의학 석사 학위 논문

성인 이관의 형태학적 연구

: 사람 사체 연구

Morphological study of the Eustachian tube in adult

: Human fresh frozen cadaver study

울 산 대 학 교 대 학 원

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곽 민 영

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이 논문을 석사 학위 논문으로 제출함

2021년 2월

울산대학교대학원

의 학 과

곽 민 영

곽 민 영 의 석사 학위 논문을 인준함

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국 문 요 약

목표 : 이관 기능 장애를 개선하기 위하여 비인강이나 중이강을 통해 이관에 직접적인 시술이나 수술을 통한 치료 방식들이 다양하게 개발되고 있다. 본 연구는 사람의 냉동 사체에서 이관의 형태를 분석하기 위하여 고안 되었다.

방법: 이관의 구성을 확인하기 위해 사람의 냉동 사체의 14귀가 분석되었다. 사체의 머리는 비강 중격과 평행한 시상 면으로 절단되어 우측과 좌측으로 나누었다. 분석에 사용한 모든 귀는 개방성 유양동 절제술을 통해 중이강 내 이관의 개방성을 확인하였다. 200-μL 피펫의 팁과 연결된 10cc 주사기를 사용하여 실리콘 제재를 비인두강의 이관 입구를 통해 이관의 내부에 주입하였다. 이관에 채워진 실리콘을 경화 시킨 뒤 이관에서 분리하기 전에 비인두 입구부의 경계와 방향(상하, 전후)을 표시하였다. 3D CT를 사용하여 전체 이관의 실리콘 모형의 부피와 형태, 길이 정보를 분석하였다. 또한 이관 풍선이나 카테터가 주로 삽입되는 부위인 비인두 입구부에서 20mm되는 지점까지의 이관 내관의 모양과 단면적 길이도 확인하였다.

결과: 이관은 비인두 입구부에서 협부까지 점차 좁아지면서 곡선의 형태를 보였으며 내관의 전방부는 오목하고 후방부는 볼록한 면을 보였다. 이관의 단면부에서 확인된 가장 확장된 부분은 이관의 하방부 였으며, 확장되지 않은 상방부는 실리콘 주입 압력에 따라 내관의 폭이 변하지 않았다. 이관 실리콘 모형의 평균 부피는 1.4 ± 0.5 ml (최소: 0.7, 최대: 2.5)였다. 오목한 전방면의 길이는 26.3 ± 3.4mm (최소: 21.4, 최대 : 32.2)를 보였고, 볼록한 후방면의 전체 길이는 30.5 ± 3.6mm (최소: 25.3, 최대: 36.6)를 보였다. 비인두 입구부에 가장 넓은 이관 단면의 높이는 10.1 ± 0.9 mm (최소: 8.9, 최대: 11.9), 너비는 8.0 ± 1.5 mm (최소: 6.1, 최대: 11.0)였다. 이관의 협부 근처 단면의 높이는 2.4 ± 0.4 mm (최소: 1.8, 최대: 3.2) 이고 너비는 1.3 ± 0.5 mm (최소: 0.6, 최대: 1.9) 였다. 비인두 입구부에서 20mm되는 지점까지의 내관 단면은 전반적으로 상부가 좁고, 하부가 넓은 아몬드 모양의 형태를 보였으며, 비인두 입구에서 멀어질수록 폭이 좁은 기다란 형태로 보였다. 비인두에서 5mm 지점 에서는 높이 8.37mm, 너비5.33mm를 보였으며, 10mm 지점에서는 높이와 너비가 각각 7.02mm, 3.46mm, 15mm지점에서는 5.96 mm, 2.65mm를 보였다. 비인두에서 20mm 떨어진 지점의 내관 높이와 너비는 각각 5.51mm과 1.94mm였다.

결론: 이관 기능 장애를 치료하기 위해 이관 풍선 확장술이나 스텐트 삽입술 등과 같이 이관을 직접 확장하는 치료들이 주목받고 있으며, 효과적인 이관의 확장을 위해서는 이관의 형태,

크기, 확장 기구의 삽입 위치와 그 범위 등에 대한 정확한 정보가 필요하다. 본 연구에서 확인한 이관의 부피, 형태에 대한 해부학적 정보는 적합한 이관 수술의 재료 개발에 기여할 수 있다.

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INTRODUCTION

Aristotle in ancient Greece first described a small pathway that connects between the ear and the back of the throat. Bartolomeo Eustachi, a 16th-century Italian anatomist, extended the knowledge of the internal ear anatomy by describing the Eustachian tube (E-tube) named after him [1]. The E-tube regulates the pressure in the middle ear cavity by ventilating the air from the upper airway. The distal one-third of the E-tube consists of a bony part that begins at the middle ear cavity. This translates into the cartilaginous part towards the nasopharynx. It is the only passage between the middle ear and outside. It protects the tympanic cavity from pathogens and helps drain secretions from the middle ear mucosa. It remains closed most of the time but opens when we swallow, chew, and yawn. E-tube dysfunction occurs when the tube does not open or close properly [2,3]. The obstructive E-tube dysfunction is defined by the dilation disorder of the E-tube, which leads to a ventilatory problem in the middle ear. A long-term E-tube dysfunction leads to the middle ear or tympanic membrane disease; middle ear effusion, atelectasis, chronic otitis media. Chronic E-tube dysfunction is usually diagnosed when symptoms and signs continued for more than three months [4].

Recently, there have been proposed therapeutic methods through direct procedures from the pharynx into the E-tube beyond conservative management. E-tube laser tuboplasty, in which mucous membrane and cartilage are resected to avoid obstruction, and transtubal drug application into the E-tube has been conducted to treat tubal dysfunction. In addition, several attempts were made to pass the catheter or stenting from the nasopharyngeal ostium or tympanic cavity, to dilate and keep patency of the E-tube. The cartilaginous portion, the medial two-thirds along the E-tube, is a mainly dilated target in balloon tuboplasty and stenting placement. The cartilaginous portion of the E-tube is a very flexible space, regulated by peritubal muscles and elastic cartilage. With the balloon in the cartilaginous part of the E-tube, the inflated balloon and catheter loosen adhesion and enlarge the mucous membranes. The long-term follow-up of patients in the months presented that the E-tube remains open more

appropriately than medical therapy alone [5]. These surgical techniques and instruments for balloon and stenting dilation varied in the literature. Particularly, E-tube balloon catheter and stenting were used in a wide range of lengths and diameters and made from various materials.

The majority of E-tube anatomic studies utilized magnetic resonance imaging (MRI), computed tomography (CT) scan [6], and cadaveric histologic analysis for the last decades. Since the surgical management of E-tube dysfunction has been recently updated, in particular with the balloon dilation of the E-tube, it is timely to evaluate this important structure again and assess what human cadaveric studies can add in terms of both our understanding and surgical intervention of E-tube. E-tube anatomy is complex with individual variations. It has a narrow and gently curving pathway, extending from the middle ear to the nasopharynx. It is passively closed but normally opens under the control of peritubal muscles during actions such as swallowing. This curved shape is not easily assessed in one plane (axial or coronal planes), and even using multi-planar reconstruction is limited in the visualization of its entire shape [7,8]. The previous histological human cadaveric studies provided for the relationship between E-tube and surrounding structures, and measurements of distance or size of E-tube; however, it is limited in determining the intraluminal shape or dilated diameter of E-tube, that is, when opened because the E-tube lumen is collapsed at rest [9,10].

This study aimed to evaluate the three-dimensional shape, length, and cross-sectional dimension at the dilated status in cartilaginous E-tube of human fresh cadavers. Besides, it is intended to establish an anatomical basis for the development of the E-tube balloon catheter and stenting and the way to increase the surgical success rate based on this evaluation. The more detailed knowledge of anatomy in E- tube shape can provide for an effective and safe surgical approach.

MATERIALS & METHODS

Sample preparation

Human fresh frozen cadaveric heads were obtained from the Anatomy Gifts Registry (Hannover, MD). Fresh-frozen cadaver heads were sealed in biohazard bags and stored at -20 °C. We defrosted the cadaver heads in a refrigerator with a temperature of 4 °C for two weeks. When the skeletal and mucosal tissue retained the colors found in a living body, all procedures were carried out. The heads were divided in the midline sagittal plane (Fig 1). Fourteen ears were ready for use. All ears presented a normal tympanic cavity structure without specific middle ear disease and a canal wall down mastoidectomy was performed through a post-auricular approach. The patency of the tympanic ostium in the tympanic cavity and nasopharyngeal ostium from the pharynx were identified. Silicon impression materials, designed for hearing aid ear molding, were prepared in various mixing ratios and injected into the E-tube through nasopharyngeal ostium. We altered the mixing ratio by adding a curing agent. When the ratio of silicone and curing agent was 1:3, it was well injected without any resistance, and the mixture was not easily slipped or broken in the wet mucous membrane in the lumen. A 200-μL pipette tip was connected to a 10 cc syringe (Fig 2). The end of the pipette was inserted into the nasopharyngeal ostium, and the mixing silicon material was injected slowly. The blue silicon was identified through the opening ostium in the protympanum of the middle ear in two cases. Therefore, we could assume that the distal portion of silicon molding was considered as a pre-isthmus. The silicone material was injected from the inside until it completely covered the mucosa of the nasopharyngeal orifice, and then the pressure was applied gently to press the silicone into the Eustachian canal (Fig 2A and 2B). The manual pressure, applied to the silicon in E-tube was checked to be 1-1.5 atm with a pressure regulator. All procedures were conducted by only one experimenter for even dilation pressure. After keeping the cadaver heads at 4°C for about 5 hours, cured silicon was separated from the E-tube lumen using mosquito forceps. Pins were marked parallel to the mucosa membrane of the ostium inlet before removing the silicon from the E-tube. The cross-section of the nasopharyngeal ostium in the E-tube was cut parallel to these markers.

Measurements

Three-dimensional computed tomography (3D-CT) imaging (PACS; Infiniti, Seoul, Republic

of Korea) of the silicone impression was obtained, the total volume of E-tube silicone was measured using volume measuring instruments (Fig 3). We investigated the overall length and dimension of the E-tube cross-section (nasopharyngeal ostium, middle point, and pre-isthmus) using a micro-caliper. In addition, details on the luminal cross-section from nasopharyngeal ostium to 20 mm point, where the balloon or stent is commonly inserted, were also investigated. The cross-sectional view of CT images was analyzed at 5 mm intervals from nasopharyngeal ostium to 20 mm toward the isthmus (Fig 4). Four sections were obtained every 5 mm, and each point was P5, P10, P15, and P20. The P5 means the point 5 mm from the nasopharyngeal ostium toward the isthmus direction. We estimated the dimensions and cross-sectional shape of each point to obtain anatomical details for the medial cartilaginous portion of the E-tube. The cross-section was measured in width and height. The greatest height of cross-section from the top (hinge joint) to the bottom, and the greatest width of the cross-section at the most dilated location between the anterior and posterior side, were measured.

RESULTS

Overall Eustachian tube Configurations

The silicone moldings of E-tubes were obtained successfully without mucosal damage in the E-tube lumen. The E-tube had an elongated curved shape (Fig 5). The E-tube began with a nasopharyngeal ostium and made anterolateral curvature at first, and run in a slightly curved posteriorly from the midpoint to the middle ear cavity.

The shape of the nasopharyngeal ostium was variable among individuals. The nasopharyngeal ostium was confirmed to have a variety of lumen positions as well as the degree of opening status. When the nasopharyngeal ostium was observed in a sagittal view, vertical axes of the ostium were observed in an anteriorly inclined status, and in other cases, those of the ostium were observed almost vertically (Fig 2. yellow dotted line). The lateral lamina cartilage is thicker than medial lamina cartilage and had a more lateral location. The relationship between the two cartilage laminae, i.e. the position angle and the thickness of the cartilage, varied depending on the samples. Therefore, the cross-section of the nasopharyngeal ostium had an angled plane, which individually varied.

The proximal area from the nasopharyngeal ostium was dilated most broadly, and the E-tube lumen narrowed toward the isthmus. E-tube was dilated when silicone was gently infused into the E-tube by pushing lateral lamina cartilage and Ostmann fat pad anteriorly. When the elastic hinge between the lateral lamina and medial lamina cartilage moved smoothly, a large amount of silicone was able to be inserted.

The most expandable portion of the E-tube was the lower part, and the upper portion contacting the hinge joint of the cartilage did not change significantly even if enough pressure was applied. The cross-section of the E-tube lumen showed an almond shape. All cadaver samples had slit-like sharp upper space measuring about less than 1 mm. Therefore, the lower portion of the cartilaginous E-tube is considered the part that can be expanded.

Length and diameter of the overall Eustachian tube

Measurements of total volume and length of the cartilaginous portion of the dilated E-tube are presented in Tables 1 and 2. Figure 6 shows the average value for each dimension. The average intraluminal volume from nasopharyngeal ostium to pre-isthmus measured by a 3D CT scan was 1.4 cc (ranging from 0.7 cc to 2.5 cc).

We measured the total length of the cartilaginous E-tube in the anterior and posterior sides. The length of the anterior concave side was 26.3 mm (ranging from 21.4 mm to 32.2 mm) and that of the posterior convex side was 30.5 mm (ranging from 25.3 mm to 36.6 mm). The mean difference in the length between both sides was 4.2 mm. We cut the midpoint of the E-tube for measuring the cross-sectional height and width. The average cross-sectional height and width at nasopharyngeal ostium were 10.1 mm (ranging from 8.9 mm to 11.9 mm) and 8.0 mm (ranging from 6.1 mm to 11.0 mm). At the midpoint of the cartilaginous portion of the E-tube, the average height was 6.4 mm (ranging from 5.0 mm to 7.4 mm) and the average width was 3.3 mm (ranging from 2.1 mm to 4.0 mm). The pre-isthmus had 2.4 mm in height (ranging from 1.8 mm to 3.2 mm) and 1.3 mm in width (ranging from 0.6 mm to 1.9 mm). The cross-sectional analysis of the lumen at the isthmus in all samples was consistent in diameter, whereas there was a variable in the other portions of the lumen near nasopharyngeal ostium.

Cross-sectional information on where the balloon or stent is placed in E-tube

The configuration of the E-tube cross-sectional dimension in every 5 mm distance (P5, P10, P15, and P20) from nasopharyngeal ostium to 20 mm toward isthmus direction as well as the configuration of each cross-section are shown in Table 3 and Figure 7. The mean cross-sectional heights at four points of the E-tube were 8.37 mm, 7.02 mm, 5.95 mm, and 5.51 mm, respectively. The mean widths of each point were 5.33 mm, 3.46 mm, 2.65 mm, and 1.94 mm, respectively.

Table 1. Volume and distance from the nasopharyngeal ostium of the dilated E-tube in fresh human cadavers.

Side (number)	Total volume (cc)	Total length (mm) NO from pre-isthmus		Length (mm) *Midpoint from NO
		concave side	convex side	
R(1)	2.5	32.1	36.6	16.0
R(2)	1.5	30.7	34.1	15.4
R(3)	1.6	29.4	33.4	14.7
R(4)	1.8	22.1	25.3	11.0
L(5)	1.3	28.4	34.2	14.2
L(6)	2.0	29.4	33.0	14.7
R(7)	1.6	26.0	31.6	13.0
R(8)	1.0	24.9	30.9	12.4
L(9)	1.1	23.4	25.3	11.7
L(10)	0.7	24.0	2738	12.0
R(11)	0.9	21.4	25.8	10.7
R(12)	1.0	28.3	32.0	14.1
L(13)	1.1	24.6	28.6	12.3
R(14)	0.8	23.8	28.2	11.9
Mean	1.4	26.3	30.5	13.2
Min	0.7	21.4	25.3	10.7
Max	2.5	32.2	36.6	16.1

NO; nasopharyngeal ostium, R; right, L; left, *midpoint of total length in the concave side

Table 2. Cross-sectional dimensions in silicone molding of dilated E-tube.

Side (number)	Nasopharyngeal ostium (NO)		Midpoint between NO and Pre-isthmus		Pre-isthmus	
	Height (mm)	Width (mm)	Height (mm)	Width (mm)	Height (mm)	Width (mm)
R(1)	11.1	10.0	6.7	3.6	2.1	1.9
R(2)	11.1	9.5	6.7	3.6	2.3	0.7
R(3)	11.9	8.8	5.0	3.5	2.5	0.7
R(4)	11.0	6.5	6.5	3.4	2.3	0.9
L(5)	9.4	7.6	5.8	2.9	1.8	1.9
L(6)	10.0	11.0	7.4	4.0	2.0	0.6
R(7)	9.5	9.0	6.7	4.0	2.5	0.8
R(8)	9.7	6.7	6.9	3.6	3.2	1.2
L(9)	10.3	7.9	6.9	2.9	2.3	1.8
L(10)	9.7	6.8	5.2	2.4	2.9	1.4
R(11)	9.8	7.2	7.2	3.6	2.5	1.5
R(12)	9.9	7.9	6.3	2.5	2.1	1.7
L(13)	9.4	6.1	5.6	3.6	2.4	1.1
R(14)	8.8	7.0	7.0	2.1	2.3	1.6
Mean	10.1	8.0	6.4	3.3	2.4	1.3
Min	8.9	6.1	5.0	2.1	1.8	0.6
Max	11.9	11.0	7.4	4.0	3.2	1.9

NO; nasopharyngeal ostium, R; right, L; left

Table 3. Cross-sectional dimensions of the segmented E-tube from nasopharyngeal ostium(NO) to the isthmus direction (P5; 5 mm from the NO, P10; 10 mm from the NO, P15; 15 mm from the NO, P 20; 20 mm from the NO).

Side (number)	P5		P10		P15		P20	
	Height (mm)	Width (mm)	Height (mm)	Width (mm)	Height (mm)	Width (mm)	Height (mm)	Width (mm)
R(1)	8.7	5.8	9	4.7	6.8	3.1	6	2.3
R(2)	8.9	6.1	7.3	4.5	7.1	3.4	6.8	2.9
R(3)	7.4	5.4	6.7	2.8	6.3	2.5	6.2	1.4
R(4)	8.3	5.1	8	3.4	5.8	2.3	5.3	1.7
L(5)	6.7	4.7	5.1	2.8	4.7	2.5	5	1.9
L(6)	9.7	7.2	8	4.7	7.1	3.5	6.5	3
R(7)	8.5	5.1	6.4	4.2	6.4	3.3	5.8	2.3
R(8)	7.8	5.5	6.6	4	5.8	3	5.7	1.9
L(9)	8.4	4.6	7.1	2.9	7.4	2.3	6.4	1.8
L(10)	9.2	5.1	6.1	2.5	4.7	1.3	3.9	0.8
R(11)	8.8	5.4	6.8	3.1	5	2.2	4.3	1.8
R(12)	8.5	4.8	7.3	2.7	5	2	4.4	1.5
L(13)	8.9	5.8	6.7	3.9	6.5	3.9	6.5	2.4
R(14)	7.4	4	7.2	2.3	4.7	1.8	4.3	1.4
Mean	8.37	5.33	7.02	3.46	5.95	2.65	5.51	1.94
Min	6.70	4.00	5.10	2.30	4.70	1.30	3.90	0.80
Max	9.70	7.20	9.00	4.70	7.40	3.90	6.80	3.00

NO; nasopharyngeal ostium, R; right, L; left

Figure 1. Sagittal anatomy of a human fresh frozen cadaver. 1. sphenoid sinus, 2. nasal septum, 3. soft palate, 4. hard palate, 5. tongue, 6. epiglottis, 7. pituitary gland, 8. torus tubarius 9. nasopharyngeal ostium of E-tube, 10. vertebrae, 11. oropharynx

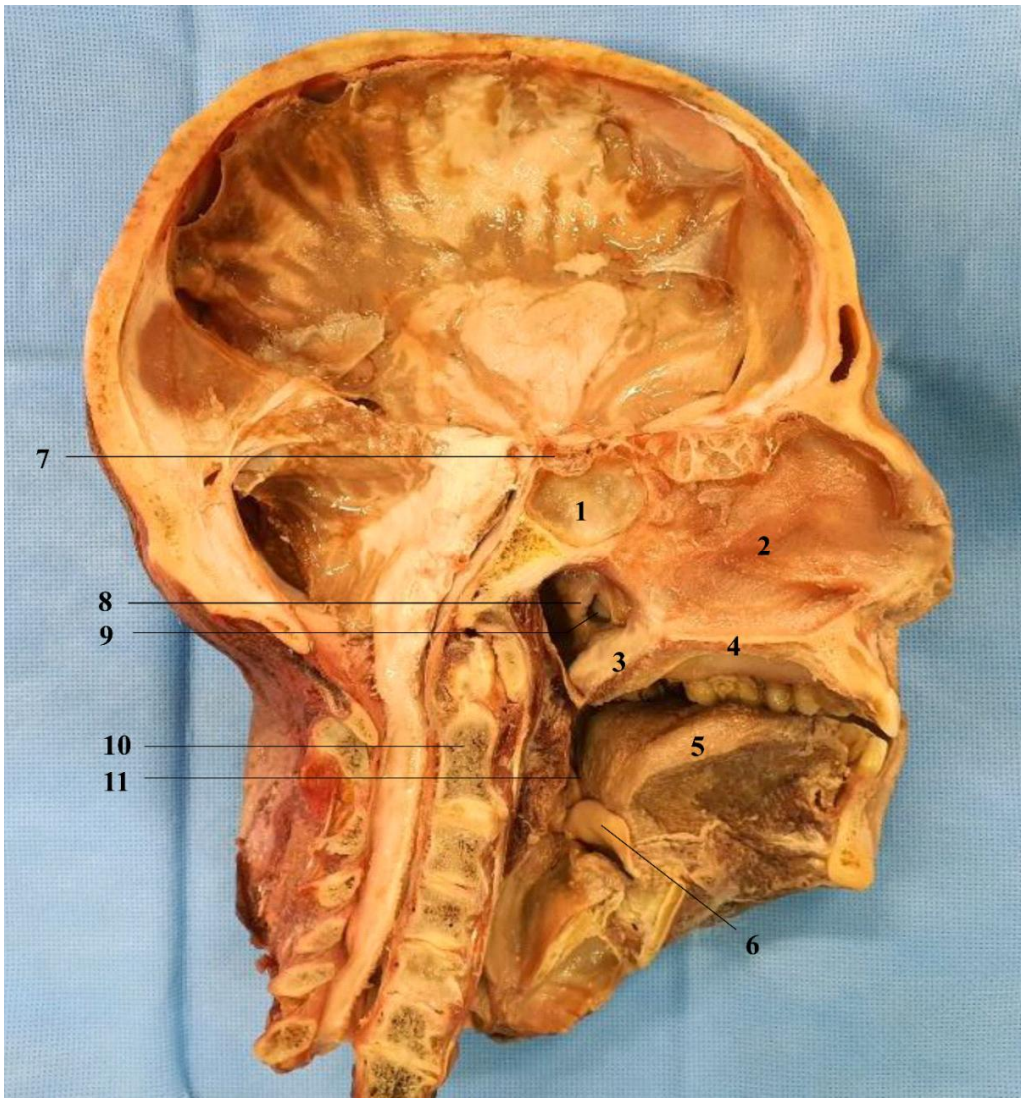


Figure 2. (a) Nasopharyngeal ostium of E-tube in the right ear was identified. (b) The silicone material was injected until it completely covered the mucosa of the nasopharyngeal orifice. (*: lateral lamina cartilage, **: medial lamina cartilage, arrow: hinge joint of cartilage, yellow dotted line: vertical axis of the ostium)

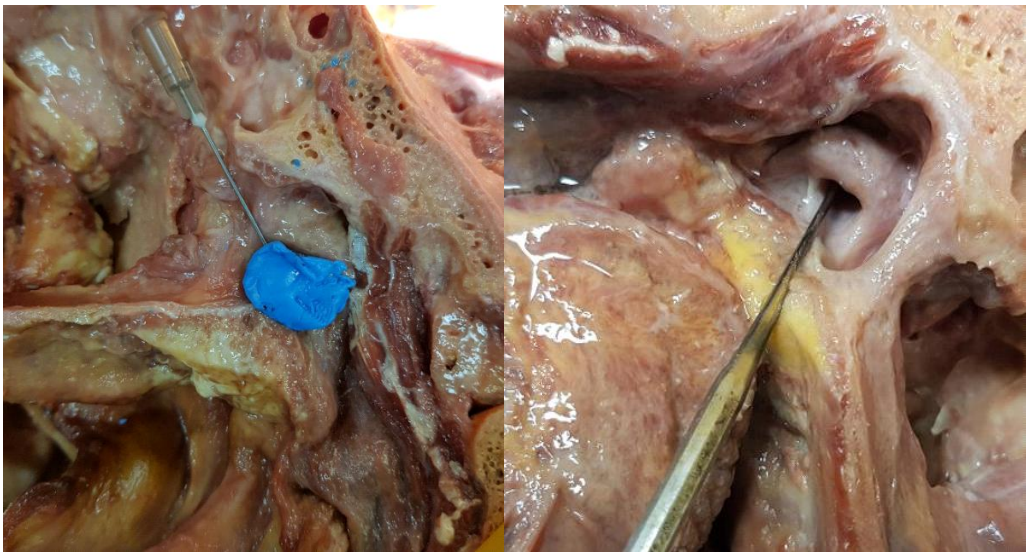


Figure 3. 3D CT images of E-tube silicone

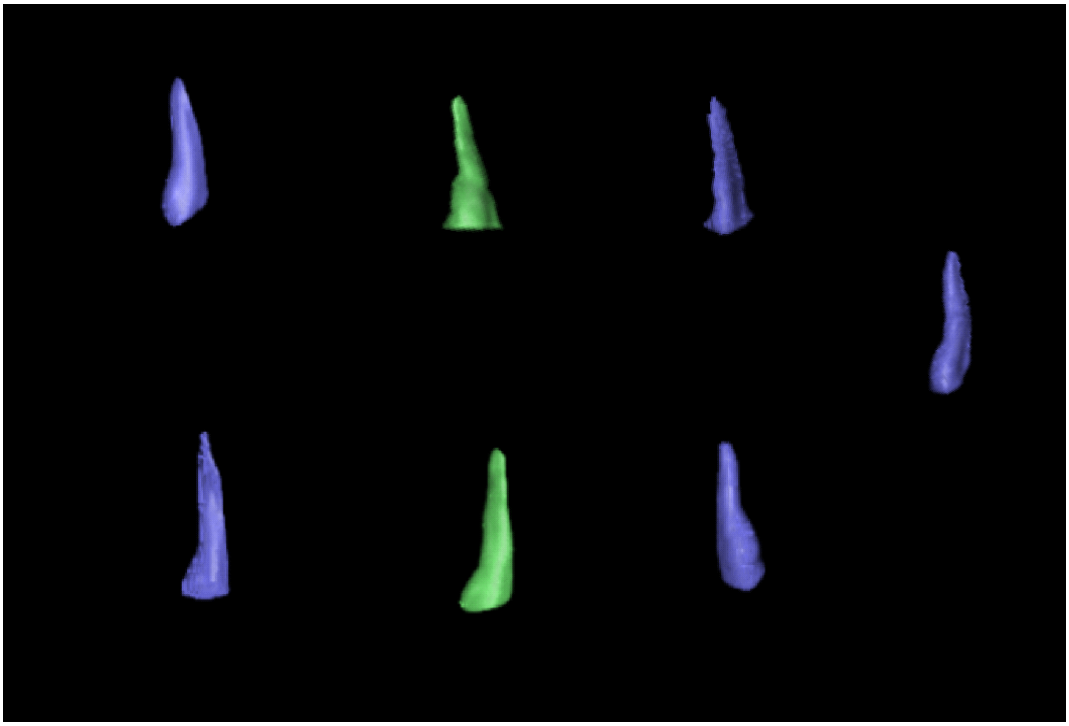


Figure 4. Measurement of height and width of the E-tube cross-sectional view. The E-tube was divided into 5 mm intervals from the nasopharyngeal ostium (NO) to 20 mm. (a) Length and width at the 5 mm from the NO, (b) 10 mm from NO, (c) 15 mm from NO, (d) 20 mm from NO.

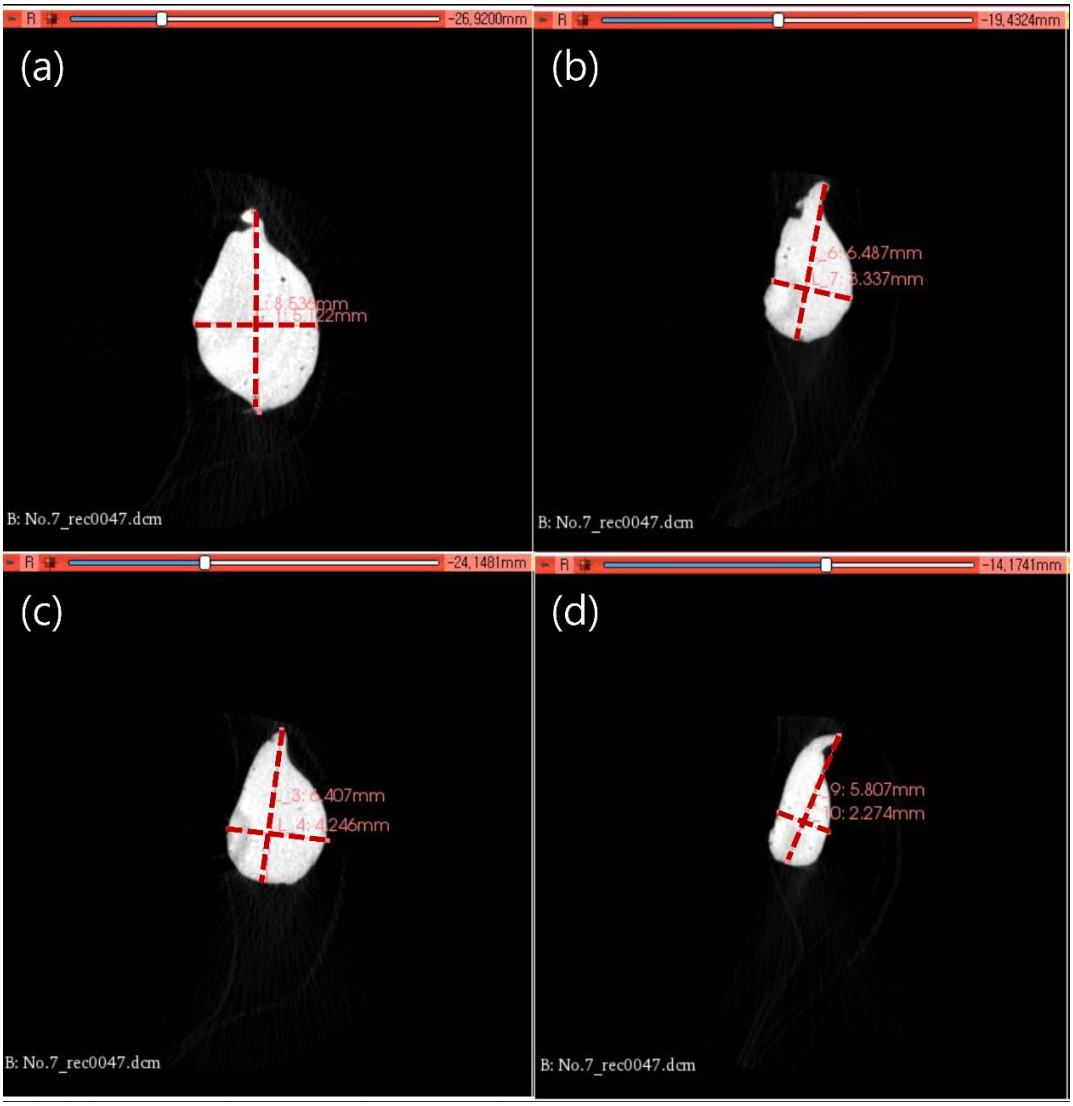


Figure 5. E-tube configuration in various aspects. The pin clip marks the hinge joint between medial and lateral laminae of E-tube cartilage, and it indicates the upper direction of the E-tube. (NO; nasopharyngeal ostium, Isth; isthmus)

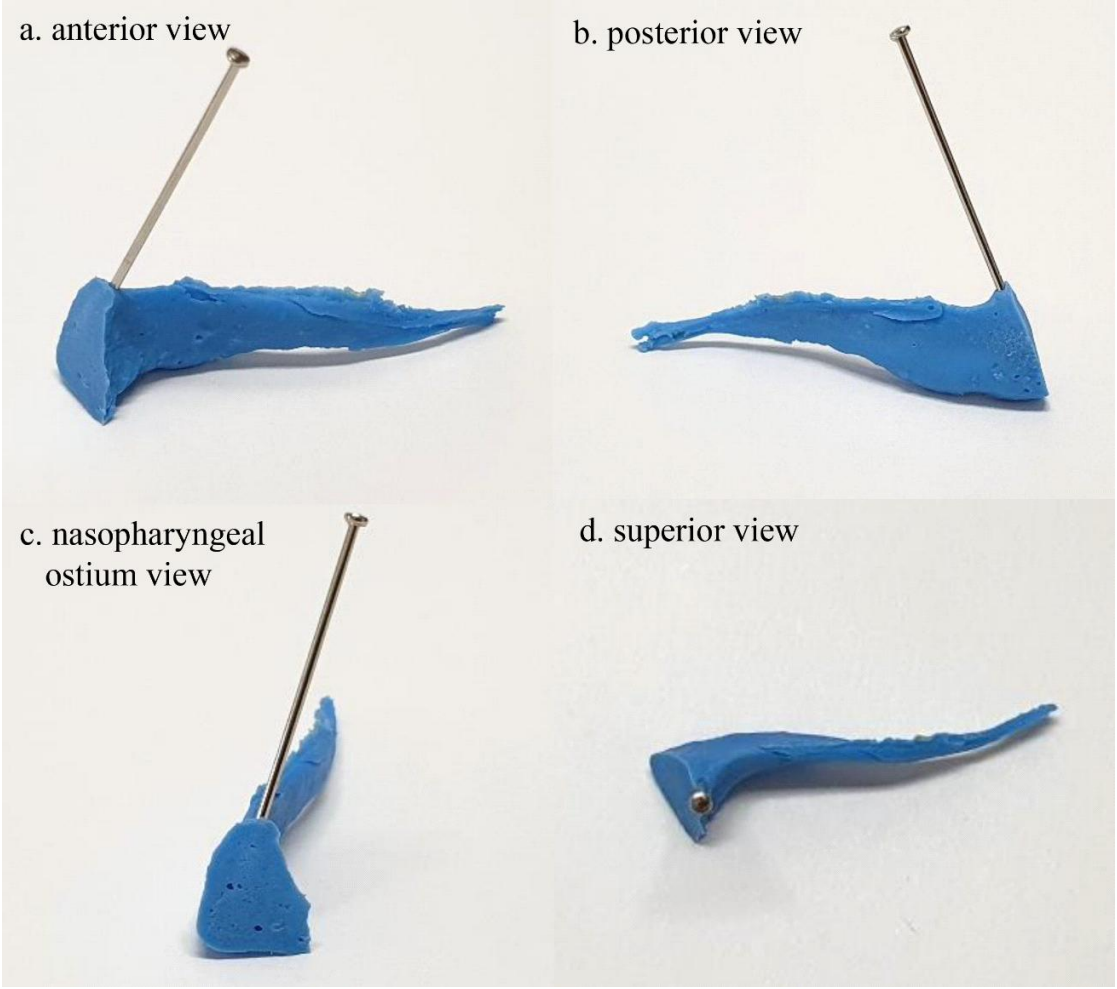


Figure 6. Average dimensions for left E-tube silicone samples on anterior view. The pin clip marks the hinge joint between medial and lateral laminae of E-tube cartilage, and it indicates the upper direction of the E-tube.

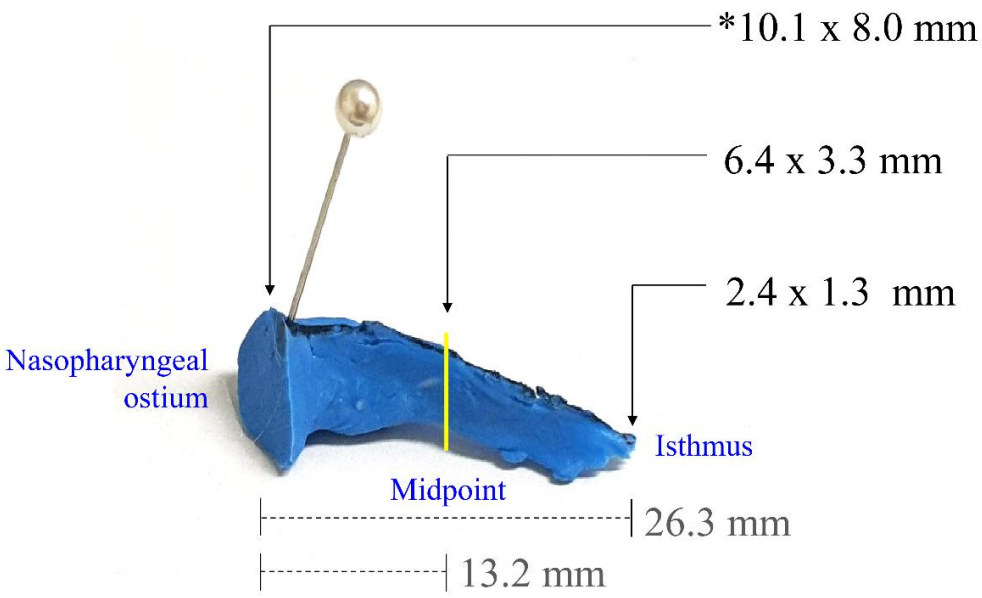
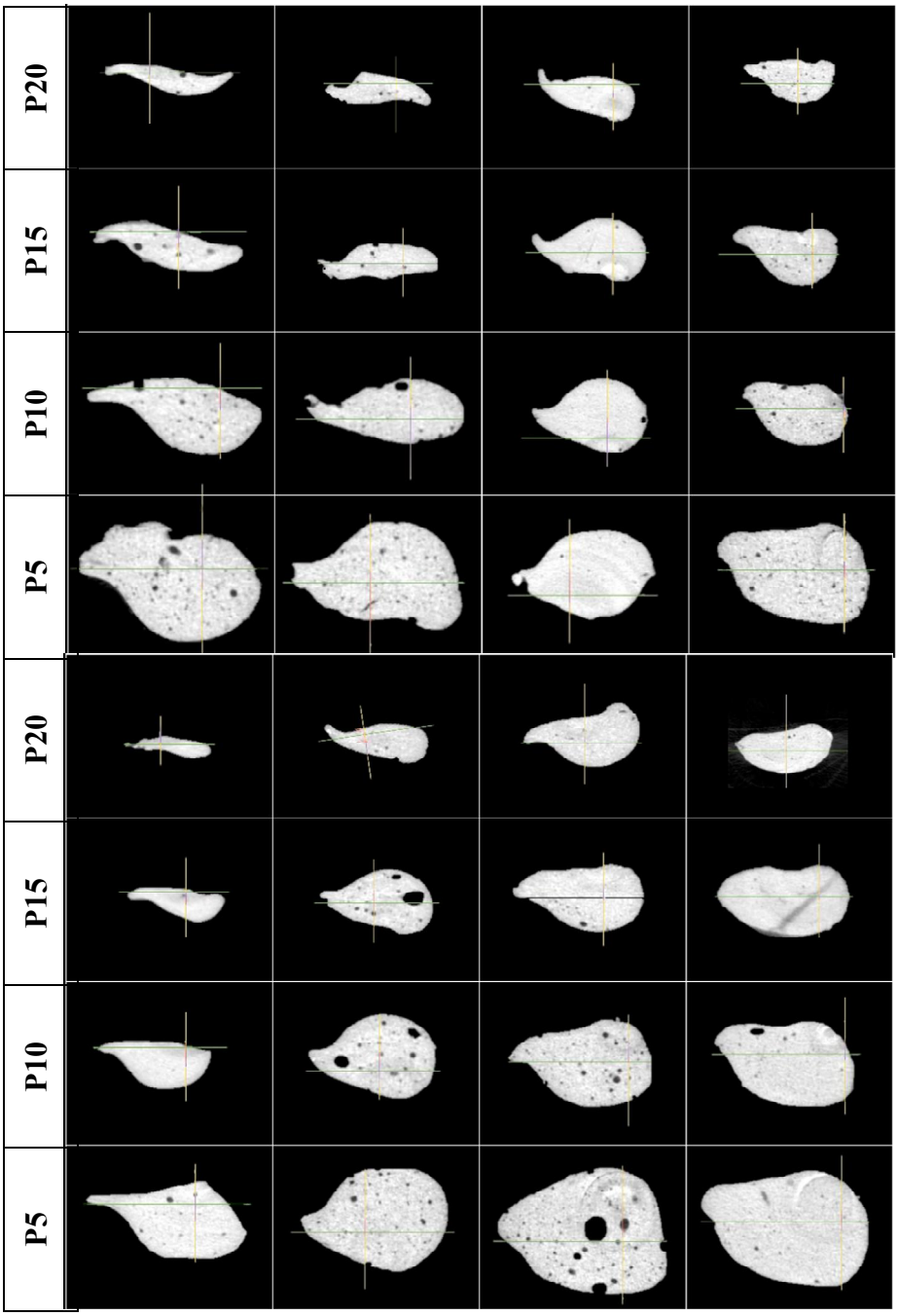


Figure 7. Cross-sectional views of E-tubes (P5; 5 mm from NO, P10; 10 mm from NO, P15; 15 mm from NO, P20; 20 mm from NO).



DISCUSSION

E-tube is the only connection between the pharynx and the middle ear cavity. Renewed surgical treatments for obstructive E-tube dysfunction have been developed, focusing on direct intervention for E-tube patency. E-tube patency refers not only to how much E-tube is open, but also to make ideally normal middle ear cavity pressure. Recently, balloon dilation of the E-tube is being used as a minimally invasive technique using a balloon catheter to anatomically dilate the cartilaginous E-tube in support of middle ear ventilation [11]. In addition, E-tube stenting devices have been developed for insertion into a cartilaginous E-tube from the nasopharynx without elevating the tympanic membrane in preclinical trials. The insertion depth of balloon catheter or stenting devices needs accurate references for the E-tube configuration along its course. The cartilaginous portion of the E-tube is flexible and possible to dilate with a much larger diameter, whereas the bony portion of the E-tube is limited to dilate due to the vital structures like the internal carotid artery. The cartilaginous E-tube anatomy and its clinical significance have been investigated using human cadavers as well as radiologic studies, but a single modality cannot provide an overall anatomical understanding of the E-tube. Surgical intervention on the cartilaginous E-tube requires information on the anatomical dynamic ranges associated with the opening and closing of the E-tube. Most radiologic or histologic E-tube studies have measured the dimension of E-tube at resting, and it is limited to measure the opened E-tube condition. Therefore, more details about human cartilaginous E-tube anatomy should be specified.

We demonstrated the overall shape and dimension of the dilated E-tube by silicon insertion. In the previous histologic analysis, the E-tube lumen was usually considered to be “closed” at resting state. Manual dilation with silicone, presented 1-1.5 atm which was lower than usual balloon dilation pressure (10 atm), may have reflected the shape of E-tube lumen, when it was open or dilated with low pressure.

The craniomedial side of the E-tube is surrounded by tubal cartilage (lateral lamina anteriorly and medial lamina posteriorly), and the inferolateral side is surrounded by a membranous wall, mainly consists of the tensor veli palatine muscle (TVPM) and the levator veli palatine muscle (LVPM)[12]. E-tube cartilage is firmly connected with the skull base by suspensory ligaments. A dome between the short lateral lamina and long medial lamina of tubal cartilage is composed of the radial organization of elastic fibers which facilitates the motion of the lateral lamina. Contraction of the surrounding muscles moves the lateral membranous wall of the E-tube and the lateral lamina cartilage inferolaterally. Poe et al. described that the E-tube opens by dilation of the lateral wall of the E-tube, which alters the profile of the interior of the lumen from a crescent shape to a round shape [13]. When we observed the dilated E-tube lumen from the medial to lateral, the silicone dilation pressure was forced to expand into the posterolateral wall toward the lateral lamina of cartilage. Thus, the silicone molding of the dilated E-tube lumen had a concave side anteriorly, and the concavity of the anterior wall may be formed by the pressure of resistance from the musculo-membranous wall. E-tube dilation action mainly pushed backward, creating the convex curve posteriorly. This shape got narrower in a crescent shape, at the point of 15 mm from the nasopharyngeal ostium.

The Eustachian tubal lumen is comprised of two compartments: the Rüdinger′s safety canal and the auxiliary gap. A cranial space, the Rüdinger safety canal, is sited between the lateral and medial lamina of the cartilage, and the diameter of this space is about 0.4-0.5 mm [14,15]. The opening of the E-tube is limited to this space [12]. As the results of our study showed, the dilatory pressure did not expand this upper space of the lumen. The auxiliary gap, the inferior part of the lumen, mainly surrounded by the muscular and membranous walls, and it had an important role in contributing to dilation. Thus, the shape of the E-tube lumen got narrow from the medial to lateral, and it looked more triangle shape than round shape, showing a narrow top. A previous analysis about patulous E-tube by sitting 3-D CT showed E-tube lumen, traced lumen from the pharyngeal orifice to the tympanic orifice showed

similar shape with silicon E-tube of present study [16].

E-tube is an anatomically complex structure. The accurate measurement of its dimension is ambiguous according to the previous studies. The total length of the E-tube was from 31 to 44 mm in cadaver studies more than 60 years before [16,17]. They noted that two-third of the total length, measuring 24.6-25 mm, was considered as a cartilaginous part. In a length analysis by 3D reconstruction with temporal bone, conducted in the Japanese group in 2000, the distance from the cartilaginous portion was average 29.60 ± 3.37 mm, and the length of E-tube was defined as a curve connecting midpoints of the lumen in virtual sections [18]. The measured distance was similar to our observation of 30.5 mm in the length of the cartilaginous portion at the convex side. In a recent analysis of E-tube length, they compared the length of the cartilaginous portion between CT images and catheter measurements in 2018, and both had no significant difference [19]. The total length of the cartilaginous E-tube length was 26.7 ± 2.1 mm (range: 21.7~32.6) which was similar to our results for the length of the concave side, 26.3 mm (ranging from 21.4 mm to 32.2 mm). E-tube does not take a straight course through the petrous bone toward the middle, curving an inverted s shape. Therefore, curvature distance between nasopharyngeal ostium and isthmus can be estimated up to 30 mm, and direct distance between two points can be approximately 26 mm, usually measured with CT image. Thus, when using a 20 mm length balloon, the balloon may not widen enough near the isthmus portion. A balloon with a longer length can be considered. If the 20 mm length balloon is used, the proximal end of the balloon marked on the catheter (ex. proximal blue marker in Accelant catheter) should be inserted into the nasopharyngeal ostium. If the balloon is not fully inserted, the distal end of balloon may not reach at the distal portion of the cartilaginous E-tube.

According to previous literatures on the width of the isthmus, it is reported to be 0.2-1.5 mm, and its height is variously reported to be 2 to 3 mm [16]. The measured value of the dilated isthmus in the present study is 1.3 mm in width and 2.4 mm in height, which was similar to the previous studies. The average width of the nasopharyngeal ostium was reported from 4 mm to 5 mm, and the average height

has a range of 8 to 9 mm in height [16,20] Our study showed a mean width of 8.0 mm and the mean height of 10.1 mm, which were larger than the results of the previous studies. The difference may come from that the previous studies were measured in the closed state of the E-tube, and the present study measured under consistent pressure in an opened state. One study measured the dilated E-tube diameter by 6 mm diameter balloon catheter in different pressure conditions [21]. They reported that the proximal diameter reached 4.6 mm at 3 atm, and 5.3 mm at 10 atm in proximal diameter, and 3.6 mm and 4.9mm at 3 atm and 10 atm respectively in distal diameter. The difference from this study was observed because they measured the diameter of the dilated balloon (maximum diameter of 6 mm) under high pressure, not the dilated E-tube lumen. Balloon dilation under higher pressure may contribute to dilate the distal portion of the E-tube towards the isthmus, and the lower manual pressure could not affect sufficiently in this area. In summary, luminal analysis for E-tube was mainly measured in a closed state in previous studies or dilated status under high pressure (10 atm), the present study identified the dimension and morphology in being opened E-tube lumen with lower pressure (1 atm). Also, the measurement targets were usually for nasopharyngeal ostium, isthmus, and the bony portion of E-tube in studies to date that has investigated the E-tube anatomy. Few studies have analyzed the cross-sectional dimension and shape by dividing the cartilaginous E-tube into several parts.

The commercially available balloon dilation systems to treat E-tube dysfunction are various by the manufactures. The diameter of the inflated balloon ranges from 3~6 mm, and the length of the balloon is 16~20 mm by companies. Nominal pressure is specified in 10~12 atmospheres (ATM)[22]. A balloon with a 3 mm diameter was generally used for the dilation in European countries, whereas a 6mm balloon diameter was commonly used in the Unite State. They reported a similar success rate in balloon dilation for E-tube dysfunction. Therefore, it is not a matter of how large the balloon expands, but whether the depth or location of the balloon inserted into the E-tube is carefully assumed to be an important factor in the success of the expansion. When analyzing the length and cross-sectional

dimensions of the cartilaginous E-tube, the more than 20 mm portion from nasopharyngeal ostium is difficult to be affected by the current balloon length. A Japanese study demonstrated that the site of the minimum circumference of the E-tube lumen was always located in the cartilaginous portion of the E-tube, and the mean values of the circumference were 5.32 mm in adults, which was 24 mm apart from the nasopharyngeal ostium [23]. When using a balloon with a length of 20 mm, it is recommended that the catheter should be inserted deep enough so that the dilated balloon cannot be visible from the nasopharyngeal ostium. Given that previous studies had heterogeneity of balloon insertion depth or degree of balloon dilation by surgeons, it needs to be standardization [24]. In addition, the longer length and different shapes of balloon and catheter tip can be considered, taking into account the E-tube shape and dimensions shown in the present study. The 15 mm point from the nasopharyngeal ostium was identified as 2.6 mm or less. In obstructive E-tube dysfunction, it may be difficult to access near the isthmus, assuming this area is narrower. Therefore, the catheter and its tip should be made thinner than 2 mm in order to access near isthmus.

In E-tube stenting research, preclinical trials with animals were investigated to test the dimension of stenting for human application [25]. The stenting device into the cartilage portion of the E-tube can maintain the expanded status. In animal models, various types of E-tube stents were implanted and investigated. The stenting for the sheep model was designed with 2.0~2.7 mm in diameter and 20~26 mm in length [26]. Therefore, further research for humans on the size, length, thickness, shape, material, and fixation of the E-tube stenting device is evaluated, under the information identified from this study. The part that physiologically contributes to the expansion is the lower part of the E-tube lumen. A design of cross-section in an E-tube balloon or stent could be considered in a triangle shape or oval shape with a narrow top, rather than round shape. A shape which narrows toward the distal portion can contribute for the maintenance stability. Further directions for studying E-tube dilation include the development of a suitable balloon catheter or stenting design by comparing results using various types.

Fresh cadaver studies are useful for providing practical anatomical evaluation and detailed information, but the procedure for specimen management lead to the shrinkage of mucosa and cartilage tissue. This study was performed by one researcher and tried to insert silicon at the consistent pressure, but it has a limitation that the same pressure was not objectively applied in all samples. Also, the study was carried out with a small number of samples.

In summary, the study may be critical in understanding the anatomical dimension of the dilated E-tube and developing the subsequent stent or balloon design. It eventually serves as a basis for further investigation of E-tube treatment.

CONCLUSION

Surgical treatments for E-tube is promising, and various attempts have been made to analyze the configuration of E-tube regarding size, shape, and dilation range. Information on the volume and morphology of the E-tube from this study can contribute to developing the most suitable E-tube balloon catheter or stenting devices for dilation.

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Summary

Objectives: Various methods to evaluate the anatomical configuration for the Eustachian tube (E-tube) have been attempted. This study aimed to evaluate the E-tube configuration in human fresh cadavers.

Methods: Fourteen ears of human cadavers were used to identify the configuration of the E-tube. The cadaver head was cut in the sagittal plane parallel to the nasal septum, dividing it into right and left sides. Using a 10 ml syringe connected to a 200-μL pipette tip, impression material was filled inside the E-tube through the nasopharyngeal orifice. The blue impression material was identified through the tympanic cavity. The impression material in the E-tube was cured in the refrigerator for 6 hours. Before taking the impression material out of the E-tube, the superior and the anterior part of the impression at the level of the nasopharyngeal ostium (NO) were marked. The volume and length of the impression were measured using 3D CT imaging. The shape and cross-sectional dimension of the E-tube from the nasopharyngeal ostium to 20 mm, where the ear canal balloon or catheter is commonly inserted, was also analyzed.

Results: The E-tube narrowed from the NO to the isthmus. The E-tube surface was concave anteriorly and convex posteriorly. The most dilated portion was the lower portion of the E-tube, and it had an upper ridge along the tubal passage. The average volume of the E-tube impression was 1.4 ± 0.5 ml (min: 0.7, max: 2.5). The total length of the convex side was 30.5 ± 3.6 mm (min: 25.3, max: 36.6) and that of the concave side was 26.3 ± 3.4 mm (min: 21.4, max: 32.2). The widest E-tube area near the NO presented 10.1 ± 0.9 mm (min: 8.9, max: 11.9) in height, and 8.0 ± 1.5 mm (min: 6.1, max: 11.0) in width. The medial end near the E-tube pre-isthmus was 2.4 ± 0.4 mm (min: 1.8, max: 3.2) in height, and 1.3 ± 0.5 mm (min: 0.6, max: 1.9) in width. The cross-section of the E-tube from the NO to 20 mm was observed generally narrow in the upper part and wide in the lower part. At 5 mm from the NO, the height and width were 8.37 mm and 5.33 mm, respectively. The height and width of the E-tube at 20 mm from the NO were 5.51 mm and 1.94 mm, respectively.

Conclusion: E-tube dilatation is a promising technique, and various attempts have been made to analyze the configuration of E-tube regarding size, shape, and dilatation range. Anatomical configuration on the volume and morphology of the E-tube from this study can contribute to developing the most suitable E-tube balloon catheter and stent for dilatation.