


Final 5-Year Results Of The Zilverpass RCT Comparing Prosthetic PTFE Bypasses With ZILVER PTX (Cook) Stents To Treat Long Fempop Lesions: Clinical And Financial Results And Their Implications



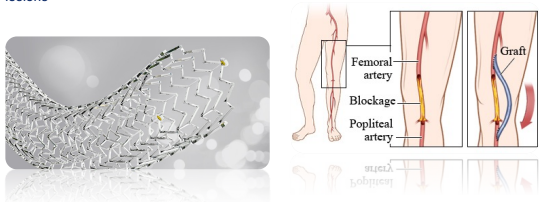
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My disclosures

- I do not have any potential conflicts of interest to report
- I have the following potential conflicts of interest to report:
 - Consulting: Biotronik, Boston Scientific, Cook, Shockwave
 - Employment in industry
 - Stockholder of a healthcare company
 - Owner of a healthcare company
 - Other(s)

STUDY OBJECTIVES

To evaluate the performance of the Cook Zilver PTX paclitaxel-eluting stent compared to bypass surgery for the treatment of femoropopliteal TASC C & D lesions



ZILVERPASS study

A prospective, randomized, multi-center study

1:1 randomization
220 patients

4 countries
13 clinical centers

Zilver PTX vs Prosthetic bypass

PRIMARY ENDPOINTS

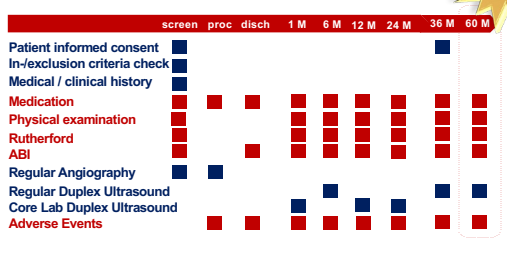
Primary patency at 12 months, defined as:

ZILVER PTX	BYPASS
Absence of binary restenosis or occlusion within treated lesion*	Absence of binary restenosis or occlusion at proximal and distal anastomoses and over the entire length of the bypass graft*
Without TLR within 12 months	Without clinically driven reintervention to restore flow in the bypass.

* Based on CFDU measuring a PSV ratio <2,4

STUDY TIMELINE


5 year results available



screen proc disch 1 M 6 M 12 M 24 M 36 M 60 M

- Patient informed consent
- In-/exclusion criteria check
- Medical / clinical history
- Medication
- Physical examination
- Rutherford
- ABI
- Regular Angiography
- Regular Duplex Ultrasound
- Core Lab Duplex Ultrasound
- Adverse Events


INSELSPITAL INCLUSION CRITERIA



1. Patient presenting with lifestyle-limiting claudication, rest pain or minor tissue loss (**Rutherford Clinical Category 2 to 5**)
2. Stenotic or occlusive **de novo lesion** located in the **femoropopliteal arteries**, suitable for endovascular therapy and for bypass surgery.
3. Total target lesion length is **at least 150mm**.

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INSELSPITAL EXCLUSION CRITERIA



1. **Any previous surgery and/or endovascular procedure in the target vessel.**
2. **Perioperative unsuccessful ipsilateral percutaneous vascular procedure to treat inflow disease** just prior to enrollment
3. **Any planned surgical intervention/procedure within 30 days** of the study procedure.
4. Major distal amputation (above the transmetatarsal) in the study or non-study limb.

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INSELSPITAL PATIENT DEMOGRAPHICS

		Total N = 220	ZILVER PTX N = 113	BYPASS N = 107	Signific
Gender	Female	27.73% (61/220)	30.97% (35/113)	24.30% (26/107)	P = 0.267
	Male	72.27% (159/220)	69.03% (78/113)	75.70% (81/107)	
Rutherford Baseline	Claudication	63.20% (139/220)	70.80% (80/113)	55.14% (59/107)	P = 0.018
	CU	36.80% (81/220)	29.20% (33/113)	44.86% (48/107)	
Age	(years)	68.63 ± 10.52	69.58 ± 10.84	67.63 ± 10.12	P = 0.305

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INSELSPITAL RISK FACTORS

		Total N = 220	ZILVER PTX N = 113	BYPASS N = 107	Signific
Hypertension	Yes	73.20% (161/220)	65.49% (74/113)	81.31% (87/107)	P = 0.008
	No	26.80% (59/220)	34.51% (39/113)	18.70% (20/107)	
Obesity	Yes	13.60% (30/220)	8.85% (10/113)	18.69% (20/107)	P = 0.033
	No	86.40% (190/220)	91.15% (103/113)	81.31% (87/107)	
Hypercholesterolemia	Yes	57.70% (127/220)	50.44% (57/113)	65.42% (70/107)	P = 0.025
	No	42.30% (93/220)	49.56% (56/113)	34.58% (37/107)	

However randomization was predefined and blind, patients from the bypass cohort seemed to have significantly higher amount of patients with: **hypertension, obesity & hypercholesterolemia.**

No differences were seen in other risk factors (smoking history, diabetes, coronary artery disease, cardiovascular disease, renal insufficiency)

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INSELSPITAL LESION CHARACTERISTICS

Very complex lesions:
94.55% were occluded and mean lesion length was 247.11mm

		Total N = 220	ZILVER PTX N = 113	BYPASS N = 107	Signific
Study Limb	Left	51.80% (114/220)	53.98% (61/113)	49.53% (53/107)	P = 0.509
	Right	48.20% (106/220)	46.02% (52/113)	50.47% (54/107)	
Lesion Type	Stenosis	5.45% (12/220)	7.96% (9/113)	2.80% (3/107)	P = 0.092
	Occlusion	94.55% (208/220)	92.04% (104/113)	97.20% (104/107)	
Lesion Length	mm ± SD (min - max)	247.11 ± 69.26 (100* - 400)	241.67 ± 63.33 (120* - 400)	252.96 ± 74.89 (100* - 400)	P = 0.104
Prox Ref Vessel Diameter	mm ± SD (min - max)	5.88 ± 0.73 (4.00 - 8.00)	5.72 ± 0.65 (4.40 - 8.00)	6.05 ± 0.77 (4.00 - 8.00)	P = 0.320

*6 PD's were seen with lesion length <150mm

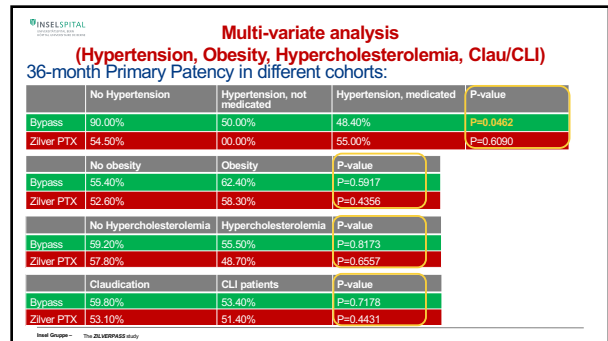
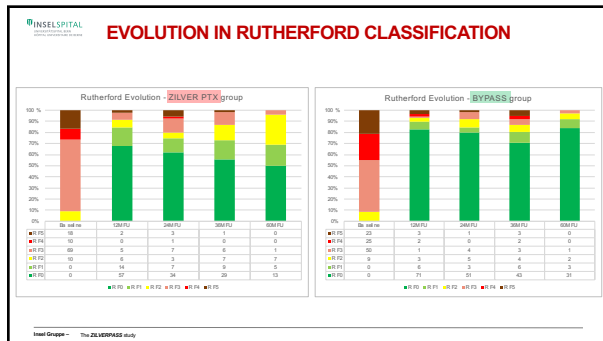
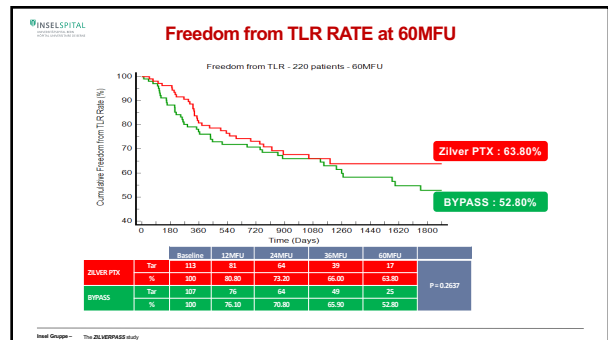
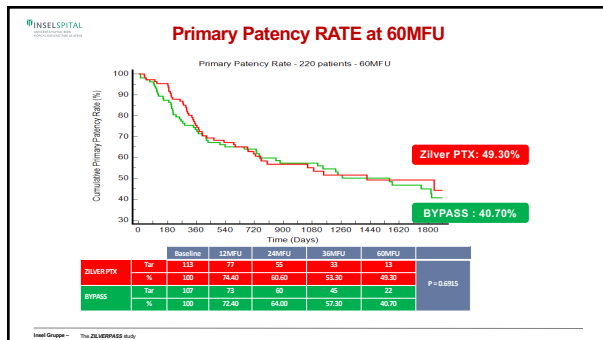
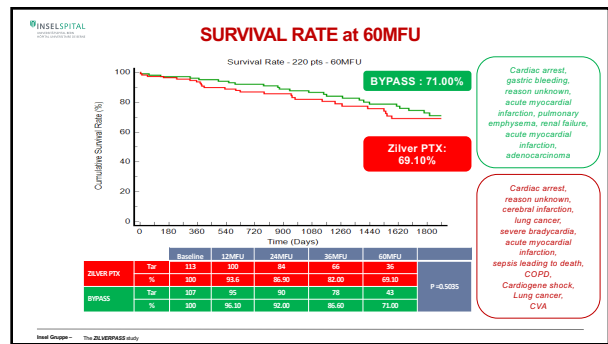
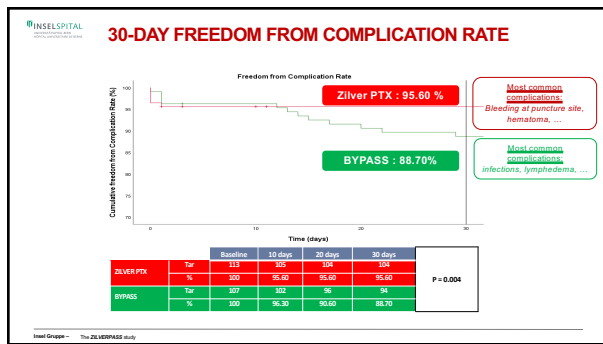
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INSELSPITAL PROCEDURAL CHARACTERISTICS


		Total N = 220	ZILVER PTX N = 113	BYPASS N = 107	Signific
Procedure Time	minutes ± SD (min - max)	90.45 ± 44.77 (17 - 240)	89.60 ± 23.65 (17 - 189)	123.09 ± 38.89 (53 - 240)	P < 0.001
Cross-over performed?	Yes		71.68% (81/113)		
	No		28.32% (32/113)		
Scopy Time*	minutes ± SD (min - max)		17.91 ± 15.71 (4.00 - 33.00)		
Contrast dose*	ml ± SD (min - max)		107.24 ± 51.10 (10.00 - 200.00)		
	Dacron			39.25% (42/107)	
Bypass material	PTFE			60.75% (65/107)	
	Hospital stay*	Nights (min - max)	5.26 ± 5.65 (0.00 - 24.00)	2.52 ± 3.50 (0.00 - 20.00)	8.14 ± 6.03 (1.00 - 24.00)

*Data on hospital stay for 219 patients. 1 patient (ZILVER PTX group) died during hospital stay.

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ECONOMICAL ANALYSIS (GERMANY)




	Per Patient	
	BYPASS	ZILVER PTX
Intervention costs	€ 7.477,-	€ 3.816,-
30-day complication costs	€ 57,-	€ 161,-
Costs for TLR at 12MFU	€ 1.431,-	€ 1.132,-
Costs for TLR at 24MFU	€ 392,-	€ 327,-
Costs for TLR at 36MFU	€ 75,-	€ 336,-
TOTAL	€ 9.432,-	€5.773,-

ZILVER PTX stent treatment was associated with lower costs for the payer in the German Reimbursement Model.

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ECONOMICAL ANALYSIS (USA)




	Per Patient	
	BYPASS	ZILVER PTX
Intervention costs	\$ 17.727,-	\$ 11.975,-
30-day complication costs	\$ 1.324,-	\$ 441,-
Costs for TLR at 12MFU	\$ 4.985,-	\$ 3.926,-
Costs for TLR at 24MFU	\$ 1.866,-	\$ 1.507,-
Costs for TLR at 36MFU	\$ 396,-	\$ 1.413,-
TOTAL	\$ 26.297,-	\$ 19.261,-

ZILVER PTX stent treatment was associated with lower costs for the payer in the USA Reimbursement Model.

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- CONCLUSION**
- Final 60-month results show at least a **non-inferiority of Zilver PTX** versus prosthetic bypass surgery ATK, with:
 - **similar patency results**
 - **less complications**
 - **shorter hospitalization.**
 - Economic analysis**, taking into account procedural-, hospitalization- and reintervention costs, showed a **clear cost-benefit in favor of ZILVER PTX**, both for Germany & USA reimbursement model.
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