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ORIGINAL RESEARCH

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Treatment of tracheoesophageal fistulas following laryngectomy by customized prostheses—A bicentric case series

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Abstract

Objective: Tracheoesophageal fistulas (TEF) following laryngectomy cause immense restrictions due to the inability of oral feeding, loss of voice rehabilitation, penetration of saliva, and permanent need of inflatable tracheal cannulas. Patients are consistently in threat of fatal aspiration pneumonias. The failure rate of surgical approaches to close the fistulas is high and an ultima ratio option by customized silicone prostheses can be considered.

Methods: A retrospective analysis of 26 patients with a TEF was performed.

Results: The fistulas occurred in average 40 months after laryngectomy caused by an enlargement of the voice fistula in 17 patients and problems in wound healing in 6 patients. The mean diameter of the fistula was 32 × 18 mm. Eight patients were treated by a button-shaped and 18 by a tube-shaped prosthesis. Complete oral feeding was possible in 8 and additional feeding by percutaneous endoscopic gastrostomy tube in 16 patients. Voice rehabilitation by voice prostheses was possible in 18 cases. Fifteen patients died in the course of the treatment either due to oncological progression or other reasons. The median follow-up time of the patients alive was 36 months (max 88 months) with 2.2 protheses replacements in mean (max 11).

Conclusion: The treatment of TEF by customized prostheses can be considered as an ultima ration option if other approaches had failed. At least, partial oral nutrition and voice rehabilitation as well as protection from aspiration can be achieved in the majority of the patients.

Level of Evidence: 4—Case series.

KEYWORDS
aspiration, case series, laryngectomy, silicone, voice rehabilitation

Michael Herzog and Sebastian Plößl contributed equally to this work.

1 | INTRODUCTION

Persisting tracheoesophageal fistulas (TEF) after laryngectomy and radiation are a therapeutic challenge (Figure 1, Video 1). In general, surgical approaches are considered the first choice and several techniques have been reported using local tissue,[1,2] local flaps[3,4] or distant grafts[5–8] as well as bioabsorbable or fascia tissues.[9–11] Nevertheless, there is a high rate of recurrence.[12] Self-expendable covered esophageal stents have been described in malignant TEF with a limited life expectance but these stents are not recommended in nonmalignant fistulas as a permanent option.[13] In hypopharyngeal or laryngeal cancer patients treated by laryngectomy, TEF can occur in the post-therapeutic course when fistulas for voice prostheses get enlarged over the time.

Commercial devices are available for nasal and atrial septum defects. The application in fistulas has been published in several case reports.[14–18] Despite all promising reports, there is a lack of data about large cohorts, as well as failed approaches.

Another approach consists in the application of customized prostheses covering the fistula. Techniques have been previously described by some of the authors[19,20] and others.[21] The aim is to prevent aspiration, enable oral nutrition and restore voice rehabilitation by implementing voice prostheses into the fistula prostheses.

Meanwhile, the application of customized prostheses for TEF has become a standard procedure in the hands of the authors and other physicians and prosthetists. This publication provides a retrospective analysis of patients with TEF treated by customized fistula prostheses.

2 | METHODS

A retrospective 2-center evaluation (ENT-departments of the University of Halle-Wittenberg, Halle / Saale, Germany, and Carl-Thiem-Clinic, Cottbus, Germany) was performed with respect to the following parameters: Occurrence of the fistula since laryngectomy, reason for developing the fistula, size of the fistula, type of the fistulas and prostheses according to Herzog et al.,[20] number of replaced prostheses, abilities after implantation and overall survival.

The retrospective analysis was approved by the regional Ethic Committee of the Medical Chamber of Brandenburg / Germany (2021-2186-BO-ff).

2.1 | Manufacturing of the prostheses

The treatment of TEF by customized prostheses is an ultima ratio approach in the absence of alternative options. A written consent for the treatment and publication of the patients' data was given by each patient.

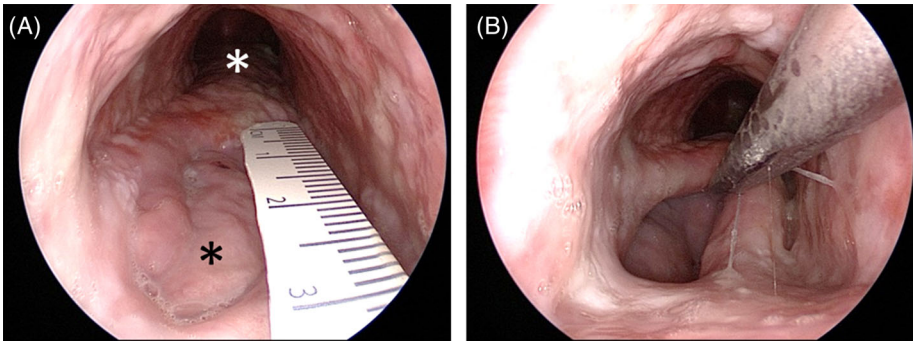
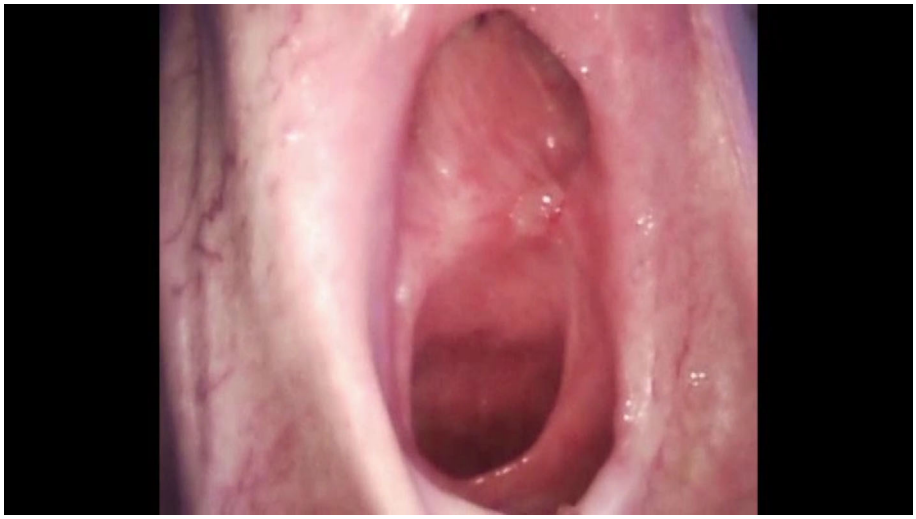


FIGURE 1 Presentation of a tracheoesophageal fistula. (A) Typical picture of a 3 cm long fistula. The trachea is marked by a white asterisk, the esophageal mucosa by a black asterisk. (B) The esophagus is enlarged by the suction. In a relaxed state under general anesthesia, the esophagus is usually collapsed and the fistula appears to be "closed." Figures 2 and 3 refer to the fistula shown in this figure.



VIDEO 1 Demonstration of a tracheoesophageal fistula. The video shows a tracheoesophageal fistula with a dimension of approximately 3–6 cm. At the bottom part of the video, the trachea is visible, at the upper part the esophagus. Bending the endoscope up, you can see the soft palate from below with the uvula. Video content can be viewed at https://onlinelibrary.wiley.com/doi/10.1002/lio2.1042

The molding of the fistula and the surrounding structures was performed under general anesthesia as described earlier[20] (Video 2). Medical liquid silicone was used for molding (Flexitime medium flow, Kulzer, Hanau, Germany or StecoForm Flex, Steco-system-technik GmBH, Hamburg, Germany). The prostheses were manufactured of medical silicone (LSR7070, Momentive Performance Materials, Waterford, NY, USA) and a voice prostheses were included when appropriate (Bloom Singer classic 4 mm, InHealth Technologies, Carpinteria, CA, USA or Provox 2 4.5 mm/Provox Vega 4 mm, Atos Medical, Hörby, Sweden).

3 | RESULTS

3.1 | Oncological history

In total, 26 patients were analyzed (male = 23, female = 3; 15 × Halle, 11 × Cottbus). The mean age at treatment was 66.1 years (median = 65, SD = 7.5, min = 56, max = 82). All patients suffered from an UICC stage IV larynx- or hypopharynx-carcinoma and were treated by laryngectomy followed by radiotherapy ($n = 15$) or radiochemotherapy ($n = 11$). A voice prosthesis was implanted in the course of the laryngectomy in 18 patients. Three patients received a secondary puncture of a speech fistula and 5 did not have a voice-fistula. Seven patients received a flap reconstruction of the pharynx during primary surgery (4× radial forearm, 3× pectoralis major) due to the large size of resected areas.

3.2 | Fistula history

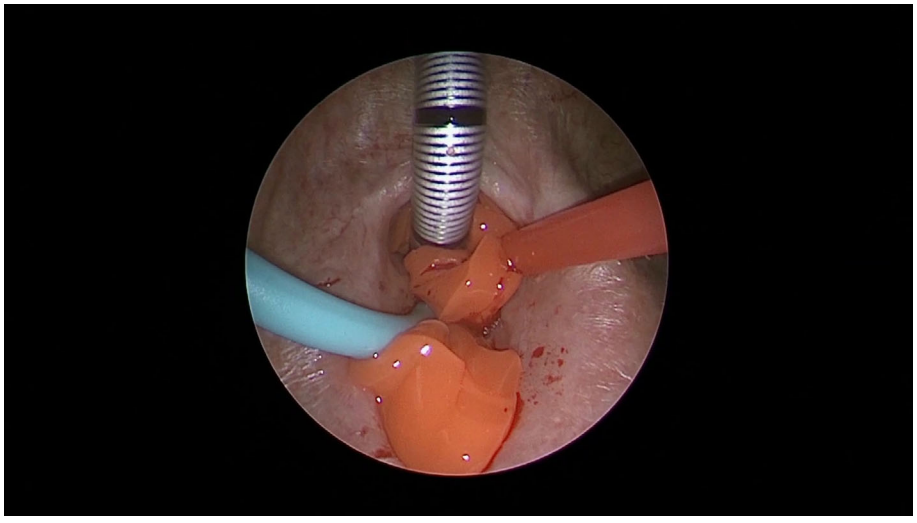
The time between laryngectomy and occurrence of the fistula was 40 months in mean (median 12, SD 52, min 0.25, and max 173). The reasons for fistula occurrence were: local wound healing problems ($n = 6$), enlargement of the speech fistula ($n = 17$), iatrogenic damage during spine surgery ($n = 1$), unknown ($n = 2$).

Surgical attempts to close the fistulas were performed in 17 patients. For the first attempt local techniques were performed in 8 patients, regional pedicle flaps were used in 7 cases and free radial forearm flaps in 2 cases. A second attempt was conducted in 8 patients (local $n = 3$, regional $n = 3$, free radial forearm $n = 2$). In two patients a third approach was performed by a regional and free anterolateral thigh-flap, respectively. Numerous conservative approaches were performed before, after or in addition to surgical procedures or alone including shrinking (all patients), material injection around the fistula ($n = 12$), silicone flanges ($n = 10$), and self-expandable esophageal stents ($n = 2$).

3.3 | Prosthetic history

At the time of prosthetic treatment all patients were free of tumor which was ruled out by endoscopy and histological examination if appropriate as well as CT-scan of the neck.

The time between occurrence of the fistula and prosthetic treatment was 27 months in mean (median = 15, SD = 37, min = 1, and max = 176). The size of the fistula in cranio-caudal dimension was 32 mm in mean (median = 30, SD = 17.5, min = 11, and max = 80) and 18 mm in lateral (median = 15.5, SD = 9.06, min = 8, and max = 50). The classification of the fistulas according to Herzog et al.[20] revealed type A ($n = 8$), type B ($n = 10$), type C ($n = 4$), and type D ($n = 4$). Accordingly, 8 button-shaped (Figures 2 and 3) and 18 tube-shaped prostheses (Figures 4 and 5, Video 3) were manufactured. Tube-shaped prostheses were applied if stenoses of the neopharynx cranial to the fistulas were present. Otherwise a button-shaped prostheses were inserted. Twenty-three prostheses were



VIDEO 2 Demonstration of molding with liquid silicone. The following video demonstrates the molding with liquid silicone. To prevent silicone dripping down the esophagus it is blocked with a urinary catheter. Then, the silicone is applied first cranial and then caudal in the esophagus. The trachea is blocked by the ventilation tube. The silicone is applied in the trachea. The whole area of the tracheostomy is covered with silicone. It takes about 5 min to harden and afterward the whole package, including the silicone and the urinary catheter as well as the ventilation tube is removed in one block. Here is the cranial part of the neo pharynx. The caudal part of the molding is removed in total. The whole molding is seen here."
Video content can be viewed at https://onlinelibrary.wiley.com/doi/10.1002/lio2.1042

manufactured on base of silicone moldings which were obtained under general anesthesia as previously described.[20] In 3 cases, fabrication was based on CT-scan data. In 13 patients, the initially applied prostheses did not seal the fistula completely when swallowing liquids. A remodeling of the prostheses without the need to take a new cast under general anesthesia was performed on base of the visual inspection by the physicians. Reimplantation had to be performed under general anesthesia in 6, in local anesthesia in 7 of 13 patients.

3.4 | Feeding and voice rehabilitation

Oral nutrition was not possible anymore in all patients since the occurrence of the fistulas (time from occurrence of the fistula until treatment in month: mean = 25, median = 15, SD = 36, min = 1, and max = 176). After implantation, complete oral nutrition was possible in eight patients (Video 4). The percutaneous endoscopic gastrostomy (PEG) was kept in all patients for safety reasons but was not used for feeding. In 16 patients, a combination of oral and PEG feeding was performed. Two patients kept on using the PEG because of disturbed tongue motility. In all tube prostheses (n = 18), the inner diameter of the tube was at least 8 mm.

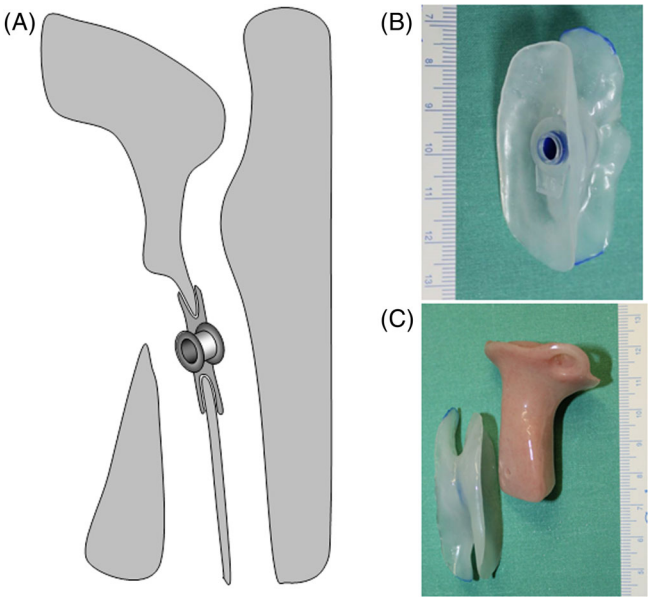


FIGURE 2 Type A fistula and button-shaped prosthesis. (A) Schematic drawing of a type A fistula with inserted button prosthesis with an implemented voice prosthesis. (B) Image of a button prosthesis with implemented voice prosthesis. (C) An individual cannula, which is manufactured according to the anatomic dimensions of the tracheostoma, helps to keep the prosthesis in place and reduces excessive movement of the prosthesis.

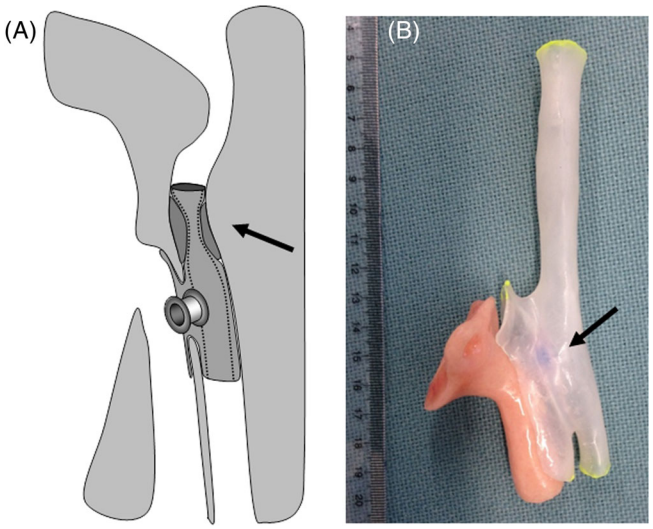


FIGURE 4 Type B fistula and tube-shaped prosthesis. (A) Schematic drawing of a type B fistula with inserted voice prosthesis. In these types of fistulas, a stenosis is present in the neopharynx cranial to the fistula. The arrow indicates the enforced part of the tube to expand the stenosis. (B) Image of a tube-shaped prosthesis with implanted voice prosthesis and corresponding individual cannula.

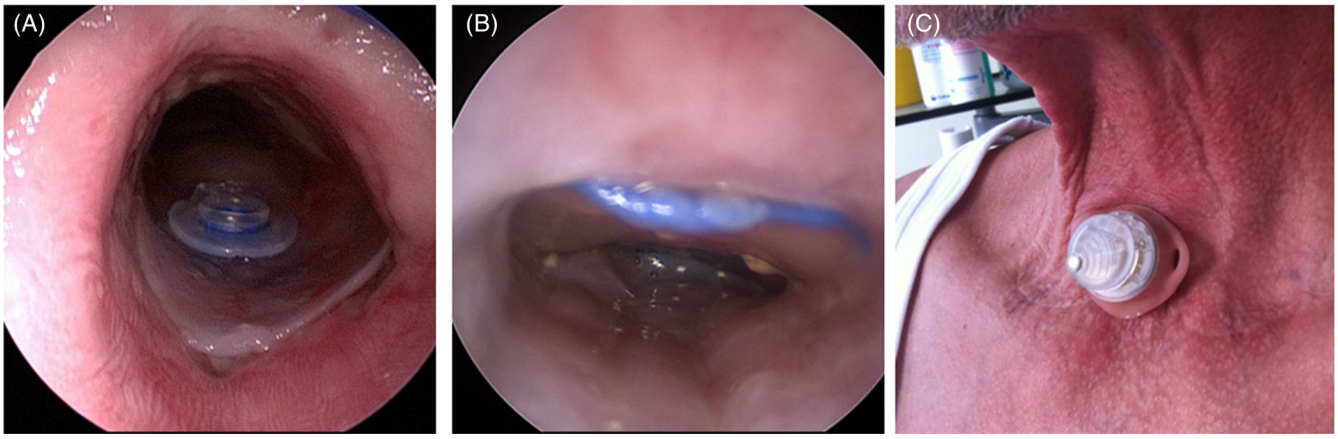


FIGURE 3 Inserted button-shaped prosthesis. (A) Tracheal view of the prosthesis. (B) Esophageal view of the prosthesis. The flanges should not compress the mucosa to prevent the growth of granulation tissue. (C) View of the patient with an applied free hand valve.

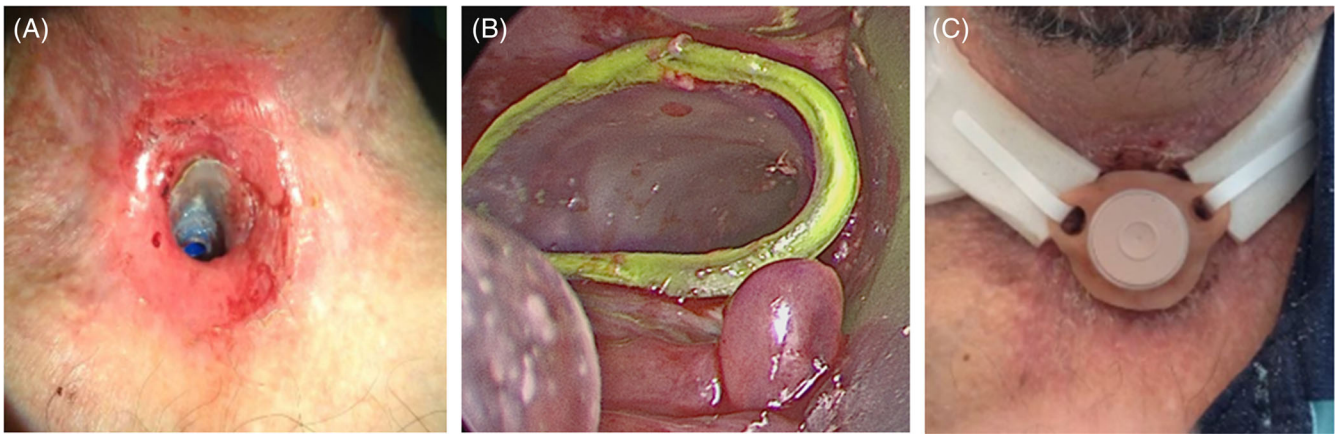


FIGURE 5 Inserted tube-shaped prosthesis. (A) External view without cannula. (B) Endoscopic view of the cranial edge of the prosthesis. The rim is marked with a yellow silicone line to improve the identifiability in situ. (C) View of the patient with an applied manual valve.

VIDEO 3 Demonstration of two tube-shaped prostheses with and without implemented voice prosthesis. This video demonstrates two tube-shaped prostheses. The dimension of the fistula is 4 cm. The prosthesis itself is made out of soft silicone and is flexible to prevent damage to the surrounding soft tissue. This is the esophagus. ("demonstration of the digestive pathway in the video"). The next prosthesis has a whole for insertion of a voice prosthesis to enable voice rehabilitation.
Video content can be viewed at https://onlinelibrary.wiley.com/doi/10.1002/lio2.1042

Voice rehabilitation was performed by integrated voice prostheses in 18 cases (Video 5). Four patients were able to communicate using esophageal speech. Four patients were not suitable for speech rehabilitation.

3.5 | Long-term results

Prosthetic treatment of TEF was carried out in 2010 for the first time and data acquisition has been performed until 2021. In the course of treatment, 15 patients died. The mean time span from initial implantation until exitus was 21.6 months (median = 14, SD = 18.4, min = 5, and max = 62). The causes of death were: local tumor recurrence ($n = 2$), occurrence of distant metastases ($n = 4$), not related to oncological disease ($n = 5$), prosthesis related bleeding ($n = 1$), unknown ($n = 3$). Eleven patients are still alive and under prosthetic treatment.

The mean follow-up time of all patients was 21 months (median = 13, SD = 22, min = 1, and max = 88). The mean follow-up period of the patients still alive at time of data evaluation was 36 months (median = 31, SD = 24, min = 1, and max = 88).

The mean number of applied prostheses per patient was 2.2 ($1\times$ $n = 13$, $2\times$ $n = 8$, $3\times$ $n = 3$, $4\times$ $n = 1$, $6\times$ $n = 1$, $9\times$ $n = 1$). The prostheses were renewed after 10–18 months due to germinal growth and shape alteration of the silicone which resulted in an insufficient sealing of the fistula and leakage. In total, 59 prostheses were implanted in all 26 patients.

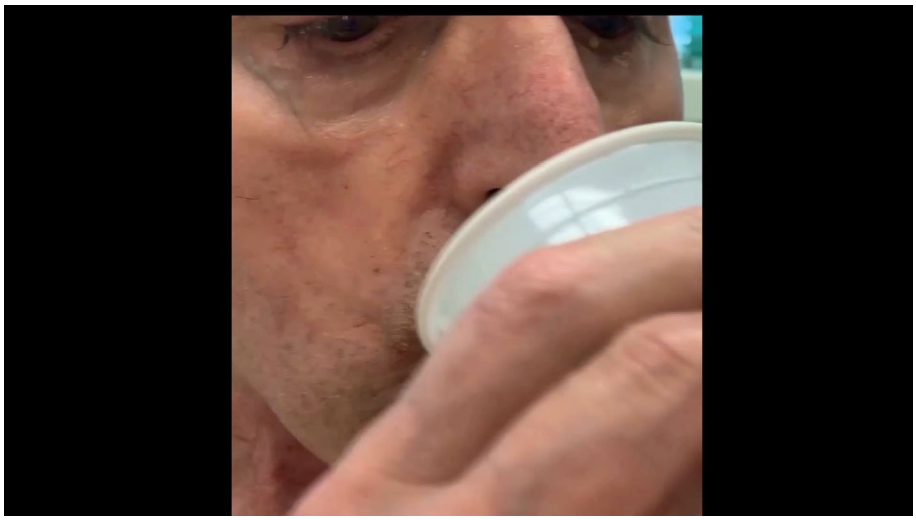
3.6 | Change of the anatomical dimensions

Due to an enlargement of the fistula or occurrence of stenosis a change from a button- to a tube-shaped prosthesis was necessary in two cases. The size of the fistulas remained stable in the long run whereupon metric data are not available.

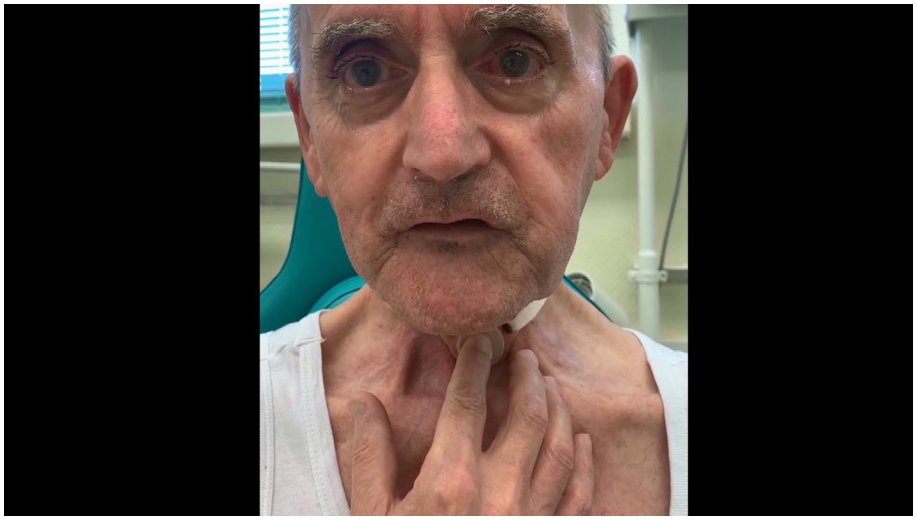
4 | DISCUSSION

Usually, patients suffering from TEF undergo several surgical or conservative attempts of closure. However, a complication rate of almost

VIDEO 4 Swallowing test with customized prosthesis. This video demonstrates swallowing test of colored water. You can see the colored liquid running down the pharynx into the esophagus behind the transparent prosthesis.
Video content can be viewed at https://onlinelibrary.wiley.com/doi/10.1002/lio2.1042



VIDEO 5 Voice test with a customized prosthesis with implemented voice prosthesis. Voice testing in a patient with customized prosthesis with implemented voice prosthesis. The patient is counting from one to five in German.
Video content can be viewed at https://onlinelibrary.wiley.com/doi/10.1002/lio2.1042



40% has been reported.[22] In fear of major or even fatal complications, further surgical interventions are often refused by the surgeon or the patient. Yet, a persisting TEF poses a permanent health threat which can result in fatal aspiration pneumonias within a couple of weeks.[23] Additionally, normal life is restricted as oral nutrition is not possible anymore, inflatable cannulas are mandatory, voice rehabilitation is impossible, and fluid penetration is permanently present via the fistula. According to the presented data as well as clinical experience, these restrictions can last for months and years. Unfortunately, the majority of patients die from recurrent aspiration pneumonias in the long run.[24] Individual fistula prostheses represent an ultima ratio treatment option in difficult to treat TEF.

4.1 | Determination of the anatomical dimensions

In 23 of our cases, prostheses were designed on the basis of a silicone cast and in three cases on the basis of computer tomographic data as a 3-D-reconstruction. In our view both methods have pros and cons. Silicone casts provide a detailed copy of the anatomical situation and prostheses can be manufactured accordingly. Stenotic areas and the diameter of the digestive pathway can be evaluated more precise in situ. These casts, however, need to be obtained under general anesthesia in most of the cases. Computer tomographic evaluation of the fistula and its surrounding structures can be performed without general anesthesia is not necessary. Prostheses can be developed on radiographic data as long as the bounding surface between tissue and intraluminal air is clearly detectable, which is mostly not the case in stenosis.

4.2 | Clinical experiences for a sufficient fit

If a patient is considered suitable for an individual fistula prosthesis a decision between a tube-shaped or button-shaped prosthesis needs to be made. Button-shaped protheses (with or without implemented voice prosthesis) are the first choice (Figures 2 and 3) in the absence of pharyngeal stenoses. According to our experience, the flanges of the buttons need to exceed the cranial and caudal edges of the fistula by at least 6 mm and the lateral edges by 3 mm. Care should be taken

to avoid a close contact to the lateral tracheal and/or esophageal wall because granulations can be induced by flanges rubbing against the lateral wall mucosa. If pharyngeal stenoses are present tube-shaped prostheses need to be applied to keep the pharyngeal lumen open. To enable oral nutrition an inner diameter of the tube of at least 8 mm should be achieved to the experience of the authors. For best prosthetic results, a good communication between physician and prosthetist is essential, and it is advisable that the prosthetist is present during the procedure of taking the cast.

4.3 | Loss of quality of life

TEF cause an immense reduction in the quality of life. To prevent aspiration pneumonias, patients need to wear a cannula with an inflated cuff—mostly without voice fenestration. Voice rehabilitation is not possible under such circumstances neither by voice prosthesis nor by esophageal speech. Moreover, oral alimentation is not advisable due to the risk of aspiration via the TEF. Nutrition needs to be administered via PEG permanently. Additionally, there is a permanent leakage of saliva through the fistula out of the tracheostomy which can lead to social isolation due to unhygienic cervical conditions. From the clinical experience, almost all patients reported that the absence of oral food intake and the lack of gustatory and olfactory stimuli over a long time are the most impairing restrictions. Even if complete oral nutrition was achieved only in one-third of the patients (8/26) the majority (24/26) was able to have at least partial oral food uptake, leading to a regaining of quality of life.

4.4 | Aims of treatment

The main goal using customized prostheses is the prevention of aspiration and resultant pneumonias. Our patients did not suffer or die from aspiration pneumonias after implantation of the prostheses. When interviewing the patients during follow-up visits most patients report a slight leakage of fluids from time to time, which was not perceived as a restriction or threat.

Another important goal is the uptake of oral food, which is extremely appreciated since the patients did not have gustatory and olfactory sensations for numerous months or even years.

Voice rehabilitation via implemented voice prostheses is an additional gain in the quality of life. Like in regular laryngectomized patients, implemented voice prostheses serve as a bypass valve for the expiratory airflow which induces a vibration of the pharyngeal mucosa. In patients with button-shaped prostheses, there is enough mucosa available for an induction of vibration. In patients with tube-shaped prostheses, the mucosa of the pharynx is compressed by the tube and unable to vibrate. Here, a vibrating tone is induced by saliva which is stuck in the tube. A similar mechanism applies to esophageal speech.

4.5 | Long-term results

A high mortality rate within 6–12 weeks after occurrence of TEF due to pulmonary sepsis is reported.[25] The mean follow up time for all patients of the presented study ($n = 26$) was 20 months. Fifteen patients died in the course of treatment but it needs to be kept in mind that until death the patients were able to communicate as well as having oral nutrition. In one patient, a prostheses related fatal bleeding occurred due to an erosion of the internal carotid artery. She had a type D fistula with a large cavity flanked by the vessels and just covered by a thin layer of mucosa. This patient had been informed about potential fatal bleeding prior to treatment. On the basis of these experiences, a sufficient tissue coverage around the carotid artery is advisable.

4.6 | Limitations

The presented data were obtained by retrospective analysis of the patients' records. A standardized evaluation of the regained abilities like oral feeding and voice rehabilitation as well as quality of life by standardized questionnaires has not been performed. Future evaluations need to be performed prospectively under standardized conditions.

5 | CONCLUSION

TEF can be treated by customized prostheses as an ultima ratio approach. In the majority of the patients at least partial restoration of oral nutrition and voice rehabilitation is possible. The prevention of aspiration pneumonias, which is the major aim of this therapeutic approach, can be achieved reliably according to the presented data.

AUTHOR CONTRIBUTIONS

Michael Herzog, Sebastian Plößl, Daniel Grafmans, Vasyl Bogdanov, Alexander Glien, Stefan Plontke, and Ulrich Kisser were involved in the treatment of the patients including taking the silicone casts and implanting of the prostheses. Michael Herzog, Sebastian Plößl, Daniel Grafmans, Vasyl Bogdanov, Alexander Glien, Stefan Plontke, and Ulrich Kisser contributed to data collection, data analysis, data interpretation as well as writing. Figure preparation were performed by Michael Herzog and Sebastian Plößl. Michael Herzog and Sebastian Plößl contributed equally to the publication.

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CONFLICT OF INTEREST STATEMENT

The authors declare that they have no conflict of interest.

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