Why the Zilver PTX DES (Cook) Is A Durable Effective Treatment for Long-Segment Femoral-Popliteal Lesions: Worldwide Trials and Real-World Experience

Charles J Bailey, MD, RPVI, FSVS
Assistant Professor of Surgery
University of South Florida-Morsani College of Medicine
Director, Heart & Vascular Institute- Limb Preservation-PAD Program

TGH Tampa General Hospital | HEART & VASCULAR INSTITUTE

Presenter Disclosure

- Presenter: Charles J Bailey, MD, RPVI, FSVS
- Relationships with commercial interests:
  - Speakers Bureau / Honoraria / Consulting Fees
    - Cook Medical
    - Shockwave Medical
    - Penumbra
    - Silk Road (Boston Scientific)
- Mitigation of conflict- Evidence-based, free from conflict, transparent

Drug-coated devices for the win

- Benefits of paclitaxel-coated devices (PCD)
  - Improved primary patency
  - Freedom from target-lumen revascularization (TLR)
    - Zilver PTX — *Dake et al. Circ Cardiovasc Interv, 2011*
    - IN.PACT SFA — *Tepe et al. Circulation, 2015*
    - LEVANT II — *Rosenfield et al. N Eng J Med, 2015*
    - ILLUMENATE — *Krishnan et al. Circulation, 2017*
    - IMPERIAL — *Gray et al. Lancet, 2018*
- No association between paclitaxel exposure and risk of death — *Parikh et al. Lancet, 2023*

TransAtlantic ~~Consensus~~ Debate

- BEST-CLI, MALE
- BASIL-2, AFS
- **Optimal treatment for advanced PAD without consensus**

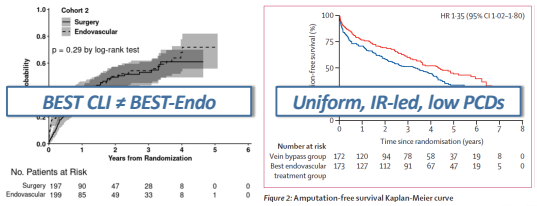


Figure 2: Amputation-free survival Kaplan-Meier curve

Meta-analysis of Long Femoral-Popliteal (FP)

- Summararize studies investigating endovascular therapies for FP lesions > 15 cm
- 44 Manuscripts, N=4847 patients, N=5282 treated limbs
- Outcomes- 1-year primary patency, secondary patency, freedom from TLR
- Pooled analysis
  - Primary patency 71%, Secondary patency 87%, freedom TLR 79%
- Device specific 1-year primary patency
  - Bare stent 68%
  - Covered stents 67%
  - Drug eluting stent 74% [Secondary patency 92%]
  - Drug coated balloon 83%

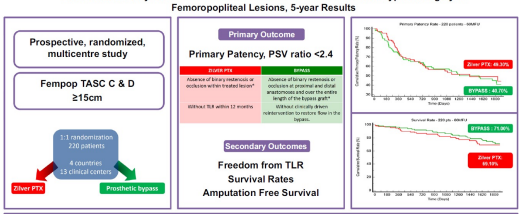
Zilver PTX in TASC C/D Lesions

- Zilver PTX Single Arm Study
  - Prospective, multi-centre, N=787 patients (900 lesions)
  - Long *de novo* TASC C/D subgroup, N=135
    - Mean length 226 ± 43.6mm
    - KM-estimates at 1-year
      - Primary patency, 77.6%
      - Event free survival, 84.7%
      - Freedom from TLR, 85.4%

"…outcomes may equal those of bypass graft surgery" — *Bosiers et al. J Cardiovasc Surg, 2013*

ZILVERPASS Study

ZILVERPASS Study: ZILVER PTX Stent vs Prosthetic Above-The-Knee Bypass Surgery in Femoropopliteal Lesions, 5-year Results

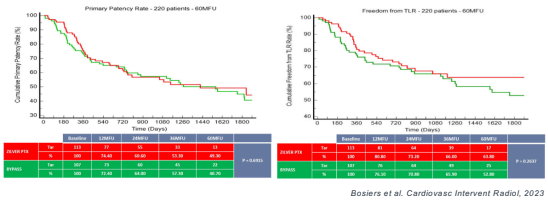


- non-inferiority of the ZILVER PTX stent compared to above-the-knee prosthetic bypass up to 5 years
- comparable effectiveness and safety profiles makes ZILVER PTX valid alternative for prosthetic bypass

Bosiers et al. Cardiovasc Intervent Radiol, 2023

ZILVERPASS Outcomes

- Comparable effectiveness and safety of Zilver PTX vs AK Prosthetic bypass



Bosiers et al. Cardiovasc Intervent Radiol, 2023

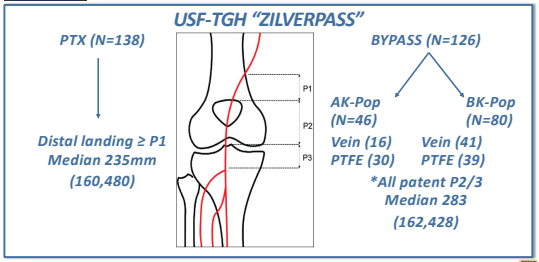
Aims

- University of South Florida / Tampa General Hospital
  - Cook Zilver PTX stent as primary therapy (Market release 2013)
  - Utilized broadly in femoral-popliteal (FP) disease
- Goal
  - Examine quaternary referral center experience
  - Comparative analysis of Zilver PTX versus surgical bypass
  - Institutional "ZILVERPASS"
  - Hypothesis-
    - Equivalent outcomes in long-segment FP disease

Methods

- Single-center retrospective review (2013 – 2020)
- Inclusion criteria
  - TASC C & D Femoral-popliteal lesions, >15cm, patent P2/P3
  - *de novo* Zilver PTX stent placement (Cook Medical)
  - *Index* Open surgical bypass
- Exclusion
  - TASC A & B Femoral-popliteal lesions
  - Acute limb ischemia, trauma, popliteal aneurysms
  - Bypass after attempted or failed endovascular therapy

Results



Pre-procedure Demographics

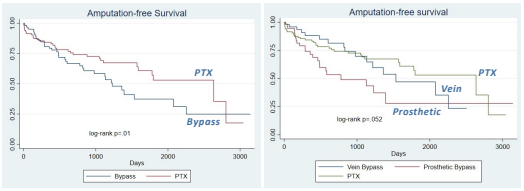
Patient characteristics	All patients	Revascularization		
		Zilver PTX	Open Bypass	P-value*
n	264	138	126	
Age in years, median (IQR)	63 (57, 72)	63 (57, 72)	62.5 (58, 72)	.53
Female gender (%)	111 (42.1)	55 (39.9)	56 (44.4)	.46
Hypertension (%)	238 (90.2)	123 (89.1)	115 (91.3)	.68
Diabetes mellitus (%)	146 (55.3)	78 (56.5)	68 (54.0)	.71
Hyperlipidemia (%)	192 (72.7)	93 (67.4)	99 (78.6)	.053
Ever smoker (%)	214 (81.1)	112 (81.2)	102 (81.0)	1.0
Active smoker (%)	104 (39.4)	58 (42.0)	46 (36.5)	.38
History of CAD (%)	147 (55.7)	78 (56.5)	69 (54.8)	.81
History of CHF (%)	42 (15.9)	26 (18.8)	16 (12.7)	.18
History of COPD (%)	56 (21.2)	31 (22.5)	25 (19.8)	.65
History of CKD (%)	51 (19.3)	24 (17.4)	27 (21.4)	.44
BMI, median (IQR)	26.5 (22.6, 30.8)	26.5 (23.7, 30.8)	26.5 (22, 30.9)	.31
Pre procedure antiplatelet	177 (67.1)	86 (62.3)	91 (72.2)	.09
Pre procedure anticoagulant	40 (15.2)	18 (14.3)	22 (15.9)	.73

Anatomy & Physiology

Patient characteristics	All patients	Revascularization		
		Zilver PTX	Open Bypass	P-value*
n	264	138	126	
ABI/TP severity				
Within normal limits	7 (2.6)	4 (2.9)	3 (2.4)	
Mild	12 (4.6)	8 (5.8)	4 (3.2)	
Moderate	93 (35.2)	56 (40.6)	37 (29.4)	
Severe	102 (38.6)	45 (32.6)	57 (45.2)	.18
Not documented	50 (18.9)	25 (18.1)	25 (19.8)	
TASC class				
C	101 (29.3)	54 (39.1)	47 (37.3)	.80
D	163 (61.7)	84 (60.9)	79 (62.7)	
Rutherford Class				
Claudication (R 1-3)	110 (41.7)	72 (52.2)	38 (30.2)	<.001
CLTI (R 4-6)	154 (58.3)	66 (47.8)	88 (69.8)	

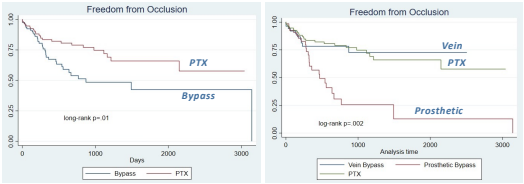
Amputation-free Survival (AFS)

- Overall greater AFS in Zilver PTX cohort (p=0.01)
- Trend of improved AFS in Zilver PTX or vein bypass (p=0.052)



Freedom from Occlusion

- Superior freedom from occlusion in Zilver PTX cohort (p=0.01)
- Greater freedom from occlusion in Zilver PTX & vein bypass (p=0.002)



Clinical Outcomes

- 1-year Primary patency
  - Prosthetic bypass, 55.3%
  - **Zilver PTX, 79%**
  - Vein bypass, 79.1%
- Multivariable analysis
  - Prosthetic bypass as risk for occlusion
    - (aHR: 2.87; 95% CI: 1.35-6.08; p=0.006)
  - CLTI as predictor of decreased AFS
    - (aHR: 2.5; 95% CI: 1.45-4.45; p=0.001)

1-Year Primary Patency
Cook Zilver PTX Trial Data
RCT[1] 82.7%
RCT[2] 84.4%

1-Dake et al. Circ Cardiovasc Interv. 2011
2-Dake et al. Cardiovasc Intervent Radiol. 2020

Conclusions

- USF-TGH Experience
  - Safety and efficacy of Zilver PTX in long-segment disease
  - Zilver PTX outcomes similar to autologous vein bypass
  - Supports an endovascular-1[st] approach to FP segment
    - *Primary therapy, Absence of adequate vein*
- Limitations
  - Single centre, retrospective review
  - Potential biases
    - Treatment (Bypass for CLI) offset by Operator (Do what you do best)?
  - Longer-term follow up and surveillance imaging

Charles J Bailey, MD, RPVI, FSVS
Assistant Professor of Surgery
Division of Vascular Surgery
Director, Limb Preservation & PAD
cbailey5@usf.edu