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Bilayer Graft for Incisionless In-Office Endoscopic Repair of Tympanic Membrane Perforations: A Pilot Study

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Abstract

Tympanic membrane (TM) perforations may result in significant patient morbidity. While intraoperative myringoplasty or tympanoplasty allow for effective repair, not all patients are candidates for general anesthesia. Herein, we describe a novel graft design and technique for in-office repair of TM perforations in the clinic setting. Two pieces of porcine submucosa material were interdigitated to create a bilayer design with lateral and medial flanges. Topical and injected lidocaine were used for local anesthesia. The perforation was rimmed. Grafts were grasped, and medial flanges were placed through the perforation, with lateral flanges resting on the TM surface. TM repair occurred in 5 awake patients with a mean age of 72 years. There were no complications. All perforations healed, with 1 case requiring a minor in-office revision. Audiometry was performed at 4 weeks. The preoperative air-bone gap (mean 0.25, 0.5, 1, 2, and 4 kHz) was 12.2 ± 4.1 dB, and postoperatively, it was 4.2 ± 2.4 dB ($P = .001$). Novel design of available graft material may allow for effective in-office TM repair.

Keywords

[myringoplasty](#), [tympanoplasty](#), [endoscopic ear surgery](#), [endoscope](#), [porcine submucosa](#)

Tympanic membrane (TM) perforations can be reconstructed via myringoplasty or tympanoplasty. The gold standard tympanoplasty technique is the underlay graft, in

which materials are placed medial to the surgically elevated TM through postauricular or endaural incisions. Underlay tympanoplasty commonly requires general anesthesia and is performed in the operating room (OR). Given the morbidity and cost of traditional surgery, there has been interest in office-based repair. Paper patching,² cartilage buttons,¹⁻³ and growth factors⁴ have been trialed but have not gained clinical adoption because of problems with displacement, patient tolerance, and a lack of demonstrated efficacy.⁴⁻⁶

To minimize the morbidity of traditional approaches to TM repair, eliminate the need for general anesthesia, and maintain high surgical success rates, an in-office technique would apply the surgical principles of an underlay graft using an effective “off the shelf” material. This would eliminate the need for surgical graft harvest, saving time and patient morbidity. Herein, we pilot a novel TM graft design and minimally invasive transcanal endoscopic technique for myringoplasty in an office-based setting.

Methods

Study Design and Outcome Measures

The study was approved by the UMass Memorial Medical Center Institutional Review Board. Patients were retrospectively analyzed if they had TM repair in the clinic using a Food and Drug Administration–approved biologic TM graft made from porcine intestinal submucosa (Biodesign, Cook Medical, Bloomington, Indiana). Previous studies have demonstrated the efficacy of the Cook porcine submucosa otologic repair graft in the OR setting.^{7,8} Inclusion criteria were patients with nonhealing chronic perforations (>6 months) and available pre- and postoperative threshold audiometry, including tympanometry. There were no exclusion criteria. Patients were analyzed for feasibility of repair, rate of TM perforation closure, and changes in air-bone gap.

Surgical Preparation and Approach

Patients were placed in the supine position in the clinic setting and were awake throughout the procedure. After cleaning the ear with betadine, sterile cotton balls soaked in 4% viscous lidocaine were inserted to fill the ear canal. Four milliliters of 1% lidocaine with epinephrine 1:100,000 was instilled around the meatus. Using a

3-mm, 14-cm rigid Hopkins rod telescope (Karl Storz, Tuttlingen, Germany) to visualize the TM, a Rosen needle and alligator were used to measure and rim the perforation. The endoscope was introduced into the tympanic cavity for inspection. A cotton ball soaked in 1:100,000 epinephrine was placed on the TM.

Graft Design and Placement

Under sterile conditions, a 6-mm punch biopsy was used to fashion a circular biologic graft (**Figure 1**). Linear cuts were made at the 12 and 6 o'clock positions, leaving a roughly 0.5-mm gap, preventing bisection of the graft. The grafts were then interdigitated, creating a bilayer graft with 4 sets of flanges in 2 planes (medial and lateral). The graft was then soaked in sterile saline.

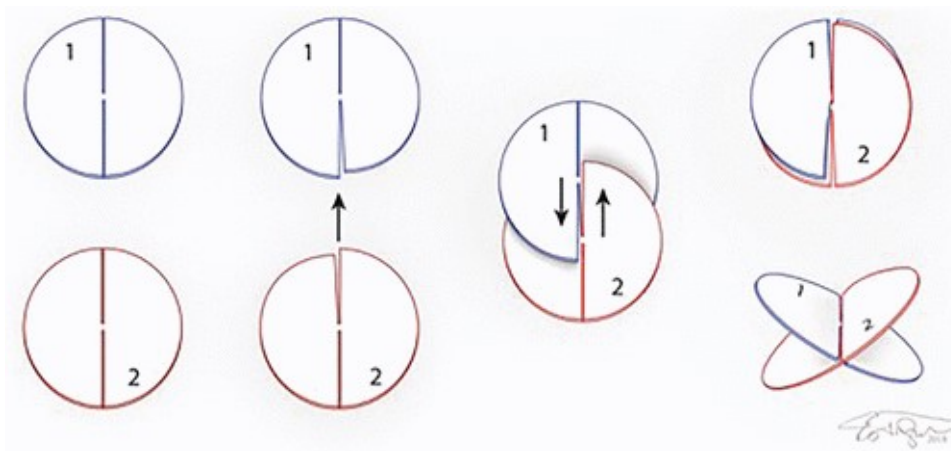


Figure 1. Construction of the bilayer graft. Illustration demonstrates configuration of the bilayer using two 6-mm discs of graft material.

The bilayer graft was held by smooth alligator forceps and placed directly on the lateral surface of the TM. No packing was placed into the middle ear. Using a Rosen needle, the 2 flanges contacting the TM were inserted through the perforation, medial to the TM, while the lateral 2 flanges remained lateral to the TM (**Figure 2**). An absorbable gelatin sponge soaked in antibiotic suspension was placed lateral to the graft. The canal was filled with antibiotic ointment.

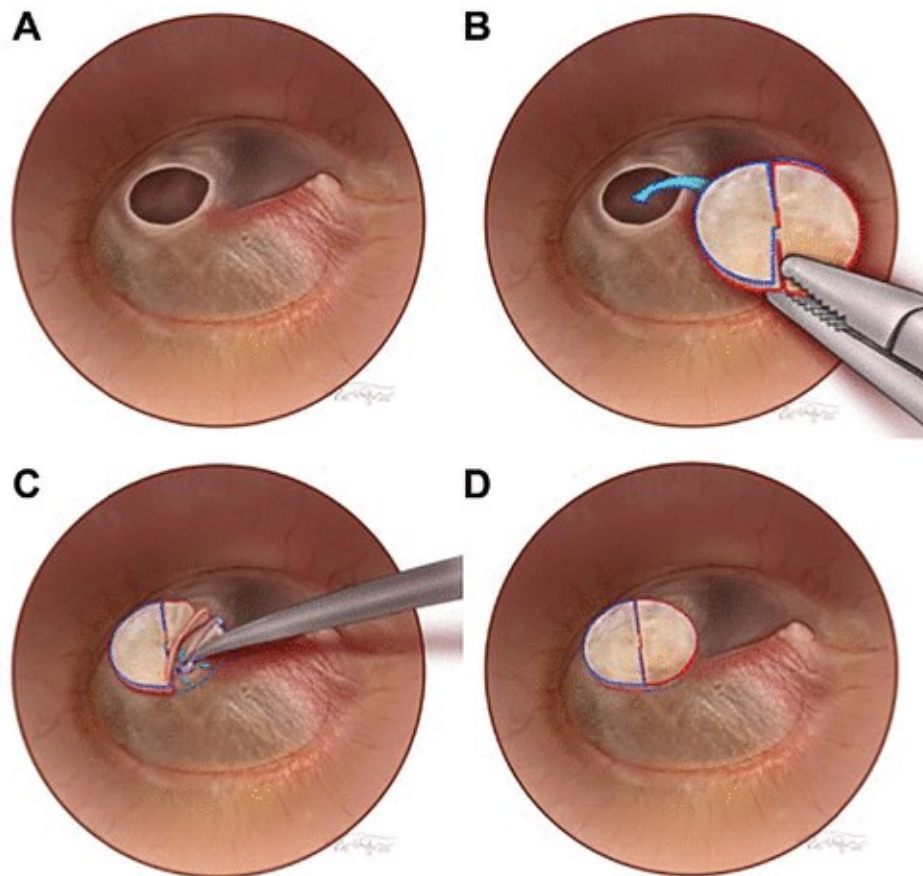


Figure 2. Transcanal endoscopic surgical approach. Illustration shows central perforation (A) and graft placement with an alligator forceps (B). A curved needle (C) is used to tuck medial grafts beneath the tympanic membrane (D).

The remaining packing was removed 14 days postoperatively at the first postoperative clinic visit. Audiometry and tympanometry were performed.

Results

In-office TM repair occurred in 5 female patients (mean age 72 years; range, 61-89 years; [Supplemental Table 1](#)). The mean size of the perforation was 3.5 mm (range, 2-4 mm). There were no issues related to graft placement around the ossicular chain. Procedures were performed entirely under local anesthetic and took on average 25 min (range, 15-45 minutes). There were no complications. There were no issues with the malleus or annulus during placement. All 5 perforations healed with clear evidence of vascular ingrowth to the graft ([Figure 3](#)). One patient (case 5) had a

residual (<1 mm) perforation, and a revision bilayer graft was placed that resulted in complete TM closure.

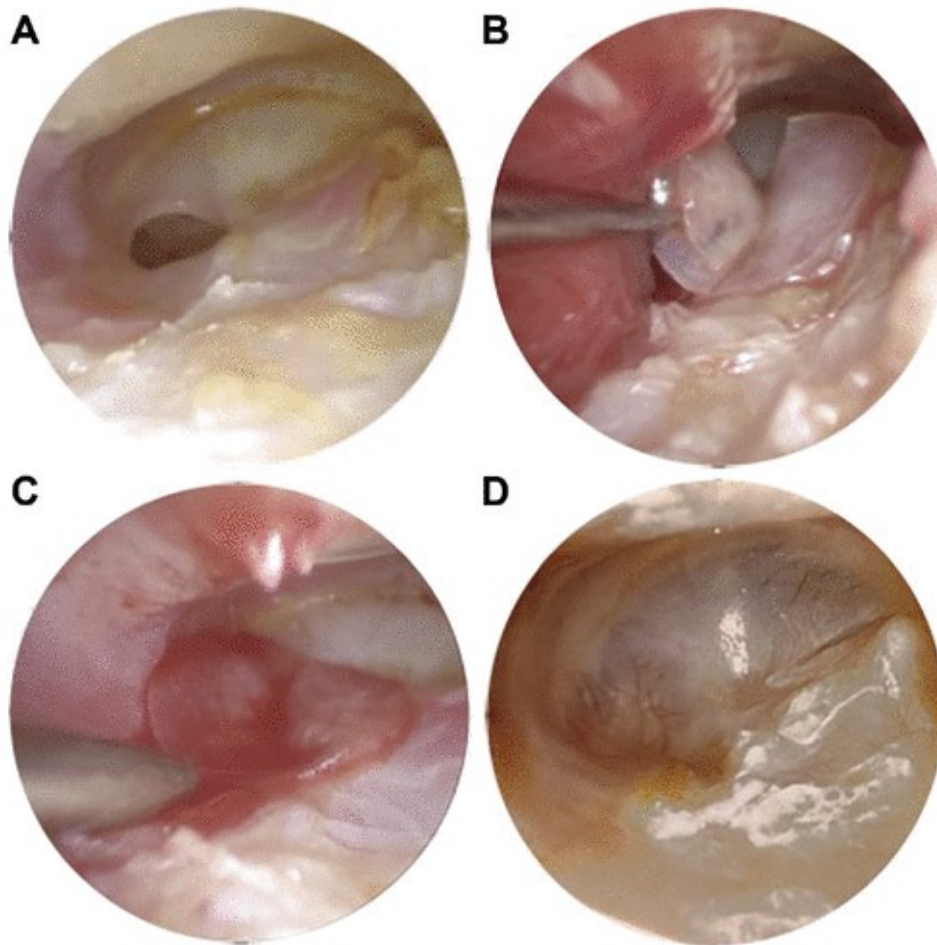


Figure 3. Representative pre- and postoperative images. Chronic tympanic membrane (TM) perforation (A) and positioning of medial flanges with the curved needle (B). Final position of graft (C) and healed TM with robust vascular ingrowth at 3 months (D).

In terms of audiometry, the preoperative air-bone gap (mean 0.25, 0.5, 1, 2, and 4 kHz) was 12.2 ± 4.1 dB. Postoperatively, there was significant improvement, with an air-bone gap of 4.2 ± 2.4 dB, $P = 0.001$). The mean duration of follow-up was 15 weeks (range, 6-24 weeks). Tympanometry reflected a change from type B to A tympanograms in all cases.

Discussion

This pilot study details a novel TM graft design and in-office approach to the placement of a bilayer TM graft for the repair of small- to medium-sized perforations. We observed no complications. The use of the endoscope facilitated placement of the graft, especially for complete visualization of the perforation; however, the graft design could also be used with a microscope. In addition, the approach did not necessitate use of gel foam in the middle ear. The absence of gel foam placement facilitated the speed of the procedure and minimized patient discomfort, especially in the awake setting.

There are several limitations of this study. First, the graft material was “off the shelf,” and there may have been additional cost to the patient versus autologous tissue. However, the cost was likely offset by avoiding general anesthesia, surgical equipment and disposables, and OR time. While we describe the use of an “off the shelf” graft, the design could be readily applied to other materials, including autologous ones. Second, there was a relatively small sample size and relatively short duration of follow-up. However, type A tympanograms and robust vascular ingrowth were apparent in all completed cases. Lastly, the perforations were roughly of similar sizes and were all repaired using a 6-mm graft size. Biopsy punches are available in a variety of sizes and could be selected based on the specific patient need.

In summary, the presented surgical technique and graft design add to the armamentarium of otolaryngologists for in-office repair of TM perforations. The approach may be readily applied in the OR. Additional studies should build on the described technique with longer patient follow-up and comparison with alternate materials to fully delineate efficacy compared with traditional approaches.

Author Contributions

Elliott D. Kozin, conception, study design, data collection, analysis, interpretation of the results, writing and approval of the manuscript; **Daniel J. Lee**, interpretation of the results, writing and approval of the manuscript; **Aaron K. Remenschneider**, conception, study design, data collection, analysis, interpretation of the results, writing and approval of the manuscript.

Disclosures

Competing interests: Elliott D. Kozin and Aaron K. Remenschneider received research funding from Cook Medical Foundation for an unrelated project related to laser Doppler vibrometry measurements in human cadaveric and in vivo animal models. There are no personal financial connections to Cook Medical Foundation.

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Supplemental Material

Additional supporting information is available at

<http://journals.sagepub.com/doi/suppl/10.1177/2473974X18869911>.

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