

Formaldehyde-treated temporofascial graft versus cartilage graft in repairing failed tympanic membrane grafting

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Aim

The aim of this study was to compare the anatomical and functional outcomes of grafting the tympanic membrane (TM) – that is, previously failed grafting – by two graft materials: the first was formaldehyde-treated temporalis fascia graft (FTFG) and the second was tragal cartilage composite graft. Graft-take, hearing results, and complications were compared.

Patients and methods

The present study included 36 patients with chronic suppurative otitis media with recurrent TM perforation. Nineteen patients received tragal cartilage graft, and 17 patients received the FTFG. For each patient, history taking and complete general and ENT examinations were performed. Graft-take, preoperative and postoperative pure tone average, air–bone gap, and tympanometry scores were calculated and compared.

Statistical analysis

Data entry and data analysis were carried out using statistical package for social science version 19.

Results and conclusion

The present study showed that for repairing TM grafting, cartilage graft and FTFG were comparable in both graft-take and hearing results. The FTFG reflected the true configuration of tympanometry. It can be used in cases where the cartilage graft is previously consumed.

Keywords:

cartilage graft, failed grafting, formaldehyde-treated temporalis fascia

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Introduction

Perforation of the tympanic membrane (TM) may be due to trauma or due to chronic suppurative otitis media. If the perforation fails to heal spontaneously or by conservative therapy, it will require surgical closure. The vibratory area of the TM and the round window protection will be restored after TM perforation repair, and consequently hearing will be improved and exposure of the middle ear (ME) to external infection will be prevented [1].

The biological graft materials act as a scaffold of tissue matrix when applied to seal the perforation, and this subsequently revascularizes in readiness for migration of fibroblasts and epithelium. Autologous graft materials include vein, fat, fascia lata, temporalis fascia (TF), perichondrium, and cartilage. The materials vary with regard to their ease of harvesting, preparation time, placement ease, viability, graft-take, and hearing improvement. Such abundance of materials implies that there is no clear-cut favorite, and the choice of the graft depends on individual surgeon preferences [1].

The TF and the perichondrium are the most commonly used grafting materials because of their proximity, translucency, and suppleness [1]. It has been found that TF changes its dimensions during the first few days of healing. Poor dimensional stability or shrinkage of temporal fascia grafts may be responsible for the residual perforation that may occur after grafting [2]. Other causes of re-perforation may be faulty technique, persistent ME disease, poor Eustachian tube function [3], or graft necrosis [4].

Placement of TF in a small formaldehyde basin causes cross-linking of collagen and imparts a shape memory to the graft to overcome shrinkage [5]. The formaldehyde-treated fascia graft (FTFG) can be more easily manipulated during the operation because of its tough nature [6].

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Cartilage graft is usually used as a preferred graft material in cases of recurrent perforation and other situations with high risk for failure [7].

In this study, we compared the anatomical and functional outcomes of grafting perforated TM that had previously failed between tragal cartilage and FTFG. Complications and ease of both techniques were also compared.

Patients and methods

This study was conducted at the ENT Department, Assiut University Hospital between 2013 and 2016. The present study included 36 patients with chronic suppurative otitis media with recurrent perforation of 15 years old or more. A minimum gap of 6 months should be present between the two surgeries. For each patient, history taking, full general and ENT examinations, and routine laboratory investigations were carried out. Patients with upper respiratory tract infection, nasal allergy, or local ear infections were treated before surgery. Dry ear for at least a month was a must. Patients with diabetes, malnutrition, and any other condition that may impair healing were excluded. Patients who were lost to follow-up for a minimum of a year were also excluded. Pure tone air and conduction thresholds were measures, and tympanometry was performed. Air–bone gap (ABG) was calculated. Patients were then subjected to surgery. All surgeries were performed under general anesthesia utilizing the hypotensive technique. Postaural incision was used in all patients. The edge of the perforation was refreshed, and any adhesions between the TM and the ME mucosa from the previous surgery were divided. Cortical mastoidectomy was performed for all cases. In 19 patients, the tragal cartilage with the covering perichondrium at one side was used to seal the TM. The cartilage was slipped in the ME with the perichondrium under the TM remnant. A slit in the cartilage was made to adapt the handle of malleus when required. In 17 patients, the FTFG was prepared by harvesting a 2×1.5 cm elliptical piece of the TF. The fascia was dried and then placed in solution of formaldehyde 4% at pH 5.6 for ~12 min. This process causes cross-linking of collagen and imparts a shape memory to the graft. Subsequently, the fascia was placed in three baths of Ringer solution for 5 min each to remove any unbound formaldehyde from the tissue. This produces a permanent graft shape that will not deform in blood or fluid.

The external canal (EC) was then packed with gelatin sponges, and a vasilinized gauze soaked with antibiotic

solution was packed in the EC. The wound was closed in layers. After 1 week, the stitches were removed, and the pack was removed after 2 weeks. Steroid-containing antibiotic drops were given to the patients. At the third postoperative week, the EC was cleaned of debris and gel-foam and checked for healing. Granulations were cauterized with diluted chromic acid, and ear drops were given if required. The patient was asked to come back at the third postoperative month for re-examination where the status of the TM was checked again. The postoperative audiological evaluation was performed at the sixth month. Patients were asked to come back for a final checkup by the second year or if any complication developed. The key points of successful surgery were graft-take and postoperative ABG. Postoperative ABG of 20 dB or less was considered successful, whereas postoperative ABG more than 20 dB was considered as a failure. In addition, deterioration of bone conduction threshold of 15 dB or more was considered as a failure. All complications during and after surgery were reported for both groups

Data entry and data analysis were performed using statistical package for the social science version 19 (SPSS Inc., Chicago, Illinois, USA). Data are presented as numbers, percentages, mean, and SD. The χ^2 -test and the Fisher exact test were used to compare qualitative variables. The Mann–Whitney test was used to compare quantitative variables between two groups. The Wilcoxon signed rank test was used to compare quantitative variables before and after surgery in case of nonparametric data. *P*-values were considered statistically significant when less than 0.05.

Informed consent was obtained from each patient or from parents of young patients. Approval from the ethics committee was obtained before starting the study.

Results

The age of the patients in this study ranged from 15 to 37 years with a mean of age is 22.08±5.20 years. Fifteen (41.67%) patients were males and 21 (58.33%) patients were females. Nineteen patients underwent tragal cartilage tympanoplasty and 17 patients underwent FTFG. In cartilage group, the other ear was normal in 13 (68.4%) patients and perforated in six (31.6%) patients. In FTFG group, the other ear was normal in 10 (58.8%) patients and perforated in seven (41.2%) patients.

The results with regard to the success of graft-take in both group are shown in Table 1.

Table 1 Number and percentage of graft-take in both groups at the end of the follow-up period

Graft-take	FTFG (<i>n</i> =17) [<i>n</i> (%)]	Cartilage (<i>n</i> =19) [<i>n</i> (%)]	<i>P</i> value
Successful	15 (88.2)	13 (68.4)	0.236
Failed	2 (11.8)	6 (31.6)	

FTFG, formaldehyde-treated temporalis fascia graft.

Table 2 Preoperative and postoperative hearing thresholds in both groups

Hearing threshold	FTFG (<i>n</i> =17) (mean±SD)	Cartilage (<i>n</i> =19) (mean±SD)	<i>P</i> value
Preoperative	32.86±7.04	32.42±5.04	0.827
Range	25–48	20–40	
Postoperative	23.89±6.71	21.53±6.21	0.660
Range	15–33.3	13–32	

FTFG, formaldehyde-treated temporalis fascia graft.

Table 3 Mean and SD of hearing gain in both groups

Hearing gain	F-FG	Cartilage	<i>P</i> value
Mean±SD	8.99±3.49	11.08±7.34	
Range	1.0–17.0	3.0–25.0	0.999

FTFG, formaldehyde-treated temporalis fascia graft.

The graft was displaced medially in three cases of cartilage grafting, infection occurred in three cases of the cartilage group after 6 months, infection occurred in two cases after 24 months in the FTFG group, and retraction and ME effusion occurred in one case of the FTFG group, which resolved 3 months later.

By the end of the first postoperative year, tympanometry showed type B tympanogram in all successful cases of the cartilage group, whereas it was type A in all successful cases of the FTFG group.

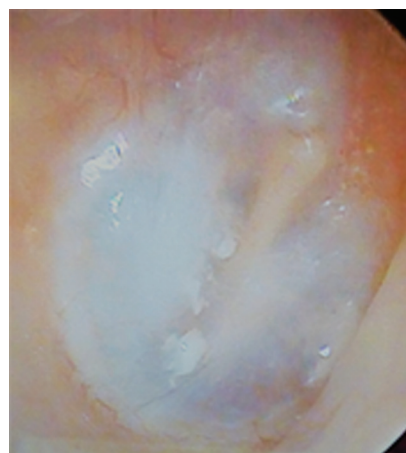
As shown in Table 2, the overall comparison of the audiological results between the two groups did not reveal any significant difference.

The difference between the mean hearing gain of the two groups as shown in Table 3 was not statistically significant ($P=0.961$) (Figs 1 and 2).

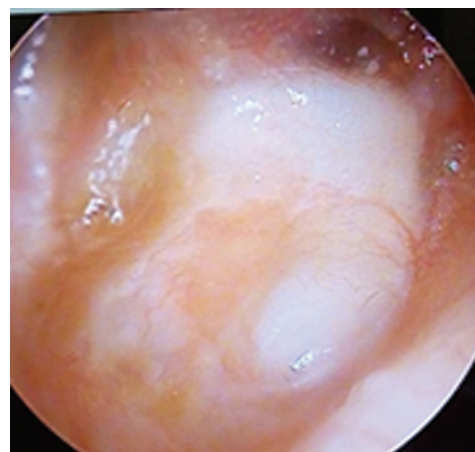
Discussion

The prerequisites for successful grafting are repair of the defect to close the tympanic cavity, the neotympanum should be able to resist ME pressure changes in case of Eustachian tube dysfunction, and the acoustic properties should be similar to a healthy TM [8].

Cartilage grafting has a reputation for excellent graft healing but potentially sacrifices maximum hearing improvement and creates difficulty during postoperative follow-up, resulting from opacity and immobility [9]. TF and perichondrium alone display acoustic properties similar to those of the TM;

Figure 1

The otoscopic appearance of formaldehyde-treated temporalis fascia graft in a right ear 1 year postoperatively

Figure 2

The otoscopic appearance of cartilage graft in a right ear 1 year postoperatively

however, they may not withstand negative ME pressure in the postoperative period causing retraction and reperforation [8].

We used FTFG to maintain excellent hearing, resistance to infection, and improve mechanical stability, as well as compare our results with the cartilage graft results. The definition of success, evaluated by otorhinolaryngologists, should include integrity of the graft, postoperative gain minimum of 10 dB in the auditory threshold or conservation of hearing in normal hearing ear, and complete healing aerated ME space manifested by the graft located in the correct anatomical position, with neither atelectasis nor otitis media with effusion [10]. There are many reasons for highly variable outcomes in comparative studies, such as sample size, surgical technique used, the size of the TM perforations, various ME pathologies, and follow-up period. All these factors affect the functional and anatomical success rates of tympanoplasty [11].

In this study, we used two types of graft materials – tragal cartilage graft in 19 cases of recurrent TM perforation, which was successful in 68.4% of cases, and FTFG in 17 cases, which was successful in 88.2% of cases. Different types of grafts have been used in many revision cases studies. Hough [12] showed that properly applied fascial graft can usually solve any difficult when revision grafting is necessary. Sismanis [13] used cartilage shield grafts in 43 cases, and graft-take was achieved in 93.5% of cases. Djalilian [14] used a subcutaneous scar tissue graft in 35 patients with 91% success rate. Suzuki *et al.* [15] used a thin-sliced cartilage in seven patients with 87.5% of ears successfully closed. Yetişer *et al.* [3], used a solvent – dehydrated human duramater (tutoplast) – in 45 patient with 86.7% success. Moore [9] utilized fossa triangularis cartilage in 83 patients with 100% success. Altuna *et al.* [16] also used island cartilage tympanoplasty in 60 revision cases with 92% success.

In this study, we used TF graft treated with formaldehyde 4% to increase the stability of the graft, resistance to infection, and normal appearance resembling the TM. Although it appeared slightly opaque, it reflected the normal configuration of the tympanogram. Formaldehyde grafts have been previously used as described by Perkins in a 20-year experience with autogenous TF that is formed and shaped by formaldehyde with special fasciaform molds for the repair of large TM perforations. All perforations were successfully closed by this technique [17]. Dokuzlar *et al.* [6] in a study on 54 patients found that the formaldehyde treatment of the temporalis muscle fascial graft used in tympanoplasty did not differ in closing perforations, and the operation length compared to its direct dry use in primary cases. However, he concluded that the graft could

be more easily manipulated during the operation as it becomes more tough [6].

The result of graft-take in the cartilage group was 68.4%, and is comparable with 88.2% in the FTFG group. Postoperative bone gap in the cartilage group was 11.08 ± 7.34 dB, and was 8.99 ± 3.49 dB in the FTFG group, which is a comparable result and not differ significantly. There are very few studies on revision myringoplasty to compare the types of the grafts used. However, on primary cases, there are several comparison studies. These studies have been on which cartilage shows better results in TM reconstruction, but the disadvantages of cartilage compared with fascia are primarily due to its greater thickness. Owing to cartilage opacity, serous effusion and cholesteatoma are difficult to visualize postoperatively with type B tympanogram, as in our case in the cartilage group. Moore [9] also showed that the cartilage is opaque and stiff, and therefore tried to use the fossa triangularis cartilage, which is thinner, and showed a large shift in the tympanogram configuration from type B to type C.

Lacovou *et al.* [18] in their systematic review of 12 studies systematically analyzed a total number of 1286 treated patients: cartilage was used in 536 and TFG was used in 750 cases. They concluded that the use of cartilage in type I tympanoplasty is associated with higher graft integration rates as compared with fascia reconstructions. In addition, the obtained audiometric results appeared to be at least comparable, and the rate of reperforation was lower [18]. Cartilage improves the compliance of the repaired TM-ossicular chain system, resulting in smaller impedance, as it eliminates the increased stiffness, by increasing the mass of the system [18]. Although cartilage is primarily used as a grafting material in cases of Eustachian tube dysfunction, adhesive otitis media, and subtotal perforation in everyday surgical practice, a wider utilization for the reconstruction of the TM in myringoplasties can be considered [18].

Also in our study, the postoperative tympanogram in the cartilage group was type B and opaque, not indicating the condition of the ME cavity.

In conclusion, according to the result of our study, cartilage and FTFG were comparable in graft-take and hearing result in the revision cases, and the FTFG reflected the true configuration of tympanometry and can be used in cases where the cartilage graft is consumed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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