Extracellular collagen Matrix as a Replacement for Gelfilm® for Post-Tympanostomy Tube Myringoplasty

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Introducction

Most otolaryngologists will remove tympanostomy tubes that have not extruded spontaneously by 2-3 years after placement.1-3 When tubes are removed under general anesthesia, it is common practice to freshen the margins of the resulting perforation and to patch the tympanic membrane.4

Gelfilm® (Pfizer Pharmaceutical) has been a favored patch material in recent decades.5-8 It is thin, sterile, and easily trimmed with scissors. It adheres to the drum for about a month before peeling away. Tympanic closure rates as high as 90% have been reported with this technique.6

In fall 2018, Gelfilm® became unavailable from its sole manufacturer. To date, Gelfilm® has not returned to the market. As a substitute for Gelfilm®, we chose Extracellular Collagen Matrix (Biodesign®, Cook Medical). It is sterile; it adheres to the tympanic membrane; it is United States Food and Drug Administration approved for tympanic membrane repair.

This report summarizes our one-year experience with the material for post-tube removal myringoplasty.

Methods and Materials

Retrospective cohort study:
• Surgeries were performed in the same manner by the same surgeon supervising residents during consecutive time periods.
• Control group – Children who had undergone Gelfilm® myringoplasty with at least one month follow-up. (January 2016 – August 2018)
• Collagen matrix group – Children who underwent a collagen matrix myringoplasty with at least one month follow-up. (September 2018-December 2019)
• Patient age at time of surgery
• Gender
• Presence or absence of a persistent perforation at one month follow-up
• Otooscopy and tympanometry were used to determine successful closure.
• Visually closed but with large volume tympanogram is considered an initial treatment failure.
• Persistent perforations that closed on subsequent follow-up is considered as an initial treatment failure.

Results

Table 1. Characteristics of patients and ears undergoing Gelfilm® or Collagen matrix myringoplasty.

28 Gelfilm® myringoplasty patients (36 ears) – 5 initial treatment failures
27 Collagen matrix myringoplasty patients (35 ears) – 3 initial treatment failures

There was no significant difference in the rate of persistent perforation between the two materials by Fisher’s exact test by patients (p = 0.7049) or by ears (p = 0.7101; OR: 1.72; 0.38–7.82).

Discussion

Some controversy continues regarding the need for patch myringoplasty after removal of retained tympanostomy tubes. No prospective trial comparing simple removal to myringoplasty exists. Available retrospective reports showing no difference between simple removal and repair may be subject to selection bias.9,10 Perforations in high risk populations (older age, long-term tube, tymiitis 2) were more likely to be patched.

In 1992, Baldwin and Lottin described the use of sterile gelatin film for residual perforations after tympanostomy tube removal.9 Modifications of their technique became popular since then with favorable results compared with paper patching (96% vs 78% closure).10 When applied to the surface of the tympanic membrane after tube removal, a blood film usually forms beneath the Gelfilm® patch. It also evokes little visible inflammatory reaction and consistently peels away in 1-2 months.

Our group used Gelfilm® myringoplasty consistently until the material became unavailable in the fall of 2018. While looking for a replacement material we found Biodesign® Otologic Repair Graft which is a modification of Surgifilm® (Cook Medical, West Lafayette, IN) a graft material derived from porcine small intestinal submucosa. Biodesign® was originally designed as a xenograft for underlay tympanoplasty. Healing results were similar to autologous temporalis fascia in a pediatric tympanoplasty series.11,12 We were concerned initially that the collagen matrix patches would produce a continuing inflammatory response. In fact, collagen matrix behaved much like Gelfilm®, adhering to the surface of the tympanic membrane during healing, and peeling off 1-2 months after placement without apparent resection of the graft material as seen in Figure 2.

Gelfilm® and collagen matrix patches were similarly effective in this small pilot study. The children in the Gelfilm® group were slightly older (median age 5 versus 4 years) than in the collagen matrix group – a known risk factor for failure. Further children with persistent perforations were age outliers in the Gelfilm® group – 3, 3, 6, 7, and 7 years (group median 5 years), but not the collagen matrix group. This study was underpowered to show a small difference between the materials given the substantial rate of spontaneous closure without patch application.

Conclusions

For surgeons preferring to patch the tympanic membrane after tube removal, collagen matrix graft material appears to be an effective substitute for Gelfilm® with closure rates in excess of 90%.

References


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