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In office repair of tympanic membrane perforations

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Tympanic membrane (TM) perforations commonly occur as a result of chronic ear infections, direct trauma or blast injuries, as seen in military and civilian populations following terror attacks. TM perforations result in considerable morbidity, including hearing loss, pain, recurrent infections and decreased quality of life. Repair of chronic TM perforations is typically performed in the operating room under general anesthesia. Recently developed techniques for TM repair afford the option to manage patients in the clinic setting. Herein we describe our endoscopic approach for in-office, awake TM repair and review patient selection, instrumentation, technique and postoperative management. We also discuss outcomes from a cohort study including closure rates, hearing outcomes and patient reported outcome measures.

Tympanic membrane perforation, tympanoplasty,in-office ear surgery, endoscopic ear surgery

Introduction

Chronic tympanic membrane (TM) perforation is a common otologic condition in adult populations, affecting nearly 1:200 people.[1] TM perforations can be reconstructed via myringoplasty or tympanoplasty; however, the gold standard is the underlay tympanoplasty technique, in which graft materials are placed medial to the perforation following surgical elevation of the TM via a postauricular or endaural incision.[2] The limitation of this technique is that it traditionally necessitates the use of general anesthesia in the operating room (OR), which may increase patient morbidity and cost.[3] These barriers have prompted investigations into the role of in-office TM repair under local anesthesia.[4,5]

The transition of otolaryngology procedures from the operating room to the clinic, which has largely taken place in the fields of laryngology, rhinology, and facial plastics,[6-9] has followed improvements in instrumentation, surgical technique, and documentation of positive outcomes. In-office procedures in otology have recently gained interest due to improvements in ear-specific endoscopic equipment as well as an increased understanding of patient pref-

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erences. With the use of a rigid endoscope, transmeatal procedures, such as TM repair, are feasible,[4,5,10,11] even in the case of a narrow external auditory canal.

Our group has previously demonstrated successful TM repair in awake patients using an in-office technique through a pilot study which combined a novel TM graft design made of porcine small intestine submucosa (SIS) with a minimally invasive transcanal endoscopic technique.[4] In this article, we describe our endoscopic approach for in-office, awake TM repair and review patient selection, instrumentation, surgical technique and post-operative management. We also discuss outcomes from an updated cohort study including closure rates, hearing outcomes and patient reported outcome measures.

Indications

Patients should be considered for this procedure if they present with conductive hearing loss in the setting of a chronic non-healing perforation (present for greater than 3 months) that is small to medium in size (less than 50% of the total TM surface area), dry and without active infection. Patients must demonstrate a motivation for repair and the ability to reasonably tolerate awake manipulation of the external auditory canal. Patients who are otherwise not candidates for general anesthesia, including individuals who would best be served by continued use of blood thinning medications, may be considered.

Patient Evaluation

Patient evaluation begins with a full clinical exam including otomicroscopy to document location, size and associated features of the perforation. During this time the clinician should take note of how the patient tolerates the ear exam. Cleaning should be performed with the patient laying supine or in a beach-chair position. Some patients with significant cardiopulmonary disease may not tolerate a recumbent position for the duration of procedure.

Within 6 months of the procedure date, standard threshold audiometry with air and bone conduction thresholds should be performed, including immittance testing using 226Hz tympanometry. Computed tomography may be indicated if there is concern for disease of the middle ear or mastoid.

Technique

Instruments

With several exceptions, most instruments needed for in-office TM repair are typically available in the otolaryngology clinic, including a reclining chair or procedure table with adjustable back.

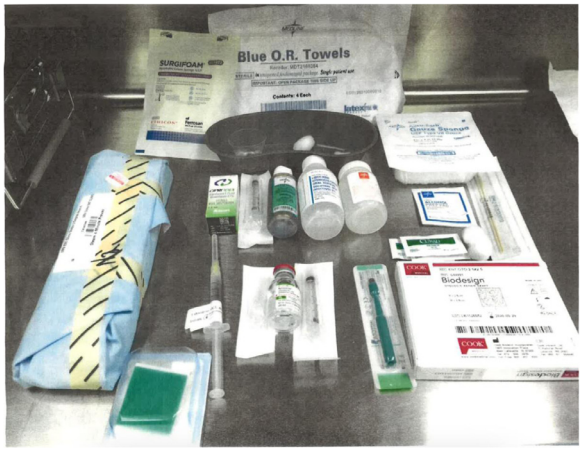

Figure 1 Depiction of equipment used for in-office tympanic membrane repair: absorbable gelatin sponge, sterile towels, sterile gauze sponges, rigid endoscope (3- or 4-mm diameter, 14-cm), ear basin, cotton balls, 3 mL syringes, antibiotic suspension, betadine, viscous lidocaine jelly 4%, sterile saline, antibiotic ointment, sterile cotton tipped applicators, syringe with 27G needle, lidocaine 1% with epinephrine 1:100,000, punch biopsies of varied sizes, porcine SIS graft, anti-fog solution with sponge.

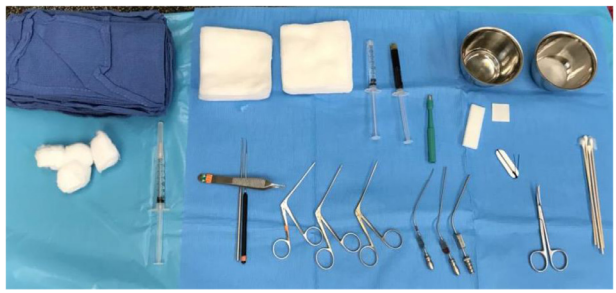

Figure 2 Sterile set-up for In-Office Tympanic Membrane Repair: sterile towels, sterile gauze sponges, 3 mL syringe with saline and betadine, punch biopsy, basin with sterile saline, basin with antibiotic suspension, absorbable gelatin sponge, merocele wick, cotton balls, syringe with lidocaine 1% with epinephrine 1:100,000, round knife, curved needle, non-toothed forceps, smooth alligator forceps, cup forceps, otologic suctions, iris scissors, sterile cotton swabs with antibiotic ointment.

An otomicroscope can be used for this technique; however, an endoscopic camera is preferred for improved visualization. Necessary camera equipment includes a 3- or 4-mm diameter, 14-cm rigid endoscope with 3CCD camera, light source and tower with display monitor. A camera drape, and sterile towels maintain sterility of the procedure. Anti-fog solution and oxymetazolin improve visualization..

Other necessary instruments include: otologic microsuctions (3, 5 and 7 French), non-toothed forceps, 4, 5 and 6-mm biopsy punches, iris scissors, cup forceps, smooth alligator forceps, a curved needle, cerumen loop, and a round knife. Additionally, two small basins for sterile saline and antibiotic suspension, gelfoam for packing, and a merocele wick for the ear are needed. Figures 1 and 2 depict necessary equipment and sample sterile set-up. An off the shelf graft material, such as porcine small intestinal submucosa

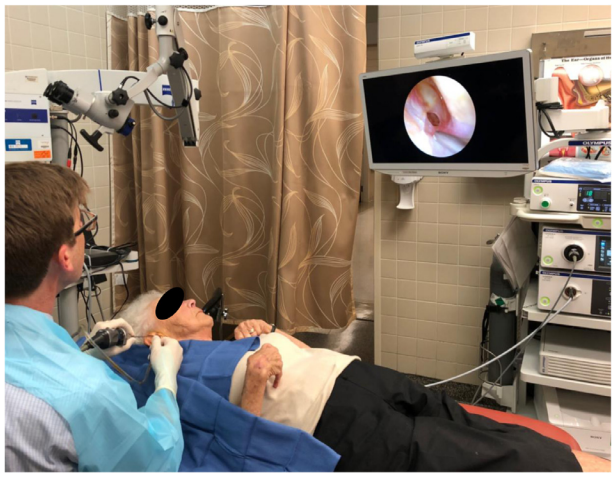

Figure 3 Patients are placed in the supine position and draped with sterile towels. The surgeon should be directly across from the endoscopic video tower to afford the patient the option to observe their procedure.

(Otologic Repair Graft, Cook Medical®) may be used, although other commercially available grafts may also be considered.

Informed Consent and Patient Preparation

Informed consent is obtained at the time the procedure is discussed with the patient. Risks of non-healing perforation, persistent conductive hearing loss, re-perforation of the TM, otorrhea and perioperative pain should be discussed. Routine risks of ear surgery including new or worsening hearing loss, dizziness, cholesteatoma formation, dysgeusia, tinnitus and facial paresis should also be reviewed.

Following informed consent, the patient is brought to the procedure room where the correct patient and ear to be treated are reviewed during a surgical time out. Patients are placed in the supine position and remain awake during the entire procedure (Figure 3). The canal is anesthetized topically using sterile cotton balls soaked in 4% viscous lidocaine. Additionally, ~3-4 mL of 1% lidocaine with epinephrine 1:100,000 is instilled posteriorly within the meatus at two injection sites.

Graft Preparation

Under sterile conditions, a 4-, 5-, or 6-mm punch biopsy is used to obtain two circular grafts of the porcine SIS. The circular diameter of the grafts should be 1-2-mm greater than that of the TM perforation. Linear cuts are then made directly opposite each other at the 12 and 6 o'clock positions, leaving a 0.5-mm bridge of intact graft between cuts. The two circular grafts are then interdigitated, creating a bilayer graft with four sets of flanges, two in the medial plane and two in the lateral plane (Figure 4). The graft is then placed in a sterile saline solution until needed.

Procedural Technique

After the lidocaine-soaked cotton balls are removed, the ear canal is cleaned with betadine solution. Once clean, the TM should be visualized using the selected rigid endoscopic. A round knife is then used measure the perforation and appropriately size the graft. The perforation is then be rimmed using a curved needle and cupped forceps. An angled endoscope may be used to inspect and document the status of the middle ear. Following this, the prepared bilayer graft is introduced lateral to the TM using smooth alligator forceps. A curved needle is then used to insert the two medial flanges of the graft through the perforation, while keeping the two lateral flanges on the lateral TM surface (Figure 5). The graft is then spun in a clockwise direction to ensure an absence of folds in the medial layers for the purposes of establishing good contact on the medial TM surface. Gelatin sponges soaked in antibiotic suspension are then placed lateral to the graft prior to making a small incision in the anesthetized external auditory canal with a round knife to generate a blood patch. The canal should then be packed with an antibiotic-soaked gelatin sponge and filled laterally with antibiotic ointment. Packing will be removed 14 days post-operatively.

Outcomes

To assess the perforation closure rate of this technique and patient experiences with in-office, endoscopic repair of TM perforations, a case series and cross-sectional survey were performed. The charts of patients who underwent in-office TM perforation repair by a single surgeon at a tertiary care center from August 2019 to September 2020 were reviewed. All subjects had non-healing chronic TM perforations (> 6 months) and at least one postoperative evaluation for outcome assessment. Cases were excluded if patients did not present for postoperative evaluation. Patients were also approached in an attempt to obtain consent for a post-procedural survey. Approval was obtained from the Human Subjects Research Committee of the University of Massachusetts Medical School Institutional Review Board: approval #H00019142.

In-office TM repair occurred in 23 ears from 22 patients (mean age 64 years, range 34-89 years, Table 1). 17 patients (74%) were female and 13 (57%) were left ears. Perforation etiology was from chronic otitis media in 83% (N = 19) of ears or trauma in the remaining 17% (N = 4). Of patients who underwent the in-office procedure, 13 patients (59%) agreed to take part in the postoperative interview.

All in-office procedures (N = 23) were performed entirely under local anesthesia. There were no observed or reported complications. On average, patients spent 145 ± 37 minutes in the clinic on the day of their procedure from check-in to check-out (range, 71-217 minutes) and the average duration of the procedure was 17 ± 7 minutes (range, 10-41 minutes). On average, perforations spanned

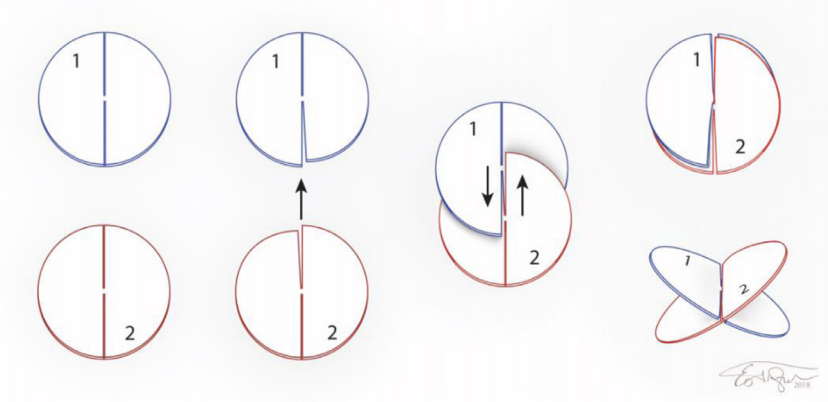

Figure 4 Bilayer Graft Design: Two discs of graft material (porcine small intestinal submucosa) are fashioned from a 4, 5 or 6mm biopsy punch. The grafts are interdigitated following linear slits to compose the bilayer design. Figure reproduced from Kozin et al. 2019 with permission.[4]

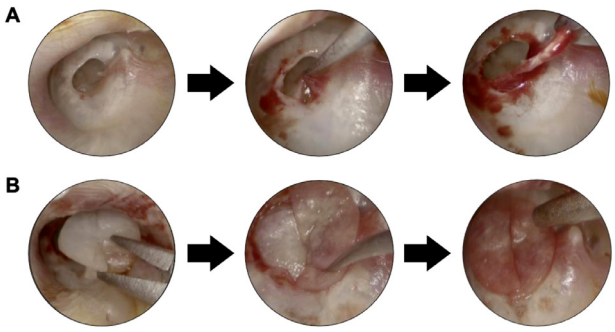

Figure 5 Transcanal endoscopic approach. (A) Identifying and rimming tympanic membrane (TM) perforation. (B) Placement of graft using alligator forceps with medial flanges tucked beneath TM using curved needle.

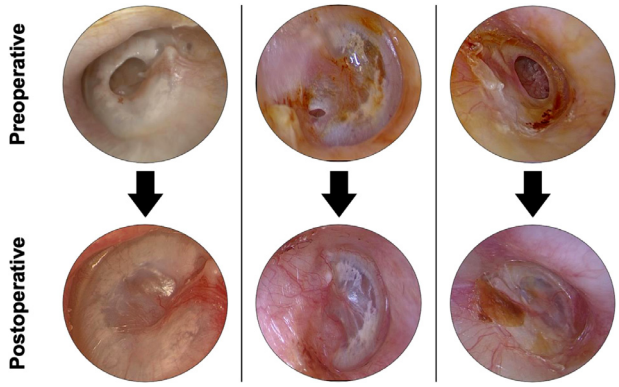

Figure 6 Representative pre- and postoperative images from three patients undergoing in-office repair. Tympanic membrane perforation (top row) with corresponding repair (bottom row).

Table 1 – In-Office Patient Demographics

Demographics	In-Office (N = 23)	(%)
Age (years):		
Mean	64	
Range	34-89	
Gender:		
Female	17	(73.9)
Male	6	(26.1)
Sidedness:		
Left	13	(56.5)
Right	10	(43.5)
Perforation Etiology:		
Trauma	4	(17.4)
Chronic Otitis Media	19	(82.6)
Duration of Perforation:		
< 1 year	8	(34.8)
1-5 years	9	(39.1)
> 5 years	6	(26.1)
Perforation Size (%):		
Mean	26	
Range	10-60	

26% of the TM surface area (range, 10-60%), with 48% (N = 11) of perforations spanning ≥ 25% of the TM surface. Perforation closure was seen in 74% of all cases, with successful closure in 92% of perforations originally spanning < 25% of the TM surface area and 55% of perforations originally spanning ≥ 25% of the TM surface area. Two patients with residual perforations underwent a revision procedure using the same bilayer graft technique, which resulted in complete TM closure in one of those patients. Representative pre- and postoperative images from three patients are demonstrated in Figure 6.

Pre- and postoperative audiometric data were available for 14 patients. Average time from surgery to postoperative audiogram was 3.2 months, with a range of 0.9 to 7.8 months. When reported in accordance with the AAO-HNS guidelines (Gurgel et al. 2012), the preoperative ABG (mean 0.5, 1, 2, 3 kHz) was 13 ± 6 dB. Postoperatively, the ABG significantly improved to 7 ± 7 dB ($P < 0.05$). The change in ABG was 5 ± 7 dB.

Patients undergoing in-office TM repair reported minimal *intraprocedural* pain (4.4 ± 3.2 on a 1-10 pain scale) and 85% of patients felt any pain experienced was adequately addressed during the procedure. Additionally, 85%

of patients enjoyed viewing the procedure on the surgeon's display. Finally, 85% of patients would repeat the in-office procedure, if needed, when provided the alternative option of going to the OR. Patient-reported *postoperative* pain (scale 1-10) experienced within the first 24 hours was minimal (2.5 $\pm$ 2.2 on a 1-10 pain scale). Perioperative anxiety was assessed on a scale of 1-10, with scores $\leq$ 3 indicating mild anxiety and scores $>$ 3 indicating moderate/severe anxiety. The proportion of patients reporting moderate/severe perioperative anxiety was low (31%). Overall treatment satisfaction was high (8.2 $\pm$ 1.9 on a 1-10 satisfaction scale).

CONCLUSION

In summary, the presented surgical technique and graft design for in-office TM repair in awake patients is both well-received by patients and effective. We report low levels of pain and anxiety and respectable rates of patient-reported satisfaction. We also found a satisfactory rate of perforation closure and short procedural times. These results support the utility of in-office TM repair in both candidates and non-candidates for general anesthesia; however, additional studies comparing traditional approaches to the presented techniques are still needed.

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Disclosures

The authors report no proprietary or commercial interest in any product mentioned in this article.

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