# Comparative Study of Underlay Tympanoplasty with Temporalis Fascia and Tragal Perichondrium

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#### Abstract:

**Background:** Hearing is a sense that enables man to establish contact with his fellows via speech to experience life more fully. Deafness in varying degrees of severity is a big impediment to the integration of a person into the social structure. The otologist in the past had not much to offer to hearing handicapped people with chronic middle ear disease. With recent times the advent of the antibiotic era, the operating microscope and modern anesthetics techniques aimed at producing a dry, magnified operating field, have radically altered the outlook.

Methods: This study comprises of patients who were subjected to tympanoplasty for the treatment of chronic suppurative otits media. Each patient was subjected to a detail examination of nose, paranasal sinuses and throat to rule out any focus of infection, which could influence the result of tympanoplasty. 20 Patients were subjected to tympanoplasty with temporalis fascia while the remaining 20 patients underwent with tragal perichondrium Tympanoplasty is performed using temporalis fascia in 20 patients and tragal perichondrium in 20 patients in the age group of 15-45 years (males and females both). Patients with the complaint of discharging ear and decreased hearing were also screened.

Results: Majority of the patients shows mild to moderate hearing loss. 47.5% of them had air-one gap up to 20 dB. 52.5% of them had air-bone gap 21-40 dB. None of them had air-bone gap above 40 dB. In the postoperative hearing analysis, 77.5% of the patients showed air- bone gap up to 20dB. 22.5% of the patients showed air- bone gap in the range of 21-40 dB. 80% of the patients operated with temporalis fascia showed air bone gap up to 20dB. 75% of the patients operated with tragal perichondrium showed air-bone gap up to 20dB. Mean improvement in hearing temporalis fascia is 09.5 dB. Mean improvement in hearing using tragal perichondrium is 09.0 dB. Mean improvement in hearing using tragal perichondrium is 09.0 dB.

**Cnclusion:** Tympanoplasty is the most effective method for control of the tubotympanic type of CSOM disease and hearing improvement. Both temporalis fascia and tragal perichondrium are excellent graft materials for closure of perforation of tympanic membrane and hearing improvement. Improvement in hearing is not significantly influenced by duration of disease, age or sex of patients.

Kew Words: Tympanoplasty, Tragal Perichondrium, Temporalis Fascia, hearing

# I. Introduction

Hearing is a sense that enables man to establish contact with his fellows via speech to experience life more fully. Deafness in varying degrees of severity is a big impediment to the integration of a person into the social structure

The otologist in the past had not much to offer to hearing handicapped people with chronic middle ear disease. With recent times the advent of the antibiotic era, the operating microscope and modern anesthetics techniques aimed at producing a dry, magnified operating field, have radically altered the outlook.

Permanent perforation of the tympanic membrane resulting as sequelae of chronic suppurative otitis media is a major cause of deafness. Stalwarts from past as far back as Hippocrates have asserted the same. Controversies range about every step of the operation from the incision to the material used for packing. A great deal of experimental work is being done often with contradictory results.

The first known attempt to close a perforation of tympanic membrane to improve hearing was made by Marcus Banzer in 1640 using prosthesis made of pig's bladder. Since then various graft materials like pig's bladder, Thiersch skin graft, Split-skin graft, Pedicle graft from ear canal skin, temporalis fascia graft, Vein graft, Sclera, Corneal graft, tympanic membrane homograft and perichondrium have been used for closure of the perforated tympanic membrane.

Various autografts have been used for repair of the tympanic membrane perforation like full thickness skin graft, Pedicled skin grafts (Frenckner 1955)<sup>5</sup>, split skin graft (Wullestein<sup>1</sup> 1952 and Zollner<sup>2</sup> 1953), vein graft (Shea<sup>10</sup> 1960), Fascia grafts (Heermann<sup>9</sup> 1960) and Perichondrium (Jansen<sup>19</sup>1963 and Goodhill<sup>22</sup> 1967). Each of these grafts material has its advantages and disadvantages over each other. The healing of tympanic

membrane perforation is preceded by ingrowths of connective tissue edges over which the epithelium migrates to close the perforation. Keeping this physiological principle in consideration it follows that connective tissue grafts, that is grafts of mesodermal origin like vein, perichondrium or fascia, prove superior to all other graft materials. Clinical investigations and animal experiments have shown that these connective tissues replace the missing fibrous element of the tympanic membrane and allow squamous epithelium and mucosal tissue to cover the medial and lateral surface.

Taking the above mentioned facts in consideration, this study was taken up to compare the results of the two connective tissue graft materials, viz temporalis fascia and the tragal perichondrium. The study includes the advantages and disadvantages of these graft materials vis-à-vis to each other.

# **Aims And Objectives**

- 1. To do comparative study of underlay tympanoplasty with temporalis fascia and tragal perichondrium
- 2. We undertook this study to know the outcome of the surgery in respect with:
- Graft uptake.
- > Hearing improvement.
- Complications .

## II. Materials And Methods

- Present study is a prospective trial which was carried out from January 2012 to August 2013 on the
  patients attending the ENT Outpatient Department M.G.M Medical college and Hospital Kamothe
  Navi Mumbai where tympanoplasty is performed using temporalis fascia in 20 patients and tragal
  perichondrium in 20 patients in the age group of 15-45 years (males and females both)
- Patients with the complaint of discharging ear and decreased hearing were screened.
- Patients, in whom tubotympanic type of chronic suppurative Otitis Media was found, were taken for this prospective study with randomization.
- The necessary permission and approval from ethics committee was taken.
- Informed written consents were obtained from the patients involved in the study according to the protocol approved by the Ethics Committee.
- This study comprises of patients who were subjected to tympanoplasty for the treatment of chronic suppurative otits media. Each patient was subjected to a detail examination of nose, paranasal sinuses and throat to rule out any focus of infection, which could influence the result of tympanoplasty. 20 Patients were subjected to tympanoplasty with temporalis fascia while the remaining 20 patients underwent with tragal perichondrium.

# **Criteria for Selection**

# **Inclusion Criteria**

- Unilateral CSOM.
- > The ear should be dry minimum for 6 weeks with intact ossicular chain.
- > Patent Eustachian Tube.
- > Nonhealed traumatic perforation.
- $\triangleright$  Patients of either sex with age group between 15 45 years.
- > Patients willing to give written informed consent.

#### **Exclusion Criteria**

- Unsafe CSOM
- Safe CSOM with sensorineural hearing loss.
- ➤ Patients < 15 years > 45 years.
- Wet ear.
- All ASOM cases.
- Congenital hearing disorder.
- Previous history of ear surgery.

# **Method of Collection of Data**

- All the patients in the study were clinically evaluated by taking detailed history and clinical examination including Tuning fork test as per the proforma.
- Swab of ear discharge was sent for culture of organisms and antibiotic sensitivity.
- Antibiotics according to the sensitivity were given to dry up the ear discharge.
- Dry aural toilet was done to remove debris from ear canal.

- Otomicroscopy was performed.
- Septic foci in the nose or in the throat were treated if present before ear surgery.
- Pure tone audiometry was done as per American speech and hearing association (ASHA).
- For all patients X- ray mastoid were taken (Schuller view)
- Cases then were diagnosed and surgical plan of management was formulated.
- The patients routine Blood tests and urine tests were done for purpose of anaesthesia and to know the general condition of the patient .
- Anaesthesia fitness was done.
- Post operative at 3 months of follow up, patients subjective hearing was enquired and recorded.
- Post operative pure tone audiometry and ear microscopy was done in every case at the end of 3<sup>rd</sup> month to record the hearing and graft uptake respectively.

#### **Operative Procedure**

Patients will be randomized and subjected to tympanoplasty by using tragal perichondrium or temporalis fascia

**Positioning and Preparation:** Patient is put in reversed Trendelenberg position with a head ring. Antiseptic dressing was done with betadine and draping was done.

**Anaesthesia:** Cases were operated under general or local anaesthesia after xylocaine sensitivity test. General anaesthesia was used in apprehensive patients.Local anaesthesia was achieved by using 2% xylocaine with 1:200,000 adrenaline in the subcutaneous tissue of post auricular region and four quadrant of external auditory canal.

# Follow Up:

Patients will be followed up after 1st week, 2<sup>nd</sup>week, one month, and third month after surgery. At follow up patients will be evaluated by otoscopic examination to determine the condition of the graft, pure tone audiometry is done to calculate air bone gap closure will be assessed.

Data Analysis – Observations were tabulated on a spread sheet by using Microsoft excel. Statistical analysis of the patients was carried out with Student't' test and "Z" test. A 'P value'<0.05 was considered statistically significant.

#### III. Results:

# **Table-1: Sex Distribution**

The above table indicates that there were 18 (45%) males and 22 (55%) females. The male to female ratio is 1:1.22.

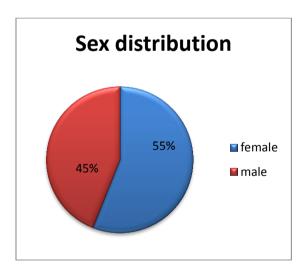


Table-2: Shows Age wise Distribution

18
16
14
12
10
8
6
4
2
0
<20
21 - 30
No of patients

>40

No of patients

Table-3: Preoperative Hearing Levels.

Preoperative	No. of Patients			
Air- Bone Gap	Temporalis Fascia	Tragal Perichondrium	Total	Percentage
<20	10	09	19	47.5%
21-40	10	11	21	52.5%
> 40	0	0	0	0%

Majority of the patients shows mild to moderate hearing loss.

47.5% of them had air-bone gap up to 20 dB.

52.5% of them had air-bone gap 21-40 dB.

None of them had air-bone gap above 40 dB.

**Table-4: Postoperative Hearing Levels.** 

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Postoperative	No. of Patients	No. of Patients		
Air- Bone Gap	Temporalis Fascia	Tragal Perichondrium	Total	Percentage
<20	16	15	31	77.5%
21-40	4	5	9	22.5%
>40	0	0	0	0%

In the postoperative hearing analysis,

77.5% of the patients showed air- bone gap upto 20dB.

22.5% of the patients showed air- bone gap in the range of 21-40 dB.

80% of the patients operated with temporalis fascia showed air bone gap upto 20dB.

75% of the patients operated with tragal perichondrium showed air-bone gap upto 20dB.

Table-5: Postoperative Hearing Levels with Respect to Sex.

Postoperative	No. of Patients			
Air- Bone Gap	Male	Female	Total	Percentage
<20	15	17	32	80%
21-40	3	5	8	20%
>40	0	0	0	0%

In the postoperative hearing analysis.

75% male patients showed air bone gap upto 20dB.

85% female patients showed air bone gap upto 20dB.

**Table 6: Post Operative Hearing Improvement Level** 

Mean change in	No of patients			Donasmtono	
hearing levels in dB	Temporalis fascia	Tragal perichondrium	Total	Percentage	
No change or worsen	4	5	9	22.5%	
1-15	16	15	31	77.5%	
16-30	4	5	9	22.5%	
>30	0	0	0	0%	

Hearing at 3 months, 31 out of 40 patients showed improvement in hearing (77.5%). Out of these patients, 16 out of 20 patients were operated using temporalis fascia showed improvement in hearing i.e. (80%) and 15 out of 20 patients were operated using tragal perichondrium showed improvement in hearing i.e. (75%). There is not much statistical significant difference in hearing improvement, using temporalis fascia or perichondrium for tympanoplasty.

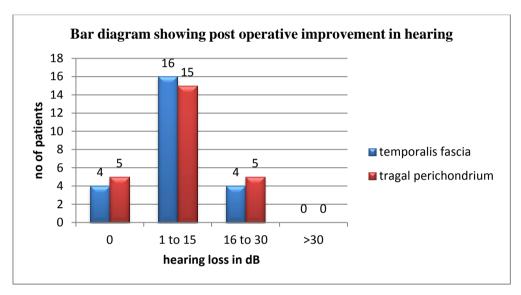


Table 7: Mean Hearing Level in Tympanoplasty using Temporalis Fascia and Tragal Perichondrium

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	Mean levels of hearing				
Type of graft	Preoperative hearing levels	Post operative hearing levels	Post operative change in hearing		
Temporalis fascia	399/20 = 19.99	209/20 = 10.45	190/20 = 09.5		
Tragal perichondrium	452/20 = 22.6	272/20 = 13.6	180/20 = 9		
Total	851/40 = 21.27	481/40 = 12.02	370/40 = 9.25		

- Mean improvement in hearing temporalis fascia is 09.5 dB
- Mean improvement in hearing using tragal perichondrium is 09.0 dB.

P>0.05, we found that there was no statistically difference in mean improvement in hearing using either temporalis fascia or tragal perichondrium.

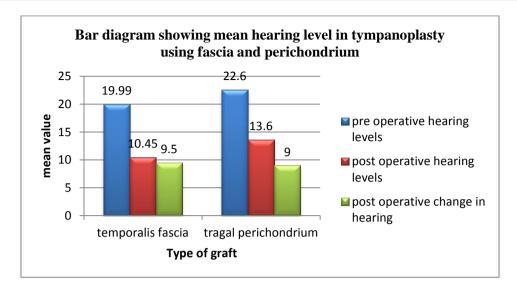


Table no 8: Graft Uptake Rate

Type of graft	Graft uptake	Percentage
Temporalis fascia	16/20	80 %
Tragal perichondrium	15/20	75%
Overall	31/40	77.5 %

The above table indicates that 16 (80%) out of 20 ears operated using temporalis fascia graft healed completely at the end of 3 months with well taken graft.15 (75%) out of 20 ears operated using tragal perichondrium were dry with graft in place at the end of 3 months. No statistical significant association was found in graft uptake with respect to type of graft (P>0.05). Z=0.36, p>0.05

Most of the smaller perforations here were taken for tympanoplasty when they failed to respond to medical treatment and weekly trichloro – acetic acid cautery or when patient cannot come for repeated sittings.

# **Factors Affecting Graft Take Rate**

Age and sex of the patients were also compared with graft take rate:

Table 9: Graft Uptake Rate with Respect to Age of the Patients (n = 40).

Age in years	No of patients	Percentage %
≤ 20	4/6	66.66
21 – 30	14/16	87.5
31 – 40	6/8	75
>40	7/10	70

From the above table it is seen that maximum graft uptake rate observed in the age group 21-30 years (87.5%).

Table 10: Graft uptake Rate With Respect to Sex (n = 40).

Sex	Graft uptake	Percentage %
Male	14/18	77.77%
Female	17/22	77.27%

The above table shows that graft uptake rate was 77.77 % (14 out of 18 ears) in males and 77.27 % (17 out of 22 ears) in female.

Z=0.75, P>0.005

There is no statistical significant difference seen in graft uptake rate in sex.

#### **Discussion** IV.

This is the prospective study of 40 tympanoplasties on patients between the age of 15 to 45 years, who were admitted in the Department Of E.N.T and Head and Neck Surgery at M G M Medical College, Kamothe, Navi Mumbai, between January 2012 to August 2013. This entire study group of patient suffered from Chronic Suppurative Otits Media. Patients in this study were from all socioeconomic groups, including patients referred from other practitioners also.

Conservative measures were first tried in all cases, particularly for small to moderate sized perforations. These included systemic antibiotics, trichloro-acetic acid cautery, repeated aural toilet in ears with active infections. Cases of ear diseases with suspected central septic focus were operated with tonsillectomy, adenoidectomy, septoplasty, etc. as needed before ear surgery, 20 patients were subjected to tympanoplasty with temporalis fascia remaining 20 with tragal perichondrium. Follow up of postoperative cases was for 3months.

# **Duration of Pre operative Dry Ear**

Palva et al (1987)<sup>35</sup> in their study of 165 cases of myringoplasties, which was carried out only when the ear was dry for atleast 3 months success rate was 96%.

Gibb AG, Chang SK (1982)<sup>30</sup> in their study of 206 cases of underlay myringoplasty found the uptake rate of 91.4% for dry ear and 80.9% for wet ear.

Gersdoff M et al. (1995)<sup>51</sup> long term result of myringoplasty in adult and children and found the state of middle ear at the time of operation influences surgical outcome; wet ear have higher rate of reperforation. Brown C et al. (2002) 55 in their study of 165 cases of myringoplasty found success rate 75% if perforation is dry 64 % if perforation is wet.

In our study of 40 cases of tympanoplasty all cases had dry ear preoperatively atleast for 6 weeks hence overall graft uptake rate was 77.5%, which correlates well with the quoted literature.

# **Technical Aspects**

Tympanoplasty is technically more difficult in patients having a narrow canal, undergoing revision surgery, by transcanal approach and in anterior perforations.

Post-auricular approach is commonly used in our institution;

The contour of tragus was found to be satisfactory in postoperative period without any cosmetic deformity.

#### **Graft Uptake Rate**

The graft take rate after 3 months was 77.5%. Similar report was given by Palva T et al (1995)<sup>52</sup> with graft take rate were 97%.

In our study, graft uptake rate for temporalis fascia was 80% as compared to tragal perichondrium was 75%. Graft take-rate was slightly better for temporalis fascia than for tragal perichondrium (not significant p>>0.005). This marginal difference however, is not significant. Various studies showed the grafts uptake was in the ratio of 80 to 90%, for either temporalis fascia or tragal perichondrium.

These reports compare well with similar study conducted by Jyoti P Dabholkar (2007)<sup>56</sup> whose postoperative graft uptake rate with temporalis fascia was 84% and tragal perichondrium showed 80%.

Jain CM (1968)<sup>24</sup> who reports 83.33% success rate with temporalis fascia, Ahad SA (1986)<sup>31</sup>, with 83.30% success with homologous temporalis fascia, Blanshard JD (1990)<sup>41</sup>, 78% take-rate with temporalis fascia in pediatric tympanoplasty. P.K Parida, S.K Nochikattil (2012)<sup>57</sup> in their study found 80% uptake rate with temporalis fascia.

Quraishi et al 50 reported success rate of 94% in 32 cases of primary myringoplasty with tragal perichondrium.

Most of graft failures seen in the follow-up period were due to infection probably transmitted either along Eustachian tube or along external auditory canal.

#### **Hearing Result**

77.5% of cases showed improvement in hearing, while 22.5% of them showed no improvement, at 3 month follow-up period. About 80% cases operated with temporalis fascia showed hearing improvement, while similar percentage (75%) of cases who were operated using tragal perichondrium showed improvement in hearing (statistically not significant p>> 0.05) as shown in the Table-6.

Mean improvement in hearing using temporalis fascia was 09.50 dB and that with tragal perichondrium it is 09.0dB (statistically not significant p>>0.05) as shown in Table -7. These results compare well with Strauss et al (1975) who found that improvement in air bone gap was 15 dB. These result also compare well with Ophir D (1987)<sup>37</sup>, Terry RM (1988)<sup>38</sup>, result with fat myringoplasty.

Hartwein (1992)<sup>46</sup> claims reduction of air bone gap of around 15 dB with tragal perichondrium graft.

Jyoti P. Dabhalkar (2007)<sup>56</sup>reported hearing result in total 50 patients, temporalis fascia group improved in 76% while tragal perichondrium group achieved 75% hearing gain.

This study also compares well with Sunita Chhapola, Inita Matta (2011)<sup>58</sup> whose postoperative hearing assessed after 6 months of surgery, with temporalis fascia graft showed air bone gap of less than 10dB in 82% of patients and more than 10dB in 18% patients, air bone gap closure with tragal perichondrium was less than 10 dB in 78% patients and more than 10dB in 22% of patients.

The patient population attending our hospital was also from low socioeconomic status, many had poor personal hygiene and poor nutritional status. These were probably some of the factors which contribute to graft rejection.

# **Factors Affecting Graft Take-rate**

Size of perforation operated in our study were small / moderate central perforation. Uptake rate was nearly similar for all the sites and sizes of perforations, maximum for perforation in posterior quadrant of the drum , followed by perforation in anterior quadrant of the drum and also perforation in both the quadrants of the drum have healed well. Finally, then take-rate is not influenced by site and size of perforation.

Similar opinion is expressed by Blanshard JD (1990)<sup>41</sup> who opines that age at operation, size of perforation and prior adenoidectomy had no significant influence on the success rate or audiological outcomes. Factor such as duration of illness, age and sex of patients, did not significantly affect graft uptake rate in our study. Vartiainen E (1993)<sup>49</sup> also states that the preoperative factor like dryness or discharging ear, site of perforation of technique (onlay/underlay) do not affect the take rate.

Berger G, et al (1997)<sup>54</sup>, stated that results of myringoplasty were independent of patient's age ,sex, location and size of perforation.

# V. Conclusions

- Tympanoplasty is the most effective method for control of the tubotympanic type of CSOM disease and hearing improvement.
- Both temporalis fascia and tragal perichondrium are excellent graft materials for closure of perforation of tympanic membrane and hearing improvement.
- Graft uptake rate is good for both with slightly better take rates for temporalis fascia, than tragal perichondrium.
- Hearing improvement does not depend on type of graft (No statistically significant difference p>>0.5).
- In our study, uptake rate of graft was neither influenced by the site or size of the perforation.
- Improvement in hearing is not significantly influenced by duration of disease, age or sex of patients.

# VI. Summary

- 40 tympanoplasties were performed on indoor basis.
- Age range from 15-45 years with mean age of patients 29.12 years.
- 18 (45%) males and 22 (55%) females with male to female ratio 1:1.22.
- Majority of the patients preoperatively showed mild to moderate hearing loss. 47.5% patients showed up to 20 dB air bone gap range, 52.5% patients showed 21-40dB air-bone gap and none of the patients showed above 40dB.
- Surgeries were performed by post-aural approach.
- In all surgeries grafts were placed as underlay technique.
- 20(50%) patients were operated using temporalis fascia and 20(50%) patients using tragal perichondrium.
- Graft take rate was overall 77.5%.
- All the patients selected for tympanoplasty had dry ear for atleast 6 weeks which might explain good graft take rate of 77.5%.
- Graft uptake rate was 80% with temporalis fascia and 75% with tragal perichondrium.
- In postoperative hearing analysis, 80% patients showed air-bone gap up to 20dB.
- Overall mean improvement in hearing was 09.25dB.
- Mean improvement in hearing for temporalis fascia was 09.5 dB and for tragal perichondrium was 09.0 dB.
- Uptake rate of graft was not influenced by the size/ site of perforation.
- Improvement in hearing was also not significantly influenced by the type of graft used.

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