

Total tympanic membrane reconstruction: AlloDerm versus temporalis fascia

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BACKGROUND AND OBJECTIVE: Patients who require surgery for chronic otitis media with perforation and cholesteatoma frequently provide no residual tympanic membrane that is usable in grafting procedures. A novel technique of total tympanic membrane reconstruction (TTMR) is described that maximizes perforation closure rate in these situations while minimizing mucosalization, incomplete healing, and anterior blunting. The specific aim of this report is to assess the safety and efficacy of TTMR and to compare the results obtained with AlloDerm compared with temporalis fascia as a grafting material.

METHODS: The records of 50 patients operated within the years 1999 and the 2004 were reviewed. TTMR with intact canal wall was performed in all cases. Both clinical and audiometric data were analyzed.

RESULTS: Overall perforation closure rate was 92%. There was no statistical significance in closure rate when grafting with AlloDerm versus temporalis fascia. A statistically significant shortened healing time was observed with AlloDerm grafting.

CONCLUSIONS: TTMR is a highly effective and safe technique. (*Otolaryngol Head Neck Surg* 2005;132:906-15.)

Patients who require surgery for chronic otitis media with perforation and cholesteatoma frequently have scarce residual tympanic membrane (TM), or keratin matrix adherently involving its undersurface. These situations prove poor for standard underlay tympanoplasty techniques. Other techniques involving rotational flaps and grafting lateral to the tympanic annulus have been described to better handle these situations.¹⁻³ In our experience, these techniques can result in de-

layed epithelialization of exposed canal wall bone and mucosalization of the neotympanum. Techniques that involve grafting lateral to the tympanic annulus may result in intratympanic cholesteatoma formation.⁴ Repair of perforations involving and including the anterior segment additionally predisposes to anterior blunting as well as graft lateralization.⁵

For these reasons, a reliable and safe tympanoplasty technique was developed to manage total TM reconstruction (TTMR) and avoid the above-mentioned complications. The technique uses a large free anterior canal wall skin graft, with sacrifice of the residual tympanic annulus and external canal stenting with silicone to recreate the anterior angle. Indications include total perforations, large subtotal perforations with full anterior marginal extension, subtotal perforations with mucosalization or refractory granular inflammation of the tympanic remnant, or cholesteatoma adherently involving a significant portion of the TM undersurface.

Occasionally, surgery for long-standing chronic otitis media and recurrent cholesteatoma is complicated by lack of native grafting material. Temporalis fascia is no longer available, and tragal perichondrium has been previously harvested. The repair of total TM perforation requires a material that is thin yet durable and is easily manageable intraoperatively. Numerous alternatives to native grafting material have recently become available. Our center has begun to incorporate the use of AlloDerm (LifeCell Corporation, Branchburg, NJ) in chronic ear surgery.

AlloDerm is a preserved acellular dermal matrix that is processed from human cadaveric skin from an approved tissue bank according to the guidelines of the American Association of Tissue Banks. It is processed in accordance with the Food and Drug Administration's guidelines for human tissue (21 CFR, Part 1270 and 1271), and donors are screened for HIV types 1 and 2, human T-lymphotrophic virus type I, hepatitis B and C, and syphilis. Furthermore, the tissue-processing techniques improve the safety of the graft by solubilizing the cellular components and thus leaving no reservoir for viral replication or antigenic targets for host immune responses.⁶ The patented freeze-drying technique preserves the matrix protein of the AlloDerm graft, which acts as a scaffold for fibroblast and endothelial cell ingrowth, with subsequent revascularization and re-epithelialization.

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The use of AlloDerm in nonotologic procedures is well documented in the literature. Initially described for the treatment of full-thickness burns,⁷ AlloDerm has been employed successfully for repair of septal perforations,⁸ cleft palate repair,⁹ aesthetic soft tissue augmentation,¹⁰ and other surface grafting procedures.

In addition to its general applications, AlloDerm has been previously employed in otologic surgery. Youssef¹¹ first described its use in myringoplasty in 1999 with a rigid endoscope through the transcanal approach. He successfully closed 27 of 30 dry central tympanic membranes (TMs). In his study, a 0.3-mm-thick graft was inserted to overlap the medial surface of the drum by at least 2 mm and was supported in place by a disc of Gelfoam (Pharmacia & Upjohn [Kalamazoo, MI]) over the promontory while the canal was packed with Gelfoam soaked in an antibiotic ointment.

McFeely et al¹² further investigated the use of AlloDerm in the repair of TM perforations by using a chinchilla model with $\geq 30\%$ marginal perforations. In this study, TM perforations were closed in 9 of 10 control ears that were repaired with autologous fascia or perichondrium and in 8 of 10 experimental ears that were repaired with AlloDerm (0.127 mm thick) by using a stuff-through technique. No difference was found in healing rates between lateral or medial position of the AlloDerm basement membrane, nor did complication rates differ between experimental and control groups. No ears showed evidence of cholesteatoma formation. Of note, those investigators commented that the autologous fascia grafts appeared more translucent than did the AlloDerm grafts. Extending upon this work, Laidlaw et al¹³ compared the use of AlloDerm (0.08 to 0.01 mm thick) versus rice paper patch for closing dry TM perforations (40% to 60% of the pars tensa) in 23 adult chinchillas. In this model, 78% of AlloDerm-treated and 66% of the paper patch-treated ears healed successfully. Histologic evaluation showed a trend toward trilaminar membrane formation in the AlloDerm group as compared with the bilaminar and atrophic trilaminar membrane formations found in the rice paper-patch group. Again, the investigators noted an increased thickness in the AlloDerm-repaired areas of the TM versus in the rice paper-patched and nonperforated regions of the TM.

Downey et al¹⁴ investigated AlloDerm (0.3 mm thick) versus autologous fascia grafts for the closure of 30% to 40% dry TM perforations. A statistically significant decrease in operative time was shown in the AlloDerm group (47 minutes versus 68 minutes, $P = 0.001$). Although 90% of the ears repaired with AlloDerm and 100% of the ears treated with fascia healed, histologic analysis showed the absence of micropor-

erations, epithelial hyperplasia, myringosclerosis, fibrosis, or granulation tissue in any of the grafts. Basement membrane complexes were maintained in 80% of the AlloDerm-treated TMs, versus 89% for the fascia grafts. In addition, neovascularization was present in 80% of the AlloDerm group, versus in only 44% of the fascia group. Average postoperative thickness of the AlloDerm was 0.051 mm versus 0.023 mm for the fascia-grafted TMs, which would appear to be consistent with the observation made by McFeely et al.¹²

Recently, the use of AlloDerm has been extended from the animal model into the treatment of chronic TM perforations in both the office and operating room setting.^{6,15,16} Saadat et al⁶ described the successful closure of 6 of 7 dry central 10% to 30% TM perforations by using an office-based transcanal myringoplasty technique with 0.3-mm-thick AlloDerm. All showed improvement in hearing, and none showed rejection of the graft at 1-year follow-up. The 1 failure was attributed to inability to comply with dry ear precautions. Benecke¹⁵ performed a retrospective chart review of 20 tympanoplasties with temporalis fascia and 20 with AlloDerm. Those patients who underwent AlloDerm tympanoplasty with an underlay technique did not have any suitable fascia because of harvesting during prior procedures. All perforations healed in each group, and no statistical significance was noted in residual postoperative air-bone gaps between the 2 treatment groups (5.35 dB versus 5.45 dB, $P = 0.7762$). Fayad et al¹⁶ showed similar results in a retrospective review of 24 patients who were repaired with an AlloDerm (0.15 to 0.3 mm thick) underlay tympanoplasty (21 patients) or with overlay technique (3 patients) with or without mastoidectomy. Thirteen of the patients had total perforations without middle ear disease, and complete healing was shown in 87.5% of patients repaired with AlloDerm. Those investigators reported a similar healing rate in 250 tympanoplasties without AlloDerm that were performed during the same time period.

The aim of this report is to describe a specific surgical technique, TTMR, and to determine its safety and efficacy; then, we will compare the results obtained when using 2 different grafting materials: native temporalis fascia and allograft acellular dermal matrix (AlloDerm).

MATERIAL AND METHODS

Study Design

Retrospective analysis of all patients operated for chronic ear disease by a single surgeon (A.J.F.) at either New York University Medical Center's Tisch Hospital or New York City Health and Hospital Corporation's Bellevue Hospital, between 1999 and 2004. These fa-

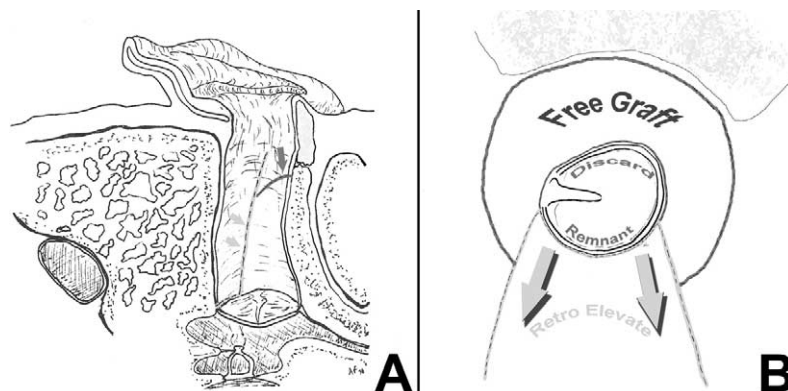


Fig 1. (A) Cross-sectional schematic of incision placement. *Single arrow* demarcates lateral free skin graft harvest incision placed at the bony cartilaginous junction. *Double arrow* demarcates long pedicled Koerner's incisions. (B) Transcanal schematic of free graft harvest incisions and Koerner's flap.

cilities function as a tertiary care referral complex with a residency training program.

Inclusion Criteria

Patients who underwent TTMR for the indications detailed above. Only intact canal wall procedures either with or without concomitant mastoidectomy were evaluated. Patients with minimal cavity inside-out mastoidectomies were excluded from the study.

Data

Data extracted included the following: age; length of follow-up in months; preoperative diagnosis; details of surgical procedure (\pm mastoidectomy; \pm ossiculoplasty); intraoperative findings (ossicular chain status; tympanosclerosis); time to complete epithelialization in weeks; and residual perforation, postoperative mucosalization, or any other complications or need for additional therapies.

Surgical Technique of TTMR

Postauricular access to the external auditory canal is provided through a long Koerner's flap taken just lateral to the posterior tympanic annulus. This flap will provide a vascularized pedicle to the forming neotympanum. Care is taken to remove any mucosalization at the distal flap tip that may eventually grow onto the underlying graft. Neither the annulus nor any residual TM remnant is included in this flap (Fig 1A, double arrow).

The anterior canal wall skin is harvested as a free graft. A lateral incision is made at the level of the bony cartilaginous junction so that the maximum available size is provided (Fig 1A, single arrow). A medial incision is made just lateral to the annulus so that no mucosa cells are included in this segment. Again, the residual TM and annular remnant are not included.

Adequate size is achieved by the extreme lateral position of the anterolateral incision that is placed at the bony cartilaginous junction.

All residual TM remnants are removed, including the annular ligament. Similarly to the case with traditional lateral onlay grafting, this technique does not allow the mucosa-lined TM undersurface to be placed atop the graft material, thereby minimizing the complication of neotympanic mucosalization and "wet ear." Unlike traditional lateral onlay, the tympanic annulus is not preserved. The tedious removal of the keratinized epithelium from its surface is bypassed, and the inherent predisposition to intratympanic postoperative cholesteatoma formation is avoided. In many instances, the additional exposure that is provided by minimally widening the annular ring into the hypotympanum and posterior mesotympanum without regard for annulus preservation is useful for complete exenteration of disease. Additional widenings can be reconstructed easily with tragal or conchal cartilage if need be.

A generous canalplasty is mandatory (Fig 2, cross-hatched area). The intent of the canalplasty is not only to provide maximum visibility for transcanal middle ear work but also to create a less acute anterior as well as inferior angle and to create an anterior shelf upon which to apply the rigid silicone stent during external canal packing (Fig 2, arrow). Creating a generous inferior canalplasty eliminates the acute inferior canal-to-neotympanic angle, thereby maximizing the surface area of the neotympanum and theoretically improving the neotympanum to footplate area ratio-dependent sound pressure amplifier.

Grafting is performed with a large teardrop-shaped graft of either temporalis fascia or AlloDerm, long enough to drape partially onto the anterior canal wall as well as completely up the posterior canal wall (Fig 3A

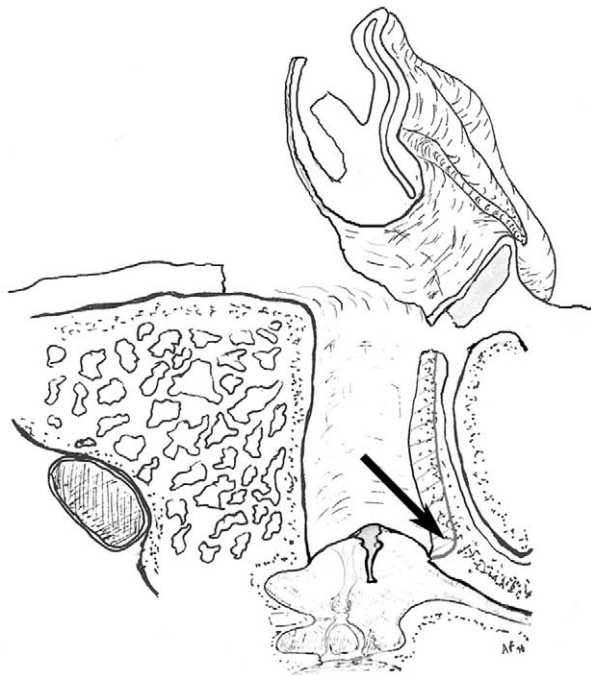


Fig 2. Cross-sectional schematic of canalplasty. The cross-hatched area represents the region of bone removal. The black arrow denotes the resultant anterior ledge.

and B). AlloDerm graft is shaped from a 2×4 cm, 6- to 12- μ m-thickness stock (Fig 1). The middle ear is filled with small cut squares of gelfilm to maintain a middle ear space. Primary ossiculoplasty is performed at this point in appropriate cases by using conventional techniques.

The free anterior wall skin graft is placed as in Figure 3C so that it bridges both the canal wall bone and covers the exposed malleus handle.

Split-thickness skin grafting from the postauricular wound edge is used to resurface any accessible exposed bone of the external auditory canal (Fig 3C).

Once the free-skin and split-thickness skin grafts are in position, the anterior silicone stent is placed. Care is taken to secure the stent against the shelf created during the canalplasty (Fig 4). The Koerner's flap is replaced onto the posterior graft, and the external auditory canal is packed with bacitracin-soaked cotton gauze strips introduced along the anterior silicone stent to act as a rigid unit during the healing period and thereby minimize the risk of graft lateralization.

Postoperative Management and Evaluation

An appropriate cephalosporin or quinolone antibiotic (in cases of cholesteatoma) is given for 14 days postoperatively. Three weeks postoperatively, the ex-

ternal auditory canal packing is removed, with the exception of the silicone stent. The wound is repacked with 1/8-in. cotton gauze strips coated with a mixture of antibiotic (neomycin, polymyxin B, and bacitracin), clotrimazole, and hydrocortisone ointments. The pack is left in place for another 3 weeks, after which time all material, including the silicone stent, is removed and the ear is examined. Degree of epithelialization and presence of granulation tissue are determined. Any granulation tissue is cauterized with topical silver nitrate. If epithelialization is near complete, Gelfoam is focally applied, and reexamination is performed weekly until healing is complete. Additional cotton gauze packing is placed at this point only if required, and an additional 3 weeks is allowed to pass.

Otic drops are administered throughout the postoperative course, beginning after the mastoid dressing is removed and continuing until complete epithelialization has occurred and all packing is removed.

Healing Time

Healing time was recorded in weeks and was determined at the point of the 1st observed complete epithelialization of the intact neotympanum and external auditory canal. A comparison was performed between AlloDerm and fascia. Any patient who had failed closure of perforation or who underwent or would have required a secondary operating room procedure to produce complete healing, was removed from the calculation.

Audiometric Data

Pre- and postoperative recordings were analyzed. Data obtained included 3-tone pure tone average of 0.5, 1, and 2 kHz, air-bone gap average at 0.5, 1, and 2 kHz, and speech discrimination score. To detect evidence of any potential inner ear trauma, bone thresholds were examined at 4 kHz, and any postoperative drop larger than 10 dB was recorded.

RESULTS

Study Groups

Fifty patients were included in the study. The study population was divided into 2 groups on the basis of grafting material: AlloDerm ($n = 19$) or temporalis fascia ($n = 31$).

AlloDerm Group. The total number of patients grafted with AlloDerm was 19. The average age was 35.6 years (range 8 – 70, median 36). Length of follow-up ranged from 4 to 25 months, with an average length of 8.2 months, and a median of 7.

Six patients had cholesteatoma (3 [50%] with associated significant middle ear tympanosclerosis). Eight patients had chronic otitis media with perforation (1

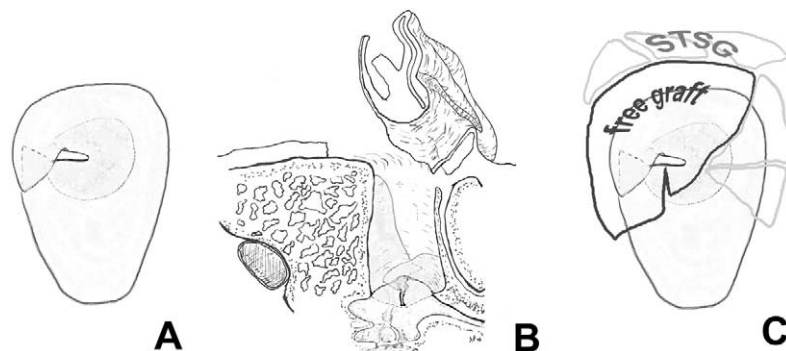


Fig 3. (A) Transcanal schematic of tympanoplasty graft placed with notch for malleus handle. (B) Cross-sectional schematic of same. (C) Transcanal schematic demarcates position of free-skin and split-thickness skin grafts.

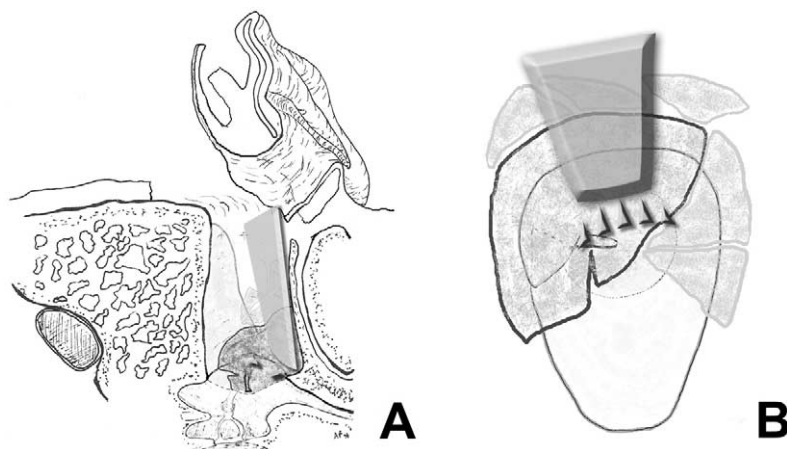


Fig 4. Cross-sectional (A) and transcanal (B) schematic of proper placement of silicone stent.

[12.5%] with significant middle ear tympanosclerosis). Five patients had dry total perforations without a recent drainage history (2 [40%] with significant middle ear tympanosclerosis).

Fourteen patients underwent TTMR in conjunction with intact canal wall mastoidectomy (3 primary incus interpositions; 1 primary incus columellar reconstruction; 4 staged PORP reconstructions; 1 patient is awaiting staged 2nd-look reconstruction for cholesteatoma).

TTMR without mastoidectomy was performed in 5 patients (1 primary incus interposition).

Fascia Group. The total number of patients grafted with fascia was 31. The average age was 33.7 years old (range 3 – 76, median 30). Length of follow-up ranged from 3 to 55 months, with an average length of 14.5 months and a median of 10 months.

Seven patients had cholesteatoma (3 congenital). Seventeen patients had chronic otitis media with perforation (4 [24%] with significant middle ear tympanosclerosis). Seven patients had dry total perforations (4 [57%] with significant middle ear tympanosclerosis).

Twenty-eight patients underwent TTMR in conjunction with intact canal wall mastoidectomy (2 primary incus interpositions; 2 staged PORP reconstructions; 2 staged TORP reconstructions; 2 patients await staged reconstruction).

TTMR without mastoidectomy was performed in 3 patients.

Perforation Closure Rate and Healing Time

Three patients grafted with AlloDerm had residual perforation. Only 1 patient grafted with native temporalis had residual perforation. Among the AlloDerm failures, 2 residual perforations were estimated as 5% size and were successfully repaired with a simple underlay procedure (follow-up times of 13 and 5 months). One patient with a 40% central perforation declined revision surgery. The single-fascia grafting failure was also successfully grafted with a simple underlay technique (20 months follow-up time).

There was an overall success rate of 92% (46/50) for all patients who underwent TTMR. When AlloDerm

Table 1. Healing time: AlloDerm vs. temporalis fascia

		AlloDerm (N = 16)		Fascia (N = 29)	
Healing time (wk)	Mean	7.06	Mean	8.14	
	Median	7	Median	8	
	Std. deviation	1.39	Std. deviation	2.43	
	Minimum	4	Minimum	3	
	Maximum	10	Maximum	12	

was used as a grafting material, there was an associated 84% (16/19) success rate. When native temporalis fascia was used, there was a 97% (30/31) success rate.

A comparison of the success rates of TTMR using AlloDerm versus fascia was performed by χ^2 analysis. Because of the small number of failures in both groups, a Yates continuity correction to Pearson chi-square measure = 1.108 was required and ultimately yielded $P = 0.293$ (statistical significance level, < 0.05 ; trend determined as < 0.10).

A comparison of healing time for TTMR with AlloDerm versus fascia are summarized in Table 1. The 4 patients with residual perforation were excluded from analysis. One patient in the fascia group was also excluded. This pediatric patient was refractorily and acutely infected with a multi-drug resistant *Pseudomonas* and required additional weeks of postoperative intravenous antibiotics plus a secondary examination under anesthesia and laser debridement of granulation tissue from the external auditory canal. The exclusion is based on the observation that the fascia group was more likely to show a longer healing time and that the inclusion of this atypical case within the fascia group may have been unfairly biased to data in favor of the AlloDerm group. The case was included in the analysis of closure, however, because at the time of EUA, the neotympanum was intact and epithelialized.

A comparison of the healing times of TTMR using AlloDerm versus fascia requires a bit more complex analysis. Because the time data is not clearly normally distributed, a Mann-Whitney test was used to compare the 2 distributions. They were not statistically different by this test (Mann-Whitney $U = 177.5$; $P = 0.189$). If the test is considered as a single-tailed analysis, based on the observation that AlloDerm had a shorter outcome clinically, it signifies a statistical trend ($P < 0.20$). However, because this result is fairly close to being a significant difference, a Kolmogorow-Smirnov test was performed that suggested that there is insufficient evidence to conclude that the data are not normally distributed. Therefore, a t test appropriate for normally distributed data was performed and yielded a P value of 0.066 ($t = -1.888$). This result is very close to statistical significance and at a minimum shows a statistical trend toward faster healing when grafting is performed with AlloDerm as opposed to temporalis fascia, even if considered as a 2-tailed analysis.

The hypothesis that AlloDerm grafting heals faster than native temporalis fascia was further evaluated by dividing the subjects by time to heal at 6, 7, 8, and 9 weeks. Figure 5 shows the percentage of healed subjects for each group distributed over time in weeks. A division at 9 weeks gives a χ^2 result that is close to being statistically significant ($P = 0.186$ because of a necessary Yates continuity correction). If the division is made at 8 weeks, the differences become statistically significant ($P = 0.032$, after a Yates continuity correction).

Postoperative Care Requirements

Topical office-based silver nitrate cautery of minor granulation tissue was required in 4 patients grafted with AlloDerm and in 4 patients grafted with fascia. No

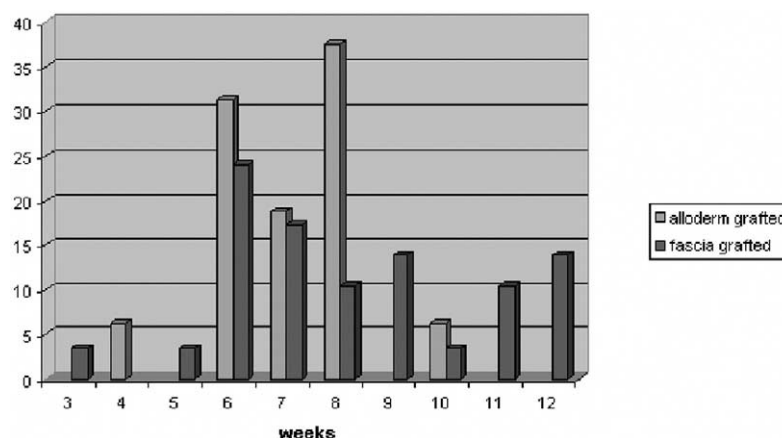


Fig 5. Percentages of subjects in procedure groups needing given number of weeks to heal.

Table 2. Audiologic data – AlloDerm group

Patient	Age (y)	F/U (mo)	Mastoid	Tscler	Chol	COM	OCR	Pre PTA	Post PTA	Pre ABG	Post ABG	Pre SD	Post SD	Additional findings
1	35	4	+	+	+	+	1° Incus Interpos.	50	22	40	12	92	92	
2	54	4		+			1° Incus Interpos.	55	43	40	20	100	100	Incus malleus fixation / malleus head removed
3	48	7	+			+	1° Incus Interpos.	35	20	40	20	ND	96	
4	70	25	+	+		+	1° Incus Columella	87	68	35	17	80	88	
5	40	14	+	+	+	+	2° PORP	55	23	60	5	100	100	Incus malleus fixation / IS joint erosion
6	44	16	+	+			2° PORP	48	23	35	10	92	88	Ossicular encasement-fixation / mobile Stapes
7	44	4						55	30	40	3	92	88	
8	34	4						42	18	30	5	92	88	
9	25	7	+		+			15	10	17	7	100	100	Cochlear erosion reconstructed with Bone Pate
10	12	13						17	22	10	10	96	100	Secondary underlay tympanoplasty
11	30	9	+			+		30	23	30	10	92	92	
12	22	4	+	+	+	+		17	23	8	15	100	96	
13	31	7	+			+		62	47	47	33	92	92	

Mastoid, mastoidectomy performed; *Tscler*, significant tympanosclerosis noted; *Chol*, cholesteatoma noted; *COM*, recent chronic otitis media; *OCR*, ossicular chain reconstruction; *Pre*, preoperative; *Post*, postoperative; *PTA*, pure tone average; *ABG*, air-bone gap; *SD*, speech discrimination score.

more than 2 successive treatments were required. An additional pediatric patient grafted with fascia underwent EUA and laser debridement of anterior canal wall granulation tissue, as described in the Perforation Closure Rate and Healing Time section.

Two patients grafted with fascia had small keratin pearls on the canal wall requiring unroofing with the office microscope. One 3-year-old child who was operated for congenital cholesteatoma and was also grafted with fascia had a 1.5-mm intracanal pearl located on the bony posterior tympanic rim at the junction with the neotympanum. It was discovered during a planned staged 2nd-look procedure. Because of its location, the resultant defect was repaired with underlay tragal perichondrium grafting.

Mucosalization

Only a single patient (grafted with AlloDerm) had a small nonkeratin-producing region on the midanterior canal wall, well lateral to the neotympanum. This patient awaits staged middle-ear exploration for cholesteatoma and will have the region locally treated at that time.

Complications

One adult and 1 child, both grafted with fascia, developed a minor wound infection. Both presented at 6 weeks postoperatively with perimeatal cellulitis and pain that resolved promptly with a single course of oral anti-staphylococcal antibiotics.

A single patient had a 20-dB depression of the bone line at 4 kHz, indicative of possible inner ear trauma. It should be noted that dissection of middle ear tympanosclerosis was performed, reducing the likelihood that this bears a direct causative relation to the technique of TTMR.

There were no cases of facial nerve injury, cerebrospinal fluid leak, or any other complications.

Audiometric Evaluation

Thirty-five patients were included in the analysis. Eight patients either recently had staged reconstruction or are awaiting it. Their initial postoperative audiograms, however, were included in the evaluation of bone threshold at 4 kHz. The remainder had insufficient data available for evaluation.

Table 3. Audiologic data – Fascia group

Patient	Age (y)	F/U (mo)	Mastoid	Tscler	Chol	COM	OCR	Pre PTA	Post PTA	Pre ABG	Post ABG	Pre SD	Post SD	Comments
1	3	40	+		+		2° PORP	18	10	12	10	ND	92	Congenital cholesteatoma
2	3	30	+		+			35	18	33	13	100	100	Congenital cholesteatoma
3	38	10	+		+	+	1° Incus Interpos.	35	25	17	10	ND	ND	2nd look—no recurrence
4	49	13	+			+		33	15	23	2	96	92	
5	76	36	+			+		32	22	12	3	84	84	
6	46	6						40	23	22	5	100	96	Implosion trauma
7	49	6		+				n/a	28	n/a	5	76	76	
8	69	3	+	+		+		45	28	20	5	76	80	
9	26	10	+	+				28	10	20	7	96	92	
10	10	6	+			+		37	13	30	8	96	96	
11	29	18	+			+		43	22	32	10	92	88	
12	21	4	+			+		33	13	17	10	88	92	
13	56	9	+			+		56	43	27	13	96	96	Aspergillus mastoiditis
14	30	7	+			+		65	40	28	15	ND	ND	
15	29	5						23	37	12	17	ND	96	
16	38	26	+	+		+		48	28	40	17	ND	ND	
17	63	13	+	+		+		37	45	15	17	92	92	Ossicular encasement - Fixation 20 dB drop in 4K / Pre & Post SRT unchanged 35dB
18	25	25	+			+		23	27	15	18	92	92	
19	45	3	+			+		63	52	25	20	96	96	
20	33	10	+	+				32	22	30	22	88	96	
21	7	11	+			+		43	33	20	22	ND	ND	Concurrent adenoidectomy
22	57	39	+			+		62	70	20	28	ND	ND	Nasopharyngeal SCCa - s/p XRT

Mastoid, mastoidectomy performed; *Tscler*, significant tympanosclerosis noted; *Chol*, cholesteatoma noted; *COM*, recent chronic otitis media; *OCR*, ossicular chain reconstruction; *Pre*, preoperative; *Post*, postoperative; *PTA*, pure tone average; *ABG*, air-bone gap; *SD*, speech discrimination score.

The results of the AlloDerm group are detailed in Table 2. The results for the Fascia group are detailed in Table 3. The overall postoperative air–bone gap was less than or equal to 20 dB in 89% of all patients undergoing TTMR. Sixty-six percent of patients achieved an air–bone gap of less than or equal to 15 dB. Fifty-one percent had an ultimate air–bone gap of 10 dB or less.

DISCUSSION

The use of autologous temporalis fascia for grafting is well documented in the literature.¹⁷⁻²⁰ Successful closure was documented by Kartush et al¹⁷ in 120 patients at 6 months' follow-up who were undergoing an over–under technique; however, 12 patients developed late TM perforations. Singh et al¹⁸ showed similar results (93.3% closure rate) using an overlay and un-

derlay technique in 60 patients with dry subtotal perforations secondary to chronic suppurative otitis media.¹⁸ However, Khan et al¹⁹ reported a TM closure rate of 84% at 5-year follow-up in 69 patients who underwent an underlay tympanoplasty with temporalis fascia. Similarly, Berger et al showed a success rate of only 52.8% in revision myringoplasty patients. Of the failures, 39.4% were caused by complete no-take of the graft material.²⁰ In general, success rates of more than 90% can be achieved regardless of surgical technique employed.²¹ Rates of closure have been similar with AlloDerm. Fayad reports an 87.5% closure rate in his recent article.¹⁶

TTMR differs from traditional lateral onlay in that the entire annular ligament is removed, along with any unusable TM remnants. It is characterized by an extreme lateral anterior free graft harvest incision, sili-

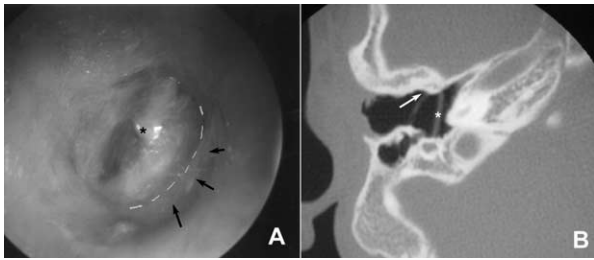


Fig 6. (A) Transcanal photograph of postoperative healed TTMR using described technique. *Dotted white line* denotes anterior neotympanic margin without blunting and good surface area. *End of malleus handle. *Small black arrows* delineate anterior bony ledge. (B) Postoperative axial CT of a different patient. Note the nonblunted anterior angle of the neotympanum (*white arrow*). *A sheet of silicone that was placed deep to the initial reconstruction in the mesotympanum. This patient had extensive congenital cholesteatoma and recently underwent a staged TORP.

cone stenting, and split-thickness skin grafting. The 92% overall closure rate obtained with TTMR is comparable to those reported in routine cases using traditional techniques. Considering that TTMR is designed to address those severe cases without available residual TM, this is a highly favorable outcome.

One of the perforations in the AlloDerm group occurred by a distinctly observed process. Three pore holes were noted to be opening in the AlloDerm at the time of the first packing change. At the 6-week packing removal, there was an obvious central perforation in that location. In subsequent procedures, we have examined the AlloDerm for microperforations and have discarded a number of pieces on that basis.

The introduction of AlloDerm as a grafting material was initially considered in revision surgery when temporalis fascia was not readily available. It was later incorporated for primary procedures, particularly when TTMR was performed, because of its significant subjective ease of use and its rapid epithelialization. The complexity that arose in evaluating the statistical significance of the healing times is likely a result of the wound care protocol, which with rare exceptions pushes the minimum up to 6 weeks, thus skewing the normality of result distribution. Despite this, the clear significance of the improved healing by AlloDerm noted by 8 weeks is particularly notable, because 9 weeks implies the application of an additional cotton gauze packing cycle.

Silicone stenting serves 2 purposes. It results in the formation of a good anterior angle and greatly facilitates intraoperative and postoperative packing placement while protecting the split-thickness skin grafts. The resultant anterior canal wall is consistently well

epithelialized, and the formation of a good anterior angle provides maximal neotympanum surface for optimal sound conduction (Fig 6).

Hearing outcomes, though varied, are quite good considering the increased severity of disease present in cases that require TTMR. The technique does not prohibit primary ossiculoplasty in appropriate cases.

Last, the technique of TTMR, once learned, is consistent and rapid, and it is easily taught to residents in training.

CONCLUSIONS

1. TTMR is a highly effective and safe procedure, yielding a 92% rate of success.
2. There was no statistical difference in closure rate when grafting with AlloDerm versus native temporalis fascia.
3. AlloDerm showed a statistically significant shorter healing time.
4. TTMR produces good postoperative hearing outcomes.

Statistical analysis was performed in consultation with Dr Sue Walker Toledo, World Analysis.

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