

## Main Article

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# Is external ear canal packing necessary following underlay myringoplasty?

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## Abstract

**Objective.** The objective of this study was to evaluate graft success, hearing improvement, and complications following perichondrium–cartilage underlay myringoplasty without external auditory canal packing.

**Methods.** In this prospective study, we examined 37 ears of 37 patients with large perforations who underwent endoscopic perichondrium–cartilage underlay myringoplasty without external auditory canal packing. Patients were followed up for six months.

**Results.** At one week after the surgery, the graft was in situ in 35 (94.6 per cent) ears. At 2–3 weeks post-surgery, among the 35 ears without infection, the graft was in situ in 29 (82.9 per cent) ears, and the graft was bulging in 6 (17.1 per cent) ears. At six months post-surgery, the graft success rate was 94.6 per cent (35 of 37 ears). No graft lateralisation or graft medialisation was encountered during the follow-up period.

**Conclusion.** The absence of external auditory canal packing did not affect the graft success or hearing improvement following underlay myringoplasty. Thus, external auditory canal packing does not appear to be necessary for underlay myringoplasty.

## Introduction

Underlay myringoplasty is the main procedure used to repair perforation of the chronic tympanic membrane. Packing of the external auditory canal after middle-ear surgery is an established practice in many ENT centres. Since introduction of the first Gelfoam packing technique in 1973,<sup>1</sup> various types of external auditory canal packing materials have been described.<sup>2–5</sup> From a theoretical perspective, external auditory canal packing could promote healing of the tympanic membrane, provide structural support to the graft, and hold the tympanomeatal flap in the correct position to avoid external auditory canal stenosis.<sup>6,7</sup> Packing could also aid local haemostasis and help avoid lateralisation blunting. However, external auditory canal packs need to be removed 7–21 days post-operatively, depending on the surgical procedure and the surgeon's habits, which may result in conduction hearing loss and ear fullness for several weeks.<sup>3</sup> In addition, external auditory canal packing may disturb the graft and increase pain during the packing process and/or subsequent pack removal.<sup>6,7</sup>

Most previous otologic studies have focused on auditory performance or surgical complications associated with ear packing,<sup>2–5</sup> but none examined the effects of post-operative absence of external auditory canal packing on graft outcomes. There is currently no consensus regarding the utility of external auditory canal packing following underlay myringoplasty. Accordingly, the objective of this study was to evaluate the graft success, hearing improvement, and complications of endoscopic perichondrium–cartilage underlay myringoplasty without external auditory canal packing.

## Subjects and methods

### Ethical considerations

Ethical approval for the procedures of the present study was obtained from the Medical Ethical Committee of Yiwu Central Hospital. Informed consent was obtained from all of the participants.

### Patient selection

Study subjects were recruited from consecutive patients diagnosed with chronic perforation who visited the Department of Otorhinolaryngology, Head and Neck Surgery at Yiwu Central Hospital. Cases that met the following criteria were analysed: adults with a small (12.5–25 per cent) or subtotal (50–75 per cent) tympanic membrane perforation, a dry ear for

at least three months prior to surgery, and an air–bone gap (ABG) < 40 dB. The exclusion criteria were revision cases, cholesteatoma, ossicular chain abnormality, middle-ear inflammation, fungal otitis externa, and other underlying diseases. Computed tomography was performed prior to surgery.

Audiometric data were obtained pre-operatively and at six months post-operatively. Pure-tone averages (PTAs) were calculated for both air conduction and bone conduction by averaging the thresholds at 500, 1000, 2000, and 3000 Hz. In most cases, a threshold of 4000 Hz was used to interpolate the threshold of 3000 Hz, per the standards of the Hearing Committee of the American Academy of Otolaryngology–Head and Neck Surgery. Pre- and post-operative ABG values were calculated by subtracting the bone conduction PTA from the air conduction PTA. Air–bone gap closure was calculated as the pre-operative ABG minus the post-operative ABG.

### **Surgical technique**

All patients underwent endoscopic perichondrium–cartilage underlay myringoplasty with no tympanomeatal flap elevation. A single-layer perichondrial composite cartilage graft was harvested from the ipsilateral tragus. The lateral perichondrium was peeled circumferentially, and the pedicle was used to attach the cartilage graft. Full-thickness cartilage was used as the graft material (i.e. thinning of the cartilage was not done). The cartilage graft was shaped to be 1 mm larger than the perforation margins, and the perichondrium was 1–2 mm larger than the cartilage graft. The middle ear was explored by 0° and 30° rigid endoscope and the mobility of the ossicles was evaluated. The perforation margins were not de-epithelialised, although the epithelium was removed from the distal malleus handle. A notch in the cartilage graft was created to accommodate the malleus handle.

The middle ear was packed with biodegradable NasoPore (Stryker, Portage, Michigan). The perichondrium–cartilage composite graft was positioned via trans-perforation. The cartilage graft was placed medial to the remnant tympanic membrane and the annulus. The perichondrium was placed medial to the remnant tympanic membrane and the annulus but lateral to the malleus handle, if present. External auditory canal packing of any antibiotic ointment and biological materials were not used.

### **Post-operative follow-up**

All patients were discharged on the day after surgery. Outpatient endoscopic inspections were scheduled at 1, 2, 3, and 4 weeks post-operatively, and at 3 and 6 months post-operatively. Audiometric evaluations were performed at six months post-operatively. All intra- and post-operative complications were recorded.

Graft success was defined as a completely intact tympanic membrane at the six-month post-operative visit. Graft failure was defined as the presence of residual perforation. Graft extrusion was defined as partial or complete detachment of the graft from the remnant tympanic membrane or annulus, and separation from the perforation. A normal graft was defined as complete inosculation of the graft and remnant tympanic membrane, and preservation of the graft in situ. A graft bulge was defined as the complete inosculation of the graft and remnant tympanic membrane without residual perforation, but with expansion of the graft partially or completely above the remnant tympanic membrane.

### **Statistical analyses**

Statistical analyses were performed using SPSS Statistics (version 20; IBM Corp, Armonk, NY, USA). Data are expressed as means (standard deviations) and numbers (percentages). Differences between pre-operative and post-operative ABGs were analysed using the paired-samples *t*-test; *p* < 0.05 was considered statistically significant.

## **Results**

### **Demographic data**

We included 37 ears in this study. Of the 37 patients, 21 (65.1 per cent) were female and 16 (34.9 per cent) were male (mean age at surgery, 46.1 ± 3.8 years; range: 37–58 years). Surgery was conducted on the left ear in 22 (51.2 per cent) patients and on the right ear in 21 (48.8 per cent) patients. The perforation duration was 11.6 ± 2.5 years. Small perforation was in 12 (32.4 per cent) patients and subtotal perforation in 25 (67.6 per cent). All the perforations showed intact ossicles and good mobility.

### **Endoscopic observation and graft success rate**

At the end of the first post-operative week, the graft was in situ in 35 (94.6 per cent) ears, which were pale and showed signs of oedema. In these ears, we observed inosculation of the graft and the remnant tympanic membrane. In contrast, we observed post-operative infection and partial extrusion of the graft in two (5.4 per cent) perforations.

At 2–3 weeks post-operatively, all 35 ears without infection showed complete inosculation of the graft and the remnant tympanic membrane, as well as intense partial or complete neovascularisation (Fig. 1). Of these ears, the graft was in situ in 29 (82.9 per cent) and was bulging in 6 (17.1 per cent). Of the 6 ears with bulging graft, one was in small perforation and 5 in subtotal perforation.

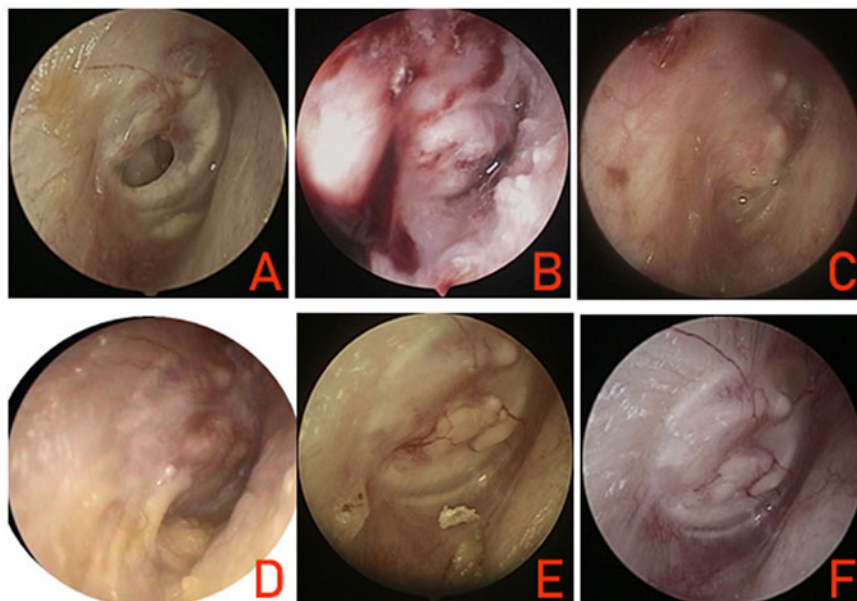
At 5–6 weeks post-operatively, all 35 ears without infection showed graft survival, closure of the perforation, and decreased neovascularisation of the graft. Of the six ears with a bulging graft, the graft gradually returned to a normal position and did not result in residual perforation (Fig. 2). Although the infection was controlled in the two ears with post-operative infection, a small amount of residual perforation was still seen. Overall, the graft bulge did not affect the final graft success rate, which was 94.6 per cent (35 of 37) at six months post-operatively.

### **Hearing improvement and complications**

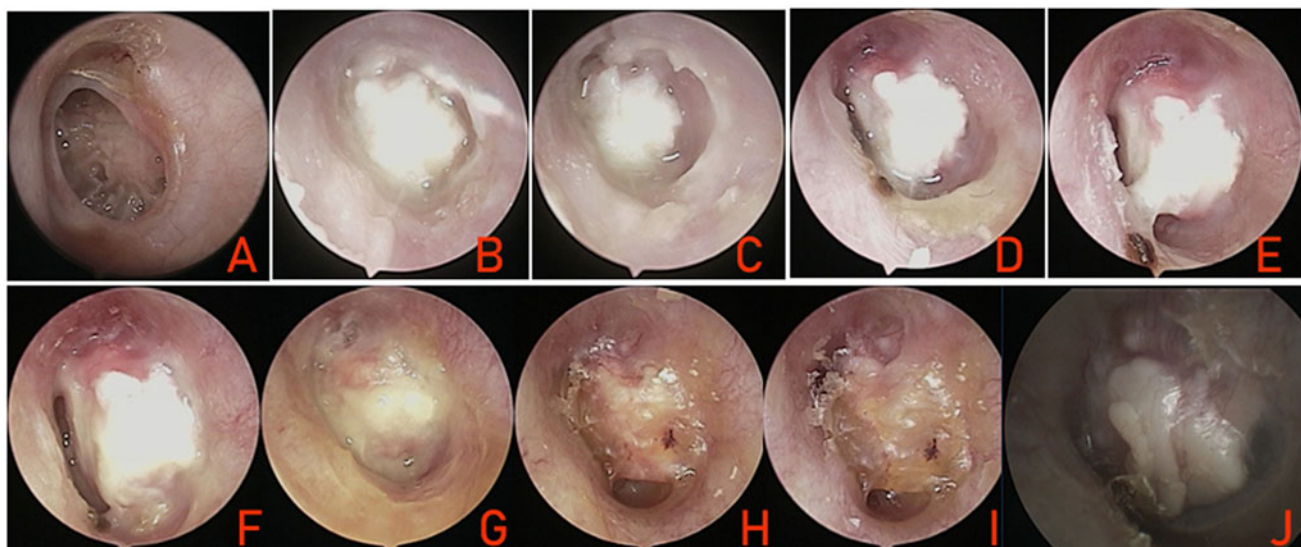
Of the 35 patients without infection, 14 (40.0 per cent) reported hearing improvement at one week post-operatively, 17 (48.6 per cent) at two weeks post-operatively, and two (5.7 per cent) at four weeks post-operatively. There was no improvement in two (5.7 per cent) patients at four weeks post-operatively. Of the 35 patients, nine (25.7 per cent) reported ear fullness.

Audiological testing was achieved in 35 patients at six months post-operatively, showing that there was no sensorineural threshold shift. The overall mean pre-operative ABG was 32.6 ± 2.8 dB, while the overall mean ABG at six months post-operatively was 19.5 ± 3.1 dB; the difference between these values was significant (*p* < 0.05; paired-samples *t*-test).

The mean pre-operative ABG was 31.8 ± 4.6 dB in 29 ears without graft bulging and 32.1 ± 1.9 dB in six ears with graft bulging;



**Figure 1.** (A) Pre-operative perforation. (B) Post-operative one week. (C) Post-operative two weeks. (D) Post-operative four weeks. (E) Post-operative two months. (F) Post-operative six months.



**Figure 2.** (A) Pre-operative perforation. (B) Post-operative one week. (C) Post-operative 10 days. (D) Post-operative two weeks. (E) Post-operative 17 days. (F) Post-operative three weeks. (G) Post-operative four weeks. (H) Post-operative five weeks. (I) Post-operative seven weeks. (J) Post-operative three months.

this difference was not significant ( $p = 0.842$ ). The ABG at six months post-operatively was  $17.6 \pm 5.4$  dB in 29 ears without graft bulging and  $20.8 \pm 2.7$  dB in six ears with graft bulging; this difference was not significant ( $p = 0.473$ ). Although the ABG gain in the 29 ears without graft bulging was high ( $3.1 \pm 0.7$  dB) compared with the six ears with graft bulging, this difference was not significant ( $14.6 \pm 3.8$  vs  $11.9 \pm 4.6$ ,  $p = 0.521$ ). Graft bulging did not significantly affect hearing improvements.

No graft lateralisation or medialisation was encountered during the follow-up period. None of the patients experienced sensorineural hearing loss or intractable tinnitus.

## Discussion

It is routine practice to place a dressing pack within the external auditory canal following myringoplasty. However, the material

of choice tends to be based more on tradition than evidence.<sup>2,6,7</sup> External auditory canal packing is thought to protect the operated site, hold the graft in situ, and prevent sagging of the posterior canal wall. However, post-operative ear pack removal is a significant source of anxiety and discomfort, especially in older patients. In addition, the pack produces temporary conductive hearing loss until removed, which is particularly problematic when the patient has hearing loss in the unoperated ear or is considering bilateral surgery.<sup>6,7</sup> Renard *et al.*<sup>3</sup> surveyed a group of 57 surgeons and found that 96 per cent were reluctant to refrain from packing the external auditory canal after otologic surgery. Although various packing materials have been tested, including tri-actortyl ointment,<sup>6</sup> fibrin glue,<sup>8</sup> silastic sheets,<sup>9</sup> bismuth iodoform paraffin paste,<sup>10</sup> and non-stick triple wicks<sup>2</sup> for use instead of the traditional absorbable biological materials, the packing substance is generally consistent within institutions. Otolologists reported being concerned

that omitting external auditory canal packing would lead to graft extrusion following underlay myringoplasty.<sup>4,11–13</sup> To date, however, evidence regarding the outcomes of graft surgeries without external auditory canal packing is lacking.

In the present study, we performed a series of endoscopic dynamic observations at four weeks after endoscopic perichondrium–cartilage underlay myringoplasty without any external auditory canal packing. This study found that 94.6 per cent of the examined ears showed inosculation of the graft and the remnant tympanic membrane at one week post-operatively; the only exceptions were two patients who had infections. Among all the patients, the blood vessels were dilated and congested in the remnant tympanic membrane, and neovascularisation was initiated in a few grafts. At 2–4 weeks post-operatively, complete inosculation of the graft and remnant tympanic membrane had occurred, along with complete neovascularisation. At 5–6 weeks post-operatively, we observed graft survival and successful closure of the perforation in 35 ears.

In this study, only two ears exhibited residual perforation as a result of post-operative infection during the six-month follow-up period. Both cases of infection and residual perforation occurred at the marginal perforation of subtotal perforation. We speculate that the marginal perforation could be a risk factor of post-operative infection and residual perforation. Thirty-five ears achieved complete closure; therefore the graft success rate was 94.6 per cent (35/37), which was similar to that obtained using the underlay technique or the over–under technique with external auditory canal packing. Saraf *et al.*<sup>11</sup> reported a success rate of 86.6 per cent. Other scholars using the underlay technique reported graft success rates of 95.0 per cent,<sup>12</sup> 89.7 per cent,<sup>13</sup> 85.3 per cent,<sup>14</sup> and 95.2 per cent.<sup>15</sup> Our recent study reported a success rate of 92.6 per cent using topical antibiotic ointment packing. Bao *et al.*<sup>4</sup> and Erbele *et al.*<sup>16</sup> used the over–under technique and gelatine sponge packing and reported graft success rates of 95 per cent and 97 per cent, respectively.

Of the 35 ears without infection in this study, the graft was in situ in 82.9 per cent during the follow-up period, and graft bulging was noted in 17.1 per cent. However, complete inosculation of the graft and the remnant tympanic membrane was achieved in six ears with graft bulging, as the graft gradually returned to its normal position and did not affect the graft success. Graft bulging has also been reported in patients who received external auditory canal packing.<sup>14,17</sup>

We found that graft bulging mainly occurred at 2–3 weeks post-operatively, at which point the packing material has been removed in patients who receive external auditory canal packing. Thus, we speculate that the graft bulging was related to the middle-ear packing. With the gradual increase of exudation of the middle ear and graft, the absorbent biological packing materials in the middle ear could gradually expand, leading to a graft bulge. Subsequently, with gradual liquefaction and absorption of biological materials, the graft could gradually return to its original state. Interestingly, although we observed graft bulging, the risk of tearing of the inosculation was low because the graft and remnant tympanic membrane reached complete inosculation at two weeks post-operatively.

We speculate that graft bulging could lead to graft extrusion if the graft is too small. Accordingly, we recommend that the graft size be as large as possible. In this study, we did not trim the perforation margins. Our previous study showed that preserving perforation margins did not affect graft neovascularisation or the short- or long-term graft success rate.<sup>18,19</sup>

Preserving perforation margins has at least one advantage: preserving more remnant tympanic membrane in contact with the graft. Although external auditory canal packing of biological materials was not applied in our recent study, erythromycin ointment packing was used,<sup>17</sup> however, no antibiotic ointment or biological materials packing was applied in the present study. In addition, patients with medium perforations (25–50 per cent of the tympanic membrane) were recruited in our previous study but patients with small and subtotal perforations were selected in present study.

In this study, of the 35 patients with no residual perforation, 88.6 per cent reported hearing improvement at two weeks post-operatively. Furthermore, 74.3 per cent of the patients did not report ear fullness within four weeks post-operatively. These data represent significant improvements in the overall mean post-operative and pre-operative ABG closure rates.

Full-thickness cartilage was used as the graft material (i.e. thinning of the cartilage was not done). Usually, cartilage thickness of 0.3–0.4 mm is stated to be optimal for improved hearing results.<sup>20–22</sup> However, some clinical studies showed that hearing gain was not statistically different between thin and full-thickness cartilage graft.<sup>23–25</sup> Thus, full-thickness cartilage graft was applied in most of present clinical studies.<sup>4,13,15,17,18</sup> The improvement in air–bone conduction mainly depended on perforation closure for the perforations with normal ossicles. When we evaluated the degree of hearing improvement in patients with and without graft bulging, we found that although the ABG gain in the 29 ears without graft bulging was high ( $3.1 \pm 0.7$  dB) compared with the six ears with graft bulging, the difference was not significant ( $p = 0.521$ ). We speculate that graft bulging may affect the contact between the graft and the malleus handle, thereby decreasing the effect on sound conduction. Fortunately, graft bulging did not significantly affect hearing improvement. Moreover, the absence of external auditory canal packing did not affect the graft lateralisation or medialisation. Thus, we judge that external auditory canal packing is not necessary following underlay myringoplasty.

External auditory canal packing has the following disadvantages: (1) it produces temporary conductive hearing loss; (2) there is a risk of inadvertently disturbing the graft and external auditory canal during the packing process or subsequent pack removal, especially for patients with a narrow external auditory canal; and (3) it increases medical costs related to frequent follow-up assessments. One advantage of this study is that no patients were lost to follow up, which demonstrates the success of our method. In addition, we were able to observe changes in the graft at different follow-up points via endoscopy because of the absence of external auditory canal packing. However, limitations of this study include the single-centre study population and small sample size, especially in terms of the number of patients with graft bulging. Multi-centre studies with large sample sizes should be conducted in the future.

- Packing of the external auditory canal after underlay myringoplasty is an established practice in many ENT centres
- Absence of external auditory canal packing did not affect the graft success and hearing improvement following underlay myringoplasty
- No external auditory canal packing will save operation time and medical costs
- No external auditory canal packing is beneficial to dynamically observe graft changes

## Conclusion

This study suggests that the absence of external auditory canal packing did not affect the graft success or hearing improvement following underlay myringoplasty, thus indicating that external auditory canal packing for underlay myringoplasty should be avoided.

**Data availability statement.** All data generated or analysed during this study are included in the published article.

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**Competing interests.** The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

**Author contributions.** Yajian Shen: interpretation of data, design of the work, analysis of data, drafting the manuscript, final approval of the version to be published. Zhengcai Lou: interpretation of data, design of the work, analysis of data, drafting the manuscript, agreement to be accountable for all aspects of the work; final approval of the version to be published.

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