

AATS  
ANNUAL  
MEETING  
2014

April 26–30, 2014

Metro Toronto Convention Centre  
Toronto, ON, Canada

# 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  
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# Bio-Absorbable Airway Stents

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

1. Bunger CM, Grabow N, Sternberg K, et al. A biodegradable stent based on poly(L-lactide) and poly(4-hydroxybutyrate) for peripheral vascular application: preliminary experience in the pig. *J Endovasc Ther* 2007;14:725–33.
2. Dhar A, Topping J, Johns E, O'Neill D. Biodegradable stents in refractory benign oesophageal strictures—first report of 4 patients from UK. *Gastrointest Endosc* 2009;69:254–5.
3. Kemppainen E, Talja M, Riihela M, et al. A bioresorbable urethral stent. An experimental study. *Urol Res* 1993;21: 235– 8.
4. Petrtyl J, Bruha R, Horak L, et al. Management of benign intrahepatic bile duct strictures: initial experience with poly- dioxanone biodegradable stents. *Endoscopy* 2010;42(Suppl 2):E89 –90.

- Stenting of tracheobronchial stenosis since 1998

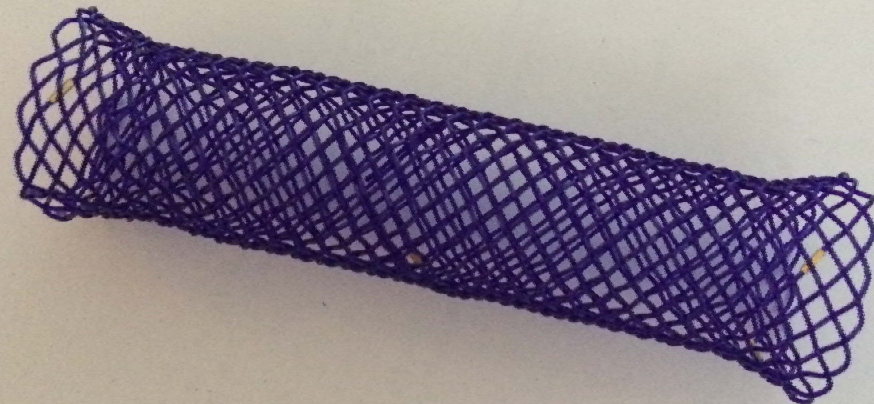
- . Korpela A, Aarnio P, Sariola H, et al. Comparison of tissue reactions in the tracheal mucosa surrounding a bioabsorbable and silicone airway stents. *Ann Thorac Surg* 1998;66: 1772– 6.
- . Lischke R, Pozniak J, Vondrjs D, Elliott M.J. Novel biodegradable stents in the treatment of bronchial stenosis after lung transplantation. *Eur J Cardiothorac Surg* (2011) 40 (3): 619-624.

# Background

Traditional airway stenting pose the risk of:

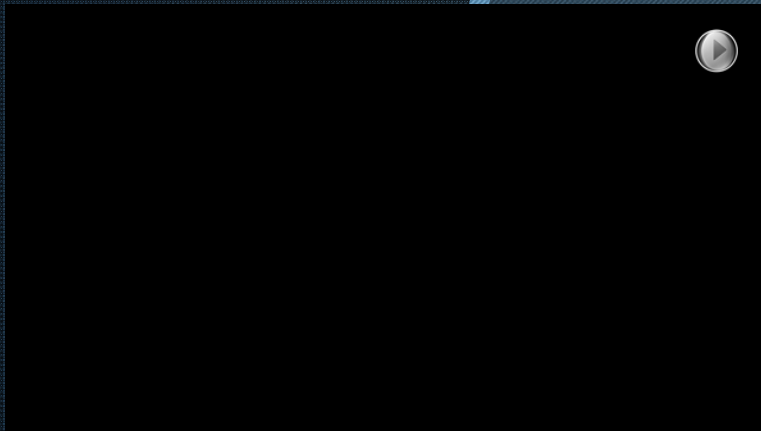
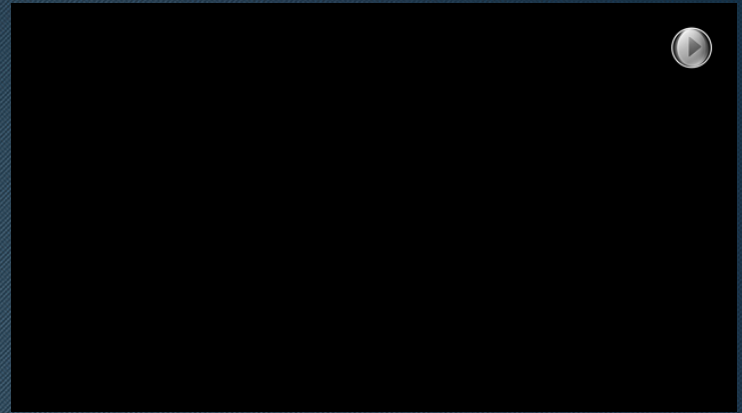
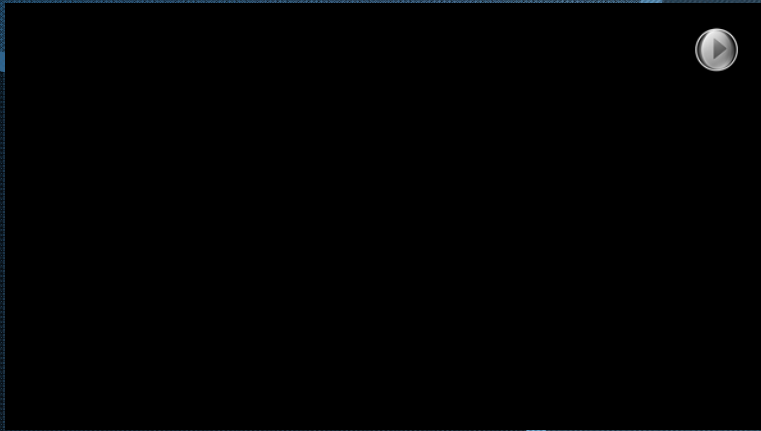
- granulation
- erosion
- haemorrhage
- infection
- worsening proximal and distal airway

**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  $56,4 \pm 16,9$  years) affected by **benign** tracheo-bronchial disease

**Computer Tomography (CT)** and **flexible bronchoscopy** were used for monitoring the airway in the intervals between treatments.

Demographic features, clinical features, stents placed and outcome of the cases treated between 2011 and 2013

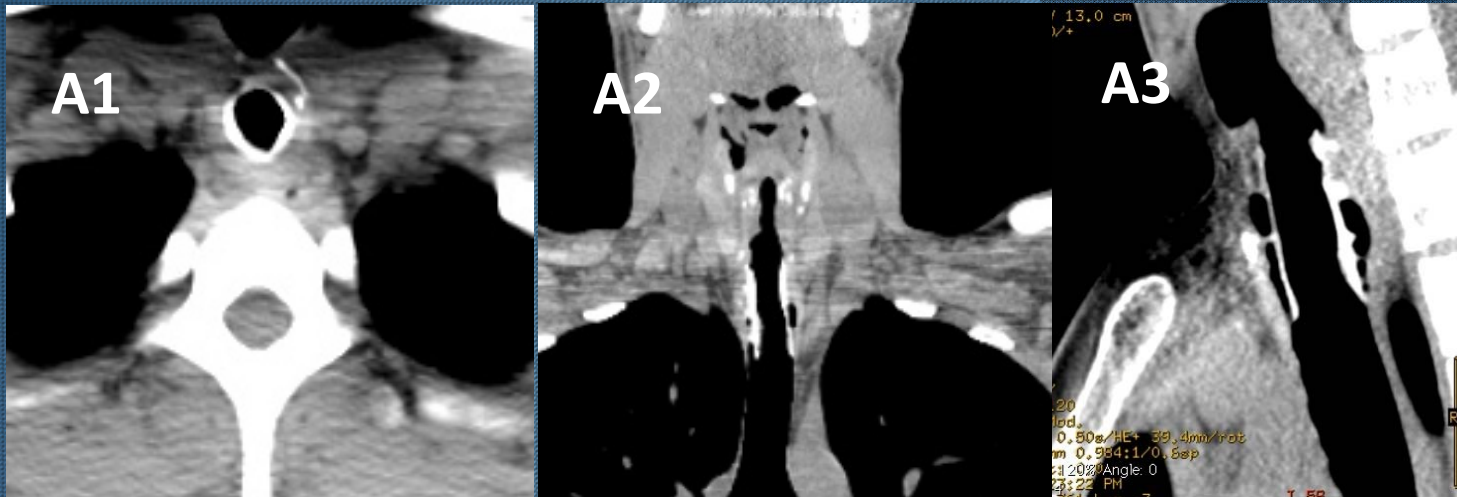
Patient n=10	Sex (M:F=6:4) / Age (years): mean=56, 4±16,9	Pathology	Major Contraindication to Surgery	Stent Placed (n°)	Treatment Period (Months)	Outcome
1	F/56	Benign Stenosis	tracheomalacia and tracheal scoliosis in thyroid surgery	2	6	Resolved
2	M/67	Benign Stenosis	Previous Mediastinal Surgery	2	6	Resolved
3	M/23	Benign Stenosis	Short Trachea	5	12	Resolved
4	M/71	Benign Tracheal Stenosis	Stenosis Length and obesity in cardiac failure	3	8	Retrieved for surgery
5	M/71	Tracheal Anastomotic Dehiscence	Previous Tracheal Surgery	1	3	Resolved
6	F/61	Benign Tracheal Stenosis	Previous Tracheal Surgery	5	16	Resolved with laryngomalacia
7	F/35	Benign Tracheo-Bronchial Stenosis	Previous Tracheo-Bronchial Surgery	10	32	Unresolved
8	M/67	Benign Stenosis and	tracheomalacia in previous thyroid surgery; patient compliance	1	3	Unresolved (patient compliance)
9	M/54	Carinal Pneumonectomy Anastomotic Fistula and Malacia	Pleural Cavity Infection	1	1	Died
10	F/38	Benign Stenosis	Stenosis length	1	3	Resolved

# Stents and procedure features

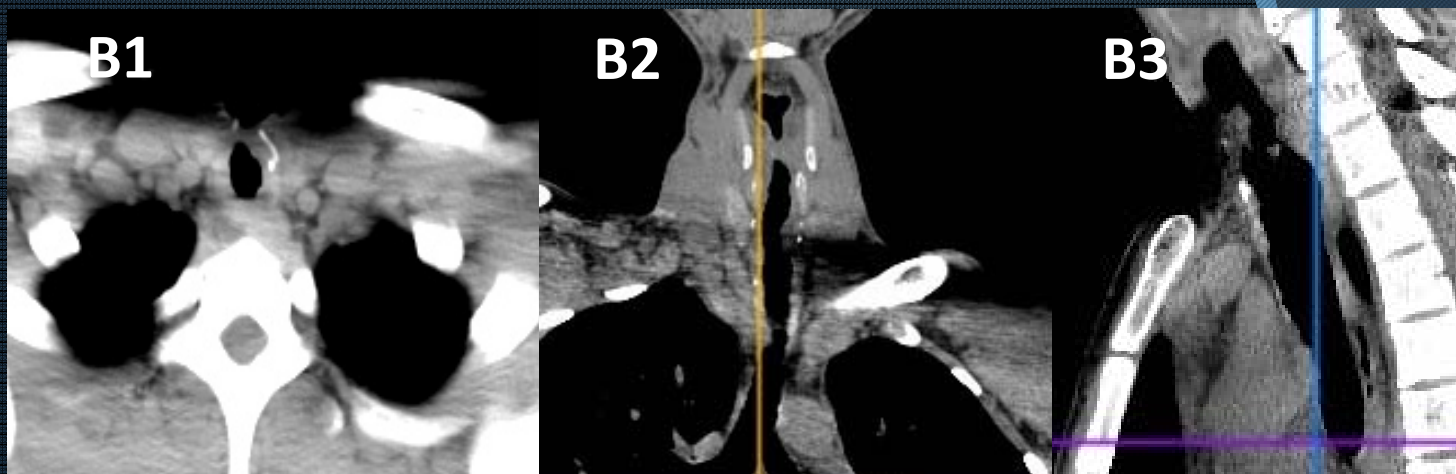
- Patients were treated for a mean **period** of  $9 \pm 9,3$  months.
- Mean **stent number** per patient of  $3,1 \pm 2,9$  (range: 1-10).
- Mean **replacement interval** of  $3,6 \pm 1,4$  months (range: 1-8).
- Mean stent **diameter and length** were  $17,5 \pm 3,3$  mm and  $38,1 \pm 15,3$  mm respectively.

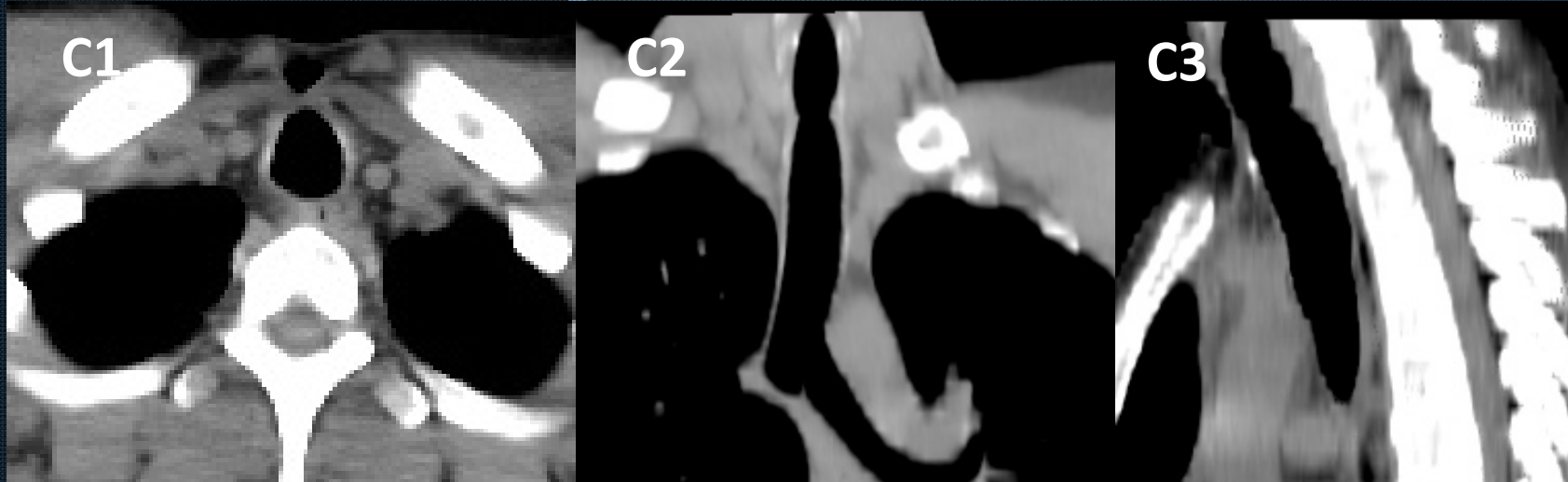
# RESAULTS

- 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  $\pm$  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.



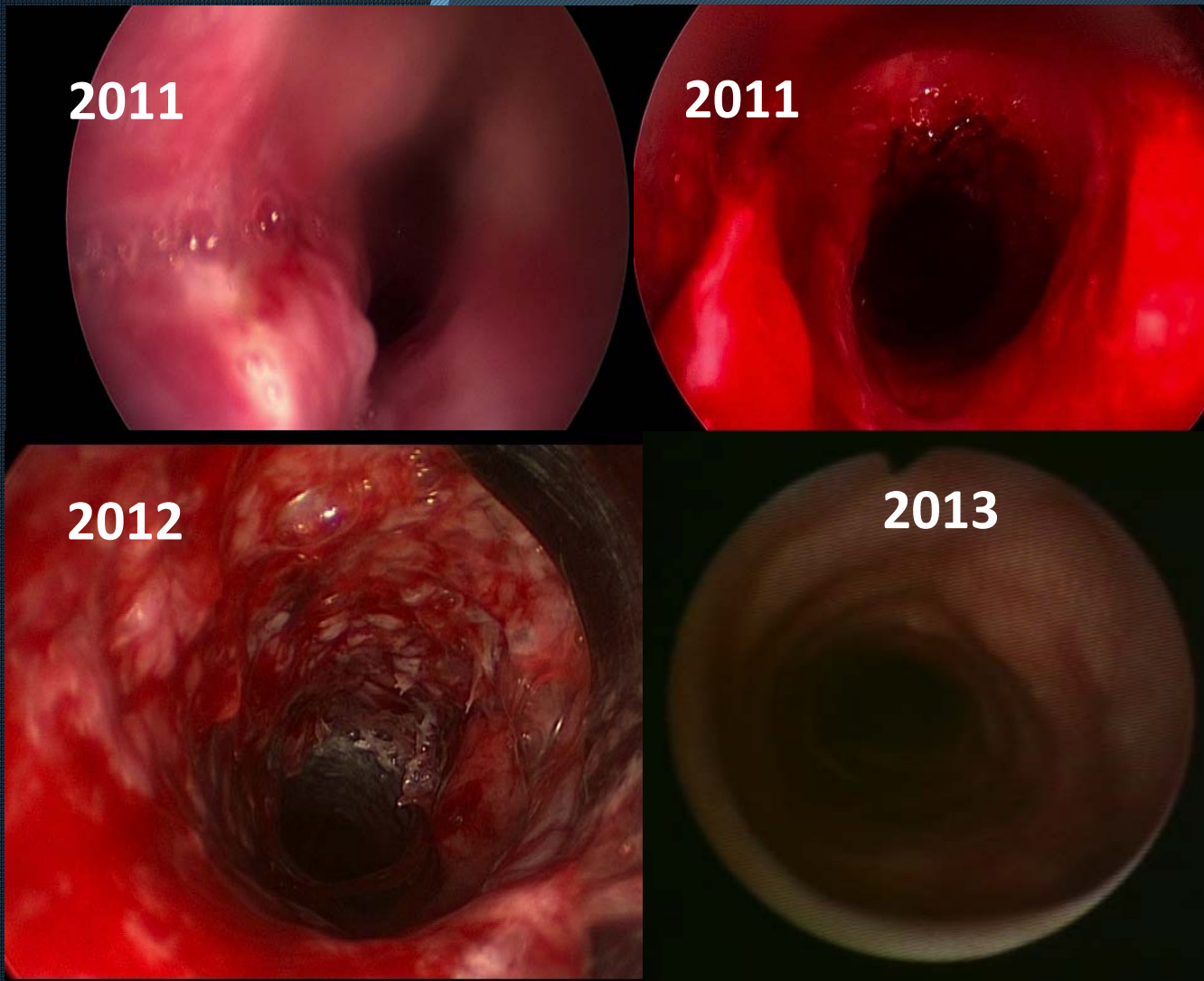
CT scan documents a tracheal stenosis how it initially presented to our attention: before (A1-A3) and after (B1-B3) After Dumon Stent removal





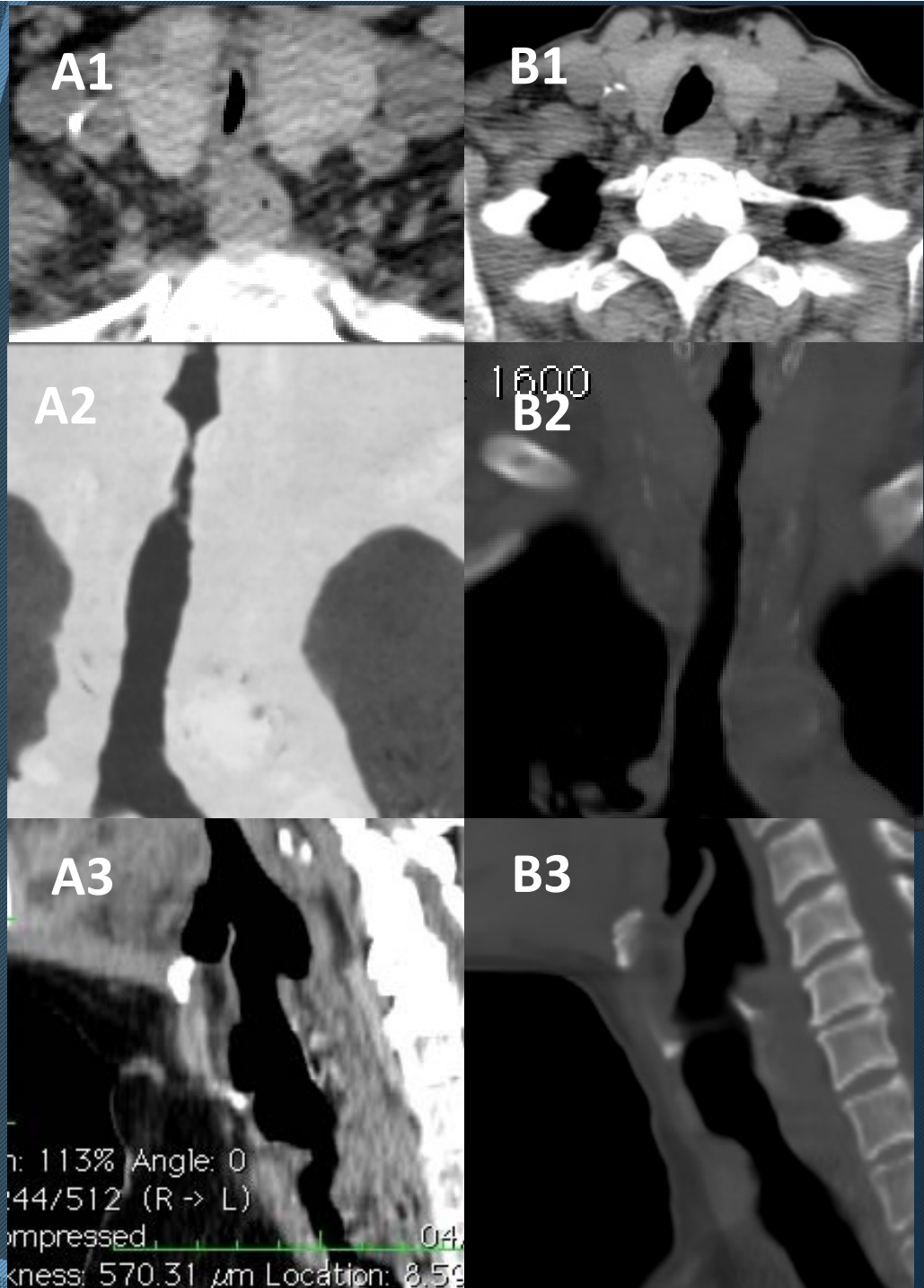
Pictures C1-C3: treatment with adsorbable stent  
the result in 2013 after five sequential procedure, at 1  
year follow-up

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.





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



## Follow-up 2013



## Follow-up 2014



# 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

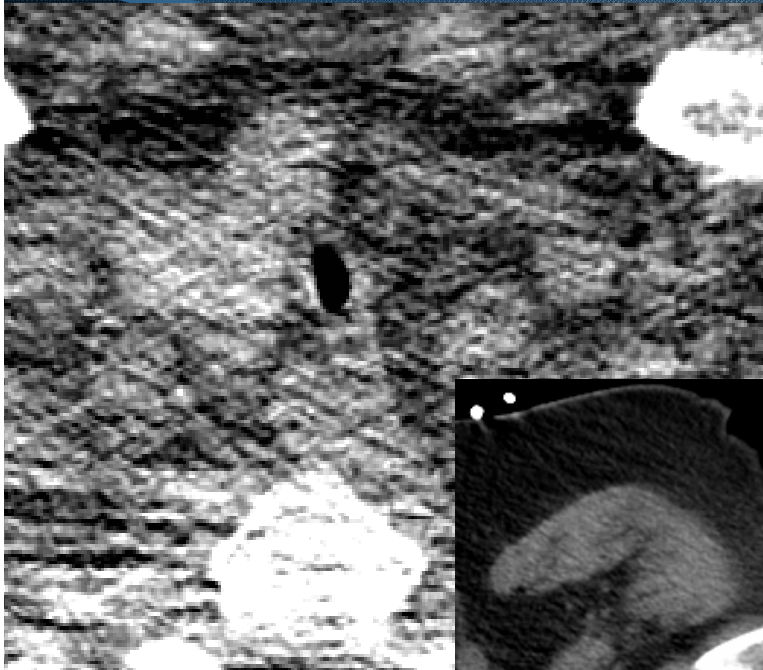
- One patient (10%) affected by sub-glottic stenosis was treated with three consecutive stenting to successfully **bridge** him to surgery after cardiac and respiratory function improvement .
- The same patient have been treated with stenting after surgery also to resolve an obstructive dehiscence of laryngo-tracheal anastomosis



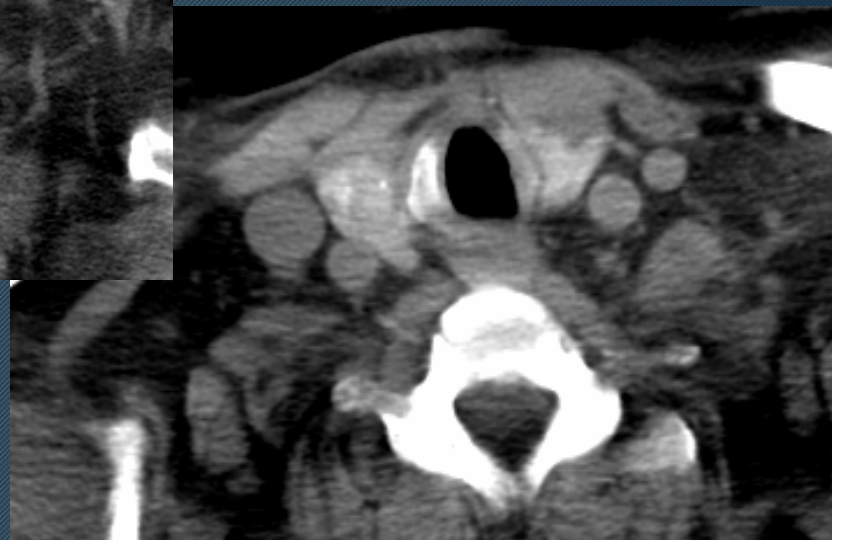
# Tracheal anastomosis dehiscence treatment

**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.