



# Determinants influencing success rates of myringoplasty in daily practice: a retrospective analysis

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## Abstract

**Objectives** The aim of this study was to determine influencing factors on tympanic membrane closure and their consequence on absolute risks of closure and hearing improvement in myringoplasties.

**Design** Retrospective cohort.

**Setting** Medium-sized medical centrum.

**Participants** 195 patients were analysed who underwent a myringoplasty between January 2015 and February 2017 at the Jeroen Bosch Hospital in The Netherlands.

**Main outcome measures** Patient-related data, descriptions of the tympanic defect, surgical data, and the most important follow-up data were collected. Primary outcome is successful closure of the tympanic membrane and the secondary outcome is the amount of air–bone gap improvement after surgery.

**Results** The overall success rate of the myringoplasty graft was 74.9%. If cartilage and butterfly graft were used, higher success rates of 85.4% and 85.5% were achieved compared to temporalis fascia (61.3%). Success rate of the operation was dependent of the skills of the surgeon. Chances of success are 91.9% if the operation is performed by an experienced surgeon using cartilage and 66.7% if a less experienced surgeon uses fascia. If a postoperative complication occurs or when silastic sheets are used, this might have a negative effect on the success of the operation. The mean ABG improved 10.10 dB if the perforation was closed compared to 3.38 dB after an unsuccessful procedure.

**Conclusion** The success rate of a myringoplasty is dependent of the skills of the surgeon and type of graft used and varies between 91.9 and 52.0% depending on these factors.

**Keywords** Myringoplasty · Tympanic membrane perforation · Hearing · Otolological surgical procedure · Comparison · Anatomical success · Functional success

## Introduction

Myringoplasty, or a type I tympanoplasty, is a frequently used surgical procedure to close perforations of the tympanic membrane to prevent infections and to improve the hearing levels.

Myringoplasty has evolved significantly. The search for an ideal graft material, and an ideal technique of performing the surgery kept evolving. Nowadays, multiple surgical techniques and graft materials are used in everyday practice.

Previous research has been carried out to determine variables that positively influence surgical outcomes of myringoplasty. It has been found that a non-smoking patient, a longer dry ear, a healthy opposite ear, a relatively smaller perforation, and a senior surgeon were positive influences, among others [1]. Furthermore, age, mucosa inflammation, pathological contralateral ear (perforation, otitis media, cholesteatoma), and surgical experience seem to influence this result as well [2]. Furthermore, a recent meta-analysis found that cartilage grafts got better graft integration rates than temporalis fascia grafts but similar improvements in the hearing outcome postoperative [3].

However, these studies have been performed with several factors probably influencing the surgical outcome. Most of these studies have been performed in research settings in university medical centres and follow-up time is generally

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short. Therefore, it is difficult to translate these data into daily clinical practice in a secondary hospital, where patients are followed for a longer period of time and the operations are not performed in a research setting. Which factors are still important determinants influencing outcomes of myringoplasty when our common daily clinical practise is evaluated over a longer period?

In addition, what are clinically relevant absolute risks of closure of the perforation considering the several possible determining factors? And what can we tell our patients about the amount of hearing improvement to be expected after a successful procedure?

The aim of this retrospective study is to determine influencing factors on tympanic membrane closure and their consequence on absolute risks of closure and hearing improvement in a common daily practice in a secondary hospital.

## Patients and methods

### Participants and data collection

This study is a retrospective cohort study including patients who underwent myringoplasty surgery in the time frame of January 2015 up until February 2017 in a top clinical medical centre in the Netherlands (Jeroen Bosch Hospital).

Selection of patients was done using the treatment-code for myringoplasty in the time frame stated above ( $n = 245$ ). Patients who underwent a tympanoplasty, mastoidectomy, ossicular reconstruction or cholesteatoma surgery were excluded. Primary as well as secondary procedures were included. Following these exclusion criteria, we selected a total of 195 myringoplasties.

Of these, we collected data regarding gender and age, the side of the perforation, the type of the perforation, site of perforation, size of perforation which could either be small (1 quadrant), subtotal (2 or 3 quadrants) or complete, the number of ear infections in the year before the surgery and previous ear surgery. Regarding the surgery itself, we collected the data about the surgeon, the surgical approach, graft material used, presence of tympanosclerosis, and the postoperative use of silastic sheets. We also collected data about the follow-up length (in months), postoperative antibiotics, and complications after surgery.

Concerning the surgical approach we studied each surgical report and classified the approach on the following; if an end aural incision was mentioned it was categorized as end aural approach, if the endomeatal incision was mentioned it was classified as endomeatal, if a postauricular incision mentioned it was classified as postauricular approach and if the graft was placed through the perforation without the use of any of these incisions, for example the butterfly technique, it was classified as transmeatal.

All operations were performed in general anaesthesia. The grafts were placed by underlayment and supported by gel foam (Willospoon) and covered by gelfoam. Some surgeons used silastic sheets as onlay. When the diablo technique was performed biflanged cartilage was placed in the perforation and covered with gelfoam. Antibacterial drops en postoperative antibiotics were prescribed on indication.

Pre- and postoperative audiometry was evaluated. Audiograms were made using Affinity, Interacoustics. We only included audiograms at least 6 months before and/or after the surgery without present infection. Mean bone- and air conduction thresholds were calculated (500 Hz, 1000 Hz, 2000 Hz and 4000 Hz) and subsequently the mean air–bone gap (ABG) using these data.

Primary outcome was successful closure of tympanic membrane, i.e., grafting success following myringoplasty. Tympanic closure was classified as successful if a closed tympanic membrane was noted during the whole follow-up period. Tympanic closure was classified as unsuccessful or failure if there was either a re-perforation or pinpoint perforation or if a reoperation was needed during the follow-up period.

The secondary outcome was the auditory outcome measured by the amount of improvement of the ABG after surgery.

The database was exported to the SPSS v25 program for statistical analysis. The statistical test applied for analysing the differences in success rates of our determinants were the chi-squared test, Fisher's exact test and multiple logistic regression. The independent and paired t-test and one-way ANOVA were used for evaluating our auditory outcome. A  $p$  value  $< 0.05$  was seen as statistically significant. Mean values are represented as mean  $\pm$  SD.

### Ethical considerations

Our analysis is looking retrospectively at outcomes from a cohort of patients. Patients were diagnosed and treated according to the department and national guidelines. This research is of negligible risk and involves the use of existing patient data. Furthermore, there is no harm and/or discomforts for the participants.

All the data analysed was collected as part of an internal evaluation to improve our quality of care. The main risk in this retrospective cohort is the breach of trust or confidentiality. We minimized this risk by making the data only accessible for the researchers and data was anonymized as soon as feasible.

We believed that the expected benefits of this project would exceed this minimal amount of inconvenience.

## Results

After exclusion 195 myringoplasties were left for further analysis.

Characteristics of the patient population are outlined in Table 1. The perforation and surgical characteristic are outlined in Tables 2 and 3, respectively.

Missing data was encountered. In four cases no surgical report was available, so no reliable data could be gathered

about the surgical technique that was used. In two of these cases there was also no data about which graft was used for the tympanic closure.

Most of the missing data was about the type ( $n = 24$ ), site ( $n = 27$ ) or size ( $n = 17$ ) of the perforation as this was frequently not described by the surgeon.

Concerning the hearing results, we missed the ABG data of 53 patients. This was mainly because bone conduction thresholds were not measured postsurgery, especially in

**Table 1** Patient characteristics affecting success rate of myringoplasties

Factor	Number of patients (percentage of total)	Successful tympanic closure (percentage successful)	<i>p</i> value	Significant*
Gender				
Women	112 (57)	62 (75)	0.962	NS
Men	83 (43)	84 (75)		
Age				
Children (0–17 years)	77 (39)	57 (74)	0.826	NS
Adults ( $\geq 18$ years)	118 (61)	89 (75)		
Number of ear infections previous year				
0	81 (41)	62 (77)	0.864	NS
1–2	93 (48)	68 (73)		
> 2	21 (11)	16 (76)		
Previous ear surgery				
Yes	81 (42)	59 (73)	0.581	NS
No	114 (58)	87 (76)		

\*NS statistically not significant, S statistically significant ( $p < 0.05$ )

**Table 2** Characteristics of the perforation affecting success rate of myringoplasties

Factor	Number of patients (percentage of total)	Successful tympanic closure (percentage successful)	<i>p</i> value	Significant*
Side of perforation				
Left ear	99 (51)	78 (79)	0.200	NS
Right ear	96 (49)	68 (71)		
Type of perforation				
Central	137 (80)	107 (78)	0.201	NS
Borderline	34 (20)	23 (68)		
Size of perforation				
Small	108 (61)	84 (78)	0.619	NS
Subtotal	60 (34)	43 (72)		
Complete	10 (6)	7 (70)		
Site of perforation				
Superior	15 (9)	11 (73)	0.790	NS
Inferior	125 (74)	95 (76)		
Superior and inferior	28 (17)	20 (71)	0.443	NS
Anterior	67 (38)	54 (81)		
Posterior	56 (32)	41 (73)		
Anterior and posterior	52 (30)	37 (71)		

\*NS statistically not significant, S statistically significant ( $p < 0.05$ )

**Table 3** Surgical characteristics affecting success rate of myringoplasties

Factor	Number of patients (percentage of total)	Successful tympanic closure (percentage successful)	<i>p</i> value	Significant*
<b>Surgeon</b>				
1	34 (17)	24 (71)	<b>0.001</b>	<b>S</b>
2	36 (19)	28 (78)		
3	8 (4)	6 (75)		
4	10 (5)	4 (40)		
5	53 (27)	34 (64)		
6	54 (28)	50 (93)		
<b>Surgical technique</b>				
Transmeatal	64 (34)	52 (81)	0.415	NS
Endomeatal	63 (33)	43 (68)		
Endaural	28 (15)	21 (75)		
Postauricular	36 (19)	27 (75)		
<b>Graft used</b>				
Temporalis fascia	80 (42)	49 (61)	<b>0.002</b>	<b>S</b>
Cartilage	41 (21)	35 (85)		
Butterfly	55 (29)	47 (86)		
Epidisc	4 (2)	4 (100)		
Tutopatch	2 (1)	0 (0.0)		
Temporalis fascia + cartilage	8 (4)	6 (75)		
Temporalis fascia + butterfly	1 (1)	1 (100)		
Cartilage + tutopatch	2 (1)	2 (100)		
<b>Tympanosclerosis</b>				
Yes	33 (17)	24 (73)	0.755	NS
No	162 (83)	122 (75)		
<b>Silastic sheets used</b>				
Yes	80 (41)	54 (68)	<b>0.048</b>	<b>S</b>
No	115 (59)	92 (80)		
<b>Postoperative antibiotics</b>				
Yes	56 (29)	40 (71)	0.482	NS
No	139 (71)	106 (76)		
<b>Complication</b>				
Yes	26 (13)	15 (58)	<b>0.030</b>	<b>S</b>
No	169 (87)	131 (78)		

Bold values indicate a direct relation between the determinant and the success of the operation

\*NS statistically not significant, S statistically significant ( $p < 0.05$ )

children, or due to patients not showing up for the hearing test postsurgery.

The overall success rate of closure of the perforation was 74.9%. Within the first 6 months this success rate was 80.5%. In total 49 patients had an unsuccessful tympanic closure of which 11 had a pinpoint re-perforation and 9 needed a second surgery.

Of these 49 patients 25 had a failure of closure reported at the first control visit after surgery ( $\pm 7$  weeks after surgery). The other 24 patients had a re-perforation occurring between 9 weeks and 12 months with an average of 5.5 months after surgery.

The mean follow-up time was  $8.39 \pm 6.18$  months with a range of 2–28 months.

Of the 154 patients with a successful tympanic closure the mean follow-up time was  $7.5 \pm 5.8$  months and for patients with an unsuccessful tympanic closure  $11.9 \pm 6.3$  month closure ( $p < 0.001$ ).

The success rate of tympanic closure between the surgeons differed significantly ( $p = 0.001$ ) ranging from surgeon 6 with a success of 92.6% to surgeon 4 with a success of only 40.0% (see Table 3).

There was a significant difference between the grafts used for tympanic closure ( $p = 0.002$ ) (see Table 3). We compared

the success rates of cartilage to temporalis fascia (OR 3.69; 95% CI 1.39–9.73;  $p=0.009$ ) and butterfly graft to temporalis fascia (OR 3.72; 95% CI 1.55–8.91;  $p=0.003$ ). Thus, using cartilage or butterfly graft has a higher chance of success than temporalis fascia. No difference in success rate was found between the butterfly or cartilage graft usage.

Patients who had a complication after surgery had a success rate of 57.7% compared to 77.5% when they did not have a complication ( $p=0.030$ ). These complications were either peroperative or postoperative. An overview of these complications is outlined in Table 4.

In the 80 surgeries, where silastic sheets were used 67.5% were successful compared to 80%, where silastic sheets were not used ( $p=0.048$ ).

There was no significant difference for the following factors; gender, age, the amount of ear infections, previous ear surgery, the side, size, site or type of perforation, surgical technique, tympanosclerosis or the use of antibiotics.

**Table 4** Overview of reported complications

Complications	N
Postoperative bleeding	4
Hematoma	2
Inflammation/infection	12
Complications per-operative	4
Problems with obtaining graft material	
A second perforation made during procedure	
Conversion from postauricular to transmeatal because of excessive bleeding	
Complications with graft postoperative	4
Graft displacement	
Granulation on graft that needed treatment	
Atrophy of cartilage	

A logistic regression was performed to ascertain the effects of the graft used (temporalis fascia, cartilage or butterfly), the use of silastic sheets, the presence of a complication and the surgeon on the likelihood that the patients had a successful or unsuccessful tympanic closure. This showed that the surgeon and the graft used were still significant factors influencing our primary outcome. The presence of a complication and the usage of silastic sheets were no longer a significant determinant.

We correlated the surgeon and the graft they used to see its influence on success rates.

All our surgeons had an equal amount of years of experience. So, we divided the surgeons based on how many surgeries they performed each year, assuming the more surgeries they perform the more experienced they would be in performing this surgery (see Table 5). Seeing as there is no current literature about the correlation between experience and the amount of surgeries each year we divided the surgeons ad hoc in a way that each group had two surgeons who had a corresponding amount of surgeries per year.

Success rates of temporalis fascia stayed poor, even when used by an experienced surgeon (52.0%). Cartilage used by a surgeon who performed more than 25 procedures a year ( $n=37$ ) scored the highest (91.6%) but comparisons are hard to make since sample sizes were small in the other groups ( $n=1$  and  $n=3$ ). Butterfly graft had good success rates when used by both the experienced (87.1%) as the intermediate surgeons (88.9%). When used by unexperienced surgeons butterfly graft had the same success rate as temporalis fascia.

The audiological data results are outlined in Table 6.

A significant correlation between the hearing results and the success rate of the tympanic closure was found. Patients with a successful tympanic closure ( $n=104$ ) had a mean ABG improvement of  $10.10 \pm 8.80$  dB compared to  $3.38 \pm 5.31$  dB after unsuccessful procedure ( $n=38$ ) (95% CI 4.30–9.13;  $p<0.001$ ).

**Table 5** Success rates of successful tympanic closure for every graft material shown per expert level of surgeon

Surgeon	Grafts used	N	Successful tympanic closure	Success rate (%)
Experienced*	Fascia temporalis	25	13	52.0
	Cartilage	37	34	91.9
	Butterfly	31	27	87.1
Intermediate**	Fascia temporalis	46	30	65.2
	Cartilage	1	1	100
	Butterfly	18	16	88.9
Unexperienced***	Fascia temporalis	9	6	66.7
	Cartilage	3	0	0
	Butterfly	6	4	66.7

\*Surgeons who performed  $\geq 25$  procedures per year

\*\*Surgeons who performed 15–25 procedures per year

\*\*\*Surgeons who performed  $\leq 15$  procedures per year

**Table 6** Mean, four frequencies, audiometric results before and after surgery and after successful and unsuccessful closure

	Audiometry results (dB ± SD)		Audiometric gain <sup>†</sup> (dB ± SD)	p value
	Pre-operative	Postoperative		
Air conduction (n = 155)	28.46 ± 14.23	18.74 ± 13.86	9.72 ± 10.19	<0.001
Bone conduction (n = 142)	10.66 ± 12.91	9.80 ± 12.22	0.86 ± 6.62	0.125
Air–bone gap (n = 142)	18.45 ± 9.21	10.15 ± 8.17	8.30 ± 8.53	<0.001
	Audiometric gain <sup>†</sup> (dB ± SD)			p value
	Successful closure	Unsuccessful closure		
Air conduction	11.87 ± 10.18	3.33 ± 7.13		<0.001
Bone conduction	1.25 ± 7.10	− 0.22 ± 4.96		0.243
Air–bone gap	10.10 ± 8.80	3.38 ± 5.31		<0.001

<sup>†</sup>A positive audiometric gain indicates improved hearing

No other significant difference in mean ABG improvement was found within any of our other variables. Neither the size or site of the perforation, the type of graft used, technique of the surgery or which surgeon performed the surgery had an influence on the ABG postoperative.

## Discussion

### Synopsis of findings

The overall success rate of the myringoplasty graft was 74.9%. If cartilage and butterfly were used, higher success rates of 85.4% and 85.5% were achieved compared to temporalis fascia (61.3%). Success rate of the operation was dependent of the skills of the surgeon. Chances of success are 91.9% if the operation is performed by an experienced surgeon using cartilage.

If a complication occurs, this might have a negative effect on the success of the operation. Remarkably, the use of silastic sheets (mostly used to improve the healing process) did not improve the success rate; moreover, this use might lead to more unsuccessful myringoplasties. The mean ABG improved 10.10 dB if the perforation was closed compared to 3.38 dB after an unsuccessful procedure.

This is so far the first study to determine absolute risks of success combining several determinants. The influence of these factors is more pronounced than expected with a success rate varying from 52.0 to 91.9%.

### Comparison with other studies

Previous research has been carried out to determine variables that positively influence surgical outcomes of myringoplasty. Our study confirms that surgical experience [1] and the use of cartilage grafts [3, 4] leads to better results.

There are studies that did not find experience of surgeon to be a significant determinant [5–7]. However, these studies use years in practice as an experience marker. We determined experience level based on the amount of surgeries performed each year. We did not find any other study that used this variable.

Studies by Wasson et al. [6], Dangol et al. [7] and Sharma et al. [8] have not found the approach or size to be a significant factor influencing the success rate of myringoplasty. We can corroborate that approach technique and perforation size has been found not to be a significant determinant factor for successful myringoplasty in our study and are in line with the most recent studies.

The success rates of myringoplasties in this study are not as high as reported in other studies [6, 7]. However, most studies in this subject look at the perforations that occur in a period of 6 months or less after the surgery. In our study, with a higher mean of 8.39 month follow-up, 38 of 49 failures occurred within 6 months. This shows that even after this period failure can still occur. It is questionable if this perforation is a real failure of the surgery or just a new perforation, unrelated to the surgery. The point remains that in clinical practice, our patient returns with a re-perforation.

### Limitations of the study

To our knowledge this is the first study reporting on long term success rate of myringoplasty. However, there are some limitations.

First, we conducted a retrospective cohort analysis. Occurrence of missing data is unavoidable. This might have affected the constituency of our data. Nonetheless missing data in this study was quite low.

Second, since some graft types are not used that often, we ended up with some small sample sizes. Although epidisc implicates to have a high success rate and tutopatch a very low success rate, sample sizes are too small to draw

conclusions and more experience with these grafts is needed in our department.

Third, in our study we classified pinpoint perforation as failures. However, pinpoint perforations in the tympanic membrane are less likely to infect and seldom lead to clinically functional hearing problems [9]. So, in some cases, having a pinpoint perforation after the surgery is a clinically successful result.

Lastly, seeing this is a retrospective cohort, it might be possible that the choice of graft or the decision to use silastic sheets is affected by the condition of the ear and/or the type of perforation. Still, we didn't find any significant correlation between the type of graft/the use of silastic sheet and the site/size of the perforation or the number of ear infections in the previous year. So, bias that might occur because of this lack of randomisation should be limited.

### Clinical applicability

When we translate these data into clinical practice, we can conclude that experience of the surgeon is an important determinant for success of the procedure. As mentioned earlier some surgeons performed less than 10 myringoplasties per year with significant more failures as result. Because of this outcome we decided that in our clinical practice ENT-surgeons no longer perform myringoplasties if they do not perform more than 15 procedures per year. As already mentioned, we are the first study to use this variable as a marker of experience. Therefore, we cannot conclude that this should be introduced everywhere. More research needs to be done to see if this applies to or differs from every practice.

Independent of experience level of the surgeon, closure of a perforation with cartilage is much more beneficial than when temporal fascia is used. According to our data, the use of temporal fascia is no longer advocated in clinical practice.

Using chi-square test there is a significant negative relation between the use of silastic sheets and the outcome of the myringoplasty. When correlating this for the other predictor variables no significant difference is found. Although, this is still an unexpected result. In general, silastic sheets are used to improve the healing process and to stabilize the graft with the hypothesis that they have a positive effect on the success of the myringoplasty. Since silastic sheets do not improve the outcome of the surgery in a positive way and might even lead to more failures, we no longer advocate the use of it.

Our study also showed that there is a significant difference in success when a complication occurs. Unfortunately, our numbers are too small to distinguish between the types of complications as mentioned in Table 4. However, in 12 of the 26 cases infection/inflammation occurred, so it could be discussed if anti-bacterial drops should be given to each patient preoperative to limit the risk of infection. No clinically relevant research has been done about this subject yet.

### Conclusion

Myringoplasty is a successful approach for restoring the tympanic membrane and functional hearing results. The success rate of a myringoplasty is dependent of the skills of the surgeon and type of graft used. Chances of success are 91.9% if the operation is performed by an experienced surgeon using cartilage and 66.7% if a less experienced surgeon uses fascia.

If a complication occurs, this might have a negative effect on the success of the operation. Remarkably, the use of silastic sheets (mostly used to improve the healing process) did not improve the success rate.

### Compliance with ethical standards

**Conflict of interest** The authors declare there is no conflict of interest.

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