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### ABSTRACT

**Objective:** The purpose of this study is to evaluate the safety and feasibility of a novel treatment for chronic Eustachian tube dysfunction (ETD). Through radiographic and cadaveric analysis, we have sought to develop a new technique for inoffice endoluminal treatment of Eustachian tube dysfunction we term endoscopic balloon Eustachian tuboplasty (EBET).

Methods: Radiographic analysis of 33 sequential high-resolution CT scans using Voxar threedimensional (3-D) reconstruction software was performed to characterize the lengths and angles of different anatomical reference points from the nasal spine through the bony ET. Thereafter, the safety and feasibility of the use of a dilation catheter was evaluated in four human cadaver heads. CT scans obtained before and after EBET were analyzed for both evidence of catheter-induced trauma and efficacy of dilation.

**Results**: The distance from the nasal spine to the anterior cushion of the pharyngeal ostium (ACPO) of the ET and the total length of the cartilaginous portion of the ET averaged 71.5 and 27.9 millimeters, respectively. The mean angle from the posterior septum to ACPO was 135.7 degrees. Using these measurements, a balloon-dilation catheter was utilized to target the cartilaginous ET and its valve portion. Catheters successfully dilated all eight of the ET in the cadaver heads. CT scan demonstrated that dilation caused no trauma to surrounding structures, specifically the carotid canal. Furthermore, there was subjective evidence that EBET expanded the endoluminal area of the cartilaginous ET.

Conclusion: This initial study suggests that endoluminal dilation of the Eustachian tube can be done safely. Additional testing in patients is indicated to gain further safety information and to investigate the efficacy of endoscopic balloon Eustachian tuboplasty for chronic ETD in adults.

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# **Endoscopic Balloon-Dilation of the Eustachian Tube: Safety and Feasibility**

### INTRODUCTION

The insertion of pressure equalization tubes (PET) has been the mainstay of surgical treatment for chronic Eustachian tube dysfunction (ETD).

While PET placement is often effective at treating the pressure disequilibrium between the middle ear and external auditory canal, it effectively bypasses the ET and offers no treatment to the presumed cause of the problem. Additionally, PET are associated with known complications such as otorrhea, myringosclerosis and tympanic membrane perforation.<sup>1</sup>

Recently, Poe and others have examined the pathophysiologic process of ETD and have agreed with earlier researchers that the cause of dysfunction occurs in the cartilaginous portion of the ET.<sup>2</sup>

Other advances in balloon catheter-based treatment techniques, in the areas of tracheal stenosis, chronic sinus disease, and esophageal strictures have expanded the surgical armamentarium.<sup>3</sup>

The purpose of this investigation is to explore the safety and feasibility of endoscopically-guided balloon catheter dilation of the ET lumen we term endoscopic balloon Eustachian tuboplasty (EBET).

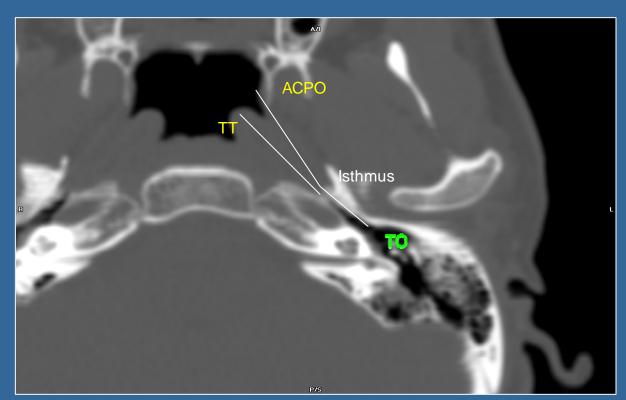


Figure 1. Double Oblique MPR image of Eustachian tube. Anatomic reference points and measurements. Anterior cushion pharyngeal orifice (ACPO), Torus tubarius (TT), Tympanic orifice (TO).

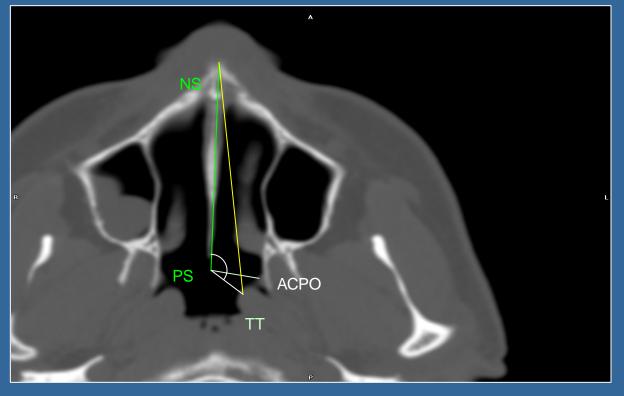


Figure 2. Double Oblique MPR image of Eustachian tube. Anatomic reference points and measurements. Nasal spine (NS), Posterior septum (PS), Torus tubarius (TT), Anterior cushion pharyngeal orifice (ACPO)

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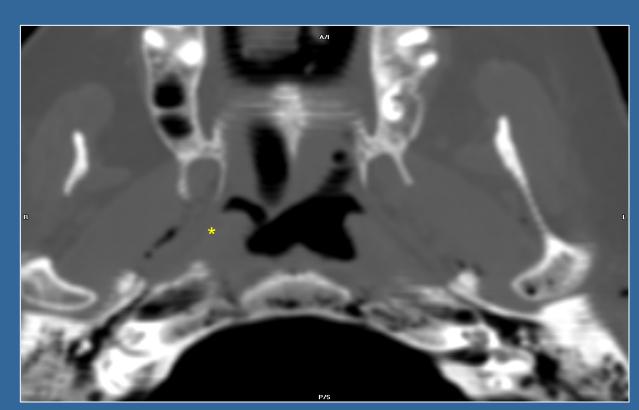
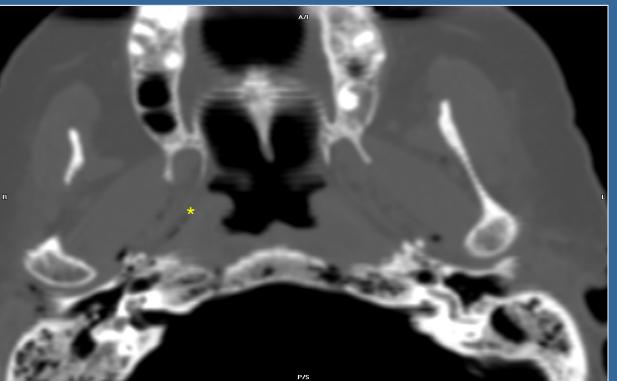


Figure 3. Pre-dilation Double Oblique MPR. Right Eustachian tube (\*) shows no aeration.



**Figure 4.** Post-dilation Double Oblique MPR. Right Eustachian tube (\*) shows aeration.

### METHODS AND MATERIALS

The study group consisted of 33 patients' high resolution computed tomography (CT) scans with normal Eustachian tube anatomy.

Radiographic analysis was performed on the 66 Eustachian tubes of these 33 patients (19 males, 11 females; mean age 58 years; range 38-86 years). The axial CT images from each patient were inputted into the Voxar 3D software for multiplanar reconstruction (MPR) analysis.

Double oblique MPR images (Figures 1 and 2) of each Eustachian tube from the pharyngeal orifice to the tympanic orifice were made to perform precise measurements of anatomic reference points.

These anatomic reference points were then used to accurately execute an endoscopic balloon-dilation of the ET in four human cadaver heads to test its safety and utility.

An Olympus ENF-T3 rhinolaryngoscope with 2.2 mm forceps channel and an inflated-diameter 3.0 mm x 20 mm Maverick<sup>2</sup> Monorail angioplasty balloon catheter were utilized. The balloon was inflated to 4 atmospheres of pressure.

Pre- and post- EBET CT scans were obtained and then imported into the Voxar 3D software for MPR analysis. They were reviewed for any evidence of trauma to the carotid canal.

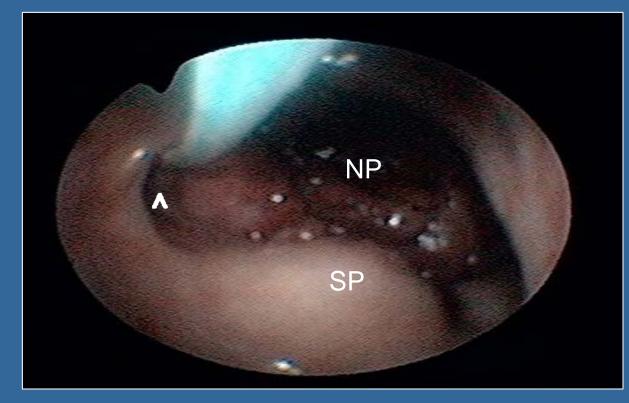
The mean values and standard deviations (SD) of the various lengths and angles corresponding to the anatomic reference points are given in Table 1.

All eight cadaver Eustachian tubes were successfully dilated with the endoscopically-guided balloon catheter.

No evidence of trauma to surrounding bony structures including the carotid canal was noted on post-dilation CT scans.

No comparable data for ET lumen diameter is available for pre- and post-dilation CT scans.

ET lumen.



Anatomical Reference Points
NS - PS
PS - ACPO
NS - TT
PS - TT
ACPO - Isthmus
TT - Isthmus
Isthmus - TO
Anatomical Reference Points
Angle PS -ACPO
Angle PS - TT

**Table 1.** Lengths and angles of different anatomical
 reference points from the nasal spine through the bony ET. Nasal spine (NS), Posterior septum (PS), Anterior cushion pharyngeal orifice (ACPO), Torus tubarius (TT), Tympanic orifice (TO).

### RESULTS

One set of images from MPR analysis of pre- and postdilation CT scans has been included for subjective review. Within these double oblique reconstructions (Figures 3 and 4), there does appear to be increased aeration in the

The mean length of the ET in this study was 40.5 mm with the cartilaginous portion representing 27.5 mm and the osseous section accounting for 12.6 mm. This corresponds to previously reported data.<sup>4,5</sup>

The mean angle of the torus tubarius reported in this study was 135.7 degrees with a sagittal line drawn through the nasal septum. Therefore, the rhinolaryngoscope with its 130 degrees of rotation and forceps channel was ideally suited for introducing the balloon catheter into the ET.

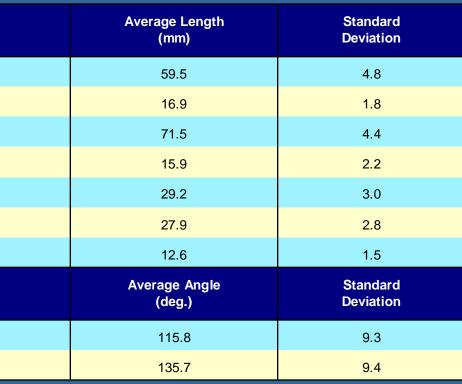
Since the valve of the ET, in the present radiographic analysis, was located on average 17.9 - 22.9 mm from the torus tubarius of the pharyngeal orifice, a 20 mm balloon length was selected for optimal placement of the balloon at the valve and proximal to the carotid canal. A balloon diameter of 3.0 mm was chosen based on previous measurements of the lumen width at this location to be around 2 x 1 mm.<sup>4</sup>

The most important result of the study is that the carotid canal sustained no inadvertent trauma from balloon dilation. The proximity of the internal carotid artery must be respected when considering endoluminal treatment of the ET.

The pre- and post- dilation CT scans were unable to be compared accurately because of several variables: condition of cadaver head, positioning changes on CT scanner, location of measurement.

Furthermore, endoluminal diameter of the ET, as a correlate of functional status, has not been studied in vivo.

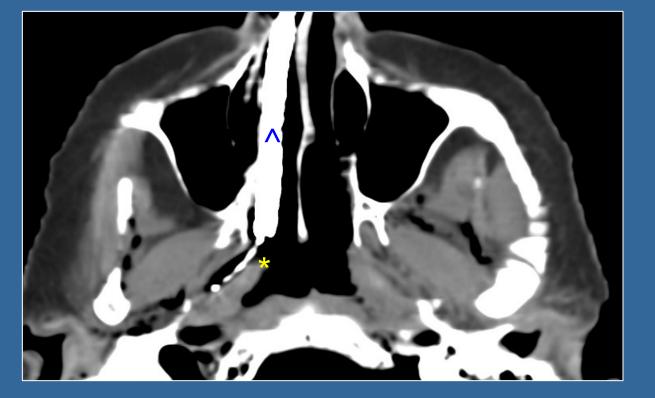
Figure 5. Endoscopic view of balloon catheter in right eustachian tube (^). Nasopharnyx (NP) Soft palate (SP)





Endoscopic balloon Eustachian tuboplasty (EBET) offers the promise of a direct treatment of Eustachian tube dysfunction in adults. If it proves to be a low cost, low morbidity option for patients with chronic ETD, it might avail otolaryngologists with this difficult problem. Further investigation needs to be performed to fully evaluate its potential clinical impact. From this study, low risk to the internal carotid artery and carotid canal should be expected from this intervention. However, this potentially serious complication should always be considered when engaging in endoluminal treatment of the ET.

**Figure 6**. Experimental Setup showing endoscope and balloon catheter in place in human cadaver head



**Figure 7.** Double oblique MPR image showing endoscope (^) in right nasal cavity with inflated balloon catheter (\*) extending into right Eustachian tube.

### DISCUSSION

### CONCLUSIONS

### REFERENCES

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