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Original Research Article

Effect of canal widening (type I tympanoplasty) on hearing sensitivity

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ABSTRACT

Background: Chronic otitis media (COM) is a chronic inflammation of the middle ear cleft that is characterised by discharge from the middle ear through a perforated tympanic membrane for at least 6 weeks. The pattern and degree of hearing loss greatly vary in individuals with COM. Conductive hearing loss is the most common pattern. This could be managed conservatively or surgically. Mastoidectomy and/or tympanoplasty are frequently used management procedures for COM. The study aimed to investigate the efficacy of the type I tympanoplasty through a canal widening procedure on hearing sensitivity.
Methods: Two groups participated in the study. Group I included 25 participants who underwent type I tympanoplasty with canal widening procedure and group II included 25 participants who underwent type I tympanoplasty without canal widening procedure. The audiometric results of pre-operative condition and post-operative condition at 1 month and 3 months were documented for further analysis.
Results: The mean difference of pre-post (1 month) air conduction threshold was 12.68 dB in group I and 5.5 dB in group II participants. The mean difference of pre-post (3 month) air conduction threshold was 18.86 dB in group I and 8.24 dB in group II participants. There was a significant difference in thresholds that was obtained between the two groups and across conditions.
Conclusions: The study provides clear evidence that Type I tympanoplasty with canal widening procedure provides a better improvement in hearing sensitivity for individuals with COM, where surgical procedure is an indication.

Keywords: Air and bone conduction thresholds chronic otitis media, Hearing sensitivity, Pre-post operation

INTRODUCTION

The ability to hear is an important sensory function for communication and better quality of life. Disorders affecting hearing can be congenital or acquired. The leading cause of hearing loss in acquired disorders being chronic otitis media (COM) is both preventable and correctable to certain extent as well. COM is the chronic inflammation of mucoperiosteal lining of the middle ear cleft characterized by ear discharge, a permanent perforation of the tympanic membrane and impairment in hearing.[1] It is estimated that 6% of Indian population suffer from chronic middle ear disease and the majority of the cases especially seen in the rural population.[2,3] The incidence of COM is high in developing countries because of poor socioeconomic status, overcrowding, poor personal hygiene, poor nutrition and lack of health education.[4] COM of mucosal variety can be managed in two ways, conservative and surgical management. However, the main aim is to restore the anatomy and function of the middle ear. Small perforations usually heal spontaneously but when the edges of the perforation are covered by stratified squamous epithelium, a perforation becomes permanent and does not heal

spontaneously.[5] Procedures such as grafting the tympanic membrane alone, or in combination with ossiculoplasty (tympanoplasty with ossicular chain reconstruction), an intact neo tympanum with normal hearing acuity can be achieved. Type-1 tympanoplasty is performed when there is tympanic membrane perforation without any ossicular damage and patent external ear is prerequisite for successful ear surgery.[6]

The widening of external auditory canal is called canalplasty which is an integral part of tympanoplasty technique. The removal of overhanging canal walls provides complete exposure of the anterior edge of tympanic membrane. Drilling the posterior and inferior walls, widen the bony canal which allows complete visibility of the entire tympanic annulus. This helps in better placement of the graft material.[7] However, the effectiveness of this surgical procedure can be ascertained well with the evaluation of the difference in the audiometric procedural results of an individual. The hearing outcomes using temporalis fascia graft for tympanic membrane reconstruction in type 1 tympanoplasty has been evaluated pre and post operatively and hearing gain of 14.55 dB and the mean air bone gap reduction of 11.94 dB has been achieved.[8] However, there is dearth in the literature on comparison across tympanoplasty procedure of with and without canal widening. Hence, in this study, an attempt has been made to study the efficacy of the Type I tympanoplasty with and without canal widening procedure on hearing sensitivity.

METHODS

This study was prospective interventional study conducted in Department of Otorhinolaryngology and Department of Audiology, All India Institute of Speech and Hearing, Manasagangothri, Mysuru, after taking informed written consent from participants and required approval from Ethical committee. The period of study was from January 2016 to April 2017. The sample size was determined based on the earlier studies who have used similar methods for assessing the efficacy of the Type I Tympanoplasty procedure on hearing sensitivity.[9,10] For an effect size of 0.50, power of 0.80 and significant of 0.05, the sample size obtained in the G* power (version 3.1.9.2) software was 21. A total number of 50 participants were included in the study. The participants were divided into two groups. Group I includes 25 participants who underwent Type I tympanoplasty with canal widening procedure and group II includes 25 participants who underwent type I tympanoplasty without canal widening procedure.

Inclusion criteria

Medium and large dry central perforation of pars tensa with overhanging canal wall; mild (26-40 dB) and moderate (41-55 dB) degree of conductive hearing loss; no acute upper respiratory tract infection (URTI) at the time of surgery.

Exclusion criteria

Ossicular pathology detected by preoperative pure tone audiometry and intra operative evaluation or mixed hearing loss; presence of granulation tissue, cholesteatoma, or polyp in the ear prior to surgery; revision cases, cases with tympanosclerosis and bony ankylosis or graft failure following surgery; clinically significant predisposing focus of infection in the sinuses, nose or throat; complications of otitis media or multiple tympanic membrane perforations; underlying diseases such as diabetes or poor immune system.

Preoperative assessment

All participants were subjected to detailed pre-operative history taking and clinical examination including oto-microscopic and oto-endoscopic examination.

Procedure

The study that was conducted was classified as three conditions:

Condition 1 (pre surgery): All the participants (both the groups) were assessed for their audiometric thresholds before surgery. Pure tone audiometry (PTA) was carried out using GSI 61 clinical audiometer (Grason-Staler, Eden Prairie, MN) for air and bone conduction thresholds for frequencies between 250 Hz to 8 kHz and from 250 Hz to 4 kHz respectively using Modified Hughson and Westlake procedure.[11] Speech audiometry which includes speech recognition thresholds (SRT), and speech identification scores (SIS) was also measured. Immittance audiometry was carried out using GSI Tympstar middle ear analyzer (Grason-Staler, Eden Prairie, MN) to test middle ear pathologies and ear canal volume. The obtained thresholds and values were documented. After this initial evaluation, the participants were advised for the surgery.

a) Operative technique (type I tympanoplasty with canal widening)

All participants were operated under general anaesthesia with post aural approach. With post auricular incision, temporalis fascia graft was harvested. A rim of tissue was removed to freshen the perforation margins and under surface of the remnant tympanic membrane scraped to ensure completely de-epithelialized medial surface of the remnant tympanic membrane. The posterior Tympanomeatal flap was created by making vertical incisions at 6’0 clock and 12’0 clock positions, 5 mm lateral to the annulus, and medial ends of these two incisions are joined by a horizontal incision. This flap was elevated from medial to lateral up to the bony-cartilaginous junction. The superior tympanomeatal flap

was created by extending the medial end of 12'0 clock incision anteriorly up to the 2'0 clock position. The Inferior Tympanomeatal flap was created by extending the 6'0 clock incision anteriorly up to 4'0 clock position. All these flaps were joined and elevated along with the annulus following skeletonising of handle of malleus, where in the superior Tympanomeatal and the posterior Tympanomeatal flaps were joined and secured anteriorly. The external auditory canal was widened with conical cutting and diamond burrs eliminating all bony overhangs particularly in the posterior and inferior part routinely and superiorly when there is prominent tympanosquamous suture. Malleus handle was skeletonised. After placing the temporalis fascia graft and the tympanomeatal flaps, the tympanomeatal flap is reflected anteriorly and the lateral process of the malleus is palpated using a sharp micro scissors the temporalis is reflected and cut precisely over the malleus up to the tip and the graft slided beneath the malleus and the tympanomeatal flaps reflected back to its original position and the gel foam was kept in the external auditory canal. Post auricular wound was closed and a snugly fitting, mastoid bandage was applied.

Condition 2 (post surgery, 1 month)

All the participants who had been treated surgically were followed up for the re-evaluation of audiological testing after a period of one month. The air conduction, bone conduction audiometric thresholds and the speech audiometry that were obtained before the surgery were again re-evaluated and documented. The status of the tympanic membrane was also viewed and recorded through endoscopic examination. However, during the follow up after 1 month the tympanometry was not recommended as the healing process continued. Hence ear canal volume was not documented in condition 2.

Condition 3 (post surgery, 3 months)

After the period of three months of post-surgery, the participants were again followed up for the re-evaluation of audiological testing. The air conduction, bone conduction audiometric thresholds, speech audiometry and ear canal volume were again re-evaluated and documented. The status of the tympanic membrane was again recorded. All audiometric testing was carried out in a sound treated room.[12]

Outcome of surgery was regarded as successful if the ear gets dry, the tympanic membrane heals and intact and mobile at the end of 3rd month.

Statistical analysis

Appropriate statistical analyses for comparison of the conditions across the two groups were performed using the Statistical Package for Social Sciences (SPSS) version 20 software (released 2011; IBM Corp., Armonk, NY).

RESULTS

The participants in group I were in the range of 15-50 years (mean age- 27.4 years, SD- 9.9), with 8 males and 17 females. Group II includes participants in the age group of 15-50 years (mean age- 26.6 years, SD- 8.5) with 16 males and 9 females.

Shapiro-Wilk test of normality were administered for checking the distribution of the data. As the normality was not observed ($p>0.05$), non-parametric test Friedman test and Wilcoxon Signed-rank test were done for further analysis of the data. Descriptive statistics were analysed for the data that were measured: pure tone average (PTA) for the frequencies 250 Hz, 500Hz, 1 kHz, 2 kHz, 4 kHz, and 8 kHz of air conduction threshold and 250 Hz, 500Hz 1 kHz, 2 kHz, and 4 kHz for bone conduction threshold, speech recognition threshold (SRT), speech identification scores (SIS) and ear canal volume (ECV) across the conditions 1) Pre-surgical treatment (condition 1), 2) Post-surgical treatment after 1 month (condition 2) and 3) Post surgical treatment after 3 months (condition 3).

Comparison across three conditions for type I tympanoplasty with canal widening

Figure 1 shows the mean and standard deviation (SD) values of pure tone average, speech recognition threshold, speech identification scores across three conditions and ear canal volume across two conditions for type I tympanoplasty with canal widening procedure.

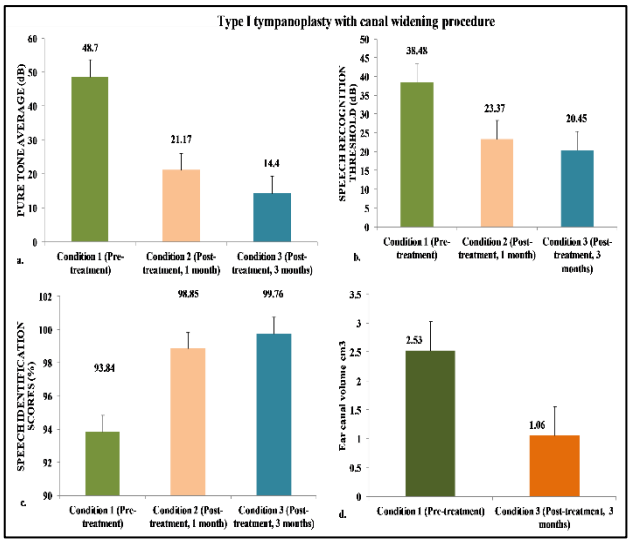

Figure 1: The mean and standard deviation of- a) pure tone average, b) speech recognition threshold, c) speech identification scores across three conditions d) ear canal volume across two conditions for type I tympanoplasty with canal widening.

The Figure 1 reveals that the scores of the PTA and SRT has improved from condition 1 to 2 and then to the

condition 3. The SIS scores also have improved across the three conditions. The ear canal volume between condition 1 and condition 3 in participants has also improved. Further non parametric test of Friedman test was done for within group (group I) comparison between conditions. A non–parametric Friedman test of differences among repeated measures was conducted for the measures pure tone average (χ^2=47.89, p=0.00), speech recognition threshold (χ^2=40.23, p=0.00), and speech identification scores (χ^2=27.88, p=0.00) revealing significant difference across the three conditions for all the parameters that were measured. Wilcoxon Signed-rank test results reveal that there was significant difference (p<0.05) across all the parameters and conditions (p<0.05) for PTA, SRT and SIS**.** The results of Wilcoxon Signed-rank test for the analysis of ear canal volume revealed that there was significant difference between the conditions 1 and 3 (Z=4.145, p=0.000, η=0.592). The statistical analysis was also done to compare across the conditions for the air and bone conduction thresholds. The Figure 2 represents the air and bone conduction thresholds obtained across the test frequencies for different conditions for group I participants.

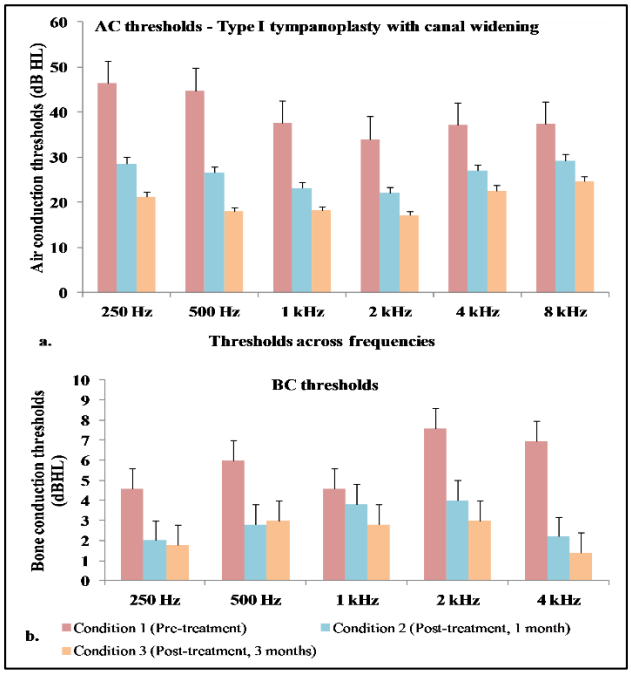

Figure 2: a) Air conduction and b) Bone conduction thresholds across the test frequencies for different conditions for group I participants.

Interpreting the Figure 2 it reveals that the hearing loss at the lower frequencies (250 Hz and 500 Hz) are higher compared to the other frequencies in condition 1. However, comparing with condition 2 and 3 the improvement in air conduction thresholds at lower frequencies are higher than the mid and high frequencies. And also the thresholds were within the normal range across all the three conditions for all the test frequencies of bone conduction.

Further Friedman test of differences was done across conditions for the measure of air conduction thresholds from 250 Hz to 8 kHz and bone conduction thresholds at different frequencies from 250 Hz to 4 kHz for group I participants. The results revealed there was significant difference across all the conditions for all the test frequencies of air conduction threshold. Hence, Wilcoxon Signed-rank test was done for pair wise comparison. The results indicated that there was significant difference across all the pairs (p<0.05). However for bone conduction thresholds there was significant difference only at 2 kHz and 4 kHz. Further, Wilcoxon Signed-rank test was done for pair wise comparison for bone conduction thresholds. The results for 2 kHz reveal that there was significant difference across the pairs for the conditions 1 and 2 (Z=-2.59, p=0.01, η=0.52) and for the conditions 1 and 3 (Z=-3.056, p=0.002, η=0.61). The results for 4 kHz also reveal that there was significant difference across the pairs for the condition 1 and 2 (Z=-3.169, p=0.002, η=0.63) and for the pair 1 and 3 (Z=-3.429, p=0.001, η=0.68). These results indicate that there was marked difference across all the test frequencies for the air conduction threshold across the three conditions whereas there was significant difference only at 2 kHz and 4 kHz for bone conduction thresholds between the two pre and post treatment after one month of evaluation. The below figure 3 depicts the endoscopic view of tympanic membrane of a participant (Figure 3).

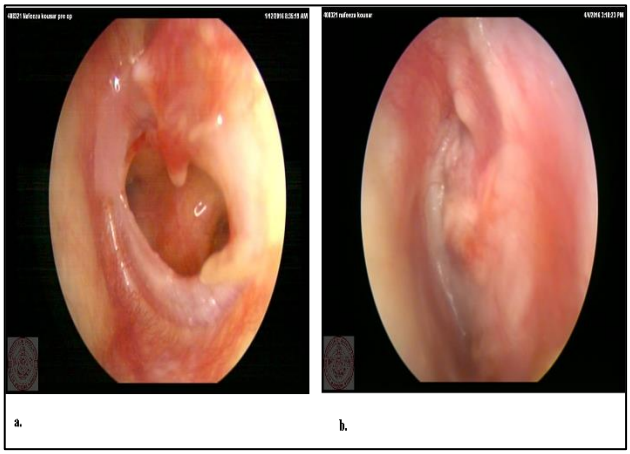

Figure 3: An endoscopic appearance of a participants' left ear tympanic membrane (a) Pre-operative image (b) Post-operative image at 3 months after the operation.

The above Figure 3(a) depicts the central perforation of the tympanic membrane. The pre-operative hearing loss is 47.5 dB (moderate conductive hearing loss). Figure 3(b) depicts the neotympanum after 3 months of surgery. The improvement in hearing thresholds is 18.86 dB after 3 months post operatively.

Comparison across three conditions for type I tympanoplasty without canal widening

Figure 4 shows the mean and standard deviation values of pure tone average, speech recognition threshold, speech identification scores across three conditions and ear canal volume across two conditions for type I tympanoplasty without canal widening procedure.

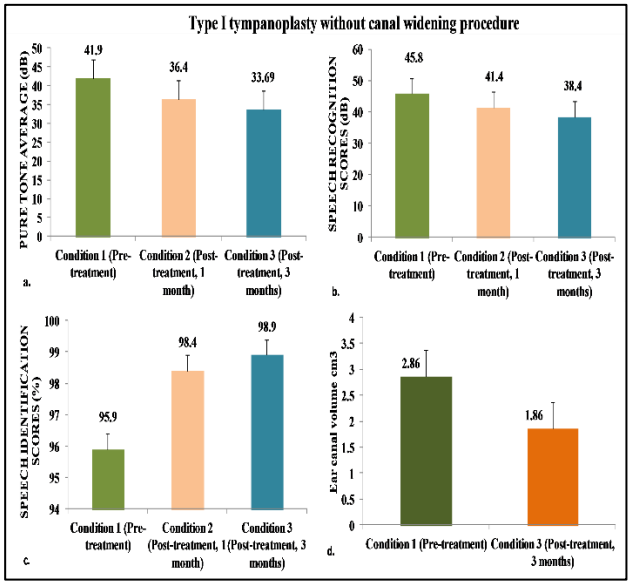

Figure 4: The mean and standard deviation of a) pure tone average, b) speech recognition threshold, and c) speech identification scores across three conditions d) ear canal volume across two conditions for type I tympanoplasty without canal widening.

The Figure 4 reveals that the scores of the PTA and SRT has improved from condition 1 to 2 and then to the condition 3. The SIS scores also have improved across the conditions. The ear canal volume between condition 1 and condition 3 in participants has also improved.

Further non parametric test of Friedman test was done for within group comparison between conditions and results reveal pure tone average (χ^2=28.42, p=0.00), speech recognition threshold (χ^2=19.66, p=0.00), and speech identification scores (χ^2=13.66, p=0.00). Wilcoxon Signed-rank test was done for pair wise comparison and there was significant difference (p<0.05) across all the parameters and conditions except for the SIS of condition 2 and 3, which showed that there was no significant difference (Z=-1.194, p=0.233). The results of Wilcoxon Signed-rank test for the analysis of ear canal volume revealed that there was no significant difference between the conditions 1 and 3 (Z=-1.646, p=0.100). The Figure 5(a) represents the air conduction thresholds obtained across the test frequencies and figure 5(b) represents the bone conduction thresholds obtained across the test frequencies for different conditions for group II participants.

The Figure 5 reveals that there was difference across the three conditions. These differences are more at the lower frequencies than at the higher frequencies. And it can also be interpreted that the threshold were within the normal range across all the three conditions for all the test frequencies of bone conduction. Friedman test of differences was done across conditions for the measure of air conduction and bone conduction thresholds at test frequencies for group II participants. The results reveal that there was significant difference (p<0.05) across all the frequencies except for the 4 kHz of condition 2 and 3, which showed that there was no significant effect (Z=-1.252, p=0.210) and at 8 kHz between condition 1 and 2 (Z=-1.122, p=0.262) for air conduction. Whereas, the bone conduction, the threshold did not show any significant difference across any of the three conditions.

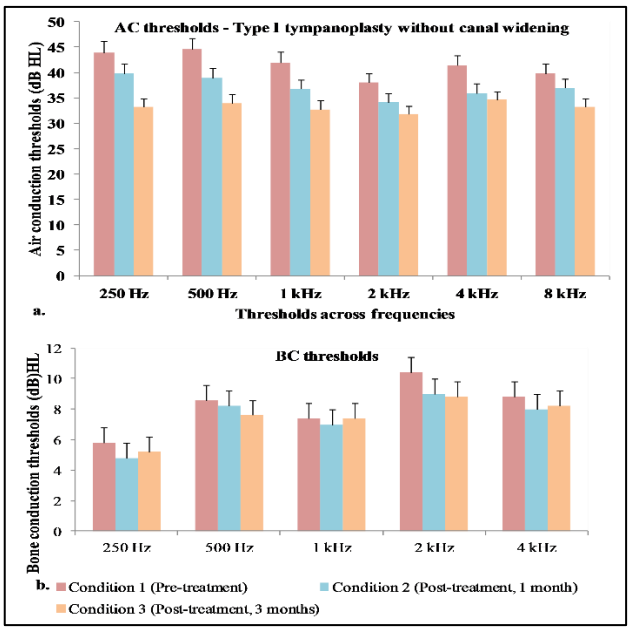

Figure 5: a) Air conduction and b) Bone conduction thresholds obtained across the test frequencies for different conditions for group II participants.

Comparison between the conditions for type I tympanoplasty with and without canal widening

Figure 6 shows the mean and standard deviation values of a) pure tone average, b) speech recognition threshold, c) speech identification scores across three conditions and d) ear canal volume across two conditions for both groups of participants.

The Figure 6 reveals that there was difference across the condition 2 and condition 3 across both groups of participants for pure tone thresholds and speech recognition thresholds. Mann-Whitney test was done for comparison between two groups of participants for pure tone thresholds, speech recognition thresholds and speech identification scores across the respective condition. Table 1 indicates the results of Mann-Whitney test.

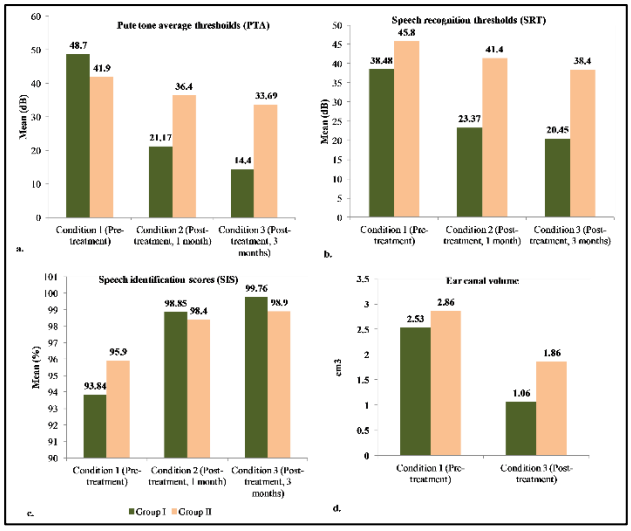

Figure 6: The mean and standard deviation of a) pure tone average threshold, b) speech recognition threshold, and c) speech identification scores across three conditions d) ear canal volume for two conditions for both groups of participants.

The results of Table 1 reveals that there was no significant difference between two groups of participants in condition 1 for all the parameters whereas there was significant difference between groups across respective conditions of 2 and 3 for the pure tone thresholds and speech recognition scores. And speech identification scores have significant difference only in condition 3 between groups. This revels that the two different surgical treatments had significant difference in the performance related to hearing abilities. It can be inferred that the effect of type I tympanoplasty with canal widening procedure was significantly better compared to type I tympanoplasty without canal widening procedure. Similarly Mann-Whitney test was done across all the air conduction thresholds, bone conduction thresholds and air bone gap between two groups and across respective conditions. The results reveal that the air conduction thresholds from 250 Hz to 8 kHz had significant difference ($p<0.05$) for condition 2 and 3 between the groups. The improvement in hearing ability with respect to difference in threshold (dB) was studied. Table 2 reveals the improvement in hearing in pure tone thresholds after 1 and 3 months of type 1 tympanoplasty with and without canal widening procedure.

Table 1: Results of Mann-Whitney test comparing across two groups for pure tone average thresholds, speech recognition thresholds and speech identification scores.

Parameters	Conditions	Z	P value	η
Pure tone threshold	Condition 1	-1.301	0.193	-
	Condition 2	-3.145	0.002	0.63
	Condition 3	-3.933	0.000	0.79
Speech recognition thresholds	Condition 1	-1.231	0.219	-
	Condition 2	-2.969	0.003	0.59
	Condition 3	-3.536	0.000	0.70
Speech identification scores	Condition 1	-0.745	0.456	-
	Condition 2	-1.309	0.191	-
	Condition 3	-2.013	0.044	0.40

Table 2: Mean improvement in hearing thresholds (dB) after 1 and 3 months of surgery across two groups.

Surgery techniques (groups)	Pre-operative mean PTA (dB)	Post-operative (1 month) mean PTA (dB)	Mean difference Pre-post 1 month PTA (dB)	Post-operative (3 months) mean PTA (dB)	Mean difference Pre-post 3 months PTA (dB)
Group I	38.14	25.46	12.68	19.28	18.86
Group II	41.93	36.43	5.5	33.69	8.24

The results of Table 2 deciphered that there is an improvement of 18.86 dB in group I participants and 8.24 dB in group II participants. The different in improvement with respect to two different surgical procedures was by 10.62 dB.

DISCUSSION

Chronic otitis media (COM) is a major cause of acquired hearing impairment especially in developing countries. It also gives rise to various extra and intra cranial complications which can be fatal, if untreated. Restoration of the sound conducting mechanism of the middle ear can be accomplished by a surgical technique. Tympanoplasty is a surgical technique defined as reconstruction of the hearing mechanism with reconstruction of tympanic membrane. The term tympanoplasty was considered to be a simple, easy to complete otologic surgery, with good success rate both anatomically and functionally.[13] Canaloplasty is the surgical procedure whereby the external auditory meatus is widened. It is usually done in conjunction with the procedures employed for correction or eradication of primary disease in middle ear. It can also be done as a primary procedure in cases of anterior bony overhang or exostosis.

In our study, comparative analysis of anatomical and functional outcomes of type I tympanoplasty with canal widening (canaloplasty) and without canal widening was done. In the present study maximum number of cases was in the age of 21-30 years with a mean age of 27.4 years

for group I participants and mean age of 26.6 years for group II participants. It has been reported in a study that maximum number of patients diagnosed with COM were in the age group <40 years. The reason behind this could be due to presence of newer diagnostic tools to diagnose the disease at the early stage and the awareness created among the public by health care professionals related to complications associated with chronic otitis media.[14]

Various surgeons have used different kinds of grafts to repair tympanic membrane perforations. Most popular are autogenous grafts. The pedicle ear canal skin graft and vein graft were used to close tympanic membrane perforations.[15-17] In current scenario, most of the ENT surgeons uses temporalis fascia as a grafting material in tympanoplasty procedures.[18] The graft success rate depends on various factors such as the size and site of perforation, functioning of Eustachian tube, graft placement techniques, the experience of the operating surgeon etc. In the present study also we have used temporalis fascia graft along with underlay technique to close the perforations and could able to achieve good results both in terms of drum healing and postoperative hearing improvement. Narrow external ear canals and small middle ear structure are known factors which lower the success of tympanoplasty. In the present study, type I tympanoplasty with canal widening procedure (canaloplasty) for 25 patients, by removing the bony overhangs in the external canal wall creating complete visibility of the tympanic membrane and annulus was done. The shape of the external auditory canal following canaloplasty corresponds to an inverted truncated cone. Advantages of canalplasty over Type 1 tympanoplasty without canal widening procedure are as follows- (a) better visualisation- this facilitates placement of graft particularly in the anterior anchoring of graft in subtotal perforation (b) better exposure (c) postoperative care easier- there will be no problems with the self-cleansing mechanism of external auditory canal (d) prevent lateralisation of tympanic membrane (e) promotes healing earlier because of rich blood supply to the graft material (f) time gain- the time spent for performing a canal widening procedure is compensated by the time gained by improved exposure during grafting of tympanic membrane. In the present study, at the end of 3rd post-operative month the graft success rate was 100% in type I tympanoplasty with canal widening procedure and 96% in type I tympanoplasty without canal widening procedure. In a report it has showed 92% graft success rate in canalplasty technique and 84% in type I tympanoplasty without canal widening procedure.[19] An increase of graft uptake to 91.3% in cases when tympanoplasty was combined with canalplasty had also been reported.[7] According to prospective interventional study which support the present study that, in cases when canalplasty is done, it increases the middle ear space and also enhances the vibrating mechanism of the tympanic membrane. This helps in preventing anterior blunting and gives better hearing results with 9 dB increase gain.[20]

Yu JF et al showed that different bends of ear canal revealed that the gain in the ear canal is not only by the length of the external auditory canal but also by the interior shape.[21] This also supports our present study there is a difference in the gain between pre and post canaloplasty compared to tympanoplasty without canalplasty. The present study had two groups of participants. The results revealed there are improvement in both the groups; however the improvement was more who had undergone tympanoplasty with canal widening procedure. Olusesi et al conducted a study on pre and post-operative hearing scores in 201 patients who had undergone tympanoplasty.[22] The thresholds of air bone gap improved by 9dB for a mean of 4 frequencies which provides evidences for efficacy of tympanoplasty. Our study provides evidences supporting the tympanoplasty with canal widening procedure to be more superior and efficiency than just tympanoplasty.

CONCLUSION

The ultimate aim of tympanic membrane grafting technique is to have new reconstructed tympanic membrane with functions as close as possible to original tympanic membrane and to prevent complications. Thus, this present study confirms the efficacy of tympanoplasty with canalplasty for better visualization of the anterior sulcus of the external auditory canal and the outcomes of the audiometric thresholds for those who underwent tympanoplasty with canalplasty are superior, effective and efficient. This study also provides a better evidence for the clinical implementation of the tympanoplasty with canalplasty as a better surgical procedure for those with conductive hearing loss due to chronic otitis media for whom surgery is indicated.

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Conflict of interest: None declared
Ethical approval: all testing procedures adhere to the conditions of the Ethics Approval Committee of the institute (Basavaraj, 2009) and has been approved

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