Stents for the treatment of laryngotracheal stenosis: review and proposal of a 3D-printed solution

Avaliação de moldes no tratamento de estenoses laringotraqueais para elaboração de proposta de confecção em Impressão 3D

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ABSTRACT

Laryngotracheal stenosis is the leading indication for tracheostomy in children. Correction of stenosis and removal of the tracheostomy is a multi-stage process, and laryngeal stents are sometimes necessary to maintain the patency of the endolaryngeal lumen. Several laryngeal stents are commercially available, with varying designs, materials, and costs. The present study will give an overview of these devices. After a review of the literature and considering the expertise of our team, we conclude that computed tomography imaging and 3D printing technology can be used to make custom laryngeal molds designed to meet the individual needs of each patient.

Keywords: Laryngeal stenosis; 3D printing; Artificial larynx; Surgical molds.

RESUMO

A estenose laringotraqueal é o principal motivo para a realização de traqueostomia em crianças. O tratamento para correção e remoção da traqueostomia apresenta diferentes etapas onde por vezes é necessário o uso de molde laringeos a fim de manterem a luz endolaringea pérvia. Existem diversos moldes laringeos disponíveis no mercado, apresentados a seguir neste trabalho, que variam em forma, consistência de material e custo. Após nosso levantamento e a expertise de nossa equipe verificamos a necessidade de realizar a confecção de moldes personalizados para a necessidade de cada paciente através do uso de imagens de tomografia computadorizada e da tecnologia de impressão tridimensional.

Palavras-chave: Laringoestenose; Impressão tridimensional; Laringe artificial; Moldes cirúrgicos.
INTRODUCTION

Subglottic stenosis is one of the main congenital causes of stridor in childhood, and the leading indication for tracheostomy in the first year of life (SCHROEDER; HOLINGER, 2008). It may be classified by cause (congenital or acquired) or by clinical or anatomical characteristics (hard or soft, severity of or percent obstruction).

The normal diameter of the subglottis ranges from 4.5 mm to 5.5 mm in full-term neonates. Tucker et al. (TUCKER; TUCKER; VIDIC, 1977) note that the superior and posteromedial portions of the cricoid cartilage are V-shaped (more rounded in children), while the middle portion of the cartilage and its lumen are elliptical. Only in the inferior portion does the cartilage take on a more rounded shape (Figure 1) (HOLINGER; CG, 1997) (MONNIER PHILIPPE, 2011a).

The terms subglottic stenosis, laryngeal stenosis, and tracheal stenosis are found in the medical literature. Each refers to a specific anatomic site of obstruction; however, in most cases, more than one site is involved. Laryngotracheal stenosis is the most appropriate term to describe narrowing of the supraglottic, glottic, and subglottic regions. Over 90% of all cases of acquired laryngotracheal stenosis result from injury after orotracheal intubation (MONNIER PHILIPPE, 2011b).

The overall prevalence of laryngotracheal stenosis among children and adults in the Brazilian population is estimated at 1 to 4%, but specific data are lacking in the literature (JOHNSON; ISAIAH, 2018) (KLOPPER; ADENIYI; STEPHENSON, 2021).
The diagnosis of laryngotracheal stenosis is established by examination of the airway, which consists of a variety of tests to evaluate laryngeal function (mobility of the vocal folds, phonation, sensitivity of the supraglottic region and its behavior during breathing and swallowing) and patency (changes in laryngeal and tracheal anatomy that might reduce the normal diameter of the airway)(MONNIER et al., 2015).

Direct laryngoscopy with tracheoscopy (or airway endoscopy) performed through a rigid endoscope provides the greatest wealth of necessary clinical information(AVELINO et al., 2017). Airway endoscopy is performed in the operating room, under spontaneous ventilation, in order to visualize the airway during spontaneous breathing, which allows evaluation of vocal fold mobility (or lack thereof) and of the effects of respiratory effort on the laryngeal region (laryngomalacia), subglottis (congenital and acquired stenosis), and trachea (tracheobronchomalacia).

Different classifications for laryngotracheal stenosis are available. Those most used in clinical practice are the Myer-Cotton subglottic stenosis grading scale(MYER; O’CONNOR; COTTON, 1994); the McCaffrey classification scheme(MCCAFFREY, 1992), which is divided into stages according to the craniocaudal extension of the stenosis; and Monnier’s classification(MONNIER PHILIPPE, 2011c), which adds glottal involvement and clinical comorbidities to the Myer-Cotton scale.

Surgical procedures to correct laryngotracheal stenosis can be divided into endoscopic (endolaryngeal) and open (cricotracheal resection and laryngotracheal reconstruction). The indications for each type of surgery vary according to the degree of stenosis, presence of associated glottic involvement, and clinical comorbidities(MONNIER PHILIPPE, 2011d).

Endoscopic procedures aim to enlarge the stenotic lumen with an expander device (Hegar dilator, orotracheal tube, or dilation balloons). Some authors(AVELINO; MAUNSELL; JUBÉ WASTOWSKI, 2015) recommend endoscopic treatment for recent stenoses, in which the edematous mucosa is more pliable and susceptible to intervention without changing the underlying osteocartilaginous framework.

In more severe cases, with greater narrowing of the lumen, open surgery is recommended. Several surgical techniques have been described in the literature; we will address two that take different conceptual approaches to the problem.

The first is laryngotracheal reconstruction (LTR), which seeks to augment the laryngeal framework with an autologous cartilage graft. The second is cricotracheal
Both types of open surgery may be performed in a single stage, whereby the tracheostomy is resected, and the patient remains intubated after the procedure so that the orotracheal tube itself acts as a laryngeal stent. One advantage of this approach is that the stoma is excised during surgery. Its major disadvantage is the need to keep the child sedated, in an intensive care setting, for about 7 to 10 days.

The other type of approach is double-stage surgery, where either reconstruction (LTR) or resection (CTR) is followed by placement of a stent at the previous site of stenosis in order to shape the airway and prevent formation of new scar tissue. The advantage of this technique is that it does not require intubation or admission to an intensive care setting. On the other hand, the main disadvantages are that the tracheostoma is kept in place for subsequent (second stage) removal and the patient must be fitted with a laryngeal stent, which does not always have the optimal shape and pliability.

METHODS

This study was conducted at the Health Innovation Laboratory of Universidade Federal de São Paulo – Escola Paulista de Medicina, from February 2022 to September 2022. Google and PubMed were searched using the queries [“estenoses laringotraqueais” AND “moldes” AND “cirurgias abertas”] and [“laryngotracheal surgeries” AND “molds” AND “open surgeries”]. Clinical studies of commercially available stents and molds were selected for analysis, as well as the websites of manufacturers or distributors of these products.

RESULTS

Available stents

Although several laryngeal stents are described in the literature, we will focus on those most widely used in research and practice. The selected models were the Aboulker stent; Montgomery® T-Tube; Healy® Pediatric T-Tube; Montgomery® LT-Stent; Eliachar LT-Stent; and LT-Mold®.
Characteristics

Monnier (MONNIER PHILIPPE, 2011c) has reviewed the various types of stents that are already available on the market for use in open surgery to correct laryngotracheal stenosis, highlighting the major disadvantages of each and proposing instead use of the LT-Mold® (his design) (MONNIER, 2003).

Aboulker stent (ABOULKER, 1968) (Figure 2)

Designed by a French otorhinolaryngologist in the 1960s, this stent is made of rigid Teflon®, which is associated with several complications (largely due to granulation tissue, necrosis of the stented area, and scar formation).

Montgomery T-Tube (MONNIER PHILIPPE, 2011c) (Figure 3)

Furthermore, granulation tissue commonly develops at each end of the stent (MONNIER simple silicone tube, open at both ends, connected at 90° to another tube that projects outward. Because it is more pliable, it can be more easily localized and positioned through the tracheostoma. Its disadvantages are mainly due to its open design, which allows saliva and pharyngeal secretions to enter the lower airway. Furthermore, granulation tissue commonly develops at each end of the stent (MONNIER PHILIPPE, 2011c).
The Healy tube was designed to avoid the buildup of secretions and plugging that commonly occur with the Montgomery T-Tube by using a 70° connection angle instead. However, its internal diameter remained far too small to prevent buildup of secretions (MONNIER PHILIPPE, 2011c).

**Montgomery LT-Stent** (MONNIER PHILIPPE, 2011c)(MONTGOMERY; MONTGOMERY, 1990) (Figure 5)

Designed mainly for the treatment of transglottic stenoses (i.e., those affecting the glottis and subglottis), this stent is made of extremely rigid silicone and has a very small interarytenoid space, which prevents an appropriate fit to the glottic region.
Eliachar LT-Stent (MONNIER PHILIPPE, 2011c) (ELIACHAR; NGUYEN, 1990) (Figure 6)

The Eliachar LT-Stent is made of soft silicone and is hollow inside, causing less trauma to the laryngeal mucosa, but its shape adapts unfavorably to the interarytenoid space and anterior commissure. It was initially designed to prevent chronic aspiration in adult patients with tracheostomies (MONNIER PHILIPPE, 2011c) (ELIACHAR; NGUYEN, 1990).

Rutter Supra-Stomal Stent (SCHWEIGER; RUTTER, 2017) (Figure 7)

Developed by Michael Rutter, this stent is a soft cylindrical silicone tube that does not interfere with placement of the tracheostomy. It can be capped at the proximal end to prevent aspiration of saliva. However, it does not allow proper phonation, as the fenestrated cap provides very little room for air passage. Its main disadvantage is the absence of a more anatomical shape for the anterior commissure region.
Monnier LT-Mold (MONNIER PHILIPPE, 2011c)(MONNIER, 2003) (Figures 8, 9, 10, and 11)

The LT-Mold advocated by Philippe Monnier is made of a special silicone with compliance and rigidity properties that prevent necrosis of the laryngeal mucosa in the splinted region. Because it was created by molding actual human larynges, it maintains the appropriate glottal proportion for transglottic use(16). The LT-Mold is available in 10 different sizes (external diameter 6 to 15 mm) and 4 different lengths.

Despite being extremely well-made and very useful in surgical correction of laryngotracheal stenosis, the LT-Mold is difficult to find and is only available on the European and U.S. markets. It is not approved by the Brazilian Health Surveillance Agency (Anvisa) and has never been marketed in the country.
Figures 10 and 11 – LT-Mold® designed by Philippe Monnier

(MONNIER PHILIPPE, 2011c)

Table 1 – Pros and cons of different stent designs

<table>
<thead>
<tr>
<th>TYPE OF STENT</th>
<th>PROS</th>
<th>CONS</th>
</tr>
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<tbody>
<tr>
<td>Aboulker stent</td>
<td>One of the first models available</td>
<td>Rigid material, predisposes to granuloma formation</td>
</tr>
<tr>
<td>Montgomery T-Tube</td>
<td>Low cost, widely available</td>
<td>Buildup of secretions, granuloma formation</td>
</tr>
<tr>
<td>Healy Pediatric T-Tube</td>
<td>Less buildup of secretions compared to Montgomery T-Tube</td>
<td>Narrow space still allows buildup of secretions</td>
</tr>
<tr>
<td>Montgomery LT-Stent</td>
<td>Widely commercially available</td>
<td>Rigid, does not conform to interarytenoid region</td>
</tr>
<tr>
<td>Eliachar LT-Stent</td>
<td>Avoids aspiration</td>
<td>Difficult fixation</td>
</tr>
<tr>
<td>Rutter Supra-Stomal Stent</td>
<td>Pliable material</td>
<td>Non-anatomic shape</td>
</tr>
<tr>
<td>Monnier LT-Mold</td>
<td>Pliable material</td>
<td>High cost, very large number of measurements needed</td>
</tr>
</tbody>
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DISCUSSION

The Montgomery T-tube has been widely used in surgical correction of laryngotracheal stenoses, although it poses several major disadvantages due to its non-anatomic shape, with its ends promoting the formation of granulation tissue along the edges of the tube. Placement of the proximal end below the vocal folds can lead to granuloma formation in the subglottic region, while placement above the vocal folds can lead to greater aspiration of saliva or food. Another major disadvantage of this model
when used in children is the increased risk of obstruction when the tube diameter is less than 8 mm.

The Montgomery LT-Stent seeks to address the issues of the cylindrical shape at the supraglottic region and its opening at the proximal end, to avoid aspiration; however, its rigid material impedes a better fit of the stent to the larynx and prevents it from reaching the optimal position.

The LT-Mold designed by Philippe Monnier best approximates the ideal laryngeal stent: its pliable material allows for better accommodation to the airway mucosa, reducing the risk of regional ischemia or lacerations. Its shape was based on molds of actual human larynges, and it is available in 40 models (10 sizes with 4 different lengths each). This wide range of sizes makes it more adaptable to individual patients, but simultaneously hinders its commercial distribution.

The stent we recommend for future use in research and practice will be made by the additive manufacturing technique of 3D printing, allowing it to be customized for each patient with the most precise measurements possible, obtained through computed tomography (CT) imaging. The use of CT imaging will allow better measurement of the parameters needed to manufacture the mold and is also less invasive.

In the context of the Brazilian health system, where resources in the public sector are often limited, the use of a laryngeal mold following surgeries for laryngotracheal stenosis correction can be particularly beneficial. By reducing the need for prolonged stays in the Intensive Care Unit (ICU) with an endotracheal tube, it helps alleviate the strain on ICU resources and frees up beds for patients in critical condition. This can lead to more efficient utilization of healthcare resources and potentially lower healthcare costs for the public system. Moreover, the faster recovery and reduced hospitalization time associated with the use of a laryngeal mold can help mitigate the burden on healthcare facilities, allowing them to accommodate more patients within their capacity constraints. Ultimately, while the Brazilian health system faces challenges related to resource constraints, the implementation of innovative techniques like the use of laryngeal molds can contribute to optimizing patient care and resource allocation in the face of such limitations.

Our future research, we aim to address the cost considerations associated with using custom-made laryngeal molds produced through 3D printing compared to pre-made molds available in the medical market. While pre-made molds offer convenience and immediate availability, they can be expensive, particularly for healthcare systems with
limited financial resources like the Brazilian health system. On the other hand, custom-made laryngeal molds produced through 3D printing have the potential to significantly reduce costs, as they can be tailored precisely to the patient's anatomy and manufactured at a fraction of the price of traditional methods. By leveraging the cost-effectiveness and scalability of 3D printing technology, we anticipate that our research will provide a viable solution for improving access to laryngotracheal stenosis correction procedures in resource-constrained settings, ultimately enhancing patient care while optimizing healthcare expenditure.

The average cost of hospitalization for a patient with airway disorders is approximately US$174.94 per day (SOUZA; PEREIRA; SILVA, 2020). If ICU admission and antibiotic therapy are required, the daily cost may reach US$3,200.00 (LEAL; FREITAS-VILELA, 2021).

From the perspective of the Brazilian public health care system, double-stage open surgery is an extremely valuable option, as it reduces the length of hospital stay and, consequently, the cost per surgery performed.

Hoetzenecker et al. (HOETZENECKER et al., 2019) demonstrated that a 3D print of the patient’s airway was better understood by physicians than either endoscopic examination of the airway or CT imaging. Wasserzub (WASSERZUG et al., 2021) and Fiorelli (FIORELLI et al., 2018) also found that physicians considered a 3D print of the airway to be of great importance for patient education and surgical planning. Reighard et al. (REIGHARD et al., 2019) were able to create a low-cost prototype for training surgeons in laryngotracheal reconstruction (LTR) with good reproducibility of the main landmarks of the patient’s airway.

The additive manufacturing technique of 3D printing has become increasingly widespread in the medical field due to its potential for fabrication of surgical training models, orthotics, and prosthetics customized to each patient’s individual needs (GROSS et al., 2014).

Before a part can be 3D-printed, a compatible material must first be selected. Several such materials are available, usually in filament form. The most commonly used material is (poly)lactic acid (PLA), a bioplastic polymer that has excellent pliability, ease of processing, and comes in a variety of colors and properties.

In the literature, there are reports of 3D printing being used to replicate a patient’s airway for diagnostic purposes (HOETZENECKER et al., 2019), surgical
planning (WASSERZUG et al., 2021) (FIORELLI et al., 2018), and medical training (REIGHARD et al., 2019) (PARK et al., 2021).

Within this context, the present study sought to review the literature and evaluate the applicability of 3D printing in the fabrication of custom-made laryngeal stents for patients undergoing surgical correction of laryngotracheal stenosis.

CONCLUSION

Additive manufacturing is a viable and affordable technology which can be used to assist in surgical correction of laryngotracheal stenosis. As 3D printing allows custom-made molds to be manufactured for each patient, it obviates the need for availability of commercial stents or molds in an extremely wide range of sizes (width and length).

REFERENCES


**ANNEX**