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Uncomplicated type I tympanoplasty with bovine xenografts versus human allografts: functional results and prognostic factors for graft success

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Abstract. *Objective:* This study investigated the success rates of xenograft and human allograft materials as alternatives to more common autograft materials like fascia, fat, or cartilage.
Study Design: Retrospective cohort study.
Patients: The study retrospectively included 71 con-secutive patients who underwent type I tympanoplasty with a bovine xenograft (n = 38) or a human allograft (n = 33).
Intervention: Myringoplasty.
Main outcome measures: Closure rate and postoperative hearing gain at last follow-up. The analysed independent variables were age, period without ear discharge, smoking habits, perforation size and location, perforation cause, revision or first-time case, the state of the non-operated ear, surgical approach, preoperative state of the middle ear and ossicular chain mobility, follow-up time, and postoperative adverse effects. Pre- and postoperative audiometry results were compared.
Setting: General hospital centre.
Results: The overall closure rate was 81.6% for xenografts and 78.8% for allografts (p = 0,768), and pure-tone averages and air-bone gaps were equally improved in the two groups. Of the analysed factors, only postoperative myringitis significantly influenced outcome, being more prevalent in the allograft group. This was related to intratympanic tympanosclerosis and ossicular fixation.
Conclusions: Bovine xenografts and human allografts can be used safely as graft materials in myringoplasty, have acceptable closure rates, and produce functional results that are similar to those of autografts like fascia or fat. Xenografts or allografts might be less sensitive to graft failure for larger perforations. Postoperative myringitis was more frequently observed with the use of allografts in tympanosclerotic ears and was the only factor that influenced graft outcome.

Introduction

The goals of a myringoplasty, also called a type I tympanoplasty, are to repair the tympanic membrane in order to avoid infections of the middle ear and to improve hearing levels. Autografts with fascia temporalis, tragal cartilage, and/or perichondrium can be used to repair small or mid-sized perforations and require a skin incision for graft harvesting. At our institution, surgeons often use tympano-ossicular allografts to perform myringoplasty in cases with larger perforations. Tympano-ossicular allografts, which were introduced by Marquet some 50 years ago,[1] are human transplants of the tympanic membrane either alone or with the ossicles. Although near-normal anatomical and physiological reconstruction can be achieved, there are also disadvantages. Specifically, harvesting is time-consuming, and eliminating the risk of disease transmission is both time-consuming and expensive. Due to very stringent selection procedures that are used to prevent disease transmission, human allografts have become less available. Tympano-ossicular allografts may still be the material of choice for extensively diseased middle ears that are destroyed by chronic otitis media, with or without cholesteatoma. However, in uncomplicated myringoplasty, we have begun to use bovine xenografts as an alternative to allografts in order to avoid both the use of human allografts and

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autografts harvested from the patient. Harvesting is not without morbidity, since postoperative complications such as haematoma, infection, pain, and delayed healing sometimes occur.

The aim of this study was to compare the anatomical and functional success rates and to analyse the different prognostic factors that could affect graft success in uncomplicated primary myringoplasty using xenografts and human allografts.

Materials and methods

This retrospective cohort study enrolled all patients who underwent primary uncomplicated myringoplasty for chronic tympanic membrane perforations between 2008 and 2016 with Tutopatch® bovine xenografts or human allografts.

All surgeries were performed by the senior author (FD). Tutopatch® is a collagen membrane that is extracted from solvent-preserved bovine pericardium and sterilized with gamma radiation (Taureon, Rijswijk, The Netherlands). All patients underwent a CT scan of the temporal bone, and all had an intact ossicular chain. The exclusion criteria were myringoplasty in combination with mastoidectomy and/or ossiculoplasty or removal of cholesteatoma. A total of 71 patients were included in the study, 38 in the bovine xenograft (XG) group and 33 in the human allograft (AL) group.

The following variables were analysed: the size and location of the tympanic membrane perforation, age at the time of surgery, smoking habits, preoperative and postoperative hearing levels, follow-up period (number of days from the surgery to the latest follow-up appointment at which an audiogram was performed), revision case versus new case, status of the ear (dry ear versus 'wet ear', which was defined as discharge from the middle ear at the time of the preadmission surgery appointment or a history of discharge within 3 months before surgery), perforation cause (traumatic versus chronic otitis media), surgical technique (endaural versus postaural), status of the middle ear during surgery (normal versus the presence of disease like inflammation or intratympanic tympanosclerosis), ossicular mobility, graft material (xenograft versus human allograft), status of the contralateral non-operated ear, and adverse effects during postoperative follow-up (myringitis, blunting, lateralisation).

The perforation size was graded relative to the surface of the tympanic membrane from I (0%y25%) to IV (75%5100%). The location of the perforation was categorised as follows: perforation in the anterior half, the posterior half, the inferior half, or a subtotal/central perforation. Hearing assessment was performed by pure-tone audiograms in accordance with the British Society of Audiology recommended procedure[2] at the time of the preoperative visit and at each postoperative follow-up visit. Values are given in decibel hearing level (dB HL). Average hearing levels (pure-tone averages, PTAs) and air-bone gaps (ABGs) were calculated at the thresholds of 0.5, 1, and 2 KHz.

The primary outcome measure was closure rate at the last recorded follow-up visit. The secondary outcome measures were the presence of adverse events (re-perforation, myringitis, blunting, latera lization) and the degree of improvement in conductive hearing loss. Descriptive statistics for the clinical characteristics of patients are presented as means (standard error) for continuous, normally distributed variables and as medians with interquartile range (IQR; Q3-Q1) for non-normally distributed variables. The normality of distribution was assessed using the Kolmogorov-Smirnov test.

Intergroup differences of categorical variables were analysed with the Pearson's chi-square or Fisher's exact tests. For independent continuous variables, the Mann-Whitney U test was used to test the significance of differences of medians. To compare pre- and postoperative non-parametric continuous variables like PTA and ABG, a Wilcoxon signed-rank test was used. The statistical analysis was performed with SPSS 24 (IBM, Chicago, IL, USA). A p-value <0.05 was considered statistically significant.

Xenograft technique

All surgical interventions were performed under general anaesthesia. The approach depended on the location of the perforation. For better visualisation, a postaural approach was chosen when the perforation was located anterior of the malleus.

First, the edge of the perforation was debrided. A postauricular incision was marked posteriorly to the auricular crease extending from the mastoid tip to the temporal line. The incision site was injected with 1:100,000 epinephrine diluted in saline, and the incision was performed through the skin and

subcutaneous tissue. The tympanomeatal flap was raised, and the annular ligament dislocated out of the bony sulcus. The tympanomeatal flap was elevated from the malleus handle. The middle ear was packed with Gelfoam soaked in antibiotic eardrops to press the graft against the tympanic membrane. The bovine xenograft, a disk 14-mm in diameter, was appropriately trimmed so that it covered the entire tympanic defect and was placed as an underlay. The graft was laid over the malleus handle, annulus, and denuded bone of the external meatus. The graft was then fixed to the tympanomeatal flap with fibrin glue. The entire tympanomeatal flap was laid back and the postauricular incision closed in a layered fashion. The ear canal was packed with a circular Gelfoam and sponges with antibiotic ointment. A pressure dressing was applied for 48 hours.

When the tympanic membrane perforation was located posteriorly, an endaural approach using a Rosen incision was performed. Apart from the incision, the grafting technique was the same as in the postaural approach. In the group who received xenografts, 15 patients (38.5%) were operated using an endaural approach and 24 (61.5%) using a retro-auricular approach.

Human allograft technique

Human allograft surgery was always performed using a postaural approach. The technique has been extensively described in the past by Somers *et al*.[3] and by Van Rompaey *et al.*[4]

Results

Patient characteristics: bovine xenograft versus human allograft group

The study included 38 patients, 30 female and 8 male, with a median age of 34 years (IQR: 37 years) who underwent myringoplasty with a bovine xenograft to repair a perforation in the tympanic membrane (XG group). The median preoperative PTA was 31 dBHL and the ABG was 18 dBHL. The study also included 33 patients, 18 female and 15 male, with an average age of 21 years (IQR: 31.5 years) who underwent myringoplasty with a human allograft to repair a perforation in the tympanic membrane (AG group). The median preoperative PTA was 35 dBHL and the ABG was 20 dBHL. In the XG group, 29% were children (<18 years old), while in the AG group, 48.5% were children.

Primary outcome of xenograft and allograft surgeries: closure rate

The overall graft success (closure rate) was 81.6% in the XG group and 78.8% in the AG group; this difference was not statistically significant ($p = 0.768$). Regarding failures, 7 cases (21.2%) reperforated in the AG group as did 7 cases in the XG group (18.42%). In the AG group, complete necrosis of the human allograft tympanic membrane developed in 2 cases (6.1%), probably due to an allergy to the preservative (formaldehyde). The other 5 cases demonstrated inadequate healing due to a lack of vascularisation of the graft with subsequent necrosis and reperforation. In the XG group, there was 1 case (2.6%) in which perforation occurred due to postoperative infection. In the other 6 cases, the grafts had healing problems and subsequently reperforated. No allergic (graft versus host) reactions were seen in the XG group.

Other than graft failure, there were no major adverse effects after any of the surgeries. Although the median follow-up time was considerably longer in the AG group than in the XG group (259 days versus 143 days, respectively), this difference was not statistically significant ($p = 0.461$).

Analysis of variables in the AG group versus the XG group

We compared variables in the AG group versus the XG group and found that almost none of the pre- and peroperative parameters were significantly different except for the approach, perforation size, and location, all of which are biased by the surgeon's graft preference (Table 1). Only the presence of myringitis was significantly different between the groups in terms of postoperative parameters. Postoperative myringitis was significantly more frequent in the AG group ($p = 0.044$). Only 1 case (2.6%) in the XG group had postoperative myringitis, and it resolved with local medical therapy. However, 6 cases (18.18%) in the AG group had postoperative myringitis. All inflammatory reactions in the AG group were resolved with local medical therapy as well. Lateralisation and/or blunting were observed infrequently and were comparable in both groups ($p = 0.507$).

Audiometric results in the AG group versus the XG group

Table 1

Analysis of the influence of the indicated variables on myringoplasty performed with allografts versus xenografts

Variable		Allograft		Xenograft		p-value
		(n=33)		(n=38)		
Age	median years, IQR	20.7	31.82	33.93	36.73	0.066
Follow-up	median days, IQR	259.00	595.00	142.50	332.75	0.109
Perforation size	perforation size < 50% (n, %)	14	42.42%	28	73.68%	0.002*
	perforation size > 50% (n, %)	19	57.58%	10	26.32%	0.025*
Perforation location	inferior perforation (n, %)	11	33.33%	21	55.26%	0.003**
	subtotal or central perforation (n, %)	16	48.48%	8	21.05%	
	posterior perforation (n, %)	3	9.09%	32	84.21%	
	anterior perforation (n, %)	5	15.15%	16	42.11%	
Otorhea	dry < 3 months (n, %)	12	36.36%	7	18.42%	0.089
	dry > 3 months(n, %)	21	63.64%	31	81.58%	
Smoking habits	smoking (n, %)	5	15.15%	9	23.68%	0.367
	non-smoking (n, %)	28	84.85%	29	76.32%	
Status of the other ear	pathology in other ear (n, %)	17	51.52%	14	36.84%	0.214
	normal other ear (n, %)	16	48.48%	24	63.16%	
Side	left (n, %)	18	54.55%	18	47.37%	0.546
	right (n, %)	15	45.45%	20	52.63%	
Cause of the perforation	traumatic (n, %)	3	9.09%	6	15.79%	0.165
	COM (n, %)	30	90.91%	32	84.21%	
Preoperative PTA	median dBHL, IQR	35.00	23.15	30.85	24.95	0.492
Preoperative ABG	median dBHL, IQR	20.00	14.10	18.30	13.8	0.117
Revision status	revision (n, %)	4	12.12%	5	13.16%	0.896
	no revision (n, %)	29	87.88%	33	86.84%	
Approach	endaural (n, %)	0	0.00%	14	36.84%	0.000**
	postaural (n, %)	33	100.00%	24	63.16%	
Peroperative inflammation	(n, %)	2	6.06%	2	5.26%	0.884
Ossicular mobility	mobile chain (n, %)	27	81.82%	33	86.84%	0.560
	fixed chain (n, %)	6	18.18%	5	13.16%	
Closure rate	overall success rate (n, %)	26	78.79%	31	81.58%	0.768
Postoperative myringitis	(n, %)	6	18.18%	1	2.63%	0.044*
Postoperative blunting/ lateralisation	(n, %)	7	21.21%	2	5.26%	0.064
Postoperative PTA	median dBHL, IQR	26.60	18.15	23.30	21.73	0.913
Postoperative ABG	median dBHL, IQR	13.70	14.10	11.65	8.30	0.141
Pre-post PTA	median dBHL, IQR	-5.00	18.30	-7.65	11.08	0.786
Pre-post ABG	median dBHL, IQR	-6.70	16.60	-7.50	15.00	0.734

Data are presented as median (IQR) unless otherwise stated.
ABG: air-bone gap; COM: chronic otitis media; IQR: interquartile range; PTA: pure tone audiometry.

Table 2

Analysis of the association of the indicated variables with graft success in myringoplasty.

Variable		Succes		Failure		p-value
		(n=57)		(n=14)		
Age	median years. IQR	28.12	34.72	23.63	26.4	0.315
Follow-up	median days. IQR	190.00	422.50	230.5	428.75	0.461
Perforation size	perforation size < 50% (n, %)	36	63.16%	6	42.86%	0.394
	perforation size > 50% (n, %)	21	36.84%	8	57.14%	
Perforation location	inferior perforation (n, %)	36	63.16%	7	50.00%	0.330
	subtotal or central perforation (n, %)	9	15.79%	4	28.57%	
	posterior perforation (n, %)	13	22.81%	9	64.29%	
	anterior perforation (n, %)	9	15.79%	0	0.00%	
Otorhea	dry < 3 months (n, %)	14	24.56%	5	35.71%	0.398
	dry > 3 months (n, %)	43	75.44%	9	64.29%	
Smoking habits	smoking (n, %)	11	19.30%	3	21.43%	0.858
	non-smoking (n, %)	46	80.70%	11	78.57%	
Status of the other ear	pathology in other ear (n, %)	23	40.35%	8	57.14%	0.256
	normal other ear (n, %)	34	59.65%	6	42.86%	
Side	left (n, %)	30	52.63%	6	42.86%	0.512
	right (n, %)	27	47.37%	8	57.14%	
Cause of the perforation	traumatic (n, %)	9	15.79%	2	14.29%	0.889
	COM (n, %)	48	84.21%	12	85.71%	
Preoperative PTA	median dBHL, IQR	33.30	24.20	32.35	24.58	0.937
Preoperative ABG	median dBHL, IQR	20.00	15.00	19.00	13.35	0.378
Revision status	revision (n, %)	9	15.79%	0	0.00%	0.112
	no revision (n, %)	48	84.21%	14	100.00%	
Approach	endaural (n, %)	9	15.79%	5	35.71%	0.093
	postaural (n, %)	48	84.21%	9	64.29%	
Peroperative inflammation	(n, %)	3	5.26%	1	7.14%	0.785
Ossicular mobility	mobile chain (n, %)	48	84.21%	12	85.71%	0.889
	fixed chain (n, %)	9	15.79%	2	14.29%	
Implant type	Xenograft (n, %)	31	54.39%	7	50.00%	0.768
	Allograft (n, %)	26	45.61%	7	50.00%	
Postoperative myringitis	(n, %)	5	8.77%	2	14.29%	0.618
Postoperative blunting/ lateralisation	(n, %)	8	14.04%	1	7.14%	0.507
Postoperative PTA	median dBHL, IQR	25.00	18.85	26.50	21.60	0.965
Postoperative ABG	median dBHL, IQR	11.70	11.60	10.85	12.68	0.823
Pre-post PTA	median dBHL, IQR	-6.70	15.80	-8.30	10.95	0.778
Pre-post ABG	median dBHL, IQR	-6.70	15.15	-8.30	12.75	0.654

Data are presented as median (IQR) unless otherwise stated.
ABG: air-bone gap; COM: chronic otitis media; IQR: interquartile range; PTA: pure tone audiometry.

The mean postoperative hearing level and ABG were significantly reduced in both groups compared to preoperative measurements. In the XG group, the mean hearing gain after surgery was 7.55 ± 1.42 dBHL, and the mean ABG improvement was 7.69 ± 1.45 dBHL ($p<0.001$). In the AG group, the mean hearing gain after surgery was 7.42 ± 2.05 dBHL, and the mean ABG improvement was 7.58 ± 1.86 dBHL ($p = 0.001$). The audiometric outcomes were not significantly different between the XG and AG groups (Table 1).

Single variable analysis for type I tympanoplasty graft success

Except for postoperative myringitis, the XG and AG groups did not show significant differences in the analysed variables. Accordingly, we analysed preoperative, perioperative, and postoperative variables in the entire patient cohort (n = 71) to determine whether they influenced the efficacy of myringoplasty (Table 2). None of the variables we analysed were statistically significant predictors of graft success, and age did not show any significant effects using either a cut-off age of 9 years ($p = 0.282$) or 18 years ($p = 0.678$). In addition, within the XG and AG groups, these variables were not significantly associated with graft failure or success.

The effect of ossicular fixation on audiometric results and graft success

The presence of ossicular mobility problems during surgery had a considerable influence on the functional outcome (Table 3). Although all patients demonstrated intact ossicular chains on CT scan, in 11 cases an ossicular immobility [6 cases (18%) in the AG group and 5 cases (13%) in the XG group] was found during surgery that was caused by intratympanic tympanosclerosis. The mean preoperative PTA was considerably lower in these cases (58.82 ± 5.32 dBHL), and the mean preoperative was ABG higher (32.90 ± 3.70 dBHL). The mean postoperative PTA was 55.15 ± 6.32 dBHL and the mean postoperative ABG was 6.54 ± 3.79 dBHL; neither changed significantly after surgery ($p = 0.440$ and $p = 0.085$, respectively).

Considering all 71 myringoplasty cases together, the 80th percentile for postoperative ABG was 20 dBHL; this dropped to 46.2 dBHL in ears with ossicular problems. Otherwise, in the 60 cases with normal ossicular mobility, the mean ABG improved significantly postoperatively by 7.84 ± 1.19 dBHL ($p<0.001$). The mean postoperative PTA decreased to 25.17 ± 1.48 dBHL ($p<0.001$). A fixed ossicular chain was more common in older patients (median: 43 versus 25 years; $p = 0.029$) (Table 3).

Although graft success was not significantly impaired by the presence or absence of ossicular fixation ($p = 1.00$), further analysis demonstrated that patients with a fixed ossicular chain due to intratympanic tympanosclerosis were more prone not only to myringitis ($p = 0.035$) but also to graft lateralisation and blunting ($p = 0.013$) (Table 3).

Discussion

The primary aim of myringoplasty is to repair the tympanic membrane to prevent infections of the middle ear. Its secondary aim is to improve hearing levels. Different graft materials can be used in myringoplasty. Fascia temporalis is used most often as it is easy to work with and has a good success rate. A systematic literature review by Lacovou *et al.*[5] reported an 84% success rate with fascia temporalis. In more recent years, fat and cartilage have also been used as graft materials with very good results. Kalcioglu *et al.*[6] reported a 94% graft success rate with cartilage, and Yilmaz *et al.*[7] reported that cartilage from the tragus is easily accessible and produces better postoperative hearing results than fascia. This trend was confirmed in a meta-analysis by Tan *et al.*[8]

In the present study, statistically similar results were achieved in the XG and the AL groups: the success rate was 82% for xenograft tympanoplasty and 79% for allograft tympanoplasty. De Dorlodot *et al.*[9] reported a comparable success rate of 75.8% in a study in which 66 patients received bovine xenografts. The success rate of myringoplasty using human allografts has been reported to be as high as 92%.[10]

The use of autografts involves an additional surgical step, resulting in a longer surgery and in the possibility of complications related to graft harvesting, such as pain, infection, or haematoma. The use of an allograft or xenograft reduces the potential for these complications. However, human allografts are expensive and are not easy to obtain in most countries. In contrast, xenografts are more readily available. As early as 2006, Gérard and Gersdorff reported that myringoplasty with a bovine xenograft yields similar anatomical and audiological results as myringoplasty with fascia temporalis, perichondrium, or tragal

Table 3

Analysis of the association of the indicated variables with ossicular mobility in myringoplasty.

Variable		Mobile chain		Fixed chain		p-value
		(n=60)		(n=11)		
Age	median years. IQR	24.94	15.07	42.92	40.98	0.029*
Follow-up	median days. IQR	149.50	400.50	312.00	657.00	0.144
Perforation size	perforation size < 50% (n, %)	37	61.67%	5	45.45%	0.305
	perforation size > 50% (n, %)	23	38.33%	6	54.55%	
Perforation location	inferior perforation (n, %)	28	46.67%	4	36.36%	0.492
	subtotal or central perforation (n, %)	20	33.33%	4	36.36%	
	posterior perforation (n, %)	15	25.00%	6	54.55%	
	anterior perforation (n, %)	9	15.00%	0	0.00%	
Otorhea	dry < 3 months (n, %)	14	23.33%	5	45.45%	0.150
	dry > 3 months(n, %)	46	76.67%	6	54.55%	
Smoking habits	smoking (n, %)	14	23.33%	0	0.00%	0.106
	non-smoking (n, %)	46	76.67%	11	100.00%	
Status of the other ear	pathology inother ear (n, %)	27	45.00%	4	36.36%	0.745
	normal other ear (n, %)	33	55.00%	7	63.64%	
Side	left (n, %)	28	46.67%	8	72.73%	0.194
	right (n, %)	32	53.33%	3	27.27%	
Cause of the perforation	traumatic (n, %)	9	15.00%	0	0.00%	0.194
	COM (n, %)	51	85.00%	11	100.00%	
Preoperative PTA	median dBHL, IQR	30.00	18.20	55.00	22.00	0.000**
Preoperative ABG	median dBHL, IQR	18.30	13.40	31.70	25.40	0.001**
Revision status	revision (n, %)	7	11.67%	2	18.18%	0.622
	no revision (n, %)	53	88.33%	9	81.82%	
Approach	endaural (n, %)	12	20.00%	2	18.18%	1.000
	postaural (n, %)	48	80.00%	9	81.82%	
Peroperative inflammation	(n, %)	4	6.67%	0	0.00%	1.000
Closure rate	(n, %)	48	80.00%	9	81.82%	1.000
Implant type	Xenograft (n, %)	27	45.00%	6	54.55%	0.560
	Allograft (n, %)	33	55.00%	5	45.45%	
Postoperative myringitis	(n, %)	4	6.67%	3	27.27%	0.035*
Postoperative blunting/ lateralisation	(n, %)	5	8.33%	4	36.36%	0.013*
Postoperative PTA	median dBHL, IQR	23.15	16.28	50.00	24.00	0.000**
Postoperative ABG	median dBHL, IQR	10.95	9.68	23.30	0.40	0.000**
Pre-post PTA	median dBHL, IQR	-7.65	14.98	-2.00	15.30	0.294
Pre-post ABG	median dBHL, IQR	-8.30	15.00	-4.60	16.70	0.656

Data are presented as median (IQR) unless otherwise stated.
ABG: air-bone gap; COM: chronic otitis media; IQR: interquartile range; PTA: pure tone audiometry.

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perichondrium-cartilage.[11] They further reported that the use of bovine xenograft reduces wound complications due to autograft harvesting and reduces the negative cosmetic and psychological impact of myringoplasty.

In the past, there were concerns about the safety of xenografts and human allografts because of the risks of transmitted diseases. The process used to prepare Tutoplast® allografts thoroughly inactivates pathogens, destroys cells, and removes cell residues; notably, there are no confirmed cases of disease transmission associated with Tutoplast® use in the past 35 years (Taureon, Rijswijk, The Netherlands). Finally, the techniques used to prepare human allografts and the safety procedures used during their preparation are legally regulated and guarantee a high degree of safety.

The mean postoperative hearing gain was 7.55 dBHL in the XG group and 7.42 dBHL in the AG group. A study by Phillips *et al.*[12] showed a comparable improvement of 9.14 dB after primary myringoplasty using fascia or cartilage. However, the presence of tympanosclerosis in the middle ear, which was diagnosed during surgery in 15% of the cases, considerably affected the functional outcomes in that study. Kinney found postinflammatory ossicular fixation due to intratympanic tympanosclerosis in about 20% of his tympanoplasty cases.[13] The presence of tympanosclerosis and ossicular fixation is reflected in differences in hearing outcome: a hearing gain of 8.19 dBHL was found when myringoplasty was performed in ears with a mobile ossicular chain, while the hearing gain was only 3.66 dBHL in ears with fixed ossicles.

Concerning the functional results, the 80th percentile for postoperative ABG for all myringoplasty cases was 20 dBHL in the present study. Claes *et al.*[10] reported that an ABG of 21 dBHL or less was achieved by allograft surgery in 80% of their cases. In the present study, there were considerably more cases of myringitis in the postoperative period in the AG group than in the XG group (18.2% versus 2.6%; $p = 0.044$). This finding could be linked to intratympanic tympanosclerosis and subsequent ossicular fixation. The presence of tympanosclerosis in the middle ear appears to increase the likelihood not only of postoperative graft inflammation but also of graft lateralisation and blunting in the AG group. Although intratympanic tympanosclerosis was similar in in the XG group, postoperative myringitis was observed in only 1 case.

It is possible that allograft vascularisation is diminished by tympanosclerotic involvement. Tympanosclerosis is most often seen in older patients, as in our cohort. It is characterized by the progressive deposition of hyaline material around the tympanic membrane and by hypertrophic submucosa in the middle ear cavity due to inflammation.[14] Calcification around the tympanic membranes and ossicles limits their mobilization, leading to conductive or mixed hearing loss.

The variables we studied were not significantly different between the XG and AG groups except for approach and perforation size and location; notably, these factors influence the surgeon's choice of graft. Specifically, allografts were chosen more frequently then xenografts for bigger perforations and for perforations that were more anteriorly situated. In contrast to xenografts, allografts were always placed using a postaural approach.

As in the present study, a meta-analysis by Tan *et al.*[8] found that the presence of discharge in ears did not significantly influence the primary outcome when fascia, cartilage, or fat was used for the graft. No individual studies assert that perforations that are wet have a lower success rate for closure. A study by Shankar *et al.*[15] of 35 wet and 35 dry ears that underwent myringoplasty with fascia found no differences in the two groups in terms of successful outcome. Furthermore, a study by Carr *et al.*[16] of 394 patients and another study by Mills *et al.*[17] found no difference in closure rates in active versus inactive chronic otitis media. Although it is not strictly necessary for surgical success, it seems reasonable to try to create a dry ear preoperatively.

We found that the status of the other ear and the cause of the perforation did not affect the primary outcome. Claes *et al.*[10] studied 181 cases that underwent allograft myringoplasty and found that the contralateral pathology did not influence the 1-year or 3-year postoperative status of the eardrum. In contrast to Tan *et al.*[8], we did not find that larger perforation size had a significantly negative effect on graft success: size did not matter in the XG group ($p = 0.283$) or in the AG group ($p = 0.953$), even though larger perforations were more often treated with an allograft than a xenograft (Table 1). The present analysis indicates that xenografts and allografts may be less sensitive to graft failure in larger perforations.

Smoking status did not influence graft success in our study, but Uguz *et al.*[18] reported that smokers have a significantly lower success rate (52% in smokers versus 77% in non-smokers) when fascia is used for tympanoplasty. Phillips *et al.*[12] found the same success rate in smokers and non-smokers (90%) at a 6-month postoperative interval in 495 cases, but they cautioned that longer-term follow-up might show different results.

The state of the contralateral tympanic membrane did not have a statistically significant effect on graft success in the present analysis. This is in accordance with studies by Carr *et al.*[16], Claes *et al*.[10], and Albera *et al.*[19], but not in accordance with a study by Onal *et al.*[20]

As in the study by Tan *et al.*[8], we did not find that follow-up time significantly affected surgical success. Notably, in our population, graft failures were always found in the first weeks after surgery and were due to inadequate vascularisation. The literature indicates that paediatric myringoplasty has a greater failure rate than adult myringoplasty. For example, Rosendom *et al.*[21] reported higher rates of persistent and recurrent perforation in patients under 9 years old. The meta-analysis by Tan *et al*.[8] found that age was a significant factor when a cut-off age of 18 years was used. In our study, we did not find a significant age effect using a cut-off age of either 9 or 18 years. Additional studies are needed to determine a recommended minimum age for tympanoplasty.

Conclusion

To our knowledge, this is the first study to compare xenografts and allografts in type I tympanoplasty. Bovine xenografts and human allografts can safely be used as graft materials in myringoplasty as they have acceptable closure rates and show functional results that are similar to those of autograft materials like fascia, fat, and cartilage. Our results indicate that xenografts and allografts may be less sensitive to graft failure in larger perforations. Both graft materials represent valuable alternatives in selected cases. Graft outcome was not influenced by the studied factors except for the presence of postoperative myringitis, which was more frequently observed when tympanosclerosis was found in the middle ear. The postoperative hearing results were also significantly affected by the status of the ossicular chain.

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