Acta Scientific Otolaryngology (ISSN: 2582-5550)

Volume 8 Issue 4 April 2026

Research Article

Cadaveric Evaluation of a Novel Everting-Membrane Balloon for Eustachian Tube Dilation

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DOI: 10.31080/ASOL.2026.08.0802

Received: March 18, 2026

Published: May 22, 2026

Abstract

Objective: Balloon dilation of the cartilaginous Eustachian tube (ET) has emerged as a therapeutic option for obstructive ET dysfunction following the foundational cadaveric work by Poe., *et al*. which demonstrated feasibility and significant luminal expansion but reported mucosal injury in a subset of specimens [1]. Early clinical translation followed shortly thereafter. Catalano., *et al*. reported one of the first human clinical series evaluating balloon catheter dilation of the Eustachian tube [2]. Given ongoing concerns regarding tissue trauma and safety—particularly in anatomically narrow Eustachian tubes—a novel everting-membrane balloon (Tracker™) was developed to minimize axial advancement forces and improve intraluminal pathway conformity.

Methods: A cadaveric protocol analogous to prior ET balloon studies was applied to 17 adult human cadaveric ETs across two cohorts. Balloon dilation was performed endoscopically at 6 atmospheres for 2 minutes. Pre- and post-dilation computed tomography (CT), contrast instillation, endoscopic inspection, and detailed gross anatomical dissection were performed to assess luminal dimensions and tissue effects.

Results: All cartilaginous ETs were successfully dilated. Mean luminal diameter increased from 2.31 mm pre-dilation to 5.37 mm post-dilation, with a mean increase of 3.06 mm. Calculated intraluminal volume increased from a pre-dilation range of 0.09–0.16 cm^3 to a post-dilation range of 0.27–0.88 cm^3, representing volume increases of 132–857%, comparable to or exceeding those reported in the foundational Poe cadaver study. Magnified gross, endoscopic and radiologic inspection identified a 0% rate of mucosal tears, cartilage fractures, or osseous injuries.

Conclusions: Balloon dilation of the cartilaginous ET using an everting-membrane design was feasible and produced substantial luminal expansion without evidence of mucosal or structural injury in this cadaveric model. These findings support the mechanical viability of this balloon architecture and justify further clinical investigation [1].

Keywords: Eustachian Tube Dilation; Balloon Catheter; Tracker™ Balloon; Otitis Media; Cadaver Study; Safety

Introduction

Obstructive Eustachian tube dysfunction (OETD) affects both pediatric and adult populations and is associated with recurrent otitis media with effusion, conductive hearing loss, barochallenge intolerance, and chronic middle ear disease. Conventional management strategies—including medical therapy, adenoidectomy, myringotomy, and tympanostomy tube placement—provide symptomatic relief but do not directly address Eustachian tube dysfunction [6,7].

Balloon dilation of the Eustachian tube (BDET) is a minimally invasive approach intended to directly target obstruction within the cartilaginous portion of the Eustachian tube. Clinical studies have demonstrated improvements in tympanometric outcomes, middle ear ventilation, and patient-reported symptoms, leading to regulatory approval for adult use and, expanded indications in pediatric patients. However, the underlying mechanical and biological mechanisms of balloon dilation remain incompletely understood, and optimal device design parameters continue to evolve [2,11].

Importantly, despite widespread clinical use, only one published cadaveric study has directly demonstrated and quantified luminal dilation of the cartilaginous Eustachian tube using balloon technology. In their foundational work, Poe and colleagues evaluated balloon dilation in fresh human cadaver heads and demonstrated feasibility, reporting a mean increase in intraluminal volume from 0.16 cm^3 to 0.49 cm^3. That study also documented mucosal injury in approximately 19% of dilated specimens. As such, the Poe cadaver study remains the primary preclinical benchmark against which subsequent Eustachian tube dilation technologies must be interpreted [1].

Since that initial report, multiple commercial balloon systems have entered clinical use; however, no additional cadaveric studies have been published that directly demonstrate Eustachian tube dilation or quantify luminal changes using balloon devices. As a result, contemporary device development has proceeded largely without comparative preclinical data evaluating whether newer balloon designs achieve mechanical dilation equivalent to the original cadaveric benchmark, or whether design modifications may influence tissue interaction and injury risk.

The Tracker™ balloon was developed to address potential limitations of conventional Eustachian tube balloon systems, which rely on axial advancement of an inflatable balloon into the tubal lumen. The Tracker™ employs an everting membrane design that deploys by controlled unrolling after intraluminal positioning, allowing the balloon to follow the native axis of the Eustachian tube while minimizing axial advancement forces [3,8-10].

The present study was designed to evaluate this novel balloon architecture in a cadaveric model, using the Poe cadaver study as the historical comparator. Given the absence of tissue recoil, remodeling, or physiologic response in cadaver specimens, this investigation is intentionally limited to assessment of mechanical dilation and tissue interaction. No conclusions regarding clinical efficacy or long-term outcomes are implied.

Study aims

The objectives of this cadaveric investigation were:

- To describe the design and deployment mechanism of the Tracker™ everting-membrane Eustachian tube balloon [3,9].
- To evaluate whether the Tracker™ balloon achieves cartilaginous Eustachian tube dilation comparable to that reported in the foundational Poe cadaver study.
- To assess mucosal integrity and gross tissue effects following dilation with the Tracker™ balloon in a cadaveric model.

Materials and Methods

Study design and rationale

This study utilized a human cadaveric model to evaluate the mechanical effects of dilation and device–tissue interaction associated with the Tracker™ balloon. Cadaver testing was selected to permit direct endoscopic visualization, computed tomographic (CT) measurement, and gross anatomical dissection of the Eustachian tube following dilation.

Post-dilation measurements obtained in this study were interpreted relative to the volumetric and dimensional changes reported by Poe., *et al*. which serves as the historical benchmark for Eustachian tube balloon dilation [5].

Cadaver specimens

Two cadaveric cohorts were included. The first cohort consisted of three frozen, un-embalmed adult cadaver heads bisected in the

midline sagittal plane, yielding six Eustachian tube specimens; one specimen was excluded due to distorted anatomy. The second cohort consisted of six additional adult cadaver heads, similarly, bisected to yield twelve Eustachian tube specimens. All specimens were thawed prior to experimentation.

Figure 1A and 1B depict the cadavers and highlight the eustachian tube.

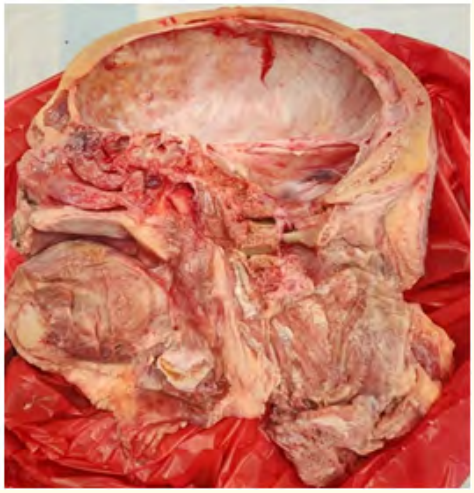

Figure 1A: A half-headed adult cadaver cut in the sagittal plane, with brain and additional contents removed from the skull.

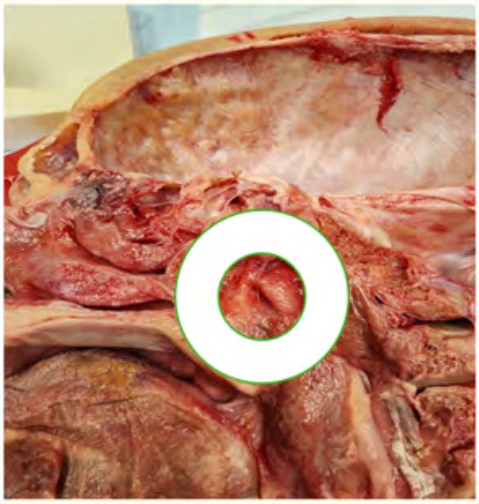

Figure 1A: A half-headed adult cadaver cut in the sagittal plane, with brain and additional contents removed from the skull.

Pre-dilation assessment

Pre-dilation CT imaging (Xoran MiniCAT) and endoscopic visualization (0° and 30° Hopkins rod endoscopes, 4mm, 3-chip CCD camera) were performed to ensure patency of the ET and confirm the absence of ear or nose pathology. Initial measurements of ET diameter were taken via CT by placing the half-head in the supine position. A wire was inserted into the ET to aid in the identification of the cartilaginous tubal lumen and postprocedural image comparison. All CT scans were obtained in the axial plane with a 0.625 mm slice thickness (Figure 2).

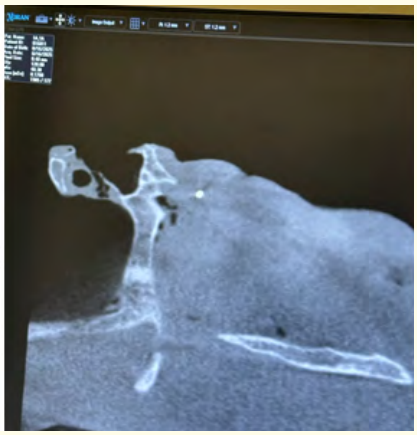

Figure 2: An image of a CT where a guide wire was inserted into the Eustachian Tube for identification. There is a small white line and dot in the lumen of the eustachian tube where the wire appears as hyperdense. The lumen was too narrow to measure.

Balloon dilation procedure

The Tracker™ balloon catheter was introduced directly into the Eustachian tube orifice under endoscopic visualization. The device consists of a flexible catheter housing an everting balloon membrane that deploys by controlled unrolling once positioned at the entrance of the torus tubaris. In a clinical setting, access to the ET is obtained through the nasal cavity by passing a eustachian tube balloon dilation catheter with a 30° tip angle along the floor of the nasal cavity. In this study, the Tracker™ balloon was inserted directly into the ET orifice, and the balloon catheter (6 mm outer diameter, 3.5 cm length) was inflated to 6 atm for 2 minutes. Starting with cadaver 9 of cohort 2, a 3.5-mm Tracker™ balloon was used for all subsequent specimens. The process is depicted in Figures 3-4B. The process is depicted in (Figures 3-4B).

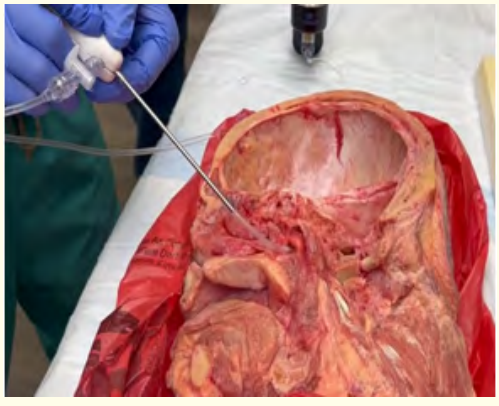

Figure 3: A half-headed headed adult cadaver cut in the sagittal plane with a physician performing Eustachian Tube dilation with the Tracker device.

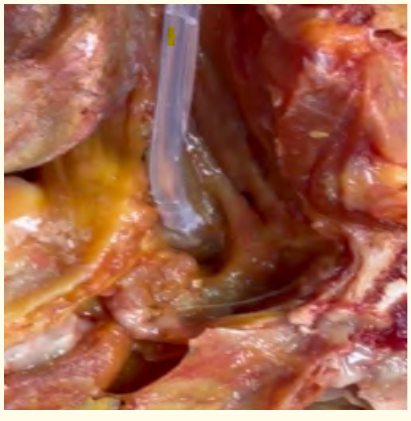

Figure 4A: A focused image where the Tracker device is dilating the Eustachian Tube and can be seen inflated within the lumen.

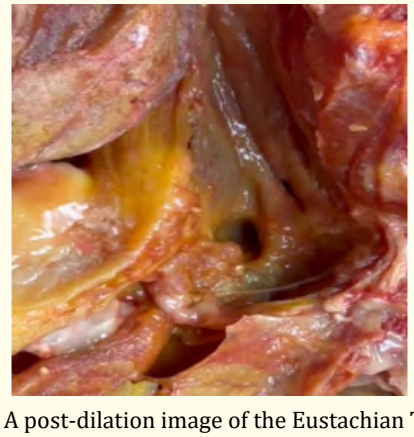

Figure 4B: A post-dilation image of the Eustachian Tube mucosa from Figure 4A that shows a markedly increased diameter and successful dilation.

Post-dilation evaluation

Following dilation, Omnipaque contrast was instilled into the Eustachian tube to confirm luminal patency. Post-dilation CT imaging was obtained using identical acquisition parameters to pre-dilation scans. Luminal diameters were measured at standardized locations along the cartilaginous Eustachian tube. Volumetric calculations were performed using established assumptions regarding cartilaginous Eustachian tube length, consistent with prior cadaveric literature [8]. All post-dilation CT scans were independently reviewed by a board-certified neuroradiologist to evaluate for osseous injury involving the temporal bone, basisphenoid, or pterygoid plates (See Figure 2).

Endoscopic inspection was performed to assess mucosal integrity immediately following dilation. Each specimen subsequently underwent gross anatomical dissection under magnification, including circumferential and longitudinal incisions of the tubal mucosa to expose the medial and lateral cartilaginous laminae. Particular attention was directed toward identification of mucosal tears, cartilage fracture, or injury to adjacent soft tissue structures.

Results

Cadaveric eustachian tube dilation

Balloon dilation of the cartilaginous Eustachian tube was successfully performed in all cadaveric specimens using the Tracker™ everting-membrane balloon. Device positioning, deployment, and inflation were achieved without technical difficulty in all cases. Post-dilation luminal patency was confirmed endoscopically and by contrast-enhanced computed tomography (CT) in every specimen [5].

Balloon dilation was successfully performed in all specimens. Across both cohorts, mean luminal diameter increased from 2.31 mm pre-dilation to 5.37 mm post-dilation, representing an average increase of 3.06 mm. In several specimens the pre-dilation lumen was too narrow to quantify on CT imaging, but all demonstrated clear post-dilation patency. Detailed cohort measurements are summarized in Tables 1–2.

During the latter portion of the cadaveric series, a reduced-diameter (3.5-mm) Tracker™ balloon prototype was utilized. Despite the smaller nominal balloon size, post-dilation diameters consistently exceeded 5 mm, indicating reproducible dilation performance across balloon diameters.

Cadaver Cohort 1	Before (mm)	After (mm)	Δ (mm)	Mucosal tear (mm)
1a	NM	5.69	-	0
2a	2.04	6.32	4.28	0
3a	2.15	6.22	4.07	0
4a	NM	5.44	-	0
5a	NM	4.66	-	0

Table 1: Table showing Eustachian tube diameters before and after dilation in five cadavers. Two specimens had pre-dilation diameters of 2.04 mm and 2.15 mm, which increased to 6.32 mm and 6.22 mm. Three specimens were non-measurable before dilation and had post-dilation diameters of 5.69 mm, 5.44 mm, and 4.66 mm. No mucosal tears were observed.

Cadaver Cohort 2	Before (mm)	After (mm)	Δ (mm)	Mucosal tear (mm)
1b	2.04	5.66	3.62	0
2b	2.26	3.44	1.18	0
3b	2.26	4.12	1.86	0
4b	NM	4.00	-	0
5b	2.00	5.69	3.69	0
6	2.15	4.82	2.67	0
7	2.53	5.38	2.85	0
8	2.56	6.25	3.69	0
9	2.56	5.66	3.10	0
10	2.68	5.91	3.23	0
11	2.26	5.26	3.00	0
12	2.53	5.12	2.59	0

Table 2: Table showing Eustachian tube diameters before and after dilation in twelve cadavers. Pre-dilation diameters ranged from 2.00 mm to 2.68 mm in measurable specimens. Post-dilation diameters ranged from 3.44 mm to 6.25 mm. One specimen was non-measurable before dilation and had a post-dilation diameter of 4.00 mm. No mucosal tears were observed.

Volumetric analysis

Volumetric calculations of the cartilaginous Eustachian tube lumen were performed using a standardized cartilaginous length of 28.6 mm, consistent with prior cadaveric literature [8]. Pre-dilation intraluminal volumes ranged from 0.090–0.161 cm^3, increasing to 0.266–0.877 cm^3 following dilation. Percentage increases ranged from 132–857% (Tables 1–2). These volumetric changes fall within—and in several cases exceed—the range reported by Poe., *et al*. who documented an average increase from 0.16 cm^3 to 0.49 cm^3. These findings indicate that the Tracker™ balloon achieves mechanical dilation of the cartilaginous Eustachian tube comparable to the established cadaveric benchmark (Figure 5).

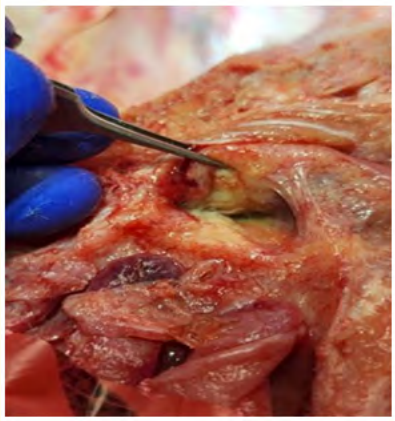

Figure 5: A focused image of the post-dilation Eustachian Tube lumen that was cut open to analyze for mucosal injury. The Eustachian Tube is being held open with forceps by a physician, and the dissection revealed no mucosal injury.

Mucosal integrity and structural assessment

Immediate post-dilation endoscopic inspection demonstrated preservation of mucosal integrity in all specimens. No mucosal tears, perforations, devitalized tissue, or evidence of false passage creation were observed [10].

Gross anatomical dissection under magnification confirmed these findings. Circumferential and longitudinal mucosal incisions with elevation of submucosal flaps revealed intact medial and lateral cartilaginous laminae, without fracture, delamination, or abnormal mobility. The posterior cushion demonstrated expected medialization without excessive laxity. Adjacent soft tissue structures, including the tensor veli palatini muscle, levator veli palatini muscle, and Ostmann fat pad, appeared intact (Figure 6). This is in contrast to the approximately 19% mucosal tear rate reported by Poe, no mucosal tears or structural injuries were observed in the present series.

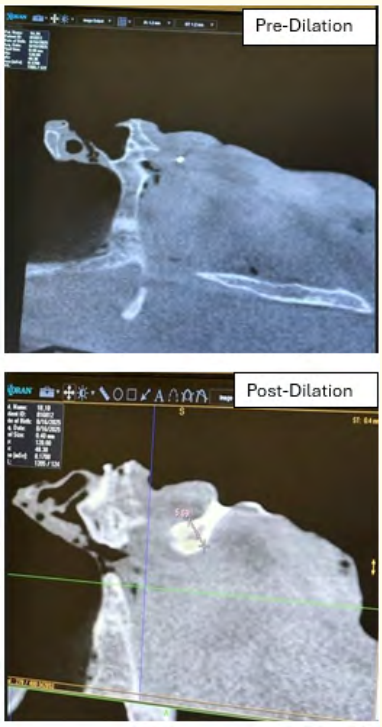

Figure 6A: An image of a CT where a guide wire was inserted into the Eustachian Tube for identification. There is a small white line and dot in the lumen of the eustachian tube where the wire appears as hyperdense. The lumen was too narrow to measure.

Figure 6B: An image of a contrast-enhanced CT of the Eustachian tube. The image shows the same location seen in Figure 6A following Tracker dilation, demonstrating an enlarged, patent lumen.

Radiologic assessment

Independent review of all pre- and post-dilation CT scans by a board-certified neuroradiologist demonstrated no evidence of osseous injury in any specimen. Specifically, there were no fractures or cortical irregularities involving the temporal bone, basisphenoid, or pterygoid plates. Contrast-enhanced CT imaging confirmed luminal patency without extravasation or abnormal contrast tracking.

Cadaver	Pre-dilation volume (cm^3)	Post-dilation volume (cm^3)	% increase
1a	-	0.73	
2a	0.094	0.90	857
3a	0.104	0.87	736
4a	-	0.66	
5a	-	0.49	

Table 3: Table showing Eustachian tube volumes before and after dilation in five cadavers. Two specimens had pre-dilation volumes of 0.094 cm^3 and 0.104 cm^3, which increased to 0.90 cm^3 and 0.87 cm^3, representing increases of 857% and 736%. Three specimens were non-measurable before dilation and had post-dilation volumes of 0.73 cm^3, 0.66 cm^3, and 0.49 cm^3.

Cadaver	Pre-dilation volume (cm^3)	Post-dilation volume (cm^3)	% increase
1b	0.093	0.720	670
2b	0.115	0.266	132
3b	0.115	0.381	232
4b	-	0.359	-
5b	0.090	0.727	709
6	0.104	0.522	403
7	0.144	0.650	352
8	0.147	0.877	496
9	0.147	0.720	389
10	0.161	0.785	386
11	0.115	0.621	442
12	0.144	0.589	310

Table 4: Table showing Eustachian tube volumes before and after dilation in twelve cadavers. Measurable pre-dilation volumes ranged from 0.090 cm^3 to 0.161 cm^3. Post-dilation volumes ranged from 0.266 cm^3 to 0.877 cm^3. Percentage increases ranged from 132% to 709%. One specimen was non-measurable before dilation and had a post-dilation volume of 0.359 cm^3.

Discussion

Balloon dilation of the Eustachian tube has become an increasingly utilized intervention for obstructive Eustachian tube dysfunction; however, the preclinical evidence base supporting device design and mechanical behavior remains limited. To date, the cadaveric investigation by Poe., *et al*. represents the only published study directly demonstrating and quantifying luminal dilation of the cartilaginous Eustachian tube using balloon technology. That foundational work established feasibility, documented substantial luminal expansion, and identified mucosal injury in approximately 19% of specimens. The present study was designed as a focused cadaveric evaluation to determine whether a novel everting-membrane balloon achieves mechanical dilation comparable to that benchmark, while characterizing immediate tissue interaction [1-3,5].

The results of this study demonstrate that the Tracker™ balloon produces cartilaginous Eustachian tube dilation within the volumetric and dimensional range reported by Poe., *et al*. Using similar cadaveric assessment techniques, post-dilation luminal patency and expansion were consistently observed across specimens. These findings indicate that the Tracker™ balloon achieves mechanical dilation equivalent to that previously demonstrated using conventional balloon designs, supporting its functional viability as a Eustachian tube dilation device.

A notable observation in the present series was the absence of gross mucosal injury following dilation. In contrast to the mucosal tears reported by Poe, no mucosal lacerations, perforations, or cartilage disruptions were identified endoscopically, radiographically, or on gross dissection. While cadaveric tissue lacks physiologic recoil and healing response, immediate tissue disruption remains a relevant safety surrogate in preclinical evaluation. The absence of observed mucosal injury in this model suggests a favorable immediate tissue interaction profile for the Tracker™ balloon and may also imply a reduced propensity for mucosal perforation or false passage creation during device advancement.

The Tracker™ device differs fundamentally from previously described balloon systems in its deployment mechanics. Conventional balloons rely on essentially blind axial advancement of an inflatable balloon into the Eustachian tube, a maneuver that may generate shear forces along the tubal wall and increase the likelihood of focal stress, mucosal disruption, or unintended pathway deviation at points of angulation or narrowing. In contrast, the Tracker™ balloon deploys by controlled eversion of a membrane from within the catheter after intraluminal positioning, allowing the balloon to unroll along the native axis of the Eustachian tube prior to radial expansion. This design minimizes axial advancement force, incorporates a blunt distal profile, and limits balloon length via tethered deployment. While this study was not designed to directly measure applied forces or stress distribution, the identified tissue preservation is consistent with the hypothesized mechanical advantages of this deployment strategy and its potential to reduce the risk of mucosal perforation and false passage formation [8]. These observations highlight the importance of deployment mechanics in influencing intraluminal navigation behavior and provide a rationale for complementary preclinical models designed to isolate false-passage risk under controlled conditions.

Importantly, the intent of this investigation was not to establish clinical efficacy or long-term outcomes. Cadaveric models are inherently limited to assessment of mechanical dilation and immediate tissue effects. They cannot predict tissue remodeling, inflammatory response, symptom improvement, or durability of clinical benefit. Rather, cadaveric studies serve as an appropriate preclinical platform for evaluating whether a device achieves its intended mechanical function and for identifying gross safety signals prior to human use [3,9].

In this context, the present study provides an updated cadaveric reference point for Eustachian tube balloon dilation devices, extending the foundational work of Poe., *et al*. by demonstrating that a newer balloon architecture achieves equivalent dilation while exhibiting a lower observed rate of immediate mucosal injury in a controlled cadaveric environment. These findings support progression to clinical investigation, where the true safety and efficacy profile of this design can be evaluated *in vivo* [5].

Study limitations

This study has several important limitations. First, the use of cadaveric specimens precludes assessment of physiologic tissue recoil, vascular response, inflammation, healing, or long-term remodeling. The absence of mucosal injury observed in this model does not guarantee similar outcomes in living patients, nor does it predict clinical efficacy.

Second, comparison in this study relies on historical data from the Poe cadaver investigation rather than contemporaneous testing with alternative balloon devices. While Poe., *et al*. represents the only published cadaveric benchmark for Eustachian tube balloon dilation, differences in specimen preparation, imaging techniques, and measurement methodology limit the precision of cross-study comparison [5].

Third, the sample size was modest and all dilations were performed by experienced operators under controlled conditions. Inter-operator variability and performance in more challenging anatomic scenarios were not assessed and may influence outcomes in clinical practice.

Finally, volumetric and dimensional measurements obtained in cadaveric tissue should be interpreted as indicators of mechanical dilation rather than predictors of functional improvement. The clinical relevance of specific degrees of luminal expansion remains incompletely defined and will require correlation with patient-centered outcomes in future studies.

Conclusion

In a cadaveric model, the Tracker™ everting-membrane balloon achieved cartilaginous Eustachian tube dilation comparable to that reported by Poe. Dilation was consistently achieved across specimens, and no mucosal tears or structural injuries were observed in this series. While cadaveric models cannot predict clinical outcomes, these findings support the mechanical feasibility of this balloon design and justify further evaluation in controlled clinical studies.

The controlled, directional expansion of the everting-membrane design may suggest potential safety advantages; however, direct comparative conclusions cannot be drawn from the present study. Additional preclinical evaluation in a ballistic gel model further characterizes expansion dynamics and tissue interaction properties (Catalano., *et al*. manuscript submitted for publication) [12].

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