

Middle Ear Packing and External Ear Packing With Fibrin Glue Enhance the Success of Fat Myringoplasty Without Hyaluronic Acid Disc

JONGMIN KIM^{1*}, HYUNG-JOO PARK^{2,3*}, DAE-NEUNG LEE¹ and CHUL HO JANG¹

¹Department of Otolaryngology, Chonnam National University Medical School, Gwangju, Republic of Korea;

²Department of Otolaryngology, Cheomdan General Hospital, Gwangju, Republic of Korea;

³Postgraduate School, Chonnam National University Medical School, Gwangju, Republic of Korea

Abstract. *Background/Aim:* Recently, hyaluronic acid disc has been known to enhance the success rate of fat myringoplasty. However, hyaluronic acid disc (Epidisc) is not covered by south Korean medical insurance. To date, fat myringoplasty using middle ear packing has rarely been reported. In this study, we studied whether middle ear packing with dexamethasone soaked gelfoam and fibrin glue over the fat graft could promote the success rate of tympanic membrane perforation (TMP) closure without hyaluronic acid disc, regardless of perforation size. *Patients and Methods:* Between January 2005 and July 2020, a total of 209 patients who underwent fat myringoplasty due to chronic TMP at a tertiary referral center were enrolled, and the success rate and audiologic outcomes were analyzed. *Results:* The mean successful tympanic membrane (TM) closure rate was 88.0%. The success rate by different age groups showed no significant difference. Further, the size of perforation showed no significant difference, and the perforation site (anterior or posterior) was not significant. The preoperative mean thresholds of air conduction (AC), bone conduction (BC), and air-bone gap (ABG) were 55.71, 12.98, and 42.73 dB respectively. The postoperative mean thresholds of AC, BC, and ABG were 23.67, 12.98, and 10.69 dB, respectively. Change in preoperative and postoperative hearing showed was statistically significant. *Conclusion:* Middle ear packing by gelfoam combined with

external ear canal packing using fibrin glue enabled stable adhesion between the remnant TM and the fat graft. Regardless of the size of the TMP, the success rate of the fat myringoplasty by our technique can be enhanced without use of hyaluronic acid disc.

Myringoplasty is the standard of care for chronic tympanic membrane perforation (TMP) and is commonly performed in the otologic field due to the high incidence of TMP. To perform tympanoplasty for the repair of TMP, various autologous materials such as the temporalis fascia, the perichondrium, and cartilage graft have been used, depending on the surgeon's choice. For the graft, the temporalis fascia is the most common material used for the closure of TMP.

Fat myringoplasty appears to be safe and suitable for stable, dry, small sized perforations in geriatric patients with underlying disease. Since Ringerberg (1) first introduced this technique, it has become an accepted successful technique for small TMPs in geriatric patients. In published reports, the average success rate of fat myringoplasty has been reported to range from 72.9% to 92.2% (2-13). Recently, Salabi *et al.* reported that fat myringoplasty with hyaluronic acid (Epidisc Otologic Lamina; Xomed-Medtronic, Jacksonville, FL, USA) compared to simple fat myringoplasty enhanced the success rate for both small and large perforations of the tympanic membrane (TM) (14-18). The principle in this study was to provide a more natural scaffold using hyaluronic acid for keratinocyte migration. However, hyaluronic acid disc (Epidisc) is not covered by south Korean medical insurance.

The classical fat myringoplasty technique consists of de-epithelialization of the perforation edges and subsequent filling of the perforation using fat tissue from the earlobe or abdominal fat. Saliba *et al.* recommended that lateral fat bulging should not be too high; ideally, the middle ear cavity should be filled with two-thirds of the fat, while

This article is freely accessible online.

*These Authors contributed equally to the study.

Correspondence to: Chul Ho Jang, Department of Otolaryngology, Chonnam National University Hospital, Hakdong 8, Gwangju, Republic of Korea. Tel: +82 622206774, e-mail: chulsavio@hanmail.net

Key Words: Tympanic membrane, fat, myringoplasty, outcome.

one-third should form a lateral fat bulge in the external ear canal (15). When the middle ear cavity is filled with fat, the fat can easily come in contact with the ossicle and may obliterate the middle ear space, inducing poor acoustic properties.

In our experience, external fat over the perforation flattens over time, eventually reaching the same level as the TM; however, the fate of the fat in the middle ear is difficult to assess using otoendoscopy. A histopathological study revealed that in the middle ear, the fat preserved its volume after being covered by a fibrous layer (19). If the fat comes in contact with the middle ear mucosa, it remains as a focal adhesion. If the site is near to the protympanum, it causes obstruction of the eustachian tube.

In this study, we used dexamethasone soaked gelfoam middle ear packing before fat filling to improve stability and prevent adhesion of the fat to the promontory or protympanum. Gelfoam is frequently used as middle ear packing material in tympanoplasty. The majority of the gelfoam can be resorbed over time. However, resorption of the gelfoam is not effective in the case of eustachian tube dysfunction or in the presence of a mucosal defect, and it can frequently induce middle ear fibrosis or adhesions (20). Our previous experimental study reported that the use of gelfoam soaked with a corticosteroid prevented fibrosis in the middle ear (21). Experimentally and clinically, topical or injectable administration of dexamethasone during surgery has been shown to be protective for the inner ear (22, 23).

To date, fat myringoplasty using middle ear packing with antibiotic-dexamethasone-coated gelfoam has not been reported. In our previous study, we performed middle ear packing using antibiotic-dexamethasone soaked gelfoam in a geriatric patient (24) and observed good results.

The purpose of the present study was to investigate the success rate of fat myringoplasty with middle ear packing using gelfoam instead of simple fat filling, as middle ear packing supports the even distribution of fat tissue easily contact the entire perforation margin.

Patients and Methods

Patients. In a retrospective chart review, a total of 209 patients with chronic otitis media who underwent fat myringoplasty at our tertiary otolaryngologic care centers between January 2005 and July 2020 were examined. This study was approved by the internal review board of our institution (approval no. CNUH-2020-153). The duration of the perforation was more than 12 months, and the patients were referred to a senior surgeon for fat myringoplasty. The perforation was captured by otoendoscopy (2.7 mm, 0° Karl Storz Co., Tuttlingen, Germany), and the records were saved in the electronic chart. Pure tone audiometry and temporal bone CT were routinely performed. Eustachian tube function was indirectly assessed by pneumatization of the mastoid air cell in temporal bone CT. Cases of active otorrhea, cholesteatoma, marginal perforation, and ossicular defect were excluded.

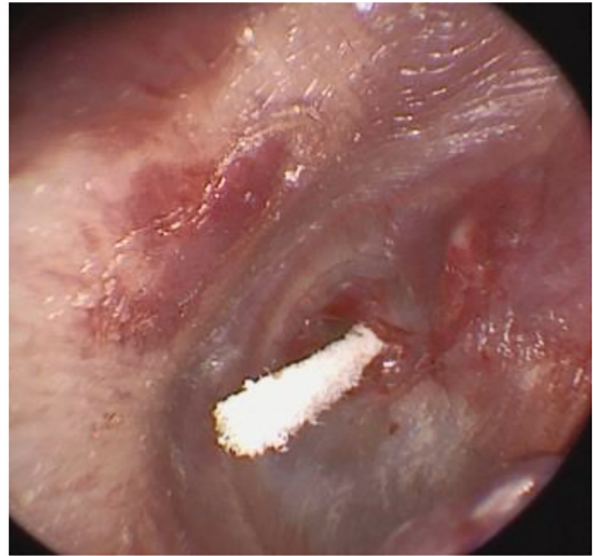


Figure 1. *Toothpick-like gelfoam was inserted into the small perforation for middle ear packing.*

The perforation size was divided into four groups according to the modified Saliba's subdivision (17). The four groups were defined based on the perforation size of the four quadrants of the TM: pinhole perforation (less than 10%), small perforation (grade I, less than 25%), medium perforation (grade II, 25-50%), and large perforation (over than 50%).

Surgical procedure. All fat myringoplasties were performed under local anesthesia with infiltration of dental lidocaine (1% lidocaine with 1: 100,000 epinephrine) with the transcanal approach using a surgical microscope. After antiseptic painting, an incision was made along the earlobe margin. After fat was taken from earlobe, the incision was approximated by nylon. Using an ear speculum, de-epithelialization of the perforation rim prior to repair was performed with a sharp pick and alligator cup forceps. After the middle ear and external ear canal irrigation using normal saline, the middle ear packing was performed using ciprofloxacin-dexamethasone soaked gelfoam, according to the size of the perforation. If the perforation was small, the compressed gelfoam which was cut in the shape of a toothpick was inserted into the middle ear through the perforation, especially in the protympanum, because fat may intrude into the protympanum (Figure 1). The ciprofloxacin-dexamethasone solution was dropped over the gelfoam with a 1 ml syringe. If the perforation was large, ciprofloxacin-dexamethasone impregnated gelfoam was packed into the middle ear *via* the perforation.

After completion of middle ear packing, fat was inserted into the perforation using alligator forceps and a pick. The stability of the fat graft was identified by using the fine suction tip. If the perforation size was larger than 50% after de-epithelialization of the perforation margin, compressed fat was used after middle ear packing. After taking as much fat as possible from the earlobe, the fat was compressed using House gelfoam press (Figure 2). The compressed fat graft was placed in the perforation by transtympanic underlay myringoplasty technique and supported by fibrin glue on the fat graft and external bony canal. Although the fat graft was

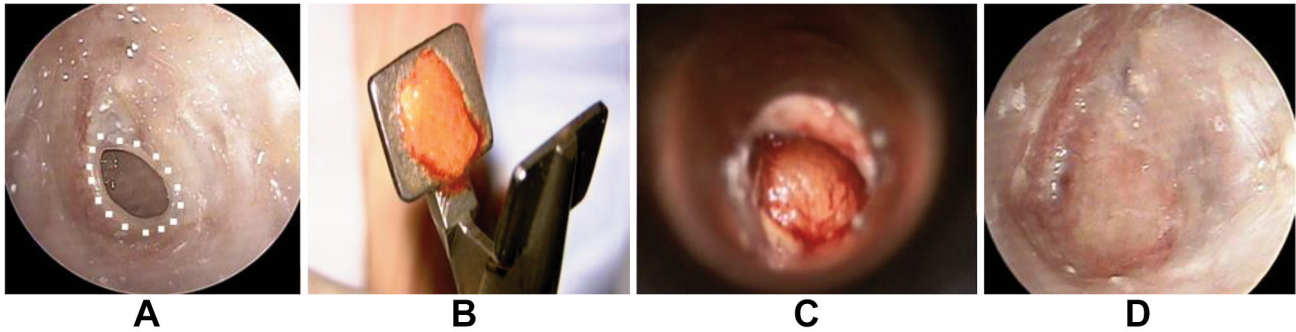


Figure 2. After trimming of the perforation, the perforation size can be defined as large (A). The compression flattens the fat (B). The compressed fat is placed by transtympanic underlay technique after middle ear packing using gelfoam (C). Postoperative endoscopy shows an intact neodrum at 6 weeks post surgery (D).

compressed, the compressed fat was thicker than the fascia graft, as thick compressed fat tissue is better at adapting to the vascular bed than a thin fascia graft (25, 26).

It is important to ensure that the evenly distributed fat tissue is in contact with the entirety of the perforation margin; fat is therefore distributed using a very fine suction tip. The patients were instructed to avoid exposing the operated ear to water for 3 weeks and were followed up 3 weeks postoperatively. After watchful observation using otoendoscopy, patients were instructed to use otological antibiotic drops (ciprofloxacin), which resolves the dried gelfoam and dried fibrin glue over the fat graft and stabilizes the tympanization. The first follow-up was performed 3 weeks after surgery; patients were instructed to administer the otic drop (ciprofloxacin) twice per day to resorb the glue remnants over the fat graft. If the fat graft showed incomplete epithelization, an additional self-putting otic drop was recommended. The patients were examined at approximately 6 weeks, 6 months postoperatively, and follow-up was subsequently performed every 1 year. The postoperative outcomes using otoendoscopy and pure tone audiometer in all patients were assessed at the 6-month follow-up post surgery.

Statistical analysis. Statistical analysis was performed using Prism software (v 8.8; GraphPad). Analysis of the preoperative and postoperative hearing assessment was performed by *t*-test. The data were considered statistically significant when the *p*-value was less than 0.05.

Results

In total, 209 patients were included in the study. The mean age was 58.35 (range=3-86) years; 60.2 (range=13-86) years for females; and 56.5 (range=3-85) years for males. The mean follow-up period was 14.4 months (range=7-38 months). The fat graft was evaluated by endoscopy 6 weeks after surgery; the majority of patients showed an intact neodrum with neovascularization on the surface and complete epithelization of the neodrum within 6 weeks post-surgery. In the majority of patients whose neodrums were intact at 6 weeks, they were maintained even after 6 months and 1 year post-surgery.

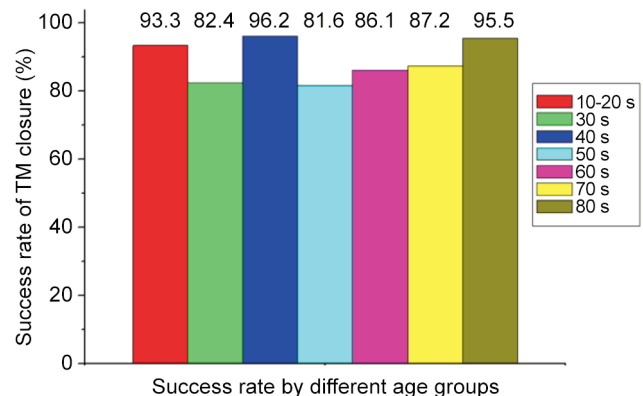


Figure 3. The success rate of myringoplasty did not show a statistically significant difference between age groups.

The postoperative success rate was analyzed by age. The mean successful TM closure rate was 88.0%. The success rate by different age groups showed no significant differences: 93.3% (10-20s), 82.4% (30s), 96.2% (40s), 81.6% (50s), 86.1% (60s), 87.2% (70s), 95.5% (80s) (Figure 3). The success rate was especially high in individuals in their 80s.

The successful closure rate based on the size of perforation was as follows: 88% for the pinhole size (n=38/43), 90.9% for grade I (n=110/121), 78.8% for grade II (n=26/33, follow-up loss 1), and 81.8% for grade III (n=9/11). Thus, the success rate showed no significant difference based on the size of the perforation (Figure 4). The success rate according to the perforation site was divided into the anterior and posterior less than grade I. The success rate of anterior perforation was 88.5% (n=131/148) and that of posterior perforations was 85.2% (n=52/61). The perforation site was not significant. Hearing change of pure conductive hearing loss was evaluated at 6 months

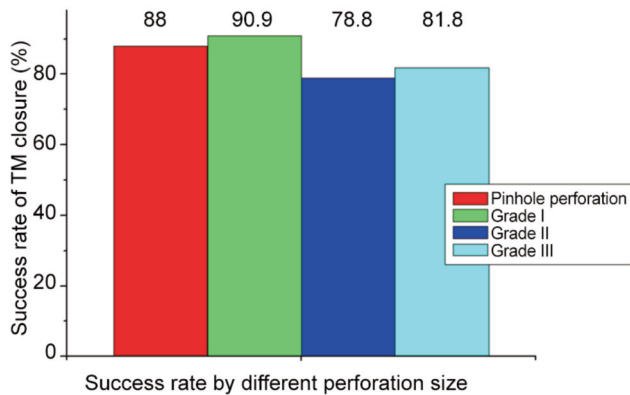


Figure 4. The success rate of myringoplasty did not show a statistically significant difference among different perforation sizes.

postoperatively. The preoperative mean thresholds of air conduction (AC), bone conduction (BC), and air-bone gap (ABG) were 55.71, 26.75, and 28.96 dB, respectively. The postoperative mean thresholds of AC, BC, and ABG were 23.67, 12.98, and 10.69 dB, respectively (Figure 5). The change in preoperative and postoperative hearing showed statistical significance (AC threshold: $p=0.0001$, BC threshold: $p=0.0002$).

Discussion

Natural closure of chronic TMP is very rare, as the TMP margin is generally covered by squamous epithelium and ingrowth to the medial layer; this condition therefore requires treatment. Tympanoplasty requires middle ear exploration by tympanomeatal flap elevation. Compared to conventional tympanoplasty, fat myringoplasty does not require this tympanotomy procedure.

Compared to simple fat myringoplasty, fat myringoplasty with hyaluronic acid (Epidisc) results in a higher success rate (14, 17). However, the success rate of the simple fat myringoplasty group was 69.9% in the study that compared it with hyaluronic acid fat myringoplasty, which is quite different from that of other reports. Our study showed a graft success rate of 88.0%, while the success rate of the hyaluronic acid fat graft group was 84-90.1% (17); there was no significant difference between the two groups. The success rate according to the size of perforation was controversial. Deddens *et al.* (6) and Konstantinidis *et al.* (2) reported that TMP size is a critical factor affecting success rate, and they recommend that fat myringoplasty should be applied when the TMP size is less than 30% of the TM. Li *et al.* (7), Kim *et al.* (5), Gun *et al.* (9, 10), and Konstantinidis *et al.* (2) showed poor success rate for large perforations, but Knutsson *et al.* (10) reported a higher

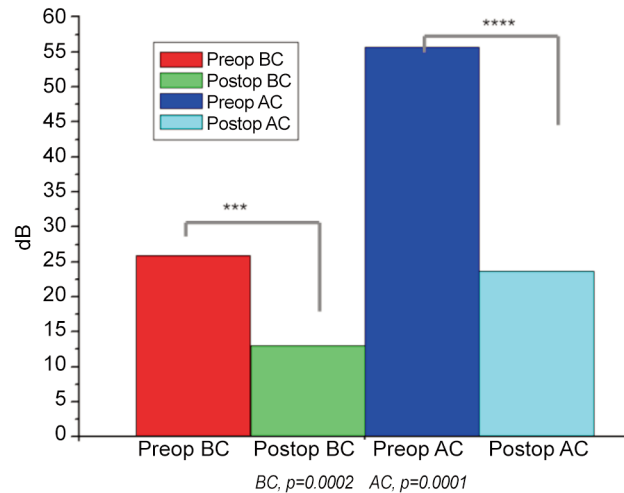


Figure 5. Change in preoperative and postoperative hearing showed statistically significant differences (AC threshold: $p=0.0001$, BC threshold: $p=0.0002$).

success rate for large perforations than for small perforations. In this study, the success rate was not proportional to the size of the TMP. The compressed fat was applied in large perforations in elderly patients who showed a good success rate. Saliba (17) reported that he designed the harvested fat as an hourglass shaped plug and inserted it into the perforation site. He also used gelfoam packing in the middle ear when the perforation size was greater than medium sized. Compared to the hourglass shaped plug, our compressed fat was easier to insert into the perforation. Furthermore, the physiologically hourglass shaped fat plug used in larger perforations may obliterate the middle ear and induce poor acoustic properties. Our compressed fat graft does not obliterate the middle ear cavity because of its flat shape and because we performed middle ear packing using ciprofloxacin/dexamethasone soaked gelfoam to support the fat graft. Sakagami (25, 26) and Yuasa (27) reported that the subcutaneous connective tissue was much better than the temporalis muscle fascia in simple underlay myringoplasty, because thick subcutaneous connective tissue is better at adapting. The compressed fat is thicker than the fascia, and therefore is easy to adapt.

In this study, we performed middle ear packing using ciprofloxacin/dexamethasone soaked gelfoam. Middle ear packing is known to cause fibrosis and adhesion formation in the middle ear as well as airway mucosa. Fibroblasts and α -SMA (in response to profibrotic agents such as transforming growth factor-beta, TGF- β) play an important role in fibrosis formation (28). Dexamethasone reduced the expression of alpha-smooth muscle actin and the short isoform of myosin light chain kinase in the airway mucosa (29).

In our previous experiment, we performed an *in vitro* and *in vivo* evaluation of the antifibrotic effects of dexamethasone and alginate coating on a silicone sheet. The dexamethasone-coated silicone sheets effectively limited the *in vitro* fibroblast attachment and proliferation due to the controlled release of dexamethasone. Dexamethasone showed an antifibrotic effect by inhibiting the expression of α -SMA in the guinea pig mucosa (20). The middle ear packing supports the graft to promote stability and prevent retraction. The best position for the graft is between the perforation of the TM and the gelfoam bed in the middle ear, with autografts such as the fat or perichondrium. The middle ear packing using dexamethasone soaked gelfoam showed an antifibrotic effect (30).

Fibrin glue packing over the compressed fat graft using the simple underlay technique is helpful in promoting better hearing in geriatric patients because it is a simple process without the need for elevation of the tympanomeatal flap.

In fact, Sakagami *et al.* (26) performed simple underlay myringoplasty without middle ear packing. In the present study, the middle ear packing using dexamethasone soaked gelfoam supported the compressed fat graft in large perforations. Sakagami *et al.* (26) and Yuasa *et al.* (27) showed that the postoperative re-perforation rate by simple underlay myringoplasty without middle ear packing was higher than that for conventional methods. The success rate was 76-77%. In fact, their success rate was lower than our results. We believe that this enhanced success rate was due to middle ear packing. In this study, measurement of the audiological outcomes in pure conductive hearing loss patients revealed that the AC and BC thresholds were improved after the operation. The BC threshold could be increased in chronic otitis media due to both mechanical and chemical factors and can be improved by tympanoplasty or tympanomastoidectomy, which not only closes the air bone gap, but also improves the BC threshold (31). According to previous report by Tuz M *et al.* (32), they report that BC threshold is not always a true representation of the sensorineural hearing capacity of the ear. That is, depressed BC threshold does not always represent the cochlear injury. Recently by Wiatr *et al.* (33), reported that significant improvement of bone conduction after myringoplasty was observed in the patients with dry perforation with intact ossicular chain. They explained that normalization of the preoperative granular mucosa and discharge is a positive impact on improvement of bone conduction after myringoplasty.

In our study, there was no significant difference in the closure rate of each size of perforation. The advantage of our technique is that fat myringoplasty can be performed in large perforations. It can be performed without hyaluronic acid disc. For large perforations, the middle ear packing and fibrin glue over the compressed fat graft stabilize the compressed fat graft to aid TMP closure. The disadvantage

of this technique is that middle ear fullness can occur until resorption of gelfoam in the middle ear compared to conventional fat myringoplasty. However, middle ear ventilation can be recovered within postoperative weeks 3 or 4, in general by our experience.

Conclusion

Our results show that simple trimming of the perforation edge and middle ear packing with external ear canal packing using fibrin glue induced stable adhesion between the remnant tympanic membrane and the fat graft. Regardless of the size of the TMP, the success rate of the fat myringoplasty by our technique can be enhanced without use of expensive hyaluronic acid disc.

Conflicts of Interest

The Authors have no conflicts of interest to declare.

Authors' Contributions

C.H.J. designed the research, J.M.K. B.J.S. and H.J.P. collect and analyzed data. J.M.K and C.H.J wrote the article

Acknowledgements

This study was supported by the National Research Foundation of Korea (NRF) Grant funded by the Ministry of Science and ICT for Bioinspired Innovation Technology Development Project (NRF-2018M3C1B7021997) and the Korea Medical Device Development Fund grant funded by the Korea government (the Ministry of Science and ICT, the Ministry of Trade, Industry and Energy, the Ministry of Health & Welfare, Republic of Korea, the Ministry of Food and Drug Safety) (Project Number: 202013C05), and also by the National Research Foundation of Korea (NRF) grant funded by the Korea government (MSIT)(No. 2021R1A2C101417611).

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Received October 11, 2021

Revised November 14, 2021

Accepted November 19, 2021