# Type I Tympanoplasty Meta-Analysis: A Single Variable Analysis

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**Objective:** To determine which independent variables influence the efficacy of type I tympanoplasty in adult and pediatric populations.

**Data Sources:** A search of the PubMed database and Cochrane Database of Systematic Reviews using the key words "tympanoplasty OR myringoplasty" from January 1966 to July 2014 was performed.

**Study Selection:** Studies reporting outcomes of myringoplasty or Type I tympanoplasty in primary non-cholesteatomatous chronic tympanic membrane (TM) perforation were included.

**Data Extraction:** Of 4,698 abstracts reviewed, 214 studies involving 26,097 patients met our inclusion criteria and contributed to meta-analysis.

**Data Synthesis:** The primary outcome of success was defined as closure rate at 12 months. The independent variables analyzed were age, follow-up period, approach, graft material, perforation cause, size, location, ear dryness,

Type I tympanoplasty is a relatively common procedure in otolaryngology. The history of the management of a perforated tympanic membrane (TM) can the traced back to 1644, when Banzer (1) used a tube of elk's claw covered in pig's bladder to close the perforation in a TM. It was not until the nineteenth centuries that the British otologists, James Yearsley and Joseph Toynbee, targeted an improvement in hearing with their innovative devices (2,3). Berthold introduced the term "myringoplasty", when he performed the first surgical closure of a TM perforation in 1878 (4). However, myringoplasty was not widely accepted until Wullstein and Zollner, utilizing the operative microscope, re-introduced it in 1951 (5). Tympanoplasty is the surgical repair of the TM and/or the middle ear ossicles. Wullstein (6) classified it into five and surgical technique. Only those studies providing data on a given parameter of interest could be included when comparing each variable.

**Conclusion:** The weighted average success rate of tympanic closure was 86.6%. Based on this meta-analysis, pediatric surgery has a 5.8% higher failure rate than adults and there is no correlation between follow-up period and success. Other variables associated with improved closure rates include perforation with a size less than 50% of total area (improved by 6.1%) and the use of cartilage as a graft (improved by 2.8% compared with fascia), while ears that were operated on while still discharging, those in different locations of the pars tensa, or using different surgical approaches or techniques did not have significantly different outcomes. **Key Words:** Meta-analysis—Myringoplasty—Tympanic membrane perforation—Tympanoplasty.

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types as described first in 1956. Type I tympanoplasty, involving an intact ossicular chain, involves the grafting of TM alone onto an intact ossicular chain. The difference between type I tympanoplasty and myringoplasty is that tympanoplasty involves the raising of a tympanomeatal flap whereas myringoplasty does not, although the terms are often used interchangeably (7). To avoid confusion for the remainder of this analysis both type I tympanoplasty and myringoplasty will be referred to as tympanoplasty. Two previous meta-analyses investigate outcomes in pediatric populations only (8,9). This study aims to identify and analyze the variables that influence the success of TM repair in terms of closure rates and hearing outcomes in both the adult and pediatric population.

# **METHODS**

This meta-analysis was performed in accordance with the PRISMA guidelines (10).

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Search Method and Study Selection

All observational and experimental studies reporting closure rates were eligible for inclusion. Using the key words of tympanoplasty or myringoplasty a systematic literature search

of the PubMed database and Cochrane Database of Systematic Reviews for studies published, in the English language, from January 1966 to July 2014 was conducted (July 2nd, 2014), yielding 4,698 articles. The search strategy for PubMed was ("myringoplasty" [MeSH Terms] OR "myringoplasty" [All Fields]) OR ("tympanoplasty" [MeSH Terms] OR "tympanoplasty"[All Fields]) AND ("1966/01/01" [PDAT]: "2014/07/ 01"[PDAT]). The primary author reviewed all abstracts of studies found with the above search strategy before two other independent authors selected studies for inclusion based on the defined criteria. If there were any abstracts that lacked clarity or adequate detail in their methodology or results, the full article was read to assess suitability for inclusion. The inclusion and exclusion criteria were only applied after detailed assessment of full-text articles. Duplicate reporting of results by authors were discarded. Studies were classified by a particular variable, if at least 90% of the population fitted into that category, otherwise the options of unclassified, mixed, or other were used and, therefore, being excluded in data analysis.

## **Study Inclusion Criteria**

The inclusion criteria for individual studies were any observational (retrospective or prospective) or treatment (randomized or non-randomized clinical trials) study reporting the outcome of tympanoplasty in adult and pediatric populations. Only studies reporting clinically diagnosed, primary non-cholesteatomatous chronic TM perforations were included. Studies were excluded if they reported patients who had tympanoplasty for acute perforations, for conditions other than perforation, revision surgery (if >10% of study population required revision surgery), other types of tympanoplasty (non-type I), ossicular chain pathology, or mastoidectomy.

#### Variables

Variables examined included: the patient's age (at the time of surgery), follow-up period (months from surgery to the latest follow-up appointment), surgical approach (endaural or postaural), perforation cause (otitis media or traumatic-as defined by individual studies), graft material (cartilage, fascia, fat or other materials), perforation size (above or below 50% of TM surface area), perforation location (anterior, central, or posterior), ear status (dry ear or "wet" ear-defined as discharge from the middle ear at time of preadmission surgery appointment or a history of discharge within 3 months before surgery), and surgical technique (underlay, inlay, or overlay graft positioning). For clarification, only chronic perforations were included and traumatic or other perforations that were not chronic were not included. Age and follow-up period were analyzed as a continuous variables with the range of ages, mean age, and mean follow-up period extracted from each study.

#### **Outcome Measures**

The primary outcome measure was the complete closure of the TM perforation, defined as an intact neo-membrane at 12 months follow-up. Secondary outcome measures were the presence of adverse events (re-perforation, re-operation/revision surgery, blunting, lateralization) and degree of improvement of conductive hearing loss (by pure tone audiometry).

## Assessment of Risk of Bias in Included Studies

Risk of bias was assessed at the individual study level at time of first appraisal and in the finally included studies, using the studies own summary assessment of the risk of bias. No studies were excluded on this basis.

## **Data Synthesis**

A meta-analysis applying the methodology of Einarson was performed using S-PLUS 2000 (Insightful Corporation, Seattle, WA) (11). An overall success rate was calculated, as well as rates for each variable. For each category, the number of studies that the results were based on was recorded, and the homogeneity of the studies (p < 0.05 indicates a non-homogeneous population), the meta-analytic average success rate, the standard error, and 95% confidence intervals were calculated. A p value less than 0.05 was considered statistically significant. Linear regression technique was used to analyze the correlation between follow-up period and success rate.

## RESULTS

The search strategy identified 4,704 articles after duplicates were removed. Figure 1 shows the method of study identification according to PRISMA (10). After screening, 321 full-text articles were assessed for eligibility and 107 articles were excluded. A total of 214 studies were included in quantitative analysis (see Supplemental Digital Content, http://links.lww.com/ MAO/A426). Of the 214 studies, two were randomized control trials and the rest were observational retrospective or prospective cohort studies. Across 214 included studies, there were 26,097 patients and the mean number of patients in each study was 122 (121.92  $\pm$  149.51, range of 7-1298 patients). The mean closure rate was 86.6%(range of 46.8-100%, 95% CI [85.3, 87.9]) and the mean age of patients in the included studies was 28  $(27.63 \pm 13.59)$ , range of 5.50-70.70 years of age). Figure 2 demonstrates the increasing trend in the number of articles published concerning Type I tympanoplasty or myringoplasty since 1970.

The results of the meta-analysis are plotted in Figure 3 and summarized in Table 1, showing that the overall meta-analytic average success rate for closure of perforations was 86.6%. Highest failure rates were detected in studies with follow-up periods greater than 12 months (4.38% worse with follow-up periods >12 months compared with  $\leq 6$  months). Though a decreasing success rate is observed with average longer follow-up times (<6months: 87.15%,  $\leq 12$  months: 85.61%, >12 months: 82.77%), simple linear regression analysis calculated no correlation between success rate and follow-up period (Pearson's r = 0.037, p = 0.625, after adjusting for outlier studies). The adult population (defined as 18 years and above) had 5.8% better closure rates compared with the pediatric population (defined as 17 years old and below) (adult: 89.25%, pediatric: 83.42%). Within the pediatric population, children <12 years had the worst closure rate of all age groups ( $\leq 12$  years: 83.11%, >12 years 88.23%, 13-17 years: 92.81%). Patients with otitis media preoperatively had 3.4% worse closure rates compared with patients with traumatic perforations (otitis media: 83.86%, traumatic: 87.25%). Patients with actively discharging ears had 3.6% worse closure rates compared with pre-operatively dry ears (dry: 87.02%, wet: 83.44%). Perforations greater than 50% have a 6.1% lower success rate than those less than 50% in size



**FIG. 1.** Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (10) flowchart summarizing the search results and the application of eligibility criteria.

 $(\leq 50\%$  perforation size: 85.56\%, >50\% perforation size: 79.44%). Anterior perforations had lower closure rates than central or posterior perforations by 0.6% and 3.3% respectively (anterior: 85.42%, central: 85.42%, posterior 88.72%). The postaural approach had an increased closure rate of 2.0% compared with endaural approach, but the difference was not statistically significant. The underlay technique was the most commonly used graft technique (used in 75.5% of patients: 13,359 of 17,697 total patients where surgical technique was specified). The overlay technique was only 0.1% better in achieving successful closure compared with the underlay technique, and the inlay technique was the least common and successful (underlay: usage 75.5%, success 86.71%, overlay: usage 15.5%, success 86.83%, inlay: usage 9.0%, 85.39%). Cartilage had superior closure rates compared with temporalis fascia, fat, and "other" materials such as paper, alloderm, perichondrium, other synthetic materials (cartilage: 90.80%, fascia 88.00%, fat: 86.52%, other 85.39%). Pairwise comparisons of graft materials showed that cartilage compared with fascia as the only significant pair comparison with a p value of 0.048. When cartilage was compared with fat or to "other" materials, there was no significant advantage (p value 0.366 and 0.110, respectively). Likewise, fascia compared with fat and to "other" materials was not significant (p value 0.581 and 0.560, respectively). Lastly, fat compared with "other" materials was not significant (p value 0.4692). Audiometry data were inconsistently reported, and a mean improvement in ABG postoperatively could not be ascertained. However, data at the 10 dB, 20 dB, and 30 dB postoperative ABG thresholds was available in 29, 32, and 30 studies. respectively. Looking at the postoperative ABG within these studies, 42.5% of patients (n = 1,380 of 3,247) were within 10 dB, 68.6% (n = 2,428 of 3,540) within 20 dB and 95.5% (n = 2,797 of 2,928) within 30 dB.

# DISCUSSION

The overall closure rate for this meta-analysis was 86.6%, with an adult population success rate of 89.2% and a pediatric population success rate of 83.4%, which is the same success rate identified in a 2015 meta-analysis of pediatric tympanoplasty (9).

# Follow-up Period Does Not Correlate to Graft Success Rate

Through linear regression analysis, this study demonstrates that there is no correlation between follow-up period and success rate. In some series, the follow-up period is as little as 2 months while in others it was as high as 12 years (12-15). Some authors have suggested that late graft failure is relatively rare, therefore, stating that a graft follow-up period of 6 months is sufficient (16,17). However, others have compared short and longterm follow-up periods and demonstrated that a significant number of failures occur after 1 year (18,19). It has been observed that regardless of any factors that can be controlled, a 10% deterioration in closure rate occurs





FIG. 2. Graph of results depicting the overall closure rate and success rates stratified by each variable.

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FIG. 3. Displays the results depicting the overall closure rate and success rates stratified by each variable.

within the first 2 years postoperatively (13). These late re-perforations are attributed to either underlying Eustachian tube dysfunction or to avascularity and inappropriate thickness of the graft (20). Future studies should aim to follow-up graft success for a minimum of 12 months.

# **Adult Populations Have Superior Closure Rates**

In our analysis, it was demonstrated that adults had a better closure rate than the overall pediatric population. Interestingly, the teenage subgroup (13 to 17 years of age) had the highest success rate (92.81%), 9.7% higher than for children  $\leq$ 12 years (83.11%), and 9.4% higher than success rate for children  $\leq$ 17 years (83.42%) suggesting within children, better outcomes are found in older children. However, direct comparison of age groups above and below 12 years was not significant, and

no comparative analysis could be made between <12years and 13 to 17 years. Our findings are consistent with a meta-analysis of pediatric tympanoplasty performed in 1997, which identified that age was a significant factor, and that in children better outcomes are found with increasing age (8). However, a more recent meta-analysis of pediatric tympanoplasty has found through subgroup analysis that age was not a significant factor affecting the closure rate (9). The lower success rate of tympanoplasty in children is thought to be related to Eustachian tube function and its relationship with otitis media (21-25). There remains debate as to whether there should be a minimum age for tympanoplasty or not, with some studies suggesting it should be performed after the Eustachian tube is at adult development after 7 years of age (22,26-31). The decision to perform tympanoplasty in children remains a balance of the risks and

Variable	Туре	No. Studies	No. Patients	Success (%)	95% CI Range	р
	Overall success	214	26,097	86.62	85.27-87.92	_
Age	≤12	20	1,182	83.11	77.38-88.21	0.075
	>12	66	5,469	88.23	85.55-90.68	
	$\leq 17$	53	4,136	83.42	81.01-85.70	0.017
	>17	26	2,049	89.25	84.17-93.52	
	13 to $\leq 17$	5	214	92.81	88.49-96.33	_
Follow-up period	$\leq 6$ months	12	2,502	87.15	82.28-91.38	_
	$\leq 12$ months	33	8,279	85.61	83.07-87.98	0.320
	>12months	45	10,907	82.77	79.11-86.15	
Approach	Endaural	69	5,341	86.02	83.35-88.51	0.112
	Postaural	64	8,188	88.06	86.12-89.88	
Perforation cause	Otis Media	69	8,597	83.86	80.33-87.12	0.8610
	Traumatic	10	472	87.25	70.21-98.62	
Graft material	Cartilage	33	1,746	90.80	86.85-94.19	0.048
	Fascia	121	14,806	88.00	84.13-91.44	
	Fat	22	1,507	86.52	84.91-88.05	0.469
	Other	36	4,217	85.39	80.23-89.92	
Perforation size	$\leq$ 50%	74	5,859	85.56	82.39-88.48	0.019
	>50%	58	3,374	79.44	74.06-84.40	
Perforation location	Central	53	4,948	86.03	83.08-88.77	0.822
	Anterior	32	1,268	85.42	80.68-89.66	
	Posterior	22	479	88.72	83.28-93.41	
Ear status	Dry	105	13,048	87.02	85.09-88.85	0.155
	Wet	14	741	83.44	76.24-89.69	
Surgical technique	Underlay	110	13,359	86.71	85.09-88.26	0.712
	Overlay	36	2745	86.83	82.78-90.45	
	Inlay	29	1593	85.39	79.69-90.36	

TABLE 1. Variables and their effects on the primary outcome of tympanoplasty success

CI indicates confidence interval. Boldface indicates statistical significance.

benefits within the individual patient with the additional added risk of an increased rate of failure. To determine a recommended minimum age for tympanoplasty, future studies should aim to report age-specific closure rates.

# Discharging Ears and Perforations Because of Otitis Media Do Not Significantly Affect Closure Rates

Closure rates in tympanoplasty performed in perforations because of otitis media and in those perforations that were still discharging were not significantly affected. It is important to recognize that discharging ears may not necessarily be infected, with multiple factors including tympanomastoid space mucosa, ventilation and Eustachian tube dysfunction influencing the occurrence and presentation of infection (28). Individual studies looking at this specific issue have reported mixed results (15,17,22,26,32–36). Given that this meta-analysis and no individual study claims that perforations that are wet have a higher success rate for closure, it would seem reasonable to attempt to create a dry perforation but not make this a necessary condition for surgery.

# Perforation Size Matters, but Location Does Not

This meta-analysis indicates that perforations greater than 50% have a lower success rate, while the location of the perforation had no significant effect on success rate. Several individual studies also found a significantly ies where perforation size was not observed to affect overall results (16,22,24,36,39-46). The major reasons thought to be responsible for graft failure in larger perforations are increased technical difficulty, reduced visibility, reduced graft overlap with the residual TM, a poor vascular bed for the graft and poor graft support or fixation (16,34). Some studies have claimed that anteriorly placed perforations are associated with a poorer outcome, possibly because of reduced vascularity or exposure of the anterior TM (13,15,47,48). While our meta-analysis did not demonstrate statistical significance with the location of the perforation, it is important to acknowledge that large-sized perforations often include the anterior segment, as anterior-only perforations are uncommon (49). Anteriorly located perforations also had the lowest success rate (85.42% versus 86.03% for central and 88.72% for posterior) and so the site of the perforation while not proving to be significant for success rate remains an important factor.

higher rate of failures in larger perforations

(9,17,20,26,32,34,37,38). There are also individual stud-

# No Surgical Approach Has an Advantage

The type of surgical approach did not have an impact on outcomes. Surgical approach depends on many factors including the perforation size, location, visualization, and the individual surgeon's preference. Typically, an

endaural or transcanal approach is used for smaller, more posterior perforations in wider canals. Because there are a number of variables that contribute to the decision of approach and these are biased by the individual surgeon's preferences it is not surprising that this meta-analysis did not detect a difference.

# There Is No Superior Graft Placement Technique

This meta-analysis demonstrates that there is no significant difference between the grafting techniques used (underlay, overlay, and inlay). While the underlay technique was the most commonly used graft technique (75.5% of patients in this meta-analysis), there was no significant benefit of any individual technique. Some individual studies have claimed superiority in closure rates for the overlay technique (50,51). Others have reported no difference: however, there is an identified increased risk of blunting of the anterior tympanomeatal angle and lateralization of the TM are more common when utilizing the overlay technique (52-54). Blunting may result in a persistent conductive hearing loss (16). The inlay technique was initially used for small perforations utilizing a plug of adipose tissue (4,55). More recently, this technique has been applied using cartilage (56-58). There does not appear to be a definitive indication for each technique, so to a large extent the choice usually depends on the surgeon's view of each technique's relative advantages or disadvantages (59,60). As each surgeon has personal preferences, it is almost impossible to compare grafting techniques performed by the same surgeon and excellent outcomes are achieved with all techniques (16,51,61-64).

# **Cartilage Has Superior Closure Rates**

The most commonly used graft materials are temporalis fascia, cartilage, and fat, which are all readily accessible at the surgical site. Over the years many other natural and synthetic materials have been trialed, but there are very few published studies on outcomes. Our meta-analysis shows that cartilage (90.80%) has a small but significant superior closure rate to temporalis fascia (88.00%), with pairwise comparisons of other material choices demonstrating no significance. A small randomized prospective clinical trial comparing fascia (20 ears) to cartilage (18 ears) found the graft uptake rates and hearing outcomes were not significantly different at 24 months (84.2% and 80% respectively) (65). Since the literature review date of this meta-analysis one other randomized control trial showed a benefit for cartilage in closure rate at 12 months, while another reported a reduced postoperative infection rate with cartilage (57,66,67). One possible suggested explanation of this difference in cartilage success, between these two trials, is that poorer results may occur with cartilage thickness over 500 µm (67). While graft choice ultimately depends on the perforation type, size and surgeon preference, our meta-analysis has shown that cartilage, as an independent variable, is a superior graft choice compared with temporalis fascia in both the pediatric and adult populations

in terms of perforation closure. Cartilage is also often used as a graft material for smaller sized perforations, which innately have higher healing rates, and this may account for the increased closure rate with cartilage compared with other graft material. Different graft materials can also be used in different situations and the superiority of cartilage must still be balance for an individual patient's situation and the surgeon's experience with a particular material.

# Hearing Outcomes Were Inconsistently Reported

Hearing outcomes after tympanoplasty are inconsistently reported which limits the conclusions that are able to be made. In this meta-analysis 39% (83 of 214 studies) of the studies recorded postoperative hearing results. Because of inconsistency in reporting the overall mean hearing gain could not be calculated. The range of mean postoperative air-bone gap (ABG) closures in individual studies was 1.2 to 25.5 dB. A total of 32 studies in this meta-analysis contributed data with complete reporting of postoperative ABG (20,24,43,48,56,57,61,64,68-91). Data at the 10, 20, and 30 dB postoperative ABG thresholds was available in 29, 32, and 30 studies, respectively. Looking at the postoperative ABG within these studies, 42.5% of patients (n = 1,380 of 3,247) were within 10 dB, 68.6% (n = 2,428 of 3,540) within 20 dB, and 95.5% (n = 2,797 of 2,928) within 30 dB, demonstrating that only a minority of patients achieved the best postoperative ABG (< 10 dB). While the ideal outcome in tympanoplasty is the complete closure of the postoperative ABG to 0 dB (indicating no hearing loss), achieving a postoperative ABG <10 dB should be considered good clinical outcome as an ABG greater than 10 dB indicates a conductive hearing loss. Though data were collected on pure-tone air-conduction thresholds, very few studies documented findings in adequate detail for a meaningful analysis. When examining other individual studies ability to achieve a postoperative ABG within 20 dB there are reports ranging from 60% to 90%, consistent with our finding of 69% (12,35,48,51,70,72,92,93). The impact of variables on hearing outcomes could not be determined because of the poor quality of reporting. Future studies should report audiometric outcomes in accordance to the American Academy of Otolaryngology, Head and Neck Surgery's Hearing Committee and with audiometry test results before and after surgery (94).

#### **Secondary Outcomes and Complications**

The complications detected in this meta-analysis are reported in Table 2. Complication rates were reported in only 21% of studies (44 of 214 studies). The most commonly reported complications were reperforation (11.9%), revision surgery (11.4%), blunting (6.7%), and lateralization (4.2%). Re-operation or revision surgery was defined as any operation caused by an event requiring return to theatre, or as defined by the individual study. Future studies should aim to report complications in greater details to help future analysis of specific complications.

Complication	Number of Studies	Mean (%)	Range (%)	SD
Reperforation	22	11.88	2.25-31	7.72
Reoperation	14	11.43	1-87%	23.25
Blunting	17	6.65	1-54%	12.36
Lateralization	17	4.24	1-13%	3.75

TABLE 2. Complication rates as reported by individual studies included in this meta-analysis

SD indicates standard deviation.

## The Effect of Mastoidectomy

Mastoidectomy or other surgical adjunctive procedures were not included as a variable as the majority of studies did not discriminate between cholesteatoma and non-cholesteatoma etiology when considering mastoidectomy. The current body of literature has been unable to demonstrate a clear benefit for TM healing when mastoidectomy is performed concurrently with tympanoplasty. Several studies retrospectively compared tympanoplasty alone to tympanoplasty with mastoidectomy for TM perforation repair and did not find any statistical difference in repair success or hearing outcomes for adults or children (95-98). A large prospective randomized study of adults with chronic suppurative otitis media compared graft success rate and mean postoperative-ABG between tympanoplasty only to tympanoplasty with cortical mastoidectomy and concluded there was no significant difference (99). Regarding non-cholesteatomata chronic suppurative otitis media perforations, a literature review examining 26 articles concluded that there was no additional benefit to performing mastoidectomy with tympanoplasty for uncomplicated TM perforations (100).

# Limitations

Any meta-analysis is limited by the quality of the primary data. In the 214 included studies, there were only three experimental studies, with the majority of studies being retrospective cohort studies. Most studies did not report hearing outcomes adequately, or were inconsistent with outcome reporting. We relied on individual studies to determine the chronicity of perforations, as well as their definition of a "chronic traumatic" perforation. Differences in surgical technique were not accounted for as these are highly variable between individual surgeons, difficult to define and mostly unreported.

# **CONCLUSION**

Based on this meta-analysis, the weighted average success rate of tympanic closure was 86.6%. Pediatric surgery has a larger failure rate than adults. Poorer outcomes are found in those perforations with a size over 50% of the total area. Perforations discharging around the time of surgery and those perforations of different locations of the pars tensa did not have significantly different outcomes. The length of follow-up period

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does not correlate to graft success. Surgical factors that led to improved closure rates include the use of cartilage while other factors such as surgical approach or technique of graft placement did not influence the closure rate overall. Future studies should, at a minimum, report closure rates, hearing outcomes, complications, and report follow-up of at least 12 months.

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