The Serial follow-up of jailed side branches after implantation of bioresorbable scaffold – Insights from the ABSORB Cohort B trial using three-dimensional optical coherence tomography

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Background:

- Bioresorbable scaffolds consisting of poly-lactic are inherently programmed to bioresorb in three years.
- It is still unknown how the struts implanted in front of a side branch behave during bioresorption.
- The purpose of this study was to assess the fate of bioresorbable struts jailing side branch ostia at 6, 12, 24, 36 and 60 months after implantation of the everolimus-eluting Absorb scaffold with three-dimensional (3-D) optical coherence tomography (OCT) reconstruction.
Why 3D OCT? In the ABSORB Cohort A trial...
Why 3D OCT? In 2008, we speculated

BL

6M

2Y
In the ABSORB Cohort A trial, Bioresorption of jailed side branch are real phenomenon. (M2/3, 1-3mm/s, 15-20fps) Okamura et al. EHJ 2010)
Absorb Cohort B

- Lower MCUSA (maximum circular unsupported surface area)
- More even support of arterial wall
- More uniform strut distribution
- Lower late stent area loss
- Higher radial strength
- Improved stent retention
- Unchanged:
  - Material
  - Strut thickness

Photos taken by and on file at Abbott Vascular.
What is the feasibility of 3-D OCT reconstruction?

In-vitro experiment
3-D reconstruction of OFDI-OCT (TERUMO)

Distal

From Inside

Proximal
Classification of Jailed sidebranch ostium according to number of compartment created by the overhanging struts with different configuration (e.g. V, T and H type)

Absorb Cohort B (n=17)

Today, with 3-D OFDI we can further evaluate the bioresorption process.
3D OCT is also feasible at FUP
There are no clinical events related to sidebranch.

<table>
<thead>
<tr>
<th></th>
<th>BL (n=15)</th>
<th>6M (n=15)</th>
<th>2Y (n=13)</th>
<th>p(BL-6M)</th>
<th>p(BL-2y)</th>
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</thead>
<tbody>
<tr>
<td>No. of Compartments</td>
<td></td>
<td></td>
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<tr>
<td>Ostium area free from Strut, mm²</td>
<td>2.13±1.1</td>
<td>1.93±1.0</td>
<td>1.31±0.69</td>
<td>0.1</td>
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<td></td>
<td>0.58 ± 0.12</td>
<td>0.85 ± 0.26</td>
<td>0.3 ± 0.36</td>
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<td>10.8</td>
<td>1.4±0.85</td>
<td>1.18±0.41</td>
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<td></td>
<td>0.91 ± 0.64</td>
<td>0.47 ± 0.38</td>
<td>0.68±0.38</td>
<td>0.002</td>
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</tr>
</tbody>
</table>

Preliminary results
Analysis ongoing for 5Y
At Baseline

Distal

A
B
C
D
E
F

Prox

At 6Mo

Distal

G

H

At Baseline

At 6Mo
Bioresorption over time: OCT/ histology in animal

Onuma, Serruys Circulation 2010

Molecular Weight

Mass Loss

Support

1 3 6 12 24 36 Mo 48Mos

HU HU HU HU

PO PO

HU HU PO PO
Limitation

• By design, major side branches were excluded from the trials although some major side branches incidentally included resulted in protocol violation.

• Longitudinal resolution is limited and subject to cardiac motion artefact.
Summary

• In the ABSORB B trial, OCT 3-D analysis showed that the ostial area free of struts remained unchanged at 6 months compared to baseline. At 12 and 24 months, the ostium area reduced due to growing tissue covering over and between the struts. However there are so far no clinical consequences of this phenomenon.

• In the preliminary analysis, the ostium area seems to increase from 1 year to 3 years due to the reduction of neointima and recreation of bifurcation carina.

• 5 year analysis is ongoing…
Reduction of ostium area also occurs with metallic DES