

COLLAGEN PATCH REPAIR OF TYMPANIC MEMBRANE PERFORATION

DR.M.K.Rajasekar*

Professor Department Of Ent, Sree Balaji Medical College And Hospital
7, Works Road, Shankar Nagar, Chromepet, Chennai, Tamil Nadu 600044
*Corresponding Author

**DR.Shwetha
Shashikumar**

Department Of Ent, Sree Balaji Medical College And Hospital
7, Works Road, Shankar Nagar, Chromepet, Chennai, Tamil Nadu 600044

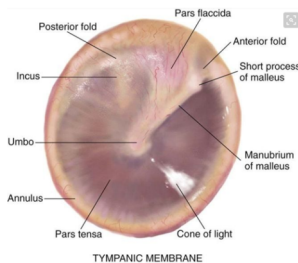
DR.Monica

Department Of Ent, Sree Balaji Medical College And Hospital
7, Works Road, Shankar Nagar, Chromepet, Chennai, Tamil Nadu 600044

ABSTRACT

The aim of this study was to investigate how fibrinogen-based collagen graft repair of central perforation, performed endoscopically improves both hearing and ear discharge.

This study was done to see the effectiveness of closure of small tympanic membrane perforations using collagen patch and was performed on 30 patients. This procedure in all the patients was carried out as an office procedure under local anaesthesia, and all patients included in this study had consented to participate in the study after hearing the merits and demerits of fibrinogen based collagen patch closure of tympanic membrane perforations.

KEYWORDS :**FIG 1: Normal Tympanic Membrane****INTRODUCTION**

One of the common problems in Otorhinolaryngology is perforation of tympanic membrane, may result in hearing loss and persistent otorrhoea when left untreated. Although many small perforations heal spontaneously over time, some may persist due to infection.

Down the century, many graft materials have been used with varying success rates. Graft materials like temporalis fascia, perichondrium, conchal or tragal cartilage, fat, xenografts like porcine small intestine submucosa, and biomaterials like paper patch, gelfoam and hyaluronic acid derivatives, and genetically engineered biomaterials like silk fibroin, calcium alginate, chitosan and collagen have been tried. This study was designed to find out the efficacy of collagen patch technique. The fibrinogen-based collagen consists of a sponge-like patch which is composed of equine collagen and is coated with a mixture of human fibrinogen, bovine thrombin, and bovine aprotinin. Fibrinogen-based collagen adheres strongly to tissue and forms a waterproof membrane.

**FIG 2: Left Tympanic Membrane With Small Central Perforation (anteroinferior - Most Common Location Of Cp)****CASE HISTORY**

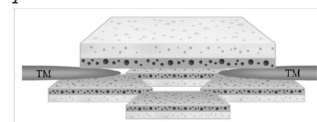
• This study was done over a period of one year (June 2019 –

June 2020) in the ENT department of Sree Balaji Medical College and Hospital, to see the effectiveness of collagen patch in the closure of small tympanic membrane perforations. History was taken, clinical examination, and preoperative work up was done.

- Pure tone audiometry (PTA) was done both preoperatively and postoperatively. A-B gap was estimated at 0.5, 1 and 2 kHz for all the patients in this study.
- 30 patients were included in this study and all patients had consented to participate after hearing the merits and demerits of fibrinogen based collagen patch closure of tympanic membrane perforations.

TECHNIQUE

- This procedure was carried out as an office procedure under local anaesthesia by placing 4% Xylocaine solution soaked cotton ball in the external auditory canal.
- Patients were placed in supine position with head placed over the head ring and turned to opposite side of perforation.
- Under strict aseptic precautions, using Hopkins 0° endoscope, local anaesthesia was given in EAC using 2% Xylocaine mixed with Adrenaline.
- Margin of perforation was freshened using a sharp dissector.
- Collagen sheet was trimmed approximately to twice the size of perforation and put in sterile saline solution.
- The collagen patch was inserted into perforation, such that it sticks to the overlying surface; to keep it in position and to promote healing, pieces of gelfoam were kept on and around the collagen patch.
- All patients were advised to keep the ear dry, avoid straining or nose blowing for atleast 1 month, and to regularly follow up in OPD at the end of 7, 14, 30 and 60 days.
- The appearance of dimeric tympanic membrane was monitored in each follow up.
- Audiometry was done at the end of 1 and 2 months.

**FIG 3: Schematic illustration of placement of the fibrinogen-based collagen. The smaller pieces of the fibrinogen-based collagen were inserted into the middle ear cavity; larger pieces were placed onto the lateral side of tympanic membrane.**

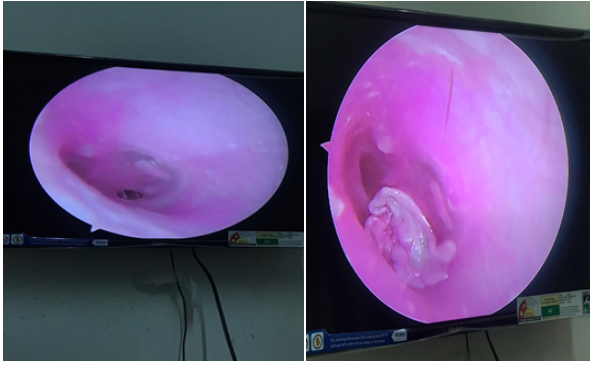


FIG 4: Preop - Left Ear CP

FIG 5: Postop - Collagen Patch Repair Of Left Ear CP

OBSERVATIONS

- The aim of this study was to investigate how fibrinogen-based collagen graft repair of central perforation, performed endoscopically improves both hearing and ear discharge.
- This procedure has an advantage of least pain and trauma to the ear drum due to the absence of skin incisions, meatal flap dissections and fewer complications. Collagen grafts are fully transparent and hence the margins of the perforations can be easily seen by the surgeons. It facilitates monitoring of the postoperative events due to its transparency. These procedures also have an added advantage of maximum improvement of the air-bone gap after the procedure. However, it cannot be always an alternative to the conventional surgical myringoplasty in every tympanic membrane perforation.
- The study consisted of 30 patients, of which 11 were male and 19 were female between the age group 15-50 years. Patients with smaller size perforations were chosen as part of the study. The outcome measures of this study were based on perforation closure, post operative A-B gap, absence of any complications like infection, persisting defect in the tympanic membrane, collagen patch extrusion or otomycosis.

FIG 6: Sex Distribution

SEX	Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Female	19	63.3	63.3
	Male	11	36.7	100.0
Total	30	100.0	100.0	

- Out of the study population, 63.3% were female and 36.7% were male (FIG 6).
- Anterior quadrant perforations were found to be more in our study and the most common were antero-inferior quadrant (50%). 10% cases comprised of Antero-superior quadrant perforation. Superior quadrant perforation was comparatively less in our study. 6.7% cases comprised of posterosuperior quadrant perforation and posteroinferior quadrant perforations were found in 33.3% cases.
- Infective (50%) & traumatic causes (33.3%) of perforation were found at a higher level. Post-myringoplasty cases (16.7%) were found to be less common.

CHI SQUARE TEST

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	30.000 ^a	2	.000	.000	
Likelihood Ratio	36.652	2	.000	.000	
Fisher's Exact Test	29.017			.000	
Linear-by-Linear Association	20.471 ^b	1	.000	.000	.000
N of Valid Cases	30				

Chi-Square Tests	
	Point Probability
Pearson Chi-Square	
Likelihood Ratio	
Fisher's Exact Test	
Linear-by-Linear Association	.000 ^b
N of Valid Cases	

FIG 7: Chi Square Test

- a. 4 cells (66.7%) have expected count less than 5. The minimum expected count is 2.10.
- b. The standardized statistic is -4.524.

2nd MONTH					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Healed cp	7	23.3	23.3	23.3
	Complete Closure	14	46.7	46.7	70.0
	Incomplete Closure	9	30.0	30.0	100.0
Total		30	100.0	100.0	

FIG 8: Table Showing Outcome

Outcome					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Failure	9	30.0	30.0	30.0
	Success	21	70.0	70.0	100.0

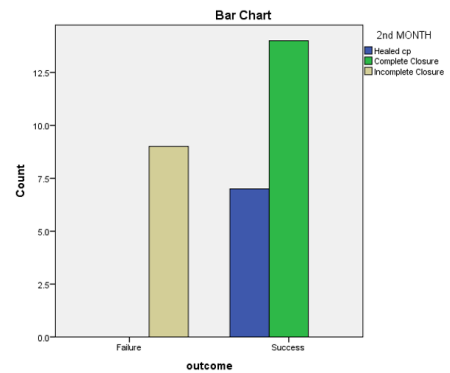


FIG 9: Bar Graph Showing Outcome

- In our study, collagen was found to have 70% success and is a viable graft material for small perforations (FIG 9).
- Traumatic (38.1%) and post-myringoplasty (19%) cases had shown a higher success rate compared to infective group (42.9%).
- Failure rate was higher in infective causes (66.7%) when compared to other causes (traumatic - 22.2%, post myringoplasty - 11.1%).
- In our study, 30% of failure cases were due to collagen extrusion as compared to other causes.
- Audiogram of a patient with 45dB hearing loss. Two months after collagen patch closure of the perforation a gain of 20Db was noted, indicating improvement in hearing.

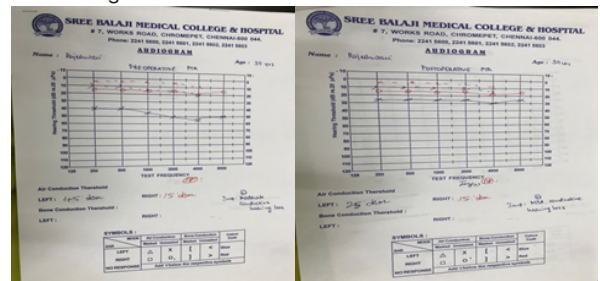


FIG 10: Preop PTA

FIG 11: Postop PTA (After 2 months)

FIG 12: Table Showing Initial And 2nd Month Ab Gap

N	AGE		INITIAL AB GAP (dB)	AB GAP (Db) 2nd MONTH
	Valid	30	30	30
	Missing	0	0	0
Median	36.00	22.00	14.00	
Range	34	8	10	
Minimum	16	18	10	
Maximum	50	26	20	
Percentiles	25	26.25	20.00	12.00
	50	36.00	22.00	14.00
	75	42.00	24.00	16.00

RESULTS

While analyzing the collagen patch uptake, and the preoperative and postoperative air-bone gap, it was observed that 46.7% of the patients (n=14), showed complete closure of the tympanic membrane perforation following collagen patch application. 23.3% of the patients (n=7) showed healed perforation after the 2 month follow up period. Whereas, 30% of the patients (n=9) showed incomplete closure following the procedure. When statistically comparing the uptake of collagen patch between the outcome groups, chi square value was found to be 30.00 which was significant, with a df = 2.

DISCUSSION

Collagen patch closure is a simple, short, cost effective procedure. Fibrinogen-based collagen adheres strongly to tissue and forms a waterproof membrane. Collagen helps maintain the integrity and resilience of the tympanic membrane, which is important in maintaining the physiological functions of normal tympanic membrane. According to this study, collagen was found to have 66.7 % success, making it a viable option for repair of small perforations. Traumatic (38.1%) & post-myringoplasty (19%) cases have shown a higher success rate compared to infective group (42.9%).

The failed cases were mostly of infective origin and 30% was due to extrusion of collagen patch. However these can be minimized with proper postoperative antibiotic cover and care. The hearing improvement in A-B gap during follow up PTA were compared with pre-operative Air Bone gap, the use of collagen patch in the defect showed significant improvement in hearing following the procedure.

No complications had been encountered in the study and patient compliance was comparatively better when compared to myringoplasty as it was less traumatic and time consuming. Collagen patch technique is incisionless and hence less painful and also cosmetically better. Collagen grafts are fully transparent and hence the margins of the perforations can be easily seen by the surgeons. It also facilitates monitoring of the postoperative events due to its transparency. The results of collagen patch repair are better than those of conventional myringoplasty or paper patching in the literatures. Some studies of patch materials to treat the tympanic membrane perforation are listed below (FIG 15).

Author, year	Country	Model	TMP duration	Cause of TMP	Patch material (patient's number)	Control group	Assessment methods	Result
Lee, et al., 2008 ¹⁰	South Korea	Human	Chronic	COM	Paper patch after trimming with CO2 laser (9)	None	Endoscopy, audiometry	Healing rate (n=52): Improvement of ABG in all the cases where the TM healed to normal status.
Hakuba, et al., 2010 ¹¹	Japan	Human	Chronic	COM	Silicone film with tFGF and atelocollagen (87)	None	Endoscopy, audiometry	Healing rate (n=92): Hearing threshold improvement by 10 dB or more in 51 patients. 13.4 dB % of average hearing improvement
Lou and He, 2011 ¹²	China	Human	Acute, <3 days	Trauma	Gelfoam patch (30)	No treatment	Endoscopy, hearing time, infection rate	Healing rate (n=97): 97 (study group), 85 (control group) (p<0.05) Healing time (days): 14.1±5.4, 18±4.7 (study group) & 30±10.1 (control group) (p<0.05) Infection rate (n=3): 3 (study group), 7 (control group)
Saliba and Woods, 2011 ¹³	Canada	Human	Chronic, >4 months	COM	Hyaluronic acid fat graft myringoplasty (131)	Underlay technique with 19/29 overlay technique with 19/17 TP	Endoscopy, audiometry	Healing rate (n=92): 92 (study group), 92 & 92.6 (control group) (p<0.05) ABG (dB HL): clinically and statistically significant improvement in hyaluronic acid fat graft myringoplasty
Araujo, et al., 2012 ¹⁴	Brazil	Human	Chronic	COM	Myringoplasty with polyethylene latex bioceramics (39)	Myringoplasty only, myringoplasty with silicone film	Endoscopy, audiometry	Healing rate (n=74.4): 74.4 (study group), 70.8, 57.1 (control group) (p<0.05) Vascularization: significantly greater in myringoplasty with polyethylene bioceramics ABG (dB HL): 23.5 → 12.9* (study group), 25.2 → 11.9* & 28.5 → 10.1* (control group) (p<0.05) Healing rate (n=92.3): 92.3 (study group), 89.7 (control group) (p<0.74)
Jun, et al., 2014 ¹⁵	South Korea	Human	Acute, <3 months	Trauma	Egg shell	Perforation-edge-approximation	Endoscopy, hearing time	Healing rate (n=42.8): 42.8 (study group), 87.2±41.3 (control group) (p<0.02) Healing rate (n=90.9): 90.9 (study group), 76.7 (control group) (p<0.05) ABG (dB HL): 23.4 → 1* (study group), 26.1 → 5* (control group) (p<0.001)
Smeek and Akin, 2014 ¹⁶	Turkey	Human	Acute, <10 days	Trauma	Paper patch (33)	No treatment	Endoscopy, audiometry	Healing rate (n=90.9): 90.9 (study group), 76.7 (control group) (p<0.05) ABG (dB HL): 23.4 → 1* (study group), 26.1 → 5* (control group) (p<0.001)
Present study	South Korea	Human	Acute & chronic, >14 days	Trauma	Fibrinogen-based collagen fleece (29)	None P ¹⁷	Endoscopy, audiometry	Healing rate (n=100): 100 ABG (dB HL): 13.9 → 2.4*

FIG 15 : STUDIES OF PATCH MATERIAL FOR TYMPANIC MEMBRANE PERFORATION TREATMENT

(Preoperative average ABG → postoperative average ABG. TMP: tympanic membrane perforation, COM: chronic otitis media, ABG: air-bone gap, TM: tympanic membrane, TF: temporalis fascia, TP: tragal perichondrium, bFGF: basic fibroblast growth factor)

CONCLUSION

In this study, we found that using collagen patch as a graft material for the repair of small tympanic membrane perforations is effective. The postoperative Air-Bone gap differed significantly from the preoperative. Furthermore, the technique requires no hospitalization, and can be used to avoid traditional tympanoplasty in cases with small perforations.

REFERENCES

- Wamald PJ. Myringoplasty. In: Bleach N, Milford C, Van Hasselt A, eds. A Operative Otolaryngology. Ch.9: Blackwell Science Ltd., 1997:44-51.
- Kristensen S. Spontaneous healing of traumatic tympanic membrane perforations in man: a century of experience. J Laryngol Otol. 1992;106:1037-1050.
- Chun SH, Lee DW, Shin JK. A clinical study of traumatic tympanic membrane perforation. Korean J Otolaryngol-Head Neck Surg. 1999;42:437-441.
- Lee SH, Jin SM, Lee KC, Kim MG. Paper-patch myringoplasty with CO2 laser for chronic TM perforation. Eur Arch Otorhinolaryngol. 2008;265:1161-1164.
- Hakuba N, Iwanaga M, Tanaka S, Hiratsuka Y, Kumabe Y, Konishi M, et al. Basic fibroblast growth factor combined with atelocollagen for closing chronic tympanic membrane perforations in 87 patients. Otol Neurotol. 2010;31:118-121.
- Lou ZC, He JG. A randomised controlled trial comparing spontaneous healing, gelfoam patching and edge-approximation plus gelfoam patching in traumatic tympanic membrane perforation with inverted or everted edges. Clin Otolaryngol. 2011;36:221-226.
- Saliba I, Woods O. Hyaluronic acid fat graft myringoplasty: a minimally invasive technique. Laryngoscope. 2011;121:375-380.
- Araujo MM, Massuda ET, Hyppolito MA. Anatomical and functional evaluation of tympanoplasty using a transitory natural latex biomembrane implant from the rubber tree Hevea brasiliensis. Acta Cir Bras. 2012;27:566-571.
- Jun HJ, Oh KH, Yoo J, Han WG, Chang J, Jung HH, et al. A new patch material for tympanic membrane perforation by trauma: the membrane of a hen egg shell. Acta Otolaryngol. 2014;134:250-254.
- Levenson MJ. The Management of traumatic perforation of tympanic membrane. In: Blitzer A, Pillsbury HC, Jahn AF, Binder WJ, eds. Office based surgery in otolaryngology. Ch. 15: Thieme Medical Publisher; 1998:95-107.