Airway Remodeling: Preliminary Experience with Bio-Absorbable Airway Stents in Adults

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Disclosure Statement

THE AUTHORS HAVE NO CONFLICT OF INTEREST TO DISCLOSE
Bio-Absorbable Airway Stents

• Biodegradable stents already employed (esophageal, urethral, biliary and vascular stenosis)


• Stenting of tracheobronchial stenosis since 1998


Background

Traditional airway stenting pose the risk of:

- granulation
- erosion
- haemorrhage
- infection
- worsening proximal and distal airway
Polydioxanone is a semicrystalline, biodegradable polymer belonging to the polyester family.

The self-expandable, biodegradable, PDS stents were custom manufactured in appropriate sizes (Ella-Cs, Ltd., Hradec Kralove, Czech Republic)
• Stents were placed during **rigid** bronchoscopy.

• In patients with stenosis, stent placement was preceded by airway endoscopic **coring–out** to remove granulations and scar tissue.
Between 2011 and 2013:

31 bio-absorbable polydioxanone stents were implanted in 10 patients (6 males; mean age 56.4±16.9 years) affected by benign tracheo-bronchial disease

Computer Tomography (CT) and flexible bronchoscopy were used for monitoring the airway in the intervals between treatments.
<table>
<thead>
<tr>
<th>Patient n=10</th>
<th>Sex (M:F=6:4) / Age (years): mean=56, 41±16.9</th>
<th>Pathology</th>
<th>Major Contraindication to Surgery</th>
<th>Stent Placed (n⁰)</th>
<th>Treatment Period (Months)</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F/56</td>
<td>Benign Stenosis</td>
<td>tracheomalacia and tracheal scoliosis in thyroid surgery</td>
<td>2</td>
<td>6</td>
<td>Resolved</td>
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<tr>
<td>2</td>
<td>M/67</td>
<td>Benign Stenosis</td>
<td>Previous Mediastinal Surgery</td>
<td>2</td>
<td>6</td>
<td>Resolved</td>
</tr>
<tr>
<td>3</td>
<td>M/23</td>
<td>Benign Stenosis</td>
<td>Short Trachea</td>
<td>5</td>
<td>12</td>
<td>Resolved</td>
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<td>M/71</td>
<td>Benign Tracheal Stenosis</td>
<td>Stenosis Length and obesity in cardiac failure</td>
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<td>8</td>
<td>Retrieved for surgery</td>
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<td>M/71</td>
<td>Tracheal Anastomotic Dehiscence</td>
<td>Previous Tracheal Surgery</td>
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<td>3</td>
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<td>F/61</td>
<td>Benign Tracheal Stenosis</td>
<td>Previous Tracheal Surgery</td>
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<td>Resolved with laryngomalacia</td>
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<td>Benign Tracheo-Bronchial Stenosis</td>
<td>Previous Tracheo-Bronchial Surgery</td>
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<td>32</td>
<td>Unresolved</td>
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<tr>
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<td>M/67</td>
<td>Benign Stenosis and</td>
<td>tracheomalacia in previous thyroid surgery; patient compliance</td>
<td>1</td>
<td>3</td>
<td>Unresolved (patient compliance)</td>
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<td>M/54</td>
<td>Carinal Pneumonectomy Anastomotic Fistula and Malacia</td>
<td>Pleural Cavity Infection</td>
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<td>F/38</td>
<td>Benign Stenosis</td>
<td>Stenosis length</td>
<td>1</td>
<td>3</td>
<td>Resolved</td>
</tr>
</tbody>
</table>
Stents and procedure features

- Patients were treated for a mean period of $9 \pm 9.3$ months.

- Mean stent number per patient of $3.1 \pm 2.9$ (range: 1-10).

- Mean replacement interval of $3.6 \pm 1.4$ months (range: 1-8).

- Mean stent diameter and length were $17.5 \pm 3.3$ mm and $38.1 \pm 15.3$ mm respectively.
RESULTS

• Monitoring CT scans and bronchoscopies showed a progressive airway **remodeling** along the shape of the stent, with an improvement of the stenosis and/or malacia, maintained also **after the complete stent re-absorption** (mean: 16,4 months ± 9,5).

• There were no cases of bleeding, perforation, stent displacement or size mismatching after implantation and there wasn’t any case of granuloma formation.
CT scan documents a tracheal stenosis how it initially presented to our attention: before (A1-A3) and after (B1-B3) After Dumon Stent removal
Pictures C1-C3: treatment with adsorbable stent
the result in 2013 after five sequential procedure, at 1 year follow-up
Endoscopic view before and after the initial placement of the adsorbable stent (2011), of an intermediate control (2012) and of the last follow-up (2013). In 2012 and 2013 controls the airway maintained its patency without the need of the stent.
CT scan showing the stenosis with a Dumon stent implanted (A1-A3), the stenosis after the Dumon removal (B1-B3), and the final result after the treatment with two absorbable stent (C1-C3).
A completely successful airway stabilization in a sub-glottic stenosis with employing two absorbable stents. A1:-3 at the presentation; B1-3: at 1 year follow-up.
Preliminary Experience with Bio-Absorbable Airway Stents in Adults

• Airway disease definitely resolved in 6 patients (60%) without the need of any further treatment.

• In 3 cases (30%) treatment was unsuccessful:
  - post-pneumonectomy fistula (septic shock).
  - left tracheo-bronchial anastomosis with multiple stent replacement, recurrent stenosis.
  - segmental tracheomalacia, refused other treatment.
Preliminary Experience with Bio-Absorbable Airway Stents in Adults

• One patient (10%) affected by sub-glottic stenosis was treated with three consecutive stenting to successfully bridge him to surgery after cardiac and respiratory function improvement.

• The same patient has been treated with stenting after surgery also to resolve an obstructive dehiscence of laryngo-tracheal anastomosis.
Tracheal anastomosis dehiscence treatment
Pre-treatment

Post-operative
dehiscence

1 year
Follow-up
CONCLUSIONS

• The indications for absorbable stents could grow in the next future thanks to their flexibility and wide possibilities of customization to the specific patient.

• We need further investigations for a better definition of their field of application.