Bioabsorbable Coronary Stents

- What are they?
- Why have they been developed?
- The Clinical Trials
- Commercial Utilization and Outcomes
The History of Angioplasty and Stent Technologies

- **1970s: Balloon Angioplasty**
  - ↓ Mortality
  - ↓ Abrupt Closure
  - ↓ Stenosis
  - ↓ Clinical Events
  - ↓ Restenosis (10-20% at 1 yr)

- **1980-2000: Bare Metal Stents**
  - = Mortality
  - ↓ Revasc
  - ↓ Restenosis (<5-10% at 1 yr)

- **2000-2010: Drug Eluting Stents**
  - ↓ MI, ST*

- **2010: Present: Absorbable Stents**
  - ↓ Restenosis

*MI (myocardial infarction); ST (stent thrombosis)

The Anatomy of a Drug-Eluting Stent...

- Vessel Wall
- Drug
- Polymer
- Stent/Scaffold

- Implant
  - 2-12 Wks
  - 3-36 mo
  - 1-3 Years

- Drug Elution
  - Conventional DES
  - Bioabsorbable Polymer
  - Bioabsorbable Scaffold
The Anatomy of a Drug-Eluting Stent…

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Why Bioabsorbable Stents?

- Progressively smaller
- Less shear
- Less injury
- Less inflammation?
- More conformable
- Less restenosis

Foin et al. 2014, Int J Cardiology

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Why Bioabsorbable Stents?

- Might they retain vessel function?
- Preserve side branches?
- Preserve graft targets?
- Reduce restenosis?
- Reduce late thrombosis?
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EVOLVE II Trial
Efficacy and Safety of a Novel Bioabsorbable Polymer-Coated, Everolimus-Eluting Coronary Stent

Patients (n = 1684) undergoing percutaneous intervention were randomized*.

* STEM: I.M., CTO, SVG, ISR excluded

Kereiakes et al. 2015, Circ Cardiovasc Interv
**EVOLVE II Trial**

**Efficacy and Safety of a Novel Bioabsorbable Polymer-Coated, Everolimus-Eluting Coronary Stent**

Patients (n = 1684) undergoing percutaneous intervention were randomized*.

With respect to death, target lesion infarction and revascularization, the SYNERGY bioabsorbable POLYMER is non-inferior to Promus DES at 1 year.

*STEMI, LM, CTO, SVG, ISR excluded

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**ABSORB III Trial**

**Everolimus-Eluting Bioabsorbable Scaffolds for Coronary Artery Disease**

Patients with angina undergoing percutaneous intervention (n = 2008) were randomized*.

* ACS, complex lesions excluded
Patients with angina undergoing percutaneous intervention (n = 2008) were randomized.*

With respect to death, target lesion infarction and revascularization, the Absorb bioabsorbable SCAFFOLD is non-inferior to Xience DES at 1 year.

* ACS, complex lesions excluded
The Clinical Trials….

NON-INFERIOR
FDA Approved

2-12 Wks

Conventional DES

2-12 Weeks

3 - 36 mo

Bioabsorbable Polymer

1-3 Years

Bioabsorbable Scaffold

FDA Approved Bioabsorbable Stents

EVOLVE Trial

- Boston Scientific
- Synergy Stent
- Bioabsorbable Polymer
- FDA Approved

ABSORB Trial

- Abbott
- Absorb Stent
- Bioabsorbable Scaffold
- FDA Approved

Non-inferior to current generation drug eluting stents
Bioabsorbable Coronary Stents

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Broader Experience Raises Concerns…

1-year outcomes with the Absorb bioresorbable scaffold in patients with coronary artery disease: a patient-level, pooled meta-analysis

Gregg W Stone, Brooke Gap, Takeshi Kimura, Dean Kandzari, Stephen G Ellis, Yoshikazu Ohama, Wai-Fung Cheung, Jennifer Jones-McMains, Xiaoku Su, Zhou Zhang, Patrick W Serruys

- Increase 12-mo rate of stent thrombosis
  - RR 2.09 (0.92-4.75)

Safety and efficacy outcomes of first and second generation durable polymer drug eluting stents and biodegradable polymer biolimus eluting stents in clinical practice: comprehensive network meta-analysis

- 29% increase in myocardial infarction

Bare metal stents, durable polymer drug eluting stents, and biodegradable polymer drug eluting stents for coronary artery disease: mixed treatment comparison meta-analysis

- Increased mortality after 1 year
  - HR 1.52 (1.02 – 2.22)
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2000-2010 Drug Eluting Stents

2010- Present Absorbable Stents
? Mortality
? MI, ST*
? Restenosis

*MI (myocardial infarction); ST (stent thrombosis)

Conclusions

Advantages
- May reduce restenosis
- Vessel function
- Side-branch
- Bypass-targets

Disadvantages
- Lower device success
- Simple lesions
- More fragile
- Observational concerns

These are early generation technologies
Concepts remain valid
Conservative adoption while awaiting device improvements.
THANK YOU

Scott M Lilly MD PhD
Interventional Cardiology
The Ohio State University
scott.lilly@osumc.edu