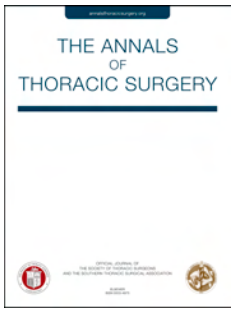
Journal Pre-proof



Novel duckbill-shaped laryngo-tracheal stent for management of subglottic stenosis

Claudio Andreetti, MD, PhD, Erino Angelo Rendina, MD, Mario Santini, MD, Alfonso Fiorelli, MD, PhD

PII: S0003-4975(20)31224-8

DOI: https://doi.org/10.1016/j.athoracsur.2020.05.167

Reference: ATS 34116

To appear in: *The Annals of Thoracic Surgery*

Received Date: 29 February 2020

Revised Date: 16 May 2020

Accepted Date: 24 May 2020

Please cite this article as: Andreetti C, Rendina EA, Santini M, Fiorelli A, Novel duckbill-shaped laryngo-tracheal stent for management of subglottic stenosis , *The Annals of Thoracic Surgery* (2020), doi: https://doi.org/10.1016/j.athoracsur.2020.05.167.

Novel duckbill-shaped laryngo-tracheal stent for management of subglottic stenosis

Running title: Duckbill-shaped laryngo-tracheal stent

Claudio Andreetti[1], MD, PhD, Erino Angelo Rendina[1], MD, Mario Santini[2], MD, Alfonso Fiorelli[2], MD, PhD

[1]Division of Thoracic Surgery, Sant'Andrea Hospital, University of Rome 'Sapienza', Rome, Italy;
[2]Division of Thoracic Surgery, Università degli Studi della Campania "Luigi Vanvitelli", Naples, Italy

Word Count: 1.445

Key words: subglottic stenosis, customized stent, airway stent

Corresponding Author:

Alfonso Fiorelli MD, PhD

Thoracic Surgery Unit

University of Campania "Luigi Vanvitelli"
Piazza Miraglia, 2

I-80138 Naples, Italy

Email: alfonso.fiorelli@unicampania.it

ABSTRACT

A 23-year-old man developed subglottic stenosis six months after tracheal resection for post-intubation stenosis. A standard Dumon stent was placed; however, two months later the stenosis extended superiorly, near the vocal folds. A modified Dumon stent with a longitudinal cut was then placed through the vocal folds, over the proximal end of the previous stent to cover all the stenosis. Thirty days later, this was replaced with an industry custom stentfeaturing a thin duckbill-shape proximally that fit the vocal folds without impairing their movement. Two-month follow-up demonstrated normal airway patency and vocal fold movement.

Tracheal resection and reconstruction (TRR) is the treatment of choice for benign tracheal stenosis, with a success rate ofover 90%.However, restenosis can occur in 4-16% of cases, as reported in a major case series, and presents a treatment challenge [1]. Patients unfit for re-TRR, and with insufficient subglottic space for stenting, have no alternative treatment options – other than definitive tracheostomy.

Here, we report the use of a modified Dumon stent as a temporary bridge to a novel, industry custom laryngo-tracheal stent for the treatment of life-threatening subglottic stenosis after TRR.

A 23-year-old man, with several comorbidities including obesity and diabetes, underwent TRR for post-intubation tracheal stenosis. Initially, he received a temporary T-tube at another hospital. This stent remained in place for two years;however, the stenosis recurred two months after stent removal. The patient's young age, the lack of clinical/technical contraindications to surgery, and the failure of previous stenting treatment led to the consideration of curative TRR as the most appropriate approach. The stenosis was approximately 2 cm long and about 0.5 cm from the tracheostomy stoma.However, unhealthy mucosa between the stoma and stenosis necessitated a full resection of stoma and stenosis, amounting to nearly 4 cm of tracheal length. An end-to-end anastomosis connected the remaining healthy tissue.

After an unremarkable post-operative course, restenosis occurred six months later. Redo-surgery carried a high failure risk and endoscopic dilation alone did not provide durable airway patency. Thus, a standard Dumon stent was selected and placed,rather than a T-Tube, as it did not necessitate forming a tracheostomy. The stent (length:40 mm; diameter:16 mm) covered all the stenosis, with its proximal end 0.5 cm from the vocal folds. Two months later, the patient developed severe dyspnea and dysphonia. A chest computed tomography scan demonstrated stenosis extending superiorly from the proximal end of the stent to the vocal folds, distorting the subglottic

space. However, laryngoscopy indicated normal function of the vocal folds, with no signs of injury. An emergent dilation with rigid bronchoscopy was performed. A Dumon stent (diameter: 18 mm) was shorted to 30 mm in length and modified by making a vertical incision (Figure 1/A). It was then placed over the proximal end of the previous stent,with themidpoint positioned at the level of the cricoid cartilage and the upper limit just superior to the arytenoid cartilages (Figure 1/C). The procedure was summarized in Video 1. The patient was discharged two days later. Radiologic imaging and endoscopy indicated normal airway patency and vocal fold vibration. After 30 days, this modified stent was replaced with an industry customstent (Novatech, France)(Figure 1/B and Figure 1/D). The novel stent has a unique, hourglass-like body,with differentupper and lower diametersof 18 mm and 16 mm, respectively. The proximal end features a thin duckbill-shape (0,5 mm) that fitthe vocal folds without impairing their movement. Two-month follow-up computed tomography scan (Figure 2/A) and endoscopy (Figure 2/B) demonstrated normal airway patency, and vocal fold movement. We plan to leave the stent for at least 12 months, as this is generally enoughtime to cure stenosis. In the case of recurrence, definitive tracheostomy or T-tube remain the only treatment options.

COMMENT

The case demonstrates the unique challenges of managing restenosis within the subglottic area after failure of TRR. Redo-TRR or insertion of a standard stent was not indicated because of insufficient residual subglottic space [2]; while the patient refused definitive tracheostomy or T-tube because of the negative impact on quality of life. In similar cases, some authors [3,4,5] placed a stent through the vocal folds as an alternative to definitive tracheostomy.However, none of the currently available stents met the requirements for restoring subglottic space without causing further airway damage. Bourinet et al. [3], and Chambres et al. [4] reported trans-cordal insertion of a standard Dumon stent [3] or modified silicone stent (Larynxane ST prosthesis) [4], respectively. Both stents have a roundshape that does not restore the acute anterior commissure of the glottis,

resulting in a negative impact on phonation in all treatment cases. Monnier et al.[5] proposed the transcordal insertion of a novel laryngeal stent called the Easy-LT-Mold. However, the procedure required a combined surgical and endoscopic approach, and in 10 of 30 treated patients the silicone cap of the stent was accidentally lost in the airway.

Initially, we inserted a modified Dumon stent over the proximal end of the previous stent to stabilize and maintain the expanded airway. The stent, because of a longitudinal cut, was easily inserted and did not impair arytenoid cartilage movement. It did not have long-term effects on phonation and vocal cord function, and there were no signs of trauma to the cords after its removal. For these reasons, it served as a "prototype" for industry partners to create a novel stent that fit the specific shape of stenosis. The resulting stent design features V-shaped cuts proximally that form a duck-bill shape, conformingto the inner laryngeal contours and restoring the complex triangular shape of the glottis (Figure 2/C). A very thin wall (0.5 mm) and lack of studsminimize resistance and prevent potential irritation during vocal fold movements against the stent wall. The body features a variable diameter and standard rows of studs to fit the hourglass subglottic stenosis and minimize the risk of dislocation.

For the technical success of the procedure, we recommend leavingthe temporary, modified stent in place for only a brief time, to avoid formation of dense adhesions that complicate its removal. The stents should be exchanged in the same session, without performing additional endoscopic procedures, such as dilation, that could modify airway anatomy. In case of desaturation during the procedure, ventilation may be managed by delivering 02 100 at high pressures, with a small catheter inserted in the rigid bronchoscope. The proximal end of the new stent should be placed slightlysuperior to the arytenoid cartilages - to preserve epiglottis movement and swallow function, and to avoid that the four sharp points produced by the V-shapeinjure the nearbyvocal folds.

The success of this prosthesis relies on the integrity of hypo pharyngeal peristalsis, as well as normal tongue function, to prevent aspiration and preserve stent patency. Thus, it is not indicated for patients with neurological or surgical disorders that impair swallowing.

Finally, our novel prosthesis might be a useful adjunct to the current stents for the treatment of difficult subglottic stenosis. In the future, 3D-printed customized stents will certainly facilitate the management of laryngo-tracheal region stenosis. However, lack of biocompatible material and ethical considerations are among the mainfactors limiting their routine use.

REFERENCES

1. Bibas BJ, Terra RM, Oliveira Junior AL et al. Predictors for postoperative complications after tracheal resection. Ann. Thorac. Surg. 2014;98(1):277-82

2. Fiorelli A, Mazzone S, Mazzone A et al. The digital AcuBlade laser system to remove huge vocal fold granulations following subglottic air way stent. Interact. Cardiovasc. Thorac. Surg. 2013;17(3):591-3.

3. Bourinet V, Raguin T, Fortin M et al. Experience with Transcordal Silicone Stents in Adult Laryngo tracheal Stenosis: A Bicentric Retrospective Study. Respiration 2018;95(6):441-448.

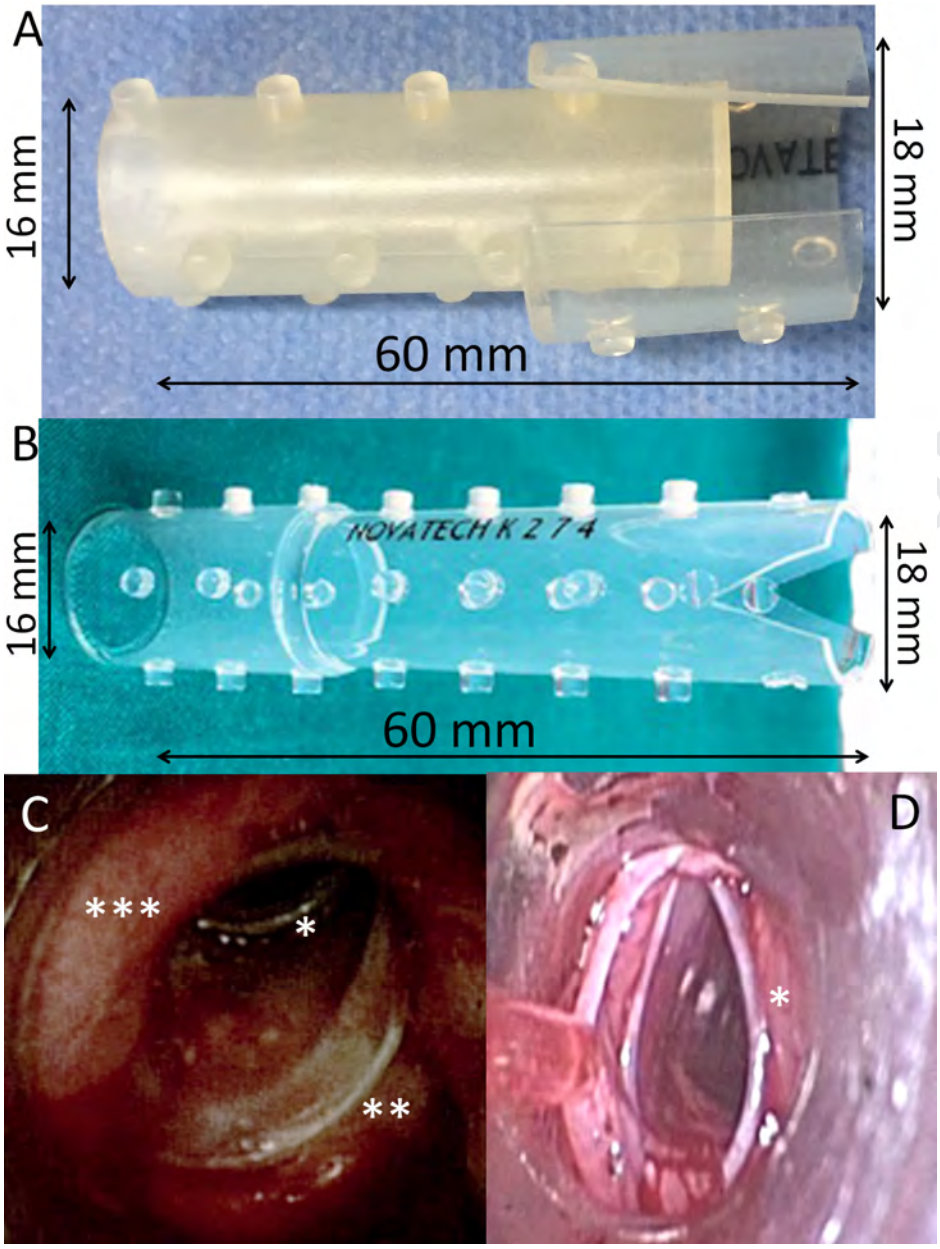
4. Chambres O, Schultz P, Debry C. The Larynxane ST intralaryngealendoprosthesis for laryngotracheal pathologies. J Laryngol Otol. 2006;120(11):942-8.

5. Monnier P. Airwaystenting with the LT-Mold: experience in 30pediatric cases. Int J PediatrOtorhinolaryngol. 2007;71(9):1351-9.

FIGURE LEGENDS

Figure 1. Modified Dumon stent (A), and industry custom stent (B). Endoscopic view showed the position of the modified Dumon stent (**) over the previous stent (*), and below the epiglottis (***) (C), and the transcordal position (*) of the industry custom stent (D).

Figure 2. Two-month computed tomography (A) and endoscopy (B) follow-up showed the transcordal position of industry custom stent that restored the glottic triangular shape (C)


A
16 mm
18 mm
60 mm
B
NOVATECH K 2 7 4
16 mm
18 mm
60 mm
C
***
*
**
D
*