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Main Article

Comparison of subcutaneous soft tissue versus temporalis fascia as a tympanoplasty graft material: a retrospective cohort study

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Abstract

Objective. This research compares the efficacy of subcutaneous soft tissue and temporalis fascia in tympanic membrane grafting for large tympanic membrane perforations.
Methods. A retrospective cohort study compared tympanic membrane graft success rate and hearing outcomes in 248 patients who underwent tympanoplasty using subcutaneous soft tissue ($n = 118$) or temporalis fascia ($n = 130$) via the post-auricular approach.
Results. Comparable results were observed in both groups. Tympanic membrane graft success rate was 98.3 per cent (116 ears) in the subcutaneous soft tissue group and 98.5 per cent (128 ears) in the temporalis fascia group. The rate of air–bone gap closure within 20 dB was 54.2 per cent (64 ears) and 60.0 per cent (78 ears) in the soft tissue and temporalis fascia groups, respectively ($p = 0.360$).
Conclusion. Subcutaneous soft tissue is a reliable and readily available tympanic membrane graft material in both revision and primary tympanoplasty for large tympanic membrane perforations.

Introduction

Background

Chronic otitis media, a chronic infection or inflammation of the middle ear and mastoid air cells, is commonly linked with tympanic membrane perforation and intermittent or continuous otorrhea. The goal of chronic otitis media surgery is to keep the tympanic membrane intact in order to recover hearing and eliminate ear drainage. It is still one of the most popular surgical procedures in otology, particularly in developing countries. Tympanoplasty, as a chronic otitis media operation, is the surgical repair of the tympanic membrane.

Even though temporalis fascia is the most commonly utilised tympanic membrane graft, various graft materials, such as skin, dura mater, periosteum, perichondrium, cartilage, vein, fat, and subcutaneous soft tissue, have been employed since the advent of tympanoplasty. The optimal tympanic membrane graft material should be acquired over the same surgical exposure, be reliable, be successful in tympanic membrane perforation closure, have low donor-site morbidity and a minimal added cost.[1]

Thus far, too little emphasis has been placed on the usage of subcutaneous soft tissue in tympanoplasty (especially in primary-stage operations) and large tympanic membrane perforation. In 1969, Sale introduced the application of the subcutaneous tissue graft in 188 cases with different tympanic membrane perforation sizes and achieved a graft success rate of 90 per cent.[2] Overall, there are four studies with relatively low sample sizes on the usage of soft tissue in tympanoplasty.[2–5] These studies include a very small number of ears with large tympanic membrane perforation. Of these four studies, only Djalilian[5] used the post-auricular approach, while others[2–4] used the endaural approach.

Objectives

The lack of a study comparing graft material via a post-auricular approach and frequency-specific comparison is a gap in the literature. To address this gap, the present study aims to compare temporalis fascia versus subcutaneous soft tissue as grafting material in large tympanic membrane perforation in both primary and revision surgical procedures.

Material and methods

Study design, setting and participants

The current study evaluated 248 ears that had chronic otitis media surgery between February 2019 and January 2021 at Dastgheib Hospital, a tertiary otology center in

Shiraz, Iran, which is affiliated with Shiraz University of Medical Sciences, and Dena Hospital, a private hospital also in Shiraz.

All subjects with primary or revision chronic otitis media operations with tympanic membrane perforation ≥ 50 per cent were included in the study. Tympanoplasty and intact canal wall tympanomastoidectomy were the two types of surgical procedures that were included. Subjects under 18 years of age and cases with pre-operative medical problems (e.g. diabetes, asthma, chronic liver/renal diseases, cardiovascular diseases, basic metabolic diseases) were excluded. Furthermore, smokers and cases with follow ups less than 12 months previously were excluded.

Ethical considerations

The local Ethics Committee of Shiraz University of Medical Sciences approved the research protocol of this retrospective study (institution research board approval code: IR.SUMS.MED.REC.1399.484). Also, informed consent was obtained from all individual participants included in the study.

Interventions

Tympanoplasty, with or without intact canal wall mastoidectomy, was performed in all cases. The first author (MF) performed all processes. As standard procedure, all ears should be dry for at least three months before the operation. The auricle was retracted anteriorly following the post-auricular incision. The perforation rim was freshened, and the tympanomeatal flap and posterior annulus were elevated to enter the middle ear cavity. Following that, the ossicular chain condition and the existence of any pathology were assessed. As a routine in our centre, ossiculoplasty was performed in the second-stage procedure. In all cases where ossicular necrosis, either the distal tip of the long process or complete stapes erosion, had occurred, a silastic sheet was placed over the promontory. Then, for tympanic membrane graft material, compressed post-auricular subcutaneous soft tissue and temporalis fascia were harvested and myringoplasty was performed by the underlay method. Gelfoam was then inserted medially and laterally into the graft, as well as into the external auditory canal. After closure of the two layers of the post-auricular wound, tetracycline gauze was inserted into the lateral third of the external auditory canal. Following surgery, all patients were given 500 mg of cephalexin every 6 hours for 1 week. Indeed, all cases were visited by the operating surgeons as part of their usual post-operative management. After a week, when the tetracycline gauze was removed, patients were assessed using microscopic otoscopy. After 3 weeks, a clinical microscopic otoscopy was performed. Patients were then observed in the second, third, fourth, sixth and twelfth months of the first year and once a year after that.

Success of the tympanic membrane graft was characterised as a dry ear with an intact tympanic membrane in the right position, a well-aerated mesotympanum and no tympanic membrane retraction.

Audiometric methods

Based on the standards of the Academy of Otolaryngology–Head and Neck Surgery, pre- and post-operative audiometric data were recorded.[6] Air- and bone-conduction thresholds at 0.25, 0.5, 1, 2, 3 and 4 kHz were recorded for each patient. When 3-kHz thresholds were not recorded, they were estimated by averaging at 2 and 4 kHz, as previously noted.[7]

Pre- and post-operative speech discrimination scores, speech reception threshold, bone conduction, air conduction, and air–bone gap (ABG) were also evaluated. The 4-frequency pure-tone average utilising 0.5, 1, 2 and 3 kHz was calculated according to Academy of Otolaryngology–Head and Neck Surgery recommendation.[6] A change in ABG (ΔABG) was determined by subtracting the pre- and post-operative ABGs. The difference between pre- and post-operative speech reception thresholds was used to compute the change in speech reception threshold (Δ speech reception threshold).

Table 1. Basic characteristics of study patients

Parameters		Soft tissue group (*n* = 118)	Temporalis fascia group (*n* = 130)	*p*-value
Gender	Male	28 (23.7)[a]	42 (32.3)	0.134
	Female	90 (76.3)	88 (67.7)	
Age (years)		38.1 ± 13.1[b]	39.6 ± 14.5	0.385
Type of surgery	Intact canal wall mastoidectomy	72 (61.0)	81 (62.3)	0.835
	Tympanoplasty	46 (39.0)	49 (37.7)	
Pre-operative hearing loss	Conductive	104 (88.1)	108 (83.1)	0.259
	Mixed	14 (11.9)	22 (16.9)	
Type of pathology	Normal	74 (62.7)	82 (63.1)	0.779
	Cholesteatoma	26 (22.0)	33 (25.4)	
	Granulation tissue	12 (10.2)	9 (6.9)	
	Tympanosclerosis plaque	6 (5.1)	6 (4.6)	
Ossicular chain condition	Normal	66 (55.9)	74 (56.9)	0.979
	Discontinuity	46 (39.0)	50 (38.5)	
	Fixed	6 (5.1)	6 (4.6)	
Stage of surgery	Primary	52 (44.1)	84 (64.6)	0.001
	Revision	66 (55.9)	46 (35.4)	

[a]*n* (%), [b]mean ± standard deviation

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Since the present study also assessed frequency-specific ABGs in patients with conductive hearing loss, low-frequency ABG was obtained as the mean ABG at 0.25, 0.5 and 1 kHz. High-frequency ABG was estimated at 4 kHz. In order to analyse the hearing outcomes, one-day pre- and post-operative audiometry within 12 months were both assessed. Post-operative ABG within 20 dB was considered successful surgery.

Post-operative sensorineural hearing loss was determined as a post-operative bone conduction threshold being more than 10 dB poorer than the pre-operative one. In addition, patients with both conductive and sensorineural hearing loss were classified as mixed hearing loss. Hearing data were also presented in a scattergram format, linking pure-tone average air conduction to the speech discrimination scores, following the recommended procedures by the Academy of Otolaryngology–Head and Neck Surgery.[6]

Primary and secondary outcomes

The primary outcome was the tympanic membrane graft success rate, while the secondary outcomes were the post-operative hearing outcomes at least 12 months following the surgery.

Statistical analysis

IBM SPSS Statistics for Windows, version 22 (IBM Corp., Armonk, NY, USA), was utilised for statistical analysis. Continuous variables were compared utilising the independent *t*-test or the Mann–Whitney U test, while pairwise comparisons were made utilising either the paired *t*-test or the Wilcoxon signed rank test. The chi-square or Fisher's exact tests were used to analyse the correlations between categorical variables. For all hypothesis testing, the basic criterion for statistical significance was set at $p < 0.05$.

Histologic study

In order to compare the histologic features of the three types of graft materials, including temporalis fascia, subcutaneous soft graft in a primary operation, and subcutaneous soft tissue in a revision case (scar tissue), the specimens were sent in 10 per cent buffered formalin for histopathology evaluation. All

Table 2. Comparison audiometric results between soft tissue and temporalis fascia groups regarding stage of surgery and mucosa status

			Primary			Revision		
		Mucosa status	Soft tissue group	Temporalis fascia group	*p*-value	Soft tissue group	Temporalis fascia group	*p*-value
$BC_{(dB)}$	Pre-operative	Normal	11 ± 8.3[a]	11 ± 8.6	0.995	10.6 ± 9.1	9.2 ± 6.6	0.523
		Abnormal	11.5 ± 2.9	13.4 ± 11.1	0.608	13.1 ± 7.2	13.5 ± 11.5	0.874
	Post-operative	Normal	8.6 ± 7.8	10.7 ± 9.9	0.257	10.8 ± 10.1	8.3 ± 6.2	0.287
		Abnormal	11.1 ± 3.5	12.7 ± 9.5	0.623	12.3 ± 7.1	14.1 ± 11.6	0.478
	Gain	Normal	2.4 ± 7.5	0.3 ± 5.9	0.118	−0.2 ± 5.6	0.9 ± 5.1	0.449
		Abnormal	0.4 ± 4.2	0.7 ± 10.6	0.926	0.8 ± 8.1	−0.5 ± 6.2	0.500
$AC_{(dB)}$	Pre-operative	Normal	35 ± 14.7	37.5 ± 13.4	0.387	36.3 ± 14.3	32.5 ± 10.4	0.274
		Abnormal	41.5 ± 11.5	40.3 ± 13.1	0.794	52.6 ± 11.9	50.5 ± 18	0.617
	Post-operative	Normal	24.3 ± 14.6	28.2 ± 15.1	0.198	30.3 ± 16.8	23.5 ± 13.6	0.111
		Abnormal	49.8 ± 16.1	36 ± 16.7	0.032	46 ± 16.4	44.1 ± 21.4	0.714
	Gain	Normal	10.7 ± 11.7	9.3 ± 12.2	0.553	6 ± 10.3	9 ± 8.8	0.258
		Abnormal	−8.3 ± 13.6	4.3 ± 16	0.036	6.7 ± 15.5	6.4 ± 18.6	0.943
$ABG_{(dB)}$	Pre-operative	Normal	24 ± 11.2	26.5 ± 10.1	0.253	25.7 ± 8	23.3 ± 7.3	0.253
		Abnormal	30 ± 9.1	26.9 ± 9.9	0.395	39.5 ± 9.7	36.9 ± 13.8	0.450
	Post-operative	Normal	15.7 ± 9.7	17.5 ± 10.1	0.372	19.5 ± 10.7	15.2 ± 10	0.131
		Abnormal	38.6 ± 13.1	23.3 ± 12.3	0.002	33.7 ± 14.1	30 ± 13.9	0.346
	Gain	Normal	8.3 ± 7.9	9 ± 11.3	0.745	6.2 ± 7.2	8.1 ± 8	0.356
		Abnormal	−8.6 ± 9.5	3.6 ± 11.6	0.006	5.8 ± 14.4	6.9 ± 17.1	0.804
$SRT_{(dB)}$								
	Pre-operative	Normal	34.3 ± 14.1	37 ± 12.9	0.324	37.8 ± 15.7	32.1 ± 10.8	0.130
		Abnormal	38 ± 9.2	39.4 ± 12.8	0.751	51.5 ± 12.4	50.9 ± 17.4	0.888
	Post-operative	Normal	24.3 ± 14	27.2 ± 14	0.300	30.9 ± 16	22.3 ± 12.2	0.025
		Abnormal	49 ± 15.8	37.3 ± 15.6	0.053	43.8 ± 15.1	42.5 ± 20.5	0.782
	Gain	Normal	10 ± 12.6	9.7 ± 12.8	0.920	6.9 ± 11.2	9.8 ± 11.5	0.344
		Abnormal	−11 ± 13.9	2.1 ± 18	0.046	7.6 ± 16	8.4 ± 18.5	0.870

Number of ears in each category are as follows: normal mucosa and primary = 42 soft tissue group and 58 temporalis fascia group; normal mucosa and revision = 32 soft tissue group and 24 temporalis fascia group; abnormal mucosa and primary = 10 soft tissue group and 26 temporalis fascia group; abnormal mucosa and revision = 34 soft tissue group and 22 temporalis fascia group; [a]mean ± standard deviation; BC = bone conduction; AC = air conduction; ABG = air–bone gap; SRT = speech reception threshold tissues were processed for standard formalin-fixed paraffin embedding. After proper paraffin embedding, a 3-µm-thick cut was made from each tissue, which was stained by hematoxylin and eosin, Masson's trichrome and elastic before being evaluated under a light microscope.

Results

In the current study, 248 ears were analysed with the mean follow-up and post-audiogram time as 13 ± 0.8 months at a range of 12–18.5 months. In the soft tissue group, 118 ears belonging to 28 men and 90 women with an age range of 38.1 ± 13.1 years old were analysed. In the temporalis fascia group, 130 ears belonging to 42 men and 88 women with an age range of 39.6 ± 14.5 years old were analysed. As shown in Table 1, no significant differences were observed between the groups regarding gender ($p = 0.134$) and age ($p = 0.385$). Most ears in each group had pre-operative conductive hearing loss: 88.1 per cent ($n = 104$) in the soft tissue group and 83.1 per cent ($n = 108$) in the temporalis fascia group. The difference in pre-operative conductive hearing loss between the two groups was insignificant ($p = 0.259$). No significant differences were observed between the groups concerning either the middle ear mucosa condition ($p = 0.779$) or the ossicular chain condition ($p = 0.979$) (Table 1).

In the soft tissue group, the graft success rate was 98.3 per cent (116 ears), and in the temporalis fascia group, it was 98.5 per cent (128 ears) ($p \approx 1$). The rate of successful ABG closure (within 20 dB) was 54.2 per cent (64 ears) in the soft tissue group and 60.0 per cent (78 ears) in the temporalis fascia group ($p = 0.360$).

As seen in Table 2, in primary surgery, neither ear with normal ($p = 0.118$) or abnormal ($p = 0.926$) mucosa showed a significant difference in bone conduction gain between the soft tissue and temporalis fascia groups. Also, the air conduction gain in ears with normal mucosa was comparable between the two groups ($p = 0.553$); however, in ears with abnormal mucosa, it was significantly high in the temporalis fascia group compared to the soft tissue group (12.6 dB, $p = 0.036$). Air–bone gap improvement in ears with normal mucosa in the soft tissue group did not differ considerably from that in the temporalis fascia group ($p = 0.745$); however, in ears

Table 3. Comparison audiometric results between soft tissue and temporalis fascia groups regarding stage of surgery and ossicular chain status

			Primary			Revision		
		OC status	Soft tissue group	Temporalis fascia group	*p*-value	Soft tissue group	Temporalis fascia group	*p*-value
$BC_{(dB)}$	Pre-operative	Normal	11 ± 8.4[a]	12.5 ± 10.4	0.468	9 ± 5	6.5 ± 4.5	0.090
		Abnormal	11.4 ± 3.2	10.2 ± 7.1	0.602	13.8 ± 9.3	14.4 ± 10.5	0.817
	Post-operative	Normal	6.8 ± 4.7	11.1 ± 10.1	0.007	10.8 ± 8	5.8 ± 3.9	0.010
		Abnormal	16.6 ± 9.3	11.7 ± 9.2	0.140	12.1 ± 9.1	14.4 ± 10.6	0.336
	Gain	Normal	4.2 ± 4.7	1.4 ± 7.6	0.043	−1.8 ± 5.9	0.6 ± 3.1	0.121
		Abnormal	−5.2 ± 8.6	−1.5 ± 7.2	0.170	1.7 ± 7.3	0 ± 6.9	0.320
$AC_{(dB)}$	Pre-operative	Normal	33.6 ± 13.5	37.8 ± 13.5	0.134	35.9 ± 14.9	28.8 ± 7.2	0.044
		Abnormal	45.2 ± 13.5	39.4 ± 13.2	0.213	50.5 ± 12.9	49 ± 16.8	0.680
	Post-operative	Normal	21.3 ± 9.6	25.5 ± 14.1	0.109	31.6 ± 20.1	20.1 ± 9.6	0.016
		Abnormal	55.5 ± 13.2	40.9 ± 14.4	0.005	42.8 ± 15.8	41.8 ± 21.1	0.842
	Gain	Normal	12.3 ± 10.8	12.3 ± 11.2	0.983	4.3 ± 10	8.6 ± 6.2	0.082
		Abnormal	−10.3 ± 9.4	−1.5 ± 13.4	0.046	7.7 ± 14.8	7.2 ± 17.7	0.889
$ABG_{(dB)}$	Pre-operative	Normal	22.6 ± 9.8	25.3 ± 9.4	0.167	26.9 ± 13	22.3 ± 6.8	0.139
		Abnormal	33.9 ± 10.7	29.2 ± 10.8	0.218	36.7 ± 8.1	34.6 ± 13.6	0.476
	Post-operative	Normal	14.5 ± 8.6	14.4 ± 7.7	0.961	20.8 ± 13.5	14.3 ± 7.1	0.044
		Abnormal	39 ± 10.5	29.2 ± 10.3	0.009	30.7 ± 13.7	27.4 ± 15.1	0.357
	Gain	Normal	8.1 ± 8	10.9 ± 10.3	0.149	6.1± 6.4	8 ± 5.4	0.291
		Abnormal	−5.1 ± 12	0 ± 10.6	0.187	6 ± 13.8	7.2 ± 16.2	0.741
$SRT_{(dB)}$								
	Pre-operative	Normal	33.3 ± 13	37.2 ± 12.6	0.135	35.8 ± 14.5	28.3 ± 8.2	0.057
		Abnormal	40.8 ± 12.9	38.8 ± 13.7	0.656	50.8 ± 13.3	49.3 ± 16.3	0.686
	Post-operative	Normal	21.5 ± 9.5	25.4 ± 13.6	0.118	31.9 ± 16.9	19.4 ± 9.4	0.003
		Abnormal	54.2 ± 12.9	40.2 ± 13.4	0.004	41.3 ± 15.8	40 ± 20	0.774
	Gain	Normal	11.8 ± 11.5	11.8 ± 12.7	0.989	3.8 ± 9.6	8.9 ± 8.8	0.085
		Abnormal	−13.3 ± 8.9	−1.4 ± 15.3	0.004	9.5 ± 15.6	9.3 ± 18.1	0.959

Number of ears in each category are as follows: normal ossicular chain and primary = 38 soft tissue group and 54 temporalis fascia group; normal ossicular chain and revision = 26 soft tissue group and 18 temporalis fascia group; abnormal ossicular chain and primary = 12 soft tissue group and 28 temporalis fascia group; abnormal ossicular chain and revision = 40 soft tissue group and 28 temporalis fascia group; [a]mean ± standard deviation; OC = ossicular chain; BC = bone conduction; AC = air conduction; ABG = air–bone gap; SRT = speech reception threshold

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with abnormal mucosa in the temporalis fascia group, air–bone gap improvement was more than in the soft tissue group (12.2 dB, $p = 0.006$). Speech reception threshold improvement was not significant between the groups in ears with normal mucosa ($p = 0.920$); however, in the temporalis fascia group, speech reception threshold improvement was more than the soft tissue group in ears with abnormal mucosa (13.1 dB, $p = 0.046$). In revision surgery, in both groups of ears with normal and abnormal mucosa, no significant differences ($p > 0.05$ in all instances) were found between the soft tissue and temporalis fascia groups in gains of any audiometric variable, including bone conduction, air conduction, ABG and speech reception thresholds.

In primary surgery, although a statistically significant difference was observed between the soft tissue and temporalis fascia groups in bone conduction gain (2.8 dB, $p = 0.043$) in ears with normal ossicular chain, it was not clinically valuable (Table 3). Moreover, bone conduction gain in ears with abnormal ossicular chain was the same in the groups ($p = 0.170$). Both groups with normal ossicular chain gained similar amounts of air conduction ($p = 0.983$); however, the temporalis fascia group gained more air conduction than the soft tissue group in ears with abnormal ossicular chain (8.8 dB, $p = 0.046$). No significant differences were observed between the soft tissue and temporalis fascia groups in ABG gains of ears with ($p = 0.149$) and without ($p = 0.187$) normal ossicular chain. No significant differences were observed in speech reception threshold gain between the groups in ears with normal ossicular chain ($p = 0.989$); however, speech reception threshold gain was higher in the temporalis fascia group in ears with abnormal ossicular chain (11.9 dB, $p = 0.004$). In revision surgery, neither bone conduction, air conduction, ABG, nor speech reception threshold was significantly different between the soft tissue and temporalis fascia groups in normal ossicular chain ($p > 0.05$ in all instances) or abnormal ossicular chain ($p > 0.05$ in all instances) (Table 3).

As shown in Table 4, in ears with pre-operative conductive hearing loss, normal mucosa, normal ossicular chain and primary surgery, no significant differences were observed in gains of bone conduction ($p = 0.105$), air conduction ($p = 0.436$), ABG ($p = 0.111$), or speech reception threshold ($p = 0.372$) between the soft tissue and temporalis fascia groups. However, in ears with pre-operative mixed hearing loss, normal mucosa, normal ossicular chain and primary surgery, gains of bone conduction (14.6 dB, $p = 0.001$), air conduction (17.7 dB, $p = 0.007$), and speech reception threshold (19 dB, $p = 0.008$) in the soft tissue group were more than the temporalis fascia group. No significant difference was observed between the groups in ABG gains ($p = 0.226$).

Following the recommendations of the Hearing Committee of the American Academy of Otolaryngology–Head and Neck Surgery,[6] scattergrams of hearing outcomes are shown in Figure 1, indicating that air conduction or/and speech discrimination scores have improved significantly in most cases after the operation.

The study analysed frequency-specific ABG changes in ears with pre-operative conductive hearing loss, normal mucosa, and normal ossicular chain. Although statistically significant differences were found between the soft tissue and temporalis fascia groups in low-frequency ABG ($p = 0.027$), they are not clinically significant (< 5 dB) (Table 5). Further, this change was not statistically significant in high-frequency ABG ($p = 0.134$) (Table 5). Improvement in low-frequency ABG was greater than high-requency ABG improvement in the soft tissue group ($p = 0.001$) and the temporalis fascia group ($p = 0.007$) (Table 5) (Figure 2).

The histologic evaluation of temporalis fascia revealed dense vascularised connective tissue with parallel-oriented collagen bundles. Also, no inflammation or fat, granuloma, foreign body reaction or necrosis replacement was observed (Figure 3a1). The histologic evaluation of both soft tissue samples again revealed well-vascularised connective tissue. The collagen fibres were well formed but without specific orientation. Adipose tissue was also observed beneath the specimen in one corner. No inflammation, granuloma or necrosis was observed (Figure 3b1, 3c1). Masson's trichrome staining also

Table 4. Comparison audiometric results between soft tissue and temporalis fascia groups regarding type of pre-operative hearing loss in ears with normal mucosa, normal ossicular chain and primary surgery

		Conductive			Mixed		
		Soft tissue group ($n = 32$)	Temporalis fascia group ($n = 35$)	p-value	Soft tissue group ($n = 6$)	Temporalis fascia group ($n = 11$)	p-value
$BC_{(dB)}$	Pre-operative	7.7 ± 3.6[a]	7.8 ± 5.9	0.990	28.5 ± 6	22.9 ± 9.4	0.365
	Post-operative	5.4 ± 3.3	7.3 ± 5.6	0.100	15 ± 3.1	24 ± 12.7	0.362
	Gain	2.3 ± 2.4	0.5 ± 6.1	0.105	13.5 ± 3.1	−1.1 ± 6	0.001
$AC_{(dB)}$	Pre-operative	30.1 ± 11.5	32.9 ± 10.4	0.302	53.3 ± 7.2	50.2 ± 14	0.615
	Post-operative	20.4 ± 10.3	21.2 ± 9.4	0.750	26.9 ± 3.1	41.5 ± 19.1	0.020
	Gain	9.7 ± 9.4	11.7 ± 11.4	0.436	26.5 ± 8.7	8.8 ± 11.8	0.007
$ABG_{(dB)}$	Pre-operative	22.3 ± 9.9	25.1 ± 9	0.237	24.8 ± 11.4	27.3 ± 10.7	0.686
	Post-operative	15 ± 9.4	13.9 ± 6.6	0.582	11.9 ± 5.4	17.4 ± 12.2	0.223
	Gain	7.4 ± 7.8	11.2 ± 11.2	0.111	12.9 ± 9	9.9 ± 9.1	0.226
$SRT_{(dB)}$							
	Pre-operative	30 ± 11.6	32.9 ± 10.8	0.301	51.7 ± 2.6	47.3 ± 12.1	0.215
	Post-operative	20.9 ± 10.4	21.3 ± 8.7	0.882	25 ± 4.5	39.5 ± 20.3	0.083
	Gain	9.1 ± 10.4	11.6 ± 12.3	0.372	26.7 ± 6.8	7.7 ± 14.7	0.008

[a]Mean ± standard deviation; BC = bone conduction; AC = air conduction; ABG = air–bone gap; SRT = speech reception threshold

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revealed that both temporalis fascia and subcutaneous tissue (in primary and revision cases) had a comparable degree of collagen fibre type I deposition (Figure 3a2, 3b2, 3c2). Furthermore, based on elastic staining, all specimens revealed typical short, parallel-oriented elastic fibres and longer fibres oriented in different directions, reminiscent of compact connective tissue (Figure 3a3, 3b3, 3c3). Thus, no subjective histologic difference was found between temporalis and subcutaneous soft tissue, either primary or revision in terms of collagen and elastic fibres.

Discussion

Synopsis of key findings

In terms of tympanic membrane graft success rate and audiometric outcomes, both primary and revision tympanoplasty utilising a subcutaneous soft tissue graft yielded similar successful outcomes as temporalis fascia.

Comparisons with other studies

Sale, in 1969, noticed good tympanic membrane vascularisation in post-operative microscopic otoscopy among cases that received subcutaneous soft tissue as a tympanic membrane graft.[2] Sale achieved a graft success rate of 63.63 per cent in 22 ears with perforation larger than 50 per cent.[2] The present work reached a much better graft success rate (98.5 per cent) and hearing improvement. The endaural approach used by Sale, which gives the surgeon less view than the post-auricular approach, may be responsible for the difference in the graft success rate.

According to Chang *et al.* and Sheehy *et al.*, the post-auricular method was linked to a higher success rate of tympanic membrane closure.[4,8] Chang *et al.* evaluated the efficiency of pressed scar tissue grafts in revision tympanoplasty to temporalis fascia and areolar tissue grafts.[4] They included 30 patients who had undergone revision tympanoplasty using pressed scar tissue with various surgical approaches, including post-auricular, endaural and endomeatal.[4] In

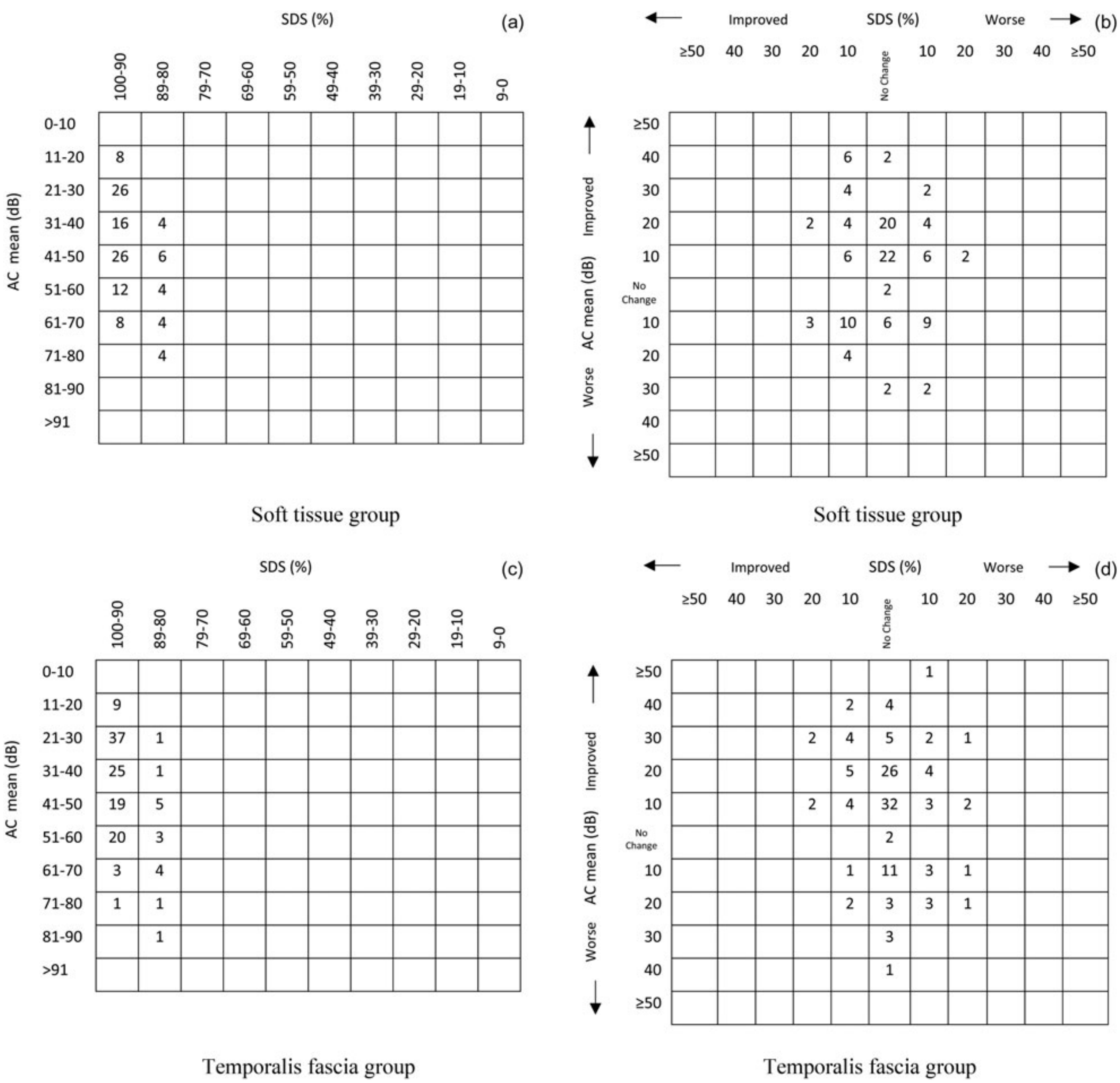

Figure 1. Scattergrams of hearing outcomes before (a, c) and after (b, d) operation. AC = air conduction; SDS = speech discrimination score; AC mean = mean of air conduction in frequencies of 0.5, 1, 2 and 3 kHz

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Table 5. Comparing low- and high-frequency air–bone gap (ABG) measurements between soft tissue and temporalis fascia groups in ears with pre-operative conductive hearing loss and normal mucosa, as well as normal ossicular chain

	Low-frequency ABG[a] (dB)			High-frequency ABG[b] (dB)			
	Pre-operative	Post-operative	Gain	Pre-operative	Post-operative	Gain	*p*-value[d]
Soft tissue (*n* = 48)	27.4 ± 8.8[c]	16.7 ± 9.5	10.8 ± 7.4	21.7 ± 9.7	16.3 ± 8.0	5.4 ± 10.3	0.001
Temporalis fascia (*n* = 51)	28.8 ± 9.5	14.2 ± 7.7	14.6 ± 11.6	25.2 ± 10.5	17.2 ± 10.5	8.0 ± 12.6	0.007
p-value[e]	0.322	0.168	0.027	0.081	0.937	0.134	

[a]Mean of ABG at 0.250, 0.5 and 1 kHz; [b]ABG at 4 kHz; [c]mean ± standard deviation, [d]low- and high-frequency ABG gains compared; [e]ABG gains between the soft tissue and temporalis fascia groups compared

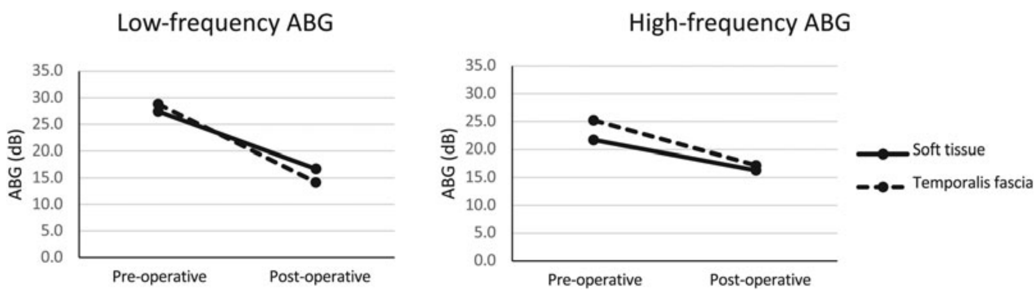

Figure 2. Low- and high-frequency ABG (air–bone gap) in the soft tissue and temporalis fascia groups in ears with pre-operative conductive hearing loss.

contrast with the present study, long-term follow up was unavailable for all subjects. Moreover, the current work included only cases with more than 50 per cent of the tympanic membrane perforated, while Chang *et al.* used tympanic membrane perforation size under 50 per cent. In revision tympanoplasty, they assessed the tympanic membrane graft success rate of pressed scar tissue graft in 29 of 30 cases (96.7 per cent).[4] In a later study by Djalilian,[5] 35 patients with

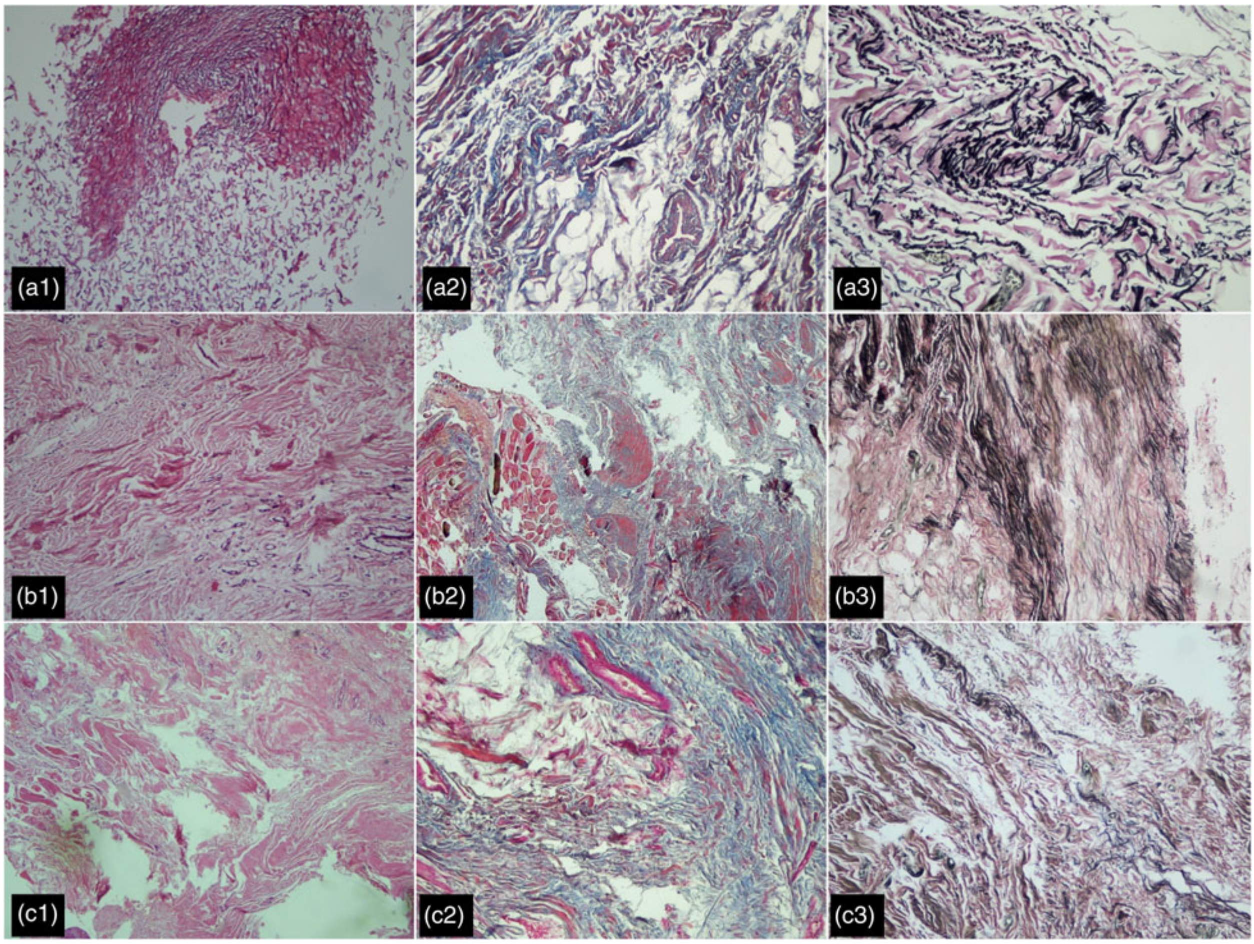

Figure 3. Low-power histopathologic images of the tympanic membrane graft materials. a1–a3: temporalis fascia; b1–b3: subcutaneous soft tissue in primary surgery; c1–c3: subcutaneous soft tissue in revision surgery (scar tissue); a1, b1, c1: hematoxylin and eosin staining; a2, b2, c2: Masson's trichrome staining; a3, b3, c3: elastic fibres staining.

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various sizes of tympanic membrane perforation underwent revision tympanoplasty using scar tissue graft via endaural or post-auricular approach. The graft success rate was 91 per cent in the scar tissue group and 92 per cent in the temporalis fascia group. The differences between the groups concerning graft success rate and hearing improvement were insignificant.[5]

- Temporalis fascia grafts are commonly used in tympanoplasty. Subcutaneous soft tissue grafts have been previously explored as an alternative to temporalis fascia grafts, with mixed results
- Subcutaneous soft tissue grafts yield similar tympanic membrane graft success rates and audiometric outcomes as temporalis fascia in both primary and revision tympanoplasty
- A higher graft success rate (98.5 per cent) was achieved in this study compared to previous research
- This study is the first with a relatively large sample size to make a frequency-specific comparison of subcutaneous soft tissue versus temporalis fascia in primary and revision operations for large tympanic membrane perforations with adequate follow up
- Subcutaneous soft tissue grafts offer advantages such as smaller incision, minimum dissection and lower bleeding risk compared to other graft materials
- This study supports using subcutaneous soft tissue as a reliable tympanic membrane graft material in both revision and primary tympanoplasty for large tympanic membrane perforations

De *et al.*[3] performed a retrospective study on 52 cases who underwent myringoplasty utilising a subcutaneous soft tissue graft by endaural approach and achieved an 82.6 per cent graft success rate. Eighteen cases had large or subtotal tympanic membrane perforation.[3] Moreover, surgeons had various levels of experience. On pure tone audiometry, average thresholds improved in 24 (57.1 per cent) cases, remained unchanged in 13 (25 per cent) cases, and worsened in one (1.9 per cent) case.[3] However, De *et al.* did not specify which audiometric variables had been improved.[3]

The literature on frequency-specific evaluation for patients with conductive hearing loss is relatively small. Polanik *et al.*[9] published a small series of 23 patients who underwent type I tympanoplasty with temporalis fascia due to trauma ($n = 14$) and chronic otitis media ($n = 9$), which is considered the first frequency-specific investigation in this field.[9] Their single study group yielded gains of 15.5 dB in low-frequency ABG and 2.6 dB in high-frequency ABG. In contrast, the present work found ABG gains of 14.6 dB and 8 dB in the temporalis fascia group and 10.8 dB and 5.4 dB in the subcutaneous soft tissue group in the low- and high-frequency ABG, respectively (Table 5) (Figure 2).[9] The differences between groups were not clinically significant (< 5 dB); however, the temporalis fascia group had a statistically better ABG gain in low-frequency conductive hearing loss (Table 5) (Figure 2).[9]

The normal human tympanic membrane is a thin, conically shaped multilayered structure with a specific form of radial and circumferential collagen fibres that allow sound waves from the external auditory canal to be converted into mechanical motion of the middle ear structures.[10] The bulk of radial fibres in normal tympanic membrane are made of type II collagen, which is useful for structural support and high-frequency sound conduction.[10] Circular fibres in the periphery are primarily composed of type III collagen, which has high elasticity and is required for low-frequency sound transmission.[11,12] Furthermore, the temporalis fascia is primarily composed of type I collagen, which provides resistance to force but lacks elasticity and sound conduction.[13] The temporalis fascia is a more basic network of linearly oriented collagen fibres, contributing to a thicker but less rigid membranous structure.[9] However, we are curious to know what happens to change in the thickness of the graft, collagen fibre orientation in reconstructed tympanic membrane, and how the orientation and dispersion might lead to different frequency changes. Thus, we think that further animal studies would be valuable.

In terms of high-frequency sound conduction, particularly above 3 kHz, a dense network of type II collagen radial fibres converge at the manubrium and umbo to offer structural rigidity that complements the elastic type III collagen circular fibres within the tympanic membrane periphery. Once subjected to high-frequency sound waves, this network contributes mechanically to the highly organised displacement pattern displayed by the normal tympanic membrane.[14] Djalilian noted that scar tissue (subcutaneous soft tissue in revision cases) provides collagen matrix as the scaffolding essential for the epithelium to regrow across the perforation, like fascia.[5]

Clinical applicability of the study

Graft materials for repairing tympanic membrane perforations may not always be readily available, owing to prior surgical procedures. Sometimes the preparation of temporalis fascia as a tympanic membrane graft is difficult in revision surgery, and surgeons have to extend the surgical incision to acquire an adequate size of fascia, thereby increasing intra-operative bleeding and post-operative pain. The subcutaneous soft tissue in primary operations and the pressed scar tissue in revision operations are graft materials that are always available at the surgical site, thereby offering obvious advantages of a smaller incision, minimum dissection and lower bleeding risk in comparison with other graft materials.

Strengths and limitations of the study

The evidence on graft success rate and hearing improvement of tympanoplasty using subcutaneous soft tissue is weak. To the best of the authors' knowledge, this is the first research with a relatively large sample size to make a frequency-specific comparison of subcutaneous soft tissue versus temporalis fascia in primary and revision operations with adequate follow-up in large perforated tympanic membranes. Furthermore, all operations were carried out by the same otolaryngologist; therefore, the variance in the skill level was not a confounding factor. The present study has the limitation of being retrospective in nature.

Conclusion

The study findings recommend applying subcutaneous soft tissue as a reliable tympanic membrane graft material not only in revision but also in primary tympanoplasty in large tympanic membrane perforations.

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Mohammad Faramarzi; formal analysis and investigation: Sareh Roosta; original draft preparation: Ali Faramarzi, Sareh Roosta, Nadia Abbasi; review and editing: Mohammad Faramarzi, Ali Faramarzi, Sareh Roosta, Ahmad Monabati; resources: Mohammad Faramarzi, Ali Faramarzi, Ahmad Monabati, Nadia Abbasi; supervision: Mohammad Faramarzi. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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