Biomechanical assessment of the longitudinal compression behaviour of contemporary coronary stents: an in vitro comparative study

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How far are stents compressed with 0.5N force?

- The Cypher Select did not shorten
- The Element shortened 5mm
- Xience 1mm
<table>
<thead>
<tr>
<th></th>
<th>Cypher Select</th>
<th>Liberte</th>
<th>Vision Xience V</th>
<th>MultiLink 8 Xience Prime</th>
<th>Driver Endeavor</th>
<th>Integrity Resolute</th>
<th>Omega ION Element</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material</td>
<td>Stainless steel</td>
<td>Stainless steel</td>
<td>Cobalt Chromium</td>
<td>Cobalt Chromium</td>
<td>Cobalt Chromium</td>
<td>Cobalt Chromium</td>
<td>Platinum Chromium</td>
</tr>
<tr>
<td>Thickness</td>
<td>140μ</td>
<td>100μ</td>
<td>81μ</td>
<td>81μ</td>
<td>91μ</td>
<td>91μ</td>
<td>81μ</td>
</tr>
<tr>
<td>Connectors</td>
<td>6 connectors</td>
<td>3 connectors</td>
<td>3 connectors</td>
<td>3 connectors</td>
<td>2 connectors</td>
<td>2 (3) connectors</td>
<td>2 connectors</td>
</tr>
</tbody>
</table>
Background : Why such a study?

New stent struts are thinner due to the development of newer metal alloys, such as cobalt chrome and platinum chrome.

New designs of stents have fewer connectors between the hoops in order to improve profile.

Back of the medal: These innovations may adversely affect stent longitudinal integrity with, as consequences, shortening or elongation of stents due to the struts being pushed together or pulled apart.

But is it so caricatural?

The first role of a stent is to support artery with a sufficient radial resistance to compression.
Goals of the present study

In vitro comparative trials of several contemporary coronary stent systems:

- direct longitudinal crush resistance (mechanical characterization, Ormiston like)

- simulation of 2 clinical relevant situations in coronary vessel models (good and mal apposition cases)
Stent type and model tested

ABBOTT - Multi-link 8, 3.0x18
BBRAUN - Coroflex Blue, 3.0x19
BIOTRONIK - Orsiro, 3.0x18
BOSTON - Promus Element Monorail, 3.0x20
MEDTRONIC - Resolute Integrity, 3.0x18
TERUMO - Nobori, 3.0x18

Other compagnies declined : BIOSENSORS ; CID ; HEXACATH
## Characteristics of the stents tested

<table>
<thead>
<tr>
<th>Samples</th>
<th>Material</th>
<th>Strut thickness (μ)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABBOTT - Multi-link</td>
<td>Cobalt chromium</td>
<td>81</td>
</tr>
<tr>
<td>BBRAUN - Coroflex</td>
<td>Cobalt chromium</td>
<td>60</td>
</tr>
<tr>
<td>BIOTRONIK - Orsiro</td>
<td>Cobalt chromium</td>
<td>60+11</td>
</tr>
<tr>
<td>BOSTON - Promus Element</td>
<td>Platinum chromium</td>
<td>81+8</td>
</tr>
<tr>
<td>MEDTRONIC - Resolute</td>
<td>Cobalt chromium</td>
<td>91+8</td>
</tr>
<tr>
<td>TERUMO - Nobori</td>
<td>316 L stainless steel</td>
<td>110 +9</td>
</tr>
</tbody>
</table>
Direct longitudinal crush resistance test

Stent deployment without external stress, to reach 3.0 mm internal diameter according to the compliance table.

<table>
<thead>
<tr>
<th>Samples</th>
<th>Balloon pressure</th>
<th>Measured $\Phi$ ext (mm) after recoil</th>
</tr>
</thead>
<tbody>
<tr>
<td>B-BRAUN</td>
<td>10 bars (nominal)</td>
<td>2.78</td>
</tr>
<tr>
<td>BOSTON</td>
<td>12 bars (nominal)</td>
<td>3.00</td>
</tr>
<tr>
<td>MEDTRONIC</td>
<td>8 bars (nominal = 9)</td>
<td>2.97</td>
</tr>
<tr>
<td>ABBOTT</td>
<td>10 bars (nominal)</td>
<td>3.05</td>
</tr>
<tr>
<td>TERUMO</td>
<td>8 bars (nominal)</td>
<td>3.24</td>
</tr>
<tr>
<td>BIOTRONIK</td>
<td>8 bars (nominal)</td>
<td>2.92</td>
</tr>
</tbody>
</table>
I. Direct longitudinal crush resistance test

- Stent sample initial length and diameter are measured using SmartScope and recorded. **3 samples were used.**
- Sample is positioned on a specific vertical stent fixture. The sample stands vertically with its inferior extremity guided by a specific stent fixture. A piston, controlled by a stepper motor, is compressing the stent upper extremity at a fixed rate while measuring the compression force. **Piston displacement and force are recorded.**

The test stops either when the force reaches 1N or the stent length reduction reaches 50%.
Direct longitudinal crush resistance: Results.

Force (N)

Longitudinal crush – shortening (mm)

P<0.001 Promus, Coroflex Blue, Orsiro/Resolute Integrity
**Mechanical compression**

**Mechanical conclusion**: Terumo, Medtronic and Abbott groups have significant higher pure mechanical resistance to longitudinal crush than Biotronik, Boston Scientific and BBraun groups (*under a 1N compressive force*).
II. Simulated use longitudinal length stability test. Clinical relevant situations

The simulated use longitudinal length stability test was performed with water at temperature of 37° C ± 2° C. The IDTE constant flow pump generated a flow of 0.02 L/min.

Simulated use longitudinal length stability bench
Simulated use longitudinal length stability test

The path is 75 cm long, has five curves of note in it. Among these are an aortic arch model (curves 1 and 2: ≈ 9 and 4 cm radius of curvature), entrance into left coronary artery (curve 3: ≈2 cm radius of curvature), and two curves in the coronary artery of 5 cm and 2 cm respectively.

Pre-defined and specific trackability tortuous path

A predefined and specific coronary vessel model to simulate good and mal apposition cases.
Simulated use longitudinal length stability test

At the end of the path a specific module is used. Each stent has its specific module.

The silicon tube is used as a model of artery. Silicon tubes are fixed within the test module.

Good apposition case.
3.1x0.5 mm transparent silicon tube, length = 120 mm
Simulated use longitudinal length stability test

Mal apposition case (in red, limit of the 3.1mm ID tube inside the 4.0mm ID tube)
Simulated use longitudinal length stability test

Crush test sequence

A video camera is used to record the stent system behavior. The second balloon (pushing balloon) is manually advance so that its distal tip reaches the distal end of the guiding catheter.

Balloon catheter advancement is maintained until a 200 grams force is measured on the IDTE proximal load cell (typical coronary system tracking force is around 100 grams). The crush test sequence is performed a maximum number of 5 times to try to catch the stent. If the 200 grams force occurs before the fifth trial, the test is stopped. The balloon is finally withdrawn manually.
Simulated use – Good apposition cases

![Graph showing stent length and apposition cases for different stent types.](image-url)
Simulated use – Good apposition cases

Coroflex Blue migrations cases excluded (3 samples)

ns
Simulated use – Mal apposition cases
Simulated use – Mal apposition cases

Coroflex Blue migration cases excluded (2 samples)

ns
Longitudinal stent compression: Clinical implications

1/To assure a good stent implantation +/- according the company abacuses (B-Braun abacuses are wrong)

2/To use a low profile balloon in case of another over dilatation of the stent and to recross with caution these modern stents

3/Practical consequences: To take account of the characteristics of these new stents and not to hesitate to choose longer lengths > 10%-15%
Direct longitudinal crush resistance. Results.

Crush (%) under a 1N compressive force

<table>
<thead>
<tr>
<th>Force (N)</th>
<th>Crush (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.7 ± 0.9%</td>
<td>11.3 ± 1.7%</td>
</tr>
<tr>
<td>30.1 ± 14.2%</td>
<td>47.1 ± 2.9%</td>
</tr>
</tbody>
</table>

Resolute (Medtronic) (mm) Nobori (Terumo) Multilink (Abbott)

Orsiro (Biotronik) Coroflex Blue (BBraun) Promus (Boston Scientific)
Simulated use – Good apposition cases -- ZOOM