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The impact of cubism graft on the outcome of tympanoplasty surgery

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***Abstract*---**Background: Tympanoplasty is a widely performed surgery for the repair of tympanic membrane perforation. Aim of the study: to compare the auditory and anatomical outcomes between two different techniques in tympanoplasty: the first with temporalis facia graft + the new “cubism” graft and the other with temporalis facia graft alone. Patients and methods: A prospective, randomized study was conducted in Otorhinolaryngology Head and Neck Surgery Department, Al-Azhar University Hospital (Damietta). Results: Cubism graft group wasn't significantly different to Temporalis fascia only group regarding ABG (p= 0.233). The ABG gain 3 month in Cubism graft group ranged from 14 to 17.5 with mean ± SD = 16.17 ± 1.15 while in Temporalis fascia only group the ABG gain 3 month ranged from 10 to 16 with mean ± SD = 14.12 ± 1.91 with statistical significant difference (p= 0.005) between the two groups. Conclusion: The novel “cubism” graft technique offers many advantages. Cartilage grafts can be thinned harmlessly while obtaining a convenient additional material in this technique. This hybrid, cartilaginous dust and PRF mixture graft can be used widely in tympanoplasty. We experienced that both functional and anatomical outcomes of this graft are very satisfying. This technique is cost-free and easy to perform.

***Keywords*---**tympanoplasty, tympanic membrane, cubism, temporalis fascia.

Introduction

Chronic suppurative otitis media is a chronic inflammation which involves the mucoperiosteal lining of the middle ear cleft characterized by chronic ear discharge due to recurrent middle ear infection through tympanic membrane perforation. (Gross, 1989). Tympanoplasty is a widely performed surgery for the repair of tympanic membrane perforation. The main goals of tympanoplasty are to get an intact tympanic membrane by closing the perforation area with a graft material and to improve the hearing. (Khan, 2016). The commonly used graft materials for the perforated tympanic membrane repair include: fascia fat, perichondrium and cartilage (Iacovou, 2013)

Platelets are rich in growth factors which stimulate extracellular matrix deposition and neovascularization. Plasma contains many factors including nutrients, vitamins, hormones, electrolytes, growth factors, and proteins that are essential for cell life and tissue healing. (Maria, 2011). Clinical research indicates that PRF (platelet-rich fibrin) are the second generation of platelet concentrates which play an important role to enhance wound healing and homeostasis in both soft and hard tissue wounds. (Mazzucco, 2008). In the endoscopic/microscopic view, of this new graft contains the cartilaginous dust pieces that look like cubic geometric forms. The view of this graft reminds of the paintings of the artists of the cubism art movement. Therefore, it has been named as the “cubism graft. (Kaya, 2021)

Patients and Methods

A prospective, randomized study was conducted in Otorhinolaryngology Head and Neck Surgery Department, Al-Azhar University Hospital (Damietta).
Patients: patients with chronic suppurative otitis media tubotympanic type.
Study design: In this prospective randomized comparative study Patients were divided in two groups A and B: Group A: include patients who undergo tympanoplasty with temporalis facia graft + the new “cubism” graft. Group B: include patients who undergo tympanoplasty with temporalis facia graft only.
Counseling and consent: Full description of the procedure was explained to the patients and free written consent was taken from each patient or his guardian. The patients were instructed to keep their operated ears dry in the immediate postoperative period and to return to the clinic if they noticed any evidence of wound infection (like pain and discharge).
Study design: All patients were operated under general anesthesia. Preoperative clinical and audiological examination was performed in all patients. Post-operative antibiotics were prescribed to all patients. Patients were examined postoperatively for bleeding and infection and audiological improvement. All patients were followed-up on 1 week, 1 month and 3 months.
Inclusion criteria: Both sex and patient with chronic suppurative otitis media with tympanic membrane perforation with a dry middle ear cavity and normal middle ear mucosa, intact ossicular chain, absence of cholesteatoma.

Exclusion criteria: Patients not willing for surgery, evidence of infection at the time of surgery and history of middle ear surgery and history of radiotherapy to the head and neck region, presence of rheumatological disease.

Preoperative evaluation

History taking including: Personal history including: Name, Age, gender, marital state, address, present history: of chronic diseases and medication, past history of HTN, DM, family history of similar condition or diabetes and history of previous surgeries. General examination in the form of Vital signs (Blood pressure, Temperature, Heart rate, Respiratory rate), Signs of (Pallor, Cyanosis, Jaundice, and Lymph node enlargement). Full ENT examination including: Oropharyngeal examinations, nasal examination was done using a 0°, 2.7 mm rigid endoscope or a 4-mm scope in older children after application of nasal vasoconstrictors using pledgets soaked in 4%lignocaine with 1: 10,000 adrenalines searching for deviated nasal septum, active infection or allergic rhinitis, ear examination searching for otitis media with effusion and adhesive otitis media and neck examination with assessment of cervical lymph nodes. Endoscopic examination: Rigid endoscopes were used to examine the ear. Pure tone audiometry: The testing procedure is repeated at specific frequencies from 250 to 8000 hertz (Hz, or cycles per second) for each ear, and the thresholds are recorded on a graph called an audiogram. Laboratory investigations: Complete blood picture (CBC), renal function test, liver Test Profile, coagulation profile

Operative procedure

The surgeries were performed under general anesthesia. All surgical procedures can be performed by either endoscope or microscope. All surgical procedures can be performed by either trans canal approach or postauricular approach. The perforation edges was deepithelized, tympanomeatal flap was elevated for visualization.

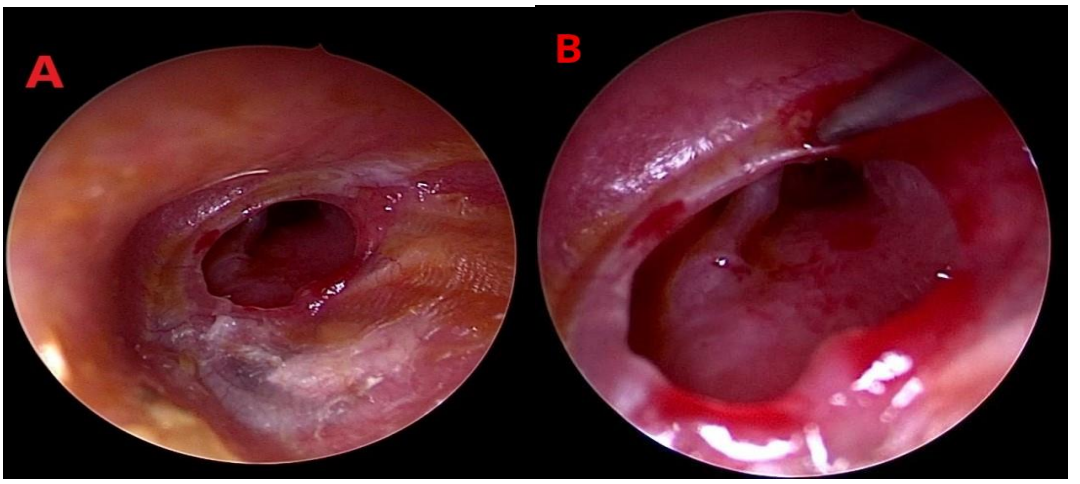

Fig 1: A. tympanic membrane before refreshing B.Refreshing edge of tympanic membrane

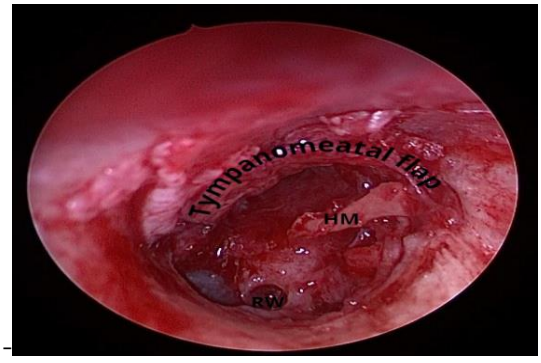

Fig.2: Complete elevation tyympano-metal flap with exposure middle ear

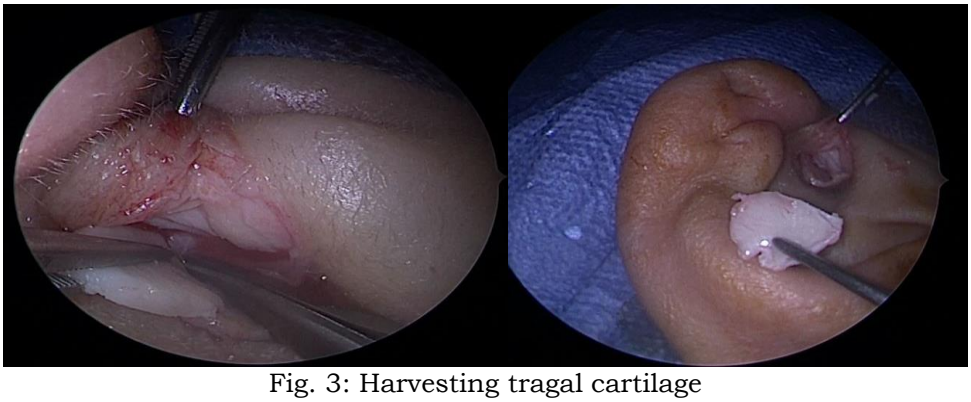

Fig. 3: Harvesting tragal cartilage

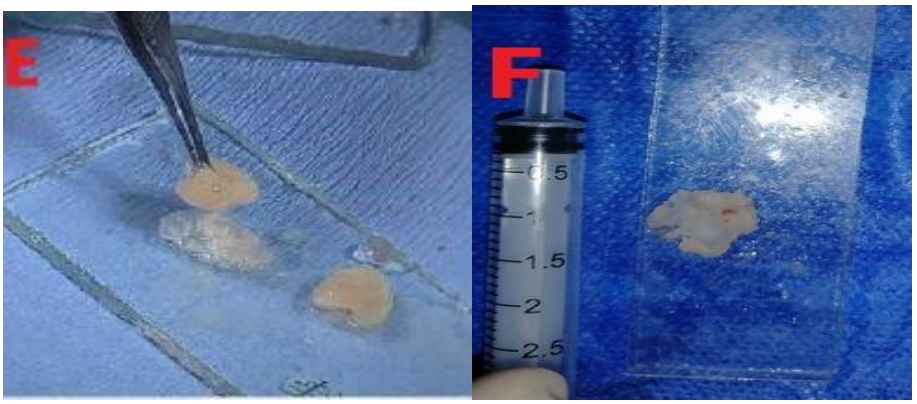

FIG.4: Surgical technique of the cubism graft. A, Holding the surgical blade perpendicular to the cartilage. B, Cumulation of cartilage dust while brushing the cartilage..C, Cutting the platelet-rich fibrin (PRF) into pieces.. D, Crushing the cartilage dust-PRF mixture between two thick glass slides. E,Addition of extra cartilage dust and PRF piece. F, The cubism graft.

At the first group Temporalis facia graft was harvested and prepared and it was easily placed in an over-underlay manner, after the placement of facia graft, the tympanomeatal flap was repositioned to the anatomical position then the cubism graft was placed over the tympanic membrane as the second layer, the external auditory canal was packed with Gelfoam. In the second group, Temporalis facia graft was harvested and prepared, and it was placed in an over-underlay manner. The tympanomeatal flap was repositioned to the anatomical position and the external auditory canal was packed with Gelfoam.

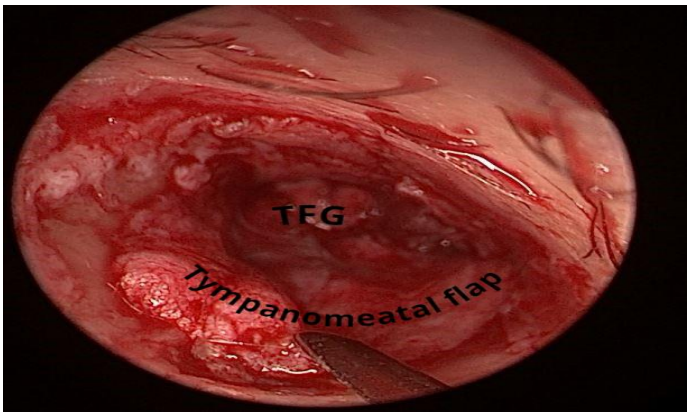

FIG.5: The view of the tympanic membrane after Placement the Temporalis facia grafts and replacement of the tympanomeatal flap

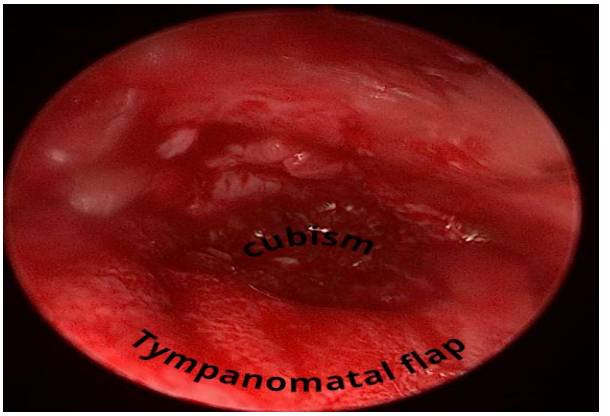

FIG.6: The view of the tympanic membrane after Placement cubism graft

Postoperative follow up

Outcomes were evaluated at 1 month, and 3 months using otoscopic, endoscopic examination. PTA was done at 1 month, and 3 months after the surgery. Postoperative first and three month-microscopic examination findings were noted: Tympanic membrane perforation size and location, and postoperative graft status.

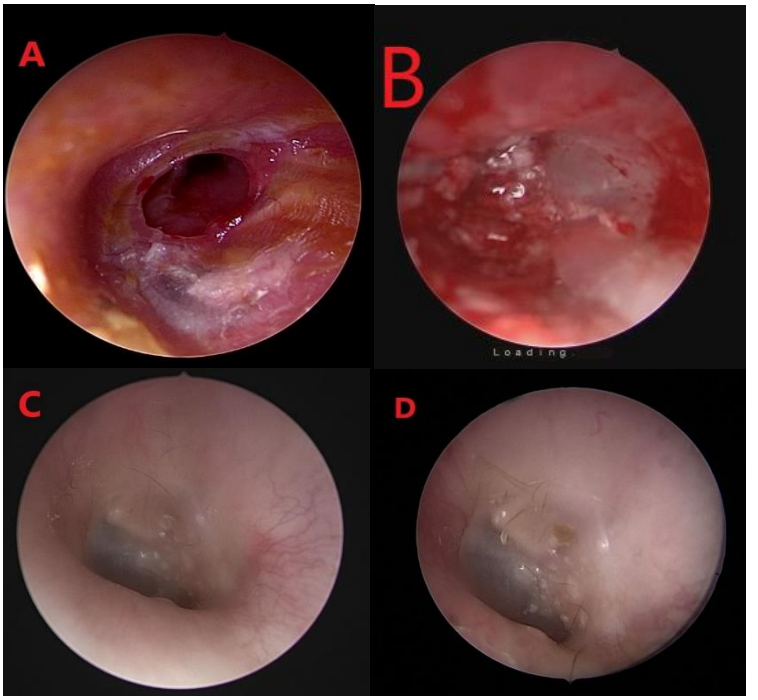

FIG.7: Follow u: A, Tympanic membrane perforation preoperative. B, Showing Tympanic membrane postoperative immediately. C, Showing Tympanic membrane postoperative 1 month. D, Showing Tympanic membrane postoperative 3 months

Statistical Analysis

All data were collected, tabulated and statistically analyzed using SPSS 26.0 for windows (SPSS Inc., Chicago, IL, USA). Qualitative data were described using number and percent. The Shapiro–Wilk test was used to verify the normality of distribution. Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. All statistical comparisons were two tailed with significance Level of P-value ≤ 0.05 indicates significant, p <0.001 indicates highly significant difference while, P> 0.05 indicates Non-significant difference.

Results

Table (1): Demographic characteristic data of the study population

	Cubism graft group (n = 20)	Temporalis fascia only group (n = 20)	Test of Sig.	p
Gender				
- Male n (%)	9 (45%)	11 (55%)	x2 = 0.400	0.527
- Female n (%)	11 (55%)	9 (45%)		
Age (years)				
Mean ± SD.	30.44 ± 9.11	28.62 ± 7.91	t = 0.488	0.632
Median (IQR)	32 (25 - 35)	30 (25 - 34)		
Range (Min-Max)	28 (17 - 45)	30 (12 - 42)		

x2: Chi- Square test SD: standard deviation
IQR: interquartile range t: Independent T test
p: p value for comparing between the studied groups
P-value > 0.05: Non significant; P-value < 0.05: Significant; P-value < 0.001: Highly significant

The Age in Cubism graft group ranged from 17 to 45 with mean ± SD = 30.44 ± 9.11 while in Temporalis fascia only group the Age ranged from 12 to 42 with mean ± SD = 28.62 ± 7.91 with no statistical significant difference (p= 0.632) between the two groups. Cubism graft group wasn't significantly different to Temporalis fascia only group regarding Age (p= 0.632). Table (1). Regarding Perforation size, There wasn't a significant difference between the two studied groups (p= 0.056). Cubism graft group wasn't significantly different to Temporalis fascia only group regarding Perforation size (p= 0.056). Figure (1)

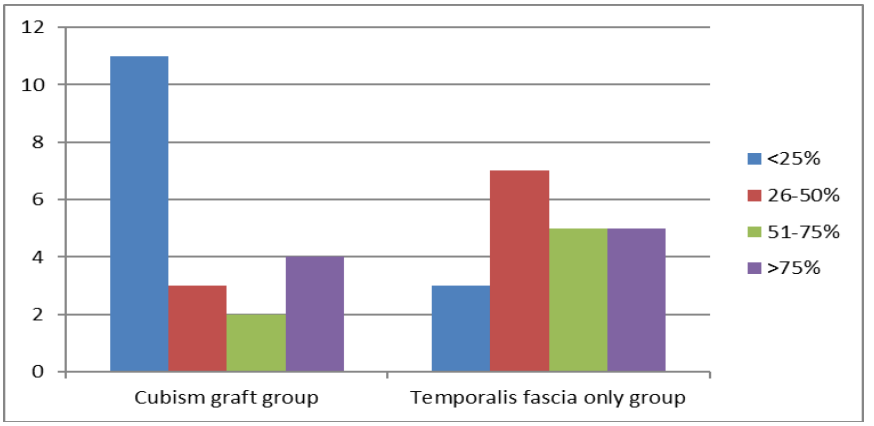

Figure (8): Bar chart showing comparison between the study groups regarding Perforation size

Table (2): Operative data of the study population

	Cubism graft group (n = 20)		Temporalis fascia only group (n = 20)		Test of Sig.	p
	n	%	n	%		
Operation type						
- Post auricular n (%)	9	45%	9	45%	x2 = 3.474	.176
- Endoscopic n (%)	11	55%	8	40%		
- Endoaural n (%)	0	0%	3	15%		
Result of graft						
- Taken n (%)	19	95%	17	85%	x2 = 1.111	.292
- Failed n (%)	1	5%	3	15%		

x2: Chi- Square test p: p value for comparing between the studied groups P-value > 0.05: Non significant; P-value < 0.05: Significant; P-value < 0.001: Highly significant

Table (2) showed operative data of the study population. Regarding Operation type, There wasn't a significant difference between the two studied groups (p= 0.176). Cubism graft group wasn't significantly different to Temporalis fascia only group regarding Operation type (p= 0.176). Regarding Result of graft, There wasn't a significant difference between the two studied groups (p= .292). Cubism graft group wasn't significantly different to Temporalis fascia only group regarding Result of graft (p= .292).

Table (3): Comparison of postoperative ABG and ABG gain outcomes between the groups

	Cubism graft group (n = 20)	Temporalis fascia only group (n = 20)	Test of Sig.	p
ABG (dB)				
Mean ± SD.	27.33 ± 2.5	25.77 ± 3.47	t = 1.229	0.233
Median (IQR)	27 (25 - 30)	25 (24 - 26)		
Range (Min-Max)	6 (25 - 31)	12 (20 - 32)		
ABG gain 1 month (dB)				
Mean ± SD.	14 ± 1.12	11.85 ± 1.91	t = 3.328	0.003
Median (IQR)	14 (13 - 15)	12 (12 - 13)		
Range (Min-Max)	3 (12 - 15)	6 (8 - 14)		
ABG gain 3 month (dB)				
Mean ± SD.	16.17 ± 1.15	14.12 ± 1.91	t = 3.146	0.005
Median (IQR)	16.5 (15.5 - 17)	15 (13 - 15.5)		
Range (Min-Max)	3.5 (14 - 17.5)	6 (10 - 16)		

SD: standard deviation IQR: interquartile range
t: Independent T test p: p value for comparing between the studied groups
P-value > 0.05: Non significant; P-value < 0.05: Significant; P-value < 0.001: Highly significant

The ABG in Cubism graft group ranged from 25 to 31 with mean ± SD = 27.33 ± 2.5 while in Temporalis fascia only group the ABG ranged from 20 to 32 with mean ± SD = 25.77 ± 3.47 with no statistical significant difference (p= 0.233) between the two groups. Cubism graft group wasn't significantly different to Temporalis fascia only group regarding ABG (p= 0.233). The ABG gain 3 month in Cubism graft group ranged from 14 to 17.5 with mean ± SD = 16.17 ± 1.15 while in Temporalis fascia only group the ABG gain 3 month ranged from 10 to 16 with mean ± SD = 14.12 ± 1.91 with statistical significant difference (p= 0.005) between the two groups.Cubism graft group was significantly different to Temporalis fascia only group regarding ABG gain 3 month (p= 0.005). Table (3), Figure (1)

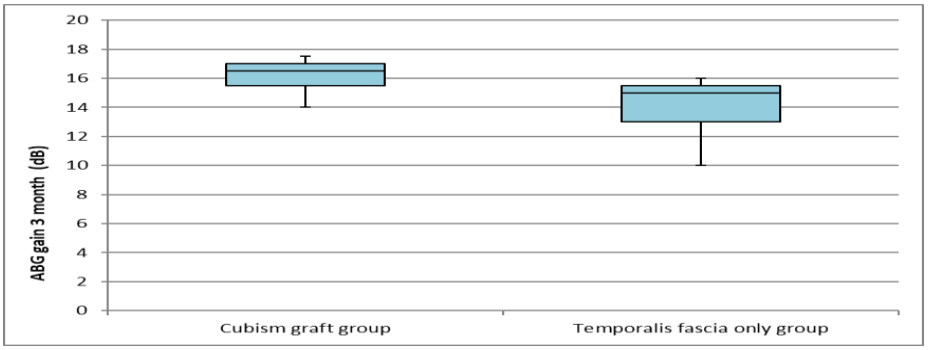

Figure (9): Box-plot showing difference between the study groups regarding ABG gain 3 month

Discussion

Tympanoplasty is a widely performed surgery for the repair of tympanic membrane perforation. The main goals of tympanoplasty are to get an intact tympanic membrane by closing the perforation area with a graft material and to improve the hearing (Khan and Parab 2016). This randomized-controlled performed at Otorhinolaryngology Head and Neck Surgery Department, Al Azhar University Hospital (Damietta). The study conducted on 40 patients with noncomplicated chronic otitis media, the patient randomly divided into 2 groups: group 1 included 20 patients treated with temporalis facia graft + the new "cubism" graft and group 2 included 20 patients treated with Temporalis fascia only technique.

Regarding the demographic characteristic data of the study population, we found that Regarding Gender, Cubism graft group wasn't significantly different to Temporalis fascia only group regarding Gender (p= 0.527). The Age in Cubism graft group ranged from 17 to 45 with mean ± SD = 30.44 ± 9.11 while in Temporalis fascia only group the Age ranged from 12 to 42 with mean ± SD = 28.62 ± 7.91. Cubism graft group wasn't significantly different to Temporalis fascia only group regarding Age (p= 0.632).Only one study was found in literature that presented the Cubism graft technique (Kaya et al., 2021), we will compare the outcome of the current study with this study and some other studies describing different methods.

The current study was in line with the study by Kaya et al., 2021 aimed to analyze the outcomes of a new graft technique in tympanoplasty and compare its outcomes with cartilage island graft plus extra perichondrium. The study included 44 patients were randomly divided into 2 double-layer graft groups: The cartilage island graft + cubism graft (study group) and the cartilage island graft + extra perichondrium (control group). Twenty-five of 44 patients (56.8%) were male and 19 (43.2%) were female. The average age of all patients was 33.6 ± 8.5 years (20-52 years). The average age of the study group was 33.5 ± 8.6 years (20-52 years) and the average age of the control group was 33.7 ± 8.7 years (20-50 years). There was no statistically significant difference between the studied groups as regard age and sex.

Also, Shinde et al., 2021 aimed to perform a comparative study of hearing outcome in patients undergoing type 1 tympanoplasty using temporalis fascia versus sliced tragal cartilage. 50 patients were divided into 2 groups and underwent type-1 tympanoplasty using temporalis fascia versus sliced tragal cartilage. The difference in age groups was non-significant between both the groups with a p value of 0.73. The gender difference was non-significant with a p value of 0.571.

In the current study, regarding operative data of the study population, we found that cubism graft group wasn't significantly different to temporalis fascia only group regarding Operation type (p= 0.176). Also, regarding Result of graft, there wasn't a significant difference between the two studied groups (p= 0.633). the success rate was non significantly higher in the cubism graft group (90%) when compared to temporalis fascia only group (85%).

The study by Kaya et al., 2021 revealed that all the studied patient was operated by trans canal endoscopic approach. The graft success rate was 100% in the first month otological examination in the study group. A successful grafting was observed in 21 of 22 patients (95.5%) in the control group. No graft failure was observed in the sixth month otological examination in the study group. The graft success rate was 95.5% in the control group in the sixth month examination. The patient with graft failure underwent a revision 6 months after the first surgery. Our results can be supported by Xing et al., 2020 who reported that the success rate was 96.7% in the partialthickness cartilage and full-thickness cartilage groups, and >90% in the temporalis fascia group. There was no difference in the success rate among the groups.

Also, the study by Singh et al., 2018 revealed that Graft uptake rate in Group I (temporalis muscle fascia) was 85% while Group II (liced conchal cartilage) patients had a uptake rate of 95% ($P < 0.001$). Loss of graft or partial uptake was there in about 20% of the patients. As well, Saranya, 2021 revealed that among the 50 patients who took part in the study (84%) had good graft uptake. In the temporalis fascia group, which had 25 patients 20 (80%) had good graft take up. In the sliced cartilage group of 25 patients 22 (88%) had positive results. The difference in graft uptake between the 2 groups was found to be statistically insignificant.

Comparison of postoperative ABG and ABG gain outcomes between the groups, showed that The ABG in Cubism graft group ranged from 25 to 31 with mean ± SD = 27.33 ± 2.5 while in Temporalis fascia only group the ABG ranged from 20 to 32 with mean ± SD = 25.77 ± 3.47. Cubism graft group wasn't significantly different to Temporalis fascia only group regarding ABG ($p= 0.233$). The ABG gain 1 month in Cubism graft group ranged from 12 to 15 with mean ± SD = 14 ± 1.12 while in Temporalis fascia only group the ABG gain 1 month ranged from 8 to 14 with mean ± SD = 11.85 ± 1.91 with statistically significant difference ($p= 0.003$) between the two groups. Cubism graft group was significantly higher than the Temporalis fascia only group regarding ABG gain 1 month ($p= 0.003$).

The ABG gain 3 months in Cubism graft group ranged from 14 to 17.5 with mean ± SD = 16.17 ± 1.15 while in Temporalis fascia only group the ABG gain 3 months ranged from 10 to 16 with mean ± SD = 14.12 ± 1.91 with statistically significant difference ($p= 0.005$) between the two groups. Cubism graft group was significantly higher than Temporalis fascia only group regarding ABG gain 3 month ($p= 0.005$). In agreement with the present study Kaya et al., 2021 found that there was no statistically significant difference in the preoperative ABG between study and control groups ($P > .05$). There were statistically significant differences in the postoperative first month ABG and ABG gain between study and control groups ($P < .001$). There were no statistically significant differences in the postoperative sixth month ABG and ABG gain between study and control groups ($P > .05$). The comparison between preoperative and postoperative sixth month ABG values was found to be significant for both groups ($P < .001$). In terms of graft status, no significant difference was found in the postoperative sixth month ($P > .05$).

However, the study by Xing et al., 2020 reported that the air conduction threshold was significantly higher before the operation than after the operation in the temporalis fascia, partial-thickness cartilage, and full-thickness cartilage groups. Although the hearing gain in the temporalis fascia group and the partial-thickness cartilage group was higher than that in the full-thickness cartilage group, there was no significant difference in the graft success rate among the groups.

Also, the study by Shinde et al., 2021 revealed that pre-operative AB gap was 29.20 and 27.4 dB respectively with non-significant p value at 0.288. The post-operative AB gap was 15 dB and 10.4 dB respectively with significant p value of 0.0041. The post-operative AB gap was significantly better in sliced tragal cartilage group. Improvement in AB gap was significantly better in group sliced tragal cartilage with a p value of 0.042. While, Saranya, 2021 reported that the temporalis fascia group had a hearing improvement of 9.04 dB and sliced tragal cartilage group had 10.3 dB. There was statistically significant difference in hearing postoperatively in both groups but there was no statistically significant difference between the two groups.

Conclusion

The novel “cubism” graft technique offers many advantages. Cartilage grafts can be thinned harmlessly while obtaining a convenient additional material in this technique. This hybrid, cartilaginous dust and PRF mixture graft can be used widely in tympanoplasty. We experienced that both functional and anatomical outcomes of this graft are very satisfying. This technique is cost-free and easy to perform.

References

Gross C, B. M. (1989). Adipose plug myringoplasty: an alternative to formal myringoplasty techniques in children. *Otolaryngol Head Neck Surg.* , 101.

Iacovou E, Vlastarakos PV, Papacharalampous G, Kyrodimos E, Nikolopoulos TP (2013). Is cartilage better than temporalis muscle fascia in type I tympanoplasty? Implications for current surgical practice. Eur Arch Otorhinolaryngol. 270:2803-2813.

Kaya, İ., Şahin, F. F., Tanrıverdi O, H., and Kirazlı, T. (2021). The new “cubism” graft technique in tympanoplasty: A randomized controlled trial. Laryngoscope Investigative Otolaryngology, 6(3), 503-511.

Khan MM, Parab SR (2016). Endoscopic cartilage tympanoplasty: a two-handed technique using an endoscope holder. Laryngoscope. 126(8):1893-1898.

Maria LNA, O. N. (2011). Pilot study on the efficiency of the biostimulation with autologous plasma rich in platelet growth factors in otorhinolaryngology: otologic surgery (tympanoplasty type I). *ISRN Surgery*.

Mazzucco L, B. V. (2008). Platelet-rich plasma and gel preparation using Plateltex. *Vox Sang* .

Saranya, M. (2021). A Comparative study between Sliced Cartilage versus Temporalis Fascia in Type I Tympanoplasty (Doctoral dissertation, Thanjavur Medical College, Thanjavur).

Shinde V, Sonar T, Shah S, Kumar A, Satav A. (2021). A comparative study of hearing outcome in patients undergoing type 1 tympanoplasty using temporalis fascia versus sliced tragal cartilage. Int J Otorhinolaryngol Head Neck Surg. 7:258-62.

Singh, S. P., Nagi, R. S., and Singh, J. (2018). A Comparative Evaluation of Audiological and Graft Uptake Results of Reinforced Sliced Conchal Cartilage Versus Temporalis Muscle Fascia Graft In Type I Tympanoplasty. Int J Clin Exp Otolaryngol, 4(1), 96-100.

Suryasa, I. W., Rodríguez-Gámez, M., & Koldoris, T. (2022). Post-pandemic health and its sustainability: Educational situation. *International Journal of Health Sciences*, *6*(1), i-v. https://doi.org/10.53730/ijhs.v6n1.5949

Tilyakov, H. A., Valiyev, E. Y., Tilyakov, A. B., & Tilyakov, A. B. (2021). A new approach to surgical treatment of victims with pelvic and femoral fracture injuries, taking into account the severity of the condition and the severity of the injury. *International Journal of Health & Medical Sciences*, *4*(3), 338-346. https://doi.org/10.31295/ijhms.v4n3.1763

Xing C, Liu H, Li G, Li J, Li X. (2020). Type 1 tympanoplasty in patients with large perforations: comparison of temporalis fascia, partial-thickness cartilage, and full-thickness cartilage. J Int Med Res. 48(8):300060520945140.