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ORIGINAL ARTICLE

A COMPARATIVE STUDY OF THE INTERLAY AND UNDERLAY TECHNIQUES OF TYMpanoplasty TYPE I FOR MANAGEMENT OF TYMpanIC MEMBRANE PERFORATION

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ABSTRACT

Background: The remaining chronic non healing perforations result in recurrent ear discharge causing great discomfort to the patient and decreased hearing.

Objectives: We aimed to assess and compare the results of the underlay and interlay techniques of tympanoplasty type I in cases of medium to large sized dry central tympanic membrane perforation.

Patients and methods: : Prospective study was carried out on 54 patients having medium to large sized central tympanic membrane perforation who were divided randomly into two groups. Group I patients underwent for underlay tympanoplasty type I, while group II patients underwent for interlay tympanoplasty type I. Hearing results were assessed by comparing the preoperative and postoperative pure tone audiogram as well as closure of the air-bone gap.

Results: In terms of graft uptake 3-months postoperatively, in the underlay group, the success rate was 92.6%, while in the interlay group, the success rate was 96.2%. In terms of hearing improvement at the end of the 3rd month, in the underlay group, 40.8% of the patients had hearing gain from 11-20 dB, while in the interlay group, 66.7% of the patients had hearing gain from 11-20 dB.

Conclusion: The success rates for the interlay technique is better than the underlay technique and have been quite promising. Therefore, such technique should be more practiced among the surgeons.

Key Words: Tympanoplasty, Interlay, Underlay, Ear.

INTRODUCTION

Tympanic membrane perforation primarily results from the middle ear infections, trauma, or iatrogenic causes. The majority of these perforations eventually heal spontaneously. However, the remaining chronic non healing perforations result in recurrent ear discharge and decreased hearing (1).

Wullstein classified tympanoplasty into five types. Tympanoplasty type I is used to repair the tympanic membrane perforation. It will award considerable benefits to the patients

including prevention of ear infections and aural discharge, improvement in hearing, and protection against long-term middle ear damage by preventing the ossicular pathology and the migration of squamous epithelium around the margins of perforation with possible consequent cholesteatoma formation (2).

Many surgical techniques of tympanoplasty type I are described. Each technique has its own advantages as well as disadvantages. The underlay technique is considered an easy and

fast technique as the graft is placed below all the three layers of the tympanic membrane with a high graft uptake rate. However, there are chances of graft medialization as well as risks of residual epithelium and anterior blunting⁽³⁾⁽⁴⁾.

In the interlay technique, the graft is placed in between the mucosal layer and fibrous layer of the tympanic membrane. Such mucosal and fibrous layer plane is the most physiological plane for keeping the graft as it is supported on both sides by the outer fibrous layer and the inner mucosal layer. Consequently, it prevents medialization as well as lateralization of the graft, prevents any reduction of the middle ear space, and there are less chances of residual epithelium and anterior blunting⁽⁵⁾⁽⁶⁾.

PATIENT AND METHOD

Patients:

This is a prospective included 54 patients having medium to large sized central tympanic membrane perforation who were selected from the outpatient clinic of Oto-Rhino-Laryngology department Faculty of Medicine, Zagazig University, Zagazig, Egypt during the period from June 2019 to December 2019. The patients were divided randomly into two groups according to the employed surgical technique and each group included 27 patients. Group I patients underwent for underlay tympanoplasty type I, while group II patients underwent for interlay tympanoplasty type I.

Written informed consent was obtained from all participants and the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University. The work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans. Inclusion criteria included patients having a medium to large central tympanic membrane perforation, the ear should be dry for at least six weeks before the surgery, the patient's age was between 14-50 years old, no mastoid opacification on CT scanning of the temporal bone. Exclusion criteria included Patients with cholesteatoma, ossicular discontinuity or necrosis, tympanosclerosis, mixed hearing loss, or past

history of tympanoplasty, mastoidectomy, or ossiculoplasty, also patients with uncontrolled diabetes mellitus, hypertension, or other systemic diseases who were not fit for surgery

Methods:

All patients were subjected to history taking of past ventilation tube, allergic and asthmatic tendencies, history of noise exposure and the duration of such exposure, if the patient underwent tympanic membrane surgery on the same ear previously, history of a bleeding tendency, type and duration of discharge. Also otoscopic assessment of the ear for infection; granulation tissue and TM perforation was done via endoscopic examination of the ear. Figure(1), (2)

Investigations included routine pre operative lab, An average of the four frequencies (500, 1000, 2000, 4000 Hz) was calculated for both the air and bone conduction thresholds to calculate the air-bone gap (ABG), CT temporal bone was done for all patients to exclude extensive ear pathology or cholesteatoma and Eustachian tube function was assessed by instillation of antibiotic ear drop, then instruct the patient to make Valsalva maneuver and inspect the ear canal for bubbling by the otoscope.

The operation was performed under general anaesthesia. Patients were positioned in a supine position with head up and turned to other side then sterilization and draping were performed. Infiltration of the skin using adrenaline dissolved in saline in a concentration of 1:200000 into the incision area and the bony external canal to induce local vasoconstriction and dissection in the field, then microscopic re-evaluation were done.

A post auricular Wilde's incision was made 5 mm behind the post auricular crease starting from the highest point of helix to the mastoid tip. The superior part of skin incision was extended over the temporal region, the fascia over the temporalis muscle was exposed, and an incision was made at the lower margin of the temporalis muscle (linea temporalis). A suitable sized temporalis fascia graft was harvested from the deep layer of the temporalis fascia and was dried in the room

air margins of tympanic membrane perforation were freshened.

The periosteal flap was elevated, posterior meatotomy was made, and a self-retaining mastoid retractor was applied. The margins of the tympanic membrane perforation were excised with the help of a needle and cup forceps in order to refresh the edges of the perforation. Regarding Interlay tympanoplasty technique, The posterior meatal wall skin flap from 1 o'clock position superiorly to 7 o'clock position inferiorly was raised from lateral to medial till the annulus was reached.

Then, the incision was extended anteriorly from 7 o'clock position inferiorly to 11 o'clock position superiorly and the anterior tympano meatal flap was raised from lateral to medial till the annulus is reached. So, the tympano meatal flap was raised all around up to the level of the fibrous annulus with preserving superiorly in the region of head of malleus forming the vascular strip which is the part of canal skin that covers the superior portion of ear canal. Then, the fibrous annulus was taken out of the bony sulcus all around. Thus, the fibrous and squamous layers were lifted off the tympanic membrane remnant along with the annulus leaving the mucosal layer behind.

The ossicles were inspected for continuity and the mobility was checked and confirmed. The tympanic membrane was gently dissected off the malleus handle all around if it was projecting into the perforation. The temporalis fascia graft was placed in such a way that it rested between the fibrous layer and mucosal layer of the drum remnant, on the bony canal all around, and under the handle of malleus and supported by the remnant mucosal layer below. The tympanomeatal flap was repositioned carefully and the external auditory canal was filled with small pieces of gel foam. Then, an ointment impregnated pack was inserted in the external auditory canal, the post auricular incision was sutured in two layers, and a mastoid dressing was applied.

Regarding Underlay tympanoplasty technique, The posterior meatal wall skin flap from 12 o'clock position superiorly to 6

o'clock position inferiorly was raised from lateral to medial till the annulus was reached. The posterior annulus was elevated out of the sulcus and the middle ear was entered. The ossicles were inspected for continuity and the mobility was checked and confirmed. The tympanic membrane was gently dissected off the malleus handle if it was projecting into the perforation. The middle ear was filled with small pieces of gel foam to support the graft and the temporalis fascia graft was placed under the remnant of drum after elevating the tympanomeatal flap along with the annulus and under the handle of malleus.

The posterior tympanomeatal flap was repositioned carefully and the external auditory canal was filled with small pieces of gel foam. Then, an ointment impregnated pack was inserted in the external auditory canal, the post auricular incision was sutured in two layers, and a mastoid dressing was applied. Follow up was carried out as the following, The patients were discharged on the 2nd postoperative day and they were given a broad spectrum antibiotics for 10 days and an analgesic for 7 days. On the 10th postoperative day, the post auricular wound sutures were removed and topical ear drops containing antibiotic and steroid was given for 1 week. On the 14th postoperative day, the endomeatal ear pack was removed.

Postoperatively, the patients were followed-up every 2 weeks and at every follow-up visit, they underwent for oto-endoscopy and / or oto-microscopy to assess the graft uptake. Pure tone audiometry was repeated at the end of 3rd month to re-evaluate the hearing. Figure (2). Hearing results were assessed by comparing the preoperative and postoperative pure tone audiogram as well as closure of the air-bone gap. Figure(3)

Statistical analysis

Data were checked, entered and analyzed using SPSS version 23 for data processing. The following statistical methods were used for analysis of results of the present study. Data were expressed as number and percentage for qualitative variables and mean + standard deviation (SD) for quantitative one.

RESULTS

The patients in both groups had medium to large sized central tympanic membrane perforations as a result of mucosal chronic otitis media and the perforations were dry for at least six weeks before the surgery Group I patients underwent for the underlay technique and their mean age was 29.3 ± 2.7 years. 17 patients were females and 10 patients were males. Group II patients underwent for the interlay technique and their mean age was 28.5 ± 3.3 years. 16 patients were females and 11 patients were males

The mean preoperative air bone gap (ABG) in the underlay group was 22.1 ± 3.5 dB with a range from 15 to 25 dB, while the mean preoperative air bone gap (ABG) in the interlay group was 18.6 ± 4.5 dB with a range from 15 to 20 dB and there was no statistically significant difference between the two groups. **Table (1)**

In the underlay group, at 3-month postoperatively, the graft was taken up in 25 patients (92.6%), while there was a residual perforation in 2 patients (7.4%) The mean postoperative air bone gap (ABG) was reduced to 10.5 ± 4.6 dB with a range from 5 to 15 dB and the change in ABG after the surgery was statistically highly significant ($P \leq 0.001$). **Table(2)**

In the interlay group, at 3-month postoperatively, the graft was taken up in 26 patients (96.2%), while there was residual perforation in one patient (3.8%) The mean postoperative air bone gap (ABG) was reduced to 9.2 ± 1.6 dB with a range from 5 to 15 dB and the change in ABG after the

surgery was statistically highly significant ($P \leq 0.001$). **Figure (4)**

Regarding to the postoperative ABG closure at the end of 3rd month, 55.5% of the underlay group patients had ABG of 5 dB, while 66.6% of the interlay group patients had ABG of 5 dB. Such difference in the postoperative air bone gap closure between the two groups was statistically significant ($P \leq 0.05$) **Figure (5) Table (3)**

As regards to the hearing gain at 3-month postoperatively, there was statistically significant difference between the two groups ($P \leq 0.05$), where in the underlay group, 11 patients (40.8%) had hearing gain from 11-20 dB, while in the interlay group, 18 patients (66.7%) had hearing gain from 11-20 dB. **Table (4)**

According to postoperative complications, none of the patients had deterioration of hearing or postoperative sensorineural hearing loss. In the underlay group, two patients developed atelectasis, while another patient developed mild right facial nerve palsy (diagnosed as being Bell's palsy) 8 days postoperatively. She has been treated with oral steroid (Prednisolone 60 mg / day for 1 week with gradual withdrawal) and she has recovered completely after 1 week. No significant other complications such as graft lateralization, blunting, infection, or formation of postoperative epithelial pearls was noted in any of the patients.

In our study, we faced a limitation which is the short period of duration for follow up of the patients and the few number of cases done.

Table 1: Comparing the preoperative air bone gap between the two studied groups:

| The pre-operative air bone gap | Underlay | | Interlay | | χ^2 | p-value |
|--------------------------------|------------|---|----------|---------|----------|---------|
| | No (27) | % | No (27) | % | | |
| 15 | 15(55.5%) | | 16 | (59.3%) | 0.8 | 0.7 |
| 20 | 11 (40.7%) | | 11 | (40.7%) | | |
| 25 | 1 (3.8%) | | 0 | (0%) | | |

There was no statistically significant difference between the two groups regarding the preoperative air bone gap.

Table 2 : Comparing the graft uptake (the success rate) 3 months postoperatively between the two studied groups:

| Graft uptake | Underlay No (27) | % | Interlay No (27) | % | χ^2 | p-value |
|----------------------|---------------------|---------|---------------------|---------|----------|---------|
| Succeeded | 25 | (92.6%) | 26 | (96.2%) | FET | 0.7 |
| Residual perforation | 2 | (7.4%) | 1 | (3.8%) | | |

FET= Fischer Exact test.

Table 3: Comparing the pre and postoperative air bone gap (ABG) in the interlay group (group II):

| Variable | Preoperative (27) mean ± SD (Range) median | Postoperative (27) mean ± SD (Range) median | Paired- test | p-value | | |
|------------------|---|--|--------------------------|---------|----------|---------|
| ABG | 18.6 ± 4.5 (15-20) 15 | 9.2 ± 1.6 (5-15) 5 | 4.1 | 0.001 | | |
| The air bone gap | Preoperative No (27) | % | Postoperative No (27) | % | χ^2 | p-value |
| 5 | 0 | (0%) | 18 | (66.6%) | 14.1 | 0.001 |
| 10 | 0 | (0%) | 8 | (29.6%) | | |
| 15 | 16 | (59.3%) | 1 | (3.8%) | | |
| 20 | 11 | (40.7%) | 0 | (0%) | | |

Statistically highly significant difference ($P \leq 0.001$).

Table 4: Comparing the pre and postoperative air bone gap (ABG) in the underlay group (group I):

| Variable | Preoperative (27) mean ± SD (Range) median | Postoperative (27) mean ± SD (Range) Median | Paired- test | p-value | | |
|------------------|---|--|--------------------------|---------|----------|---------|
| ABG | 22.1 ± 3.5 (15-25) 20 | 10.5 ± 4.6 (5-15) 10 | 5.2 | 0.001** | | |
| The Air bone gap | Preoperative No (27) | % | Postoperative No (27) | % | χ^2 | p-value |
| 5 | 0 | (0%) | 15 | (55.5%) | 10.3 | |

| Variable | Preoperative (27) mean ± SD (Range) median | Postoperative (27) mean ± SD (Range) Median | Paired- test | p-value |
|----------|---|--|--------------|--------------|
| 10 | 0 (0%) | 8 (29.6%) | | 0.001 |
| 15 | 15 (55.5%) | 4 (14.9%) | | |
| 20 | 11 (40.7%) | 0 (0%) | | |
| 25 | 1 (3.8%) | 0 (0%) | | |

Statistically highly significant difference ($P \leq 0.001$)



Figure (1) Preoperative endoscopic view of the right ear showing large sized central tympanic membrane perforation that underwent for the interlay technique of tympanoplasty type I.

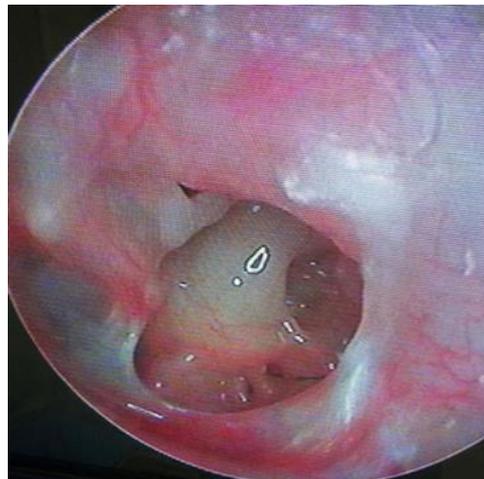


Figure (2) Preoperative endoscopic view of the left ear showing large sized central tympanic membrane perforation that underwent for the underlay technique of tympanoplasty type I.



Figure(3) Endoscopic view of the right ear 3 months post interlay technique of tympanoplasty type I showing well taken tympanic membrane graft.

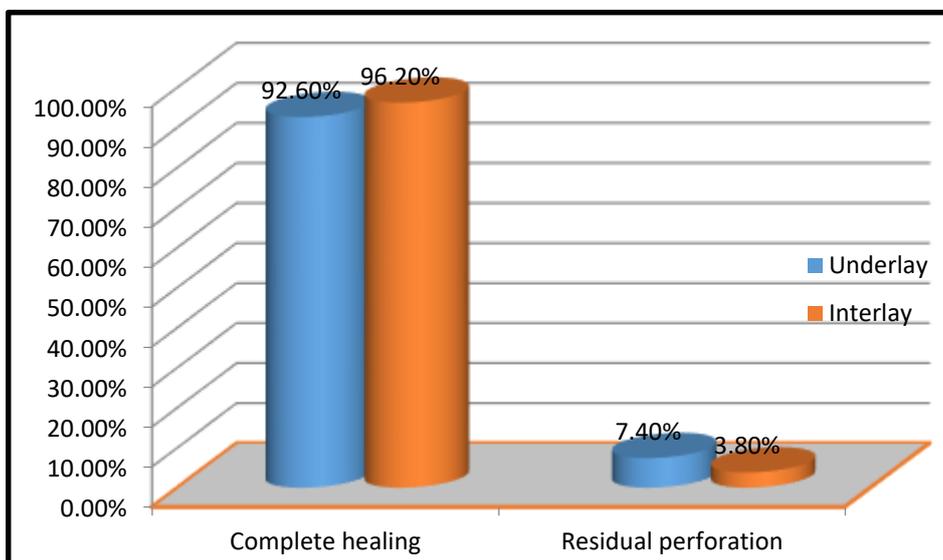


Figure (4) Bar chart for the graft uptake 3 months postoperatively between the two studied groups

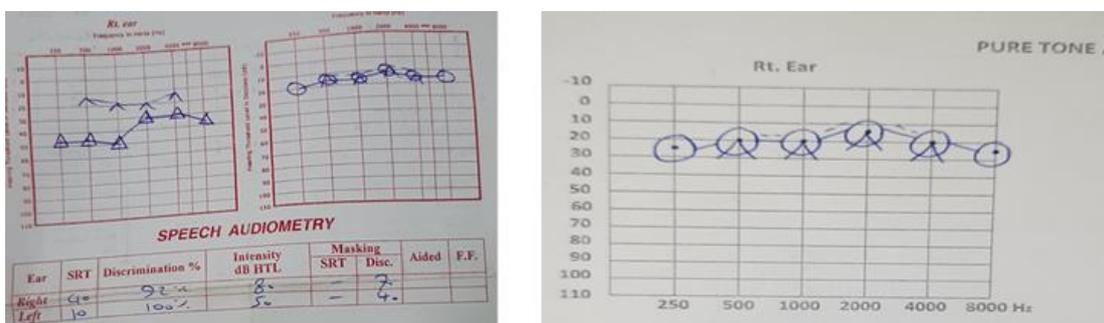


Figure (5) showing comparison between Preoperative and postoperative pure tone audiometry in a case underwent interlay technique.

DISCUSSION

There are several techniques to repair the tympanic membrane defect, among these the

underlay and overlay are quite common techniques and are widely used. In the underlay technique, the graft is placed medial

to the mucosal layer, whereas in the overlay technique, the graft is placed lateral to the fibrous layer of the tympanic membrane. In the last few years, a new technique, the interlay, has been emerged and is being successfully used with promising results⁽⁷⁾.

The present study was undertaken with the objective of comparing the graft uptake and hearing improvement in both interlay and underlay techniques of tympanoplasty type I for central tympanic membrane perforations using the temporalis fascia in all the patients. Successful myringoplasty is defined as the one that should comprise integrity of the graft, minimum postoperative hearing gain of 10 dB in the auditory threshold, and complete healing with the middle ear space aerated manifested by the graft located in the correct anatomical position with neither atelectasis nor otitis media with effusion^{(8) (9) (10)}

In the present study, there was a better graft uptake on using the interlay technique as the graft was taken up well in 26 patients (96.2%), while it was rejected with a residual perforation in one patient (3.8%). In the underlay group patients, the graft was taken up well in 25 patients (92.6%), while it was rejected with a residual perforation in 2 patients (7.4%). However, such difference between the two groups was statistically insignificant.

Our results are in accordance with that of **Sharma et al.**⁽⁷⁾ who reported graft failure with residual perforation in 10% of cases on using the underlay technique and only in 4% of cases with the interlay technique. Likewise, our results for the interlay technique were in close proximity with that of **Jain et al.**⁽¹¹⁾ who reported that only 3.4% of cases had graft failure, whereas **Hay and Blanshard**⁽⁶⁾ reported a success rate of 91% with interlay myringoplasty. As well, **Guo et al.**⁽¹²⁾ reported that the success rate was 96.2% in the interlay method group, while it was 85.7% with underlay myringoplasty.

In the underlay technique of tympanoplasty type I, the graft is placed below all the three layers of the ear drum. However, there are risk of graft medialization, danger of residual epithelium with later

cholesteatoma formation, and as well the possibility of anterior blunting⁽³⁾

In the interlay technique of graft placement, the graft is inserted underneath the middle fibrous layer and over the inner mucosal layer of the ear drum which eventually grow on the inner and the outer surface of the graft leading to successful closure of the perforation⁽⁶⁾

As the graft was supported on both sides by the outer fibro-squamous layer and inner mucosal layer, any reduction of the middle ear space was prevented and none of the patients in the interlay group had medialization or lateralization of the graft. Furthermore, the fibrous annulus that was elevated during the procedure was meticulously placed back onto the bony annulus all around and secured with small pieces of gelfoam. Therefore, none of the cases had anterior canal wall blunting.

Patil et al.⁽¹³⁾ considered that the interlay technique is better than both the onlay as well as the underlay technique as there is no reduction in the middle ear space, the bed size for the graft is not limited, and the healing time is faster.

Since the mucosal layer is below the graft, there are no chances of endothelium over growing on the graft leading to myringitis. As well, the fibro-squamous layer of the tympanic membrane is elevated completely, there is no fear of leaving residual epithelium behind leading to the formation of epithelial pearls or an iatrogenic cholesteatoma if it gets buried under the graft.⁽¹⁴⁾

In the present study, the preoperative ABG in the underlay group was between 15 and 20 dB in 26 patients and between 21 and 25 dB in one patient with a mean of 22.1 ± 3.5 dB. Whereas in the interlay group, the preoperative ABG was between 15 and 20 dB in 27 patients with a mean of 18.6 ± 4.5 dB. However, such difference between the two groups was statistically insignificant. The postoperative air bone gap closure and the hearing gain are better in the interlay group patients than in the underlay group patients.

Our postoperative hearing results coincide with that of **Patil et al.**⁽¹³⁾ who

reported that on using the interlay technique, postoperatively 76% of cases had ABG within 10 dB, 18 % of cases had ABG in the range of 11–20 dB, 4% of cases had ABG in the range of 21–30 dB, 2% cases had ABG between 31 and 40 dB, and no case had ABG > 40 dB.

As well, our study results concur with that of **Sharma et al.** ⁽⁷⁾ who mentioned that with the interlay technique, the preoperative mean air bone gap was 25.5 dB and has decreased to be 13.5 dB after 12 weeks and there was 12 dB mean hearing gain. Whereas with the underlay technique, the preoperative mean air bone gap was 26.3 dB and has decreased to be 17.6 dB after 12 weeks and there was 8.7 dB mean hearing gain.

Subsequently, the interlay technique had a statistically significant better outcome as compared to the underlay technique regarding to the air bone gap improvement. Likewise, **Guo et al.** ⁽¹²⁾ reported that the hearing recovery of the interlay method group was better than the underlay method group. Also, our results are in accordance with **Jain et al.** ⁽¹¹⁾ who has reported that with interlay type I tympanoplasty the hearing improved in 95.4% of the patients with the postoperative mean ABG has decreased to 10.12 ± 5.84 dB, while hearing has not improved in 4% of the patients, and there was deterioration in hearing in 0.6% of the patients.

The difference in the surgical success results between the studies may be attributed to the number of the patients included in each study, the mean follow-up period, the types of graft used, and the cumulative experience of the ear surgeons. Moreover, given the number of the studies, the interlay technique is not as much prevalent as the other techniques because it requires additional skills and it is time consuming as preparation of the margins for interlaying and positioning of the graft

needs precise handling and manipulation of the graft

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