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## Commentary: Malacia got you down? Unwind with a helical stent

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Severe cases of pediatric tracheobronchomalacia can require tracheostomy, prolonged periods of positive pressure ventilation, and/or invasive surgical procedures intended to stabilize the airways. Prior attempts at therapeutic internal airway stenting to avoid the need for positive pressure ventilation in children have been largely unsuccessful due to poor mucous clearance, fragmentation, and diameter reduction. Surgical approaches are invasive and carry a significant failure rate along with risks of fistulization and other complications.<sup>1,2</sup> Mondal and colleagues<sup>3</sup> describe the *in vivo* evaluation of a new airway stent designed to overcome some of these challenges.

For the design of the stent, the authors borrowed from the wine cabinet (Figure 1) and replicated a corkscrew design constructed from nitinol. The helical nickel titanium wire stents provide radial support set for a certain airway pressure, and provide spaces between the coils for normal mucociliary clearance of the respiratory epithelium. Once in place, the stent is low profile and can be removed with little trauma due to a ball forceps rotational removal system.

Five experimental swine were utilized for 4 weeks, the first 3 with the stent in place and another week without. The stents were tolerated and removed without complication, despite most showing some degree of endothelialization. One migration was noted but remained within the trachea. Polytetrafluoroethylene discs were used to evaluate airway clearance, which was deemed intact. Pathologic

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Borrowing from the wine cabinet: A helical (corkscrew) stent for tracheobronchomalacia.

### CENTRAL MESSAGE

The authors describe preclinical testing of a novel pediatric airway stent with a helical design that allows for minimal surface contact with the tracheal wall and atraumatic removal.

review showed inflammation and granulation at the sites of stent wire contact, but intervening segments were without significant tissue damage and <12% of the area was unciliated.

The strength of this study is the longitudinal live animal model with multiple static and dynamic measurements of native airway function following stent placement. The stent design also appears to have clear advantages over existing technology for airway applications. The limitations of the study and device included 1 migration and a relatively low sample size in a model with inevitable differences from human airway anatomy and lack of initial demonstrable tracheobronchomalacia.



FIGURE 1. A corkscrew inspired a novel helical stent for tracheobronchomalacia.

The diameters of the pig tracheas in this study (range, 11-14 mm) are larger than human neonatal and infant airways that may require intervention before age 1 year (range, 5-6 mm). Further dynamic longitudinal studies in smaller animals may be needed to determine whether the stent accomplishes its intended goal of preventing pediatric airway collapse.

These preclinical results show promise for a new type of stent with successful initial performance in an animal airway model. The potential influence of this new device is excellent, and it could fill a critical vacancy where no good current options exist. This represents another example of important surgical innovation from an

exemplary team, and further clinical progress is eagerly anticipated.

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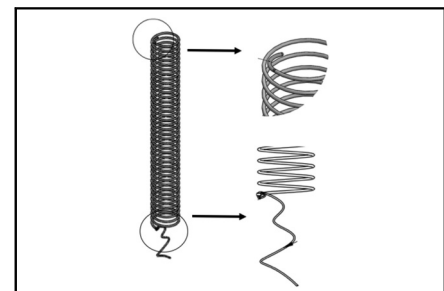
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## Commentary: Toward a more ideal pediatric airway stent for tracheobronchomalacia

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The first clinical deployment of a pediatric airway stent was in 1988 and was reported by Loeff and colleagues.<sup>2</sup> Since that time, an array of airway stents have developed to treat complex airway disease in children. Pediatric-specific applications of airway stents include use after tracheal reconstruction for congenital tracheal stenosis<sup>3</sup> and for tracheobronchomalacia<sup>4</sup> not responsive to medical therapy. However, the ideal pediatric airway stent has yet to be developed. The ideal airway stent for pediatric patients should be easy to place, should support the airway without the development of significant complications, and should be easy to remove to allow maximal growth of the airway.<sup>3</sup>



CasMin Twine helical stent.<sup>1</sup>

**CENTRAL MESSAGE**

The helical Niti-S airway stent shows promise as a more ideal prosthesis for the management of tracheobronchomalacia.

Potential stent-related complications include migration, granulation tissue formation, mucus formation, and infection,<sup>5</sup> particularly when granulation tissue develops. Despite the wide array (metallic,<sup>6</sup> silicon,<sup>7</sup> bioabsorbable<sup>8</sup>) of pediatric stents available, none of them is ideal. The known complications associated with these devices have led to a stent-related mortality rate as high as 12.9%.<sup>7</sup> Furthermore, the radial force used to keep certain kinds of stents in place has been shown to damage the microcirculation and serves as the nidus for mucosal injury and subsequent granulation tissue formation.<sup>9,10</sup>

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