Bioresorbable Scaffold Implantation Optimization

Alexandre Abizaid, MD, PhD, FACC
Institute Dante Pazzanese
Sao Paulo, Brazil
Conflicts of Interest

Research grants: Abbott Vascular, Elixir, Reva
First Lesson:

Not all BRS were born the same

1. Polymeric vs metallic scaffolds
2. Different scaffold designs
3. Most are non radiopaque
Different BRS Platforms

ABSORB

- Box-like appearance
- Low backscattering strut core, surrounded by high backscattering lining

DESolve

- Box-like appearance
- Low backscattering strut core (higher signal intensity than Absorb), surrounded by high backscattering lining

Fanton

- Hybrid appearance
- Continuous strings through the lock mechanism
- Box-like appearance backbone

MIRAGE

- Oval-shaped, high backscattering struts.
- High OCT signal intensity makes differentiation from fibrotic tissues difficult

*Post-Procedural*
Different BRS Platforms

**ABSORB**

- Preserved box appearance
- Low backscattering strut core is easily identified embedded into the NIH tissue.

**DESolve**

- Most struts retain their box-shaped appearance.
- Some struts present advanced degradation w/ diffuse boundaries.

**Fanton**

- Low backscattering long strips, locking system and backbone are easily recognized embedded into the NIH tissue.

**MIRAGE**

- High backscattering struts have an optical signal intensity close to that of fibrotic tissue, their identification difficult when embedded into NIH tissue.

6-Month Follow-up
3 Ps for Optimal Implantation of Absorb

1. **Proper Vessel Sizing**

2. **Preparation of the Lesion**

3. **Pay attention to Expansion Limits**
3 Ps for Optimal Implantation of Absorb

1. **Proper Vessel Sizing**

2. **Preparation of the Lesion**

3. **Pay attention to Expansion Limits**
#1 Proper Vessel Sizing

Vessel Sizing Using On-line QCA (\(D_{\text{max}}\))

- Measure the vessel diameter using the on-line QCA parameters distal \(D_{\text{max}}\) and proximal \(D_{\text{max}}\):
  - The maximum lumen diameter evaluated at the distal and proximal ends of the target segment to be scaffolded, respectively.

<table>
<thead>
<tr>
<th>Target Vessel Diameter</th>
<th>BRS Size to be Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>(\geq 2.0 \text{ mm and } \leq 3.0 \text{ mm})</td>
<td>2.5 mm</td>
</tr>
<tr>
<td>(\geq 2.5 \text{ mm and } \leq 3.3^* \text{ mm})</td>
<td>3.0 mm</td>
</tr>
<tr>
<td>(\geq 3.0 \text{ mm and } \leq 3.8^* \text{ mm})</td>
<td>3.5 mm</td>
</tr>
</tbody>
</table>

*Allows for 1:1 scaffold:artery sizing without exceeding expansion limit
#1 Proper Vessel Sizing
Limitations of Various Vessel Sizing Techniques

- Actual: 3.0 mm
- OCT: 3.0 mm
- IVUS: 3.1 mm
- QCA: 2.8 mm
- Visual Estimate: 2.7 – 3.3 mm

Recognize the risk of under-estimating vessel size by visual estimation.

Use pre-dilatation to help guide and confirm vessel size.

Margin of Error*
3 Ps for Optimal Implantation of Absorb

1. **Proper Vessel Sizing**

2. **Preparation of the Lesion**

3. **Pay attention to Expansion Limits**
#2 Preparation of the Lesion

- Predilatation is strongly recommended.
  - Choose a predilatation balloon that is shorter than the scaffold length.
  - Choose a balloon diameter that matches the RVD.
  - Use of a non-compliant (NC) balloon may be useful in some lesions.
  - Predilatation may be useful to help determine vessel size.

- Confirm full expansion of the predilatation balloon – do not treat patients with a greater than 40% residual stenosis after predilatation (i.e., heavily calcified lesions)

- For heavily calcified lesions consider scoring balloons and rotablator
3 Ps for Optimal Implantation of Absorb

1. **Proper Vessel Sizing**

2. **Preparation of the Lesion**

3. **Pay attention to Expansion Limits**
Expansion
Patience While Inflating

- Deploy the scaffold slowly by pressurizing the delivery system in 2 atm increments every 5 seconds, until the scaffold is completely expanded.
  - Slow pressurization is intended to promote optimal scaffold deployment and is independent of scaffold sizing considerations

- Optimal scaffold apposition may be achieved between nominal and RBP pressures.
- Maintain pressure for 30 seconds.
  - If necessary, the delivery system can be deflated and re-pressurized or further pressurized to ensure complete apposition of the scaffold to the artery wall.

This is consistent with the Absorb IFU
#3 Pay Attention to Expansion Limits

- The delivery balloon can be taken to rated burst pressure (RBP) without exceeding the expansion limits of the scaffold.
  - Do not exceed RBP.

## Expansion Limits Table

<table>
<thead>
<tr>
<th>Diameter (mm)</th>
<th>ATM (NOM)</th>
<th>kPa</th>
<th>Expansion Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5 mm</td>
<td>6</td>
<td>608</td>
<td>2.53 mm</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>709</td>
<td>2.60 mm</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>811</td>
<td>2.66 mm</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>912</td>
<td>2.71 mm</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>1013</td>
<td>2.76 mm</td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>1115</td>
<td>2.79 mm</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>1216</td>
<td>2.82 mm</td>
</tr>
<tr>
<td></td>
<td>13</td>
<td>1317</td>
<td>2.86 mm</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>1419</td>
<td>2.89 mm</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>1520</td>
<td>2.91 mm</td>
</tr>
<tr>
<td></td>
<td>16 (RBP)</td>
<td>1621</td>
<td>2.94 mm</td>
</tr>
<tr>
<td>3.0 mm</td>
<td>6 (NOM)</td>
<td>608</td>
<td>2.94 mm</td>
</tr>
<tr>
<td></td>
<td>7 (NOM)</td>
<td>709</td>
<td>3.02 mm</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>811</td>
<td>3.08 mm</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>912</td>
<td>3.15 mm</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>1013</td>
<td>3.20 mm</td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>1115</td>
<td>3.24 mm</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>1216</td>
<td>3.28 mm</td>
</tr>
<tr>
<td></td>
<td>13</td>
<td>1317</td>
<td>3.31 mm</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>1419</td>
<td>3.34 mm</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>1520</td>
<td>3.37 mm</td>
</tr>
<tr>
<td></td>
<td>16 (RBP)</td>
<td>1621</td>
<td>3.40 mm</td>
</tr>
<tr>
<td>3.5 mm</td>
<td>6 (NOM)</td>
<td>608</td>
<td>3.50 mm</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>709</td>
<td>3.59 mm</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>811</td>
<td>3.66 mm</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>912</td>
<td>3.73 mm</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>1013</td>
<td>3.78 mm</td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>1115</td>
<td>3.83 mm</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>1216</td>
<td>3.87 mm</td>
</tr>
<tr>
<td></td>
<td>13</td>
<td>1317</td>
<td>3.91 mm</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>1419</td>
<td>3.94 mm</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>1520</td>
<td>3.98 mm</td>
</tr>
<tr>
<td></td>
<td>16 (RBP)</td>
<td>1621</td>
<td>4.01 mm</td>
</tr>
</tbody>
</table>
#3 Pay Attention to Expansion Limits

- When expanding the scaffold, be sure to stay within the expansion limits of the device:

<table>
<thead>
<tr>
<th>Nominal Scaffold Diameter</th>
<th>Maximum Dilatation Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5 mm</td>
<td>3.00 mm</td>
</tr>
<tr>
<td>3.0 mm</td>
<td>3.50 mm</td>
</tr>
<tr>
<td>3.5 mm</td>
<td>4.00 mm</td>
</tr>
</tbody>
</table>

CAUTION: Do not dilate the scaffold beyond the maximum dilatation limit. Expansion beyond the dilatation limits listed above, may result in scaffold damage.

This is consistent with the Absorb IFU, Section 10.7
There are two pairs of platinum marker beads – one pair at each end of the scaffold.

Each end of the scaffold is aligned with markers on the delivery catheter.

- Scaffold markers lie near the inner edge of each marker on the delivery catheter.

NOTE: the struts are not visible under fluoroscopy.
Appendix

Final Scaffold Diameter May Appear Smaller Than It Is

- The treated segment may appear slightly smaller than it actually is, simply due to non-radiopaque struts reducing contrast density
  - Radiopaque metallic stents may enhance the contrast density at the lumen edges
- Post-dilatation balloon pressurization (atm) should be determined by desired scaffold diameter
Special Anatomical Situations

- Bifurcation
- Multiple scaffolds with overlapping
- Tortuosity
- Calcified lesions
Special Anatomical Situations

- Bifurcation
- Multiple scaffolds with overlapping
- Tortuosity
- Calcified lesions
ABSORB EXTEND
Small Side Branch Occlusion

Magnitude of post-procedural CK-MB elevation

62, male, CCS II
68, male, NSTEMI
68, male, NSTEMI

ABSORB 3.5/28 mm
68, male, NSTEMI

Pantera LEO 2.5/20 mm
68, male, NSTEMI
DE Solve Scaffold

Side Branch Dilatation: Fracture Resistance

3.0 mm NC balloon at 22 atm

EuroIntervention Feb 2015; Ormiston et al.
Special Anatomical Situations

- Bifurcation
- **Multiple scaffolds with overlapping**
- Tortuosity
- Calcified lesions
Overlap population results at parity to non-overlap population

1-year MACE rate in overlap population is comparable to non-overlap population

Farooq, EXTEND Overlap Subgroup, Rotterdam PCR Focus on BVS, 2013
44-year old female, diabetes and hypertension
OVERLAPPING

2 STENTS

POST

12-month fu
Special Anatomical Situations

- Bifurcation
- Multiple scaffolds with overlapping
- Tortuosity
- Calcified lesions
Desolve NX Serial Angiography

Pre-PCI

Post-Procedure

6-Month Follow-up

18-Month Follow-up
DE Solve NX: 36-Month Follow-up
DESSolve NX: 36-Month Follow-up
DESolve NX: 36-Month Follow-up

Daniel Chamie (Cardiovascular Research Center, Sao Paulo, Brazil)
Special Anatomical Situations

- Bifurcation
- Multiple scaffolds with overlapping
- Tortuosity
- Calcified lesions
54-year old male, former smoker, dyslipidemia, taking aspirin and statin. Asymptomatic with ischemia in the inferior and lateral wall by scintigraphy.
Summary – the Do’s and Don’ts

• Do:
  • Properly and carefully size the vessel
  • Prep the lesion thoroughly
  • Pay attention to expansion limits

• Don’t:
  • Small vessels (< 2.25 mm)
  • For bifurcations try to avoid aggressive kissing balloon technique
  • Dilate beyond the expansion limits
  • Insert Absorb when residual stenosis after pre-dil > 50%

*Kissing balloon technique is considered off-label and techniques referenced must be indicated by physician only.