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Review Article

Ear, Nose and Throat Section

Indian Perspectives on Graft Materials Used for Repair of Tympanic Membrane

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ABSTRACT

Introduction: Repair of Tympanic Membrane (TM) is one of the most common surgeries performed by the otologists. Literature reveals that Indian surgeons have contributed substantially in the research on techniques and graft materials used for the repair of tympanic membrane, though no review has been written so far highlighting their contributions.

Aim: To summarize and analyse the contributions of Indian authors who have used different graft materials for repair of TM and their studies listed in Medline search.

Materials and Methods: A literature review was conducted using a Medline search using keywords of 'myringoplasty' and 'tympanoplasty' with 'India' on 30th June 2016. A total of 243 articles were found listed onwards from year 1998. Out of these 50 articles in which type 1 tympanoplasty or myringoplasty was performed using different graft materials were selected. The content of each abstract was studied in order to identify studies related to topic.

Results: Authors have experimented with a variety of tissues as graft materials. Temporalis Fascia (TF) has been most widely used in 58.6% studies as graft material. The next popular graft is tragal perichondrium. The graft take up rates varied from 68.5% to 100%, while method of reporting of hearing gain in most studies was inconsistent amongst studies, though most studies have reported achievement of serviceable hearing of < 25 dB in most patients.

Conclusion: TF was the most prefered material due to anatomic proximity, light material and strength. It was followed in popularity by tragal perichondrium and tragal cartilage. All graft materials have given satisfactory hearing results.

Keywords: Accelerated failure time, Extended cox models, Frailty models, Multistate models

INTRODUCTION

The surgery of tympanoplasty, which involves repair of middle ear hearing apparatus, that has evolved from the basic techniques of repair of the eardrum, which we call as myringoplasty. Banzer was the first to attempt repair of perforated TM with pig's bladder in 1640. The first true tympanoplasty was performed by Berthold in 1878, using de-epithelised TM [1]. The new era of modern tympanoplasty began with the advent of operating microscope, microscopic instruments, and antibiotics in 1950s. Zollner F (1955) and Wullstein H (1971) had earlier described overlay techniques using skin grafts [2,3]. In 1960s the overlay technique consisted of removing the surface epithelium of the TM and placement of the graft lateral to the perforation. Shea first originally described Underlay Technique (UT) using vein and fascia [4]. Various techniques besides the above like sandwich, crown cork, swing door, laser assisted, micro-clip, fascial pegging, annular wedge, loop, umbrella graft tympanoplasty etc have been described as subsequent modifications of the above [5].

There had been several contributions from India in the history of tympanoplasty, though no historical review has been so far written that highlights them. This article was aimed to summarize the contributions of Indian authors who have experimented with various graft materials for repairing of TM through different techniques of type 1 tympanoplasty (T1-TP) and myringoplasty. Since summarising entire literature available on all search engines was not possible in an article, authors have limited the review to articles indexed in Medline search only.

MATERIALS AND METHODS

A literature review was conducted using a Medline search using keywords of 'myringoplasty' and 'tympanoplasty' with 'India' respectively on 30th June 2016. All articles published from India were written in English language. Though no restriction of the time was followed, the first article available on the subject was dated back to year 1998 [6]. A total of 243 articles were found, of which 50 articles [6-55] which described the use of different graft materials for repair of TM through T1-TP, were selected. The articles which did not include T1-TP or myringoplasty were not included. Data were collected by the first author with the rest of the authors arbitrating disparities of opinion.

The content of each abstract was studied in order to identify studies related to topic. All chosen articles were read in full and their references were examined to identify publications of relevance. The authors have provided a chronological account of the works published by different authors while experimenting with the techniques of eardrum repair in relation to their preference of different graft materials. For categorization, the description has been divided into three subtitles: Experiments with TF, experiments with cartilage and perichondrium and miscellaneous graft material.

RESULTS

Experiments with Temporalis Fascia

The earliest report available on Medline search is that of Bajaj Y et al., in 1998 who reported results of T1-TP with TF in children. In year 1999, Mathai J published the results of myringoplasty done with UT using TF, both claimed excellent graft take up rates [6,7].

The first and second decade of 21st century saw a lot of development on tympanoplasty with majority of authors preferring TF over other options. Singh M et al., compared UT and overlay technique for the first time and concluded that UT is a better technique in terms of ease of surgery, time consumption, time of healing and complication

rate. They however concluded that graft take up rates for both groups were not different [8]. In the year 2004, Roychoudhry BK published a report about an experiment they conducted in which a three flap tympanoplasty was performed (posterior, inferior, and posterior tympanomeatal flaps) in patients having subtotal or large perforations in TM with anterior canal wall bulge. They concluded that this was an effective technique in patients where anterior margin was lacking or there was a bony bulge in anterior canal wall [9]. In 2005 Singh GB et al., performed T1-TP in paediatric and adult patients and found that the graft take up rate to be better in the latter. They recommended that the repair can safely be performed from the age of eight years and above with equal results [10]. Later in the year Sethi A et al., published a report in which they performed myringoplasty with UT, with the aim to find out the relation between the size of mastoid air cell system and success of myringoplasty. They concluded that there is no definite relationship between the two, also that there is no correlation between the eustachian tube functional status and the degree of mastoid pneumatization [11]. In 2006 Vijayendra H et al., suggested that the avascular edges of dry central perforations should be excised for good results [12]. Later in 2007 Mishra P et al., published a prospective study in which they performed underlay tympanoplasty in patients with subtotal perforations. They incised the external auditory canal skin from 12'O clock to 1'O clock position just medial to the TM [13]. In 2008 Vijayendra H et al., published an article comparing the hearing results of T1-TP with and without canalplasty, concluding that regular canalplasty can be done by drilling the bony external auditory canal gave additional 9dB hearing gain [14]. Later in the same year Harugop AS et al., performed endoscopic assisted myringoplasty and compared with the results of microscopic assisted myringoplasty in same number of patients [15].

In 2009, numerous articles were published on different aspects of tympanoplasty most of which used TF as graft material. Yadav SPS et al., reported satisfactory results of endoscopic tympanoplasty in 50 cases using inlay technique without raising tympanomeatal flap, in perforations less than 5 mm in diameter [16]. Prasad KC et al., performed saccharine test for checking mucociliary functions of eustachian tube preoperatively in patients undergoing tympanoplasty and concluded that, T1-TP was successful in 94 % with normal eustachian tube functions and in 68% with partial dysfunction [17]. In a slightly different approach Nagle SA et al., compared the results of T1-TP with UT in 50 cases having dry mucosal COM and 50 cases of mucosal disease with scanty mucoid discharge. They concluded that scanty mucosal discharge does not interfere with the results of surgery [18]. Sharma DK et al., divided 90 patients equally in three groups in which myringoplasty was performed through permeatal, endaural and postaural route. They found that there was no statistical difference was found between success rates of the three groups [19].

Deenadayal DS et al., in 2011 applied isoamyl 2 cyanoacrylate over TF grafts and claimed that this increased graft take up rates to 99% as compared to 80-90% in other studies [20]. In year 2012, a comparative study of efficacy of graft placement with and without anterior tagging of TF graft in T1-TP for mucosal type COM was published by Hosamani P et al. They found that the overall incidence of successful graft uptake was higher in the group where tagging was done and lower in the group where tagging was not done. Moreover, closure of anterior and subtotal perforations was much successful (95.45%) in the first group [21].

Vaidya S et al., in 2014 emphasized the impact of site and size of perforation and concluded that perforations which were involving all four quadrants have maximum residual perforations after the surgery, followed by medium sized perforations [22]. Further evidence to this was provided by Das A et al., in 2015, who measured the area of TMs before repair and found that success rate for pin-point and small perforations was 100%, for medium size 80%, and for large and subtotal perforations 69.2% and 42.9% respectively [23]. Also in 2014 Rai AK et al., reported that there is no significant difference in results when surgery is attempted in both ears in the same sitting than separately [24]. In the same year Patil BC et al., claimed good results with interlay technique in 100 patients having large central perforation [25].

A study published by Batni G and Goyal R in 2015 reported the results of T1-TP and reaffirmed that TF gives best results with UT [26]. Late in 2015, Vadiya suggested that cutting the tendon of tensor tympani to free the handle of malleus in view of correcting the foreshortening to provide the advantage of lever ratio can improve the hearing results of the surgery [27].

In 2016 Singh NK et al., published a comparative study in which the postoperative results of classical postaural UT were compared with permeatal sandwich tympanoplasty. It was found that overall graft taken was better in cases of permeatal sandwich technique as compared to the postaural UT [28]. Murugendrappa MA et al., in 2016 published the results of a comparison between postaural UT and subannular graft tympanoplasty using TF. They extended the tympanomeatal flap from 1'O clock position in posterior wall to 4'O clock position in the anterior wall and claimed that the graft take up improved by circumferential sub annular grafting technique [29].

There has been a considerable debate on the justification of doing a Cortical Mastoidectomy (CM) with T1-TP in the literature though all the publications on the topic have used TF as graft material. In 2002 Krishnan A et al., performed a comparative study and concluded that CM can be considered a good practice when middle ear mucosa is unhealthy, while if the middle ear mucosa is healthy only tympanoplasty is sufficient [30]. However, in a single blinded, randomised controlled study published by Bhat KV et al., in 2009, it was concluded that there was no additional advantage in doing CM with T-1-TP [31]. Similar results were reported by other authors as well [32,33].

Experiments with Cartilage and Perichondrium

Raj A and Meher R in 2001 performed endoscopic myringoplasty using 4 mm diameter endoscopes and reported better results than microscope assisted surgery. They used tragal perichondrium (TP) as graft [34]. Anand TS et al., in 2002 performed myringoplasty making modifications in inlay technique. They harvested Tragal Cartilage (TC) with TP on both sides, and split the edges above and below with knife making the edges look like butterfly. The split edges of graft grasped the edges of perforation in between [35]. Desarda KK et al., in 2005 published an outcome of reconstructive tympanoplasty for safe and unsafe COM. They divided subjects into four study groups depending upon the extent and type of disease and surgery required. In the first group (n=300) myringoplasty was done with onlay technique using TP. The other groups of this study are outside the scope of this review [36]. In 2007, Dhabolker JP et al., reported the results of a comparative study of underlay tympanoplasty done in 50 patients with TF and TP. They evaluated the results based on graft take up rates and closure of air bone gap to more than 10 dB or more. It was inferred that both of the graft materials have comparable results based on parameters considered [37].

In year 2011, Khan MM and Parab SR described sliced composite graft for T1-TP for best post-operative results [38]. Another study evaluating the efficacy of composite graft was conducted by Chhapola and Matta in 2012, in which TF graft and CG were used to repair the perforated TM. Postoperative healing, rate of retraction and re-perforation was compared for both materials. The results in this study indicated that composite graft had an edge over TF in terms of graft take up rates and hearing gain [39]. Another article was published by Shetty S which aimed at finding the post operative hearing improvement in patients having COM with pure conductive hearing loss, using different type of tympanoplasties. They used TF

and CG for TM repair. They reported a gain of 18.8 dB in type 1, 26.46 dB in type II and 20.27 dB gain type III tympanoplasty [40].

Year 2013 witnessed some interesting developments along with reports which more or less testified the conclusions drawn in the previous literature. Mundra RK et al. in 2013 experimented by placing a semi-lunar shaped curved slice of TC from anterior part of hypochondrium to the anterior part of attic placed under the TF graft to repair subtotal perforations of TM. Air-bone gap of less than 20 dB was reported in only 56.3% of the patients [41]. In the same year Raghuvanshi SK and Asati DP, advocated the bilateral tympanoplasty in the same sitting in patients having bilateral perforations using TF and TP [42].

Kulkarni S et al., in a retrospective study published in 2014 reported that for type I tympanoplasty done in large central or subtotal perforations semi lunar shaped sliced TC support for fascia graft was a very reliable technique [43]. In another report Vashishth A et al., used full thickness broad cartilage palisades with perichondrium placed in underlay or overlay fashion, and TF placed by UT, separately in two groups of patients. They reported that cartilage palisades are more effective in terms of graft take up rates and hearing gain than fascia [44].

A retrospective study was published by Khan MM and Parab SR in 2015, where 223 ears with perforated TMs were repaired using sliced TC, while in 167 cases TF was used. After a follow up of

No.	Author	Year	n	Follow up period	Surgery	Take up Rates (%)	†ABG (%)	
							<10 dB	<25 dB
1	Bajaj Y et al., [6]	1998	45	NR	T-1	91.1	NR	NR
2	Mathai J. [7]	1999	200	5 years	M and T-1	95	NR	NR
3	Krishnan A et al., [30]	2002	44	2 years	T-1	82	NR	74
			76	2 years	T-1 + CM	95	NR	95
4	Singh M et al., [8]	2003	60	6 months	T-1	93.3	NR	NR
5	Roychoudhry BK [9]	2004	450	2 years	Type I T	94.4	87	12
6	Singh GB et al., [10]	2005	20†	6 months	T-1	80	NR	NR
			20††	6 months	T-1	85	NR	NR
7	Sethi A et al., [11]	2005	50	8 weeks	M	76	26.3	24.2
8	Vijayendra H et al., [12]	2006	20¥	NR	M	NR	NR	NR
			20¥¥	NR	M	NR	NR	NR
9	Dabholkar JP et al., [37]	2007	25	3 months	T-1	84	76	NR
			25	3 months	T-1	80	75	NR
10	Mishra P et al., [13]	2007	100	NR	T-1	97	NR	NR
11	Vijayendra H et al., [14]	2008	200	NR	T-1	NR	NR	NR
12	Harugop AS et al., [15]	2008	50	6 months	T-1 (E)	82	46	44
			50	6 months	T-1	86	20	70
13	Bhat KV et al., [31]	2009	35	6 months	T-1 + CM	82.8	NR	NR
			33	6 months	T-1	78.8	NR	NR
14	Yadav SPS et al., [16]	2009	50	>8 weeks	M	80	80	95
15	Prasad KC et al., [17]	2009	86	6 months	T-1	84.9	NR	79
16	Nagle SK et al., [18]	2009	50	12 weeks	T-1	88	16	88
			50	12 weeks	T-1	74	14	74
17	Sharma DK et al., [19]	2009	90	12 weeks	M	81	NR	NR
18	Ramakrishnan A et al., [32]	2011	31	3 months	M+CM	96.77	NR	NR
			31	3 months	M	93.55	NR	NR
19	Deenadayal DS et al., [20]	2011	542	3 months	M	99	NR	NR
20	Hosamani P et al., [21]	2012	33	6 months	T-1 ££	96.96	NR	NR
			27	6 months	T-1 £	81.5	NR	NR
21	Kamath MP et al., [33]	2013	60	3 months	T-1	80	NR	NR
			60	3 months	T-1+ CM	88.33	NR	NR
22	Vaidya S et al., [22]	2014	100	3 months	T-1±CM/MRM	86	NR	NR
23	Rai AK et al., [24]	2014	30	6 months	T-1	90	NR	90
			30	6 months	T-1 B/L	93	NR	94
24	Patil BC et al., [25]	2014	100	3 months	T-1	96	76	94
25	Kolo ES et al., [55]	2014	26	6 weeks	T (type NR)	NR	NR	NR
26	Batani G and Goyal R [26]	2015	100	1 year	T-1	88	NR	NR
27	Das A et al., [23]	2015	60	6 months	M	80	NR	NR
28	Vadiya S [27]	2015	42	6 months	T-1	95.24	NR	NR
			42	6 months	T-1	92.86	NR	NR
29	Singh NK et al., [28]	2016	52	21 days	T-1/2/3 (ST)	92.3	NR	NR
			48	21 days	T-1/2/3 (UT)	64.58	NR	NR
30	Murugendrappa MA et al., [29]	2016	88	6 months	T-1	88	NR	NR
			90	6 months	T-1	90	NR	NR

[Table/Fig-1a]: List of authors (arranged in order of year of publication) who used temporalis fascia.
n = number of ears, NR= Not Reported, T= Tympanoplasty, M= Myringoplasty, E= Endoscopic, CM= Cortical mastoidectomy, MRM= Modified radical mastoidectomy, ST= Sandwich technique, TF= Temporalis fascia, TC= Tragal cartilage, TP= Tragal perichondrium, CG= Composite graft, FL= Fascia lata, FG= Fat graft, AD= Acellular dermis, VG= Vein graft, †Air Bone Gap average at 0.5, 1, 3 KHz on post-operative pure tone audiometry, *Animal experiments on Mongrel Dogs, † Patient age group 8 to 14 years, †† Patient age group more than 14 years, ¥ Dry ears, ¥¥ Wet ears, £ With anterior tagging, ££ Without anterior tagging

No.	Author	Year of publication	n	Follow up period	Graft material	Surgery	Take up Rates (%)	†ABG (%)	
								<10 dB	<25 dB
1	Raj A and Meher R [34]	2001	21	3 months	TF	T-1	90	NR	NR
			21	3 months	AD	T-1	95	NR	NR
2	Anand TS et al., [35]	2002	20	6 months	TF, TC	T-1, 2, 3	90	30	80
3	Indorewala S et al., [48]	2004	11	NR	FL*	M	NR	NR	NR
4	Chalishazar U [49]	2005	20	6 months	FG	M	90	NR	NR
5	Desarda KK et al., [36]	2005	300	2-4 years	TP	M	96	NR	NR
6	Dhabolkar JP et al., [37]	2007	25	3 months	TF	T-1	84	76	NR
			25	3 months	TP	T-1	80	75	NR
7	Khan MM and Parab SR [38]	2011	223	2 years	TC & TP	T-1	98.20	NR	NR
8	Chhapola S and Matta I [39]	2012	71	2 years	TF	T-1	85.5	78	NR
			61	2 years	CG	T-1	98.36	82	NR
9	Shetty S [40]	2012	45	24 weeks	TF & CG	T-1, 2, 3	94	NR	NR
10	Mundra RK et al., [41]	2013	94	6 months	CG	T-1, 2, 3, 4	98.94	NR	84.75
11	Raghuvanshi SK et al., [42]	2013	64	1 year	TF, TP	T-1	93.75	70	91.6
12	Mane R et al., [51]	2013	28	20 months	TF, FL	T-1	96	92	100
13	Parida PK et al., [52]	2013	30	3 months	TF	T-1	80	60	NR
			30	3 months	VG	T-1	83	66	NR
14	Mukharjee M and Paul R [53]	2013	50	3 months	FG	M	92	NR	NR
15	Kulkarni S et al., [43]	2014	748	24 months	TF, TC	T-1	98.3	NR	NR
16	Vaidya S et al., [22]	2014	100	3 months	TF, TC	T-1, 2, 3+ CM/MRM	86	NR	NR
17	Vashishth Aet al., [44]	2014	30	48 weeks	CG	T-3	90	NR	NR
18	Khan MM and Parab SR [45]	2015	223	4 years	TC	T	97.75	NR	NR
			167	4 years	TF	T	82.63	NR	NR
19	Kulduk E et al., [46]	2015	61	1 year	CG	M (Underlay)	89.1	NR	NR
			53	1 year	CG	M (Overlay)	90.5	NR	NR
20	Indorewala S et al., [54]	2015	789	1 year	FL	T-1	98.6	NR	75.6

[Table/Fig 1b]: The list of authors (arranged in order of year of publication) who used other graft materials with or without temporalis fascia.
n = number of ears, NR= Not Reported, T= Tympanoplasty, M= Myringoplasty, CM= Cortical mastoidectomy, MRM= Modified radical mastoidectomy, TF= Temporalis fascia, TC= Tragal cartilage, TP= Tragal perichondrium, CG= Composite graft, FL= Fascia lata, FG= Fat graft, AD= Acellular dermis, VG= Vein graft, †Air Bone Gap average at 0.5, 1, 3 KHz on post-operative pure tone audiometry, *Animal experiments on Mongrel Dogs

four years, it was reported that the overall success rate in terms of graft take up rate and hearing improvement was higher when sliced cartilage was used than with TF graft [45]. In 2015 Kulduk E et al., compared success rates of underlay and over underlay techniques in patients having large perforations. In the over underlay technique, they placed the graft under the annulus and lateral to the manubrium mallei instead of the medial placement. They used CG from concha with boomerang shaped cartilage for repair. The graft success rate over-UT was reportedly better [46].

Miscellaneous Graft Material

Indorewala S conducted an interesting experiment which was published in 2002 in which they implanted measured autologus TF and Fascia Lata (FL) under subcutaneous pockets in thoracico-abdominal wall of Mongrel dogs. It was found that free FL exhibits significantly superior dimensional stability when compared with free TF during the early healing phase, before graft integration has occurred. Shrinking and thickening of TF are greater and are also more unpredictable [47].

In 2004 Indorewala S et al., kept equal size pieces of TF and FL over bare bone of a cavity created during open cavity mastoid operations in 11 of his patients being operated for Chronic Otitis Media (COM). They removed the fascia after five days and again found that the autologus TF grafts exhibited poor dimensional stability as compared to free autologus fascia grafts [48]. In 2005 Chalishazar U used Fat Graft (FG) harvested from lobule of pinna to close small perforations of TM [49].

The publications in year 2011 saw a few experiments with the graft material. Raj A et al., conducted a randomized control trail in which they compared the results of Acellular Dermis (AD) which was allograft obtained from cadaveric or donor skin banks, with TF as graft materials. They performed T1-TP through trans-canal route using AD in a group of 21 patients and TF in group of another 21 patients. Interestingly they reported reduction in operating time and postoperative pain in acellular dermis group while there was statistically no significant difference in graft take up rates and hearing improvement. The time and resources consumed in preparation of acellular dermis was however not considered. Thereafter the search of literature mentions no other work in the same topic from India [50].

Mane R et al., in 2013, advocated the bilateral tympanoplasty in the same sitting in patients having bilateral perforations using TF and FL as the graft material with UT and achieved equal results in both [51]. In the same year an interesting study was published by Parida PK et al., in which they compared the results of TF and Vein Graft (VG) harvested from prominent veins on the dorsum of hand as graft material for myringoplasty. They reported higher success rates in terms of graft take up and hearing gain with vein graft [52]. Also, in 2013 Mukharjee M and Paul R reported good results with FG harvested from lobule in small perforations of TM [53].

DISCUSSION

Most authors (97.7%) prefered autologous graft materials used to repair TM. TF was used as a graft material exclusively in 56.8% studies and along with other graft materials in 18.2% of the studies [Table/Fig-1a]. [Table/Fig-1b] shows that TP was the second most preferred graft used in 18.2% studies for the same reasons mentioned for TF. In 11.4% of studies TP was

used along with TC as a CG for increasing the strength of graft material. TP however was exclusively prefered in 4.5% studies only. Fascia lata was used in 6.8% of the studies, though out of these, two studies were published by Indorewala S et al., who has been the main proponent of this graft. Fat graft was used only for repairing small perforations in 4.5% of the studies. The least interest was however shown in VG and AD with one publication for each.

Minimum and maximum graft take up rates reported with TF were 64.58% [28] and 97% respectively [13]. The best take up rates were however claimed as 98.94% for CG [41], although high take up rates of 98.6% were also reported with FL [54]. It was found that method of reporting for hearing gain was not consistent in publications and many authors have not reported percentage of patients achieving air bone gap less than 10 dB or 25 dB after surgery. The best hearing results exclusively with TF and FL were reported as 100% patients under 20 dB and 92% under 10 dB [51], [Table/Fig-1b]. Since most of the work published on the topic under review was not in form of randomised control trials but only case series, therefore only a historical review was possible.

LIMITATION

Limitation of this review is that, due to the voluminous reports published on the topic, authors had to limit their search to articles indexed in Medline Search only, though reports published in other journals are in no way less important contributions.

CONCLUSION

Authors in India have experimented with a wide variety of tissues including vein graft, fat graft, fascia lata, acellular dermis, TF, tragal perichondrium and tragal cartilage, though choice of selection was based on criterion of ease of harvesting, preparation time, placement ease, graft uptake and hearing improvement. However, due to anatomic proximity, light material and strength, TF was the most prefered material which was followed in popularity by TP and TC. All graft materials have given satisfactory hearing results. We suggest that a consistant and uniform system of reporting of hearing gain should be established and followed by all the authors publishing on ear surgeries.

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