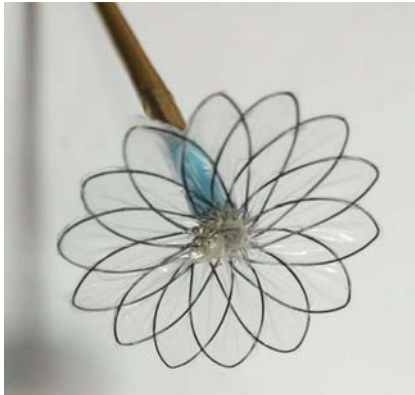


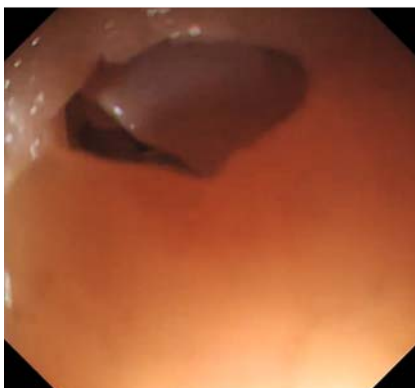
## Tracheoesophageal fistula closed by a new gastrointestinal occluder device



► **Fig. 1** Gastrointestinal occluder device and delivery device.

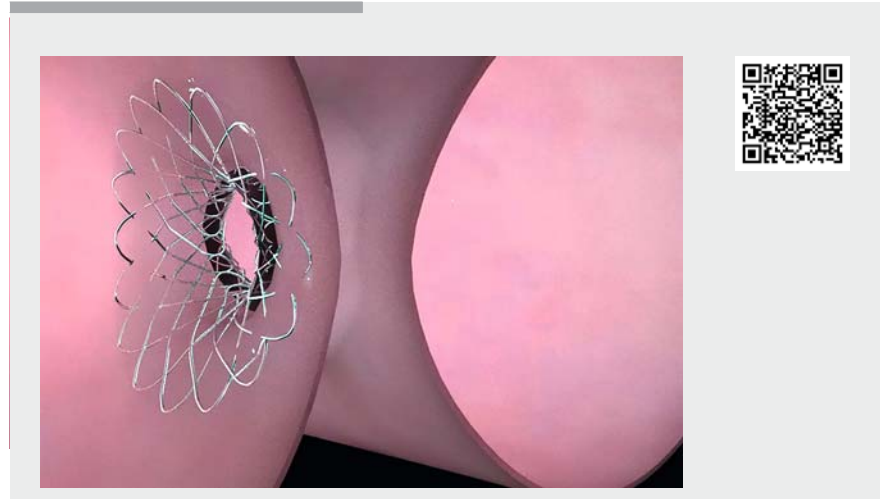


► **Fig. 2** Gastrointestinal occluder device.



► **Fig. 3** Esophageal view of the fistula orifice.

Tracheoesophageal fistulas (TEFs) are pathological communications between the airway and the adjacent esophagus that can involve serious, life-threatening complications, being associated with high mortality, short survival time, and poor quality of life [1]. According to the European Society of Gastrointestinal Endoscopy Clinical Guideline, a self-



► **Video 1** A 5-mm tracheoesophageal fistula in an in vitro porcine model closed under endoscopy with the aid of a new gastrointestinal occluder device.



► **Fig. 4** Esophageal views of the occluder device following insertion into the fistula.



► **Fig. 5** Bronchial views of the occluder device following insertion into the fistula.

panding metal stent is the preferred treatment option [2]. However, considering the poor clinical success rate of this treatment, the chance that the fistula will reopen remains high [3]. Several previous studies have shown that, in selected patients, TEFs can be healed by an Amplatzer septal occluder (AGA Medical Corporation, Plymouth, Minnesota, USA) [1, 4]. However, Daniel et al. reported the case of a patient who died of fatal hemoptysis after closure of a benign gastrobronchial fistula with an Amplatzer device [5].

Here, we propose a novel occluder device which was professionally designed for TEFs (PCT/CN2020/077659), the first to be described in the literature.

The device is made of laminated nitinol mesh with two self-expanding discs connected by a thin waist (► **Fig. 1**, ► **Fig. 2**), allowing mechanical closure of both ends of the fistula, giving a potential substrate for subsequent organized in-growth. ► **Video 1** shows upper gastrointestinal endoscopy of a 5-mm fistula with positioning of the device in an in vitro

porcine model (► Fig. 3). We introduced a 9-Fr catheter through the endoscope and thus were able to introduce the device into the airway. We released the distal disc under direct vision and gently pulled the device until it sat tight against the airway wall (► Fig. 4). While withdrawing the sheath, we slowly pulled the cable under direct vision to release the proximal disc (► Fig. 5). Once the stent was properly positioned, the cable was detached, releasing the device. Finally, we withdrew the cable and endoscope.

Compared with the Amplatzer occluder, this device may have the following advantages: (1) it has no protrusion, so even if the patient coughs, it will not damage the trachea; (2) it could be manufactured using degradable materials in future; (3) it can carry a retrieval line, and can be retrieved endoscopically if necessary. In conclusion, the use of the new device for closure of TEFs will probably provide an alternative method to mechanically close TEF defects in the future.

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### Competing interests

The authors declare that they have no conflict of interest.

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