

Tragal Perichondrium versus Pretragal Fascial Grafts for Endoscopic Myringoplasty: A Comparative Study

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Abstract:

Background: Tympanoplasty has been well studied and shown to be effective. The purpose of our research was to assess the effectiveness of the superficial musculoaponeurotic system (SMAS) as a grafting material for the reconstruction of tympanic membrane (TM) defects, in contrast to the use of tragal perichondrium (TP).

Patients and methods: This clinical prospective randomized trial was carried out on thirty individuals, their ages are between sixteen and fifty years old, with TMP, hearing loss gap not more than fifty, and dry ear (no otorrhea without medication for at least one month) for trans-canal endoscopic type1 tympanoplasty. All patients were categorized randomly into two equally distinct SMAS graft groups: used SMAS as a graft, groups: TP graft group: used TP as a graft.

Results; Operation time was recorded showing an important variance among both groups as a shorter time in TP group (P-value =0.009). The air conduction (AC) hearing thresholds at frequencies 500, 1000, and 2000 and air-bone gap (ABG) were recorded 3ms postoperatively. AC demonstrates important development at 500, 1000, and 2000 frequencies (P-value <0.001) at all frequencies, but no important variance between both groups. ABG and ABG gain demonstrate important variance and improvement of ABG in both groups among post and pre-operative (P-value=0.001) in both groups. No important variance in ABG and ABG gain between both groups post and pre-operatively.

Conclusions: There is no statistical significance between the two techniques. SMAS graft showed favorable outcomes as a grafting material that were equivalent to those achieved with TP but did not show any favorable outcome over TP. The use of the SMAS in endoscopic tympanoplasty was shown to be a safe treatment, exhibiting no significant problems.

Keywords: TP, Pretragal Fascial Grafts, Endoscopic Myringoplasty

Introduction

The method of repairing tympanic membrane perforation (TMP) with tympanoplasty has been widely acknowledged as effective and has garnered support from several investigations, starting from its first proposal by Wullstein and Zollner in 1952.¹⁻² In the past, the method included the use of a microscope for the purpose of lighting and magnification.

In some circumstances, such as those involving Asian patients, youngsters, or complicated perforations, a wide-ranging incision in the post-auricular region is often necessary to access the thin and curved external auditory meatus (EAM). The procedure known as exclusive trans-canal endoscopic tympanoplasty was first introduced throughout the 1990s.³ The technology

offers an enhanced and expanded visual perspective for surgical procedures.

Largely, it reduces the necessity for a traumatic post-auricular incision in difficult cases, it has been gaining ground rapidly in recent years.⁴⁻⁶ Although closure rates following tympanoplasty surgery can reach 90% or more, higher failure rates are seen in children, larger TMPs, chronic Eustachian tube dysfunction, and in bilateral cases.⁷

Various graft materials have been suggested over the years with the aim of enhancing surgical outcomes.⁸ Trans-canal endoscopic procedures have been advocated for bigger and more difficult holes that were previously designated for post-auricular treatments, therefore the hunt for the perfect graft continues to be a topic of research. The temporalis fascia (TF) has emerged as the predominant choice of graft material for conventional microscopic tympanoplasty procedures conducted through end-aural or post-auricular approaches. This preference can be attributed to its abundant accessibility and availability. While concerns regarding its long-term durability have been raised in recent times, it continues to be extensively employed in clinical practice.⁷⁻⁹

But because trans-canal endoscopic ear surgery (TEES) is becoming more common, more and more otologists are using it. When the surgery route changes, they switch to using the nearby tragal perichondrium (TP)/cartilage graft. The tragus is a very important part of reconstructive ear surgery¹⁰, and it comes from a limited source, so harvesting on an as-needed basis could mean that there aren't enough donors for future treatments. Additionally, the tragus is the EAM's front cartilaginous spine and helps transmit sound, so keeping it in good shape would be

helpful for future hearing device uses.¹¹⁻¹²

The first introduction of the superficial musculoaponeurotic system (SMAS) located pretragally was credited to Mits and Peyroniein. It is located in the middle of the face, above the parotid gland and mimetic muscles, and is also referred to as the superficial parotideo-muscle fascia. The facial musculature serves as a distinctive motor unit that facilitates the generation of face expressions by establishing a connection between the underlying muscles and the dermis.¹³⁻¹⁴ and Facial rhytidectomy often involves the resection of the tissue.¹⁵

It has been utilized in neck and head surgeries as a local membrane.¹⁶⁻¹⁷ However, it has never been documented in the medical literature as a transplant for tympanoplasty. The SMAS graft has significant promise because to its accessibility via the minimally invasive trans-canal approach of tympanoplasty, while also being situated at a safe distance from critical anatomical structures; therefore, it may be collected without the need for more tissue and without compromising functionality. While the clinical viability of this technique has not yet been confirmed, it has the potential to be used in many trans-canal ear procedures.

In this research, we investigated the treatment findings associated with SMAS graft when used in TEES compared with method of TP and conduct a post-treatment follow up regarding graft uptake, postoperative symptoms, operative time, donor site complications and hearing outcome, hoping to support its clinical use as a graft in ear surgeries, The objective of this research was to provide evidence supporting the clinical utility of the SMAS graft as a viable option for grafting in ear surgeries.

Patients and methods:

This clinical prospective randomized study was done on thirty patients aged above sixteen years old and less than fifty years old, with TMP, The absence of otorrhea, or discharge from the ear, without the use of medicine for a minimum duration of one month. The maximum allowable difference in auditory impairment should not exceed Fifty decibels. The study was done from October 2020 to December 2022, after approval of the ethical committee of faculty of medicine, Assiut University, Egypt .

The exclusion criteria encompassed individuals who were either younger than sixteen or more than fifty years of age, those with active central perforations that were discharging, individuals with unsafe chronic suppurative otitis media (CSOM) accompanied by cholesteatoma, individuals with suspected ossicular pathology in cases of safe CSOM where the air bone gap (ABG) exceeded 50dB, individuals who had previously undergone ear surgery, patients who were deemed unfit for surgery or had chronic medical conditions, and individuals with a narrow external auditory canal .

All patients categorized into randomly into two distinct equal groups for trans-canal endoscopic type one tympanoplasty: SMAS graft group: used SMAS as a graft and TP graft group: used TP as a graft

Patients subjected to history taken, local examination (Nasopharyngeal and Endoscopic nasal examination with (0,30-degree endoscope) and otoscopic (Riester Germany) investigation of the ear. Audiological evaluation Tuning fork tests (Rinne and Weber tests were done) and [Pure tone audiometry (PTA) (Audiometer AD229, interacoustics company, Denmark)].

Trans-canal endoscopic type 1 tympanoplasty:

Surgery was done under general anesthesia after sterilization, dressing, and positioning the patient in the standard otological position. Prophylactic intra-venous ceftriaxone was administrated one hour before surgery. We used endoscope with video system (endoscope FHD camera laptop 15-inch system 4×1-omega, YKD-9003, china) for monitoring. EAC hair trimming then Infiltration of the EAC and the tragal area with 1/200000 epinephrine for hemostasis was done. Refreshment of TMP margin with fine pick circumferentially was done then pack was applied in the EAC till harvesting the graft for hemostasis.

After processing the graft and harvesting, the wound site was closed with 4-0 vycrile suture. Incision was done using round knife to elevate TMF and the tympanic annulus. Checking the ME mucosa, prussak space, ossicles integrity and mobility, Mesotympanum and Eustachian tube and was done. The processed graft was applied by underlay technique. TMF was repositioned. Gel foam pack soaked with betadine cream was applied to be removed after two weeks. Observation was done for 24 hours before discharge. (Figure 1)

Graft preparation

1- SMAS fascia: An 8-10 mm incision was done 2 mm from the free border of the tragus. Dissection was done using curved sharp scissor between tragus and skin with preservation of tragal perichondrium then underneath skin to reach the pretragal fascia. Finally, the desired fascia diameter and thickness (length/width, approximately: 15×12mm; thickness: 2-3mm) was harvested and processed. Muscle and adipose tissue were removed from the graft which then compressed and dehydrated for grafting. The wound was closed with 4-0 vicryl suture.

2- TP: an incision was done similar to that of SMAS fascia. Dissection was done between skin and tragal cartilage using sharp curved scissor. A longitudinal incision was done along the free border of the tragus then the tragal perichondrium was dissected using graft dissector. Finally, the graft was compressed and dehydrated for grafting. The wound was closed with 4-0 vicryl suture.

Postoperative follow up :

The activity is conducted on a weekly basis inside our outpatient clinic. The pack was removed two weeks after the surgical procedure. Postoperative endoscopic evaluation of the graft and donor site recovery was conducted at one, three, six, and 18 months .

Measurement of Hearing Outcome :

Hearing findings were done by four-tone (500, 1000, 2000, 4000 Hz) means of PTA according to Neck Surgery guidelines and the American Academy of Otolaryngology–Head. We calculated the variance among the AC values of PTA one month before and three months after surgery as the PTA gain, and the ABG difference as the ABG gain.

Statistical analysis:

The statistical analysis was conducted using SPSS v26, a software developed by IBM Inc. in Chicago, IL, USA. The normality of the data distribution was assessed using the Shapiro-Wilks test and histograms. The mean and standard deviation (SD) of the quantitative parametric variables were calculated and compared between the two groups using an unpaired Student's t-test. The study used quantitative non-parametric data, which were represented using the median and interquartile range (IQR). These data were subjected to analysis using the Mann Whitney-test. The qualitative variables were represented in terms of frequency and percentage (%) and were subjected to analysis using the

Chi-square test or Fisher's exact test, as deemed suitable. A two-tailed P-value less than 0.05 was deemed to be statistically significant.

Results

The mean age of enrolled patients was $28.33 \pm 8.09SD$ and $29.27 \pm 8.74SD$ years for TP and SMAS groups respectively. Out of the studied patients; (60 %) were females and (40 %) were males for TP group and (46.7%) were males for SMAS group. It was also noticed that (53.3%) were unilateral, (46.7%) were bilateral and (60 %) were unilateral and (40 %) were bilateral for TP and SMAS group respectively. Baseline data in both groups was insignificantly variance (Table 1).

Patients had a history of ear discharge of variable duration, tinnitus, vertigo and hearing loss and none of them had earache. Preoperative examination of TM regarding perforation side and size was done and was categorized into large sized (three or more quadrants), small sized (one quadrant) and medium sized (two quadrants). Also, on examination 1/30 cases had tympanosclerosis patches and 5/30 cases had canal hump. Preoperative signs, symptoms, and postoperative symptoms with follow up were no important variance in both groups.

All the patients had conductive hearing loss of variable degree. The mean AC hearing thresholds at frequencies 500, 1000, and 2000 and average ABG were recorded one m preoperatively with was no important variance in both groups. Operation time showed important variance among both groups as shorter time in TP group with P-value 0.009 (Table 3).

The AC hearing thresholds at frequencies 500, 1000, and 2000 and ABG were recorded three ms postoperatively. Two failed cases from each group, no cases were reported

regarding donor site complications. Postoperative ABG and AC was no important variance in both groups (Table 4).

AC shows important improvement at 500, 1000, 2000 frequencies with P-value 0.000 at all frequencies, but no important variance between both groups. ABG and ABG gain shows

significant difference and improvement of ABG in both group between pre and postoperative with P-value 0.001 in both groups. No significant difference in ABG between both groups pre and postoperatively with P-value 0.908 and 0.900 respectively. No important variance in ABG gain between both groups with P-value 0.416 (Table 5).

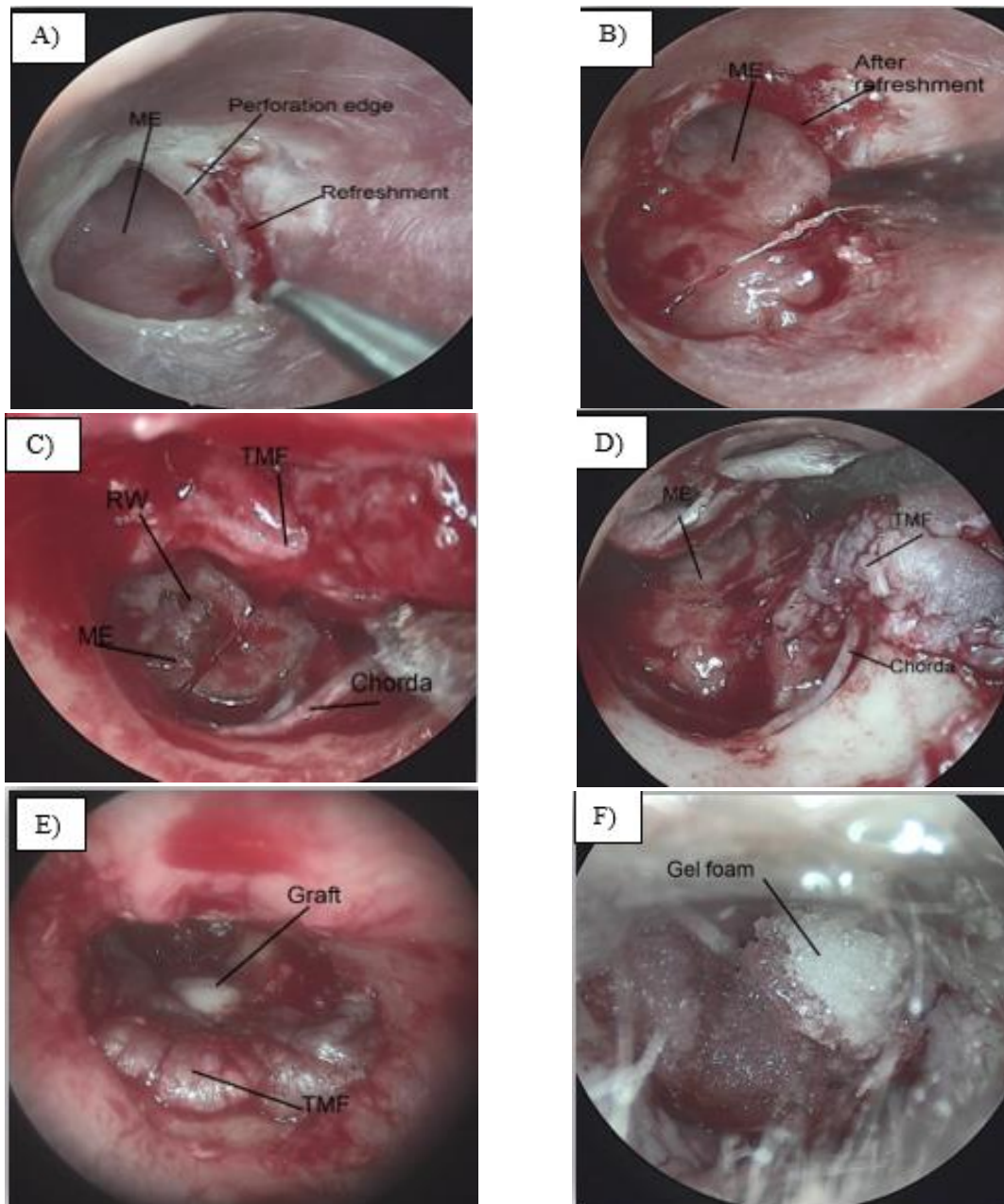


Figure 1): Steps of endoscopic tympanoplasty: A), and B) Refreshment of TM perforation. C), and D) Elevation of TMF. E) Graft inserted by underlay technique. F) Gel foam applied in EAC. (ME: middle ear, RW: round window, TMF: tympanomeatal flap).

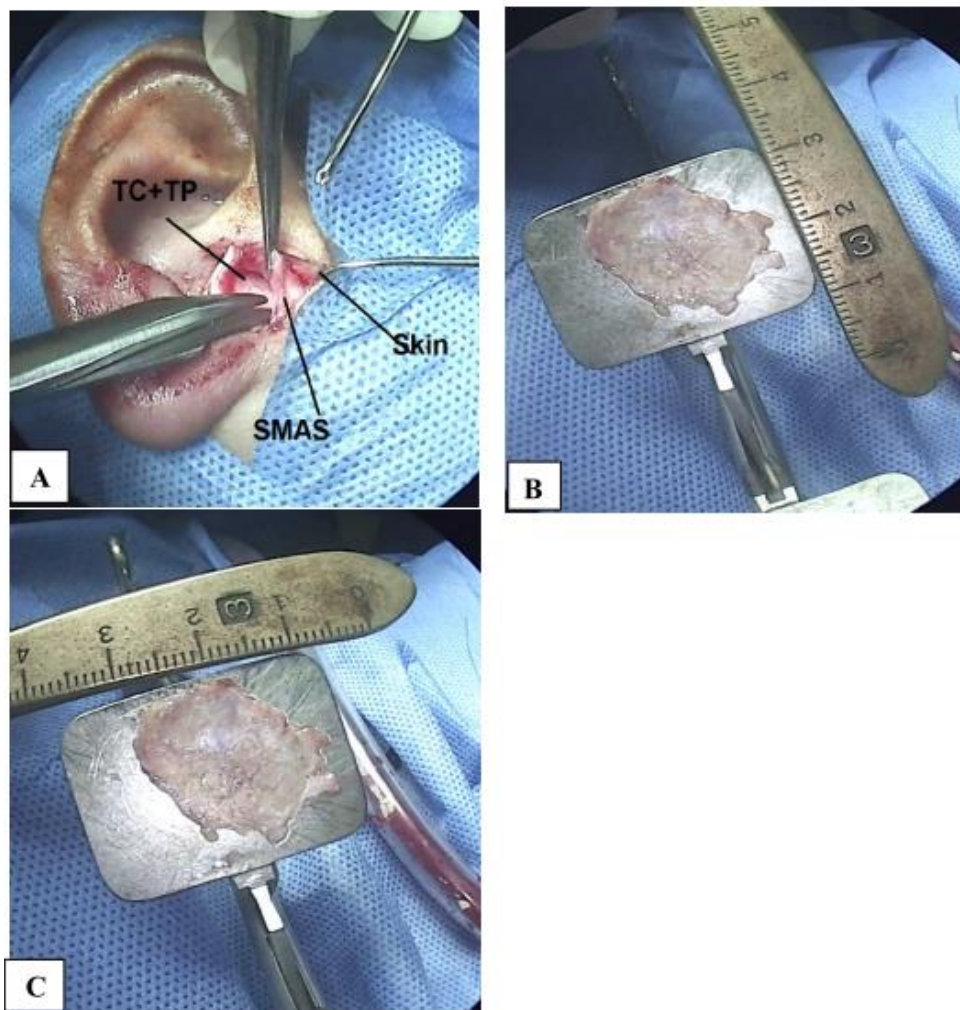


Fig. 2) Preparation of SMAS fascia graft: A) SMAS fascia dissection. B), and C) show SMAS fascia graft size. (TC: tragal cartilage, TP: tragal perichondrium)

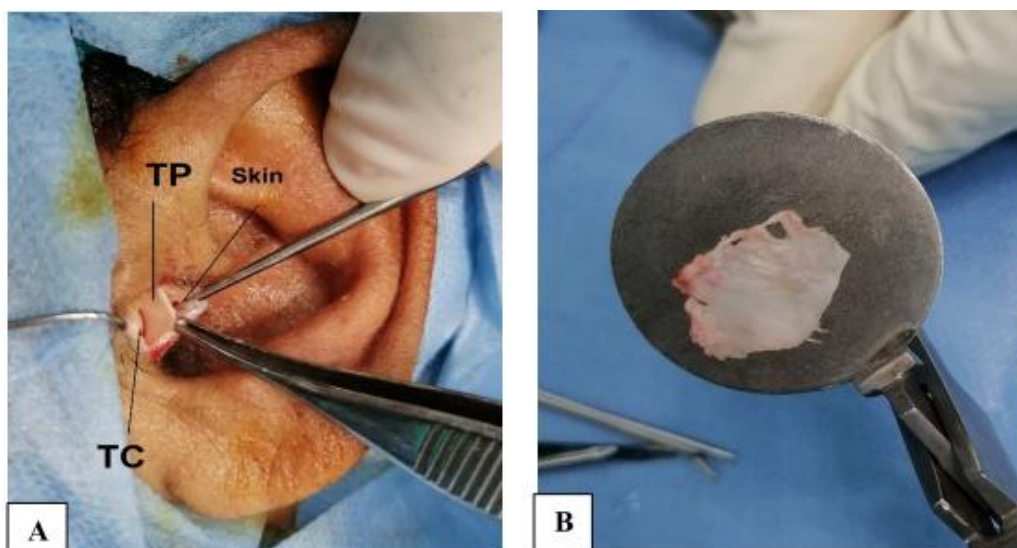


Fig. 3) Preparation of TP graft: A) TP graft dissection. B) Harvested TP graft. (TC: tragal cartilage, TP: tragal perichondrium).

Table 1: Baseline data in both groups

		TP graft group (N= fifteen)		SMAS graft group (N= fifteen)		P-value
		No.	%	No.	%	
Gender	Male	six	40.0%	7	46.7%	0.713
	Female	nine	60.0%	8	53.3%	
Age (years)		28.33 \pm 8.09		29.27 \pm 8.74		0.764
Laterality	Unilateral	eight	53.3%	9	60.0%	0.713
	Bilateral	seven	46.7%	6	40.0%	

Data expressed as number (%) or average \pm SD. P value was significant if < 0.05 .

Table 2: Preoperative symptoms, signs and post-operative symptoms in both groups

		TP graft group (N= fifteen)		SMAS graft group (N= fifteen)		P-value
		No.	%	No.	%	
Preoperative symptoms						
Earache		0	0.0%	0	0.0%	--
Tinnitus		12	80.0%	13	86.7%	1.000
Vertigo		8	53.3%	8	53.3%	1.000
Hearing loss		15	100.0%	15	100.0%	1.000
Pre-operative signs						
Otorrhea	Period of dryness	5.0 (3.0-12.0)		5.0 (1.0-12.0)		0.849
Side	Right	6	40.0%	7	46.7%	0.713
	Left	9	60.0%	8	53.3%	
Perforation size	Small	3	20.0%	2	13.3%	0.884
	Medium	10	66.7%	11	73.3%	
	Large	2	13.3%	2	13.3%	
Post-operative symptoms						
Discharge		1	6.7%	0	0.0%	1.000
Earache		0	0.0%	0	0.0%	--
Tinnitus		2	13.3%	0	0.0%	0.483
Vertigo		0	0.0%	0	0.0%	--
Hearing loss		1	6.7%	0	0.0%	1.000

Data demonstrated as number (%) or median (IQR). P value was significant if < 0.05 .

Table 3: Preoperative AC, operative time and average ABG (DB) in both groups

	TP graft group (n= fourteen)	SMAS graft group (n= fourteen)	P-value
AC			
500 HZ	46.79 \pm 13.95	44.64 \pm 9.30	0.636
1000 HZ	42.86 \pm 12.82	40.00 \pm 6.79	0.468
2000 HZ	36.07 \pm 6.56	36.07 \pm 9.03	1.000
ABG (DB)			
Pre-operative	27.02 \pm 8.92	26.43 \pm 7.73	0.908
Operative time (minutes) (n= 15)			
	48.60 \pm 4.19	52.07 \pm 2.34	0.009*

Data expressed as average \pm SD. AC, ABG: Air bone gap. P value was significant if < 0.05 .

Table 4: Postoperative ABG (DB) and AC in both groups

	TP graft group (n= fourteen)	SMAS graft group (n= fourteen)	P-value
AC			
500 HZ	25.00 ± 8.55	26.07 ± 6.56	0.713
1000 HZ	25.71 ± 8.05	25.00 ± 5.88	0.791
2000 HZ	23.93 ± 7.12	21.79 ± 5.04	0.366
ABG (DB)			
Pre-operative	8.3 (0.0-21.7)	10.0 (0.0-21.7)	0.900
Success rate (n= 15)			
Success	14 (93.3%)	14 (93.3%)	1.000
Failure	1 (6.7%)	1 (6.7%)	

Data expressed as mean ± SD or number (%). AC, ABG: Air bone gap. P value was significant if < 0.05.

Table 5: mean AC pre and postoperatively at 500, 1000, and 2000 frequencies mean ABG pre and postoperatively and ABG gain in both groups

		TP (n= fourteen)	SMAS (n= fourteen)	P-value
AC				
500 HZ	Pre-operative	46.79 ± 13.95	44.64 ± 9.30	0.636
	Post-operative	25.00 ± 8.55	26.07 ± 6.56	0.713
	P-value²	0.000*	0.000*	
1000 HZ	Pre-operative	42.86 ± 12.82	40.00 ± 6.79	0.468
	Post-operative	25.71 ± 8.05	25.00 ± 5.88	0.791
	P-value²	0.000*	0.000*	
2000 HZ	Pre-operative	36.07 ± 6.56	36.07 ± 9.03	1.000
	Post-operative	23.93 ± 7.12	21.79 ± 5.04	0.366
	P-value²	0.000*	0.000*	
ABG (DB)				
Pre-operative	27.5 (15.0-40.0)	25.0 (15.0-40.0)		0.908
Post-operative	8.3 (0.0-21.7)	10.0 (0.0-21.7)		0.900
P-value²	0.001*	0.001*		
ABG gain	16.7 (6.7-26.7)	13.3 (5.0-31.7)		0.416

Discussion:

Tympanoplasty is a surgical procedure that entails the restoration of a perforated TM with the aim of restoring auditory function.¹⁸

There was one case with tympanosclerotic patches with functional and anatomical success, this agrees with Onal et al.¹⁹ There are those who reject any correlation between myringosclerosis and a diminished efficacy in tympanoplasty procedures. However, the researches by Pinar et al.

²⁰ and Yurttas, et al.²¹, the lack of sclerotic plaques on the TM has been shown to enhance the efficacy of tympanoplasty grafting procedures.

Average pre-operative ABG was 27.02dB ±8.92 SD: 26.43dB ± 7.73 SD with median 27.5: 25.0 TP: SMAS respectively, this agrees with Lin et al.²² who found ABG mean (± SD) SMAS: TF 21.3(± 8.4): 22.7 (±10.6). Average operative time in minutes was 48.60 ±4.19 SD in TP: 52.07(±2.34) in SMAS, this duration time was less than Lin et al 2020²², also Awad and Hamid²³

According to the findings of Awad and Hamid, patients who have endoscopic operations experience a shorter duration of operation time. However, in the study of Ghaffar et al.²⁴ mean operation time was found to be 62.85 min in patients undergoing endoscopic tympanoplasty. Huang et al.²⁵ also reported that the mean operation time was 75.5 min in patients undergoing endoscopic tympanoplasty. This variation is due to the variance in graft material and technique beside the experience of learning curve and surgeon.

Fermi, Maccarrone et al.²⁶ It was determined that the average duration of endoscopic tympanoplasty surgeries was seventy-five minutes, whereas the average duration of microscopic tympanoplasty operations was ninety minutes. This demonstrates that the endoscopic method has many benefits, such as decreased operation duration, less exposure to anaesthetic drugs and their accompanying side effects, and enhanced dexterity and surgeon focus enabling the use of a reducing operation time and one-handed technique. Among 30 patients, there were five patients with canal hump, but we did not need canaloplasty, this also other advantage of endoscopic tympanoplasty approach, this also with Mokbel et al.²⁷ they found that none of their patients who underwent endoscopic tympanoplasty required interventions such as canaloplasty or curettage. However, Karhuketo et al.²⁸ stated that canaloplasty and outer ear curettage became necessary in some of their patients undergoing microscopic tympanoplasty.

Anatomical successful graft uptake was (93.3%) in TP: (93.3%) in SMAS group. In Zakir et al.²⁹ study on hundred twenty patients, successful graft uptake was ninety% in microscopic tympanoplasty compared to 91.6% in endoscopic group. Lin, Chang

et al.²² stated that successful graft uptake was (96.7%) in SMAS: (93.3%) in TF.

According to functional success, average postoperative ABG (DB) was 10.11 ± 6.89 SD: 10.33 ± 6.08 SD in TP: SMAS respectively, with significantly better than preoperative (p-value < .0001). With mean ABG gain 16.19 ± 4.91 SD: 15.36 ± 6.07 SD in TP: SMAS respectively with no importance among two types of grafts In Lin et al. [22], post-op. Mean ABG gain was 7.6 ± 5.1 SD: 8.2 ± 6.8 SD in SMAS: TF respectively.

All symptoms were improved post-operatively including (hearing loss, ear discharge, tinnitus and vertigo) with no important variances in both groups except two patients in TP group still complained of tinnitus which can be explained with preoperative high frequency sensorineural hearing loss (SNHL) in both of them.

Two out of thirty cases failed: one case with TP graft which had large perforation size preoperatively and had URTI post-operatively. We managed this case with revision of tympanoplasty endoscopically using tragal cartilage graft.

The other failed case with SMAS mostly due to URTI had small perforation with no discharge or symptoms, we have followed-up the case for six months, yet no spontaneous healing has occurred, and the patient refused revision surgery. We did not encounter any local complications at the donor site of the graft in both groups.

There are some limitations of the research such as sample size, exclusion of paediatric cases, long learning curve, inconveniences and challenges associated with instrumentation of the endoscopic techniques are also difficulties in our research.

Conclusion:

There is no statistical significance between the two techniques. SMAS graft showed favorable outcomes as a grafting material that were equivalent to those achieved with TP but did not show any favorable outcome over TP. The use of the SMAS in endoscopic tympanoplasty was shown to be a safe treatment, exhibiting no significant problems.

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Conflicts of interest: No

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