Efficacy and Tolerance of a New Silicone Stent for the Treatment of Benign Tracheal Stenosis*

Preliminary Results

Jean-Michel Vergnon, MD; Frédéric Costes, MD; and Jean-Charles Polio, MD

Study objective: In inoperable patients with tracheal stenosis who are treated using silicone stents, stent migration occurs in 18.6% of cases. To decrease the migration rate, we have designed a new silicone stent with narrow central and larger distal parts. This study analyzes the stability and tolerance of this new stent.

Design: Preliminary prospective study conducted in two French university hospitals.

Patients: Thirteen inoperable patients with benign complex tracheal stenosis due to intubation or tracheotomy.

Interventions: Tracheal stent insertion was performed under general anesthesia with a rigid bronchoscope. The patients were followed up clinically up to stent removal, which was planned at 18 months.

Results: Stent insertion or removal was very simple and did not differ from other silicone stents. No migration occurred after a mean follow-up of 22.8 months. Minimal granuloma formation occurred in only one patient (7.7%). Sputum retention remained similar to that with other silicone stents and could be improved by a smoother internal wall. Stents have been removed in seven patients after a mean duration of 19.6 months, with a complete stenosis cure in four cases.

Conclusion: This new stent combines the excellent stability of the metallic stents and the tolerance and easy removal of straight silicone stents. This allows a prolonged use in order to obtain curative action.

T racheal stenosis is a common iatrogenic complication of intubation or tracheotomy, although its occurrence has been dramatically reduced by the use of low-pressure endotracheal tubes.1,2 Tracheal stenosis was present in 10 to 19% of patients after intubation in prospective studies,3,4 but was only symptomatic in 1% of patients.4 Two types of stenosis can be observed. First, the so-called web-like stenosis is a short (<1 cm), membranous stenosis without damage to the cartilages. Laser incisions followed by gentle dilatation is the curative treatment, with a 60% success rate.5,6 Second is complex tracheal stenosis, longer with circumferential hourglass-like contraction, scarring, or malacia; surgical sleeve resection is considered the standard curative treatment.6 However, treatment failure has been reported in 5 to 15% of cases,7–9 and mortality ranged from 1.8 to 5% of patients.7–9 When the length of the stenosis, the underlying diseases, or the performance status contraindicate surgery, stents are indicated.6 Among stents, silicone Dumon stents (Tracheobronxane; Novatech; Grasse, France) are the most widely used: > 10,000 of them have been inserted to date. The results are fair in this indication, but clearly less satisfactory than in tumors. Dumon et al10 found a 18.6% migration rate, contrasting with the 6% rate in malignancies. This result was confirmed by others.11,12 The occurrence of granulomas,10 induced by an excessive mobility of the stent, also increased (17.2% vs 1.4%).

Hence, metallic wire mesh stents, which have a low migration rate,13,14 may be preferable in the treatment of benign tracheal stenosis. However, the extraction of these stents after long-term presence is very difficult.13,14 An alternative is to modify the...
stent shape to decrease the side effects of the silicone stent in these situations. A first step was achieved by Noppen et al., with his screw-thread tracheal endoprosthesis. The migration of this stent was never reported in a follow-up ranging from 4 to 18 months.

We have explored another way and have designed a new silicone stent (Tracheobronxane ST; Nova-tech). This article presents the preliminary results of efficacy and tolerance of this new stent in patients presenting with benign tracheal stenosis.

**Materials and Methods**

**Methods**

This prospective study was conducted from September 1995 to October 1998 in two university hospitals (Saint Etienne and Besançon). The new stent was inserted instead of the cylindrical Dumon stent in all patients seen in these two hospitals with a symptomatic inoperable benign complex stenosis (excluding web-like stenoses). Patients were included after informed consent was obtained. When clinically possible, lung function tests were performed before insertion and during follow-up.

All patients were followed up clinically. To improve mucus drainage in the stent, mucolytics were given daily. No bronchoscopy was planned during the follow-up unless clinical events such as persistent cough, acute dyspnea, sputum retention, or hemoptysis occurred. Removal of the stent was theoretically planned after 18 months, as recommended by Martinez-Ballarin et al., The new stenotic silicone stent is its distal parts are 2-mm larger than the central part to improve anchoring to the tracheal wall (Fig 1). This stent is available in different diameters, ranging from 12 to 16 mm in the larger parts. The 16/14/16-mm diameter stent is best indicated for male patients, and the 14/12/mm diameter stent is best indicated for female patients. The length of the stent was theoretically planned before and after stent placement in nine patients. (Table 1): seven young patients (<32 years old) who had to undergo mechanical ventilation following a suicide attempt, road accident, or decompensation of a congenital disease; four middle-aged patients with acute respiratory failure complicating miscellaneous surgical operations; and two elderly patients (>75 years old) requiring tracheotomy for acute decompensation of COPD.

The mean delay between the tracheal injury and the stent placement was 3 months (range, 2 months to 5 years) and depended on the previous treatment of the stenosis. Before stenting, the stenosis had been treated by various methods: dilatation with or without laser in eight patients, surgery in one patient, and Montgomery T tube in one patient.

**Results**

The results are summarized in Table 2: Stent insertion was successful in each case. Seven 16/14/16-mm stents (type 1) and six 14/12/14-mm stents (type 2) were inserted with an immediate improvement in dyspnea. Flow-volume curves were performed before and after stent placement in nine patients. Figure 2 shows the improvement of FEV1 in these patients. The increase of FEV1 (mean, 634.4 mL; range, 100 to 1300 mL; p < 0.0025) was observed in all patients, even those with severe underlying obstructive disease.

The mean follow-up of the stented patients was 22.8 months (range, 3 to 46 months). Patient 9 died due to terminal progression of a malignant thymoma, 3 months after stent insertion, without any tracheobronchial complications. The tolerance of stents was judged excellent (Table 2). No migration occurred during the follow-up. Minimal granulomas at the tip of the stent were observed only in one patient. Regression of these granulomas was obtained with inhaled steroids. Sputum retention requiring fiberoptic bronchoscopy aspiration was necessary only in two patients (15.3%), occurring after discontinuation of mucolytic therapy in one patient. Infected secretions

![Figure 1](http://journal.publications.chestnet.org/pdfaccess.ashx?url=/data/journals/chest/21950/ on 04/27/2017)
were observed in three heavy smokers, at 10, 17, and 24 months, respectively, after insertion. In two patients, microbial infection was identified at the time of stent removal. In the last patient, the infection (Proteus mirabilis, Pseudomonas aeruginosa) was cured by inhaled antibiotics, without necessitating stent removal.

At the present time, stents have been removed in seven patients, after a mean of 19.6 months (range, 15 to 24 months) of stent placement. A shorter duration was observed in three cases (15, 16, and 17 months). This was due to patient wishes, without any problem of tolerance in two patients and associated with stent infection in the last patient.

In four patients, no recurrence of tracheal stenosis was observed during a mean follow-up of 14.2 months (range, 2 to 22 months). In three patients (patients 3, 4, and 5), a recurrence of tracheal stenosis was present at 4, 2, and 3 weeks after stent removal, respectively. Patient 3 refused surgery and was treated with a metallic stent (Ultraflex stent; Boston Scientific; St. Quentin en Yvelines, France). Patient 4 was still inoperable and was treated with a silicone straight stent. In patient 5, the stenosis was of web-like type and was treated by dilatation alone without new recurrence. Other patients with long standing prosthesis (patients 6, 11, 12, and 13) refused stent removal.

**Comments**

In this preliminary study, we showed that a newly designed silicone stent with variable diameters was highly effective in the treatment of benign tracheal stenosis. In comparison with historical data, this stent seemed to be less prone to migration (0% vs 18.6%) and granuloma formation (7.5% vs 17.2%).

### Table 1—Patient Characteristics and Stent Indications*

<table>
<thead>
<tr>
<th>Group</th>
<th>Patient</th>
<th>Age, yr/Sex</th>
<th>Stenosis</th>
<th>Cause</th>
<th>Location</th>
<th>Previous Treatment</th>
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<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>26/F</td>
<td>PI</td>
<td>ITT</td>
<td></td>
<td>Sleeve resection, laser</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>16/M</td>
<td>PI</td>
<td>ETT</td>
<td></td>
<td>Laser and dilatation</td>
</tr>
<tr>
<td>1</td>
<td>3</td>
<td>17/M</td>
<td>PI</td>
<td>ETT</td>
<td></td>
<td>Dilatations</td>
</tr>
<tr>
<td>1</td>
<td>4</td>
<td>15/M</td>
<td>PI</td>
<td>ETT</td>
<td></td>
<td>Dilatation</td>
</tr>
<tr>
<td>1</td>
<td>5</td>
<td>26/M</td>
<td>PI</td>
<td>ETT</td>
<td></td>
<td>Dilatations, T tube</td>
</tr>
<tr>
<td>1</td>
<td>6</td>
<td>24/M</td>
<td>PI</td>
<td>ETT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>7</td>
<td>32/F</td>
<td>PT</td>
<td>ETT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>8</td>
<td>43/M</td>
<td>PI</td>
<td>ETT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>9</td>
<td>74/F</td>
<td>PT</td>
<td>ETT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>10</td>
<td>41/F</td>
<td>PT</td>
<td>ETT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>11</td>
<td>47/F</td>
<td>PI</td>
<td>ITT</td>
<td></td>
<td>Dilatation</td>
</tr>
<tr>
<td>3</td>
<td>12</td>
<td>76/M</td>
<td>PT</td>
<td>ETT</td>
<td></td>
<td>Laser and dilatations</td>
</tr>
<tr>
<td>3</td>
<td>13</td>
<td>77/M</td>
<td>PT</td>
<td>ETT</td>
<td></td>
<td>Laser and dilatations</td>
</tr>
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</table>

* M = male; F = female; PI-postintubation; PT-posttracheotomy; ETT-extrathoracic trachea; ITT-intrathoracic trachea.

### Table 2—Follow-up After Stent Placement

<table>
<thead>
<tr>
<th>Patient</th>
<th>Stent Type*</th>
<th>Insertion Date</th>
<th>Stent Follow-up, mo</th>
<th>Complications</th>
<th>Removal</th>
<th>Recurrence</th>
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<tr>
<td>1</td>
<td>2</td>
<td>6/12/97</td>
<td>24</td>
<td>No</td>
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<td>No</td>
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<tr>
<td>2</td>
<td>2</td>
<td>5/26/98</td>
<td>13</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>3</td>
<td>1</td>
<td>8/18/97</td>
<td>16</td>
<td>No</td>
<td>Yes</td>
<td>Yes, metallic stent (Ultraflex)</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>2/23/97</td>
<td>15</td>
<td>No</td>
<td>Yes</td>
<td>Yes, silicone stent</td>
</tr>
<tr>
<td>5</td>
<td>1</td>
<td>6/23/97</td>
<td>21</td>
<td>Sputum retention</td>
<td>Yes</td>
<td>Yes, dilatation</td>
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<tr>
<td>6</td>
<td>2</td>
<td>10/15/97</td>
<td>21</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>7</td>
<td>1</td>
<td>2/13/96</td>
<td>20</td>
<td>Stent infection</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>8</td>
<td>1</td>
<td>10/15/96</td>
<td>24</td>
<td>Stent infection</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>9</td>
<td>2</td>
<td>3/2/96</td>
<td>3</td>
<td>No</td>
<td>No</td>
<td>Died</td>
</tr>
<tr>
<td>10</td>
<td>2</td>
<td>4/24/96</td>
<td>17</td>
<td>Stent infection</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>11</td>
<td>1</td>
<td>9/26/95</td>
<td>46</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>12</td>
<td>1</td>
<td>2/4/97</td>
<td>30</td>
<td>Sputum retention, granulomas</td>
<td>No</td>
<td>No</td>
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<tr>
<td>13</td>
<td>1</td>
<td>9/26/95</td>
<td>46</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

*Type 1 = 16/14/16 mm; type 2 = 14/12/14 mm.
By contrast, the obstruction of the stent requiring bronchoaspiration was not reduced by the new design of the stent. As with all covered stents, mucus drainage is limited and may require saline solution nebulization or mucolytic therapy. The variation in the inner area of this new stent may increase mucus retention. This disadvantage may be corrected with a smoother internal surface. Symptomatic improvement of dyspnea and increase in functional parameters after stent insertion were obtained, as previously reported with other silicone stents in tracheal stenosis. These preliminary results also confirm the ability of stents to cure some tracheal stenoses after long-term placement. Complete cure was obtained in four of seven patients. Among the three cases with recurrence, stent placement was shorter than planned in two patients. Studies have confirmed the possible curative role of the stent after temporary placement. In a multicenter retrospective series of 263 tracheal stenosis treated with the Dumon stent, the stent was removed in 117 cases after a mean 1.2 year duration, without recurrence in 64 cases (54.7%).

Martínez-Ballarín and coworkers obtained better results (17 cured patients among 21 cases) after an 18-month placement period. These results argue strongly for silicone stents (which are easy to remove) rather than for uncovered metallic stents (which are extremely difficult to remove).

From a technical point of view, the insertion of this new stent is easier than a cylindric stent. The correct positioning of the stent is automatically obtained in the middle part of the stenotic trachea. Moreover, this stent can be adjusted in length and diameter as required to fit patient anatomy. It is possible to build a stent with a short narrow part for the treatment of inoperable recurrent web-like stenosis after failure of three sessions of laser treatment. In contrast with the available stent of Noppen et al, the Tracheobronxane ST stents adapt to a larger range of clinical situations. The extraction technique is similar to that for cylindric models. The stent must be folded, rolled on a forceps, and then removed. Due to the stent shape, this extraction is sometimes slightly difficult, requiring two forceps to pull out the stent.

In conclusion, the efficacy and tolerance of this new stent seem excellent, with a dramatic decrease in migration rate and occurrence of granulomas. Controlled studies comparing different types of silicone stents are needed to confirm these preliminary data. Drainage and colonization or infection of secretions, however, remain a clinical complication in the use of covered stents. These preliminary results reinforce our opinion that the silicone stent should be chosen first in the management of inoperable patients with benign tracheal stenosis.

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