New manufacturing process and stent design are key elements to improve clinical outcome: the iVascular IVolution stent example.

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Speaker’s name: Peter Goverde

- I have the following potential conflicts of interest to report:
  - Consulting:
    - Abbott Vascular; Angioslide; Atrium Maquet Getinge group; Bard Peripheral Vascular; Cardionovum; Cordis Cardinal Health; IMDS; Ivascular; Stille; Veyran; Ziehm Imaging
Material or Metal defects

Material or metal fatigue

Fracture
Damage
Disaster
SX stent: what are the potential clinical issues?

- STENT FRACTURE
- THROMBUS
- RESTENOSIS
Can the stent production proces be an influencing factor And can this be optimised?
**The iVascular technical solutions**

| Low | 1. Inflammatory reaction | • A) Radial Force  
|     |                           | • B) Surface treatment → passivation in order to avoid corrosion |
|     | 2. Stent Fracture         | • A) The importance of stent design  
|     |                           | • B) No inclusion (no defect) → no material weak point |
| Smooth | 3. endothelialization to prevent thrombus | • A) Stent design to enhance blood flow hemodynamics  
|       |                             | • B) Perfect surface finishing → electro polishing |
KEY POINT 1: Equilibrated radial force

- To maintain the artery open
- Without applying high permanent stress on artery wall

![Graph showing radial force comparison](image)

1. Preventing restenosis
KEY POINT 2: Surface treatment = passivation

- To avoid corrosion and Nickel release
- **Ultra thin layer of TiO2 on stent Surface after electro polishing**
- Key: adequate thickness of TiO2, or reverse effects

<table>
<thead>
<tr>
<th>Thickness (nm)</th>
<th>&gt;3500</th>
<th>420</th>
<th>130</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cracks</td>
<td>Very high</td>
<td>Medium</td>
<td>Medium</td>
<td>No</td>
</tr>
<tr>
<td>Corrosion resistance</td>
<td>Very low</td>
<td>High</td>
<td>Medium</td>
<td>Very high</td>
</tr>
<tr>
<td>Nickel on surface</td>
<td>Yes, many</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Corrosion analysis to test the passivation layer (to avoid corrosion)
1. Pitting corrosion test: conducted following the ASTM F2129 to evaluate the corrosion resistance of a stent
2. SEM analysis: to reveal the weak points in corrosion through images
1. Preventing restenosis

<table>
<thead>
<tr>
<th>Applied potential (mV)</th>
<th>iVolution</th>
<th>Smart Flex</th>
<th>Complete SE</th>
<th>Absolut Pro</th>
<th>Lifestent</th>
<th>Epic</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;1000</td>
<td>755</td>
<td>735</td>
<td>645</td>
<td>520</td>
<td>427</td>
<td></td>
</tr>
<tr>
<td>Remarks</td>
<td>No break</td>
<td>Break</td>
<td>Break</td>
<td>Break</td>
<td>Break</td>
<td>Break</td>
</tr>
</tbody>
</table>

Lowering inflammatory reaction

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2A. the importance of stent design

Best resistance to fracture = stent design without bridges nor direct connections (J. Endovascular Ther 2010 – Muller-Hulsbeck Comparison 2nd generation stents for application in SFA)

- iVolution stent doesn’t have bridges
- Continuous design
- Open cell design with short cell length
2B. Optimal quality of material

- No inclusions (no defects) = absence of weak point in the material
- There can be different kinds of inclusions in the nitinol tube:
  
  **OXYGEN**: very hard
  - Surface TiO$_2$
    - Passivation in contact with the atmosphere
    - Wall thickness of the layer
  - Inside Ti$_4$Ni$_2$O$_x$
    - Happens during ingot manufacturing
    - Can create tunnels during tube extrusion
  - > Decreased resistance to fatigue, corrosion and ductility

  **CARBIDES**: soft
  - TiC
    - Happens if the alloy is manufactured in a graphite kettle
  - > Fractures on the line of the inclusion
No inclusions (no defects)

<table>
<thead>
<tr>
<th>iVolution</th>
<th>Other commercial stents</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Image" /></td>
<td><img src="image2" alt="Image" /></td>
</tr>
<tr>
<td><img src="image3" alt="Image" /></td>
<td><img src="image4" alt="Image" /></td>
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<tr>
<td><img src="image5" alt="Image" /></td>
<td><img src="image6" alt="Image" /></td>
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<tr>
<td><img src="image7" alt="Image" /></td>
<td><img src="image8" alt="Image" /></td>
</tr>
<tr>
<td><img src="image9" alt="Image" /></td>
<td><img src="image10" alt="Image" /></td>
</tr>
</tbody>
</table>

The absence of inclusions in the tube of the final stent are key to ensure the quality of the stents and to avoid the risk of fractures.
2B. Optimal quality of material

- 6 stents are evaluated during comparative bench tests
- Inclusions are quantified with Qsix technology (Sensofar)

<table>
<thead>
<tr>
<th>Products</th>
<th>Max Inclusion Area Fraction (µ²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete SE (M)</td>
<td>36.568</td>
</tr>
<tr>
<td>Smart Flex (C)</td>
<td>10.986</td>
</tr>
<tr>
<td>Epic (BS)</td>
<td>14.566</td>
</tr>
<tr>
<td>Lifestent (B)</td>
<td>11.512</td>
</tr>
<tr>
<td>Absolute Pro (A)</td>
<td>27.906</td>
</tr>
<tr>
<td>iVolution (iV)</td>
<td>3.259</td>
</tr>
</tbody>
</table>

iVolution shows the lowest inclusion rate
3A. Stent design enhancing flow hemodynamics

6 stent designs have been evaluated during 4 sets of comparative bench tests, to assess:

• 1\textsuperscript{st} flexibility: Stent ability to adapt to the vessel anatomy:
• 2\textsuperscript{nd} flexibility test: Stent ability to recover its shape after impact
• Kinking test
• Stent resistance to bending
FLEXIBILITY is defined as the stent ability to adapt to the anatomy of the treated artery without compromising the function of the implant.
The more flexible, the more adaptability to the vessel.

<table>
<thead>
<tr>
<th>HIGH FLEXIBILITY STENTS</th>
<th>SEMI FLEXIBLE STENTS</th>
<th>NOT FLEXIBLE STENTS</th>
</tr>
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<tbody>
<tr>
<td>ivOLUTION - ivASCULAR</td>
<td>ABSOLUT PRO LL - ABBOTT</td>
<td>COMPLETE SE - MEDTRONIC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EPIC - BS</td>
</tr>
<tr>
<td></td>
<td>LIFESTENT - BARD</td>
<td>SMART FLEX - CORDIS</td>
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3A. Stent design enhancing flow hemodynamics

FLEXIBILITY as the capability of not modifying the treated vessel. The lower is the force of the stent, higher flexibility and better adaptability to the vessel anatomy.
3A. Stent design enhancing flow hemodynamics

KINKING:
- The radius at which the stents loses its structure
- Stent ability to adapt to the curvatures.

ABSOLUT PRO LL - ABBOTT
LIFESTENT - BARD
EPIC - BS
SMART FLEX - CORDIS
iVOLUTION - iVASCULAR
COMPLETE SE – MEDTRONIC
RESISTANCE TO BENDING is the measure of the stretching and shortening forces at which the stent is subjected to. The larger the force, the lower the stent resistance to leg bending.
Comparative study of the corrosion behavior of peripheral stents in an accelerated corrosion model: experimental *in vitro* study of 28 metallic vascular endoprostheses

**PURPOSE**

Clinical cases of stent-fractures show that corrosion behavior might play a role in these fractures. Implanted *in vivo*, especially in combination with other implanted foreign materials, these metallic products are exposed to special conditions, which can cause a process of corrosion. Here, we aimed to test the corrosion potential of stents made of different materials in an *in vitro* setting.

**CONCLUSION**

The analysis of corrosion behavior may be useful to select the right stent fulfilling the individual needs of the patient within a large number of different stents. Electropolished stents showed the best results.
3B. Perfect surface finishing
Importance of Electro Polishing

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**Magnification 75 X**

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3B. Perfect surface finishing
Importance of Electro Polishing

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Magnification 100

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IMPROVING STENT OUTCOMES

1. Preventing restenosis
2. Avoiding stent rupture
3. Limiting thrombus formation
4. OPTIMAL POST PRODUCTION CONTROL

Balanced radial force
Lowering inflammatory reaction
Stent Design
Enhancing flow dynamics
Perfect surface finishing
Quality of materials
Post production analysis & control:

- As important as the optimal production line
- Mostly done by randomised control
- Mostly done by human inspection
- Not every stent will be controlled

- Thus failure can slip through
The **Q six** is able to **simultaneously** acquire and analyze images of the **outer and inner surfaces** as well as the **sidewalls** of the stent structure at a rate ranging from **5 mm²/s** to **20 mm²/s**.

- High NA optical design, premium CF60-2 Nikon objectives
- multi-million pixel imaging array
- unique combination of light sources provide extremely sharp views of the complete stent surface with unprecedented real color, resolution and contrast.

- High-resolution imaging and 3D optical measurement allow for complete surface inspection of the stent structure, reducing
  - Errors
  - quality control costs
  - inspection time

- making the task of acceptance faster, easier and more reliable

**Post production control**
Post production control

Surface topography
Verify the depth of score marks or scratches of your stents. 3D Topography of a defect can be obtained in seconds with a lateral resolution of 0.5 microns and a vertical resolution of 1 nm.

Extremely high inspection rate

UP TO 1 CORONARY STENT PER MINUTE

Mapping the thickness of coatings
Check the performance of your process and coating uniformity. Thickness of optically transparent coatings is mapped all across the width of the stent with a lateral resolution of 0.5 microns and a vertical resolution of 2 nm in just a few seconds. The minimum value of the thickness that can be measured is approximately 2 microns.

Surface roughness
Check the quality of your electro-polishing process. Standard surface texture parameters are measured according to ISO 25178. The operator can select areas of measurement at the outer surface of the stent and filtering parameters.
Conclusions

iVascular technical solutions to improve SX stent clinical outcomes

| Fracture risk                      | ✓ Optimal stent design |
|                                   | ✓ Controlled manufacturing process to prevent material defect and weak points |

| Smooth endothelialization to prevent thrombus | ✓ Optimal design to respect artery and blood flow hemodynamics |
|                                            | ✓ Ideal surface finishing |

| Low Inflammatory reaction               | ✓ Balanced radial force |
|                                       | ✓ Stent passivation to prevent corrosion |

| Post production control                 | ✓ Qsix control of outer/inner/side surfaces |
|                                       | ✓ EVERY PRODUCED STENT IS INSPECTED |
Thank you for your attention!
New manufacturing process and stent design are key elements to improve clinical outcome: the iVascular IVolution stent example

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