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Novel biodegradable stents in the treatment of bronchial stenosis after lung transplantation☆,☆☆

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Abstract

Objective: To evaluate the safety and effectiveness of novel biodegradable (BD) stents to treat bronchial anastomotic stenosis in patients after lung transplantation. **Methods:** Twenty BD stents were implanted endoscopically in six patients (median age 41.5 years (range 35–57 years)) with post-transplant bronchial anastomotic stenoses, between 2006 and 2010. All stents were custom-made from bio-absorbable polydioxanone (PDS). The median stent diameter was 12 mm (8–17 mm) and median length was 20 mm (12–30 mm). All patients were evaluated clinically, by bronchoscopy and high-definition computed tomography (CT). **Results:** The stenosis was initially relieved in all cases. There was no bleeding, perforation or displacement after BD stent implantation. Four patients needed multiple stenting for anastomotic re-stenosis. Median time to any re-stenting was 5 months (2–15 months). There was one sudden death, 1 year after the last BD stent implantation, from a pulmonary embolus. All five survivors are in good clinical condition up to 4 years' follow-up (median 40 months, range 7–48 months) since first stenting and intervention-free up to 44 months (median 24 months, range 7–44 months). **Conclusions:** This small pilot study shows that BD stents are a safe, effective and reliable alternative to classical metallic stents in patients with anastomotic stenosis after lung transplantation, and may avoid the need for permanent stenting.

Keywords: Transplantation; Lung; Stent

1. Introduction

The incidence of bronchial anastomotic complications after pulmonary transplantation has fallen from 80% in the early years to between 2% and 15% [1–7] in the current era. However, such problems may still be life threatening or at least adversely affect quality of life.

Surgical technique is probably most significant factor for effective anastomotic healing, with continuous suture techniques delivering the best results [8–10].

Bronchial complications remain an issue. Stenosis, necrosis, overgrowth of granulation tissue, malacia and fistulae have all been reported and various treatments described including surgical resection, bronchoscopic dilation, lasering and stenting with non-resorbable stents [11–13].

Non-resorbable stents pose the risk of secondary stenosis due to hyperplastic granulation, erosion and haemorrhage [14]. A biodegradable (BD) alternative is thus attractive. BD stents have been developed for oesophageal, intestinal, urethral, biliary duct and vascular stenoses and, if proved applicable in the airway, could represent an important therapeutic choice [15–18].

Indeed, BD materials have been experimentally used for stenting of tracheobronchial stenosis since 1998 [19–22].

Polydioxanone (PDS) stents have been shown to be well tolerated by the tracheal mucosa, to maintain biomechanical strength for 6 weeks and to dissolve completely by 15 weeks [23,24].

This report describes the experience with six patients treated by BD stents for post-transplant bronchial complications in the University Hospital Motol in Prague between 2005 and 2010.

2. Materials and methods

Following Institutional Ethical Committee approval, this retrospective review of clinical data, obtained from the medical records of all adult patients undergoing lung transplantation (LTx) between 2005 and 2010 at our institution, was undertaken. Data gathered included age,

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sex, the indication for transplantation, examination findings and subsequent treatment after diagnosis of bronchial stenosis, type and size of the stents and length of follow-up.

2.1. Patients (study population)

Between January 2005 and January 2010, 121 lung transplants were performed in 80 patients aged between 35 and 52 years (median 45 years) at our Hospital.

The preoperative indications were chronic obstructive pulmonary disease (COPD) – emphysema ($n = 37$), idiopathic pulmonary fibrosis ($n = 22$), cystic fibrosis (CF) ($n = 15$), lymphangiomyomatosis ($n = 4$) and primary pulmonary hypertension ($n = 2$).

2.2. Procurement of donor lung

Donor lungs were procured using standard techniques of combined cardiopulmonary extraction, as previously described [10].

At dissection, the donor bronchus was shortened close to the origin of the upper lobe bronchus, with special attention to keep the peribronchial tissues undisturbed. The oblique resection of the medial (extrapulmonary) wall of the intermediate bronchus is considered important for the healing process.

2.3. Implantation technique

The recipient's main bronchus was divided one ring proximal to the branching of the upper lobe bronchus. The absorbable suture material PDS (Ethicon Inc., NJ, USA) was used. A continuous suture of the membranous wall (PDS, 4/0) and end-to-end anastomosis with interrupted single sutures (PDS, 4/0) of the cartilaginous part were performed. No telescoping was used.

2.4. Postoperative management

Postoperative bronchoscopies were performed immediately, at the time of extubation and at discharge. Late follow-up routine surveillance bronchoscopies with biopsies were performed at months 1, 3, 6 and 12, and if a clinical suspicion of bronchial complication, infection or rejection appeared.

2.5. Definitions

For the purpose of this study, the definition of an airway complication was based on previous work [12] as follows: stenosis, necrosis, overgrowth of granulation tissue, malacia, fistulae and infection. For our statistical purposes, we consider only complications severe enough to require intervention (dilatation and/or stenting). Bronchoscopy and computed tomography (CT) scans were the most important diagnostic tools to define an airway complication.

2.5.1. Stenosis

Anastomotic bronchial stenosis:

- stenosis less than 50% of bronchial diameter – small (SABS); and
- stenosis more than 50% of bronchial diameter – large (SABL).

Non-anastomotic segmental bronchial stenosis:

- stenosis less than 50% of bronchial diameter – small (SNASBS); and
- stenosis more than 50% of bronchial diameter – large (SNASBL).

2.5.2. Necrosis

Grade I: No slough or necrosis reported; anastomosis healing well (NGI);
Grade II: Any necrotic mucosal slough reported, but no bronchial wall necrosis (NGII);
Grade III: Bronchial wall necrosis within 2 cm of anastomosis (NGIII); and
Grade IV: Extensive bronchial wall necrosis extending 2 cm from anastomosis (NGIV).

2.5.3. Granulation tissue

- granulation tissue with less than 50% diameter narrowing – small (GTS); and
- granulation tissue with more than 50% diameter narrowing – large (GTL).

2.5.4. Malacia

- diffuse tracheobronchial malacia (MDTB); and
- anastomotic malacia (1 cm proximal or distal to anastomosis) (MA).

2.6. Endoscopic interventions – dilatation and stenting

If clinically significant bronchial narrowing occurred, balloon dilatations were performed. In the cases where the situation required stenting, only BD stents were implanted. The self-expandable, BD, PDS stents were custom manufactured in appropriate sizes (Ella-Cs, Ltd., Hradec Kralove, Czech Republic) (Table 1). PDS is a semicrystalline, BD polymer belonging to the polyester family. It degrades by random hydrolysis of its molecule ester bonds. The degradation is not linear and is accelerated by low pH.

3. Results

Between January 2005 and January 2010, we performed 121 lung transplants in 80 patients (39 single lung transplants (SLTs) and 41 bilateral lung transplants (BLTs)).

Seven bronchial anastomotic complications requiring invasive treatment: BD stenting (5.8%) occurred in six patients (7.5%).

There were three men and three women. Complications developed in both SLT and BLT recipients: stenosis in five airways (in four cases following a necrosis) and malacia in two cases.

Patient demographics, airway anastomotic complication type, interval to the treatment of complications and follow-up are described in Table 2.

After BD stent implantation, the stenosis was initially relieved in all cases (Fig. 1). There was no bleeding,

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Table 1. Types of stents.

Patient	Diagnosis	DOB	Tx date	Stents	Date of stenting
Patient 1	BLT for COPD	1965	08/09/2007	Ø10 mm × 15 mm + Ø15 mm × 20 mm	17/11/2007
				Ø12 mm × 15 mm + Ø17 mm × 25 mm	26/02/2008
Patient 2	SLT for COPD – left	1951	22/10/2005	Ø12 mm × 30 mm	06/10/2006
				Ø15 mm × 20 mm	20/02/2008
				Ø17 mm × 25 mm	07/09/2008
Patient 3	BLT for CF	1971	17/05/2006	Ø8 mm × 13 mm	13/12/2006
				Ø8 mm × 13 mm	09/11/2007
				Ø8 mm × 13 mm	15/01/2008
				Ø8 mm × 13 mm	26/03/2008
				Ø8 mm × 13 mm	25/08/2008
				Ø8 mm × 13 mm	25/11/2008
Patient 4	SLT for IPF – left	1966	16/01/2006	Ø14 mm × 30 mm	24/10/2006
				Ø12 mm × 30 mm	17/03/2007
				Ø12 mm × 30 mm	24/10/2007
				Ø12 mm × 30 mm	22/01/2008
				Ø12 mm × 30 mm	25/09/2008
Patient 5	BLT for COPD	1954	21/09/2006	Ø12 mm × 30 mm	22/12/2006
Patient 6	BLT for COPD	1968	10/08/2009	Ø11 mm × 12 mm	02/02/2010

SLT: single lung transplant; BLT: bilateral lung transplant; COPD: chronic obstructive pulmonary disease; IPF: interstitial pulmonary fibrosis; CF: cystic fibrosis; and DOB: date of birth.

perforation or displacement. Four patients needed multiple stenting for anastomotic re-stenosis. The 1-year freedom from re-stenting is represented in Fig. 2. There was one sudden death, 1 year after last BD stent implantation, from a pulmonary embolus. All five survivors were in good clinical condition up to 4 years' follow-up (median 40 months, range 7–48 months) since first stenting, and intervention-free up to 44 months (median 24 months, range 7–44 months).

Patient #1 had bilateral sequential lung transplant for bilateral COPD. Two months later, he developed necrosis grade III–IV with malacia of both bronchi distal to anastomoses. Both bronchi collapsed during expiration and were immediately stented with a BD stent. Two months later, the radial force resistance of both stents was lost and both bronchi collapsed again. The stents were still present, but partially absorbed. Another pair of BD stents was implanted over the previous stents. The patient was clinically well since then, and only minor stenosis of the right bronchus distal to anastomosis is visible at 3 years' follow-up.

Patient #2 developed grade III necrosis just distal to the anastomosis 3 months after left-sided LTx for COPD. The necrosis healed spontaneously, but, 9 months later, collapse and stenosis were observed and stenting was needed. The BD stent dissolved completely in 5 months, and subsequent bronchography showed normal lumen (Fig. 1). Unfortunately, re-stenosis with bronchus collapse recurred 15 months later, and further stenting was needed. As the stent dissolved over the next 5 months, dynamic stenosis occurred again. A third BD stent was implanted within the previous and dissolving stent. The patient has subsequently been clinically well and, at 2 years' follow-up, there is no recurrent stenosis, and no evidence of the stents. They have been completely resorbed.

Patient #3 (3 months after bilateral LTx for CF) developed a right bronchial necrosis (grade III) distal to the anastomosis. Repeated dilatation and stentings were necessary. After 2

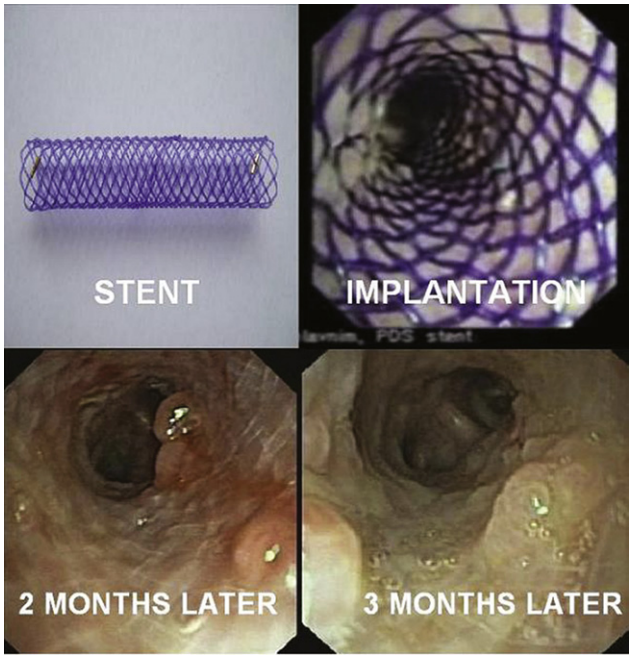

Fig. 1. Patient 2: left bronchus, first stenting and disappearing stent.

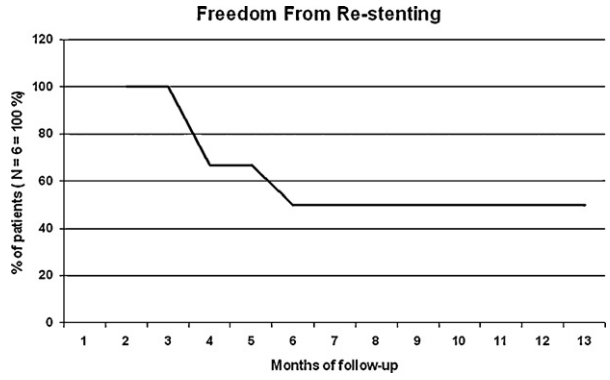

Fig. 2. Kaplan–Meier 1-year freedom from re-stenting graph.

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Table 2. Type of LTx, airway complication, BD stenting and follow-up.

Patient no.	Age (years)	Sex	Primary disease	Tx type	Complication	Stent $D \times L$ (mm)	ReST (months)	IFT (months)	1STFU (months)	POTx (months)
Patient 1	42	M	COPD	BLT	R-MA, NGIV	10 × 15				2
					L-MA, NGIII	15 × 20				2
					R-MA	10 × 15	4			6
					L-MA	15 × 20	4			6
					R-SNASBS	No				28
					R-SNASBS	No		28	32	34
Patient 2	54	M	COPD	SLT-L	L-NGIII	No				3
					L-SABS	No				11
					L-SABL	12 × 30	15	27	47	12
					L-SABL	15 × 20	4			27
					L-SABL	17 × 25				32
					No	No				59
Patient 3	35	F	CF	BLT	R-NGIII	No				3
					R-SNASBL	08 × 13				4
					R-SNASBL	08 × 13	3	10		7
					R-SNASBL	08 × 13	9			16
					R-SNASBL	08 × 13	4			20
					R-SNASBL	08 × 13	2			22
					R-SNASBL	08 × 13	5			27
					R-SNASBL	Dumon	4			31
					R-SNASBL	No				36
					Death					41
Patient 4	40	F	IPF	SLT-L	L-NGII	No				9
					L-SABL	14 × 30				10
					L-GTL	12 × 30	5	22	48	15
					L-SABL	12 × 30	7			22
					L-SABL	12 × 30	7			29
					L-SABL	15 × 30	8			37
					L-SABS	No				45
					L-SABS	No				59
Patient 5	52	F	COPD	BLT	R-SABL	12 × 30				3
					No	No		45	45	48
Patient 6	41	M	COPD	BLT	R-NGIII	No				1
					R-SABL	Dilatation				4
					R-SABL	No		7	7	5
					R-SABL	11 × 12				6
					R-SABS	No				13

POTx: post-transplant time; 1STFU: follow-up since first stenting; IFT: intervention-free time; ReST: time to re-stenting; SLT: single lung transplant; BLT: bilateral lung transplant; SABS: anastomotic stenosis less than 50% of bronchial diameter-small; SABL: anastomotic stenosis more than 50% of bronchial diameter-large; SNASBS: non-anastomotic stenosis less than 50% of bronchial diameter-small; SNASBL: non-anastomotic stenosis more than 50% of bronchial diameter-large; NGII: grade II necrosis – any necrotic mucosal slough reported – but no bronchial wall necrosis; NGIII: grade III necrosis – bronchial wall necrosis within 2 cm of anastomosis; NGIV: grade IV necrosis – extensive bronchial wall necrosis extending 2 cm from anastomosis; GTL: granulation tissue with more than 50% diameter narrowing – large; MA: anastomotic malacia – 1 cm proximal or distal to anastomosis; COPD: chronic obstructive pulmonary disease; IPF: interstitial pulmonary fibrosis; and CF: cystic fibrosis.

years of treatment, the patient was lost from our follow-up. However, an 11-mm Dumon silicone stent (Bryan Corp., Woburn, MA, USA) was implanted into the stenotic right bronchus in another hospital. Ten months later, the patient suffered sudden death on the street. The autopsy revealed massive main pulmonary artery embolisation and diffuse and necrotising parenchymal right pulmonary infection.

Patient #4 was a 40-year-old woman, who had left-sided LTx for interstitial pulmonary fibrosis. Nine months after transplantation, a necrosis grade II developed distal to the anastomosis. Next month, this bronchial segment was stenotic, and, after dilation, a 14 × 30-mm BD stent was inserted. Five months later, the stent was almost dissolved but the lumen was obstructed with exophytic granulation tissue growing through the mesh of the stent. After balloon dilation, another 12 × 30-mm BD stent was inserted. At 6–8 months' intervals, the next three stents were inserted. Seven months after insertion of the last stent, the left bronchus remained wide open with only 20% stenosis. The last stent was completely absorbed, and no remnants of stent mesh were visible. The patient remains clinically stable with not significant bronchial stenosis 49 months after the LTx.

Patient #5 had a stenotic complication (SABL) 3 months after bilateral LTx for COPD. The right anastomotic stenosis was treated with a BD stent and did not reappear for almost 4 years of follow-up.

Patient #6 had bilateral LTx for COPD. He developed NGIII distal to the right anastomosis and consecutive stenosis. Dilation secured airway lumen but attempted stenting failed because of mobility of the BD stent (9 × 13 mm: too small a diameter) It was necessary to remove the stent. Subsequent bronchoscopy has proven the extent of stenosis of bronchus intermedius, and was followed by dilation and insertion of a 11 × 12-mm BD stent. After 6 months' follow-up after stenting, the right bronchus remains wide open with the stent already absorbed (Fig. 3).

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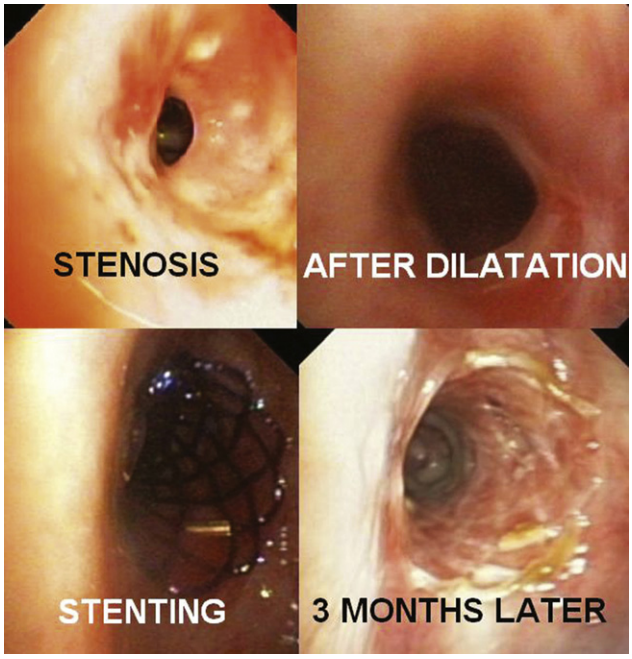

Fig. 3. Patient 6: bronchus intermedius, stenosis, stenting and disappearance of the stent.

4. Discussion

The lung transplant programme in the Czech Republic started in 1997. By January 2010, 147 patients had been transplanted.

Our institution uses the LTx methods from University Hospital Vienna, Austria. The surgical technique was constant over the years and only three surgeons performed all transplantations. The complication rate has not changed over time, and bronchial stenosis, although rare, remains problematic.

The excellent results of our technique of an end-to-end anastomosis with continuous suture of the membranous wall and interrupted single sutures of the cartilaginous part encouraged us to retain/keep using this technique even with the knowledge of different approaches [10].

Between 1997 and 2005, there were 98 lung transplants in 67 patients. We had four bronchial anastomotic complications that required stenting (4.1%) in four patients (6.0%). We have used metallic and plastic stents with good result, but with significant clinical complications and discomfort to patients.

Between 2005 and 2010, 121 lung transplants in 80 patients (39 SLTs and 41 BLTs) were performed.

We have experienced seven bronchial anastomotic complications requiring stenting (5.8%) in six affected patients (7.5%).

After our long experience with metallic stents [25], with the development of BD stents, and following encouraging experimental results from other stenotic organs (e.g., oesophagus), we decided to use these stents for airway stenosis post LTx in patients from the year 2006.

These custom-made stents, with an introducer diameter of 13–15 F, proved easy to handle. They could be placed via an endotracheal tube or directly inserted over a guiding wire into the bronchus.

The diameter and length of the stenotic bronchus must be exactly measured. The stent is self-expandable; hence, some oversizing is acceptable, and may be necessary.

Four patients from our series developed initially perianastomotic necrosis of the bronchus. During the subsequent healing process, stenosis occurred. The stenosis had stabile radial compression force in comparison with pulsatile stenosis seen in vascular compressions of bronchi.

The stent was deployed in the area of low or no movement; hence, during the subsequent degradation process, the matrix was more stabile in comparison with stents deployed in motile oesophagus or intestines. Nevertheless, some patients did experience expectoration of small stent particles. This potentially unpleasant symptom was very well tolerated. The exact process of airway BD stent degradation remains to be experimentally investigated.

This small pilot study shows that BD stents are a safe, effective and reliable alternative to classical metallic stents in patients with anastomotic stenosis after LTx, and may avoid the need for permanent stenting.

We believe that the number of indications for BD stents will grow. New BD stents with different radial-compression-force resistance are being developed. There are many situations in which either a stenotic process or a malacic process is a temporary phenomenon, for example, after surgical repair of the trachea; and a BD stent may offer significant advantages in this setting. The safety of the BD stents demonstrated in this pilot series should encourage others to try them in such situations.

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Appendix A. Conference discussion

Dr F. Rea (*Padua, Italy*): I have a question for you. In patients where you have re-stenosis, when you try to re-stent, do you have to dilate before inserting this stent?

Dr Vondrys: In one of these patients we had granulation overgrowth even while the stent was still in situ, so we had to dilate it with a balloon, which was successful, and we could put another stent over the already dissolving stent. So you can overlap the stents, and we do dilate with a balloon, yes.

Dr R. Cerfolio (*Birmingham, USA*): This topic is incredibly important and is a major problem in my practice. I don't do transplants, but I inherit all of the stenoses. We have in my practice at least 25 patients who have had wire stents put in, before I was born probably, and now they come back month after month. Have you placed any of these stents in a patient who has a wire stent that has grown into the airway totally and really cannot be removed without a very prolonged procedure, and, if so, what has been your experience?

Dr Vondrys: In the Czech Republic metallic stents were not used for bronchial stenosis.

Dr Cerfolio: Because you're smarter there than in America – I understand.

Dr Vondrys: We just adopted what was done in Austria. So we skipped the learning curve and we started with plastic, with the Dumon stents.

Dr Cerfolio: So you have no experience with putting these inside of a wire stent?

Dr Vondrys: No.

Dr Cerfolio: Can you extrapolate as to what you think might happen? Would it work?

Dr Vondrys: It would, but not forever because they dissolve. I wanted to show you on this picture. You mentioned a metallic stent.

Dr Cerfolio: Yes.

Dr Vondrys: This patient is a patient who was born with long-segment tracheal stenosis, and in his case a metallic stent was used for distal tracheal stenosis, and here you can see that the stent eroded into the aorta, and he was saved at the last minute after bleeding from the aorto-tracheal fistula. So it was one of the motivations for us to start the biodegradable stents in London, even in children.

Dr Cerfolio: But in that patient you removed the wire stent?

Dr Vondrys: In this case we removed the whole trachea.

Dr Cerfolio: My question is different, because these are patients who have wire stents that are embedded into the trachea, and the body has literally grown into them, like a tree might grow around and then through a board nailed into it. So it's a different question.

Finally, how can I get these in the United States? I'll pay you money. How can I get them?

Dr Vondrys: Get to me afterwards.

Dr Cerfolio: Okay.

Dr A. Bertani (*Palermo, Italy*): I have a quick question. How does the mucosa of the bronchus behave, especially in the long-term, after multiple stents? Does it tend to granulate or have any other specific behaviour?

Dr Vondrys: Did you read any work about biodegradable stents in the trachea so far?

Dr Bertani: No.

Dr Vondrys: So there is no evidence. We have evidence from animal studies which shows that after 4 and 5 weeks, there is a huge inflammatory reaction, and after that hypergranulation starts, but if the patient overcomes this period of inflammation and hypergranulation, there is almost no reaction of the mucosa.

Dr R. Schmid (*Bern, Switzerland*): I refer to the question of Professor Cerfolio. What are the mechanical properties of this stent? How strong is the radial force? One of the biggest problems also in lung transplantation patients is that the force of the metallic stents is too great and they create pressure on the vessel wall and migration. How do the mechanical properties of your stents compare with those of metallic stents?

Dr Vondrys: These stents are self-expandable.

Dr Schmid: Yes, but what is the force?

Dr Vondrys: They are produced with different radial forces. You can ask the manufacturer to produce a stent for you with a low expansion force or with a higher expansion force. Exact measurements haven't been done on these stents.

Dr Schmid: And the manufacturer is in the Czech Republic?

Dr Vondrys: Get to me later.

Dr Cerfolio: To follow up on that, when I ask the manufacturer and he says 'What force do you want?', I'm going to say 'Tell me what forces they come in.' So the manufacturer knows the radial forces?

Dr Vondrys: Yes.

Dr Cerfolio: And they can pre-make the stent to the length, the size?

Dr Vondrys: Yes.

Dr Cerfolio: This sounds too good to be true. This is great.

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