



Transnasal Placement of a Balloon-Expandable Metallic Stent: Human Cadaver Study of the Eustachian Tube

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ABSTRACT

Purpose: To investigate the technical feasibility of stent placement in the cartilaginous portion of the Eustachian tube (ET).

Materials and Methods: Twelve ETs of 6 cadavers were used. Two different-sized stents were placed on either the right (2.5 mm in diameter) or left (3.5 mm in diameter) side of the ET. The procedural feasibility was assessed by subtraction Eustachian tubography, computed tomography before and after the procedure, and fluoroscopic and endoscopic images. The stent location, inner luminal diameter of the stented ET, radiation dose, procedural time, and fluoroscopy time were analyzed.

Results: Stent placement was successful in 11 of 12 cadaveric specimens without procedure-related complications. In the 1 specimen, the balloon catheter with crimped stent was passed into the bony canal of the ET without any resistance. The distal end of the stent was located in the middle ear cavity. Stents were located within the cartilaginous portion of the ET ($n = 1$), the proximal tip bridging the nasopharyngeal orifice of the ET ($n = 5$), or the proximal end of the stent protruded from the tubal orifice ($n = 5$). The mean luminal diameter in the outer segment was significantly smaller than in the middle ($P < .001$) and inner ($P < .001$) segments. The mean procedure time was 128 ± 37 seconds. The mean radiation dose and fluoroscopy time of each cadaver were 3235.4 ± 864.8 cGy/cm² and 139 ± 49 seconds, respectively.

Conclusions: Stent placement of the ET under endoscopic and fluoroscopic guidance is technically feasible in a human cadaver model.

ABBREVIATION

ET = Eustachian tube

Eustachian tube (ET) dysfunction is a physiologic disorder of the ET that results in inadequate middle ear ventilation, causing aural fullness and tinnitus. Current therapeutic options for ET dysfunction, such as pharmacologic agents, mechanical devices, and nasal surgery, can be ineffective in some patients, and invasive management has historically been limited (1–4). ET balloon dilation under endoscopic guidance has been recently introduced as an alternative treatment for ET dysfunction (5–7). Although this procedure

is clinically effective in selected patients, it has not yet been standardized regarding the procedural technique, diagnosis, and indications (6,7). Recently, ET balloon dilation under fluoroscopic guidance was introduced and has several advantages over endoscopic techniques, particularly because the location and inflation status of the balloon catheter can be visualized (8). Over the years, different treatment approaches to ET dysfunction have been investigated. Various types of ET prostheses have been introduced and surgically

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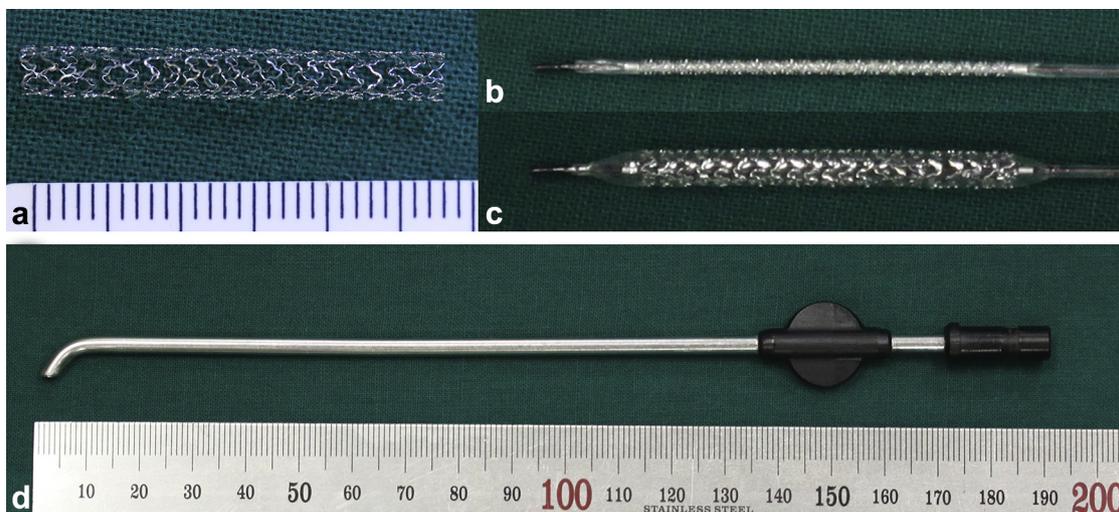


Figure 1. (a) Photograph showing a balloon-expandable metallic stent made of a cobalt-chrome alloy (2.5 mm in diameter and 28 mm in length) for the right-sided ET. Photographs showing a balloon catheter with a crimped stent before (b) and after (c) balloon dilation. (d) Photograph showing a metallic guiding sheath.

placed to evaluate their safety and tolerability in various animal and cadaver models (9–12).

For more than 20 years, temporary stent placement has been an accepted therapeutic option for a variety of refractory, benign, nonvascular strictures (13–15). To our knowledge, there is no consensus on minimally invasive techniques for ET stent placement, and the optimal size of the stent for the cartilaginous portion of the ET remains controversial. Therefore, the purpose of this study was to investigate the technical feasibility of placement of a balloon-expandable metallic stent in the cartilaginous portion of the ET and to evaluate the optimal size of ET stents for patients with ET dysfunction in a cadaver model before consideration of a human trial.

MATERIALS AND METHODS

Study Design

Twelve ETs of 6 fresh-frozen adult human cadavers were used in this study. None of the cadavers had a history of ear surgery, ear disease, or trauma. Two stents with different diameters were placed in each side of the cartilaginous portion of the ET under endoscopic and fluoroscopic guidance. The feasibility of ET stent placement was assessed by subtraction Eustachian tubography, pre- and post-procedural computed tomography (CT), and fluoroscopic and endoscopic images in cadaveric specimens.

Stents and Metallic Guiding Sheath

Two different sizes of balloon-expandable cobalt-chrome alloy stents were used in this study (Genoss Co, Ltd, Suwon, Korea) (Fig 1a–c). The stents for the right-sided ET had a 2.5-mm diameter, whereas the ones for the left-sided ET had a 3.5-mm diameter (28-mm length and 85- μ m strut thickness). The metallic guiding sheath used in this study was made from stainless steel (Genoss Co, Ltd) to facilitate its

detection under fluoroscopic guidance. The inner and outer diameters of the sheath were 2.5 mm and 3.45 mm, respectively, and the sheath was 190 mm long. The distal 10 mm of the sheath was curved in a J shape (Fig 1d). This distal tip was positioned at a 65° angle to the axis to easily access the nasopharyngeal orifice of the ET.

Stent Placement

The cadaver was positioned in the Hirtz position for the submentovertical view to visualize the location of the guidewire and place the stent under fluoroscopic guidance (Ziehm Vision RFD Hybrid Edition; Ziehm Imaging GmbH, Nuremberg, Germany). A metallic guiding sheath was advanced through the nasal cavity to the right-sided orifice of the ET under endoscopic guidance (ENF-VH Video Rhinolaryngoscope; Olympus, Tokyo, Japan) by an otolaryngologist (H.J.P., with more than 15 years of experience). A 0.014-inch, 30-cm micro-guidewire (Transcend; Boston Scientific/Medi-Tech, Watertown, Massachusetts) was inserted through the sheath and advanced to the ET until it reached the isthmus of the ET under fluoroscopic guidance by an interventional radiologist (H.Y.S., with more than 25 years of experience). The endoscope was removed from the nasal cavity. A balloon catheter (Genoss), which was crimped with a stent, was advanced over the guidewire into the ET until its tip met resistance near the bony-cartilaginous isthmus of the ET. The balloon catheter was fully inflated with contrast medium to 12 atmospheres, as determined with a pressure-gauge monitor, and then deflated immediately under continuous fluoroscopic monitoring. The balloon catheter and guidewire were removed after stent placement, with the sheath left in place. A 0.035-inch, 80-cm stiff guidewire (Radiofocus M; Terumo, Tokyo, Japan) was inserted through the sheath to the ET. A Kumpe catheter (Cook, Bloomington, Indiana) was advanced over the guidewire into the orifice of the ET to perform

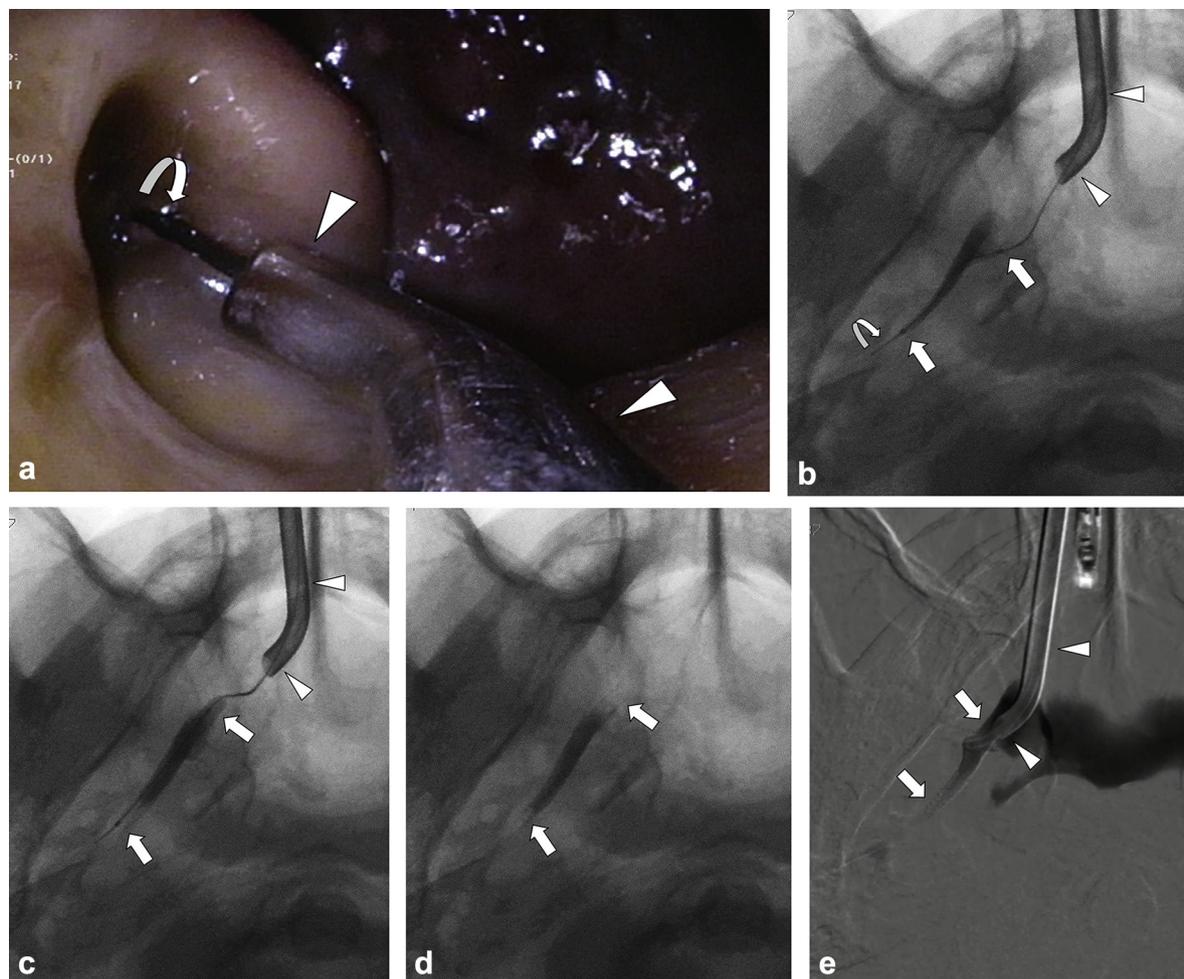


Figure 2. Endoscopic and radiographic images showing the technical steps in stent placement in a cadaver model (specimen 1R). (a) Endoscopic image showing the right-sided nasopharyngeal orifice of the ET and the metallic guiding sheath (arrowheads) and micro-guidewire (curved arrow) in fresh cadaver. (b) Radiograph showing the inserted balloon catheter with crimped stent (arrows) over the micro-guidewire (curved arrow) through the metallic sheath (arrowheads) into the cartilaginous portion of the ET. (c) The balloon catheter (arrows) was fully inflated with the use of contrast medium under continuous fluoroscopic monitoring. (d) Radiograph showing a fully expanded stent (arrows). (e) Subtraction Eustachian tubography obtained immediately after stent placement showing a good patency of the stent (arrows).

subtraction Eustachian tubography using 3 mL of contrast medium (Omnipaque 300; GE Healthcare, Cork, Ireland) to clearly visualize the stented ET in the bony or dense soft tissue environment (**Fig 2**). Each specimen was carefully evaluated for any procedure-related complications using post-procedural endoscopic examination and CT.

Study Definition and Data Analysis

Technical success was defined as successful stent placement in the cartilaginous portion of the ET and successful passage of contrast medium through the stent. The procedure time was measured from the insertion through the nose of the endoscope with a metallic guiding sheath to the final deployment of the stent. The radiation dose and fluoroscopy time for both ETs of each cadaveric specimen were measured with the use of C-arm software (Ziehm Vision RFD Hybrid Edition) during the procedure. Stent locations were analyzed using endoscopic images, subtraction

Eustachian tubography, and post-procedural CT images. Stent location was categorized into 3 types according to stent placement. In type I, the stent was located entirely within the cartilaginous portion of the ET. In type II, the stent was located in the cartilaginous portion of the ET with its proximal tip slightly bridging the nasopharyngeal orifice of the ET. In type III, the stent was located in the cartilaginous portion of the ET with the proximal tip of the stent protruding into the nasal cavity (**Fig 3a**). The stented cartilaginous portion of the ET was divided into inner, middle, and outer segments (**Fig 3b**). The inner luminal diameters of the stented ET were measured on axial CT images at the 3 different levels. Measurements were repeated 3 times at each level, yielding an average value per level. Analysis of the CT findings was performed based on the consensus of 3 observers.

All cadavers underwent CT (Somatom Sensation 16; Siemens, Erlangen, Germany) and endoscopic examinations

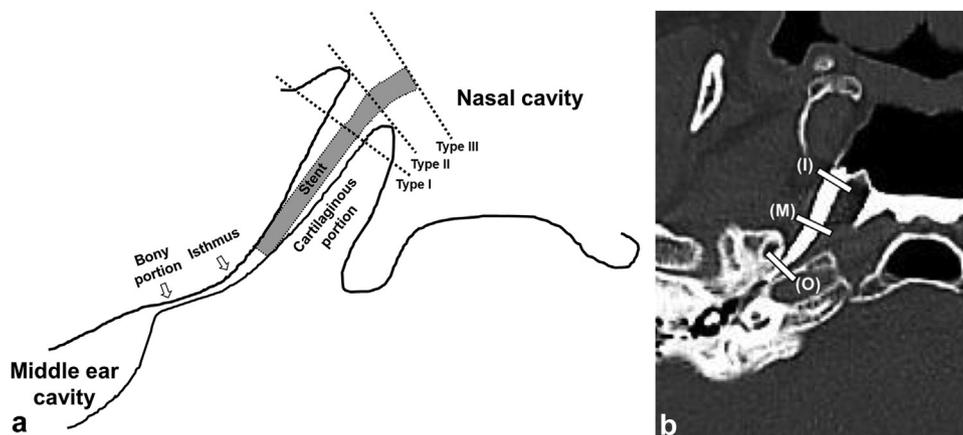


Figure 3. (a) Schematic drawing showing 3 types of stent location according to the location of the proximal end of the stent. Type I, location of the stent in the cartilaginous portion of the ET; type II, location of the proximal tip of the stent in the nasopharyngeal orifice of the ET; and type III, location of the proximal tip of the stent in the nasal cavity. (b) Axial CT image showing segments of the stented ET where the stent was present in the inner (I), middle (M), and outer (O) portions.

before and after stent placement. Baseline CT screening confirmed the absence of ear and nasal pathologies. CT scans were obtained in the supine position, and images were acquired in the axial plane with 0.5-mm slice thickness. Baseline endoscopic photographs of the nasopharyngeal orifice of the ET were also obtained. After stent placement, the ET orifice was examined by endoscopy to confirm the location of the proximal end of the stent and any possible mucosal injuries.

Statistical Analysis

Data are expressed as the mean \pm standard deviation (SD). The differences between the luminal diameters of the 3 segments were analyzed using the Kruskal-Wallis test or the Mann-Whitney *U* test, as appropriate. *P* values less than .05 were considered statistically significant. Statistical analyses were performed using SPSS software, version 23.0 (SPSS, IBM, Chicago, Illinois).

RESULTS

Stent placement was technically successful in 11 of the 12 cadaveric specimens (91.7%), and there were no procedure-related complications (Table 1). In the 1 specimen with technical failure (specimen 2R), the balloon catheter with crimped stent was inadvertently passed into the bony canal of the ET without any resistance near the bony-cartilaginous isthmus of the ET. The distal end of the stent was located in the middle ear cavity. An additional stent (2.5 mm in diameter and 28 mm long) was coaxially placed into the cartilaginous portion of the ET. Pre-procedural CT images in specimen 2R revealed that the bony isthmuses of both ETs were larger than 3 mm. The mean (\pm SD) procedure time for stent placement was 128 ± 37 seconds. The radiation dose for both ETs of each cadaveric specimen ranged from 2248.4 to 4782.1 cGy/cm² (mean, 3235.4 cGy/cm²), and the mean (\pm SD) fluoroscopy time was 139 ± 49 seconds.

In 5 of the 6 right-sided ETs treated with the 2.5-mm-diameter stents, 4 stents were located within the cartilaginous portion of the ET ($n = 1$, type I) or in the cartilaginous portion of the ET with the proximal tip bridging the nasopharyngeal orifice of the ET ($n = 3$, type II). In the remaining specimen (specimen 5R, type III), the proximal end of the stent protruded from the tubal orifice by approximately 2 mm. In the left-sided ET, the proximal end of the 4 stents (type III) protruded from the nasopharyngeal orifice because the balloon catheter slightly pulled back during dilation (Fig 4a, b). The 2 remaining stents were located in the cartilaginous portion of the ET with the proximal tip slightly bridging the nasopharyngeal orifice of the ET (type II) (Fig 4c, d).

The mean diameter values were significantly different among the 3 segments ($P < .001$, Kruskal-Wallis test). The mean luminal diameters of the stented ET in the outer segment (1.67 ± 0.35 mm in the right-sided ET and 1.59 ± 0.41 mm in the left-sided ET) were significantly smaller than those in the middle (2.46 ± 0.39 mm in the right-sided ET [$P < .001$] and 3.45 ± 0.47 mm in the left-sided ET [$P < .001$]) and inner (2.49 ± 0.23 mm in the right-sided ET [$P < .001$] and 3.47 ± 0.21 mm in the left-sided ET [$P < .001$]) segments in both ETs. The mean luminal diameters of the stented ETs were not significantly different between the middle and inner segments in both ETs ($P = .181$ for the right-sided ET and $P = .647$ for the left-sided ET, respectively) (Table 2).

DISCUSSION

The results of the present prospective preclinical study provide evidence that ET stent placement under combined endoscopic and fluoroscopic guidance is technically feasible. Its technical success rate was 91.7%, and the average time for stent placement was 128 seconds. Ho et al (16) reported that ET stent placement using 16-gauge angiocath (1.7 mm diameter and 30 mm long) with

Table 1. Results of ET Stent Placement

Specimen	Stent size		Technical success	Locations of the stent			Procedure time (seconds)	Radiation dose (cGy/cm ²)	Fluoroscopy time (seconds)
	Diameter (mm)	Length (mm)		Distal end	Proximal end	Type			
1R	2.5	28	Y	Isthmus	Orifice	Type II	133	2785.5	105
1L	3.5	28	Y	Isthmus	Orifice	Type II	179		
2R	2.5	28	N	Middle ear cavity		–	180	3318.2	124
2L	3.5	28	Y	Isthmus	Orifice	Type II	61		
3R	2.5	28	Y	Isthmus	Cartilaginous	Type I	127	4782.1	232
3L	3.5	28	Y	Cartilaginous	Nasal cavity	Type III	149		
4R	2.5	28	Y	Isthmus	Orifice	Type II	141	3408.7	154
4L	3.5	28	Y	Cartilaginous	Nasal cavity	Type III	66		
5R	2.5	28	Y	Isthmus	Nasal cavity	Type III	136	2248.4	113
5L	3.5	28	Y	Cartilaginous	Nasal cavity	Type III	109		
6R	2.5	28	Y	Isthmus	Orifice	Type II	138	2869.6	108
6L	3.5	28	Y	Cartilaginous	Nasal cavity	Type III	111		

ET = Eustachian tube.

sutures to prevent migration was intraoperatively performed to prevent otitis media with effusion after nasopharyngectomy. During healing process after surgery, granulation tissue formation occurred adjacent to the angiocath resulting in restenosis of the ET. The present technique provided a minimally invasive approach for ET stent placement; however, stent retrievability should be considered to perform ET stent placement safely. The average radiation dose and fluoroscopy time of each cadaveric specimen were 3,235.4 cGy/cm² and 139 seconds (2.3 minutes for both ETs), respectively, which was lower than those for nasolacrimal stent placement, reported in the literature as 2.2–3.2 minutes for a single-side procedure (17,18). The endoscopic approach allows greater accessibility to the nasopharyngeal orifice with no radiation exposure compared to the fluoroscopic approach; however, the location and inflation status of balloon catheters and/or stents could not be monitored (8). Continuous fluoroscopic visualization may decrease the risk of procedure-related complications and increase the technical accuracy of stent placement.

Two stents with different diameters were used in this study to evaluate the optimal size of the ET stent. In the left-sided ET (3.5-mm-diameter stent), 4 of the 6 stents (67%) protruded into the nasal cavity. A large-diameter (3.5-mm) balloon catheter with crimped stent may slightly pull back during balloon dilation at the bony-cartilaginous isthmus. In specimen 5R (type III), although the distal end of the stent was properly located in the bony-cartilaginous isthmus, the proximal end of the stent was located in the nasal cavity because of the relatively short length of the ET. A 2.5-mm stent diameter stent is more suitable than a 3.5-mm stent diameter for ET stents. In addition, 28-mm-length stents were suitable to cover the entire ET but were too long in cadaveric specimen 5. Therefore, the length of the entire ET should be carefully evaluated before stent placement to determine the optimal length of the stent for each patient

using a pre-procedural CT. In the present study, a 2.5-mm-diameter and 28-mm-long stent seemed to be relatively appropriate for ET stent placement in patients with ET dysfunction compared to a 3.5-mm-diameter stent.

Surgical insertion of pressure-equalization tubes, tympanostomy tubes, or ventilation tubes is the standard treatment for persistent ET dysfunction (3,19,20). However, these approaches are subject to crusting, infection, obstruction, extrusion, and permanent tympanic membrane perforation (19–21). Additionally, cadaver studies (4,21,22) and clinical trials (5–8) for ET balloon dilation showed that dilation of the cartilaginous portion of the ET is indicated as a minimally invasive therapeutic option for ET dysfunction. However, controlled clinical trials are warranted to verify the evidence on its efficacy and safety. Poly-L-lactide ET stents have been introduced, and their tolerability and resorption were demonstrated in rabbit and chinchilla animal models (10,11). Balloon-expandable metallic stents were evaluated in a sheep animal model (12). The diameter of the stents in the previous studies was 2.0 mm, and their lengths ranged from 9 to 20 mm in the various animal models (10–12). In the present study, diameters of 2.5 mm and 3.5 mm were used in the human cadaveric model to determine the optimal stent size. The size and location of the stent for patients with ET dysfunction as well as the indications for stent placement remain controversial. Temporary ET stent placement may be an alternative therapeutic option for patients with refractory ET dysfunction or severely persistent otitis media with effusion.

Stent placement from the nasopharyngeal orifice to the isthmus can lead to persistently patulous ET. The middle 8- to 12-mm-long segment in the cartilaginous portion of the ET functions as a valve (5). Anti-reflux valves should be considered for ET closure or significant nasopharyngeal positive pressure. Given stent-related complications such as stent migration, stent-induced granulation tissue formation, and stent malfunctions, stent retrievability is important for

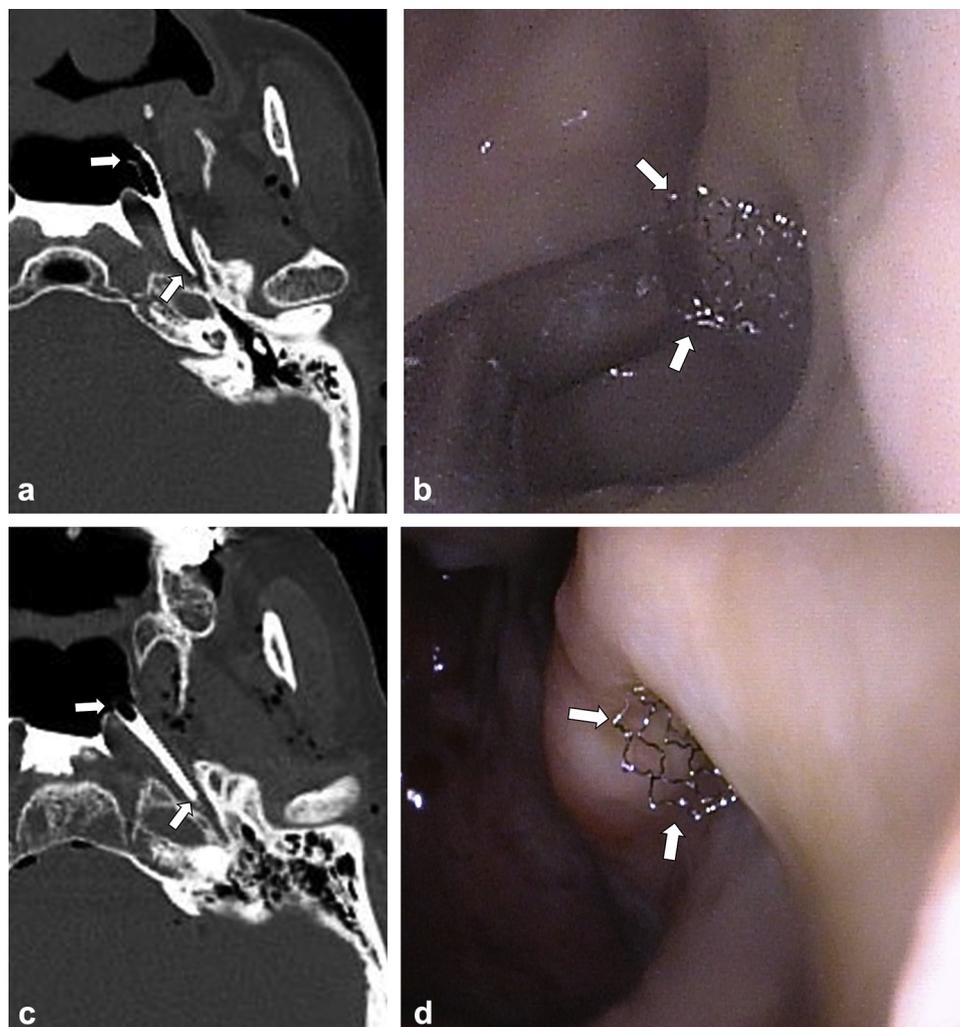


Figure 4. (a, b) Axial CT and endoscopic images showing that the proximal end of the stent (arrows) protrudes from the nasopharyngeal orifice (specimen 3L, type III). (c, d) Axial CT and endoscopic images showing that the proximal end of the stent (arrows) is located in the nasopharyngeal orifice of the ET (specimen 2L, type II).

Table 2. Inner Luminal Diameters of the Stented ETs

Side	Location	Luminal diameter (mm)	P value			
			*All	§I vs. M	§I vs. O	§M vs. O
Right	Inner	2.49 ± 0.23	< .001	.181	< .001	< .001
	Middle	2.46 ± 0.39				
	Outer	1.67 ± 0.35				
Left	Inner	3.47 ± 0.21	< .001	.647	< .001	< .001
	Middle	3.45 ± 0.47				
	Outer	1.59 ± 0.41				

Data are mean values ± standard deviation.

ET = Eustachian tube; I = inner; M = middle; O = outer.

*Kruskal-Wallis test.

§Mann-Whitney *U* test.

the safety of the approach. In addition, the stent should be placed temporarily and in the entire cartilaginous portion of the ET to improve symptoms by, for example, relieving negative pressure, draining effusion, and facilitating a Valsalva maneuver.

The principal limitation of this study was that the stented ET was not histologically analyzed. All procedures were performed by an experienced interventional radiologist and otolaryngologist, and a single type of stent design was used. However, these results may not apply to other practices and need to be verified in additional comparison studies.

In conclusion, stent placement in the cartilaginous portion of the ET under combined endoscopic and fluoroscopic visualization is technically feasible in a human cadaver model. A 2.5-mm-diameter and 28-mm-long stent seems to be relatively appropriate for patients with ET dysfunction compared to a 3.5-mm-diameter stent. Accurate placement of the stent remains technically challenging, and further studies are needed to determine the optimal stent length and diameter for the ET.

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