Annals of Otology, Rhinology & Laryngology
1–7

DOI: 10.1177/0003489419843551
journals.sagepub.com/home/aor
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Double-Layer Tympanic Membrane Graft in Type I Tympanoplasty

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Abstract

Background: Some discussion remains among otologists regarding the best grafts for tympanic membrane closure. It is unclear whether double-layer grafts are superior to single-layer and whether single-layer cartilage is superior to fascia or perichondrium alone. The objective of the current study was to examine the relative efficacy of single-layer versus double-layer tympanic membrane grafting techniques.

Materials and Methods: A retrospective review of the medical records was used to address the objective of the study. Patients operated on in an over/under technique by the same surgeon underwent single-layer perichondrium or single-layer perichondrium with a cartilage island, or a double-layer of perichondrium combined with periochondrium with a cartilage island. The outcomes assessed were tympanic membrane reperforation and hearing improvement.

Results: A total of 135/177 (76%) perichondrium grafts had no reperforation, and 43/55 (78%) perichondrium with cartilage island grafts had no reperforation; 352/390 (90%) of the double-layer closures had no reperforation. There was no statistically significant difference in reperforation rates between the 2 single-layer techniques ($P = .926$). The difference in reperforation rates after the double-layer closure versus the perichondrium single-layer closure was statistically significant ($P = .001$), as was the difference in reperforation rates after the double-layer closure versus the cartilage island single-layer closure ($P = .02$). All 3 groups showed statistically significant hearing improvement postoperatively ($P < .0001$). Preoperative hearing levels ($P = .179$), postoperative hearing ($P = .857$), and decibels of hearing improvement ($P = .356$) were the same for all 3 groups.

Conclusion: Double-layer closure gives lower tympanic membrane reperforation rates than does single-layer closure, as well as similar hearing outcomes.

Keywords

eardrum perforation, myringoplasty, tympanic membrane rupture, tympanoplasty

Introduction

In this study, the single-layer free tragal perichondrium (TP) tympanic membrane graft and the single-layer perichondrium with cartilage island (TP/CI) graft are compared to the double-layer perichondrium plus perichondrium with cartilage island (TP + TP/CI) tympanic membrane graft. The outcomes assessed are tympanic membrane reperforation rates and hearing improvement.

The inspiration for using double-layer tympanic membrane grafts was taken from early works on tympanoplasty. In 1970, Plester introduced temporal fascia underlay under the manubrium and sulcus tympanicus, augmented by a second layer of fascia, and covered laterally with the tympanomeatal (skin) flap.[1] This technique was developed to address large perforations of the tympanic membrane but was followed by high rates of desquamation and reperforation.[2] Other reports of double-layer fascia grafts reported better reperforation rates than those of single-layer fascia or cartilage,[3-5] while others compared reperforation rates between the 2 techniques and found no difference.[6]

Conditions in Ethiopia in the early 2000s, when tympanoplasty was introduced by an experienced German-trained otologist, resembled those in 1960s in Europe and other developed countries. However, having the advantage

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of previous studies of tympanic membrane grafts, perforations were approached with 2 techniques: TP/CI or TP as single-layer grafts or TP + TP/CI as a double-layer graft. For all 3 techniques, the over/under technique[7,8] was used—placing the graft over the manubrium and under the tympanic membrane remnant or sulcus tympanicus. All operations were performed transmeatal. Here, we report our findings of the relative successes of the single-layer versus the double-layer techniques. Our report is able to answer this clinical question because of the consistent use of the over/under technique for all 3 grafting strategies, the length of follow-up, and the number of patients in each arm.

Materials and Methods

This retrospective review of the medical records was evaluated by the OtoRinoENT Ethics Review Committee, which found no indication of possible injury to patients or ethical violation and gave approval for this study to proceed. In addition, this study was performed consistent with the standards of the Declaration of Helsinki and involved minimal risk to the participants.

Study Design

A retrospective review of the medical records was used to address the question of relative efficacy of a single-layer versus double-layer tympanic membrane grafting technique. No other source of information was used for this study.

Subjects

Patients with tympanic membrane perforations without ossicular chain erosion were selected. Children and adults were operated on, and only those patients found to have a tympanic membrane with intact ossicular chain were included in this report. None of the patients had previous tumors, burns, irradiation, cleft palate, or craniofacial anomalies. All ears were dry at the time of operation. Tympanic membrane integrity was determined with successive generations of Zeiss office microscopes and by tympanometry. The duration of symptoms was recorded for all patients.

Operative Technique

All patients were operated on by a single experienced otologist. In subtotal perforations, the tympanic membrane perforation edge was freshened with a sickle knife or sharp needle. In larger perforations, the mucosal layer of the tympanic membrane remnant was rasped away from the medial surface with a sickle knife. The tympanomeatal flap was elevated, and the epithelial layer of the tympanic membrane remnant was elevated off of the fibrous layer and the anulus. The tympanic membrane was sharply cut off of the manubrium, and if a better view of the ossicles was needed, the scutum was curetted with chorda preservation. The ossicular chain was inspected and freed of any granulation tissue present. Any disruption of the ossicular chain disqualified the patient/operation from inclusion in this study. The tragal perichondrium grafts were harvested: one a free tragal perichondrial flap (TP) and the other a tragal perichondrial flap with a cartilage island still attached (TP/CI). The TP graft was placed as a single layer, or the TP/CI was placed as a single-layer, or TP plus TP/CI (TP + TP/CI) was placed as a double layer. In all operations, the grafts were placed over the manubrium and under the fibrous layer of the remnant of the tympanic membrane (Figures 1-2). The cartilage graft was laid laterally upon the malleus handle without a groove cut for the handle. The tympanomeatal flap was returned to position (Figure 3). Figure 4 shows the orientation of the double-layer grafts.

The tympanic membrane perforation size and the middle ear pathology were recorded.

All recorrection operations were done with concha butterfly composite graft as the inlay tympanic membrane graft.

Outcomes

The 3 operative techniques being compared were single-layer grafts using TP or TP/CI and double-layer grafts using TP + TP/CI. Reperforation sizes and reoperation rates were the documented outcomes of the tympanic membrane status. An open postoperative tympanic membrane was identified by office Zeiss microscopy and tympanometry together and was termed "reperforation" since we could not know if this perforation was persistent or recurrent.

Preoperative and postoperative audiometry was done on all cases and documented. The extended pure tone average (ePTA) of the conductive hearing loss at the frequencies 0.5, 1, 2, and 4 kHz was calculated. (Of note, reporting of ePTA of the air bone gaps follows the 1995 American Academy of Otolaryngology/Head and Neck Surgery Committee on Hearing and Equilibrium guidelines for reporting conductive hearing losses.[9] Because word recognition testing was not available in Ethiopia before 2018, scattergram representations are not possible for this report.[10,11])

The patients were asked to follow up at 6 months; however, this was inconsistently enforced. Those with postoperative doubts came sooner, and some patients returned repeatedly for as long as 8 years later.

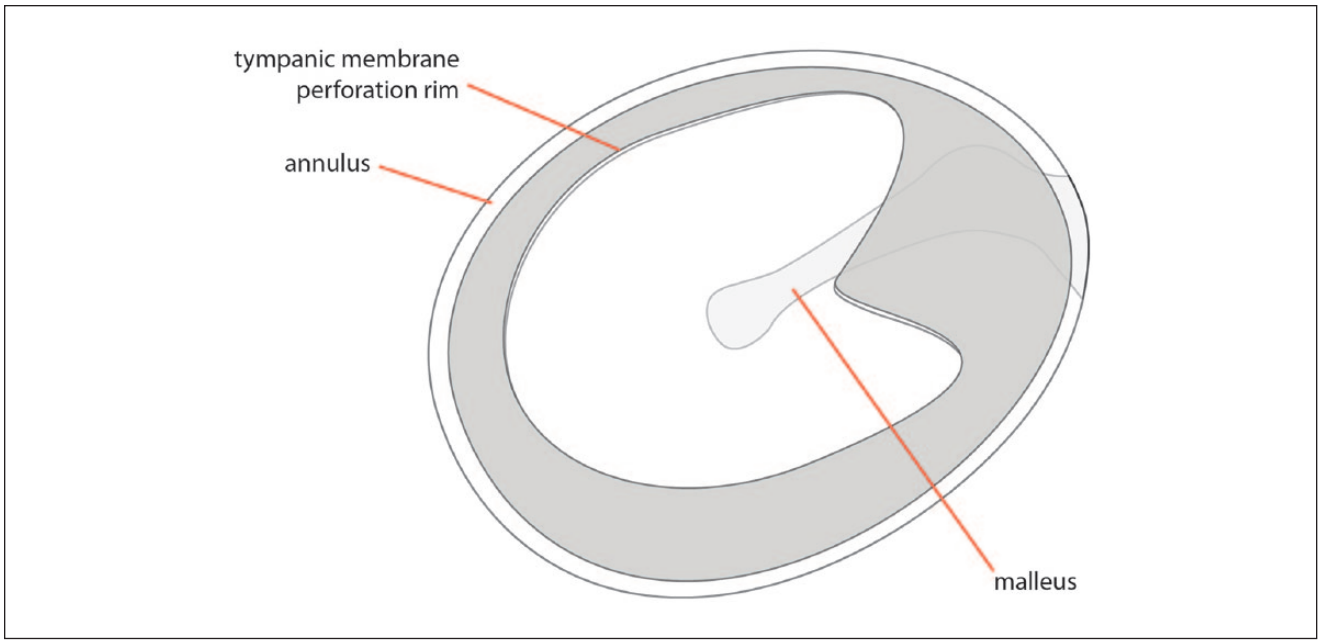

Figure 1. Tympanic membrane remnant with exposed manubrium.

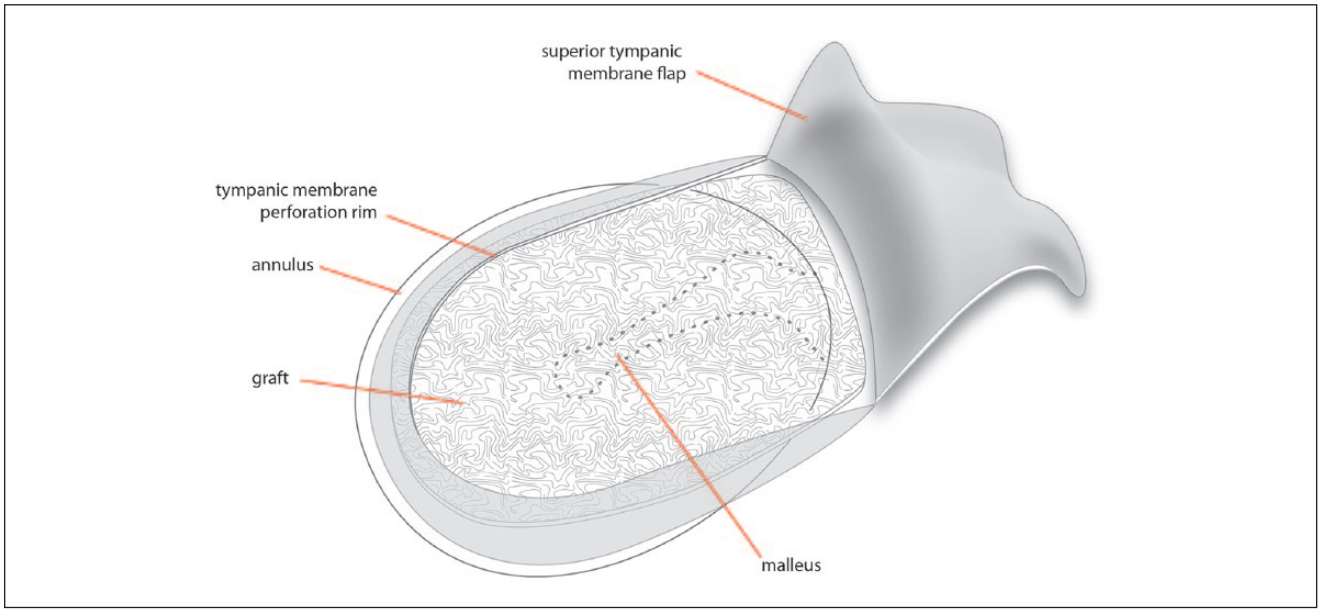

Figure 2. Superior tympanomeatal flap raised and tragal perichondrial (TP) graft in place, under the fibrous layer of the tympanic membrane remnant and over the manubrium.

Statistical Analysis

The SPSS software package version 21 was used to analyze the data. Specific tests used where appropriate were Pearson's 2-tailed χ^2 test, the likelihood ratio (χ^2) test, the Fisher exact *t* test and paired-sample *t* test, and analysis of variance. All statistical analyses were performed by a professor of statistics and public health who is also one of the coauthors.

Results

Subjects

Between November 2009 and April 2018, 558 patients were operated on, of whom 64 had operations on both ears for a total of 622 ears operated. Overall, 334 were female (60%) with a mean age of 26 years (8-57 years) and 224 were male (40%) with a mean age of 28 (4-60 years). The duration of

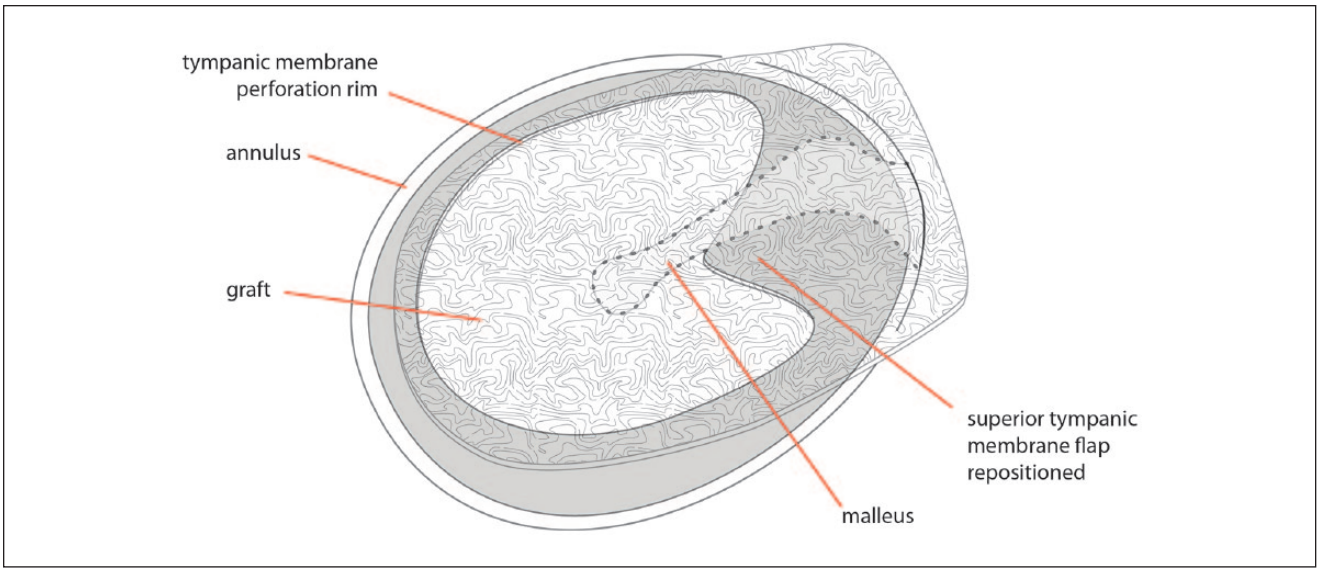

Figure 3. Superior tympanomeatal flap returned to the native position, lateral to the tragal perichondrial (TP) graft.

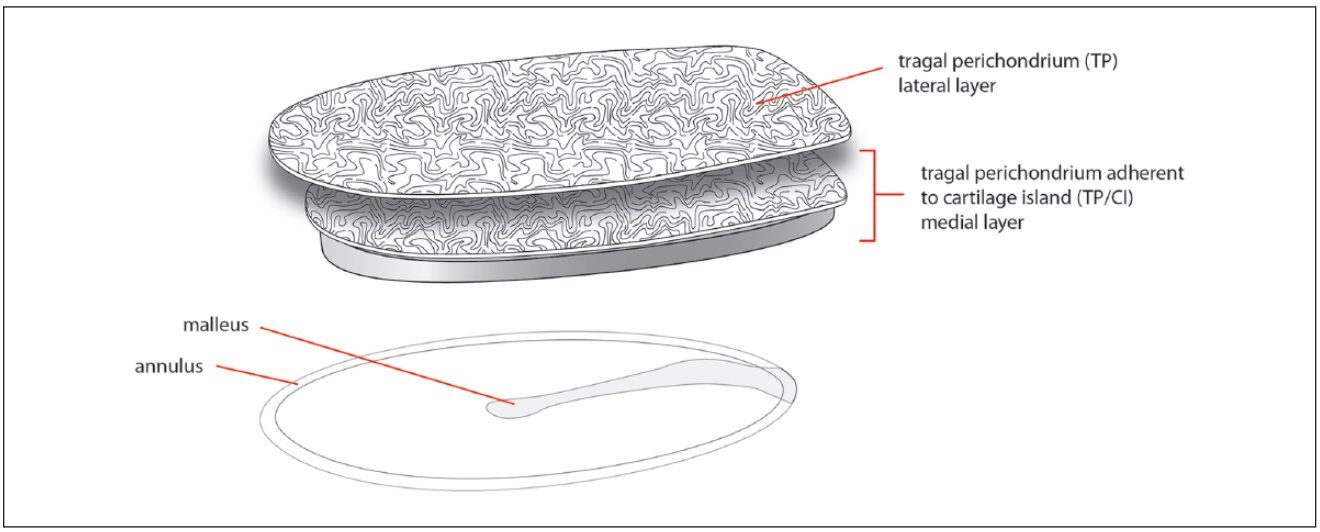

Figure 4. Orientation of the double-layer grafts. The tragal perichondrium/cartilage island (TP/CI) is oriented with the cartilage medial and the perichondrium lateral. The second-layer tragal perichondrium (TP) graft is then positioned laterally.

disease was more than 10 years in 513 patients (83%), 5 to 9 years in 30 patients (5%), and less than 5 years in the remainder of patients. Forty-five percent of the patients had a tympanic membrane perforation more than 60%.

Operations

All operations were transmeatal, and the operating microscope was used in all patients. A total of 599 ears (96%) were operated on under local anesthesia with sedation in patients whose mean age was 27 years (range, 12-60 years). Only 23 ears (4%) were operated on under general anesthesia, in patients whose mean age was 9.4 years (range, 4-16 years). Distribution of closure techniques was 177 TP grafts, 55 TP/CI grafts, and 390 TP + TP/CI grafts. The distribution of closure techniques over time were:

TP = November 2009 to August 2016
TP/CI = November 2009 to June 2017
TP + TP/CI = March 2012 to April 2018

Outcomes/Statistics

The last follow-up visit for these patients was October 2018. The follow-up was up to, on average, 6 months,

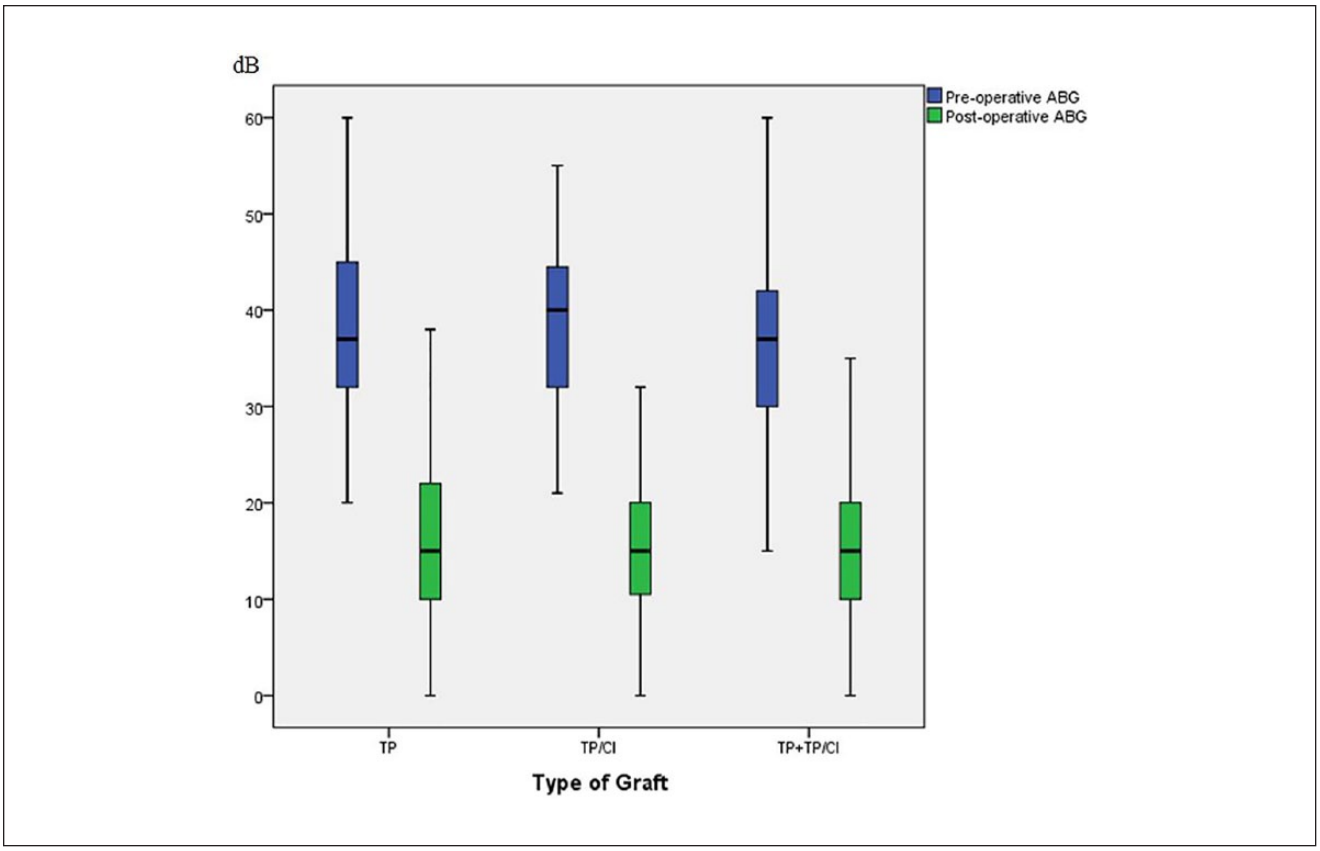

Figure 5. Box-and-whiskers representation of pre- and postoperative extended pure tone averages (ePTAs) of conductive hearing loss in decibels (average of 0.5 + 1 + 2 + 4-Hz thresholds). Baseline ePTAs and final ePTAs showed no statistical differences between the 3 closure techniques.[12]

although the range was 2 to 99 months; some patients continued to return up to 8 years postoperatively. Reperforation of the tympanic membranes was tallied. Single-layer TP was used in 177 cases, and 135 had no reperforation (76.3%). Single-layer TP/CI was used in 55 patients, of whom 43 had no reperforation (78.2%). Double-layer grafts (TP + TP/CI) were used in 390 patients, of whom 352 (90.3%) had no reperforation. The Pearson χ^2 test showed significant difference among the 3 groups ($P = .008$). The Fisher exact *t* test found the difference between the double-layer tympanic membrane graft (TP + TP/CI) and single-layer free TP was highly significant ($P < .0001$) and between the double-layer (TP + TP/CI) and single-layer TP/CI was also significant ($P = .02$). However, the difference between the single-layer free TP and single-layer TP/CI was not significant ($P = .926$).

To quantify the possible effect of surgeon experience with time, the closure rate of the 86 TP + TP/CI operations performed after the TP operation was discontinued was also noted: If the 86 double-layer operations performed after August 2016 (ie, the date of the last TP procedure) are excluded from the analysis, the TP + TP/CI closure rate still remains highest of the 3 closure techniques at 86%. This difference in closure rate remains a statistically significant difference between single-layer and double-layer closures (Pearson's 2-tailed χ^2 test: $P < .05$; the likelihood ratio (χ^2) test: $P < .04$). The closure rate of the 86 patients operated on with a TP + TP/CI double-layer after August 2016, taken alone, was 96%. Therefore, in each time frame, the TP + TP/CI closure rate is superior and statistically significantly so.

Hearing improvement was also calculated for each case and tested for significant difference between the 3 tympanic membrane graft types (Figure 5). Improvement in ePTA of conductive hearing loss after single-layer TP or TP/CI grafts was 20.7 dB and 22.1 dB, respectively. Improvement in ePTA for conductive hearing loss after the double-layer TP + TP/CI was 20.14 dB. Analysis of variance showed no significant difference among the hearing improvement in the 3 techniques ($P = .356$). Looked at more specifically, the pre- and postoperative hearing in the single-layer TP patients was 37.9 and 17.3 dB, for the single-layer TP/CI was 38.97 and 16.6 dB, and for the double-layer TP + TP/CI was 37 and 16.9 dB,

Table 1. Distribution of Preoperative Risk Factors for Reperforation between the 3 Closure Techniques.[a]

Closure Type	No Pathology	Granulation Tissue/Infection	Tympanosclerosis	Adhesions (scar)	Cholesteatoma	Mucoid Secretion	Malleopexy	Totals
TP								
- Count	100	48	11	9	2	6	1	177
- % of TP	56.5%	27.1%	6.2%	5.1%	1.1%	3.4%	0.6%	100%
TP/CI								
- Count	23	17	10	5	0	0	0	55
- % of TP/CI	41.8%	30.9%	18.2%	9.1%	0%	0%	0%	100%
TP + TP/CI								
- Count	190	112	47	22	7	7	5	390
- % of TP + TP/CI	48.7%	28.7%	12.1%	5.6%	1.8%	1.8%	1.3%	100%
Total	313 (50.3%)	177 (28.5%)	68 (10.9%)	36 (5.8%)	9 (1.4%)	13 (2.1%)	6 (1.0%)	622 (100%)

Abbreviations: TP, tragal perichondrium; TP/CI, tragal perichondrium with cartilage island; TP + TP/CI, tragal perichondrium plus tragal perichondrium with cartilage island.
[a]Specific risk factors were granulation tissue/infection, tympanosclerosis, adhesions (scar), cholesteatoma, mucoid secretion, and malleoplexy. There was no risk factor distribution difference between the 3 operative groups: χ^2 test ($P = .105$, $df = 8$).

Table 2. Distribution of Perforation Sizes between the 3 Methods of Perforation Closure.[a]

Perforation Size	TP	TP/CI	TP + TP/CI	Totals
<30% number (%)	25 (14.1)	6 (10.9)	59 (15.1)	90 (14.5)
30%-60% number (%)	69 (39.0)	24 (43.6)	158 (40.5)	251 (40.4)
>60% number (%)	83 (46.9)	25 (45.5)	173 (44.4)	281 (45.2)
Totals	177	55	390	622

Abbreviations: TP, tragal perichondrium; TP/CI, tragal perichondrium with cartilage island; TP + TP/CI, tragal perichondrium plus tragal perichondrium with cartilage island.
[a]Pearson chi-square ($P = 1.019$, $df = 4$) and likelihood ratio ($P = 1.059$, $df = 4$) 2-sided tests of significance found no difference between the 3 groups.

respectively. Analysis of variance found no significant difference in preoperative hearing levels ($P = .179$) or postoperative hearing levels ($P = .857$) among the 3 techniques of tympanic membrane grafts. However, the paired-sample *t* test for dependent variables found significant postoperative improvements in all 3 techniques ($P < .0001$).

Distribution of Risk Factors

Neither the preoperative tympanic perforation size nor the middle ear pathology had any effect on the reperforation rate or the hearing outcomes (Table 1). Middle ear pathology included granulation tissue/infection (29%), tympanosclerosis (11%), adhesions/scar (6%), mucoid secretions (2%), cholesteatoma (1%), and malleus pexied to the promontory (1%). There was no risk factor distribution difference among the 3 operative groups: χ^2 test ($P = .105$, $df = 8$). Preoperative perforation sizes ranged from less than 30% to total. Reperforation rate was not associated with preoperative tympanic membrane perforation size: χ^2 test ($P = .052$, $df = 2$). Table 2 shows even distribution of preoperative perforation sizes between the 3 closure groups. Pearson χ^2 ($P = 1.019$, $df = 4$) and likelihood ratio ($P = 1.059$, $df = 4$) 2-sided tests of significance found no difference between the 3 groups.

Discussion

The double-layer tympanic membrane graft consisting of TP + TP/CI improves the chance of the tympanic membrane healing to 90.3% over single-layer closure rates of 76% (TP) and 78% (TP/CI), respectively. The difference between the single-layer groups TP and TP/CI and the double-layer TP + TP/CI is highly significant ($P < .01$), and there is no significant difference among the single-layer groups. Surgeon experience does not seem to have altered these interpretations: Closure rates for the double-layer procedure as of 2016 (86%) were superior to either single-layer option (76% vs 78%) ($P < .05$). The closure rates for the most recent 86 operations (double-layer and after August 2016) was even higher, at 96%.

There is no significant difference in the postoperative hearing improvement comparing the single-layer closures of TP and TP/CI with the double-layer closure of TP + TP/CI. The average hearing improvement for the single-layer TP and TP/CI are 20.7 dB and 22.1 dB, respectively, while for the double-layer of TP/CI + TP it was 20.14 dB. There

is no statistically significant difference in hearing improvement between the 3 techniques ($P = .356$).

This study has several flaws. There are no clear indications for having chosen one graft technique rather than another in each patient. Another problem is that assignment to treatment groups was not randomized; therefore, equal risk factors between the 3 groups are not certain. A review of the medical record finds that there seems to have been no differences in risk factors (perforation size, condition of the middle ear, amount of preoperative hearing loss) between the subjects treated with each of the 3 techniques, but the distribution of unknown risk factors between the 3 groups is, of course, unknown. Finally, there may have been undetected outcomes of which the surgeon was unaware: Since this was a retrospective review, the follow-up times could not be better controlled, and there is a possibility that had there been standardized follow-ups for several years, the reperforation rates may have been higher in any or all of the groups.

Strengths of this study are the number of patients in each arm and the clear differences in reperforation outcomes between the single-layer and the double-layer groups. We speculate that the lower reperforation rate is due to the greater thickness of the graft, which can withstand postoperative insults, such as infections and negative middle ear pressure.

Our study worked with single-layer TP, single-layer TP/CI, and double-layers of TP + TP/CI. Others have reported that the use of single-layer cartilage reduces the reperforation rate over single-layer fascia.[4,5,13,14] However, like Kouhi et al,[6] we did not find TP/CI reperforation rates superior to those of TP alone. Our study also employed a consistent strategy toward grafting near the malleus and annulus, whether using single-layer or double-layer grafts. The grafts were placed lateral to the manubrium and medial to the annulus and tympanic membrane remnant—even into the eustachian tube—in the over/under technique. Some have found that this technique reduces reperforation while reducing blunting and lateralization,[7,15] while others found that it does not.[8]

In conclusion, despite the flaws of this study, the data clearly indicate that the double-layer tympanoplasty technique results in lower tympanic membrane reperforation rates than single-layer techniques. Hearing results are the same whether using single-layer or double-layer closure techniques.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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References

1. Hünermann T, Plester D. *Die Operationen am Ohr*. Der Operationskurs Des Hals-, Nasen- Und Ohrenarztes. Leipzig: Barth; 1970.
2. Rizer FM. Overlay versus underlay tympanoplasty. Part II: the study. *Laryngoscope*. 1997;107:26-36.
3. Nemade SV, Shinde KJ, Sampate PB. Comparison between clinical and audiological results of tympanoplasty with double layer graft (modified sandwich fascia) technique and single layer graft (underlay fascia and underlay cartilage) technique. *Auris Nasus Larynx*. 2017;45:440-446.
4. Kolethekkat AA, Al Abri R, Al Zaabi K, et al. Cartilage rim augmented fascia tympanoplasty: a more effective composite graft model than temporalis fascia tympanoplasty. *J Laryngol Otol*. 2018;132:497-504.
5. Tek A, Karaman M, Uslu C, et al. Audiological and graft take results of cartilage reinforcement tympanoplasty (a new technique) versus fascia. *Eur Arch Otorhinolaryngol*. 2012;269:1117-1126.
6. Kouhi A, Khorsandi Ashthiani MT, Jalali MM. Results of type I tympanoplasty using fascia with or without cartilage reinforcement: 10 years' experience. *Iran J Otorhinolaryngol*. 2018;30:103-106.
7. Kartush JM, Michaelides EM, Becvarovski Z, LaRouere MJ. Over-under tympanoplasty. *Laryngoscope*. 2002;112:802-807.
8. Sengupta A, Basak B, Ghosh D, Basu D, Adhikari D, Maity K. A study on outcome of underlay, overlay and combined techniques of myringoplasty. *Indian J OHNS*. 2012;64:63-66.
9. Monsell EM, Balkany TA, Gates GA, Goldenberg RA, Meyerhoff WL, House JW. Committee on Hearing and Equilibrium guidelines for the evaluation of results of treatment of conductive hearing loss. *Otolaryngol Head Neck Surg*. 1995;113:186-187.
10. Gurgel RK, Jackler RK, Dobie RA, Popelka GR. A new standardized format for reporting hearing outcome in clinical trials. *Otolaryngol Head Neck Surg*. 2012;147:803-807.
11. Oghalai JS, Jackler RK. New web-based tool for generating scattergrams to report hearing results. *Otol Neurotol*. 2016;37:419.
12. Govaerts PJ, Somers T, Offeciers E. Box and Whiskers plot for graphic presentation of audiometric results in conductive hearing loss treatment. *Otolaryngol Head Neck Surg*. 1998;118: 892-895.
13. Guler I, Baklaci D, Kuzucu I, Kum RO, Ozcan M. Comparison of temporalis fascia and tragal cartilage grafts in type 1 tympanoplasty in elderly patients. *Auris Nasus Larynx*. 2018;S0385-8146(18):30649-30647.
14. Durán-Padilla CL, Martínez-Chávez J, Amador-Licona N, Pereyra-Nobara TA. Cartilage island versus temporalis fascia in high-risk tympanic perforation [in Spanish]. *Rev Med Inst Mex Seguro Soc*. 2017;55(suppl 1):S58-S63.
15. Saeed I, Akhlaq M. Tympanoplasty type 1: a comparison between underlay technique of myringoplasty with over and under technique of myringoplasty. *PJMHS*. 2014;2:291-294.