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Novel Eustachian Tube Dysfunction Management Techniques: Prototype Feasibility Studies in Fresh Cadaveric Specimens

Jagdish Chaturvedi[1]*, Abu Saquib Tauheed[2], Pooja Kadambi[3], Aboli Joshi[4], Gaurika Singhal[4] ,Tyler John Dougan[4], Eleanor Glockner[4], Mohan Jagade[5], Ravi Jangir[1], Rohan Dsouza[1], Darien Rodrigues[1], Rishabh Sirdesai[1] and Parul Chachra[1]

[1]*ENT Consultant, Fortis Hospital, India*

[2]*Affordable Invention in MedTech (AIM) Fellow, India*

[3]*Lead System Designer, InnAccel Technologies Pvt Ltd, India*

[4]*Interns, InnAccel Technologies Pvt Ltd, , India*

[5]*Professor and Head of Department, ENT and Head and Neck Surgery, India*

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***Corresponding author:** Jagdish Chaturvedi, Department of Otorhinolaryngology, India- 560 076, Tel: +91-9650928582, Email: dr.jagdishc@ymail.com

Abstract

Background: The underlying etiology and natural history of Eustachian Tube Dysfunction(ETD) is poorly understood, associated with various symptoms and can lead to a predisposition to middle-ear disease and, thereafter, permanent deafness. In developing countries, it is a bigger burden due to negligence and lack of awareness, coupled with the high cost of treatment and limited availability of dedicated effective solutions. This lead to the need to develop an effective solution for patients with chronic ETD as a day-care to avoid middle ear diseases.

Materials and Methods: Two cadaveric studies were done in March 2017 and August 2017 to test the utility and usability of various design prototypes and understand the potential barriers in managing ETD. 17 Prototypes were tested and broadly classified into three main categories as per their nature and use- Diagnostic, interventional, diagnostic & interventional.

Results: Three designs-an articulating camera, the balloon dilator and one embodiment of the expander showed promise as products to aid in the diagnosis and treatment of ETD. The electrical impedance probe had some merit as a safety feature but a more extensive study will be needed to prove its utility.

Conclusion: One prototype demonstrated a promising technique for equalization, mucus clearance, widening and possibly long-term relief for patients with ETD. The cadaver studies suggested the further consideration of three diagnostic technologies and the elimination of several others, further studies for feedback on positioning as well as physiology will be necessary. While slight variations in technology worked with some success, the other concepts showed no further promise.

Keywords: Eustachian tube dysfunction; ET; ETD; Cadaver study; Balloon dilation; Middle ear infection; Bio-Design; Inventing Medical Device

Introduction

The Eustachian tube (ET) is a complex hourglass structure which acts as connecting tube between the middle ear and the nasopharynx, and is responsible for ventilating the middle ear. [1] It also act as a pressure regulator to equalize middle ear and ambient pressure in a complex physiological phenomenon. In this study, failure in the ventilation mechanism mentioned above due to the inability of Eustachian tube to open is referred to as "Eustachian Tube Dysfunction", though in general ETD is also used analogously in cases of patulous eustachian tube.

The 1996 World Development Report estimated that 2.163 million disability-adjusted life-years were lost due to Otitis media, of which developing world contributed to 94% of the morbidity [2]. Prevalence surveys have shown a global burden of 65–330 million individuals with draining ears due to middle ear infections , 60% of whom (39–200 million) suffer from significant hearing impairment [3]. Over 90% of this burden is borne by developing countries. Middle ear infection is uncommon in the developed countries like Australia, Middle East, Americas and Europe [3].

The underlying etiology and natural history of ETD is poorly understood [4]. There is a lack of clear diagnostic criteria [5], which further impairs our ability to study the disease and explore potential therapies. Nasal steroid sprays or anti-reflux therapies are often used as first-line options, though there is a lack of clinical data to back its effectiveness. No significant differences were found between treatment option and placebo during a randomized placebo-controlled trial with nasal steroid sprays [6].

Similarly, a recent systematic review found no statistically significant improvement with any interventions including observation, nasal steroids, and various surgical techniques [7]. In select patients there is redundant mucosa in the area at the pharyngeal end of the ET, thus impairing its dilation. Ablation of this tissue with lasers [8] or microdebriders [9] has shown promise in small studies, but these interventions are not appropriate in all patients. Other novel therapies have focused on the cartilaginous portion of the ET [10]. A recent, promising innovation, balloon dilation, is known as tuboplasty [11]. Balloon Eustachian Tuboplasty has limited data in India regarding the availability or efficacy of this technique. However, there is a high burden of morbidity in India due to the large number of patients suffering with ETD [12].

The need to develop a solution for ETD came out of a modified process research approach [13] designed to identify need specifically for Indian healthcare system based on Stanford Bio-Design process [14] which is a study dedicated to identifying unmet needs in the various field of medical science. The design and execution of these cadaver studies and the wide array of experiments demonstrates a useful approach for creating qualified medical device solutions for diagnostic and therapeutic purposes for the ET. There are limitations related to assessing the efficacy and true safety because of the nature of the cadaver model and variances in live patients.

Materials & Methods

The study was conducted in the Simulation Lab of MS Ramaiah Advanced Learning Center, Bangalore, India. The study was done in 2 phases on 30th March 2017 and 10th August 2017. The Simulation Lab of MR Ramaiah Advanced Learning Center has an operation theatre like setup with endoscopic and surgical instruments, overhead lighting, headlamps, and consumables. Jagdish Chaturvedi, ENT consultant, Fortis Hospital, Bangalore was the principal investigator and overseeing physician for both cadaveric studies, Dr Mohan Jagade, Professor and Head of Department, ENT and Head and Neck Surgery, JJ Hospital, Mumbai was also involved in the first study. Pooja Kadambi (Lead Systems Engineer at Innaccel), Gaurika Singhal and Aboli Joshi (Design Interns NID) were also involved in these studies.

Prior to the study, training was conducted for all non-medical personnel. The training was conducted by Jagdish Chaturvedi and included relevant anatomy, cadaveric study protocols and medical procedures training (endoscopy, balloon dilation of eustachian tube and tympanostomy). The study was carried out on fresh cadavers, non-frozen within 36 hrs with all the internal anatomy intact. Table 1 & 2 list the various prototypes evaluated on 30th March and 10th August cadaveric study.

Table 1: List of Prototypes tested on 30th March 2017 cadaver study.

Classification	Description	Number
Diagnostic (Devices designed around a camera, endoscope, or sensor to determine the physiology of the ET)	Fiber Optic Illumination	P1
	Flexible endoscope guide	P2
Diagnostic + Intervention (Small devices placed inside the ET to expand it and reveal its inside to a standard endoscope)	Whisk Attachment	P3
	Modified Giraffe	P4
	Bipolar Forceps	P5
Intervention (Various approach to treat ETD)	Shaped probe dilation	P6
	Nasal pack dilation	P7
	Balloon Dilator system	P8, P9, P10, P11, P12
	Vibration	P13
	Air pressure	P14
	Water flushing	P15

ET - Eustachian Tube; ETD - Eustachian Tube Dysfunction

Once the cadavers were cleaned and verified with a diagnostic endoscopy the prototypes were tested by the principal investigator and monitored for usability, utility, and safety (injury). The order and priority for testing various prototypes were given based on least to most damaging, and most likely to work to least likely to work. Measurements of the nasopharynx were taken with a metal tube probe. A septoplasty was performed on the cadaver in March 2017 to allow for access because the septal spur was blocking access to the Eustachian tube on one side Table 3.

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Table 2: List of Prototypes tested on 10th August 2017 cadaver study.

Classification	Description	Number
Diagnostic (Devices designed around a camera, endoscope, or sensor to determine the physiology of the ET)	Micro Camera System	V1, V2
	External Camera attachments	V3, V4, V5, V6
	Flexible endoscope	V7
	Rigid endoscope attachment	V8
	Electrical Probe Electrical assessment	V9
Diagnostic + Intervention (Small devices placed inside the ET to expand it and reveal its inside to a standard endoscope)	Wire Expander	E1
	Wire Basket	E2
	Hollow Tubes	E3
	Soft Nitinol basket	E4
	Coils and springs	E5
	Umbrella Expander	E6
Intervention (Various approach to treat ETD)	Balloon Dilator system	T1
	Endaural Probe	T2

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Table 3: Cadaver used for Study.

Study Time	Cadaver	Gender	Anatomical Findings
30th March 2017	1	M	Large Intact Nose
10th August 2017	1	M	Had large nasal cavity with deviated (S-shaped) septum, the septal spur was present posterior to right nostril that was blocking access to the nasopharynx
	2	M	Had a broken septum that was deviated to the left. Turbinates were small and allowed easy access to the ET.

Results

Table 4: Prototype testing and clinician feedback for 30th March cadaver study.

Classification	Concept	Number	Clinician Feedback	Results
Diagnostic	Fiber Optic Illumination	P1	Illumination does not help with assessment and cannot gauge if it reaches isthmus	Rejected
	Flexible endoscope guide	P2	Not stiff enough to prevent bending, no visualization at all, only pink and white blur visible	Rejected
Diagnosis and/ or Treatment	Whisk Attachment	P3	Not used as it could not fit around the flexible endoscope without a guide	Rejected
	Modified Giraffe	P4	Length and angle not correct, angle tip is too long	Rejected
	Bipolar Forceps	P5	Not used	Rejected
Intervention	Shaped probe dilation	P6	Correct angle and size, not sure about the performance as ET had already been dilated multiple times, flat handle of the probe was too big and blocked the view of the scope	Rejected
	Nasal pack dilation	P7	Non-indicative, small string, string lost in tissue, though expanded quickly and absorbed all fluid, ET was clearly dilated and cleared, No trauma, need to prevent expanding till inside ET, good for removing fluids	Accepted
	Balloon Dilator system	P8, P9, P10, P11, P12	Balloon entered fully into the ET, resistance felt while pushing from isthmus, post removal of the balloon the columnar ciliated epithelium was clearly visible	Accepted
	Vibration	P13	The vibration was transmitting but not reaching cartilaginous part, does not have any effect on mucous/fluid present in ET	Rejected
	Air pressure	P14	Bubbles were visible at the cartilaginous opening of the ET but no satisfactory result	Rejected
	Water flushing	P15	Water was not entering inspite of high pressure, most of the water flowed back out of ear	Rejected

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Table 5: Prototype testing and clinician feedback for 10th August cadaver study.

Classification	Concept	Number	Clinician Feedback	Result
Diagnosis	Micro Camera System	V1	Allowed partial visualization, disorienting, guiding without camera difficult	Rejected
		V2	The manoeuvrability of angle is better, allows easy access	Accepted
	External Camera attachment	V3, V4	Diameter too big to fit in the nose, caused trauma due to scraping of mucosal tissue	Rejected
		V5	Easy access due to small size, no trauma	Accepted
		V6	Too big, not tested	Rejected
	Flexible endoscope	V7	A small field of view does not provide proper visualization, difficult to manoeuvre, but was able to access opening	Re-do
	Rigid endoscope attachments	V8	Manoeuvring was a problem, field of view was blocked by tube, does not work, nothing much could be seen through mirror.	Rejected
	Electrical Probe	V9	Easy manoeuvring, too big to go beyond isthmus, variable resistance, reactance was difficult to measure	Re-do
Diagnosis and/ or Treatment	Wire Expander	E1	Easy deployment, adequate visualization with 0°, caused trauma while pulling out	Re-do
	Wire Basket	E2	Not able to enter ET, size too big	Rejected
	Tubes	E3	No proper visualization, ET wall collapsed at the tube end	Rejected
	Ureteric basket	E4	Easy to insert and remove, outward force not strong, wire pinched tissue during retraction	Re-do
	Coils and springs	E5	The plastic coil was lost inside the ET, and the metal coil was too big to fit inside the tube	Rejected
	Umbrella type	E6	The opening was difficult due to limited access, once opened provide easy expansion	Re-do
Treatment	Balloon system	T1	Easy insertion, difficult to hold stable, difficult retraction required two fingers, but successful	Accepted
	Endaural Approach	T2	Not successful, finding the ET entrance from within middle ear was challenging, metal tube pierced through ET lumen	Rejected

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Table 4 & 5 lists the clinician feedback and decisions taken for all tested prototypes on 30th March and 10th August 2017 respectively.

Description of result criteria

Accepted: Prototypes performed adequately for ETD management with no significant trauma or usability issues.

Rejected: Prototypes caused significant trauma and usability issues with failure in performing the intended function.

Re-do: Prototypes causing no significant trauma but having slight usability issues which can be improved with changes in dimensions or technology.

Discussion

The use of fresh cadavers in a surgical simulation setting was beneficial as it offered a real world usability scenario in terms of human anatomy, tactile feedback of tissue and the dangers of potential injury. The compliance of tissues and the ease or difficulty in separating one structure from another resembles those of living tissue as compared to animal or synthetic models [15].

Prototypes P1 to P15 were evaluated for their utility and usability in the first cadaver study conducted on 10th March 2017. Prototypes P1, P2, P3, P4, P5, P6, P13, P14, and P15 were rejected as they had minimal or no effect on mucosal removal and/or opening the ET obstruction. The visualization prototypes were also unable to provide adequate visualization or proper access to ET.

Balloon-based dilation prototypes P8, P9, P10, P11 and P12 showed some promising results in the dilation and management of ETD. The prototypes P8 to P12 produced adequate dilation without causing trauma. It was decided to build second-generation balloon-based prototypes for further investigation and trials. Prototype P7 also produced adequate and quick expansion but it was non-indicative and also led to an adverse event due to the loss of string in the mucosal tissue. It was acceptable for thin fluid absorption and medication delivery.

The second generation of prototypes based on balloon system and 16 other concepts were developed and tested in cadaver studies conducted on 10th August 2017. Prototypes V1, V3, V4, V6, V8, E2, E3, E5, and T1 were rejected due to the lack of safety (causing trauma) and utility. The rejections were based on the trauma caused during the procedure, the difficulty in access during insertion and retraction, the small field of view and the inability to dilate or visualize the ET for diagnostic purposes. The expanders did not have sufficient therapeutic impact to

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be considered as an interventional solutions and the risk of injury outweighed any potential temporary benefit of pressure equalization using rigid expanders.

Prototypes V2, V5, and T1 were found to be acceptable during the cadaver study. All three prototypes worked perfectly in the study and performed as per the intended design. The selection criteria was based on ease to use, ease of access of the ET, absence of trauma during insertion, adequate visualization of anatomy and landmarks, allowed for adequate expansion of tissue. Prototype V5 and V2 were also used together as a combination to attempt a hybrid approach, it allowed for adequate visualization for the diagnosis. It showed significant promise and can be further refined and applied for diagnostic purposes. Prototypes V7, V9, E1, E4, and E6 required further testing to prove their usability and utility. Prototypes that were suggested for rework showed promising results in one or more of the acceptance criteria but were either dysfunctional or non-functional. Prototype V7 and V9 provided ease of access but inadequate visualization, E1 provided adequate visualization, easy deployment but led to untoward trauma during retraction, E4 allowed for ease of access but also led to trauma during retraction and E6 provided adequate expansion of ET post access but difficult access the ET.

Study Limitations

The most significant shortcoming of these cadaver studies was the inability to quantify the depth visualization provided by the different cameras and scope-based designs. It would be beneficial to have a system in place to measure the visible distance anterior to the camera or the endoscope, such as a ruled or marked guide inserted into the ET, in future studies. The pain, discomfort and bleeding associated with the prototypes could not be objectively assessed in a cadaver especially given the high sensitivity of the ET during endoscopic examination in live patients, usually done under local anaesthesia.

During evaluation of some designs, such as the wire expanders, it was difficult to objectively assess the tissue damage due to expansion. While it was obvious that the sharp ends posed a serious danger, there was no visually evident damage to the ET lining. However, it is possible that this could possibly harm the mucosa of a living patient in a way that is not visible in a cadaver. This damage can be observed if the ET lining is inspected with the camera prototype immediately following removal of a wire expander. For future studies, it is recommended that a more thorough evaluation of the trauma of each expansion device is conducted.

Conclusions

The two-cadaver study suggests the recommendation of three diagnostic technologies for further consideration, as well as the elimination of several others. Prototype T1 demonstrated promise technique in pressure equalization, mucus clearance, widening and possible long-term relief and thus is the most favoured intervention. P7 could be worked on for specific interventions. The prototypes V5 and E1 in conjunction with a rigid endoscope, permitted excellent visualization of the first 10 mm of the ET, lumen which was suitable for diagnosis. Overall, better visual assessment of the inside of the ET from the nasal approach was considered to be the most appropriate diagnostic technique. The prototype V9 revealed positive results in distinguishing the isthmus from the cartilaginous ET, so it could be further studied as a system for feedback on positioning and possibly physiology. Prototypes that were rejected were characterized and documented to avoid any further exploration while further studies will be conducted for the those with successful outcomes. ET management involves a combination of suitable diagnosis, intervention and monitoring. Thus, the short listed concepts will be individually refined and possibly combined in the future to meet the ultimate need of better definitive management of chronic ETD.

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Conflict of Interest

The authors are affiliated to InnAccel Technologies Pvt. Ltd.

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