Self Expanding Stent Technology

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Atherosclerosis

“A man is as old as his arteries”

Thomas Sydenham, 1624-1689
A 42-year-old man who smokes and has total cholesterol of 180, good cholesterol (HDL) of 45 and systolic blood pressure of 125, has a vascular age of a 54-year-old. If he quits smoking, his vascular age could drop to 42, the same as his chronological age.

Vascular Age

WSJ 2010, Ron Winslow
Peripheral artery disease skyrocketing worldwide

People with peripheral artery disease are at a high risk of having a heart attack or stroke.

More people around the world have peripheral artery disease, which can lead to difficulty walking and amputation. And it increases the risk of having a heart attack or stroke.

The number of people with the disease has skyrocketed from about 164 million in 2000 to 202 million in 2010, according to new worldwide estimates cut Wednesday in The Lancet.

Peripheral artery disease (PAD) occurs when fatty deposits accumulate in the peripheral arteries, restricting blood flow and oxygen to the legs and feet.

"It is a very serious condition because people affected have a very high risk of having a heart attack or stroke," says the study's lead author Gerry Fowkes of the University of Edinburgh in the United Kingdom.

"The quality of life of some PAD patients can be quite poor because they often have great difficulty in walking. This can be catastrophic in poor countries where access to transport is very limited."
Global Impact

Long-Term Survival in Patients With PAD

THREE ARTERIAL LEVELS OF DISEASE

AORTO-ILIAC  FEMORO-POPLITEAL  INFRAPOPLITEAL
SFA Treatment Options

- PTA
- Drug Coated Devices
- Stent
  - Types
  - Complications
- Atherectomy
  - Laser
  - Directional
  - Orbital
  - Cryo
  - Contact
Forces simulated in SFA

Radial Compression

Longitudinal Compression / Extension

Flexion

Torsion
Forces simulated in SFA
Primary Patency (%), 95% CI

Mean

1-year data

2-year data

3-year data

4-year data

5-year data

CI=confidence interval; PTA=percutaneous transluminal angiography

Ideal Stent

- Flexibility
- Crossing profile and trackability
- Radial Strength
- Radiographic properties
- Deployment
- Biocompatibility
- Strut characteristics
Material
Self Expanding: Nitinol

- Nickel Titanium Naval Ordnance Laboratory
- William Buehler and Frederick Wang
- Resists fatigue, heat and force of impact
- Charles Dotter experiments
Nitinol: Nickel-Titanium Alloy

- Shape memory
- Super elasticity
- Self expansion (expand at 60 deg)
- High radial resistive force
- Corrosion resistance
Thermal Hysteresis

![Diagram showing Nitinol transformation with temperature]
Self Expanding Stent
Stent Types (Open)

- Nitinol mesh (slotted laser cut tube +/- drug)
Stent Types (Covered)

- Nitinol with ePTFE (Graft, interconnectors)
Stent Types (Woven)

- Made of six closed-end interwoven nitinol wires
- Constrained to three times its nominal length within the outer sheath
Deployment Technique

Pin and Pull

Trigger

Slide
Potential Problems

Restenosis  Thrombosis
Stent Fractures

**Type I**
One strut fracture

**Type II**
Multiple strut fractures

**Type III**
Complete transverse Linear fracture

**Type IV**
Complete transverse linear fracture with displacement

**Type V**
Complete transaxial fracture

Rocha-Singh KJ et al; Cath Cardiovasc Interv. 2007
Restenosis: Achilles Heel
1 Year SFA Restenosis Rates

Length of Lesion (cm)

Binary restenosis %

- PTA plus provisional stent
- Stent

Graph showing the relationship between the length of the lesion (in cm) and the binary restenosis percentage for different stent types, including PTA plus provisional stent and Stent, along with specific data points for ASTRON, ABSOLUTE, FAST, RESILIENT, FACT, and SCIROCCO (2 yrs.).
Restenosis: Risk Predictors

• Vessel Characteristics
  – Diameter and Length
  – Lesion location (Ostial, Bend areas)
  – Calcified or tortuous
  – Total occlusion

• Patient Characteristics
  – Diabetes
  – CKD
  – CHF
Restenosis: Risk Predictors

• Procedural Characteristics
  – Stent malapposition/underexpansion
  – Inadequate post procedure MLD
  – Multiple Stents
  – Extent of overlap
  – Potential for fracture
Restenosis: Pattern (coronary)

ISR Pattern I: Focal
- Type IA: Articulation or Gap
- Type IB: Margin
- Type IC: Focal Body
- Type ID: Multifocal

ISR Patterns II, III, IV: Diffuse
- ISR Pattern II: Intra-stent
- ISR Pattern III: Proliferative
- ISR Pattern IV: Total Occlusion
Restenosis: Pattern

Focal
Diffuse
Total
Stent Fracture
Restenosis: Potential Options

- PTA
- Cutting Balloon
- Cryotherapy
- Brachytherapy
- Bare Metal (nitinol) Stent
- Covered Stent Endograft
- Drug Eluting Stent (Zilver PTX)
- Atherectomy
- Drug Eluting Balloon
Treatment Options

• PTA
• Drug Coated Devices
• Stent
  – Types
  – Complications
• Atherectomy
  – Laser
  – Directional
  – Orbital
  – Cryo
  – Contact
Atherectomy and Drug Eluting Balloon

“Leave no metal behind”
Atherectomy and Drug coated balloon
Complement
1. **PRE-DILATATION**
   - Required for all lesions prior to DCB procedure
   - Size - Diameter: 1 mm less than RVD
   - Size - Length: should not be greater than planned DCB length

2. **DRUG-COATED BALLOON**
   - DCB diameter RVD = 1:1; length 1 cm beyond lesion on both ends
   - Inflation: Time ≥ 3 minutes; Pressure < RBP as required to reach full DCB expansion
   - Overlap multiple DCBs by at least 1cm

3. **POST-DILATATION**
   - If residual stenosis ≥ 50% or flow-limiting dissection
   - Standard or high pressure PTA balloon diameter 1:1 to RVD
   - Short/focal length as necessary to treat the extent of residual stenosis or dissection

4. **PROVISIONAL SPOT STENTING**
   - For persistent residual stenosis ≥ 50% or flow-limiting dissection
   - Minimum length as necessary to fully treat the residual stenosis or dissection
Drug Coated Balloon
Primary Workhorse Therapy

PTA
Pre- & Post-Dilatation

Stenting
Recoil, flow limiting dissection, residual stenosis

Atherectomy
Debulking and severe calcification
Atherectomy, PTA and DCB
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Acknowledgements

Thank You
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