Aortic stenting with Djumbodis Dissection System (DDS) in Type A and Type B dissection
Aortic dissection: Stanford Classification

Site of Origin and Extent of Aortic Involvement

**Type A**
All dissections involving the ascending aorta, regardless of the site of origin of primary tear; even if descending aorta is also involved

**Type B**
All dissections not involving the ascending aorta

In aortic medianecrosis pathologic process was revealed in the entire vessel, not only in the area of aneurysm and dissection. Manifestations of variable severity of the same process were seen in different parts of aortic wall...” Zerbino et al., 2005
Aortic dissection: emergency treatment

Replacement of the aorta by vascular synthetic graft

Limitations:

- traumatically approach;
- often needs second or repeated procedure;
- unknown fate of false lumen;
- circulatory arrest and perfusion;
- implantation of vital aortic branches in the graft;
- different performance of synthetic graft and damaged aortic wall;
- time consuming
Aortic dissection: emergency treatment

Endovascular transcatheter repair by stent-graft

Limitations:

- large delivery system;
- complicated construction and implantation technique;
- need for a sufficient sealing zone for assembling in aorta;
- not completely adjust to the true lumen and internal aortic wall;
- occlusion of aortic branches;
- migration;
- leakages;
- infection
Aortic dissection : emergency treatment

DJUMBODIS : Aortic stenting

Type-A aortic dissection

Per-Aortic, per-operative stenting : direct intraluminal stenting during ascending aorta surgery with (or without) circulatory arrest.

- Replacement of the ascending aorta.
- Stent delivery.
  - Complete circulatory arrest under deep hypothermia
  - Partial circulatory arrest (anterograde or retrograde cerebral perfusion)

- The implantation and deployment should be carried out under the control of either:
  - Direct vision – aortic arch
  - Endoscope, TEE
  - X-Ray
Type-B aortic dissection

Transcutaneous

Stenting by femoral access: aortic arch, descending aorta or abdominal aorta.

Guide wire : .035”

Introducer : 20 F

Deployment control with X-ray

Cardiac surgeons with vascular surgeons or/and radiologists
Introduction : Djumbodis Dissection System

DJUMBODIS : Concept

• To join the dissected layers
• Not to occlude collateral branches

Cicatrization and Perfusion
Arterial dissections treated by stents

• Iliac, renal, coronary, carotid,…

• Spontaneous, traumatic or angioplasty induced
Introduction: Djumbodis Dissection System

Experimental datas:


- Type B dissections in dogs
- Healing of the dissection only if covered by the stent
- Neo-intima and integration
- No branches occlusion
Introduction: Djumbodis Dissection System

DJUMBODIS: Product design

- Stent lengths: 4, 9 or 14 cm – Stainless steel 316L
- Pre-mounted on safety balloon catheter
- 8mm nominal diameter, 45mm max diameter
Introduction: Djumbodis Dissection System

DJUMBODIS: Product design

- 4cm Stent cells separated by 1cm articulation elements, allowing to follow shape of aorta
- Stent mesh is large enough, no obstruction of collateral flow
Introduction: Djumbodis Dissection System

- 30cm, 70cm* and 120cm* catheter lengths * with guide wire port

Percutaneous Djumbodis (double lumen: one for the guide – one for the syringe)
Catheter length = 70 cm – 120 cm

- 30cm, catheter lengths
- 30cm and 70cm catheter lengths
- 120cm catheter lengths
Introduction: Djumbodis Dissection System

DJUMBODIS: Product design

• The balloon is very soft, highly compliant, low pressure (0.3 bars) design
• The balloon compliance allows the Djumbodis opening to conform with aorta anatomy
• To deploy inject saline or mix of saline / contrast
• Safety feature incorporated in balloon design:
  • Balloon extends proximally / distally, if balloon is inflated beyond the required volume
  • Balloon can be deflated, repositioned and reinflated
• Safety balloon is included in package
Introduction: Djumbodis Dissection System

Characteristics of the DJUMBODIS Dissection System

<table>
<thead>
<tr>
<th>REF</th>
<th>DJUMBODIS nominal length</th>
<th>Profile</th>
<th>Balloon length</th>
<th>Maximum volume</th>
<th>Maximum diameter</th>
<th>Usable catheter length</th>
<th>Guide</th>
</tr>
</thead>
<tbody>
<tr>
<td>DJUMBODIS</td>
<td>-</td>
<td>6,8 mm</td>
<td>50 mm</td>
<td>60 ml</td>
<td>45 mm</td>
<td>300 mm</td>
<td>-</td>
</tr>
<tr>
<td>DJUMBODIS 4</td>
<td>40 mm</td>
<td>9 mm</td>
<td>50 mm</td>
<td>60 ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DJUMBODIS 9</td>
<td>90 mm</td>
<td>9 mm</td>
<td>90 mm</td>
<td>120 ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DJUMBODIS 14</td>
<td>140 mm</td>
<td>9 mm</td>
<td>140 mm</td>
<td>220 ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DJUMBODIS 19</td>
<td>190 mm</td>
<td>9 mm</td>
<td>190 mm</td>
<td>300 ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DJUMBODIS 24</td>
<td>240 mm</td>
<td>9 mm</td>
<td>240 mm</td>
<td>380 ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DJUMBODIS</td>
<td>-</td>
<td>6,8 mm</td>
<td>50 mm</td>
<td>60 ml</td>
<td>45 mm</td>
<td>700 mm</td>
<td>.035 &quot;</td>
</tr>
<tr>
<td>DJUMBODIS 4</td>
<td>40 mm</td>
<td>9 mm</td>
<td>50 mm</td>
<td>60 ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DJUMBODIS 9</td>
<td>90 mm</td>
<td>9 mm</td>
<td>90 mm</td>
<td>120 ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DJUMBODIS 14</td>
<td>140 mm</td>
<td>9 mm</td>
<td>140 mm</td>
<td>220 ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DJUMBODIS 19</td>
<td>190 mm</td>
<td>9 mm</td>
<td>190 mm</td>
<td>300 ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DJUMBODIS 24</td>
<td>240 mm</td>
<td>9 mm</td>
<td>240 mm</td>
<td>380 ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DJUMBODIS</td>
<td>-</td>
<td>6,8 mm</td>
<td>50 mm</td>
<td>60 ml</td>
<td>45 mm</td>
<td>1200 mm</td>
<td>.035 &quot;</td>
</tr>
<tr>
<td>DJUMBODIS 4</td>
<td>40 mm</td>
<td>9 mm</td>
<td>50 mm</td>
<td>60 ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DJUMBODIS 9</td>
<td>90 mm</td>
<td>9 mm</td>
<td>90 mm</td>
<td>120 ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DJUMBODIS 14</td>
<td>140 mm</td>
<td>9 mm</td>
<td>140 mm</td>
<td>220 ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DJUMBODIS 19</td>
<td>190 mm</td>
<td>9 mm</td>
<td>190 mm</td>
<td>300 ml</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DJUMBODIS 24</td>
<td>240 mm</td>
<td>9 mm</td>
<td>240 mm</td>
<td>380 ml</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Each pack contains one DJUMBODIS Dissection System and one back-up balloon catheter.
Introduction : Djumbodis Dissection System

Operative procedure :
Results:

Thrombosis of the false lumen

Type A aortic dissection involving aortic arch before treatment.

After replacement of the ascending aorta and intra-operative stenting of the aortic arch, the false lumen has disappeared.

B. Leobon et al. The J Thorac Cardiovasc Surg 2006; 131: 482-483
Results: Evolution of aortic diameters

Aortic arch stenting with Djumbodis Dissection System (DDS) in the type A dissection

Bertrand LEOBON, Daniel ROUX, Stefano SACCANI, Yves GLOCK, Tiziano GHERLI, Gérard FOURNIAL,
Archives des maladies du Coeur et des vaisseaux Vol 100, № 9 – September 2007, pp. 753-759
**Results:** Thrombosis of the false lumen Type B aortic dissection

- Replacement of the thoracic descending aorta by synthetic graft under left atrium – femoral bypass

- Per-operative direct intra luminal stenting of the abdominal aorta with (or without) circulatory arrest of the internal organs under the control of either:
  - *Direct vision; Endoscope; TEE ; X-Ray*

Type B aortic dissection: *After replacement of the descending aorta and intra-operative stenting of the abdominal aorta, the false lumen has reduced*

Y. Belov et al. 2010
CLINICAL TRIALS – SUMMARIZED CONCLUSIONS

• Successfully restores aortic wall and thromboses false lumen
• Able to treat aortic arch & thoracic aorta during type-A surgery
• Additional surgical time within 2 minutes
• Stent perfectly conforms to patient’s aortic wall
• Stented aortic diameters reduce, un-stented dilate
• Minimizes risk of further dilatation or rupture
• Stenting should be extended to the whole dissected aorta
• Endovascular treatment of residual type B aortic dissection
• No need of implantation of aortic branches
• No need for finestation
• No stent migration
• No rupture
Introduction : Djumbodis Dissection System

THANK YOU !