

ABSTRACTS

Biodesign - Otologic Repair Graft

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Pediatric Primary Tympanoplasty Outcomes With Autologous and Non-autologous Grafts

Cass ND, Hebbe AL, Meier MR, Kaizer AM, et al

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Objective: To compare rates of successful tympanic membrane (TM) closure in primary pediatric tympanoplasty between various autologous and non-autologous tissues.

Methods: A retrospective chart review was performed examining all primary pediatric tympanoplasties over a 20-year period at a single institution.

Results: In 564 pediatric tympanoplasties, no statistically significant difference existed between success rates of autologous and non-autologous grafts ($p = 0.083$). Compared with fascia, the hazard ratios (and 95% confidence intervals [CI]) for failure for each graft were as follows: human pericardial collagen (HR 0.90, CI 0.54-1.50, $p = 0.680$), porcine submucosal collagen (HR 1.07, CI 0.56-2.05, $p = 0.830$), human acellular dermal collagen (HR 1.66, CI 0.95-2.87, $p = 0.073$), and "multiple grafts" (HR 0.72, CI 0.26-1.98, $p = 0.520$). Survival curves demonstrated that 75% of graft failures occurred by 6 months after surgery, the rest occurring between 6 and 12 months postoperatively. Larger perforations encompassing more than or equal to 50% of the TM had lower success rates (HR 1.50, CI 1.02-2.21, $p = 0.041$) than smaller perforations encompassing less than 50% of the TM. Age was not correlated with success (HR 0.98, CI 0.93-1.03, $p = 0.390$).

Conclusion: This study found that non-autologous collagen grafts provide equivalent rates of healing when compared with autologous tissue in primary pediatric tympanoplasty. In addition to the potential for reduced operative time and donor site morbidity, these materials provide a viable graft alternative in fascia-depleted ears.

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

Kozin ED, Lee DJ, Remenschneider AK

OTO Open 2019 Aug 27;3(3).

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 per-

formed 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.

Porcine small intestinal submucosa (SIS) myringoplasty in children: A randomized controlled study

D'Eredita

Int J Pediatr Otorhinolaryngol 2015 Jul;79(7):1085-9.

Introduction: A novel bioactive material for tissue graft, derived from porcine small intestinal mucosa (SIS) has been marketed. This material promotes early vessel growth, provides scaffolding for the remodeling tissues, and is inexpensive and ready-to-use. We evaluated efficacy, safety, and surgery time of SIS myringoplasty, in comparison with autologous temporalis fascia (PTF) repair in children in a prospective, two-group (SIS and PTF) randomized, blinded study at a tertiary-care pediatric institution.

Materials and methods: 404 children with tympanic membrane (TM) repair were randomly assigned to receive SIS or PTF myringoplasty. Primary outcome was the healing of the TM at 6 months. Secondary outcomes were surgical time, and adverse events. Long-term follow-up ranging from 11 to 2 years was obtained in all enrolled children. Audiometric tests as pure-tone thresholds were applied in all patients. The Fisher's exact test and the Kruskal-Wallis test were applied for statistical analysis.

Results and discussions: Four-hundred-thirty-two TM perforations were treated, 217 in the SIS and 215 in the PTF groups. There were 209 stable TM closures in the SIS (96.3%) and 204 (94.8%) in the PTF arm. This difference was not statistically significant (odds ratio=0.4, 95%; confidence interval=0.12-1.41). SIS myringoplasty yielded reduced surgical time. No adverse reaction to SIS was encountered. Audiometric tests revealed no statistically significant difference in the two groups.

Conclusions: SIS myringoplasty is a safe and effective method for TM closure in children with reduced surgical time, as compared to PTF.

Tympanic Membrane Perforation Repair Using Porcine Small Intestinal Submucosal Grafting

Yawn RJ, Dedmon MM, O'Connell BP, et al.

Otol Neurotol 2018 Jun;39(5):e332-e335.

Objective: To evaluate the use of porcine small intestinal submucosal grafts for tympanic membrane repair.

Patients: Adult and pediatric patients with tympanic membrane perforations with and without chronic otitis media, and perforations after removal of cholesteatoma.

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Intervention: Endoscopic or microscopic tympanic membrane repair using porcine small intestinal submucosal grafts (Biodesign).

Main outcome measure(s): Perforation closure, bone and air pure-tone averages (PTA), air-bone gap (ABG), and word recognition scores (WRS) were recorded as outcome measures.

Results: Thirty-seven patients were included with a mean age of 25.4 years (range, 6-75), 57% men. Twenty-six cases (70%) were performed endoscopically and 34 (92%) had concomitant cartilage grafting. Three patients (8%) had postoperative pinpoint (<1% surface area) perforation, and two patients (5%) had postoperative perforation, with an overall success rate of 86.5%. The mean improvement in air-bone gap was 7.6 dB and ($p = 0.006$). There were no statistically significant differences in closure rates when comparing primary versus revision cases, endoscopic versus microscopic cases, size of perforation, cholesteatoma, concomitant mastoidectomy, age, tobacco exposure, or comorbid diabetes mellitus. Patients with concomitant cartilage graft were more likely to be successful when compared with those without cartilage graft ($p = 0.04$).

Conclusions: Porcine small intestinal submucosal grafts are effective in the repair of the tympanic membrane. These grafts are an excellent choice in total endoscopic cases as it avoids incisions necessary for allograft harvest.

Double-handed endoscopic myringoplasty with a holding system in children: Preliminary observations

Radaelli De Zinis LO, Berlucchi M, Nassif N

Int J Pediatr Otorhinolaryngol 2017 May;96:127-130.

Objectives: Endoscopic transcanal myringoplasty is a newly-introduced technique for reconstruction of tympanic membrane perforation that offers the advantage to obviate postauricular incision. The objective of this study was to evaluate the feasibility of a double-handed endoscope holder transcanal myringoplasty in children. This technique permits bimanual execution of the procedure and allows the surgeon to overcome the two significant issues of single-handed endoscope surgery, i.e. easy domination of a bloody field and smooth introduction of the graft.

Methods: A prospective non-randomized study of 10 consecutive primary endoscope holder-aided myringoplasties was performed; 3 mm or 4 mm 0° rigid endoscopes were used. A xenograft, biologic soft tissue, was applied in all cases.

Results: All procedures were performed successfully. Duration of surgery was faster than with a single-handed procedure and varied between 20 and 60 min. The tympanic membrane healed successfully in all patients.

Conclusions: In this preliminary experience in children, a bimanual endoscopic holder-aided myringoplasty technique

offers the possibility to overcome the obstacles encountered in a single-handed technique, since it can replicate the same concept of a bimanual microscopic approach and allow for easy management of a bloody field and introduction of the graft in the middle ear.

Endoscope or microscope-guided pediatric tympanoplasty? Comparison of grafting technique and outcome

James AL

Laryngoscope 2017 Nov;127(11):2659-2664

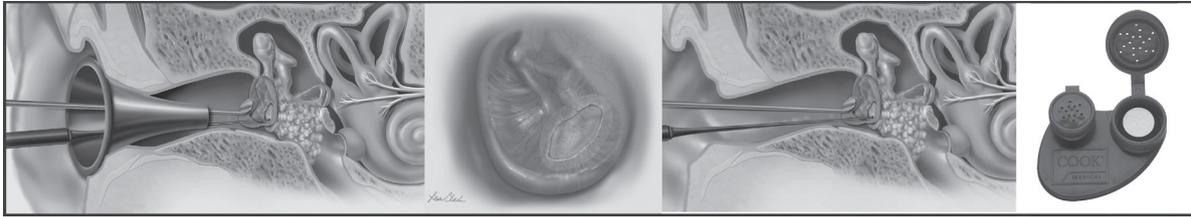
Objectives/hypothesis: To review experience from the introduction of totally endoscopic ear surgery (TEES) to a pediatric tympanoplasty practice to identify factors influencing technique selection and successful outcome.

Methods: Analysis of prospectively acquired data from a consecutive series of 295 surgeries for tympanic membrane perforation over a 12-year period. Success of perforation closure was compared between microscope and TEES grafting techniques. Impact of the acquisition of endoscopic techniques and equipment were compared with annual proportion of cases completed by TEES.

Results: Of 267 tympanoplasties, 109 (41%) were completed with TEES and 158 by a postauricular approach. The proportion completed with TEES increased gradually to 97% of cases as equipment and expertise were acquired. Young age did not prevent TEES tympanoplasty. Two hundred nineteen of 250 (88%) perforations were closed successfully by tympanoplasty, with equivalent closure rates between TEES and postauricular approaches. Underlay of tragal perichondrium was less successful than lateral graft technique using TEES ($P = .04$, Fisher exact test). "Push-through" myringoplasty using a microscope or endoscope was least successful (19 of 28 (68%), $P = .005$). The median length of stay was 13 hours shorter for TEES than postauricular tympanoplasty ($P = .04$, Mann-Whitney rank sum test). Wound complications occurred in five (3%) postauricular cases and one TEES case.

Conclusions: TEES tympanoplasty is feasible in a large majority of children given appropriate equipment and surgical experience. Nonautogenous graft material is ideal for this minimally invasive approach. TEES is recommended as providing equivalent likelihood of perforation closure to the post-auricular approach but with less postoperative morbidity.

Biodesign Otologic Repair Graft.



Biodesign® is a platform technology behind numerous tissue-repair products that span multiple medical specialties. Biodesign is natural extracellular matrix (ECM) derived from porcine small intestinal submucosa (SIS). The ECM is a complex latticework of proteins and structural molecules that helps guide the growth of cells. Cook's proprietary processing methodology decellularizes the SIS material while preserving natural matrix molecules such as collagen, proteoglycans, and glycosaminoglycans. The result is a scaffold that, when implanted, provides a location for host cells to infiltrate and remodel into vascularized tissue.

The Biodesign Otologic Repair Graft is a grafting biomaterial for tympanic membrane perforation closure. It provides the surgeon with a truly minimally invasive approach to ear surgery with no donor site required and thus no additional scar for the patient.

For further information and access to videos please visit www.CCMed.co.uk or scan the QR code

