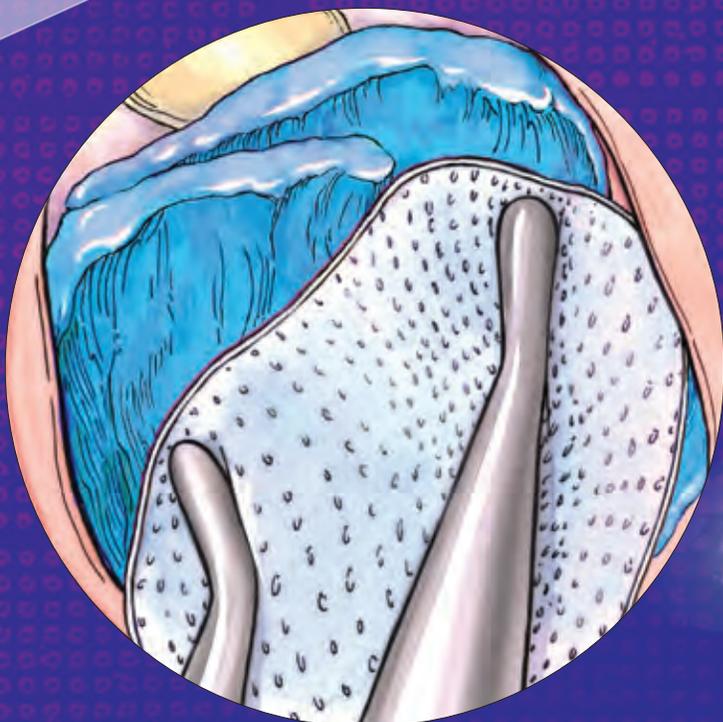




EpiDisc[®] Otologic Lamina and MeroGel[®] Otologic Packing

SURGICAL TECHNIQUE

Krueger "H.A.T." Hyaluronic Acid Tympanoplasty Technique



Surgical Technique Presented
by Wesley O. Krueger, MD

Philosophy

Little has changed in otologic surgery techniques and materials over the past few decades. The most frequently documented complications include middle ear adhesions/fibrosis, dense fibrous capsule formation in response to silicone or fluoroplastic sheeting in the middle ear and chronic granular inflammation of the tympanic membrane graft and canal wall. It is hoped that integrating the use of two unique otologic devices created from HYAFF® an esterified form of hyaluronic acid, during canalplasty, myringoplasty, tympanoplasty and stapes and mastoid surgery, will address many of the problems encountered by the otologic surgeon.

Hyaluronic Acid

Hyaluronic acid is a naturally occurring linear polysaccharide and is found in high concentrations in the extracellular matrix, particularly the synovial fluid and vitreous humor of the eye. It plays a significant role in the body during the repair process, mediating cell adhesion, differentiation, motility and blood vessel growth.

Hyaluronic acid has a well established biocompatibility profile, is bacteriostatic¹, and plays a bioactive role in the process of regenerative vs. reparative wound healing in fetuses.² More than 30 million patients have been treated with various hyaluronic acid devices, including devices that help to reduce the incidence and severity of postoperative adhesions in abdominopelvic surgery.³ In middle ear surgery, hyaluronic acid has been shown to improve the natural healing of the mastoid cavity following tympanoplasty and help reduce connective tissue formation.^{4,5}

Surgical Technique

When performing a myringoplasty or tympanoplasty, EpiDiscs® (EpiFilm® Otologic Lamina Discs) and MeroGel® Otologic Packing are utilized to separate mucosal surfaces to help minimize the formation of adhesions. This assists the natural healing process and assists with re-epithelialization of the canal and lateral surface of the graft.

EpiDisc Otologic Lamina is a thin, implantable scaffold made from esterified hyaluronic acid, HYAFF, in an 8 mm diameter disc configuration. This makes it ideal for placement on the promontory during tympanoplasty and as a scaffold on the tympanic membrane during myringoplasty or tympanoplasty procedures. EpiFilm Otologic Lamina, 2.5 cm x 2.5 cm, is a larger version of EpiDisc lamina that is useful for surgical procedures where more material is needed to cover larger surface areas of mucosa or exposed bone.

Nota Bene: The technique description herein and the use of instructions for the related procedures are made available by Medtronic ENT to the healthcare professional to illustrate the author's suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which, in the healthcare professional's judgment, addresses the needs of the individual patient.

Figure 1

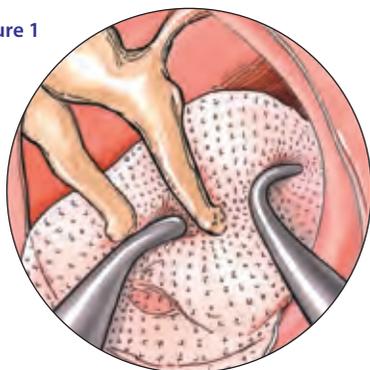


Figure 2

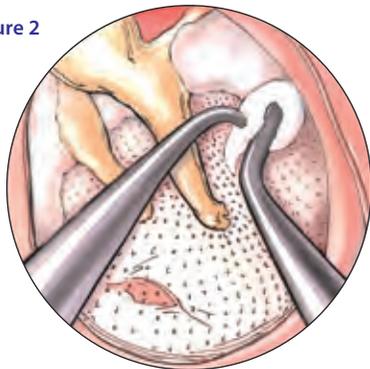


Figure 3

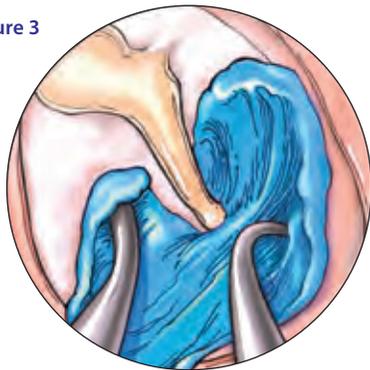


Figure 4

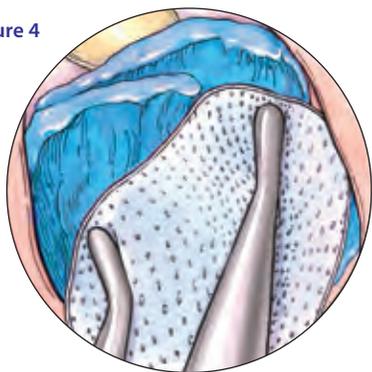
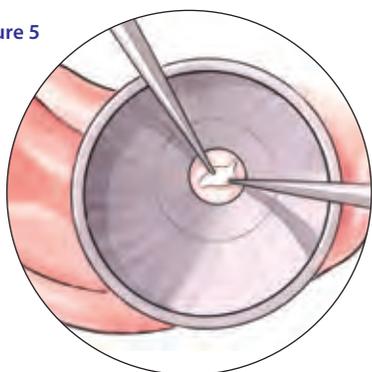


Figure 5



MeroGel Otologic Packing is a space-occupying biomaterial with a soft, cotton-like structure that can be used to pack the middle ear space to separate mucosal surfaces and support the tympanic membrane graft. It can also be used as a dissolvable external ear packing to support the external ear canal skin.

In the Krueger H.A.T. Technique, an EpiDisc lamina is placed on the promontory (Figure 1). Small pieces of MeroGel packing are hydrated with an antibiotic solution and placed in the middle ear cavity to help support the tympanic membrane graft (Figure 2).

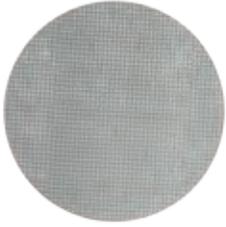
In an overlay fashion, a dried and trimmed temporalis fascia graft is then placed under and around the malleus handle and on top of the tympanic membrane annulus (Figure 3). Once the temporalis fascia graft has been properly placed, a second EpiDisc lamina is used to cover the entire graft area (Figure 4). The 40-80 micron diameter microperforations in the EpiDisc lamina allow fluid exudates to egress from the surface of the graft. When used in the middle ear, EpiDisc lamina and MeroGel packing typically dissolve in 6-8 weeks.

Finally, the external ear canal is packed with MeroGel dressing. The amount of material typically needed is available in the larger version of MeroGel packing, 4 cm x 4 cm, which is the MeroGel Nasal Dressing/Sinus Stent and Otologic Packing. Small pieces are selectively used and rolled into the desired shape, hydrated and packed into the ear canal to the meatus (Figure 5). Postoperative care is the same as with other packings and preparations, such as keeping the ear dry. However, the advantage is that the MeroGel material will dissolve when hydrated with some consistency. Typically, the patient is instructed to apply antibiotic drops to the ear canal twice daily for three weeks following the surgery. MeroGel packing will dissolve approximately two weeks after hydration.

Reference

1. Pirnazar P., et al, 1999, "Bacteriostatic Effects of Hyaluronic Acid," J. Periodontol, 70:370-374.
2. Longaker M. T., et al, 1991, "Studies in Fetal Wound Healing. A Prolonged Presence of Hyaluronic Acid Characterized Wound Fluid," Annals of Surgery, 213:292-296.
3. Grainger D. A., et al, 1991, "The Use of Hyaluronic Acid Polymers to Reduce Postoperative Adhesions: J. Gynecol. Surg. 7:97-101.
4. Martini A., Morra B., "An Open, Controlled, Randomized, Multicenter Study to Evaluate the Clinical Performance and Safety of HYAFF 11 Otomembrane in the Healing Process of Mastoid Cavity in Patients Suffering from Chronic Cholesteatomatous Otitis Media."
5. Laurent C., Hellstrom S., Stenfors L., 1986, "Hyaluronic Acid Reduces Connective Tissue Formation in Middle Ears Filled with Absorbable Gelatin Sponge: An Experimental Study," Am. J. Otolaryn., 7:181-186.

EPIDISC®



EpiDisc® Otologic Lamina 1417100

- 8 mm disc
- 2 per box



EpiFilm® Otologic Lamina 1417000

- 2.5 cm x 2.5 cm
- 1 per box

MEROGEL®



MeroGel® Otologic Packing 1517100

- 1 cm x 5 cm
- 1 per box

MeroGel Nasal Dressing Sinus Stent/Otologic Packing 1517000

- 4 cm x 4cm
- 1 per box

MeroGel Nasal Dressing Sinus Stent/Otologic Packing, Double Pack 1517002

- 2 per box

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