7.4%]	7.3% [5.8% to 8.9%]

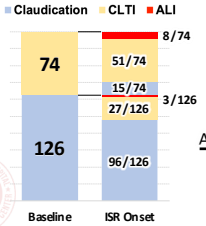


Interpretation: The annual incidence of re-occlusion and (ST) has statistically decreased, but proportion was not changed over the time.

Unpublished data

-The Light and Darkness of FP-DES in the Treatment of FP lesions-

Symptom transition at baseline versus ISR onset (Median follow-up 23.8 months)



At onset of DES ISR

Among 74 Pts with CLTI

10.8% (n=8): ALI

Among 126 Pts with claudication

21.4% (n=27): CLTI

2.4% (n=3): ALI

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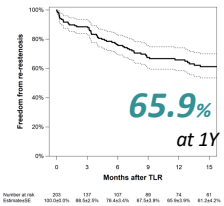
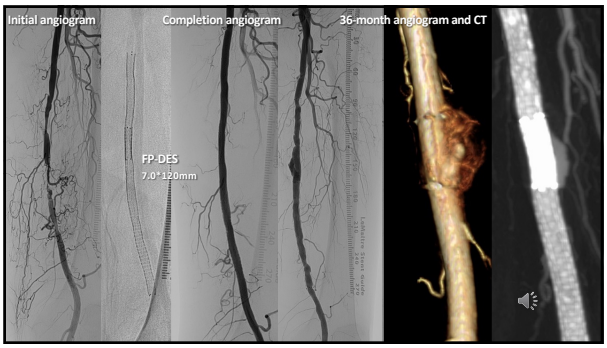
Patency after repeat EVT for FP-DES ISR and Predictors of re-ISR after repeat EVT

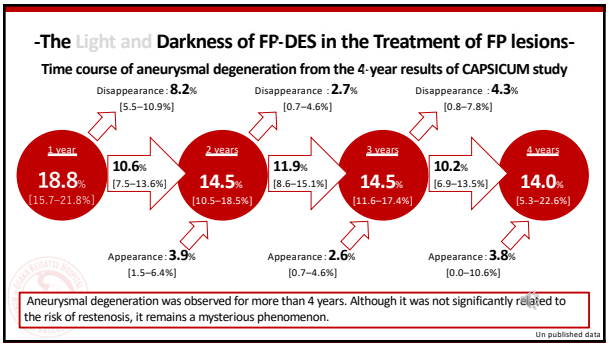
Freedom from re-restenosis after EVT

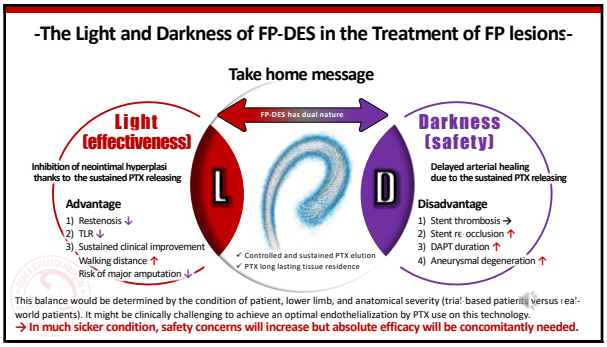


Cox proportional hazards models

Adjusted incidence hazard ratio	
Diabetes	1.07 [0.63 to 1.83] (P=0.79)
Dialysis	0.74 [0.41 to 1.36] (P=0.34)
Non-ambulatory at TLR	1.13 [0.56 to 2.31] (P=0.73)
Popliteal lesions	1.68 [0.98 to 2.88] (P=0.059)
In-stent occlusion at TLR	0.89 [0.48 to 1.63] (P=0.70)
CLTI at TLR	1.60 [0.86 to 2.97] (P=0.13)
No slow flow at TLR	0.45 [0.12 to 1.69] (P=0.24)
RS <30% in TLR	0.92 [0.46 to 1.85] (P=0.82)
DCB use at TLR	0.42 [0.24 to 0.74] (P=0.003)




-The Light and Darkness of FP-DES in the Treatment of FP lesions-
Time course of aneurysmal degeneration from the 4-year results of CAPSICUM study
Disappearance : 8.2%
[5.5–10.9%]
Disappearance : 2.7%
[0.7–4.6%]
Disappearance : 4.3%
[0.8–7.8%]
1 year
18.8%
[15.7–21.8%]
10.6%
[7.5–13.6%]
2 years
14.5%
[10.5–18.5%]
11.9%
[8.6–15.1%]
3 years
14.5%
[11.6–17.4%]
10.2%
[6.9–13.5%]
4 years
14.0%
[5.3–22.6%]
Appearance : 3.9%
[1.5–6.4%]
Appearance : 2.6%
[0.7–4.6%]
Appearance : 3.8%
[0.0–10.6%]
Aneurysmal degeneration was observed for more than 4 years. Although it was not significantly related to the risk of restenosis, it remains a mysterious phenomenon.
Un published data


-The Light and Darkness of FP-DES in the Treatment of FP lesions-
Take home message
Light
(effectiveness)
Inhibition of neointimal hyperplasi
thanks to the sustained PTX releasing
Advantage
1) Restenosis ↓
2) TLR ↓
3) Sustained clinical improvement
Walking distance ↑
Risk of major amputation ↓
FP-DES has dual nature
L
D
✓ Controlled and sustained PTX elution
✓ PTX long lasting tissue residence
Darkness
(safety)
Delayed arterial healing
due to the sustained PTX releasing
Disadvantage
1) Stent thrombosis →
2) Stent re occlusion ↑
3) DAPT duration ↑
4) Aneurysmal degeneration ↑
This balance would be determined by the condition of patient, lower limb, and anatomical severity (trial based patients versus real-world patients). It might be clinically challenging to achieve an optimal endothelialization by PTX use on this technology.
→ In much sicker condition, safety concerns will increase but absolute efficacy will be concomitantly needed.