

ORIGINAL RESEARCH

The new “cubism” graft technique in tympanoplasty: A randomized controlled trial

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Abstract

Objectives: The aim of this prospective, randomized-controlled study is to analyze the outcomes of a new graft technique in tympanoplasty and compare its outcomes with cartilage island graft plus extra perichondrium.

Methods: A total of 44 patients with noncomplicated chronic otitis media were included in this prospective randomized-controlled clinical trial. 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). The main outcome measures of the study were the air-bone gap (ABG), ABG gain, and graft status.

Results: Graft success rate was 100% and 95.5% in the study group and the control group, respectively. There were statistically significant differences in the postoperative first month ABG and ABG gain between study and control groups ($P < .05$). ABG and ABG gain showed no significant differences in the postoperative sixth month between groups ($P > .05$).

Conclusion: This study revealed that both graft techniques have satisfactory functional and morphological results compared to preoperative findings. The use of cubism graft with cartilage island graft has significantly better auditory outcomes in short-term and similar results in long-term compared to double-layered cartilage island graft with extra perichondrium. Cubism graft is a highly promising graft technique with its many advantages.

Level of Evidence: 1b.

KEYWORDS

cartilage graft, cubism graft, double-layer graft, tympanoplasty

1 | INTRODUCTION

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.¹ The commonly used graft materials for the perforated tympanic membrane repair include: fat, fascia, perichondrium and cartilage.²⁻⁵

In the last decades, cartilage graft techniques have become very popular. Cartilage graft can be easily obtained from the tragus or concha of

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the auricle. There are dozens of previous studies suggesting that cartilage is a better graft material than other graft materials.⁶⁻⁸ Cartilage can obtain the essential nutrients through diffusion, which may increase the graft-take rate.⁹ On the other hand, hearing gain can be fewer in cartilage tympanoplasty than other graft materials unless cartilage has been thinned. Several previous studies have proven that partial-thickness cartilage is better than full-thickness cartilage for improvement of hearing.^{10,11} Slicing the cartilage graft is the most commonly used method for thinning. Risks of slicing are excessive or insufficient cartilage removal, undesirable fractures of the cartilage graft. Also, cartilage graft may become over-curved because of excessive cartilage slicing. This may cause graft dehiscence and may reduce graft-take rate and auditory improvement.

To overcome such problems, we suggest a new graft harvesting technique. The idea behind this new technique is to provide a controlled thinning of cartilage by brushing, thus avoiding the cartilage damage and over-curling, and the utilization of accumulated cartilage dust.

The main objective of this randomized-controlled study is to compare the auditory and anatomical outcomes between two different

double-layer graft techniques in tympanoplasty: Cartilage island graft + the new “cubism” graft and cartilage island graft + extra perichondrium. The other objective is to describe the technique of “cubism” graft.

2 | MATERIALS AND METHODS

This prospective randomized-controlled study was conducted at a tertiary academic center between September 2019 and October 2020 after approval by the institutional review board and in accordance with the 1964 Declaration of Helsinki (Approval number: 20-11.1T/12).

2.1 | Study design and participants

Patients with chronic otitis media were examined after the approval of the study by the ethical committee. Sixty-two patients were assessed for eligibility according to inclusion and exclusion criteria.

The Flow Diagram

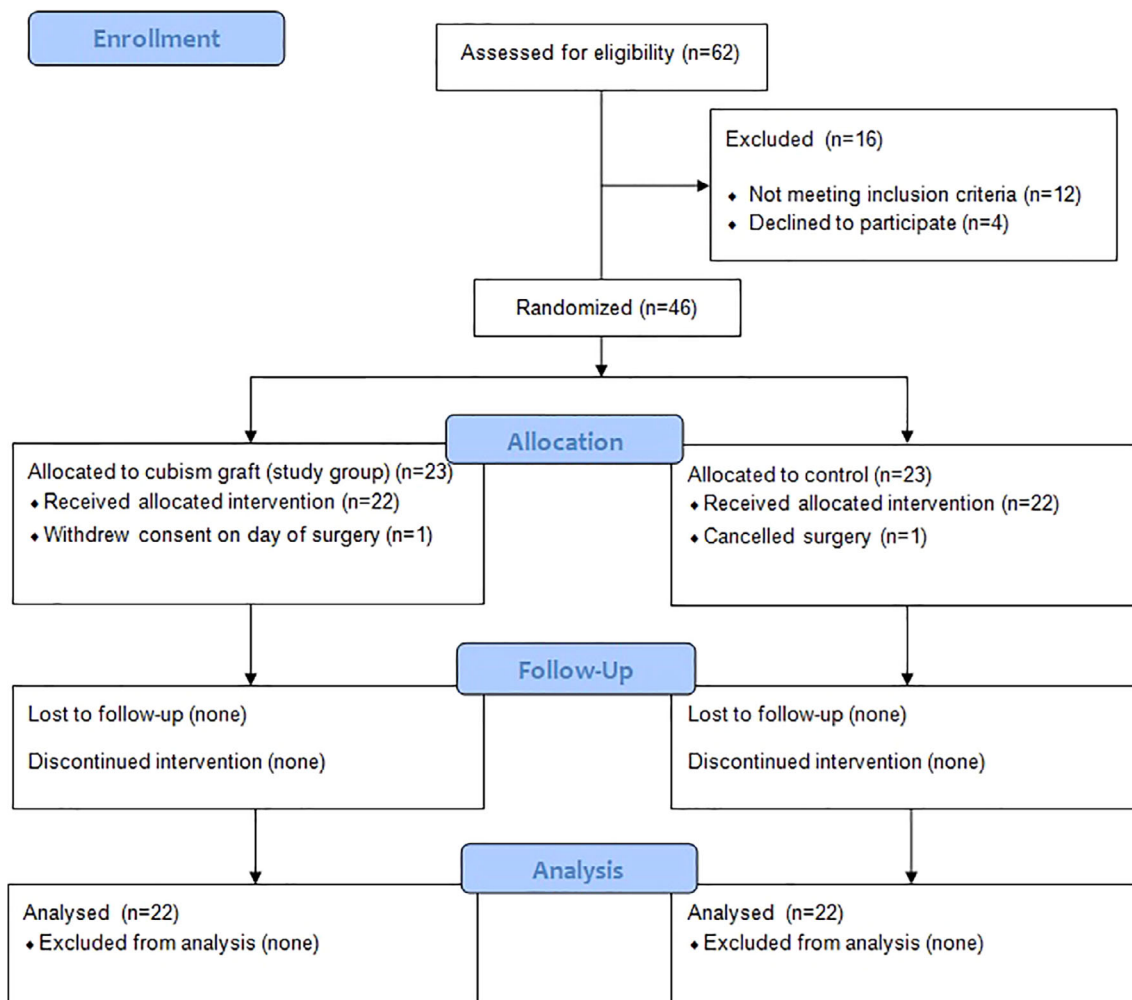


FIGURE 1 The flow diagram of the study

The inclusion criteria were the following: tympanic membrane perforation with a dry middle ear cavity and normal middle ear mucosa, intact ossicular chain, absence of cholesteatoma, absence of tobacco smoking. The exclusion criteria were the following: evidence of infection at the time of surgery, history of middle ear surgery, pediatric case (to avoid the effect of poor eustachian tube function), history of radiotherapy to the head and neck region, presence of rheumatological disease. Informed consent was obtained from all participants. All data of the patients were collected prospectively. The participants were informed about the duration, advantages and possible complications of the surgical procedures. Forty-six adult patients (46 ears) were included in this study after assessment for eligibility. These 46 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). The randomization method was the sealed envelope system. Two patients were excluded after allocation due to withdrawal of the consent and cancellation of the surgery. Ultimately, twenty-two adult patients (22 ears) were included in both the study and control groups. All the patients were evaluated with detailed microscopic and audiometric examinations preoperatively and postoperatively. None of the patients were lost to follow-up during the clinical trial. Figure 1 shows the flow diagram of this study.

2.2 | Surgical procedure

All surgical procedures were performed by the same senior surgeon (İK) with a transcanal endoscopic approach. During the surgical procedure, a high definition monitor and camera (Karl Storz, Germany), a xenon light source (Karl Storz Xenon Nova 175, Tuttlingen, Germany) and 4 mm-0° rigid endoscope (Karl Storz Endoscopes, Tuttlingen, Germany) were used.

Figure 2 shows the preoperative perforation. First, the perforation edges were deepithelized. After a hemi-circular external auditory canal incision, a posterior pedicled tympanomeatal flap was elevated for visualization. The graft material was obtained from the ipsilateral tragal cartilage.

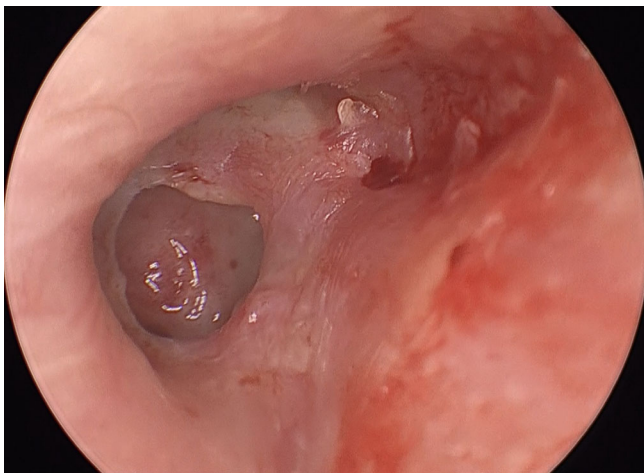


FIGURE 2 Preoperative perforation of the tympanic membrane

Perichondrium over the convex surface of the tragal cartilage graft was removed and the concave surface was left attached to the cartilage. In the study group, the perichondrium-free side of the cartilage was thinned by brushing with the scalpel blade no. 11 by holding perpendicular to the cartilage. Angular changes of the scalpel were avoided. Soft and rapid scalpel moves were made while brushing the convex surface of the cartilage. All scalpel moves were in the same direction. Meanwhile, dough-like cartilage dust was accumulated on the scalpel. While harvesting the cartilage of sufficient thickness, excessive bending of the cartilage was prevented and a flat cartilage island graft was formed. Cartilage was removed peripherally in a piecemeal fashion to produce an island of cartilage. The shape of the island graft included a notch for the malleus handle. A venous blood sample was taken in 10-ml sterile tubes without anticoagulant, then the sample (approximately 400 g) was centrifuged at 3000 rpm for 10 minutes. The platelet-rich fibrin (PRF) as fibrin clot was found in the upper layer of the tube. The PRF was collected from the tube and the cartilage dust was treated with the PRF. Then, the cartilage dust-PRF mixture was crushed between two thick glass slides. Additional dust and PRF were added into the mixture and crushed once again. Thus, a thin, sticky cubism graft was formed. Figure 3 summarizes the surgical technique of harvesting and forming the cubism graft. Then, the flat cartilage island graft was easily placed in an over-underlay manner, lateral to the handle of malleus and medial to the tympanic membrane and annulus. After the placement of cartilage island graft, the cubism graft was placed over the island graft as the second layer (Figure 4). Finally, the tympanomeatal flap was repositioned to the anatomical position (Figure 5) and the external auditory canal was packed with Gelfoam (Pharmacia & Upjohn Inc., Kalamazoo, Michigan). In the control group, cartilage was thinned by slicing, and instead of forming a cubism graft, only perichondrium was placed over island graft. PRF was not used in the control group and the other steps were the same as in the study group.

2.3 | Nomenclature of “cubism graft”

In the endoscopic/microscopic view, 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.”

2.4 | Outcome measures

Standard pure-tone audiometry (Interacoustic AC-40, Middelfart, Denmark, headphone: TDH39) for the frequencies of 500, 1000, 2000, and 4000 Hz was performed and air-bone gap (ABG) was calculated prior to surgery, in the postoperative first and sixth months. ABG gain was calculated in the postoperative first and sixth months. A clinical audiometer calibrated according to the International Organization for Standardization standard with the criteria of American Speech Language and Hearing Association was used for the audiometric analysis. Additionally, preoperative, postoperative first and sixth month-microscopic examination findings were noted:

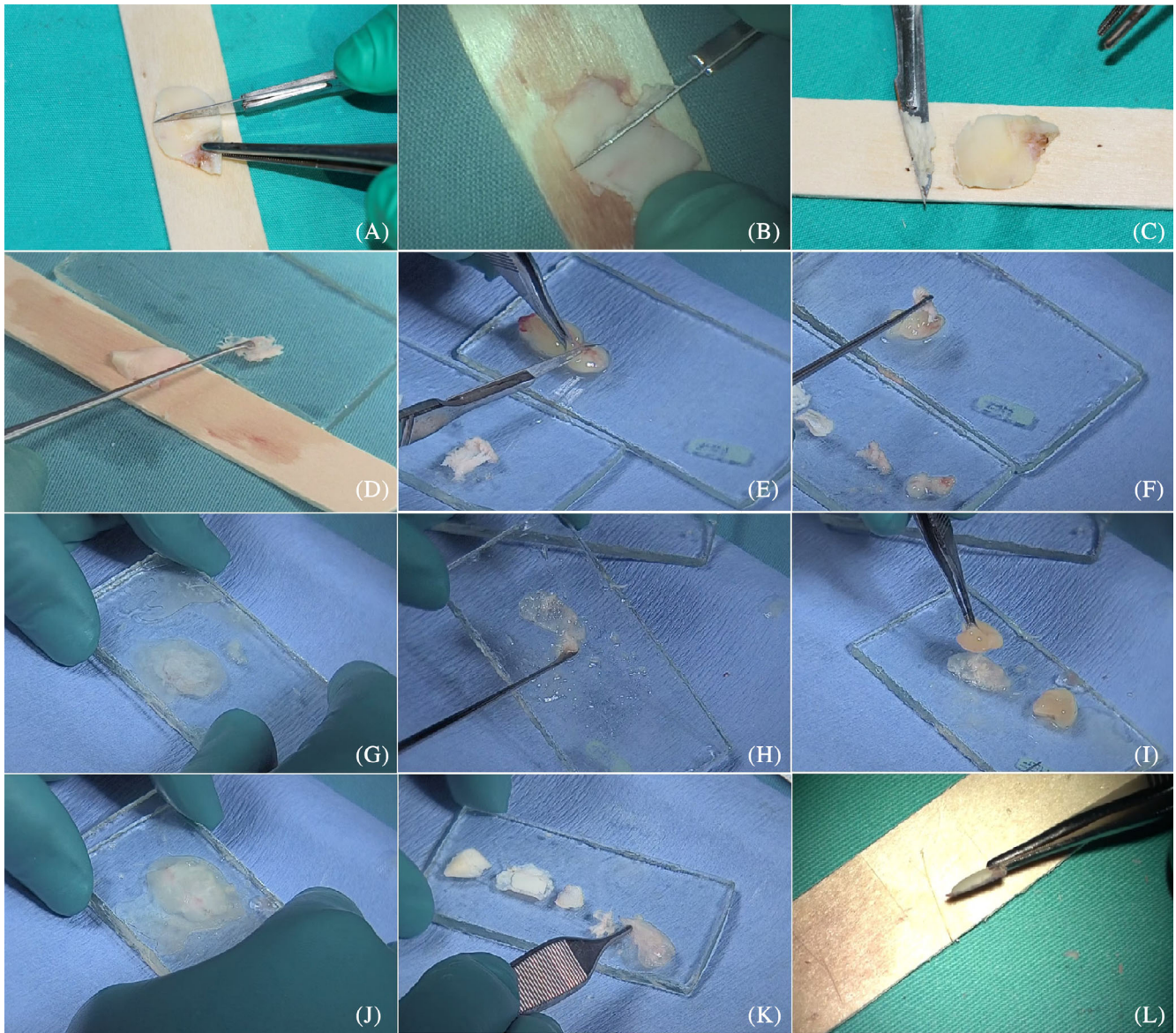


FIGURE 3 Surgical technique of the cubism graft. A, Holding the no:11 surgical blade perpendicular to the cartilage. B, Cumulation of cartilage dust while brushing the cartilage. C, Accumulated dough-like cartilage dust. D, Spreading the cartilage dust. E, Cutting the platelet-rich fibrin (PRF) into pieces. F, Mixing the cartilage dust and PRF. G, Crushing the cartilage dust-PRF mixture between two thick glass slides. H, Addition of extra cartilage dust. I, Addition of a second PRF piece. J, Crushing the mixture once more. K, From left to right; a curled partial-thickness cartilage graft after slicing, flat partial-thickness cartilage island graft after dust harvesting, a thinner cartilage graft after dust harvesting, the cartilage dust and the cubism graft. L, The flat partial-thickness cartilage island graft

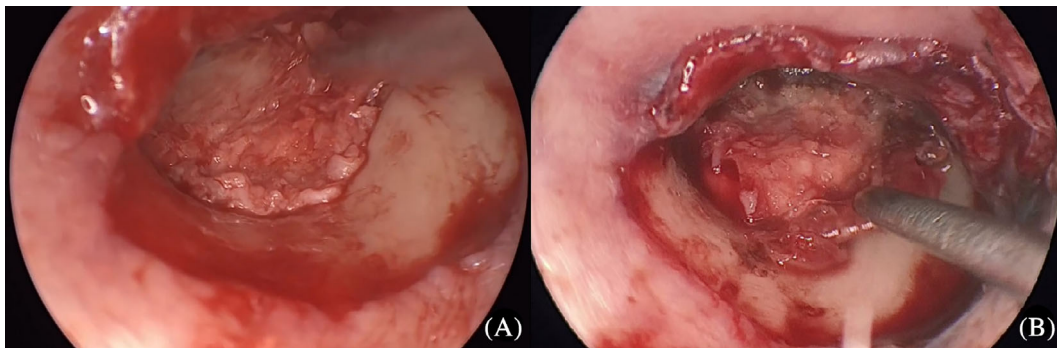


FIGURE 4 Placement of the grafts. A, Flat cartilage island graft. B, The cubism graft

Tympanic membrane perforation size and location, and postoperative graft status. The perforation size was graded using the system defined by Saliba: grade 1: $\leq 25\%$; grade 2: 26%-50%; grade 3: 51%-75%; grade 4: $>75\%$.¹²

2.5 | Statistical analysis

For statistical analysis, the Statistical Package for Social Sciences (SPSS) was used (version 22.0; SPSS Inc., Chicago, Illinois). Independent samples *t* test was used for the comparison of categorical data, while Wilcoxon and Mann-Whitney *U* tests were used for the analysis of non-parametric variables based on the distribution pattern. Independent samples *T* test was used for the comparison between ABG and ABG gain values. Using an independent samples *T* test and type I error rate of 0.05, this study has 99% and 20% power to detect a

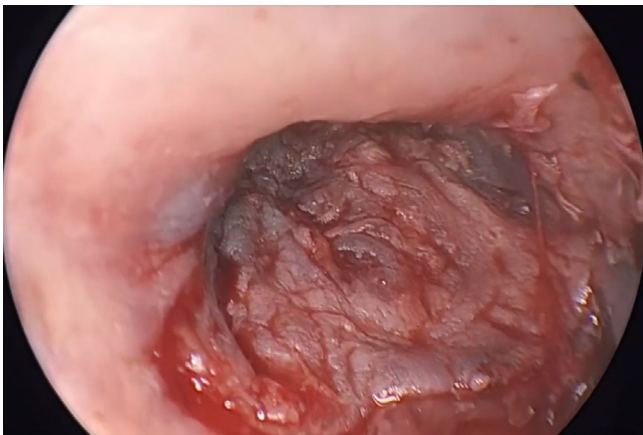


FIGURE 5 The view of the tympanic membrane after replacement of the tympanomeatal flap

TABLE 1 Demographic and preoperative characteristic data

Parameter	Study group	Control group	<i>P</i> value
Age (years)	33.5 \pm 8.6	33.7 \pm 8.7	.931
Gender (n, (%))			.373
Male	11 (50%)	14 (63.6%)	
Female	11 (50%)	8 (36.4%)	
Perforation location (n, (%))			.852
Posterior	9 (40.9%)	10 (45.5%)	
Anterior	8 (36.4%)	7 (31.8%)	
Central	5 (22.7%)	5 (22.7%)	
Perforation size (n, (%))			.980
$\leq 25\%$	6 (27.3%)	7 (31.8%)	
26-50%	10 (45.5%)	8 (36.4%)	
51-75%	4 (18.2%)	5 (22.7%)	
$>75\%$	2 (9.1%)	2 (9.1%)	
Preoperative ABG ^a (min-max) (dB)	26.8 \pm 2.9 (21.9-32.1)	25.9 \pm 3.4 (17.7-33.3)	.326

^aABG, air-bone gap.

difference in ABG gain and graft success rate comparison between the groups for estimated values, respectively. Data were expressed as “mean (standard deviation; SD),” percent (%), minimum-maximum, and “median” where appropriate. *P* < .05 was considered to be statistically significant.

3 | RESULTS

Twenty-five of 44 patients (56.8%) were male and 19 (43.2%) were female. The average age of all patients was 33.6 \pm 8.5 years (20-52 years). The average age of the study group was 33.5 \pm 8.6 years (20-52 years) and the average age of the control group was 33.7 \pm 8.7 years (20-50 years). The median follow-up time was 7 months (ranged from 6 to 9 months). None of the patients had additional preoperative complaints such as tinnitus, dizziness and ear discharge.

3.1 | Preoperative findings and results

Demographic data, preoperative ABG values and preoperative findings regarding perforation size and location are presented in Table 1. There was no statistically significant difference in the preoperative ABG between study and control groups (*P* > .05). There were no significant differences in the distributions of perforation size and location between groups (*P* > .05). None of the patients had an ossicular chain discontinuity or a diffuse otosclerosis. We intraoperatively discovered mild, limited tympanosclerotic changes in the tympanic membrane or middle ear cavity, except the ossicular chain, in just four patients. Moreover, it was considered that these changes would not have a significant effect on the preoperative air-bone gap.

TABLE 2 The comparison of postoperative ABG and ABG gain outcomes between the groups

Parameter	Study group	Control group	P value
Postoperative average ABG ^a (min-max) (dB)			
First month	13.1 ± 1.4 (10.7-15.5)	16.9 ± 1.9 (13.5-19.5)	<.001
Sixth month	10.7 ± 1 (9-12.3)	10.8 ± 1.7 (9.3-12.5)	.306
First month pre-post difference (P value)	<0.001	<0.001	—
Sixth month pre-post difference (P value)	<0.001	<0.001	—
Postoperative average ABG gain (min-max) (dB)			
First month	13.7 ± 2.7 (8.5-18.5)	9 ± 3.6 (5.5-18)	<.001
Sixth month	16.3 ± 2.9 (10.7-22.3)	14.9 ± 3.9 (8.5-22.7)	.200
Sixth month-Graft success (n (%))	22 (100%)	21 (95.5%)	.323

^aABG, air-bone gap.

TABLE 3 The comparison of ABG gain between the groups according to perforation size and location

Parameter	Postoperative first month ABG ^a gain (p value)	Postoperative sixth month ABG gain (p value)
Perforation size		
≤%25	0.24	0.28
26%-50%	0.001	0.14
51%-75%	0.055	0.11
>75%	0.03	0.06
Perforation location		
Posterior	0.24	1
Anterior	0.001	0.49
Central	0.07	0.38

Note: $p < .05$ was considered to be statistically significant. All statistically significant changes were in favor of the study group.

^aABG, air-bone gap.

3.2 | Postoperative first month

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. There were statistically significant differences in the postoperative first month ABG and ABG gain between study and control groups ($P < .001$).

3.3 | Postoperative sixth month

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. 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 ($P > .05$).

According to surgical technique, the comparison of the postoperative graft status, postoperative ABG and postoperative ABG gain values is presented in Table 2. The comparison of ABG gain between the groups according to perforation size and location is presented in Table 3. In terms of the effect of perforation size and location, the long-term results showed no significant difference in graft success rate and ABG gain between study and control groups ($P > .05$). None of the patients developed new retraction pockets during the postoperative follow-up duration. The postoperative first and sixth month view of the repaired tympanic membrane is shown in Figure 6.

4 | DISCUSSION

The graft success rate in tympanoplasty depends on many demographic and clinical factors such as tobacco smoking, location and size of the perforation, surgical technique, comorbidities and graft material. Although many graft materials have been described until today, cartilage has become more popular especially in the last decades.^{13,14} Cartilage is suggested due to its resistance against resorption, retraction and infection, and also good hearing outcomes as well as other graft materials such as fascia.^{15,16}

A partial-thickness cartilage graft is preferred to achieve better auditory outcomes in tympanoplasty. The cartilage slicer and slicing with surgical blade are commonly used methods for thinning the cartilage.^{11,17} Sometimes, the slicing method can bring some problems. After slicing the cartilage, contraction of the perichondrium may cause a bending of the graft edges to the dissected side. The placement of a curled cartilage graft may cause residual perforation at the edges. A residual perforation results in graft failure and insufficient auditory improvement. In addition, graft success rates may vary depending on the localization of the perforation. Repair of the anterior and subtotal perforations are more challenging than posterior and central perforations. Higher rates of graft medialization can be observed in anterior perforations due to lack of visualization.¹⁸ Also, graft failure rates are generally higher in anterior and subtotal/total (grade 4 in size)

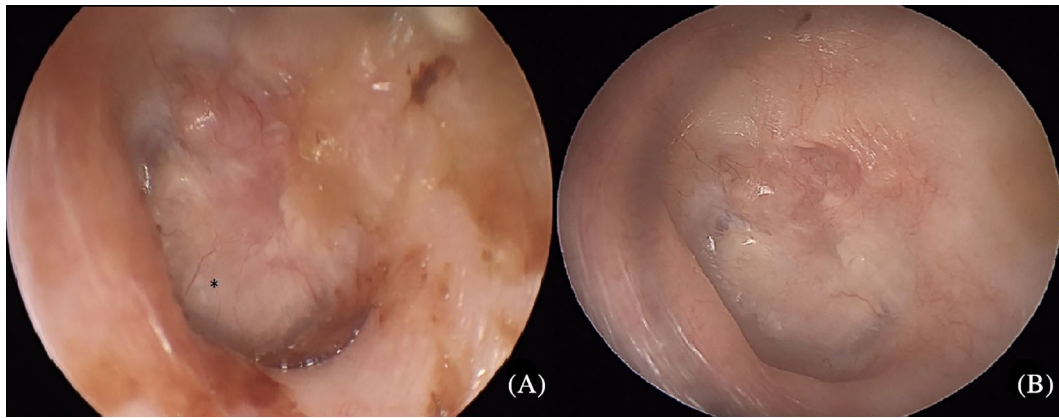


FIGURE 6 The postoperative views of the successfully recovered tympanic membrane. A, Postoperative first month, (*) marks where the cubism graft was placed. B, Postoperative sixth month

perforations compared to posterior located perforations because of poor vascularization and hump of the anterior bony wall that limits the visualization.¹⁹ Reduced blood supply of the anterior membrane remnant can cause higher risk of graft necrosis. In cubism graft technique, we observed significantly higher hearing gain and 100% graft success for anterior and grade 4 size perforations in short-term, although long-term outcomes were statistically similar between the groups. Interestingly, short-term auditory outcomes of cubism graft for grade 2 size perforations were significantly better than control group; however, long-term results were similar.

Different types of double-layer techniques have been used due to concerns on graft failure. Current studies suggested that double-layer grafting with an extra perichondrium or a fascia can provide higher graft success rates than single-layer techniques.^{20,21} Nemade compared the double-layer fascia graft with single-layer fascia and single-layer cartilage grafts. They reported significantly higher rate of graft success in double-layer technique compared to single-layer fascia and similar success rate with single-layer cartilage.²² In a study conducted by Bedri, the graft success rate of double-layer cartilage island graft with extra perichondrium was reported to be 90.3%.²³ They compared the double-layer grafting with cartilage island graft, and found no significant difference in hearing improvement between techniques. Ismi reported 96.1% graft success rate in double-layer cartilage island graft plus extra perichondrium, and found no significant difference in ABG gain compared to single-layer cartilage island graft.⁸ However, over-curling of the cartilage graft remains a disadvantage, and medialization of a double-layer graft can occur postoperatively. The “cubism graft” has been developed to prevent cartilage trimming complications such as over-curling, undesirable cartilage fractures, and to increase the hearing improvement and graft success rate. The new cubism graft technique offers a controlled thinning of the cartilage while avoiding such complications and a hybrid graft material (cartilage plus PRF) which provides efficient and rapid recovery.

Platelet-rich concentrates have been increasingly used in otorhinolaryngology, especially in the last decade. Since PRF contains many

growth factors, its clinical benefits on the healing process have been studied for many surgical procedures. Moreover, preparation of the fibrin matrix is simple and cost-free.²⁴ In a study comparing PRF and paper patch for the repair of traumatic perforations, recovery rates were found to be 93% and 83%, respectively, while the improvement of the postoperative mean ABG was found to be 14.1 dB and 12.4 dB, respectively.²⁵ They concluded that PRF provides more rapid recovery, and better audiological improvement for acute traumatic perforation, compared to the paper patch method. Kütük compared the use of PRF plus temporalis fascia graft with temporalis fascia graft alone, and reported better graft survival rate in temporalis fascia graft plus PRF, similar hearing gain between groups.²⁶ In this study, the graft success rate in cartilage island graft with an extra perichondrium was 95.5%, while the graft success rate was 100% in the study group. Both techniques were found to be reliable for the repair of anterior perforations. Although the final auditory outcomes of both groups were almost the same, the cubism graft provided a significantly better hearing improvement in the early postoperative period. The outcomes of this study revealed that the ABG gain in the “cubism” graft technique was significantly higher than the control group in the postoperative short-term. However, there was no significant difference in the long-term ABG gain, although “cubism” graft technique provided nonsignificantly better hearing improvement than the control group for each patient. Regarding graft status, there was no significant difference between the groups. Nevertheless, “cubism” graft technique provided 100% graft success, as aimed. Even though the effect of PRF on the re-epithelialization process has not been proven with an outcome measure in this study, we hypothesize that PRF might have contributed to this process and graft success in the postoperative early period. As the effect of PRF was not evaluated per se, we also hypothesize that a cartilaginous second-layer graft along with the PRF and a flat thin cartilage island graft can be effective on graft success of 100%.

The highlights of cubism graft technique are the following: (a) The brushing should be performed with soft and rapid moves of the no. 11 surgical blade in the same direction. (b) The brushing should be

continued until a thin and flat cartilage island graft is formed and stopped as soon as the curling begins. (c) Obtained dough-like cartilage dust can be treated with PRF which can contribute to viability of the graft. (d) The cubism graft contains many growth factors. Tympanic membrane recovery process may occur safer and faster thanks to this graft containing growth factors. (e) Another feature of the cubism graft is its adhesive feature due to PRF content. Since the cubism graft is very sticky, it was observed intraoperatively that it adhered to the membrane remnant without leaving any pinhole residuals. This feature may also contribute to graft success. (f) Optionally, remaining PRF pieces can be placed medial to the island graft as a supportive material to avoid the medialization, in case.

Main limitations of this study are the absence of longer follow-up outcomes and limited number of patients. Further prospective studies with larger patient series are required to substantiate these outcomes.

5 | 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. We highly recommend using this new graft technique in tympanoplasty.

ACKNOWLEDGMENTS

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

ETHICAL APPROVAL

This study was approved by the institutional ethics review committee (approval number: 20-11.1T/12).

DATA AVAILABILITY STATEMENT

The data that support the outcomes of this study are available from the corresponding author upon request.

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