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Original Article

The Impact of Cubism Graft on The Outcome of Tympanoplasty Surgery

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ABSTRACT

Background: Tympanoplasty is a common procedure for repairing tympanic membrane perforation. Over the past years, several methods of grafting have been tried with satisfactory results. However, many consequences and obstacles that may affect success rate and hearing gain had been encountered.

Aim of the work: To compare the auditory and anatomical outcomes between two different techniques in tympanoplasty: the first with temporalis facia graft with the new "cubism" graft and the other with temporalis facia graft alone.

Patients and Methods: A prospective, randomized clinical trial included 40 patients with tympanic membrane perforation due to chronic suppurative otitis media. Patients were randomly assigned to cubism graft or non-cubism graft in addition to the standard temporalis facia graft. The two groups are compared for take rate and pure tone audiometry after the surgery.

Results: Cubism graft group wasn't significantly different to Temporalis fascia only group regarding ABG [p= 0.233]. 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.

Conclusion: The novel "cubism" graft had an overall 95% take rate compared to 85% in non-cubism grafting. Furthermore, hearing improvement was significantly associated with cubism grafting. This hybrid, cartilaginous dust and PRF mixture graft can be used widely in tympanoplasty.

Keywords: Tympanoplasty; Tympanic membrane; Cubism; Temporalis fascia.

INTRODUCTION

Tympanoplasty is a surgical procedure that is commonly used to repair perforation of the tympanic membrane. Tympanoplasty's primary objectives are to restore the tympanic membrane to its original state by using a graft substance to close the perforated region and, if necessary, improve hearing in cases where hearing loss is present [1].

For the repair of a perforated tympanic membrane, fascia, fat, perichondrium and cartilage are frequently employed graft materials. However, the most often employed grafting material is temporalis muscle fascia [2].

With typically positive outcomes, temporalis muscle facia graft is frequently utilized for the repair of tympanic membrane perforations [3]. When correctly equipped, the fascia is flexible and nearly the same width as a tympanic membrane. Additionally, it is readily available in adequate size and may be cut to the required shapes. On the other hand, it is made up of fibrous connective tissue and elastic fibers organized erratically; as a result, it may exhibit abrupt and surprising changes in shape after surgery, including shortening or even bulging [4].

In recent years, a new graft has been developed to improve the outcome of the graft. The platelet-rich fibrin [PRF] technique was developed by Choukroun in 2001 [5-7]. This novel graft contains cartilaginous dust fragments that resemble cubic geometric shapes in the endoscopic/microscopic view. The design of this graffiti is reminiscent of works by cubist painters. The "cubism graft" is the moniker given to it as a result [5]. Growth factors abundant in platelets encourage the formation of extracellular matrix and neovascularization. On the other hand, vitamins, minerals, nutrients, hormones, electrolytes, growth factors, and proteins—all of which are necessary for cell survival and tissue repair—are present in plasma [6].

Clinical studies show that concentrated platelets of the second generations, platelet-rich fibrin [PRF], have a critical role in promoting wound healing and homeostasis in both soft tissue and hard tissue lesions [7].

Therefore, the present study was carried out to compare the outcomes of temporalis facia graft alone and temporalis facia graft plus the new novel “cubism graft”.

PATIENTS AND METHODS

A prospective, randomized comparative study was carried out at the Otorhinolaryngology Head and Neck Surgery Department of Al-Azhar University Hospital [Damietta].

The study included patients with chronic suppurative otitis media without cholesteatoma. Patients were divided into two groups: Group A, which comprised patients who underwent tympanoplasty with temporalis fascia graft and the new "cubism" graft, and Group B, which included patients who underwent tympanoplasty with temporalis fascia graft only.

Exclusion criteria: Patients not willing for surgery, history of rheumatological illness, signs of inflammation at the time of operation, previous middle ear operation and history of radiation to the head and neck region.

Counseling and consent: A full description of the procedure was provided to the patients, and free written consent was obtained from each patient or their guardian. Approval from the Institutional Review Board of the Faculty of Medicine, Al-Azhar University was also obtained.

Cubism graft preparation

Platelet-rich fibrin [PRF] was sourced from the patients themselves, following a standard protocol. Prior to surgery, an appropriate volume of the patient's blood was collected using standard venipuncture techniques. The collected blood sample was then centrifuged at a specific centrifugal force and duration to separate the blood components. During the centrifugation process, the blood cells including platelets and fibrinogen underwent natural clot formation. The resultant clot [PRF] contained a concentrated suspension of platelets, growth factors, cytokines, and fibrin. This PRF clot was carefully separated from the surrounding plasma and other blood components. Following the separation, the obtained PRF clot was prepared for use in the surgery. It was processed, usually by compressing or squeezing, to release the desired liquid or gel form of PRF. This PRF material was then applied and secured in contact with the temporalis fascia graft during the tympanoplasty procedure [5-7].

Pure tone audiometry: For both ears, the evaluation process is carried out between 250 and 8000 hertz [Hz, or cycles per second], and

the values of the thresholds are documented on a graph known as an audiogram.

Operative procedure

The surgeries were performed under general anesthesia. All surgical procedures were performed by the same surgeon by either endoscope or microscope. Surgical procedures were performed by either trans canal approach or postauricular approach according to surgeon's preference. The perforation edges were deepithelized, tympanomeatal flap was elevated for visualization.

In the first group, temporalis facia graft was harvested and prepared and it was clearly positioned in an over-underlay manner, after the placement of facia graft, the cubism graft was then positioned as the second layer over the tympanic membrane after the tympanomeatal flap was adjusted to its anatomical position, 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 external auditory canal was filled with Gel-foam, and the tympanomeatal flap was moved to its anatomical location.

Postoperative follow up: Participants were told to avoid touching their repaired ears for the first several days after surgery and to visit the hospital if they had any signs of wound infection, such as pain or discharge.

Outcomes were evaluated at 1 month, and 3 months using otoscopic, endoscopic examination. PTA was performed one month and three months following the operation. Tympanic membrane perforation size and location, as well as the status of the postoperative graft, were observed during the first and third postoperative months' microscopic examinations.

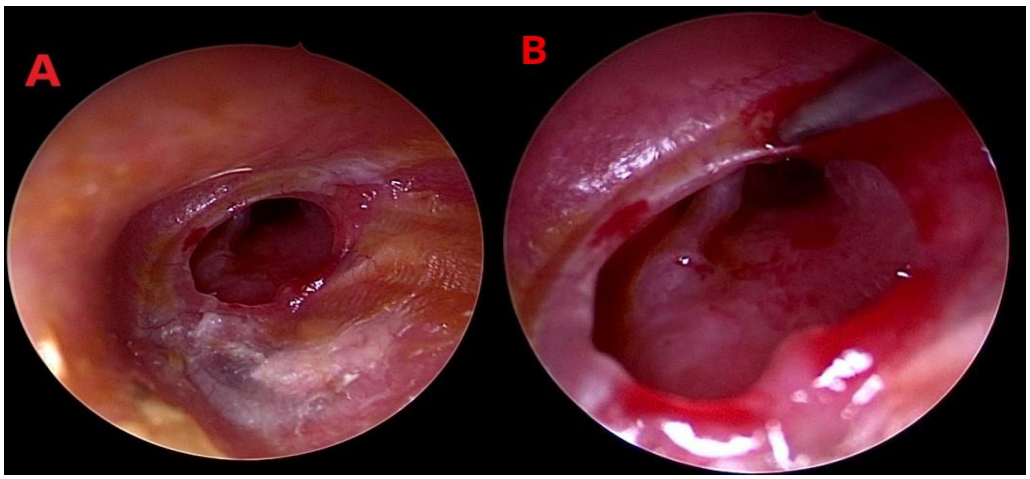

Figure [1]: [A]: Tympanic membrane before refreshing; [B]: Refreshing edge of tympanic membrane

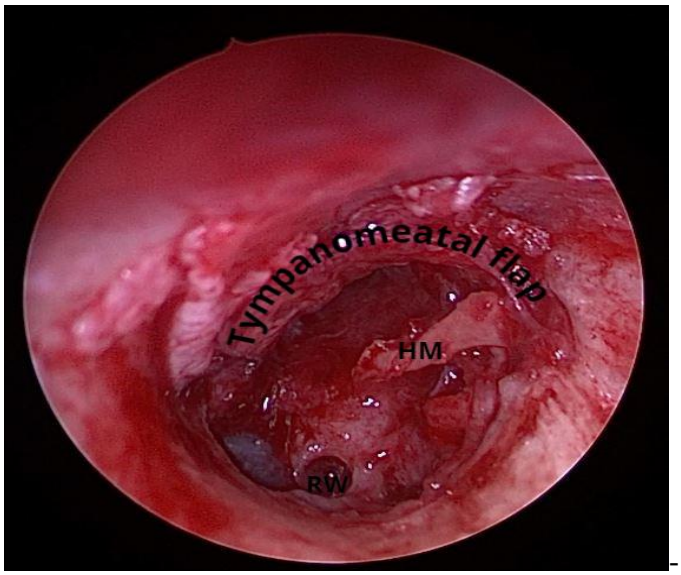

Figure [2]: Complete elevation tympanometal flap with exposure middle ear

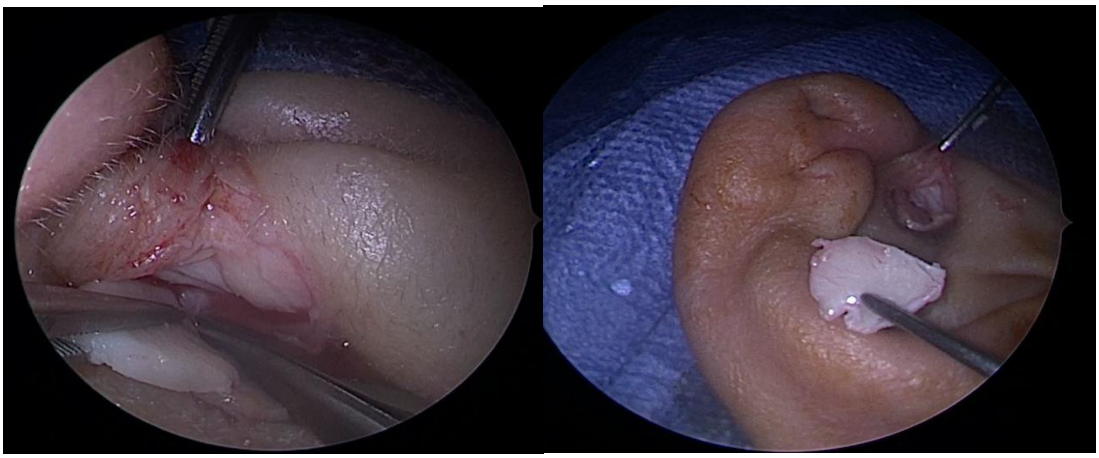

Figure [3]: Harvesting tragal cartilage

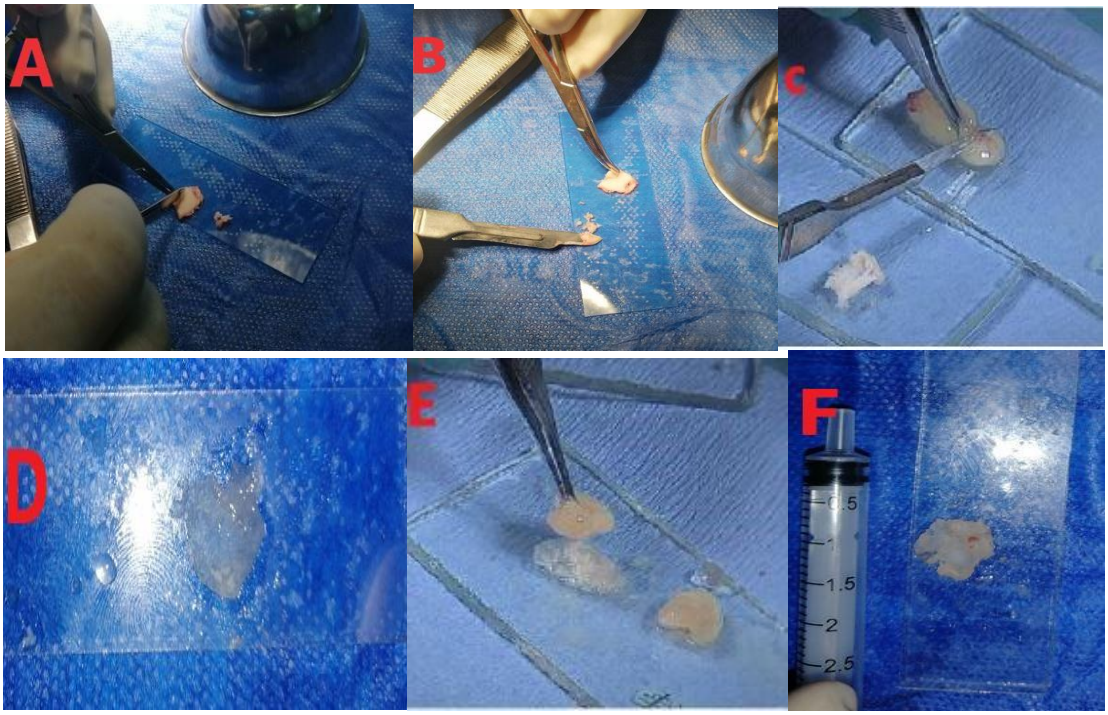

Figure [4]: Procedure for the cubism graft in surgery. **[A]**, The surgical blade being held parallel to the cartilage; **[B]:** A buildup of cartilage dust, while scrubbing the cartilage. **[C]:** Fragmenting the platelet-rich fibrin [PRF]; **[D]:** Combining cartilage dust and PRF and crushing it between two thick glass slides; **[E]:** Insertion of an additional piece of PRF and cartilage dust; **[F]:** The cubism graft

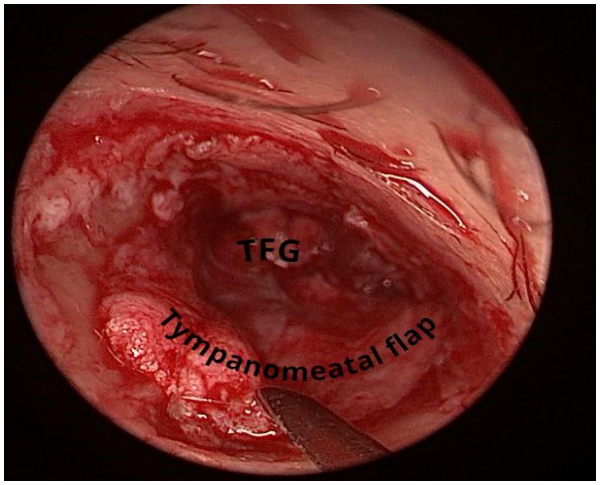

Figure [5]: Tympanic membrane after Placement the Temporalis facia grafts and replacement of the tympanomeatal flap

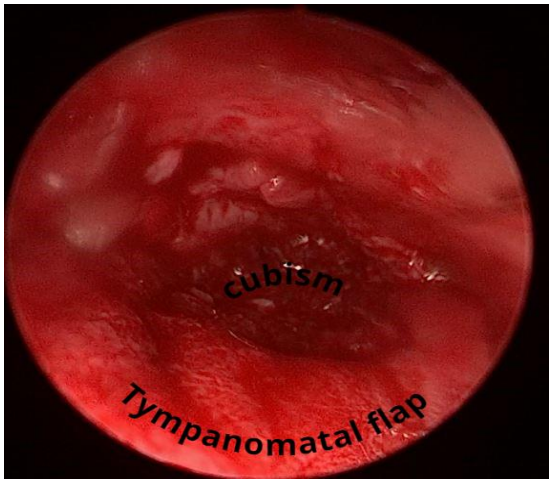

Figure [6]: Tympanic membrane after Placement cubism graft

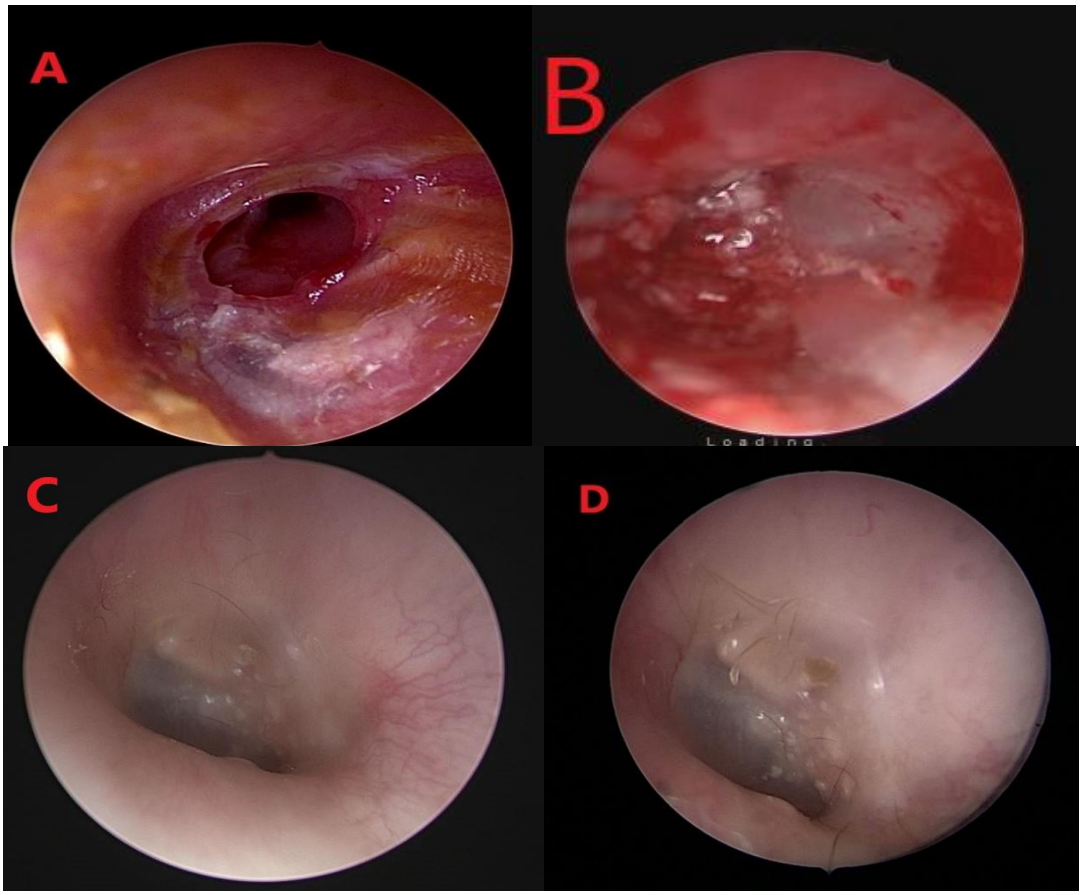

Figure [7]: Follow up: A, Tympanic membrane perforation preoperative. B, Showing Tympanic membrane postoperative immediately. C, Showing Tympanic membrane postoperative 1 month. D, Showing Tympanic membrane postoperative 3 months

Statistical Analysis: Data were analyzed using SPSS for windows [SPSS, Version 21, SPSS Inc., Chicago, IL, USA]. Data were described using mean, standard deviation, median and interquartile range [IQR] for numerical variables, and number and percentages for categorical variables. Independent t test and chi square tests were used for analysis. P value < 0.05 is considered significant.

RESULTS

In the Cubism graft group, the age ranged from 17 to 45 with a mean ± SD of 30.44 ± 9.11, while in the Temporalis fascia only group, the age ranged from 12 to 42 with a mean ± SD of 28.62 ± 7.91, showing no statistically significant difference [p= 0.632] between the two groups [Table 1]. Perforation size did not differ significantly between the two groups [p= 0.56], with no significant variance in Cubism graft group compared to the Temporalis fascia only group regarding perforation size [p= 0.56].

Operative data of the study population are presented in Table 2. There was no significant difference in operation type between the two groups [p = 0.176], indicating that the Cubism graft group did not significantly differ from the Temporalis fascia only group regarding the operation type [p = 0.176]. Additionally, there was no significant difference in the result of the graft between the two groups [p = 0.292], indicating that the Cubism graft group was not significantly different from the Temporalis fascia only group regarding graft outcome [p = 0.292].

The ABG in the Cubism graft group ranged from 25 to 31 with a mean ± SD of 27.33 ± 2.5, while in the Temporalis fascia only group, the ABG ranged from 20 to 32 with a mean ± SD of 25.77 ± 3.47, showing no statistically significant difference [p= 0.233] between the two groups. The ABG gain at 1 month was 14 ± 1.12 in the Cubism graft group and 11.85 ± 1.91 in the Temporalis fascia only group, with a statistically significant difference [p= 0.003]. Regarding the ABG gain at 3 months, the Cubism graft group had a range of 14 to 17.5 with a mean ± SD of 16.17 ± 1.15, whereas the Temporalis fascia only group had a range of 10 to 16 with a mean ± SD of 14.12 ± 1.91, showing a statistically significant difference [p= 0.005] between the two groups [Table 3, Figure 8].

Table [1]: Demographic characteristic data of the study population

		Cubism graft group [n = 20]	Temporalis fascia only group [n = 20]	Test	p
Gender [n, %]	Males	9 [45%]	11 [55%]	$\chi 2$ = 0.400	0.527
	Females	11 [55%]	9 [45%]		
Age [years]				t = 0.488	0.632
Mean ± SD.		30.44 ± 9.11	28.62 ± 7.91		
Median [IQR]		32 [25 - 35]	30 [25 - 34]		
Range [Min-Max]		28 [17 - 45]	30 [12 - 42]		

Table [2]: Operative data of the study population

		Cubism graft group [n = 20]		Temporalis fascia only group [n = 20]		Test	p
		No.	**%**	**No.**	**%**		
Operation type [n, %]	Post auricular	9	45%	9	45%	$\chi 2$ = 3.474	.176
	Endoscopic	11	55%	8	40%		
	Endoaural	0	0%	3	15%		
Result of graft [n, %]	Taken	19	95%	17	85%	$\chi 2$ = 1.111	.292
	Failed	1	5%	3	15%		

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]			t = 1.229	0.233
Mean ± SD.	27.33 ± 2.5	25.77 ± 3.47		
Median [IQR]	27 [25 - 30]	25 [24 - 26]		
Range [Min-Max]	6 [25 - 31]	12 [20 - 32]		
ABG gain one month [dB]			t = 3.328	**0.003**
Mean ± SD.	14 ± 1.12	11.85 ± 1.91		
Median [IQR]	14 [13 - 15]	12 [12 - 13]		
Range [Min-Max]	3 [12 - 15]	6 [8 - 14]		
ABG gain three months [dB]			t = 3.146	**0.005**
Mean ± SD.	16.17 ± 1.15	14.12 ± 1.91		
Median [IQR]	16.5 [15.5 - 17]	15 [13 - 15.5]		
Range [Min-Max]	3.5 [14 - 17.5]	6 [10 - 16]		

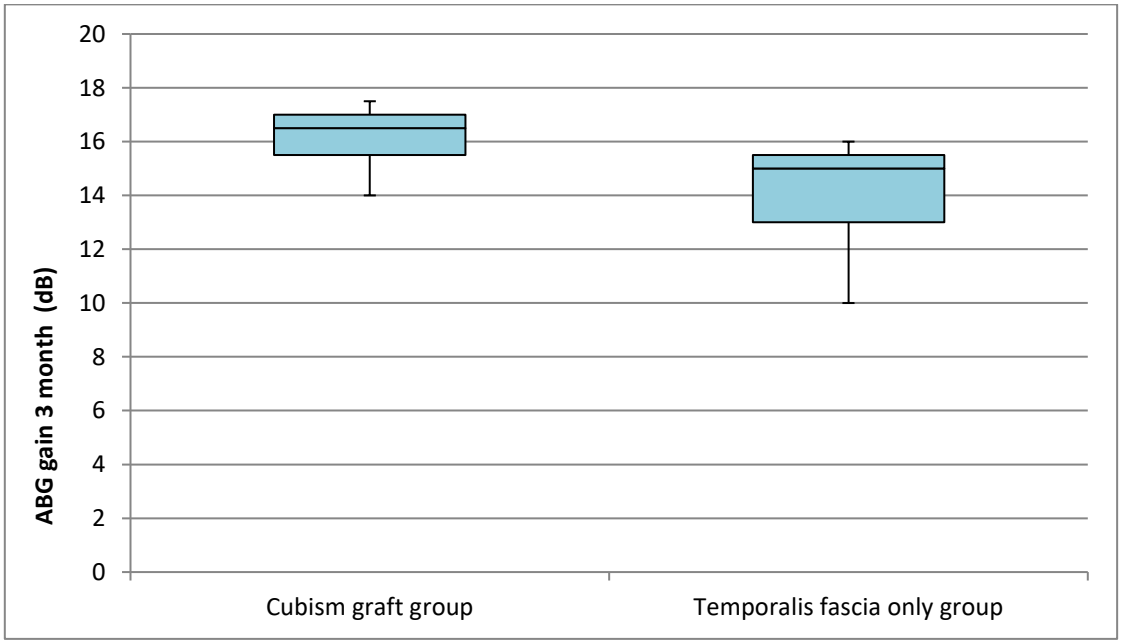

Figure [8]: Box-plot showing difference between the study groups regarding ABG gain 3 months

DISCUSSION

This study aimed to assess the efficacy of the Cubism graft in tympanoplasty surgery as compared to the temporalis fascia graft. The main findings indicated that the Cubism graft led to a notably higher graft success rate and a decreased postoperative air-bone gap.

Only one study in the literature introduced the Cubism graft technique [8]. In the current study, the success rate was non-significantly higher in the Cubism graft group [90%] compared to the Temporalis fascia-only group [85%].

The success rate of grafts in tympanoplasty is influenced by various demographic and clinical factors. Among the different graft options available, cartilage has gained popularity in recent decades due to its durability, resistance to absorption, retraction, and infection, and favorable hearing outcomes compared to materials like fascia [10].

The study conducted by **Kaya *et al.*** [8] discovered that all the patients under study underwent surgery via the transcanal endoscopic approach. In the initial otological assessment of the study group, the graft success rate was 100%. In the control group, grafting was successful in 21 out of 22 patients [95.5%]. During the six-month otological assessment of the study group, no instances of graft failure were observed. During the six-month follow-up evaluation, the graft success rate in the control group remained at 95.5%. One patient who experienced graft failure at the six-month mark underwent a revision procedure.

Additionally, the study by **Shinde *et al.*** [9] revealed that the pre-operative AB gap was 29.20 dB and 27.4 dB, respectively, with a non-significant p-value of 0.288. The post-operative AB gap improved to 15 dB and 10.4 dB, respectively, with a significant p-value of 0.0041. Notably, in the group that underwent sliced tragal cartilage procedure, there was a remarkable improvement in the post-operative AB gap. The group with sliced tragal cartilage demonstrated significantly superior improvement in the AB gap with a p-value of 0.042.

Our results are in line with those of **Xing *et al.*** [11], who reported that both the partial-thickness cartilage and full-thickness cartilage groups achieved a success rate of 96.7%, while the temporalis fascia group had a success rate exceeding 90%. The success rates across the different groups were similar. **Singh *et al.*** [12] demonstrated that the graft uptake rate was 85% in Group I [temporalis muscle fascia] and 95% in Group II [sliced conchal cartilage] patients [$P < 0.001$]. Twenty percent of the patients experienced either graft loss or incomplete uptake.

Cubism graft group and Temporalis fascia only group had similar postoperative ABG values. However, Cubism graft showed significantly better ABG gains at 1 month and 3 months post-surgery.

As per **Kaya *et al.*** [8], there were statistically significant differences in the postoperative first-month ABG and ABG gain between the study and control groups [$P < 0.001$]. On the other hand, there were no statistically significant differences in the postoperative six-month ABG and ABG gain between the study and control groups [$P > 0.05$]. The comparison of the sixth-month ABG values before and after surgery was found to be significant for both groups [$P < 0.001$]. Additionally, there was no observable difference in graft status in the sixth month following the surgery [$P > 0.05$].

However, the research conducted by **Xing *et al.*** [11] found that in the temporalis fascia, partial-thickness cartilage, and full-thickness cartilage groups, the air conduction threshold was significantly higher before the operation than after the operation. While both the partial-thickness cartilage group and the temporalis fascia group showed greater hearing improvements than the full-thickness cartilage group, there was no significant difference in the graft success rates between these groups.

To optimize auditory results in tympanoplasty, a partial-thickness cartilage graft is typically preferred. Techniques such as cartilage slicing using a cartilage slicer or surgical blade are commonly employed to thin the cartilage. However, the slicing process may lead to issues such as perichondrial contraction, resulting in a curvature of the graft edges towards the dissected side, potentially leading to residual perforations and compromised graft success [13, 14].

Conclusion: The novel "cubism" graft had an overall 95% take rate compared to 85% in non-cubism grafting. Furthermore, hearing recovery was significantly associated with cubism grafting. This hybrid, cartilaginous dust and PRF mixture graft can be used widely in tympanoplasty.

Conflict of interests: None to be declared.

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