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Commentary: Three-dimensional-printed, customized airway prosthesis—is it justified to walk the extra mile?

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Tracheal agenesis is a rare and, in most cases, fatal congenital anomaly. Possible treatment attempts aiming to restore the airway and the gastrointestinal tract are described anecdotally in the medical literature.¹ Tsai and colleagues² need to be congratulated to their excellent case report “Tracheal Aggenesis: Esophageal Airway Support with a 3D-Printed Bioresorbable Splint.” A custom-made, 3-dimensional (3D)-printed external splint was designed to support the neo-trachea formed by an esophageal conduit in a patient with Floyd type I tracheal agenesis. The surgical repair resulted in a fully restored airway with a follow-up of more than 3 years after the surgical procedure. Together with the case published in 2017 by Densmore and colleagues,³ to the best of our knowledge, only 2 survivors with this condition are documented in the United States. This underscores the outstanding medical and surgical expertise of the authors, confronted with this extraordinary, clinical problem.

3D printing and additive manufacturing (AM) technologies are increasingly used to design customized medical devices. Although AM seemingly adds an infinite number of types and shapes of airway prosthesis and thus allows a perfect fit to the individual anatomical situation, a word of caution is warranted. These customized AM devices are often implanted under the regulatory framework of

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The major aim in additive manufacturing of airway prosthesis is providing individualized, but safe, devices in a semiurgent time frame.

“compassionate use,” especially in the case of airway prosthesis. This means that less-stringent rules are applied by the authorities to facilitate ultima ratio treatment attempts. As a consequence, industry and regulators delegate the final responsibility to the hospitals and the implanting surgeons. Thus, the indication for such customized devices has to be set critically. Are there ready-made implants with appropriate safety data available that can be used off-label? In another, previously reported case of tracheal agenesis, an off-the-shelf polytetrafluoroethylene graft led to a successful stabilization of the esophagocarinoplasty.³ Therefore, the need for a more experimental treatment with an AM implant can be questioned. Correspondingly, in pediatric patients with airway collapse, both tailoring of readily available bioresorbable plates as well as 3D-printed external splints have been published.^{4,5} Although a similar number of patients were included, both series can hardly be compared because of the heterogeneity of these highly selected and complex cases. However, both techniques resulted in a reasonably good overall success rate. Thus, the decision to use a (tailored) purchased product or to design an AM product has to be made for each individual case with a certain sense for pragmatism yet without making concessions regarding the optimal clinical outcome.

When the indication for an AM device is set, the workflow of the production process should be carried out at the greatest possible standard and documented accordingly. This includes a risk analysis, quality control measures, material stress tests, and hygienic clearance of the specific final implant.^{6,7} Especially in airway pathologies, the acquisition of permission and conduction of these tests might be challenging, as the implants often have to be provided in a semiurgent manner. Noteworthy, the time from indication to

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Disclosures: The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

Received for publication Sept 9, 2021; revisions received Sept 9, 2021; accepted for publication Sept 10, 2021; available ahead of print Sept 16, 2021.

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JTCVS Techniques 2021;10:569-70

2666-2507

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<https://doi.org/10.1016/j.jtc.2021.09.025>

implantation can be shortened substantially for subsequent cases, once a workflow has been established.⁸ For some more frequent indications, outsourcing of the production process to AM companies or university spin-offs might be a valid option.⁹

Finally, applying these cutting-edge technologies should be reserved to dedicated teams with substantial experience in the management of patients with airway pathologies. The report by Tsai and colleagues illustrates what can be achieved by combining surgical excellence, an experienced, multidisciplinary team, and advanced technologies. If AM implants are beneficial for the patient, it is absolutely worth walking the extra mile.

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