Evaluation of hearing outcome of tympanoplasty using cartilage graft versus temporalis fascia graft

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Background
Various materials such as fascia, perichondrium, and cartilage have been used for the reconstruction of the tympanic membrane in middle ear surgery. Owing to its stiffness, cartilage is resistant to resorption and retraction.
Patients and methods
This study comprised a randomized, controlled trial conducted to analyze the audiological gain when using cartilage grafts in type 1 tympanoplasty compared with temporalis fascia grafts on 60 patients suffering from chronic otitis media after successful tympanoplasty. The follow-up period was at least 6 months. All patients were subjected to audiological evaluation before and at least 6 months postoperatively.
Results
There was a significant reduction in mean air-bone gap (ABG) in both groups, whereas in group A (fascial graft) the mean preoperative ABG was 25±10.2 dB and the mean postoperative ABG was 13.5±7.3 dB, whereas in group B (cartilage graft) the mean preoperative ABG was 30.6±8.6 dB and the mean postoperative ABG was 15.9±8.7 dB, analyzing the effectiveness of both surgical techniques showed that both were equally effective in reducing ABG from preintervention to postintervention with no statistical significance among both groups (P=0.212).
Conclusion
Patients who had cartilage grafts showed similar hearing outcomes to those who had fascial grafts after a successful tympanoplasty procedure.

Keywords:
cartilage graft, fascial graft, hearing outcome, tympanoplasty

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Introduction

Tympanic membrane perforations are a commonly encountered disorder by the otorhinolaryngologist. Since first described in 1878, a host of materials have been used for tympanic membrane grafting [1].

The most common etiology for tympanic membrane perforation is infection, trauma, or an extruded pressure equalization tube. Tympanic membrane perforations may be acute perforations or chronic perforations. Most acute perforations heal spontaneously but ~10–20% will become chronic [1].

Although the tympanic membrane has demonstrated a remarkable ability for regeneration and spontaneous healing, chronic perforations do commonly occur and may require grafting as a means of repair [2,3].

There are several major reasons why the complete closure of a chronic tympanic membrane perforation is desirable. With a closed tympanic membrane perforation, patients experience dramatic improvement in hearing, avoid the occurrence of otitis media, and tolerate water in the ear canal. In addition, with complete closure of the defect, recurrent otorrhea is unlikely to occur with upper respiratory tract infections and otitis media [3,4].

Temporalis fascia has been the most popular and the standard to which all other materials are compared with today. The use of cartilage in middle ear surgery is not a new concept, but the last decade has shown a renewed interest in this material as an alternative to more traditional grafting materials for tympanic membrane reconstruction. Cartilage was first introduced in middle ear surgery in 1952 and has been described for the limited management of retraction pockets and, or recently, for reconstruction of the tympanic membrane in cases of recurrent perforation, with encouraging results [4].

Various materials such as fascia, perichondrium, and cartilage have been used for the reconstruction of the tympanic membrane in middle ear surgeries. Owing to its stiffness, cartilage is resistant to resorption and retraction.

However, cartilage grafts result in increased acoustic impedance, the main limitation to their use [5]. The aim of this study was to compare the hearing results after cartilage tympanoplasty versus fascia tympanoplasty.

Aim

The aim of this study was to analyze the hearing outcome and audiological gain when using cartilage grafts in tympanoplasty compared with temporalis fascia grafts in patients suffering from chronic otitis media with safe perforations.

Patients and methods

Patients

This study was conducted in Helwan University teaching hospital ENT Department, Helwan University according to journal instructions. All patients were selected from those attending the ENT outpatient clinic. The study was conducted on a total number of 60 patients suffering from chronic suppurative otitis media proved clinically by endoscopic examination of the tympanic membrane and middle ear through the tympanic membrane perforation.

Patients who agreed to participate in the study were asked to sign a written informed consent. All procedures contributing to this study comply with the ethical standards of the (Helwan University) Research Ethics Committee guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

Inclusion criteria

(1) Both sexes were included.
(2) Age ranged from 7 to 50 years.
(3) Diagnosis of chronic suppurative otitis media was diagnosed clinically and through endoscopic examination of the tympanic membrane and middle ear through tympanic membrane perforation.

Exclusion criteria

(1) Patients who refused to participate or sign the consent.
(2) Patients who were reluctant or missed preoperative preparations before the surgery.
(3) Patients who showed signs of noncompliance to medical treatment (preoperatively and postoperatively) as this might confound the results.
(4) Patients who had immunological disorders such as systemic lupus erythromatosis or immunocompromised patients due to chronic systemic disorder or constant steroid intake or post-transplant patients were excluded from the study as this might alter the healing process.
(5) Patients having chronic medical or physical disabilities such as diabetes mellitus, hypertension, or hepatitis C virus infection were excluded from the study as this might alter the healing process.
(6) Patients who have had a residual or recurrent perforation seen 3 months postoperatively as this might obscure the audiological gain.

Methods

This study was conducted over a period of 26 months from July 2015 till September 2017. It included 60 patients. They were randomly selected using the closed envelope technique and were divided into two main groups:

(1) Fascial tympanoplasty group which consisted of 30 patients who underwent type 1 tympanoplasty with temporalis fascial graft.
(2) Cartilage tympanoplasty group which consisted of 30 patients who underwent type 1 tympanoplasty with tragal cartilage graft.

All patients were subjected to the following:

(1) Full history taking and clinical ENT examination as well as detailed otological examination and tuning fork testing.
(2) Preoperative audiological evaluation including: pure-tone audiometry (PTA), tympanometry, speech reception threshold, speech discrimination score, and then calculation of mean air-bone gap (ABG) at 500, 1000, and 2000 Hz for both ears.

Operation setting

All patients included in the study were unified to ensure accuracy of the results as follows:

(1) All patients in the study were operated upon by the same surgeon.
(2) All patients in the study received the same preoperative and postoperative medications.
(3) All patients in the study were done in the same operation theatre.

All patients underwent type 1 tympanoplasty with tragal cartilage and/or fascial graft by the underlay grafting technique, according to the group the patients were classified into [5]:

Postoperative follow-up

All patients were day cases discharged ~4 h after recovery from anesthesia and given their discharge

summary cards on which the follow-up visits are scheduled on as follows:

(1) Day 0: postoperative visit before discharge in which the dressing is checked and possible complications were examined such as integrity of the VII nerve and Weber's test. Medications were prescribed as of a quinolone for 10 days and an analgesic on demand except in patients of less than 20 years of age in which the quinolone was replaced with augmented penicillin.
(2) Day 7: The patient dressing was removed, stitches removed, and the external ear was inspected and examined by removing gently any residual blood clots or serous exudates using cotton pledgets. Inspection for possible cicatrization in the ear canal was done. Antibiotic steroid ear drops were given twice daily for ~2–3 weeks. Patients were given instructions to avoid water in the ear canal by using cotton balls soaked in Vaseline when necessary.
(3) Monthly visits started at 1 month postoperatively; the patients were examined monthly for a period of at least 6 months in which the patients were examined for any late-onset postoperative complications, graft take, healing process, tuning fork testing, any patients with failed graft take, or residual perforation were excluded and replaced using the same methods mentioned above and when healing is adequate postoperative audiological evaluation was done at 6 months postoperatively similar to the preoperative evaluation.

Statistical analysis

Data management and analysis were performed using the statistical package for the social sciences, version 23. Numerical data were summarized using mean, SDs, and ranges. Categorical data were summarized as numbers and percentages. Numerical data were explored for normality using Kolmogrov–Smirnov test and Shapiro–Wilk test. Comparisons between the two studied groups and the difference between preoperative and postoperative were done using the two-way analysis of variance with repeated measures on one factor. All *P* values are two sided. *P* values of less than 0.05 were considered significant.

Results

In group A (tympanoplasty using fascial graft) the mean age was 28.5±9.8 years (range: 10–44 years), whereas in group B (tympanoplasty using cartilage graft) the mean age was 28.1±12.1 years (range: 10–58 years) with no statistical significance (*P*=0.897).

Group A (tympanoplasty using fascial graft) comprised 20 (66.7%) women and 10 (33.3%) men, whereas group B (tympanoplasty using cartilage graft) comprised 21 (70%) women and nine (30%) men and showed no statistical significance (*P*=0.781).

Effects of treatment

In group A (tympanoplasty using fascial graft) the mean preoperative ABG was 25±10.2 dB and the mean postoperative ABG 13.5±7.3 dB, which showed a highly significant gain in decreasing ABG postsurgical intervention (*P*=0.038).

In group B (tympanoplasty using cartilage graft) the mean preoperative ABG was 30.6±8.6 dB and the mean postoperative ABG was 15.9±8.7 dB which has shown a highly significant gain in decreasing ABG postsurgical intervention (*P*=0.038).

Thus denoting that both surgical techniques whether using fascia or cartilage for tympanoplasty after success both reduce ABG significantly with better hearing outcome from preintervention to postintervention.

Comparison of the treatment options

In this study, a comparison for effectiveness of both surgical techniques has shown that both surgical techniques were equally effective in reducing ABG from preintervention to postintervention with no statistical significance among both groups (*P*=0.212) (Tables 1 and 2).

Discussion

This study comprised a randomized, controlled clinical trial conducted to analyze the hearing outcome and audiological gain when using cartilage grafts in underlay type 1 tympanoplasty compared with temporalis fascia grafts in patients suffering from chronic otitis media with safe perforations after complete closure of the perforation. The patients were followed up for a period of at least 6 months to be included in the study. Any patients with failed or residual perforation were excluded. The study sample included 19 men and 41 women.

After application of the inclusion and exclusion criteria mentioned before, all patients were subjected to audiological evaluation including: PTA, tympanometry,

Table 1 Summary of epidemiological data of the study groups

	Group A (fascial graft)	Group B (cartilage graft)
Age [mean±SD (range)]	28.5±9.8 (10–44)	28.1±12.1 (10–58)
Female [*n* (%)]	20 (66.7)	21 (70)
Male [*n* (%)]	10 (33.3)	9 (30)

Table 2 Effects of hearing gain preintervention and postintervention in both groups

	Groups					Time	Groups×time interaction
	Group A (fascial graft)		Group B (cartilage graft)		*P* values		
	Mean	SD	Mean	SD	Groups		
Air-bone gap – preoperative	25.0	10.2	30.6	8.6	0.038	<0.001	0.212
Air-bone gap – postoperative	13.5	7.3	15.9	8.7			

speech reception threshold, speech discrimination score which were done preoperatively and postoperatively and have had the ABG calculated and analyzed.

In this study, there was a significant reduction in mean ABG in both study groups where in group A (tympanoplasty using fascial graft) the mean preoperative ABG was 25±10.2 dB and the mean postoperative ABG was 13.5±7.3 dB (P=0.038), whereas in group B (tympanoplasty using cartilage graft) the mean preoperative ABG was 30.6±8.6 dB and the mean postoperative was 15.9±8.7 dB, which has shown a highly significant gain in decreasing ABG postsurgical intervention (P=0.038).

Thus denoting that both surgical techniques whether using fascia or cartilage for tympanoplasty after success both reduce ABG significantly with better hearing outcome from preintervention to postintervention.

In this study, a comparison for effectiveness of both surgical techniques has shown that both surgical techniques were equally effective in reducing ABG from preintervention to postintervention with no statistical significance among both groups (P=0.212).

This study concurs with many others in the literature, clearly indicating that cartilage produces hearing results that are comparable to temporalis muscle fascia grafts. The results of this study was comparable to several publications of which a study by, who have studied 60 pediatric cases in whom fascia graft was used as the graft material in 35 of them, and cartilage was used in 25 patients. There was no statistical significance between both groups after a 1-year follow-up in which their fascial group showed preoperative ABG was 28.2±10.1 dB, postoperative ABG was 15.1±10.2 dB, and in the cartilage group, preoperative ABG was 28.9±10.2 dB, and postoperative ABG was 16.8±10.3 dB with no significance among their study groups. Similarly, Kalcioglu *et al.* [6] performed a retrospective study on 77 patients of which 49 patients underwent cartilage tympanoplasty and 28 patients who underwent temporalis fascia graft showed no statistical significance between both groups.

Another study by Yegin *et al.* [7] studied a total of 78 pediatric patients ranging from 7 to 18 years old who followed up their patients for a period of 6 months as our study revealed that in the fascia group, the preoperative ABG was 33.68±11.44 dB and postoperative ABG was 24.25±12.68 dB. In the cartilage group, the preoperative ABG was 35.68 ±12.94 dB and postoperative ABG was 26.11 ±12.87 dB. The anatomical success rate in the cartilage group was significantly better than that for the fascia group (P<0.01). There was no statistically significant difference in functional outcomes between the fascia and cartilage groups (P>0.05).

A study by Kim *et al.* [8] included 114 patients, 31 with fascia and 83 with cartilage grafts; their mean postoperative gains in ABG were 9.70 dB for the fascia group and 9.78 dB for the cartilage group. These results demonstrate that hearing after cartilage tympanoplasty is comparable to that after fascia tympanoplasty.

Tek *et al.* [9] studied 77 patients, 40 with fascia and 37 with cartilage grafts. A PTA is done within 1 week before the surgery and at 6 months postoperatively. There was no statistically significant difference between preoperative and postoperative air conduction gain in patients with intact tympanic membrane.

Another study by Calliogu *et al.* [10] studied 108 patients; 63 patients underwent type 1 tympanoplasty with chondroperichondrial graft, compared with 45 patients in whom temporalis fascia was used. The mean value was calculated at preoperative and postoperative hearing threshold of 0.5, 1, 2, 4 kHz, and the ABG gain was compared in both cartilage and fascia groups. When preoperative and postoperative ABG gain were compared, significant decrease was seen in ABG levels (P<0.001). However, no significant difference was seen in ABG gain values (P=0.608), which was 10.1 ±7.00 dB in the cartilage group and 10.8±5.38 dB in the fascia group.Last but not least, a meta-analysis by Jalali *et al.* [11] reviewed a total of 11 prospective and 26

retrospective studies involving 3606 patients. In their review they found no significant difference in the ABG between the two groups, and concluded cartilage grafting seemed to show a higher graft integration rate compared with temporalis fascia grafting. Both cartilage and fascia tympanoplasty provided similar improvements in the hearing outcome postoperatively and further large prospective trials are necessary to collect high-quality data.

A systematic review and meta-analysis done by Yang *et al.* [12,13] based on published retrospective trials investigated the efficacy of cartilage grafts and temporalis fascia grafts in type 1 tympanoplasty. They reviewed eight eligible articles with a total of 915 patients. They found that the pooled mean ABG gain was 1.92 (95% confidence interval =–0.12–3.95; $P<0.00001$) and the difference was not significant. However, in the full thickness cartilage grafts subgroup, the pooled mean ABG gains was 2.56 (95% confidence interval=1.02–4.10; $P=0.14$) and the difference was significant, which means that the full thickness cartilage grafts subgroup got a better hearing outcome than the temporalis fascia grafts group. They concluded that tympanoplasty using cartilage grafts has a better graft take rate than that using temporalis fascia grafts. There are no significant differences between cartilage grafts and temporalis fascia grafts for hearing outcomes.

Summary and conclusion

Patients who had cartilage grafts showed similar hearing outcomes to those who had fascial grafts after a successful tympanoplasty procedure as evidenced by marked decreases in the mean ABG from preoperative to postoperative. There were no epidemiological or clinical differences that represented any variation from those discussed in the literature.

Future recommendations

(1) It is highly recommended to study both cartilage and facial tympanoplasty with a larger number of patients in each group with special stratification concerning the age such as pediatric and adult ages, different sexes due to the importance of improving hearing in young age groups, before solid conclusions could be made.
(2) Also, replicating the study in a multicenter trial to give more depth in representation of the population such as comparing different environments, socioeconomic states, occupations, and crowding effects.
(3) In addition, further studies are recommended to compare other alternative grafting materials in a trial to reach the best material ideal for grafting with better properties and cheaper cost and better feasibility and accessibility by the patients.
(4) Further elaboration of the study could be done by the addition of histological analysis of the graft lining compared with other grafting materials through small biopsy specimens that could be taken away from the grafted tympanic membrane or in failed cases in case of revision procedure is to be performed.
(5) Finally, longer follow-up periods for current patients to detect any resorption or late failures or recurrences.

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Conflicts of interest

There are no conflicts of interest.

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