Coronary Balloon Catheters

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Development of Coronary Balloon Catheters

- Percutaneous transluminal angioplasty has evolved since the 1960s, when the dilating catheters used in the first angioplasty procedures were inflexible Teflon coaxial devices limited by the need for large-bore access for increased dilation diameters.
- In addition, the advancement of the coaxial system into the stenotic lesion created an undesirable shearing force.
- During the 1970s, Teflon catheters with internal coaxially placed latex balloons provided increased radial force and eliminated the shearing force inherent to the original technique, as well as the need for large-bore access.
Development of Coronary Balloon Catheters

- However, these catheters still lacked flexibility, which limited their use. Teflon was replaced by polyvinyl chloride (PVC) balloon catheters, which added flexibility. This led to the first coronary artery angioplasty, resulting in significant improvement in vessel diameter and cardiac function.
- The flexible polyvinyl chloride (PVC) were relatively thick walled and designed for low pressure, compared with today’s high-pressure balloons.
- Cross-linked polyethylene came into use in the early to mid-1980s, about the same time that polyethylene terephthalate (PET) was adopted for high-pressure balloons; to a large degree, these two materials replaced PVC.

Development of Coronary Balloon Catheters

- Nylon balloons were introduced in the late 1980s, and polyurethane balloons followed in the early 1990s. Nylon, though not as strong as PET or as compliant as polyethylene, was seen as a compromise because it is relatively strong and can be used in relatively thin designs.
- Currently, most high-pressure medical balloons are made from either PET or nylon. PET offers advantages in tensile strength and maximum pressure rating, whereas nylon is softer.
Through the Evolution of Balloon Catheter, we realized that a good balloon catheter shall be:

- Flexible to pass through the tortious anatomy and lesions.
- Have high radial force,
- The radial or hoop tensile strength of a balloon calculated as follows:
  \[ TS = \frac{P \times D}{DW} \]
  Where
  - \( TS \) = Tensile Strength (hoop)
  - \( P \) = Burst Pressure
  - \( D \) = Diameter
  - \( DW \) = Balloon Double Wall Thickness
- Has minimal shearing stress, the form of stress in a body, part, etc, that tends to produce cutting rather than stretching or bending.

**What is Balloon Catheter?**

- Type of "soft" catheter with an inflatable "balloon" at its tip which is used during a catheterization procedure to enlarge a narrow opening or passage within the body.

- Balloon catheters used in angioplasty are either of Over-the-Wire(OTW) or Rapid Exchange(Rx) design.
Applications of Balloon Catheters

- Used to compress plaque within a clogged coronary artery it is referred to as a plain old balloon angioplasty or POBA.

- Also utilized in the deployment of stents during angioplasty.

- Supplied to the cath lab with a stent premounted on the balloon, known as balloon expandable stents.

Applications of Balloon Catheters

- Local delivery of drugs via nonstent-based platforms, drug-eluting balloons (DEB).

- Used as Atheroablative therapies through the blades or atheromes that are mounted on the balloon.

- And there are more specific indications for coronary balloon catheter.
Other Applications

- Applications also include the following:
  - Heat-transfer catheters.
  - Photodynamic therapy devices.
  - Laser balloon catheters.
  - Cryogenic catheters.
  - Arthrectomy catheters.

Different Applications require different specifications
Balloon ends are of high significance as it may cause dissection to the vessel during inflation, therefore rounded balloons are more favourable as they cause less dissection.

Also smaller balloon end is more favourable than the long for precise positioning.
Two basic types of balloons are used in the medical industry.

- **The first type**: high-pressure, nonelastic dilatation- or angioplasty-type balloons.
  - Used to apply force.
  - Molded to their inflated geometry from noncompliant or low-compliant materials that retain their designed size and shape even under high pressure. They are thin walled and exhibit high tensile strength, with relatively low elongation.

- **The second type** comprises low-pressure, elastomeric balloons, typically made of latex or silicone.
  - Used primarily in fixation and occlusion.
  - Typically dip molded in a tubular shape, and are then expanded to several times their original size during use. Thus, these balloons cannot be inflated to precise dimensions and cannot retain well-defined shapes, nor maintain high pressures.
Compliance

**Definition:**
It describes the degree to which the diameter of a balloon changes as a function of pressure.

**Types/Categories:**
- **Non-compliant:** No matter how much pressure, the balloon diameter doesn't enlarge but the pressure is applied to the vessel's wall instead.
  
  Compliance range: 5-10%.

- **Semi-Compliant:** The balloon increases as the pressure increases but to a certain diameter.
  
  Compliance range: 15-30%

- **High-Compliant:** The balloon responds and its diameter increases directly with the applied pressure.
  
  Compliance range: 100-600% or more

Properties of the different types

- **Non-compliant:**
  Ultra high-strength, thin-walled.
  Fabricated from PET.

- **Semi-Compliant:**
  High-strength, thin-walled.
  Can be fabricated from PET, Nylon, Polyurethane, other thermoplastic elastomers.

- **High-Compliant:**
  Low pressure, thin and thick-walled.
  Fabricated from Polyurethane, Nylon elastomers, and other thermoplastic elastomers.
A wide variety of coatings can be added to the surface of a balloon to enhance or change its properties to meet new requirements. Balloon coatings include the following:

- Lubricious coatings (hydrophilic and hydrophobic)
- Abrasion and puncture resistant coatings
- Tacky or high-friction coatings
- Conductive coatings
- Anti-thrombogenic coatings
- Drug-release coatings
- Reflective coatings
- Selective coatings

### Coatings

### Comparisons

<table>
<thead>
<tr>
<th>Delivery system Design</th>
<th>Trek (Abbott)</th>
<th>MiniTrek (Abbott)</th>
<th>Ryujin and Ryujin Plus (Terumo)</th>
<th>Maverick (Boston)</th>
<th>Apex (Boston)</th>
<th>Sprinter Legend (Medtronic)</th>
<th>Dura Star (Cordis)</th>
<th>Fire Star (Cordis)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Connection between Catheter and Hub</strong></td>
<td>Skive design, sliced section of the hypotube that gradually forms to a fine point, prevents kinking and provides a smooth transition between the hypotube and distal shaft.</td>
<td>PTFE coated Hypotube</td>
<td>Stainless Steel, Integrated Hypotube</td>
<td>Stainless Steel, Integrated Hypotube</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Hypotube diameters</strong></td>
<td>OD: 0.027&quot;, ID: 0.021&quot; OD: 0.027&quot;, ID: 0.021&quot; OD: 0.025&quot; OD: 0.024&quot; OD: 0.027&quot; OD: 0.025&quot; OD: 0.025&quot;</td>
<td></td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Tip</strong></td>
<td>Flexible, smooth, rounded</td>
<td>Flexible, smooth, rounded</td>
<td>New Cross Tip™</td>
<td>TrakTip™</td>
<td>FastTrac Tip™</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tip Profile</strong></td>
<td>0.017&quot; 0.017&quot;</td>
<td>0.018&quot; 0.017&quot; 0.017&quot; 0.016&quot;</td>
<td>0.019&quot;</td>
<td></td>
<td></td>
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<tr>
<td><strong>Delivery System Working Length</strong></td>
<td>145 cm</td>
<td>135 cm, 148 cm</td>
<td>143 cm</td>
<td>143 cm</td>
<td>142 (Rx), 152 (OTW)</td>
<td>145 cm</td>
<td>145 cm</td>
<td></td>
</tr>
<tr>
<td><strong>Type of Catheter (Rx/OTW)</strong></td>
<td>Rx</td>
<td>Rx, OTW</td>
<td>Rx, OTW</td>
<td>OTW, Monorail</td>
<td>OTW, Monorail</td>
<td>OTW, Rx</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Outer Shaft Coating</strong></td>
<td>Dual Hydrophilic</td>
<td>Dual Hydrophilic</td>
<td>Hydrophilic coating and distal silicon coating</td>
<td>Hydrophilic coating</td>
<td>new nano-composite material</td>
<td>Selective DuraTrac</td>
<td>Hydrophilic</td>
<td>Hydrophilic</td>
</tr>
<tr>
<td><strong>Crossing Profile</strong></td>
<td>0.021&quot;</td>
<td>0.021&quot;</td>
<td>0.023&quot;</td>
<td>0.026&quot;</td>
<td>0.024&quot;</td>
<td>0.024&quot;</td>
<td>0.028&quot;</td>
<td></td>
</tr>
<tr>
<td><strong>Inner Lumen Shaft Coating</strong></td>
<td>Microglide Inner Membrane coating</td>
<td></td>
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</table>
### Comparisons

#### G.C. System

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<tr>
<th>Trek (Abbott)</th>
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<th>Dura Star (Cordis)</th>
<th>Fire Star (Cordis)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 Fr</td>
<td>5 Fr</td>
<td>6 Fr</td>
<td>6 Fr (OTW), 5 Fr (Rx)</td>
<td>5 Fr</td>
<td>5 Fr</td>
<td>5 Fr</td>
<td>6 Fr</td>
</tr>
</tbody>
</table>

#### Enhanced radiopacity

- Two Tungsten Markers
- Two Radiopaque Markers at the balloon edges and another two depth markers
- Platinum-Iridium double marker
- Swaged Platinum Markers and two exit markers
- Swaged Platinum Markers and two exit markers

#### Balloon Specifications

<table>
<thead>
<tr>
<th>Material</th>
<th>Folding</th>
<th>Sealing Technology</th>
<th>Balloon Profile</th>
<th>Compliance of the Balloon</th>
<th>Pressure a. Nominal</th>
<th>Pressure b. Rated Burst</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pebax (Multi-layer CrossFlex™ balloon)</td>
<td>Trifold</td>
<td>Slim Seal Tech™</td>
<td>0.032” 0.026”</td>
<td>Semi-compliant semi-compliant</td>
<td>8 atm 8 atm</td>
<td>14 atm 8 atm</td>
</tr>
<tr>
<td>Peabax</td>
<td>Tri-fold</td>
<td>Tri-fold</td>
<td>0.034” 0.033” 0.032”</td>
<td>Semi-compliant semi-compliant</td>
<td>6 atm 6 atm</td>
<td>12/14 atm 12/14 atm</td>
</tr>
<tr>
<td>DynaLEAP™ Balloons</td>
<td>Tri-fold</td>
<td>Semi-compliant</td>
<td>0.034”</td>
<td>Semi-Compliant</td>
<td>6/8 atm 14 atm</td>
<td>20 atm 14 atm</td>
</tr>
<tr>
<td>SoftLEAP™ Balloons</td>
<td>Tri-fold and 5-folds</td>
<td></td>
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</tr>
<tr>
<td>Fulcrum</td>
<td>Trifold</td>
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<tr>
<td>Duralyn™ Peabax/Nylon</td>
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<tr>
<td>Duralyn™ Peabax/Nylon</td>
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#### Comparisons

<table>
<thead>
<tr>
<th>DEB</th>
<th>Company</th>
<th>Country</th>
<th>Egyptian Distributor</th>
<th>Balloon coating</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEB</td>
<td>University Charité</td>
<td>Germany</td>
<td>Temco Ghalany</td>
<td>Balloon coating 1.3 - 3µg/mm² balloon surface + Hydrophilic X-ray contrast medium, Iopromide “Ultravista”</td>
</tr>
<tr>
<td>DEB</td>
<td>B-Braun</td>
<td>Germany</td>
<td>Temco Ghalany</td>
<td>Modified Paccocath</td>
</tr>
<tr>
<td>Dior I</td>
<td>Eurocore</td>
<td>Germany</td>
<td>NADA</td>
<td>Balloon coating Crystallized Paclitaxel (3µg/mm² balloon surface) following dimethylsulphate treatment</td>
</tr>
<tr>
<td>Dior II</td>
<td>Eurocore</td>
<td>Germany</td>
<td>NADA</td>
<td>Balloon coating 3µg/mm² balloon surface + Hydrophilic Shellac matrix (1:1), Shellac is composed of network of hydroxy fatty acids and sesquiterpene acid esters with molecular weight = 1000</td>
</tr>
<tr>
<td>InPACT</td>
<td>Invatec Meditronic</td>
<td>Switzerland</td>
<td>Delta</td>
<td>Balloon coating Paclitaxel 3µg/mm² balloon surface + FreePac (Hydrophilic proprietary formulation + urea as matrix substance)</td>
</tr>
<tr>
<td>Elutax I</td>
<td>Aachen Resonance</td>
<td>Germany</td>
<td>Delta</td>
<td>Balloon coating Paclitaxel 3µg/mm² balloon surface on Structural balloon surface</td>
</tr>
<tr>
<td>Elutax II</td>
<td>Aachen Resonance</td>
<td>Germany</td>
<td>Delta</td>
<td>Balloon coating two layers of Paclitaxel (elastic and drug depot)</td>
</tr>
<tr>
<td>Wombat</td>
<td>Avidal</td>
<td>Germany</td>
<td>Delta</td>
<td>Balloon coating Paclitaxel 3µg/mm² balloon surface + proprietary drug wrap to protect the drug against the blood flow</td>
</tr>
<tr>
<td>Pantera Lux</td>
<td>Biotronik</td>
<td>Germany</td>
<td>Technowave</td>
<td>Balloon coating Paclitaxel 3µg/mm² balloon surface + BTHC carrier (Butyltry-trihexylcitrate)</td>
</tr>
<tr>
<td>Moxy</td>
<td>Lutonix</td>
<td>USA</td>
<td></td>
<td>Balloon coating Paclitaxel 2µg/mm² balloon surface + proprietary excipient</td>
</tr>
<tr>
<td>Danubio</td>
<td>Minvasys</td>
<td>France</td>
<td>Misr Medical</td>
<td>Balloon coating no additives</td>
</tr>
</tbody>
</table>

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Thank You