

## Original papers

# Biodegradable airway stents: Novel treatment of airway obstruction in children

Andrzej Zajac<sup>A-E</sup>, Mirosław Krysta<sup>C</sup>, Aleksandra Kiszka<sup>B</sup>, Wojciech Górecki<sup>F</sup>

Department of Pediatric Surgery, University Children's Hospital, Jagiellonian University, Poland

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## Address for correspondence

Andrzej Zajac  
E-mail: [zycek@poczta.onet.pl](mailto:zycek@poczta.onet.pl)

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## Abstract

**Background.** Tracheobronchomalacia is the most common cause of congenital airway obstruction in infants. An alternative for surgical approach (aortopexy) can be metallic airway stents. Usually, they are not considered as a first choice because of the relatively high risk of complications. Recent years have brought encouraging reports of biodegradable stents applied in children.

**Objectives.** The aim of this study was to report our experience in the treatment of airway malacia using biodegradable stents.

**Material and methods.** Six polydioxanone (PDS), self-expanding custom-made stents (ELLA-CS) were implanted in 2 children: 3 in the patient with left main bronchus occlusion due to postpneumectomy syndrome and 3 stents in the baby with tracheomalacia.

**Results.** Airway collapse was always relieved after stent expansion. Both patients needed repeated stenting because of limited stent lifespan. All the stents were implanted without complications through a rigid bronchoscope. The baby with stented main bronchus died because of irreversible lung lesion.

**Conclusions.** This small study shows that biodegradable airway stents seem to be an attractive option in the treatment of tracheobronchomalacia in children. We consider this method to be safe, effective, repeatable, and reversible in small children with growing airways. As a time-buying procedure they can be especially useful in the treatment of tracheobronchomalacia.

**Key words:** biodegradable airway stents, tracheobronchomalacia, airway obstruction

## Cite as

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## Introduction

Airway stenting in adults is a well-established therapeutic method for the treatment of benign and malignant tracheobronchial obstruction. Stents can be used in preventing restenosis after airway reconstruction, lung transplantation or in palliative therapy in non-resectable tumors.<sup>1</sup> In the long history of endoluminal airway support, the first stents to be invented were made of metal, later of plastic and then followed by mixed forms (hybrids).<sup>2</sup> Moreover, the last 2 decades have brought new technologies and materials that have led to the introduction of biodegradable materials in thoracic surgery. Initially, biodegradable stents were used in esophageal, intestinal, biliary, urethral, and vascular stenosis.<sup>3–5</sup> Finally, the idea was adapted for the treatment of airway obstruction.

In neonates and young children, we encounter 2 main types of pathologies: anatomical and dynamic airway obstructions. The former usually results from congenital tracheal stenosis or concomitant vascular abnormalities, and the later type is represented by dynamic obstructions with bronchial or tracheal wall collapse. Although surgical treatment is still the primary therapeutic option for patients with various types of congenital tracheal stenosis, in the second group with tracheobronchomalacia, stents could be an attractive alternative. To date, the use of metal stents in neonates has been limited due to numerous life-threatening local complications, such as tracheobronchial wall erosion, bleeding and severe mucosal tissue granulation with airway narrowing.<sup>6,7</sup> In addition, most metal stents are permanent once inserted and cannot be replaced, which greatly limits their use in the developing airways of children.<sup>8</sup>

The emergence of biodegradable airway stents seems to have opened a new chapter in the treatment of dynamic types of airway obstruction in newborns and small children. The use of polydioxanone (PDS) stents has been recently reported in a growing number of small patient series with encouraging clinical results.<sup>9–12</sup> Polydioxanone belongs to the family of biodegradable synthetic polymers and is widely used for the preparation of surgical sutures. As a monofilament fiber, it hardens binding parts of water, presents shape memory and degrades by random hydrolysis of its ester bonds with the mean biodegradation time between 12–15 weeks, proven in animal models.<sup>13,14</sup>

We report our preliminary experience with the use of bio-stents in children in the treatment of tracheobronchomalacia.

## Material and methods

Six bio-stents were implanted in 2 infants. The present clinical trial was approved by our Institutional Ethics Committee. Parental informed consent was obtained before each procedure. Self-expanding PDS bio-stents were custom-made and delivered with the introducer

by the manufacturer (ELLA-CS, Hradec Králové, Czech Republic). The decision regarding stenting was made by our multidisciplinary team: thoracic surgeons, pediatricians and anesthetists. The sizes of the ordered stents were decided after initial rigid bronchoscopy in which we measured the diameter of the airway and estimated the length of stents. Each stent was delivered expanded in an airtight container and with a separately packed introducer. Immediately before implantation, we manually pressed the stent and placed it on the introducer under a moveable sheath. All the bio-stents were implanted under general anesthesia through a rigid Karl Storz bronchoscope size 4.0. Expansion of the stent was controlled using a small-size optics (diameter 1.3 mm; length 30.6 cm), which is longer than the bronchoscope, inserted along together with the introducer and positioned laterally. After implantation, we used the same longer optics or a small-size bronchofiberscope for insertion inside the expanded stent to check the results and control both ends of the stent.

## Results

### Patient 1

A female newborn, twin delivered by a Cesarean section because of life-threatening asphyxia after 34 weeks of gestation, with birth body mass of 1,770 g, presented respiratory compromise since birth. Chest x-ray and CT scan revealed congenital cystic adenomatoid malformation (CCAM) affecting the entire right lung. The patient needed an urgent right lobectomy in the neonatal period due to severe respiratory distress and mass effect. The postsurgical course was uneventful. Six months after surgery, dyspnea appeared along with recurrent respiratory infections because of post-pneumonectomy syndrome (PPS) with a severe rightward mediastinal shift and rightward left lung expansion. Mechanical ventilatory support with intubation was mandatory. Bronchoscopy showed an almost complete collapse of the left main bronchus with bronchial tree rotation (Fig. 1).

Postnatally, the baby had extensive cerebral infarction, so the therapeutic team together with the parents abandoned the idea of possible surgical correction with cardiopulmonary bypass and decided to use a bio-stent. A PDS stent 5 × 20 mm was implanted. After 2 days, the patient was extubated and control bronchofiberscopy confirmed proper stent positioning and open bronchus. The subsequent 2 stents were implanted after the dissolution of the previous one, increasing the diameter to 6 mm and length to 25 mm, which corresponded to the increasing diameter of the airway. After implantation of the first 2 stents, the patient stayed home in good general condition, gaining weight properly. After the 3<sup>rd</sup> stenting, the parents refused further therapy. Upon their request, the baby was placed in the hospice, where she died 4 months after the last stent implantation.

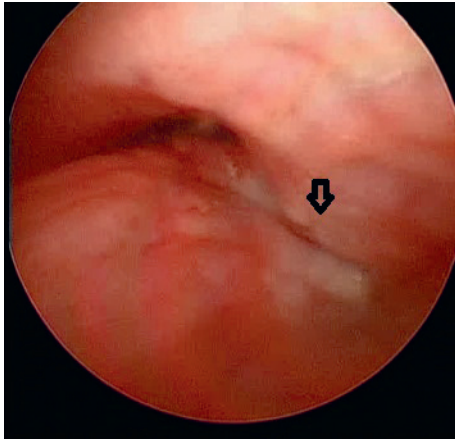


Fig. 1. Completely collapsed left main bronchus. Arrowhead points the place with stamp of the right main bronchus

## Patient 2

A male newborn twin delivered after 36 weeks of gestation with a birth body mass of 2,100 g was operated on through left thoracotomy in the 1<sup>st</sup> day of life because of esophageal atresia.

After surgery, the patient could not be weaned from ventilatory support for the first 5 months and later needed continuous positive airway pressure (CPAP). The child was discharged home, but subsequently needed emergency hospitalization due to an episode of life-threatening asphyxia. Possible concomitant abnormalities, such as vascular ring, sling and complete tracheal rings had been previously excluded using CT scan in the referring hospital. The baby was referred to our center at the age of 6 months. On admission, bronchoscopy demonstrated severe tracheomalacia in the middle segment of the trachea, surprisingly situated not in the lower segment, close to the previous fistula (Fig. 2).

We decided to implant a PDS stent 5 × 25 mm, achieving dramatic resolution of the symptoms. The baby was extubated after the procedure and discharged home early. Subsequently, 2 other stents 1 mm larger in width were placed at intervals of 12–14 weeks with excellent tolerance. At present, the patient stays at home without respiratory

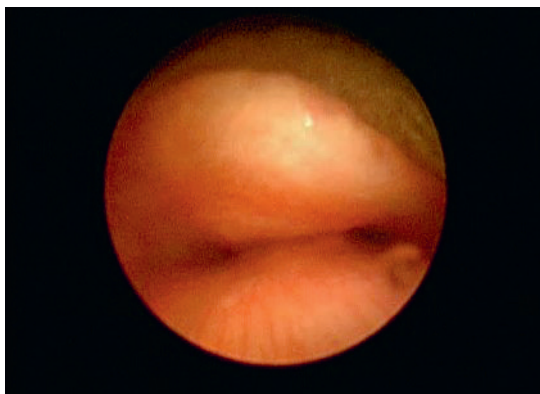


Fig. 2. Severe tracheomalacia in the middle portion of the trachea

problems. The baby is subject to follow-up bronchoscopy 12 weeks after the last stent implantation with possible consecutive stent implantation.

## Discussion

In the treatment of airway obstruction in small children, there are still no clearly defined indications for stenting and their use is considered individually for each patient.<sup>2,12</sup> Difficulty in stenting is related to the small diameter of the respiratory tract, to its growth and the possible need for stent replacement. The commonly used metal stents are considered by the majority of authors as “placed once and for good and bad” and potential replacement usually requires surgical intervention. In addition, the potential benefits of a particular stent group associated with their structure generate significant complications. For example, the risk of migration for metal stents is low, but their hard structure strongly impacts the mucosa, resulting in a high risk of granulation tissue formation and mucosal erosion with bleeding. On the other hand, softer plastic or silicone stents with a low rate of local complications present a considerable tendency for migration.<sup>2</sup>

In order to avoid the abovedescribed complications, the attention of researches has been focused on biodegradable materials. After encouraging experimental medical tests, the first bio-stents have been used with good results in adults after lung transplants.<sup>15</sup> In the last 8 years, an increasing number of reports addressing the use of bio-stents in children have been published.<sup>2,9–11,16</sup> So far, PDS stents have been used mostly in the treatment of tracheal and bronchial compression after cardiovascular procedures,<sup>9</sup> after a failed aortopexy,<sup>10</sup> after tracheoplasty due to congenital stenosis<sup>11</sup> or in the cases of severe tracheo- and bronchomalacia.<sup>12,17,18</sup>

We found the offered polydioxanon self-expanding stents CS-ELLA very suitable for the use in pediatric patients. The mechanism of self-expansion and thus self-fixing is one of the greatest advantages of PDS stents. It excludes the need for the balloon use to expand the stent and thereby reduces periods of full apnea. In our opinion, x-ray-controlled implantation with C-arm fluoroscopy is more logistically challenging and requires radiation, so we decided in favor of implantation under general vision. We first inserted the introducer with the stent to the bronchoscope 4.0 mm, having enough space to place laterally very thin optics (1.3 mm) longer than the bronchoscope. After a partial withdrawal of the rigid bronchoscope, at the critical area of the airway only the top part of the introducer was left along with thin optics with good visualization of the proximal stent border (Fig. 3A–D). Then, one of the operators withdrew the optics, the second released the mechanism of the sheath sliding and opening the stent. This maneuver allowed for the reduction of the apnea time to a few seconds only and was well

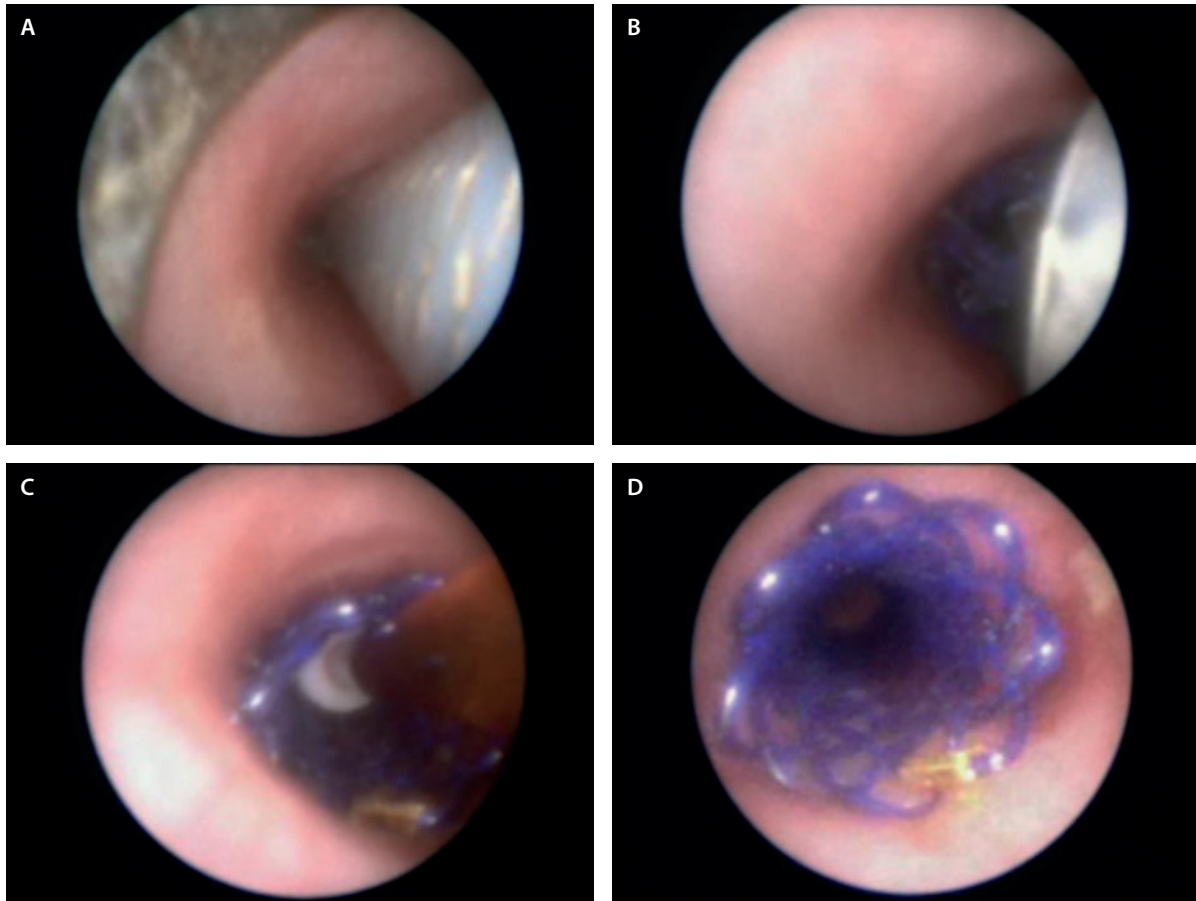


Fig. 3. A – laterally placed tiny optics shows apical portion of the introducer with a stent under the sheath; visible border of the rigid bronchoscope; B – sheath withdrawal and opening of the stent; C – final removal of the introducer; implantation completed; D – implanted and opened stent in the left main bronchus; visible golden marker at the proximal stent's border

tolerated by the patients after preoxygenation. It also allowed us to abandon the C-arm fluoroscopy and offered more space and better comfort for the operative team. After 1 implantation, when the stent after expansion was located too distally, it was easy to relocate it upward using optical forceps. In both patients, the implanted stents kept the airway open with a round shape at the collapsing area without tendency for migration. Each stent maintained its integrity and hence stiffness for 12–15 weeks without noticeable morbidity.

A potential risk for the patient may be stent fragments in the final period of biodegradation that may narrow the airways.<sup>18</sup> Thus, in every case, starting at 12 weeks after implantation, we checked the stent condition every 2 weeks using bronchofiberscopy.

In the treatment of tracheobronchomalacia, airway stenting should be considered as a time-buying procedure. A low tendency to form mucosal granulation tissue, biocompatibility and the possibility of implanting another stent with the diameter adequate to the dimensions of the growing airway naturally favor bio-stents. But, on the other hand, a limiting factor can be the rather short time of complete biodegradation and the need of frequent re-stenting.

## Conclusions

Despite our limited experience with bio-stents, we consider PDS stents an effective, safe, repeatable, and reversible option in the treatment of dynamic airway obstruction in children. Further studies should be focused on extending the “working time” of the bio-stents and reducing the thickness of stents and the size of the surgical instruments.

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