Retrievable covered metallic segmented Y airway stent for gastrorespiratory fistula of carina or main bronchi

Wei Huang, MD,[a] Qungang Shan, MD,[a] Zhiyuan Wu, MD,[a] Hecheng Li, MD,[b] Min Zhou, MD,[c] Xiaoyi Ding, MD,[a] and Zhongmin Wang, MD[a,d]

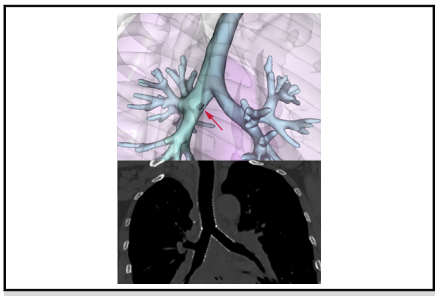
ABSTRACT

Objective: To evaluate the feasibility of new retrievable covered metallic segmented Y airway stents modified with 3-dimensional (3D) printing for gastrorespiratory fistula involving carina or main bronchi.

Methods: We designed a new retrievable covered metallic segmented Y airway stent to fit the anatomical characteristics of the carina region in individual patients. All stents were individually customized based on a 3D-printed mold. Six patients with gastrorespiratory fistula and aspiration pneumonia after esophagectomy underwent the stent implantation. The stents were retrieved when the fistula was cured or stent-related complications occurred.

Results: Seven Y stents were successfully implanted and removed in 6 patients. All stents expanded well, and the fistulas were completely sealed. Aspiration pneumonia was controlled in 6 patients. The median Karnofsky Performance Status scores significantly improved after stenting compared with those before stent implantation ($P = .024$). Sputum retention was the most common complication after stenting and was treated with aspiration under bronchoscopy (33.33%). Excessive granulation tissue proliferation was found in 1 patient (16.7%) and was treated with cryotherapy. The indwelling time of the stent was 64 days (interquartile range, 52-69 days). After stent removal, bronchoscopy, gastroscopy, and computed tomography of the chest showed cured fistulas in all patients, and no stents showed fractures.

Conclusions: Retrievable covered metallic segmented Y airway stents modified with 3D printing appear to be feasible for the treatment of gastrorespiratory fistula involving carina or main bronchi. (J Thorac Cardiovasc Surg 2021;161:1664-71)



Stents individually customized with the aid of 3D printing for gastrorespiratory fistula.

CENTRAL MESSAGE

The retrievable segmented stents individually customized with the aid of 3D printing appear to be feasible and show promising results for gastrorespiratory fistula of carina or main bronchi.

PERSPECTIVE

A customized segmented stent was made based on 3D-printed mold. Six patients with gastrorespiratory fistula underwent airway stenting. The stenting procedures were successful, and the fistulas were healed finally after stent removal in all patients, indicating that this appears to be feasible and potentially promising for the treatment of gastrorespiratory fistula of carina or main bronchi.

See Commentaries on pages 1672 and 1673.

Gastrorespiratory fistula is a rare and fatal complication with high mortality rate in patients after esophagectomy for esophageal cancer; the complication is due to various factors, such as surgical injury and ischemia, and is characterized by esophagogastric contents flowing into the airway, causing irritating cough and refractory pneumonia.[1,2] Although various treatment modalities have been applied for gastrorespiratory fistula, it still remains

From the [a]Department of Interventional Radiology, Ruijin Hospital, [b]Department of Thoracic Surgery, Ruijin Hospital, [c]Department of Respiratory and Critical Care Medicine, Ruijin Hospital, and [d]Department of Radiology, Ruijin Hospital Luwan Branch, Shanghai Jiao Tong University School of Medicine, Shanghai, China.

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Address for reprints: Zhongmin Wang, MD and Xiaoyi Ding, MD, Department of Interventional Radiology, Ruijin Hospital, Shanghai Jiao Tong University School of Medicine, No.197, Ruijin 2nd Rd, Huangpu District, Shanghai 200025, China (E-mail: wzm0722@hotmail.com or dingxiaoyi@hotmail.com).

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Abbreviations and Acronyms
3D = 3-dimensional
CT = computed tomography
IQR = interquartile range

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challenging.[3] Open surgery may be not appropriate for patients with severe infections and poor health conditions who cannot tolerate the surgical trauma.[2] The effects of conservative treatments, including anti-inflammatory and mediastinal drainage, are not sufficient.[4]

Currently, Y-shaped airway stents have been widely used for the treatment of tracheobronchial diseases involving the carina and bronchi distal to the carina as a minimally invasive approach.[5-8] The geometry of the airway is different among patients, and therefore a patient-specific stent that could satisfy each patient's needs according to the anatomical features of the airway is needed.[9,10] Advancements in imaging and 3-dimensional (3D) printing technology paved the way for this project. Patient-specific airway stents can be designed and generated rapidly to fit the personalized needs of each patient with the assistance of 3D printing molds, which are produced according to the anatomical data of airways that can be collected from computed tomography (CT) scans. Several investigators have reported the personalized customization of airway stents with the aid of 3D printing in patients with tracheobronchial disease,[8,11-15] but few have focused on the treatment of fistula, especially around the carina and bronchi distal to the carina, except for a recent case reported by us.[15] After implantation for some time, the stents should be removed due to the risk of long-term complications, including granulation tissue formation, migration, and restenosis.[16-18] However, the optimal removal time for these airway stents remains controversial.[19-21] To fit the specific anatomy of the carina region, we designed a new segmented stent that could accommodate the changes of angle between the 2 main bronchi. This study aimed to evaluate the feasibility of retrievable covered metallic segmented Y airway stents modified with 3D printing for gastrorespiratory fistula of carina or main bronchi.

METHODS

Patients

The stent is not a commercial stent and has not been approved by Chinese Food and Drug Administration. The stent was approved for use in patients with airway fistula and stenosis involving carina and distal bronchi, which were difficult to treat with commercial stents, by our institutional review board (LWEC2016010; September 5, 2016). All patients were told and provided written consent to the insertion of the stent. From March 1, 2017, to August 1, 2019, 6 patients who underwent airway stent implantation treatment for gastrorespiratory fistula after esophagectomy for esophageal cancer were included. Minimally invasive Ivor–Lewis esophagectomy with 2-field lymph node dissection, gastric conduit reconstruction, and an intrathoracic anastomosis was performed and omental patch was not applied in all patients. Before stent implantation and removal, all patients underwent CT scan of the chest, bronchoscopy, and gastroscopy. The diagnosis and location and size of the fistula were confirmed by clinical symptoms and the aforementioned examinations (Figure 1). The clinical data of the eligible patients were analyzed. The funding agency had not role in data interpretation.

Design and Customization of Stent

CT of the chest was performed with a 64-slice multidetector-row CT scanner (uCT760; United Imaging Healthcare, Shanghai, China). All axial CT images were obtained with a 1-mm slice thickness and a 1-mm interslice gap during a breath hold. These image files were created as Digital Imaging and Communications in Medicine files and were then imported into the 3D reconstruction system (Vitaworks, Shanghai, China). The airway, digestive tract, and fistula were assigned different pseudo-colors, and the image was converted into a 3D file. Each of the 3D reconstruction datasets could be saved in stereolithographic format and was sent to a 3D-printing workstation (RS600; Union Tech, Shanghai, China). A 1:1 scale model was made layer-by-layer with laminating photosensitive resin (SomosWaterShed XC; DSM, Amsterdam, Netherlands) until the complete airway was fabricated (Figure 2, *A*). The duration of the printing process was approximately 12 hours. Covered self-expandable Y-shaped metallic airway stents (Micro-Tech, Nanjing, China) were customized using nickel titanium alloy wire with a diameter of 0.22 mm with the aid of the 3D airway model. The diameters, lengths, and angles of the stents were appropriately matched to the airway dimension by tailored to the 3D-printing mold. The outer diameter of the stent was 10% larger than that of the corresponding airway. The stent was fully covered with silicone. To make the stent more fitted to the changes of angle between the 2 main bronchi, a segmented design was used. The adjoining part between the main and branching parts of the stent was made of poly(tetrafluoroethylene). In patients with fistula located in the right main bronchus, the right branch of the stent was made with a fenestration to avoid covering the opening of the right upper lobe bronchus (Figure 2, *B*).

Procedure

After entering the hybrid operating room, the patient was placed in a supine position. Their basic monitoring, including blood pressure, heart rate, electrocardiogram, and oxygen saturation, was continuously measured. General anesthesia was administered after mask oxygen inhalation. Tracheal intubation was performed with a tracheal catheter (7.0F; Tuoren, Henan, China) via a video laryngoscope. After we confirmed that the tracheal tube was in the correct position, all patients were mechanically ventilated by an anesthesia machine.

Two 0.035-inch soft guidewires (Terumo, Tokyo, Japan) and two 4F catheters (MPA-1; Cordis, Hialeah, Fla) were placed into the left and right bronchus via the working channel of the bronchoscope. The guidewires were exchanged for 0.035-inch stiff guide wires (Terumo). Under fluoroscopy, the stent delivery system was advanced to the fistula over the stiff guidewires (Figure 2, *C*). The Y stent was released and placed to cover the fistula, and the end of the stent reached at least 10 mm beyond the distal end of the fistula. Afterwards, the stent-delivery system and the guidewires were withdrawn. Immediately after the procedure, fluoroscopy, CT, and bronchoscopy were performed to check the position and patency of the

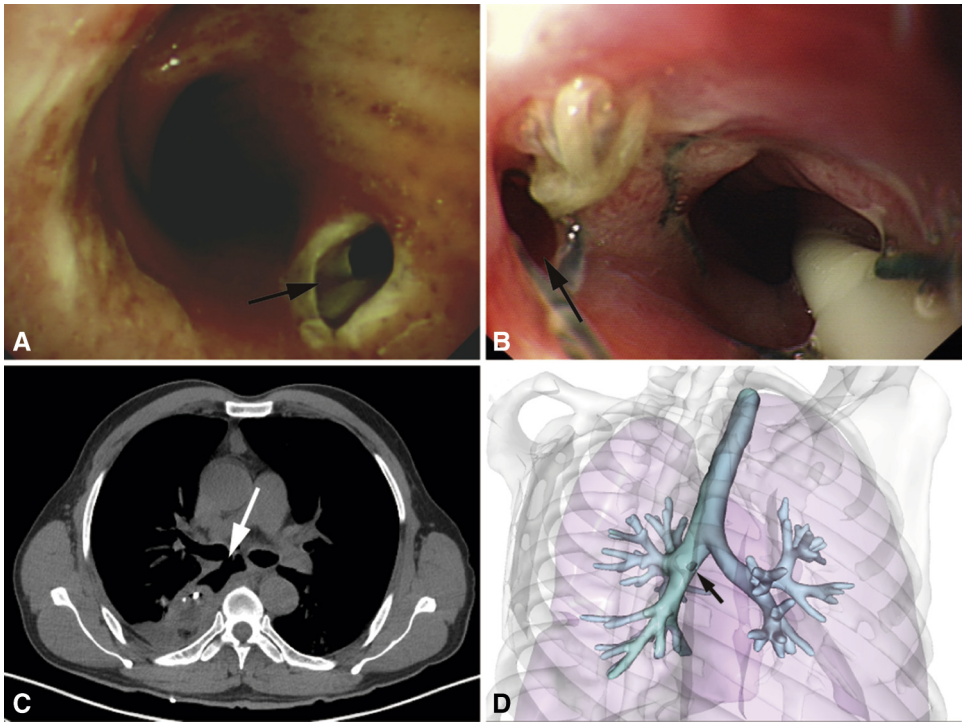


FIGURE 1. A 54-year-old man with thoracic stomach-right bronchus fistula before stenting. A, Bronchoscopy showed that the fistula located at the right main bronchus (*black arrow*). B, Gastroscopy showed that the fistula was in thoracic stomach (*black arrow*). C, Axial CT image showed that the right main bronchus communicated with the thoracic stomach (*white arrow*). D, 3D reconstruction based on CT imaging showed the patient's airway with fistula, which was close to the carina and the opening of the right upper lobe bronchus (*black arrow*).

stent and the seal of fistula (Video 1). The operation time (from the initial of mask oxygen inhalation to the deployment of the stent) was recorded.

Stent Removal

The indications for stent removal were as follows: heal of fistula according to CT, bronchoscopy, and gastroscopy, indicating that the stent was not needed; and stent-related complications, such as migration or overgrown granulation that occluded the stent. Granulation tissue was assessed and ablated through bronchoscopy before the stents were removed, when necessary. Under bronchoscopy and local anesthesia, the tip of the extractive hook was placed next to the proximal end of the stent to withdraw it through a retrievable thread. After removal, the heal of the fistula was checked again by bronchoscopy.

Follow-up

All patients were followed up by chest CT and bronchoscopy 3 days after airway stenting and every month thereafter to check the position and patency of the stent and fistula seal. Gastroscopy was performed every month after stenting. After stent removal, CT of the chest, bronchoscopy, and gastroscopy were performed at 1 month and every 3 months. The physical condition of the patients was assessed as the Karnofsky Performance Status score before and after the stenting procedure. A 4-grade scale ranging from 0 (normal food intake) to 4 (complete dysphagia) was used to evaluate the degree of dysphagia before and after stenting.[22]

A successful stenting procedure was defined as achieving an accurate position of the stent and gaining a complete seal of the fistula without major complications. Stent patency time was defined as the time from stent implantation to the loss of stent function or death due to any cause. Successful removal was defined as a removal of the stent without major complications. A cured fistula was defined as confirmed closure of the fistula by bronchoscopy after removal of the stent. The definition of complications comprised procedure-related complications (complications that occurred during the stenting procedure), stent-related complications (complications related to stenting after the stenting procedure), and removal-related complications (complications that occurred during the removal procedure). Stent failure was defined as the need to remove stent due to complications. The aforementioned definitions were confirmed according to previous studies.[16,23-25]

Statistical Analysis

Data are expressed as the median (interquartile range [IQR]). Continuous variables were compared before and after stenting using Wilcoxon tests for paired samples. Statistical analyses were performed using SPSS 22.0 (IBM Corp, Armonk, NY) and GraphPad Prism 6 (GraphPad Software, Inc, San Diego, Calif).

RESULTS

Patient Characteristics

The median age of patients was 59 years (IQR, 53-67 years). The fistulas were confirmed 10 days (IQR, 8.75-12.75 days) after esophagectomy. All fistulas involved the carina or main bronchi. All patients showed irritating cough when eating or drinking and pulmonary infections on CT imaging. Intrathoracic fluid collection was found in 4 patients. Poor effects of conservative treatment including anti-inflammatory therapy, gastrointestinal decompression, enteral nutritional support, thoracic drainage, and mediastinal

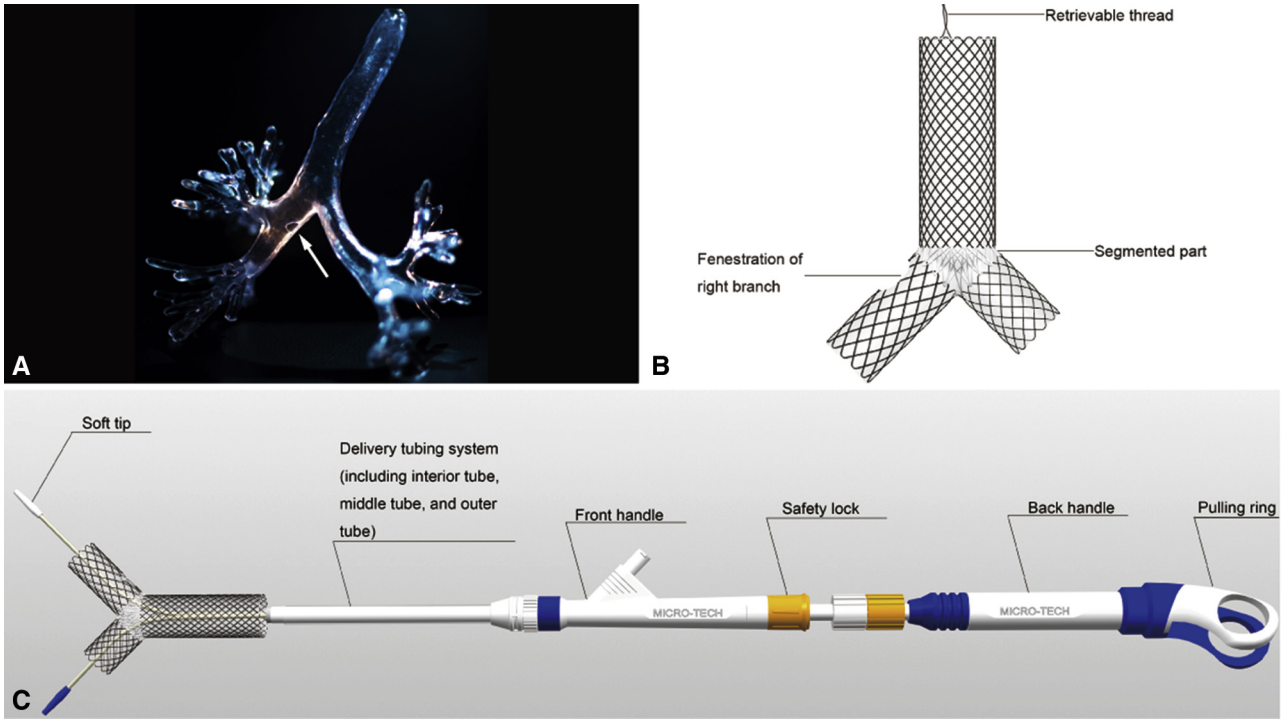
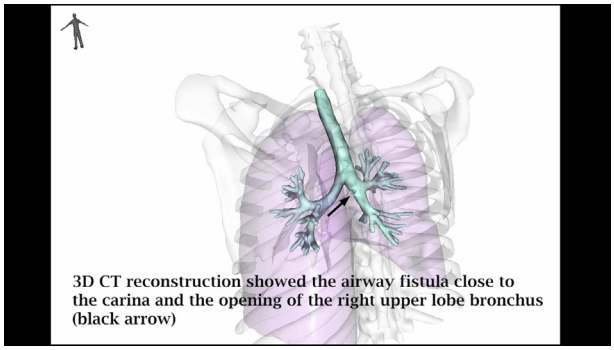


FIGURE 2. Process of designing a patient-specific stent and schematic diagram of the stent delivery system. A, The patient-specific mold of airway was made by 3D printer with laminating photosensitive resin based on CT reconstruction. The size and location of fistula can be seen clearly on the mold (*white arrow*). B, The retrievable covered metallic segmented Y airway stents were customized with the aid of the 3D-printed airway mold. The adjoining part between the main and branching parts of the stent was made of poly(tetrafluoroethylene). The right branch of the stent was made with a fenestration to avoid covering the opening of the right upper lobe bronchus. C, The schematic diagram showed the components of the stent delivery system including soft tip, delivery tubing system, front handle, safety lock, back handle, and pulling ring.

drainage were achieved. The baseline characteristics of the patients are shown in Table 1.

Technical Outcome

A total of 7 Y stents were successfully implanted in all 6 patients with a technical success rate of 100%. The procedure time ranged from 30 to 60 minutes. No procedure-related complications occurred. Bronchoscopy and CT of the chest were performed after stenting and showed that all stents expanded well and that the fistulas were completely sealed (Figure E1, *A*). The opening of the right upper lobe bronchus was kept open due to the fenestration of the right branch of the stent (Figure E1, *B*). The patients were discharged from the hospital 41 days (IQR, 5.25-61.75 days) after the procedure.



VIDEO 1. Manufacture of 3D-printed mold of airway, stenting procedure, and follow-up CT. *3D*, 3-dimensional; *CT*, computed tomography. Video available at: https://www.jtcvs.org/article/S0022-5223(20)30599-7/fulltext.

Follow-up and Complications

After stenting, the pulmonary infections were brought under control (Figure E1, *C* and *D*). Enteral nutritional support was continued before the healing of fistula. The median Karnofsky Performance Status scores of the patients after stenting were significantly improved compared with those before stent implantation (70 [IQR, 70-72.5] vs 60 [IQR, 50-60]; $P = .024$]. The dysphagia alleviated significantly after stenting (1 [IQR, 0.75-1] vs 3 [IQR, 2-3]; $P = .02$). The clinical manifestations were relieved in all patients.

The patency and indwelling time of the stent was 64 days (IQR, 52-69 days). After final stent removal, bronchoscopy, gastroscopy, and CT showed cured fistulas in all patients

TABLE 1. Baseline characteristics of the 6 patients with airway fistulas

Patient number	Sex	Age, y	Tumor stage	Pathologic pattern	Time interval between surgery and symptoms of fistula, d	Location of fistula (gastroesophageal side)	Location of fistula (airway side)	Size of fistula, mm
1	Male	58	T1bN0M0, IB	SCC	12	Anastomotic stoma	Carina	15
2	Male	72	T3N2M0, IIIB	SCC	11	Anastomotic stoma	Trachea 2 cm above carina	5
3	Male	51	T3N1M0, IIIA	SCC	15	Gastric conduit along the staple line	Right main bronchus	20
4	Male	54	T3N2M0, IIIB	SCC	9	Anastomotic stoma	Right main bronchus	7
5	Male	66	T3N1M0, IIIA	SCC	8	Anastomotic stoma	Trachea 1.5 cm above carina	8
6	Male	60	T3N3M0, IIIC	SCC	9	Anastomotic stoma	Trachea 1 cm above carina	5

Tumor stage was assessed on the basis of the 7th American Joint Committee on Cancer/International Union Against Cancer (AJCC/UICC) system. *SCC*, Squamous cell carcinoma.

(Figure 3). In total, 1 of the 6 (16.7%) patients had stenosis of the stent due to severe granulation tissue proliferation, which was found by CT and bronchoscopy 62 days after implantation. The patient was treated with cryotherapy under bronchoscopy guidance to clear the granulation tissue, and the stent was removed. The fistula was not cured after stent removal, and a second stenting procedure was then performed in this patient. The stent was removed 69 days after

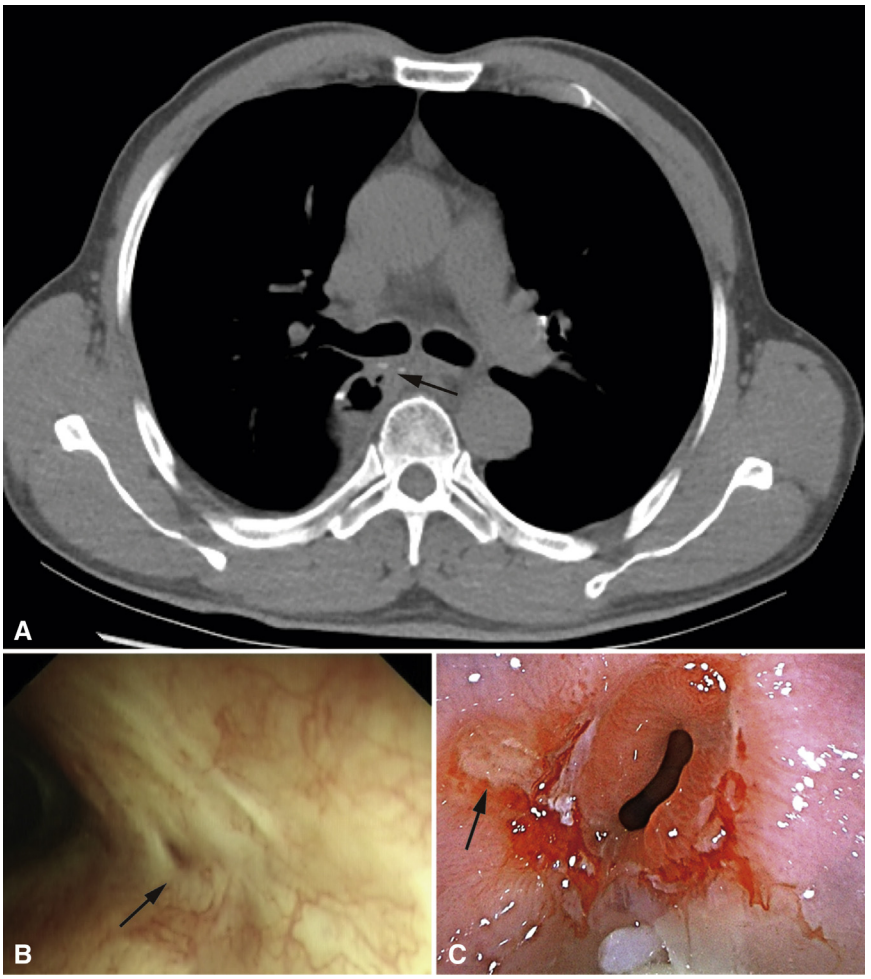


FIGURE 3. Examinations performed after stent removal. A, Axial CT image performed 1 week after stent removal showed that the fistula was healed (*black arrow*). B, Bronchoscopy and C, gastroscopy showed the well-healed fistula without recurrence 13 months after stent removal (*black arrow*).

TABLE 2. Follow-up outcome of patients

Patient number	Degree of dysphagia before stenting/after stenting	KPS before stenting/after stenting	Indwelling time of stent, d	Stent-related complications	Complication of removal
1	2/1	60/70	64	Sputum retention	No
2	3/1	50/70	50	No	No
3*	3/1	50/70	62; 69	Granulation tissue formation	Minor hemorrhage
4	2/0	60/80	52	No	No
5	3/1	60/70	70	Sputum retention	No
6	3/1	60/70	65	No	No

KPS, Karnofsky Performance Status. *The third patient underwent airway stenting twice and the indwelling time of the 2 stents was 62 and 69 days, respectively.

the second stenting and the fistula was healed (Figure E2). In total, 2 of the 6 (33.3%) patients showed sputum retention 64 and 70 days after stenting, which was aspirated under bronchoscopy. The stent failure rate was 14.3% (1/7), because 1 of the 7 stents was removed due to restenosis.

The Y stents were successfully removed in all 6 patients on the first attempt with a technical success rate of 100%. The time for procedure of stent removal ranged from 10 to 25 minutes. Minor hemorrhage occurred in 1 patient during stent removal, and the bleeding spontaneously ceased. No complications occurred during stent removal in the other patients. None of the stents showed fractures.

None of the patients showed symptoms of fistulas during the next follow-up. The follow-up time for patients after stenting was 439 days (IQR, 221.5-734.5 days). The follow-up outcomes are shown in Table 2.

DISCUSSION

In this study, the implantation and removal of covered metallic segmented Y airway stent modified with 3D printing was successful in all 6 patients, and the fistulas were healed completely after stent removal. This study demonstrated the feasibility of the stent in the treatment of gastrorespiratory fistula of carina or main bronchi.

Y airway stents have been widely used to treat airway fistula involving the carina and bronchi distal to the carina.[5-8] Metallic stents have shown advantages over silicone stents in the treatment of gastrorespiratory fistula because of their good support, larger cross-section diameter, lower rate of stent migration, and radio-opacity, and metallic stents can be inserted without rigid bronchoscopy.[5,26,27] Covered metallic stents could decrease the rate of granulation tissue hyperplasia compared with uncovered metallic stents.[28] In this study, conservative treatments including anti-inflammatory therapy, gastrointestinal decompression, thoracic drainage, mediastinal drainage, and enteral nutritional support were performed but the patients did not show significant improvement. It is difficult to cover the fistula using esophageal stent due to the change of the gastric volume between contraction and relaxation. Therefore, the decision of airway stenting was made.

The size, location, and relevant anatomical features of airway fistula vary greatly among patients, which makes it necessary to customize patient-specific stents.[9,10] Good conformity of the stent with the airway could help improve the clinical outcomes and reduce the number of stent-related complications. Advancements in 3D printing technology made it possible to design patient-specific medical devices. The anatomical features, including congenital bronchial anatomical variations, of the airways of individual patients could be precisely reflected by the 3D printing mold, enabling the stent to better suit the airway. 3D printing has been used to make patient-specific silicone airway stents to treat complex airway stenosis and tracheobronchomalacia and allows for conformity to the individual irregular airway geometries just days after the CT scan.[8,11-14] However, no previous studies have reported the application of 3D printing-engineered metallic stents for the treatment of patients with airway stenosis or fistulas, except for a case report that used removable airway stents modified with 3D printing to cure tracheoesophageal fistulas after esophagectomy.[15] In our study, the patient-specific airway stents fit well to the airway anatomy and covered the fistulas completely.

A segmented design was used for the stents in this study. The angle between the main bronchi changes during respiration and with different postures.[29] To fit the anatomical characteristics of the carina, we designed a new segmented stent. In the current study, the flexible and soft characteristics of the adjoining part of the segmented design made the stent suitable to the complex and irregular structure of the airway and changes of angle between the main bronchi. After stenting, all patients tolerated the stents well, and there was no stent migration. Further studies are needed to compare airway-segmented stents with wholly knitted stents.

For 2 patients with fistula located in right main bronchus, the right branch of the stent was made with a fenestration for the right upper lobe bronchus. If the right branch of the stent was not long enough, it could not cover the fistula located in the right main bronchus completely. However, a right branch of the stent that is too long will occlude the opening

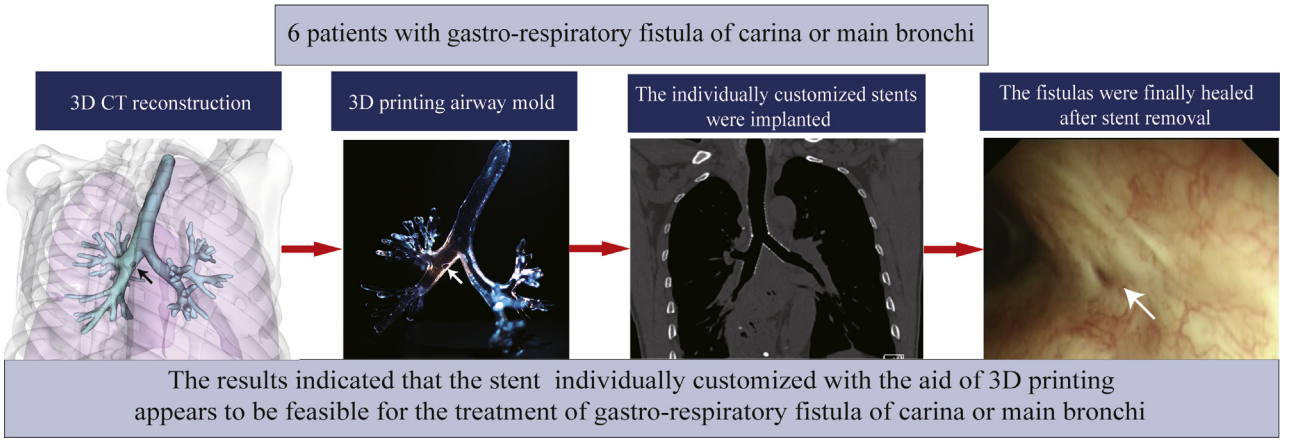


FIGURE 4. A total of 6 patients with gastrorespiratory fistula of carina or main bronchi underwent implantation of retrievable covered metallic segmented Y airway stent. The stent was individually customized with the aid of 3D printing airway mold, which was made based on 3D CT reconstruction. The stenting procedures were successful, and the fistulas were finally healed after stent removal in all patients. The results indicated that the stent appears to be feasible for the treatment of gastrorespiratory fistula of carina or main bronchi. *3D*, 3-dimensional; *CT*, computed tomography.

of the right upper lobe bronchus, which is close to the carina. Thus, our design of a long right branch with a fenestration addressed this issue. The stents completely sealed the fistulas located near the opening of the right upper lobe bronchus without covering the opening, thus maintaining the patency of the bronchus. The fenestration of the stent precisely fit the opening of the bronchus with the aid of 3D printing. Some investigators have reported the use of a combination of 2 or 3 Y stents to treat gastroairway fistulas.[30,31] The stent with a fenestration may simplify the procedures for stent implantation and removal compared with dual stents.

General anesthesia, which can reduce the stimulation of the airway, improve the comfort of the patient, and enable accurate placement of the stent, has been widely used in airway stenting.[32,33] In this study, we used a tracheal intubation with a small-diameter tube, and the bronchoscope, guidewire, catheter, and stent-delivery system passed parallel to the tracheal tube. Constant ventilation was continuously supplied during the operation, which provided a sufficient time window for stent implantation, thus improving the accuracy and safety of the procedure and facilitating its generalization.

A long stent indwelling time may lead to complications such as stent fracture, migration, excessive granulation tissue proliferation, sputum retention, and infection, limiting the use of the stent.[34] Gastrorespiratory fistulas could lead to infections, which was a risk factor of granulation tissue hyperplasia.[35] Bi and colleagues[20] reported that excessive granulation tissue was found after 142.1 $\pm$ 81.8 days in patients with airway fistulas. Therefore, the stent needs to be removed at the proper time to reduce complications. A few studies have reported the effectiveness of removable airway stents in patients with airway fistulas, but the optimal stent indwelling time remains unclear.[20,24] A shorter indwelling time is associated with a lower risk of stent-related complications, thus making the stent easier to remove. Nevertheless, a short indwelling time may not sufficiently cure the fistula and lead to an increased possibility for fistula recurrence. In our study, bronchoscopy was performed every month after stenting, and the patient was treated with cryotherapy and the stent was removed if excessive granulation tissue was found. In this study, the stents were successfully removed 50 to 70 days after stenting, and the fistulas were cured after stent removal in all patients. The optimal stent indwelling time needs to be determined with further studies with larger sample sizes.

The limitation of this study was the small sample size. In addition, assessments of the long-term outcomes after stent removal and larger prospective controlled studies are warranted.

In conclusion, our preliminary experience indicated that retrievable covered metallic segmented Y airway stents modified with 3D printing appear to be feasible in the treatment of gastrorespiratory fistula of carina or main bronchi. A graphical depiction of methods, results and implications of this study is shown in Figure 4.

Conflict of Interest Statement

Dr Wang is a coinventor on a patent covering the stent used in this study. The owner of the patent is Micro-Tech, Nanjing, China. All other authors have nothing to disclose with regard to commercial support. All authors declare that they conducted an independent research in the absence of any financial relationship with Micro-Tech, Nanjing, China.

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Key Words: airway, fistula, stents, 3D printing

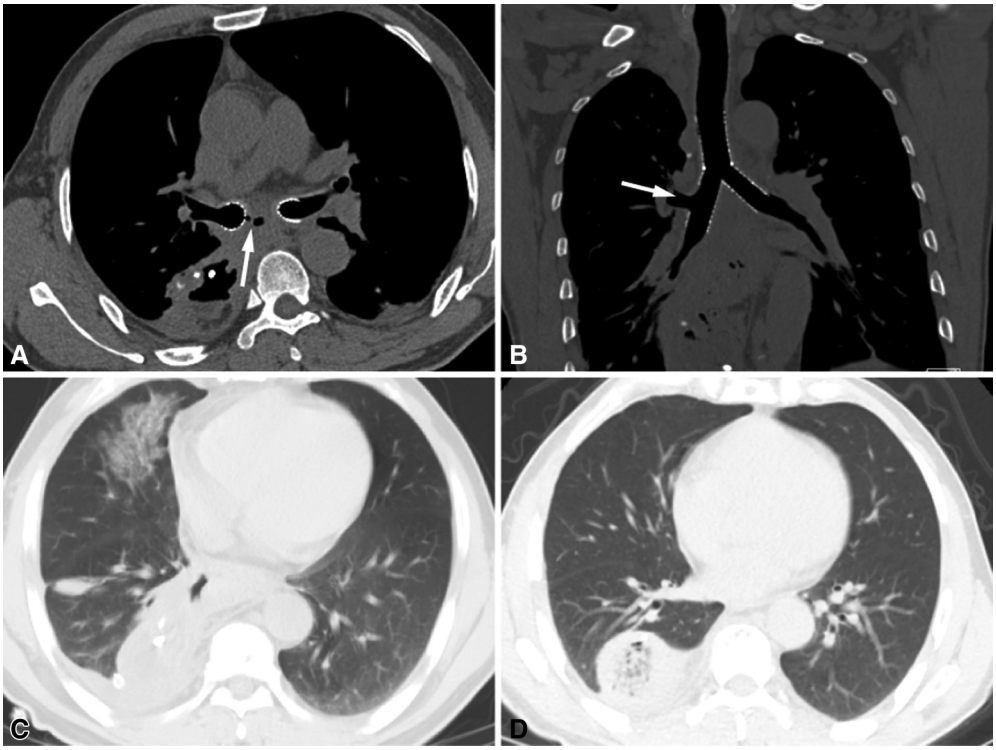

FIGURE E1. A, Axial CT image obtained after stenting showed that the fistula was completely sealed (*white arrow*). B, Coronal CT after stenting showed that the stent was in place. The fenestration of the right branch of the stent fitted well to the opening of the right upper lobe bronchus (*white arrow*). C, Axial CT image before stenting showed pneumonia in the patient. D, Axial CT image 52 days after stenting showed that the pneumonia was absorbed.

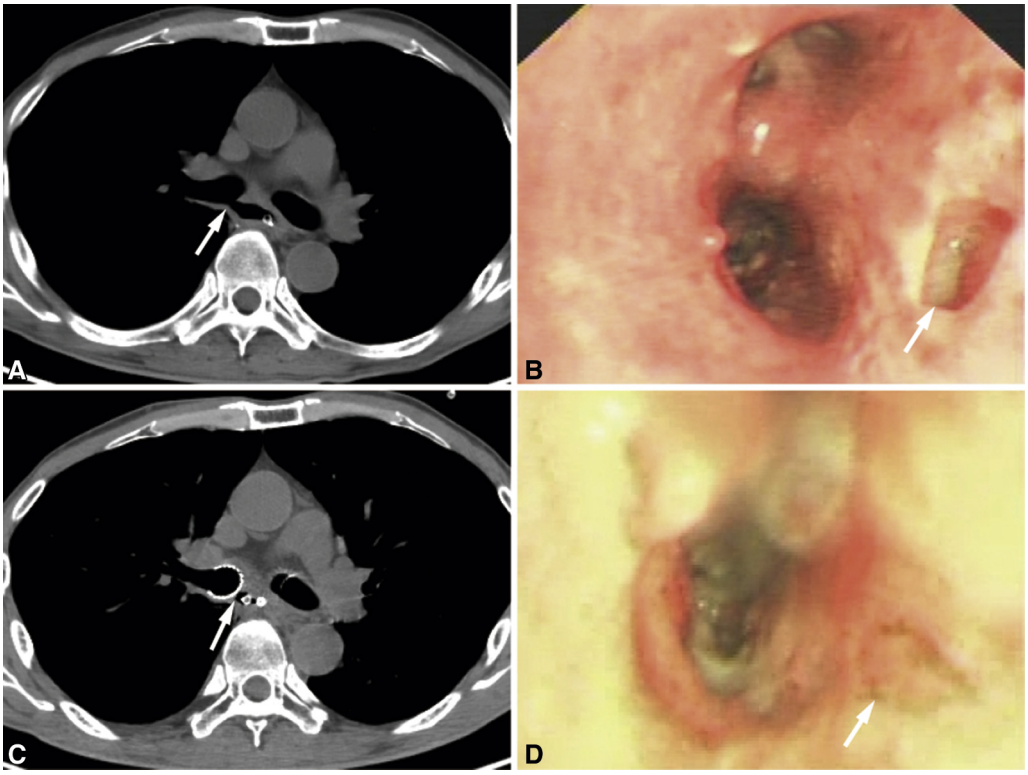

FIGURE E2. A 51-year-old man who underwent airway stenting twice. A, Axial CT image before the first stenting showed that the right main bronchus communicated with the thoracic stomach (*white arrow*). B, The stent was removed due to severe granulation tissue proliferation 62 days after the first stenting. Bronchoscopy immediately after stent removal showed that the fistula located at the posterior wall of the right main bronchus was not cured (*white arrow*). C, Axial CT image immediately after the second stenting procedure showed that the fistula was completely sealed (*white arrow*). D, The stent was removed 69 days after the second stenting. Bronchoscopy immediately after the second stent removal showed complete cured fistulas (*white arrow*).