Clinical benefits on DES
Patient’s perspectives

Dr. Skyi Pang
Vascular Surgeon
Department of Surgery
Pamela Youde Nethersole Eastern Hospital
Hong Kong
Disclosure

Speaker name: Skyi Pang

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

☑️ I do not have any potential conflict of interest
Introduction

- Endovascular therapy has become the dominant treatment in Vascular surgery worldwide
  - Technology development
  - Experience and skill advancement
  - Data accumulation
  - Improvement of healthcare system

Data from CDARS
Surgeon’s perspective

• Endovascular intervention has become the predominant treatment for peripheral vascular disease
• Surgical bypass is gold standard for TASC C/D lesion
  • Bypass is not superior in every cases
• Surgical bypass will be last resort when intervention fail
  • Avoid stent – preserve future option
• Patency is always the key concern for both endovascular/ bypass surgery
  • If a scaffold is needed, the one with better primary patency should be chosen
Patient’s aspect

• Prefer endotherapy
  • Lower morbidity

• Successful rate/Re-intervention rate
  • Primary patency/TLR

• Lower the cost if possible
Drug technology

• Drug coated balloon shows better result in peripheral intervention when compared to POBA
  • Particularly in femoropopliteal disease
    • LEVANT 2 study
    • IN.PACT SFA trial shows durable result in 3 years
  • Even in complex lesion
    • Long lesion Subgroup in Lutonix Global SFA Real world Registry
    • Long lesion cohort in IN.PACT Global Registry
    • SFA-Long study

*JACC Cardiovasc Interv. 2016 May 9;9(9):950-6*
Not applicable to all

- The promising result is usually based on the good result from initial angioplasty
Scaffold is needed

- Long lesion
- Sub-intimal angioplasty
- Dissection
- Elastic recoil
Combination of drug and stent

• The combination of drug & stent is not new
  • Sirolimus-eluting stent achieved lower incidence of ISR when compared to bare-metal stent in coronary field
    
    _NEJM 2003; 349:1315-1323_

• Late stent thrombosis
  • Delayed endothelialization
  • Polymer hypersensitivity

    _Circulation. 2005; 112:270-278_

• New Generation of DES
  • Bioabsorbable polymer
  • Polymer free
Timeline

Feb 2001 Cordis SIROCCO Trial
Polymer-based Sircolimus Eluting Smartstent™

March 2005 Cordis II Trial
No significant difference between Sircolimus Eluting Smartstent™ and BMS

May 2005 Cook Zilver PTX Trial
Polymer-free Paclitaxel eluting stent (RCT & Single-arm Global Registry)

May 2007 Abbott STRIDES Trial
Polymer-based Everolimus-Eluting Dynalink™ Stent

Aug 2009 CE Mark for Zilver PTX
1st DES approved for peripheral use after successfully completing Single-arm Global Registry

Sept 2009 STRIDES Trial results
Fail to demonstrate superiority to BMS at 12 months

Sept 2011 Abbott Absorb BTK Trial
Drug eluting bioresorbable peripheral stent for BTK lesion

Dec 2011 Abbott ESPRIT I Trial
Zirolimus-eluting bioresorbable Scaffold single arm study for iliac & SFA lesion

Nov 2012 FDA approval for Zilver PTX
Principle of Drug Eluting Stent

• Mechanical Scaffold
• Drug Elution
  • Release
    • >98% of paclitaxel coating is released from the stent within 72 hours
  • Absorption
    • Remains in artery for up to 56 days
• Inhibition
  • Binds to microtubules and inhibit mitosis
Choice of stent

- Primary patency
  - PSVR (Peak systolic Velocity ratio)
- Target Lesion Revascularization
- Safety
  - Stent fracture rate
- Performance in complex lesion
Primary Patency

Graph showing primary patency for different devices over various years:
- Complete SE SFA
- Durability II
- RESILIENT
- STROLL
- VIASTAR
- SUPERB
- Zilver PTX RCT

- 1st year
- 2nd year
- 3rd year
- 4th year
- 5th year
Primary Patency (PSVR ≤ 2.0)

- Complete SE SFA
- Durability II
- STROLL
- Zilver PTX RCT

1st year
2nd year
3rd year
4th year
5th year
Zilver PTX Randomized Trial
N=479

Length of lesion 66mm
Total occlusion 33%
Severe calcification 35%
PSVR ≤ 2.0
Primary patency

Freedom from TLR

Fracture rate at 5 year 1.9%
Target Lesion Revascularization

5-year Freedom from TLR
Zilver PTX vs. Standard Care

At 5 years, Zilver PTX demonstrates a 48% reduction in reintervention compared to standard care.

5-year Freedom from TLR
Provisional Zilver PTX vs. BMS

At 5 years, Zilver PTX demonstrates a 47% reduction in reintervention compared to BMS.
Complex lesion

Zilver PTX post-market Surveillance (PMS) study

- >1000 lesions
- Average length 14.7cm
- 42% occlusion
- 19% in-stent restenosis
- 59% diabetes
- 21% critical limb ischaemia
- Two year Freedom from TLR 85%
  - Similar to pre-market study
Complex lesion

The Zilver PTX Single Arm Study

12-month results from TASC C/D lesion subgroup

- N=135
- Mean length $226.1 \pm 43.6 \text{ mm}$
- Primary patency rate $77.6\%$ @12 month
- Freedom from TLR $85.4\%$ @ 12 month
- Stent fracture rate $2.1\%$

Bypass is always superior in TASC II C/D lesion?

ZILVERPASS

• Surgical Bypass Vs Zilver PTX stent for Long SFA lesions
• Prospective multicenter randomized study
• ? Bypass is always superior in TASC II C/D lesion
Local experience

- 200 peripheral interventions
- 10.5% - Zilver PTX (21 cases)
- Age 71.0 ± 8.9
- Male 76.1%
- Diabetes 55%
- Critical limb ischaemia 23.8%
- Mean follow up 13 months
- Mean lesion length 17.0 ± 6.2 cm
- Primary patency @12 month 82.4% (PSVR ≤ 2.5)
- Freedom from TLR @12 month 88.7%
Instent re-stenosis

- Increase occurrence
- Real challenge for re-intervention
- Increase the cost
- Classification of ISR
  - Focal
  - Diffuse
  - Total occlusion
- Distribution of DES-ISR is different from BMS-ISR
  - More Class 1 is observed


Cost

- POBA
- Special design balloon
  - Chocolate balloon
  - Angiosculpt
- Routine/provisional stenting (BMS)
- Routine/provisional stenting (DES)
- Covered stent/interwoven helical stent
- DCB ± spot stenting
- Atherectomy ± DCB ± spot stenting
Conclusion

- Endovascular treatment is the first choice for femoropopliteal disease
- Drug eluting stent should be considered if a mechanical scaffold is needed
  - 5 year data from Zilver PTX RCT
  - Consistent result in long/complex lesion
  - Less severe ISR compared to BMS from observation
  - Reasonable cost with better overall result
Clinical benefits on DES
Patient’s perspectives

Dr. Skyi Pang
Vascular Surgeon
Department of Surgery
Pamela Youde Nethersole Eastern Hospital
Hong Kong