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Utilizing Dehydrated Human Amnion/Chorion Membrane Allograft in Transcanal Tympanoplasty

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Abstract

Objective: To evaluate the utility and effectiveness of dehydrated Human Amnion/Chorion Membrane (dHACM) in transcanal tympanoplasty.

Patients: A retrospective analysis of 14 patients (8 adults and 4 children) with stable tympanic membrane perforations for greater than 6 months.

Intervention: Transcanal tympanoplasty performed by a single surgeon utilizing a dHACM allograft.

Main outcome measures: Operative time, pain, graft success and audiologic improvement.

Results: At the 6 week post-operative visit a decrease in perforation size was noted in 8 patients (57.1%) and complete closure of the perforation occurred in 6 (42.9%). For patients without tympanosclerosis (n=10) complete closure was achieved in 5 patients (50%) and complete or partial success in 7 patients (70%). Mean air bone gap decreased from a pre-operative measurement of 23.0 ± 10.1 dB to 16.8 ± 7.4 dB at 6 weeks after tympanoplasty. The technique was well tolerated. Using the transcanal method and dehydrated amnion/chorion membrane allograft, the mean operative time was 13.3 ± 0.10 minutes.

Conclusions: Commercially available dHACM appears to be a safe, viable graft material for transcanal tympanoplasty.

Keywords: Allograft; Amniotic membrane; Tympanoplasty

Introduction

Tympanoplasty is a surgical procedure used in patients to repair defects in the tympanic membrane and restore or maintain hearing function [1]. A wide variety of autologous grafting materials have been used for tympanoplasty, including cartilage, perichondrium, and loose areolar tissue, fat and most commonly, temporalis fascia [2]. Recently, commercially available allograft materials such as Alloderm (LifeCell Corp., Branchburg, NJ) derived from donated skin from human cadavers has been used as an alternative to autologous tissue in efforts to reduce scarring, infection and pain, as well as operative time [2]. Although, this material may provide a suitable grafting option, it's acellular characteristic only serves as a scaffold or template for ingrowth, which may limit its long-term success.

Human amniotic membrane has been considered to be an ideal biological dressing in that it promotes epithelialization and reduces pain while having antibacterial properties [3]. Biochemical properties of amniotic membrane help to reduce inflammation and enhance soft tissue healing [3]. Growth factors including EGF, TGF- β , FGF and PDGF A and B are present in human amniotic tissue and not only self-signaling but also mediate the tissue repair process [4]. Basic scientific research has suggested growth factor involvement in accelerating or enhancing healing of tympanic membrane [5,6]. In addition to growth factors, human amniotic membrane contains extracellular architectural elements including collagens type IV, V and VII. These materials form an important substrate and scaffold within various tissues which is needed for advanced wound healing and ingrowth of cells. The extracellular matrix of amniotic membrane is also comprised of other structural materials including fibronectin, laminins, proteoglycans and glycosaminoglycans, all which may promote the wound healing process.

A commercially available dehydrated Amnion/Chorion Membrane

(dHACM) allograft (EpiFix[®], MiMedx Group, Inc., Marietta, GA) is created through a proprietary PURION[®] process which cleans, dehydrates and sterilizes human amniotic/chorionic membrane while preserving key attributes of natural amniotic membrane. Scientific studies have demonstrated that dHACM is composed of extracellular matrix materials, growth factors, and cytokines in essentially the same amount and in a preserved state when compared with natural amniotic membrane tissue [7]. The composition of the allograft has been demonstrated both qualitatively with specific immunohistochemical testing and quantitatively with ELISA testing to document this equivalence [7].

Use of natural human amniotic membrane for tympanoplasty has been reported in studies conducted outside the United States, with positive results [8-11]. The purpose of the present analysis was to evaluate the utility and effectiveness of dHACM in patients residing in the United States undergoing transcanal tympanoplasty.

Materials and Methods

A clinical evaluation of the dHACM allograft for tympanic membrane repair was conducted. All transcanal tympanoplasties were performed by a single surgeon in an outpatient surgical setting and

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utilized dHACM for the primary graft. Clinical records were reviewed from patients with stable tympanic membrane perforation of greater than 6 months in duration undergoing transcanal tympanoplasty between November 2009 and November 2010. An Investigational Review Board (Western IRB) reviewed the project summary and determined that the project met the conditions for exemption under 45 CFR 46.101(b) [4].

Surgical technique and procedure

The procedure was performed at one of two outpatient surgical centers. Subjects underwent general anesthesia and followed standard sterile prepping technique. An operative microscope was used to perform the operation. 1% lidocaine with 1:100,000 epinephrine was infiltrated in the external auditory canal. Sterile saline was used to irrigate the ear canal. After the size of the perforation was noted the timing of the procedure was then initiated. The edges of the perforation were freshened with a straight pick and cupped forceps. The middle ear was then packed with gel foam soaked with saline until the space immediately behind the perforation was obliterated.

An appropriate sized graft of dHACM was then fashioned to cover the perforation. The size of the graft was designed to slightly overlap the size of the perforation so that there would be no visible defect. The dHACM was then hydrated with sterile saline for 30 seconds, and then placed on the lateral surface of the tympanic membrane. The edges were smoothed, allowing continuity of the graft and the native tympanic membrane. Operative photography was taken of the initial perforation and then with the graft in position. Additional saline-soaked gel foam was then placed carefully over the graft, over the borders and the central portion of the graft until the graft was not visible and to secure its position. Once completed, timing was then halted.

Data collection and analysis

Medical record review was conducted to collect patient demographics, clinical presentation at time of surgery, duration of surgery, results of audiometric testing and results of surgery, including documented patient satisfaction. Post-operative office visits were conducted at 1, 3, and 6 weeks after surgery. Audiometric testing was conducted preoperatively and at the 6 week follow-up visit. Outcomes assessed included closure of perforation at 6 weeks, reduction in size of perforation, pain or swelling at the operative site, auditory response, length of operation, and patient and clinician satisfaction with the product.

Results

Over the one year period, dHACM was utilized in 14 patients undergoing transcanal tympanoplasty. Other than all patients presenting with tympanic rupture of at least 6 months duration, patients had different clinical presentations, which is tabulated in Table 1.

Post-operative observations at weeks 1, 3 and 6 are presented in Table 2. Drainage was reported by two patients at week one and three, though this is believed to be related to the gel foam that was used to secure the graft in position. No infections or other adverse events were identified. By post-op week 6, all 14 patients (100%) reported return of hearing. Audiometric testing was performed prior to surgery and at 6 weeks post-op. Overall, mean air bone gap decreased from a pre-op measurement of 23.0 ± 10.1dB to 16.8 ± 7.4dB at 6 weeks post-op (two-tailed p value of 0.058). The eight patients with improved audiometric scores had a mean difference of 13.6 ± 8.9dB between pre-op and 6 week post-op mean air bone gap measurements.

	N=14
Mean Age (years)	42.8 ± 22.5 (9,79)
>18 years	10 (71.4%)
≤ 18 years	4 (28.6%)
Male gender	7 (50%)
Cholesteatoma	1 (7.1%)
Tympanosclerosis	4 (28.6%)
Prior surgery on ear	2 (14.3%)
Size of perforation:	
<25%	9 (64.3%)
25-50%	3 (21.4%)
>50%	2 (14.3%)

Data presented as n (%) as indicated

Table 1: Clinical presentation.

	Week 1 (n=14)	Week 3 (n=14)	Week 6 (n=14)
Pain at surgical site	1 (7.1%)	1 (7.1%)	1 (7.1%)
Swelling	1 (7.1%)	0	0
Drainage	2 (14.3%)	2 (14.3%)	0
Infection	0	0	0
Auditory response	9 (75%)	13 (92.9%)	14 (100%)

Data presented as n (%) as indicated

Table 2: Post-operative observations.

Overall, complete closure of the tympanic membrane occurred in 6 of the 14 patients (42.9%), complete or partial closure occurred in 8 patients (57.1%). Of the 8 patients with continued perforation at 6 weeks post-op, 4 (50%) had tympanosclerosis, 2 were children, and 4 had >25% perforations at time of surgery. Of the 2 patients with prior surgery of the affected ear, one had successful healing and one did not. For those patients without tympanosclerosis (n=10) complete success was achieved in 5 patients (50%) and complete or partial success in 7 patients (70%).

Mean duration of surgery was 13.3 ± 0.10 minutes (range 9.1-23.7 minutes), median 12.2 minutes. Overall, 11 patients reported satisfaction with the procedure and 13 of 14 patients would opt to use the material and operative technique again if future surgery in either ear was required.

Discussion

Investigations conducted outside the United States have reported on the use of natural human amniotic membrane for tympanoplasty [8,9]. Harvinder et al. [9] compared human amniotic membrane and temporalis fascia graft for underlay myringoplasty, concluding that amniotic membrane was a suitable graft material for repairing perforated tympanic membranes. Permeatal, endaural or postauricular approach was used and final outcome was assessed after 6 months. Successful closure was achieved in 13 of 20 (65%) of patients in the amniotic membrane group and in 17 of the 30 (56.7%) of the temporal fascia group. Difficulty in obtaining human amniotic membrane and issues with cleaning and sterilizing the tissue were noted. An Egyptian study by Fouad et al. [8] included 64 patients age 18-50 without cholesteatoma, infection, or prior surgery, reported similar success rates in the temporal fascia group and amniotic membrane groups of 87.5% and 84.4% respectively, although mean operative time was significantly reduced with the use of amniotic membrane [10]. This is an important observation in that avoiding a separate incision to harvest graft material results in reduced operative time, patient discomfort and scarring, and eliminates risk for infection of the harvest site. In the

Fouad study a postauricular approach was used and final outcome was assessed after 3 months. In the present evaluation of dHACM applied via transcanal approach, and including patients with cholesteatoma, tympanosclerosis, and prior surgery, complete closure was observed in 42.9% of patients and partial or complete closure in 57.1%. As differences in surgical approach, patient history and timing of follow up exist between the current study and previous reports results are not comparable.

For over a century, human amniotic membrane has been used in the treatment of various types of wounds [12]. Historically, widespread use of human amniotic membrane has been limited due to issues related with tissue preparation, stabilization and storage. Derived from placentas, human amniotic membranes are often difficult to obtain, prepare and store. The PURION process allows for the creation of a dHACM allograft available in multiple sizes with a shelf life of 5 years at ambient temperature. This is the first evaluation on the use of dHACM to repair tympanic membrane perforations in the United States.

Weaknesses of the present study are those characteristic of retrospective studies and small study samples. The small numbers of patients preclude evaluation of factors that may impact treatment success such as presence of tympanosclerosis, size of perforation, medical history, age, and tobacco use. The lack of controls eliminates the ability to compare results to other treatment modalities. Variable surgical methods, and underlay vs. overlay technique may also contribute to successful closure, but this cannot be assessed with the current data. In addition, patients were only followed for 6 weeks after surgery, a longer follow-up period may allow for better assessment of graft effectiveness.

Although further studies are needed to determine efficacy of dHACM for tympanoplasty and which types of patients may most benefit from its use, the current evaluation provides useful preliminary information and suggests that dHACM may be an acceptable, safe and well tolerated graft material in patients requiring tympanoplasty, especially those where a shorter operative time and/or avoidance of additional graft-harvesting wound is desired.

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