Methods
Children with life-threatening tracheobronchomalacia (TBM) were implanted with airway splints under the FDA Expanded Access Program. Splints were custom designed from each patient’s inspiratory and expiratory CT (Figure A and B), 3D printed, sterilized, and implanted (Figure C). A pre-op and post-op Minimum Slice Patency Ratio (MSPR) for each malacic segment was calculated by first calculating the patency ratio in the malacic region for each slice, and then selecting the minimum value, as follows:

\[
\text{MSPR} = \min\left(\frac{\text{CSA during expiration}}{\text{CSA during inspiration}}\right)
\]

Where CSA is cross-sectional area.

Results
• Before treatment, all children had tracheostomies and were ventilator dependent.
• 11 of 13 children were experiencing arrests related to their TBM; 9 required sedation (and 4 required paralysis) in an intensive care setting to maintain ventilation.
• Splint implantation occurred at a mean age of 9 months (range 3-25 months).
• Of the 21 splinted regions with acceptable CT data, the MSPR improved from 0.29 (SD 0.24) pre-op to 0.54 (SD 0.21) post-op (p<0.0001, paired t-test) (Figure D).

A biopresorbable airway splint improves the airway patency in children with life-threatening tracheobronchomalacia

A computer model (top) and an actual 3D printed airway splint (bottom).

A model of a patient’s airway (Figure A) with the splint virtually (Figure B), and actually implanted (Figure C) on a malacic left mainstem bronchus.

A B C

A computer model (top) and an actual 3D printed airway splint (bottom).

A B C

Figure D: The Minimum Slice Patency Ratio (MSRP) from 29% pre-op to 54% post-op.

• Of the 10 survivors, one child is decannulated, and the remaining nine children continue to have a tracheostomy with: no ventilator (n=1), intermittent (usually nighttime) ventilation (n=6), and weaning continuous ventilation (n=2).

Conclusion
• We demonstrate successful treatment of life-threatening TBM with patient-specific, 3D printed, biopresorbable airway splints in thirteen children.

Dr Green and Dr Hollister have a patent for the airway splint which has been licensed to Materialise. European release of the device is expected in 2019.

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