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A Novel Combined Cartilage-Fascia Technique for Anterior Perforation in Type-1 Underlay Tympanoplasty

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Abstract

Background: Biomaterials and surgical techniques for reconstructive tympanic membrane surgery are under development.
Objectives: The objective of this study is to analyze the functional and surgical outcomes of a novel fascia with cartilage reinforcement technique for anterior tympanic membrane perforation in tympanoplasty.
Methods: Records of 198 patients with anterior tympanic membrane perforation who underwent tympanoplasty between August 2018 and March 2021 were prospectively reviewed. Patients with dry anterior quadrant perforations of the tympanic membrane were included and underwent tympanoplasty using two methods: Type 1 tympanoplasty with temporalis fascia only, and tympanoplasty with fascia and cartilage reinforcement. Postoperative functional and surgical outcomes were analyzed.
Results: Comparing the pre-operative and post-operative air conduction levels and air-bone gaps showed significant improvement in both groups ($P < 0.001$). Additionally, no significant difference was observed between air-bone gap closure ($P = 0.316$) and increase in air conduction levels ($P = 0.222$) according to graft type.
Conclusions: Both temporalis muscle fascia and temporalis muscle fascia with cartilage reinforcement revealed satisfactory functional and surgical outcomes. Furthermore, the novel combined cartilage-fascia technique had a comparable graft take rate and hearing results in anterior perforations, with no significant change in tympanic membrane vibratory properties.

Keywords: Temporalis Fascia, Ear Cartilage, Tympanoplasty

1. Background

Biomaterials and surgical techniques for reconstructive tympanic membrane (TM) surgery are under development. Tympanoplasty, the mainstay for TM reconstruction, was first described in 1952 by Wullstein and Zöllner (1-4). Historically, various materials, including autogenous, allogenous, and exogenous grafts, as well as various alternative methods for surgical repair, have been used for TM reconstruction. Today, tympanoplasty with temporalis muscle fascia is the most commonly used method, boasting a success rate of 70 - 90% (5-7).

Temporalis muscle fascia has several advantages that make it an ideal choice for TM perforation grafting: It is readily available in the operative field, provides stable results for TM reconstruction, and has ideal handling properties (8). The need for more rigid grafting, particularly in patients with eustachian tube dysfunction and severe TM retraction, has led to the use of cartilage grafts (2). Although cartilage grafts have proven to be a suitable alternative to temporalis muscle fascia grafts, potential hearing loss remains a concern (7). Additionally, the most common region of graft failure is the anterior superior part due to weak graft support and poor vascularity (9). Therefore, in cases of anterior perforation, fascia can be supported by adding a cartilage graft medial to it. While cartilage strengthens the fascia and prevents retraction formation, there is concern about impairing the vibratory properties of the TM.

Moreover, a review of studies on cartilage reinforcement techniques revealed conflicting findings. The literature on the results of cartilage-fascia tympanoplasty in anterior perforations is also scarce. This overview describes cartilage-fascia tympanoplasty as a new reconstructive method and evaluates the success rates and outcomes of this novel technique

compared to traditional fascia tympanoplasty in anterior TM perforation.

2. Materials and Methods

2.1. Design Overview

This study was approved by the local ethics committee of Shahid Beheshti University of Medical Sciences (IR.SBMU.MSP.REC.1396.68). All participants provided written informed consent.

2.2. Setting and Participants

Between August 2018 and March 2021, 198 patients underwent tympanic membrane perforation reconstruction by the senior author using two methods: Type 1 tympanoplasty with temporalis muscle fascia only, and tympanoplasty with fascia and cartilage reinforcement, at Taleghani Hospital, a tertiary referral center in Tehran, Iran. The functional and surgical outcomes were compared between the two groups.

The study included patients with chronic otitis media and anterior tympanic membrane perforation (involving anterior quadrants and reaching up to the annulus fibrosis) who had a dry ear for at least one month before the operation. The exclusion criteria were as follows: A history of previous ear surgery, cholesteatoma, middle ear polyp, need for concurrent ossiculoplasty or mastoidectomy, sinonasal allergy or polyp, and cleft palate (10).

To determine the appropriate sample size, we employed the following formula, based on data reported by Onal et al. In their study, the air conduction threshold was 28.54 ± 14.20 dB for the fascia group and 22.97 ± 8.37 dB for the cartilage group. The bone conduction threshold was 11.71 ± 8.50 dB for the fascia group and 7.15 ± 5.56 dB for the cartilage group. We calculated the sample size with alpha set at 0.05 and power at 0.8. Using these parameters, and assuming a 95% confidence level and 80% statistical power, we determined that the required sample size is 99 for each group (11).

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 \left(\delta_1^2 + \delta_2^2\right)}{\left(\mu_1 - \mu_2\right)^2} = 99$$

2.3. Surgical Technique

All patients underwent underlay tympanoplasty performed by the senior author under general anesthesia. In group A, fascia was harvested from the ipsilateral temporalis muscle and placed medial to the remnant of the tympanic membrane.

In group B, the cartilage graft was harvested from the tragus and prepared. First, fascia was placed as a lateral graft, then the cartilage–perichondrium graft was placed as a medial graft for additional coverage.

In both groups, the middle ear space was packed using an absorbable gelatin sponge.

2.4. Outcomes and Follow-up

The ear dressing was removed on the third postoperative day. The first post-surgical evaluation was performed four weeks after surgery by microscopic examination. Additionally, an intact tympanic membrane at six postoperative months was documented as a surgical success. The postoperative functional outcome was described by audiometric analysis, using the four-frequency (500, 1000, 2000, and 4000 Hz) pure-tone average air-bone gap (ABG) and air conduction (AC) level at six postoperative months.

2.5. Statistical Analysis

The continuous variables are summarized as mean ± SD, and categorical variables are presented as frequency (percentage). Fisher's exact test and chi-square test were employed for the comparison of categorical variables as required. Analysis of continuous variables between the two groups and within a group was performed using a *t*-test and paired *t*-test, respectively. SPSS 22.0 software was used for statistical analyses. P-values less than 0.05 were considered statistically significant.

3. Results

Patients were recruited from August 2018 to March 2021. A total of 212 patients were assessed for eligibility, and 14 were excluded due to previous ear surgery (5 patients), cholesteatoma (4 patients), the need for concurrent mastoidectomy (4 patients), and sinonasal polyp (1 patient).

Finally, 198 patients (52.5% male and 47.5% female) aged between 15 and 71 years (mean age: 28 ± 10.9 years) were included in the study (Table 1). All participants underwent tympanoplasty in the Department of Otorhinolaryngology-Head and Neck Surgery at Taleghani Hospital of Shahid Beheshti University of Medical Sciences. This study analyzed otoscopic examination results and audiometric analysis of patients who underwent perforated tympanic membrane reconstruction. The overall closure rate was

90%, with 18 cases of failure detected six months after surgery (Table 2). The surgical success rate was 92.92% in the cartilage-fascia group and 88.88% in the fascia group (P-value = 0.121).

Table 1. Characteristic of Patients in Study Groups [a]

Variables	Fascia Group	Combined Fascia Cartilage Group
Age	28.5 ± 9.8 (15 - 71)	28.1 ± 12.1 (16 - 69)
Female	48 (48.4)	46 (46.4)
Male	51 (51.5)	53 (53.5)

[a] Values are expressed as No (%) or mean ± SD.

Table 2. Graft Takes Up Results in Our Study

Variables	No. (%)
Fascia group (n = 99)	
Graft takes up	92 (92.92)
Residual perforation	7 (7.08)
Combined fascia cartilage graft (n = 99)	
Graft takes up	88 (88.88)
Residual perforation	11 (11.11)

The reconstructive method used in this study applied two main materials as grafts: In 50% (n = 99) of patients, cartilage was utilized in conjunction with temporalis fascia, while in the other 50% (n = 99), only temporalis muscle fascia was used. Pre-operative ABG and AC levels were 29.2 ± 9.8 dB and 37.7 ± 11.2 dB, respectively, for the combined fascia-cartilage group. On the other hand, pre-operative ABG and AC levels were 31.4 ± 8.6 dB and 36.2 ± 8.9 dB, respectively, for the fascia group (Table 3). Comparing the pre-operative and post-operative air conduction levels and air-bone gaps showed significant improvement in both groups (P-value < 0.001). No statistical significance was found between air conduction levels (P-value = 0.222) and air-bone gaps (P-value = 0.316) between the cartilage-fascia and fascia groups.

4. Discussion

Historically, temporalis muscle fascia has been the most prevalent graft in tympanoplasty. Recently, several advantages have encouraged otologists to prefer cartilage grafts. It is now well demonstrated that cartilage can be used successfully for tympanoplasty in both clinical and experimental studies (1, 2, 5).

Each graft material, fascia and cartilage, may have its own problems. Temporalis muscle fascia is mainly composed of connective tissue and elastic fibers, thus their postoperative quantities are unpredictable. On the other hand, cartilage has a rather constant shape and is firmer than fascia. Cartilage is resistant to re-absorption and inflammatory reactions (2, 8, 12). Fascia grafts are now the choice for more straightforward cases such as central perforations, while cartilage is often reserved for more severe cases like revision surgeries and retractions. The prognosis for healing of the tympanic membrane in patients with total perforations, severe retraction, and revision surgery is not reliable. Atrophy of fascia may result in failure of graft take in such cases (3).

The stability of the structure and function of cartilage, and its resistance, especially in patients with eustachian tube dysfunction, has made cartilage the proper graft in these cases. Although cartilage has many advantages over fascia, there is a potential disadvantage: Problems with conducting vibrations. A normal tympanic membrane is 0.1 mm thick, while tragal cartilage is approximately 1 mm thick. Thus, conduction properties have been proposed as a major problem in cartilage tympanoplasty in many studies (13).

However, while there is concern that cartilage may have a negative impact on hearing, no supporting data are documented in the literature (7, 11, 14). The overall graft take rate in this study was found to be about 90%, which is comparable to similar studies (1, 3, 7, 15). No statistical significance was found between the two graft materials in the graft take rate.

We concluded that there is a significant improvement in air conduction levels and air-bone gap closure postoperatively in both fascia and cartilage-fascia groups. However, multivariate analysis showed no significant difference for air-bone gap closure (P = 0.316) and increase in air conduction levels (P = 0.222) according to graft type. This result is comparable to many similar studies comparing the results of graft take rate and hearing improvement in cartilage and fascia tympanoplasty (2, 8, 9).

The present study has some limitations. First, it was a single-center study with a small sample size. Second, there was no long-term follow-up; the patients in this study were followed for six months. Although there is some evidence that cartilage reinforcement improves the surgical and functional outcomes in tympanoplasty, the conclusive evidence for anterior tympanic membrane perforation reconstruction is weak. Finally, a high population study with prolonged follow-up is suggested to increase the accuracy of the results.

4.1. Conclusions

Table 3. Effects of Hearing Gain in Study Groups [a]

Variables	Fascia Group	Combined Fascia Cartilage Group	P-Values
Preoperative air-bone gap (dB)	31.4 ± 8.6	29.2 ± 9.8	0.316
Postoperative air-bone gap (dB)	12.8 ± 6.4	14.9 ± 8.7	

[a]Values are expressed as mean ± SD.

Based on our findings, the combined cartilage-fascia technique revealed satisfactory functional and surgical outcomes. Thus, cartilage-fascia can be used as a safe graft material with an acceptable graft take rate and hearing results for tympanoplasty, especially in anterior tympanic membrane perforations.

Footnotes

Authors' Contribution: B. B. supervised the study, designed the study, re-evaluated the experimental data, and revised the manuscript. M. A. conceived and designed the study and evaluation and drafted the manuscript. Z. KH. participated in designing the evaluation, performed parts of the statistical analysis, and helped draft the manuscript. M. A. and Z. KH. collected the data, interpreted them, and revised the manuscript. B. B. performed the experiments and helped to draft the manuscript. All authors read and approved the final manuscript.

Conflict of Interests Statement: The authors declare that there is no conflict of interest.

Data Availability: The dataset presented in the study is available on request from the corresponding author during submission or after publication.

Ethical Approval: Ethics approval (IR.SBMU.MSP.REC.1396.68) was obtained from the Research Center of the Faculty of Medicine of Shahid Beheshti University of Medical Sciences.

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Informed Consent: Written informed consent was received from each participant.

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