Synthetic Sealants in Tympanic Membrane Repair
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Introduction

• The goal of this study was to describe a novel use of tissue sealants (Tisseel and Duraseal) to repair tympanic membrane (TM) perforations.
• Current treatment techniques for TM perforations yield highly variable results and often have to be performed in the operative room.
• The ultimate objective of this project is to develop a technique to heal TM perforations using sealants alone (without the use of lobule fat) as an in-office procedure.

Background

• TM perforations can arise from a variety of sources including infection (acute suppurative otitis media), iatrogenic (extrusion of PE tubes), and trauma to name a few
• Perforations can result in conductive hearing loss (CHL), cholesteatoma, and infection
• CHL is caused by the loss of normal TM:stapes footplate surface area ratio as well as allowing sound to simultaneously reach the oval and round window, canceling cochlear fluid movement.5 5
• Myringoplasty is by definition a Type 1 tympanoplasty
• Variable success rates for closure have been described 3
• Multiple studies demonstrate a higher success rate with smaller perforations (<50% or less than 4mm) 4 5
• Multiple graft materials have been described; temporalis fascia is universally the most common graft for all TM perforations 6
• Fat graft myringoplasty is commonly used for smaller perforations
• The concept of applying a synthetic sealant was to provide a better medium for TM epithelium to grow

Methods

• This study was a prospective series of patients undergoing fat graft myringoplasty treated with synthetic sealants in the operating room
• IRB approval was granted
• 22 patients, 23 TM perforations were operated on in this preliminary study
• One patient was removed from the study due to using Duraseal alone without fat graft
• Preoperative clinic visits and audiograms recorded the size of the perforation, the air-bone-gap (ABG), speech recognition threshold (SRT), and word recognition score (WRS)
• Fat graft myringoplasties were performed in standard fashion, followed by a covering of Tisseel (9) and Duraseal (14)

Table: Causes of TM Perforation

<table>
<thead>
<tr>
<th>Causes of TM Perforation</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Suppurative Otitis Media</td>
<td>21</td>
</tr>
<tr>
<td>Scuba Diving</td>
<td>1</td>
</tr>
<tr>
<td>Cholesteatoma</td>
<td>1</td>
</tr>
</tbody>
</table>

Results - Continued

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Pre-operative</th>
<th>Post-operative</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air-bone-gap (n=18)</td>
<td>33.3</td>
<td>14.2</td>
<td>p = 0.001</td>
</tr>
<tr>
<td>SRT (n=17)</td>
<td>30.9</td>
<td>22.6</td>
<td>p = 0.001</td>
</tr>
<tr>
<td>Word Recognition Score (n=17)</td>
<td>94%</td>
<td>93.9%</td>
<td>p = 0.985</td>
</tr>
</tbody>
</table>

Discussion

• In the current study, 20 of 23 (87%) TM perforations have healed at long-term follow-up (> 4 weeks)
• No major complications were noted
• Adding synthetic sealants did not add to operative time
• Problems with technique – not treating the root cause of perforation (except in the case of trauma)
• We switched from the sealant Tisseel to Duraseal midway through our study
due to the rare possibility of an anaphylactic reaction and because it has human components
• The 3 failures originally had perforations of 5%, 35%, and 45%
• After the procedure, the perforations measured 30%, 20%, and 40% respectively

Conclusion

• Fat graft myringoplasty is a common procedure used to correct small to moderately sized TM perforations
• This preliminary study demonstrates good results with this technique
• It is our goal to evolve this procedure to be able to heal moderately to large TM perforations
• It is also our goal that this technique can be performed safely in the office and ultimately without the need for biologic tissue, i.e. sealants alone
• This study provides the basis for next IRB approved study

References