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Original Article

Comparison of Hyaluronic Acid Fat Graft Myringoplasty, Fat Graft Myringoplasty and Temporal Fascia Techniques for the Closure of Different Sizes and Sites of Tympanic Membrane Perforations

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OBJECTIVE: To compare the efficacy of three different myringoplasty techniques, namely hyaluronic acid fat graft myringoplasty (HAFGM), fat graft myringoplasty (FGM), and temporal fascia for the closure of different sizes and sites of tympanic membrane perforations.

MATERIALS and METHODS: We retrospectively analyzed the medical records of patients who had undergone a type 1 tympanoplasty operation at our clinic between May 2007 and February 2013. The patients were divided into three groups depending on the patient's choice of technique as follows: Fat Graft Myringoplasty (FGM) (Group I), Hyaluronic Acid Fat Graft Myringoplasty (HAFGM) (Group II), and Temporalis Fascia (TF) (Group III). A total of 136 patients were included in the study, split in to the FGM (57 patients; 56.1% female; median age: 30 years), HAFGM (31 patients; 54.8 female; median age: 25 years), and TF (48 patients; 58.3% females; median age: 33 years) surgery technique groups.

RESULTS: The patients were further divided into two groups, depending on the size of the perforation (small and large), and into three groups, depending on its location (anterior, inferior, and central). None of techniques provided a significantly better success rate in terms of perforation location ($p>0.05$). Also, none of the techniques provided a significantly better success rate in terms of perforation size ($p>0.05$).

CONCLUSION: We propose using HAFGM for large perforations and FGM alone for small perforations. The TF technique is a successful and well-defined technique for tympanic membrane perforations; however, in our opinion, its technical difficulties make it a secondary choice, particularly for small-sized perforations.

KEYWORDS: Myringoplasty, fat graft, hyaluronic acid, temporal fascia

INTRODUCTION

Tympanic membrane (TM) reconstruction is one of the most common surgical procedures in otologic practice. Myringoplasty has been used for the reconstruction of TM for centuries. Many reconstructive materials have been used for myringoplasty, but the use of autogenous materials became popular at the end of the 19th century [1]. Since the introduction by Storrs, temporalis fascia (TF) is still the favored technique of many surgeons worldwide [1]. However, there are disadvantages and ongoing controversies regarding the use of temporalis fascia [2].

Fat tissue has been known to have a high capacity of resistance and is used as an autogenous material for different surgeries [1-3]. Ringenberg was the first surgeon to use fat tissue for the closure of perforations of TM in 1962 [3]. Other studies also confirmed the efficacy of fat grafts for the reconstruction of TM [3-11]. Hyaluronic acid (HA) ester was first used in its liquid form for middle ear packaging in otologic practice [12-14]. Because HA is a component of the extracellular matrix of many tissues in the body, its biocompatibility is very high [12-14]. Guneri et al. [14] and Stenfors applied topical HA in their studies to show the positive effect of the material on the healing of acute traumatic TM perforations and showed some good results. Prior et al. [15] used another material made of a solid polyester form of HA (Epifilm; Xomed Surgical Products, Sherbourne House Croxley Business Centre Watford, UK) for myringoplasty. However, they concluded that the repair of TM perforations with HA ester films alone is not recommended because the application failed in their first five patients [15].

Saliba and Woods reported a new technique in 2008 combining fat graft myringoplasty (FGM) with the use of HA solid polyester form and reported better results compared with those of the temporalis fascia technique. Since the introduction of the hyaluronic

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acid fat graft myringoplasty (HAFGM) technique, there has not yet been a study done comparing the efficacy of HAFGM with the other techniques commonly used to close the TM perforations. Therefore, in the present study, we aim to compare the HAFGM, FGM, and TF techniques in the closure of TM perforations of different sizes and at different sites of the TM.

MATERIALS and METHODS

This retrospective study involved patients who underwent myringoplasty between 2007 and 2013 at our Otolaryngology Department. The main patient selection criteria were as follows: the presence of clear-margined TM perforations and the normal appearance of the mucosa of the middle ear. The exclusion criteria were as follows: an ear discharge in the past 3 months, acute infection, ossicular inconsistency, cholesteatoma, and marginal perforations.

The patients were divided into three groups: FGM (Group I), HAFGM (Group II), and TF (Group III). All the patients were informed about the techniques before the operation. The study was approved by the ethics committee of our institution and conducted in accordance with the ethical principles stated in the Declaration of Helsinki. Written informed consent was obtained from patients or patients' parents who participated in this study.

Study Procedures

Preoperative records of age, gender, side, history of previous ear surgeries, perforation site on the TM, and the size of the perforation were obtained from the clinic's software system. Ears were examined with a microscope before the operation and an endoscopic image of each TM perforation was recorded before the operation as well as at the first, sixth, and twelfth postoperative months.

The mean values of the pre- and postoperative bone-conduction and air-conduction (AC) thresholds at the frequencies of 500, 1,000, 2,000, and 4,000 Hz were obtained from the records of the patients.

Operation success was determined on the following two criteria: if there was a full healing of TM and an improvement of hearing. Any residual perforation was considered as a failure. Audiography was performed at the sixth and twelfth postoperative months to determine the hearing improvement.

Surgical Techniques

All patients were operated under general anesthesia. All surgeries were performed by the same surgeon (TG). The mean durations of the operative procedures were 10, 25, and 45 min for the FGM, HAFGM, and TF groups, respectively.

Temporalis fascia technique: An underlay method was used in which the temporalis fascia graft was placed under the tympanomeatal flap onto the medial surface of the drum remnant. Sponge gels were placed inside the middle ear and over the graft to support the graft in position against the drum remnant.

Fat graft myringoplasty technique: De-epithelization with a sharp prick was performed to the perforation margins. For small perforations, fat was harvested from the medial surface of the pinna. In patients with large perforations, fat tissue was obtained from the abdomen. It is important that the fat graft should contact all parts of the margins of the perforation, with some fat bulging over the TM remnant. Several pieces of fat tissue were used to close large perforations. Then, the fat tissue was placed through the perforation in an hourglass fashion. Several sponge gels were placed over the graft to keep it in position. The incision of the graft site was closed with 3/0 vicryl suture. Topical ciprofloxacine was prescribed for daily use in the following 2 weeks, and then the gel foams were removed with suction. The patients were instructed to keep their ears dry.

Hyaluronic acid fat graft myringoplasty technique: Saliba et al. [12] described this surgical technique, and we used the same process with minor modifications in this study. First, de-epithelization with a sharp prick was performed to the perforation margins. The fat graft was inserted through the perforation as an hourglass shape. The fat volume should not be too high to place the EpiDisc® (Epidisc otologic lamina, Xomed-Medtronic; Jacksonville, FL, USA). Correct contact is crucial between the EpiDisc®, the fat graft, and the TM. The EpiDisc® should be cautiously placed to overlap all the intact epithelium edge around the perforation. The HA EpiDisc® should cover the fat graft and the medial edge of the external ear canal skin near the annulus in the case of total perforation. The HA EpiDisc® and the ear canal are supported with sponge gels. Patients were instructed to keep their ears dry and were prescribed to use topical ciprofloxacine.

Statistical Analysis

The patients were divided into two groups, depending on the size of the perforation (small and large), and into three groups, depending on its location (anterior, inferior, and central). Perforation sizes of 1–2.99 mm were defined as small perforations, and sizes of 3–6 mm were defined as large perforations. Large perforations are defined as central. The perforation size to the entire TM was calculated using the image analysis software Paint.net (ver.73 3.5.10; dot PDN LLC; Kirkland, WA, USA).

Categorical variables were summarized by count and percentage, and comparisons were made with the Chi-square or Fisher's exact test. Continuous variables were summarized by the median (minimum and maximum) and were compared using the Kruskal–Wallis variance analysis because of the non-normal distribution patterns. Type 1 error was set at 5%. Analyses were performed on IBM SPSS Statistics version 21 software (SPSS Inc.; Chicago, IL, USA).

RESULTS

Of the screened patients, 136 were included in the study, split into the FGM (57 patients; 56.1% female; median age: 30.0 years), HAFGM (31 patients; 54.8 female; median age: 25.0), and TF (48 patients; 58.3% females; median age: 33.0 years) surgery technique groups. The three surgery technique groups were similar in terms of gender and age (Table 1).

Patients in the FGM group mostly presented with anterior perforation (50.9%), whereas those in the HAFGM groups presented with inferior perforation (45.2%), and those in TF with central perforation (41.7%), and the three groups were not similar regarding the perforation site (p=0.012) (Table 1). Perforations were mostly small in the FGM, HAFGM, and TF groups (77.2%, 64.5%, and 5.83%, respectively), and the groups were similar in terms of perforation size (p=0.110) (Table 1).

Table 1. Demographics of patients and characteristics of tympanic membrane perforations

	FGM (n=57)	HAFGM (n=31)	TF (n=48)	p*
Gender (female), n (%)	32 (56.1)	17 (54.8)	28 (58.3)	0.950
Age (year)*, median (min-max)	30.0 (8.0–97.0)	25.0 (7.0–54.0)	33.0 (10.0–66.0)	0.246
Perforation site, n (%)				
Anterior	29 (50.9)	6 (19.4)	12 (25.0)	0.012
Central	13 (22.8)	11 (35.5)	20 (41.7)	
Inferior	15 (26.3)	14 (45.2)	16 (33.3)	
Perforation size, n (%)				
Large	13 (22.8)	11 (35.5)	20 (41.7)	0.110
Small	44 (77.2)	20 (64.5)	28 (58.3)	

FGM: fat graft myringoplasty; HAFGM: hyaluronic acid fat graft myringoplasty; TF: temporal fascia
*Kruskal–Wallis test was used for age, Chi-square test was used for others.

Table 2. Preoperative and 12 month postoperative hearing results

	FGM (n=57)	HAFGM (n=31)	TF (n=48)	p*
Air-bone gap, median (min-max)				
Preoperative dB HL	21.0 (10.0–35.0)	19.0 (12.0–32.0)	19.0 (11.0–35.0)	0.609
Postoperative dB HL	13.0 (6.0–36.0)	15.0 (5.0–32.0)	12.0 (5.0–35.0)	0.772
Air-conduction, median (min-max)				
Preoperative dB HL	21.0 (10.0–35.0)	19.0 (11.0–32.0)	19.5 (10.0–39.0)	0.461
Postoperative dB HL	16.0 (8.0–34.0)	15.0 (5.0–30.0)	15.0 (5.0–32.0)	0.219

FGM: fat graft myringoplasty; HAFGM: hyaluronic acid fat graft myringoplasty; TF: temporal fascia
*Kruskal–Wallis test was used for age, Chi-square test was used for others.

Table 3. Success rates according to perforation size and location in the three surgery technique groups

	FGM (n=57)	HAFGM (n=31)	TF (n=48)	All surgeries (n=136)
All perforations	50 (87.7)	27 (87.1)	45 (93.8)	122 (89.7)
Perforation size, n (%)				
Large perforations	13 (100.0)	10 (90.9)	17 (85.0)	40 (90.9)
Small perforations	37 (84.1)	17 (85.0)	28 (100.0)	82 (89.1)
p*	0.186	1.000*	0.066*	0.749
Perforation location, n (%)				
Anterior	25 (86.2)	6 (100.0)	12 (65,3)	43 (91.5)
Central	13 (100.0)	10 (90.9)	17 (85.0)	40 (90.9)
Inferior	12 (80.0)	11 (78.6)	16 (100.0)	39 (86.7)
p*	0.258	0.380	0.106	0.711

FGM: fat graft myringoplasty; HAFGM: hyaluronic acid fat graft myringoplasty; TF: temporal fascia*Fisher's exact test, Chi-square tests were used for unmarked (for some comparisons, the requirements of the Chi-square test were violated)

Follow-Up Result

The fat graft volume regressed to 70% of its bulging at the second postoperative month in Groups I and II. At the postoperative twelfth month, in Group I, there was a bulky volume of fat after closing the large perforations (Figure 1), however, we observed a small mark of the fat graft in the TM in patients of Group II (Figure 2). The mean postoperative follow-up was 17.5, 21.2, and 14 months for Groups I, II, and III, respectively. Recurrent perforations were usually observed in the first four postoperative months in 90% of the patients. No other complications were noted.

Preoperative and postoperative median air-bone gaps of the groups were similar (p=0.609 and p=0.772, respectively) (Table 2). Similarly, preoperative and postoperative median AC of the groups were similar (p=0.461 and p=0.219, respectively) (Table 2). No worsening of the air-bone gap or AC was noted postoperatively in all the groups (Table 2). However, audiological outcomes of the FGM group alone for larger perforations were worse.

The global success rate was (89.7%) and it varied between 87.1% and 93.8% in the groups, while no significant difference was found between the groups regarding the success rate (p=0.516). The FGM and HAFGM techniques seemed to result in a higher success rate for large perforations, whereas for TF it was for small perforations, but none of the techniques provided a significantly better success rate regarding perforation size (p>0.05 for all) (Table 3). FGM provided complete success for central perforations, whereas HAFGM did for anterior, and TF for anterior and inferior; however, none of techniques provided a significantly better success rate regarding the perforation location (p>0.05 for all) (Table 3).

DISCUSSION

Ringenberg [3] was the first surgeon to describe fat myringoplasty and the characteristics of fat tissue for otologic procedures in 1962. After Ringenberg [3], many authors reported good results with the FGM technique [11]. Ringenberg [3] also compared three graft sites, namely the abdomen, buttock, and ear lobe, in his study and concluded that the ear lobe showed better epithelial and mucosal tympanic growth because of its high density. But in our study, we preferred to use abdominal fat, as the ear lobule fat volume is not enough to cover the larger perforations completely. We observed no differences between the donor sites regarding the success of the operation. However, this finding was based on observation and there is still a need for a study to compare the success results of the three graft sites.

Deddens et al. [4] believed that the perforation size is the most important factor for the success of FGM procedure. However, some other authors, such as Gun et al. [5], Landsberg et al. [8] and Kim et al. [9], used the FGM technique in the repair of small versus large TM perforations and reported no significant difference . They also postulated that the fat graft just needs an oval surface to stick, regardless of size [5, 8, 9]. The overall success rate of the FGM procedure in this study was found to be 88%. There was no statistical difference of closing regarding small versus large perforations (p=0.516). Kim et al. [9] postulated that success rates did not change according to the perforation size, but that patients with large perforations had bad audiological results. Kim et al. [9] speculated that too much fat graft volume in the large perforation group causes a bulky appearance. This bulky appearance obscures the TM vibration, and also it is impossible to create a flat TM after FGM [9]. Gun et al. [5] confirmed the finding of a bulky appearance and that the audiological results of the large perforation group were worse than for the small perforation group.

Figure 1. The bulky appearance of fat after closing large perforations in a patient representative of FGM

Figure 2. Postoperative appearance of the HAFGM procedure. Note the flat tympanic membrane obtained contrary to the result of the FGM procedure alone

Figure 3. Closed anteriorly located small perforation after the FGM procedure

This study also confirms the finding of a bulky appearance and its relation to the bad audiological results of the FGM procedure for large TM perforations (Figure 1). With the HAFGM procedure, we observed a flat TM postoperatively and better audiological results, which makes the technique a better procedure than the FGM technique for large perforations (Figure 2).

Hyaluronic Acid Fat Graft Myringoplasty was first introduced by Saliba [12]. The liquid form of HA has been used in otologic practice for many years [13-15]. The solid polyester form is reabsorbed in eight weeks [13]. Stenfors [13] studied the efficacy of liquid HA for TM perforations after repeated application of the material and showed that the material quickened the closure of perforation. HA EpiDisc® was also used alone for the myringoplasty operation, but it dissolved completely in 80% of the patients [14]. By adding HA to FGM, Saliba [12] observed a high success rate independent of the perforation size and comparable to the TF technique in their series.

The Tympanic Membrane has significant characteristics, particularly during the healing process. TM has a distinct auto-reparative capacity that makes it different from other tissues' healing processes [13-15]. These processes include a continuous migration of the outer squamous epithelial layer toward the external ear canal and the absence of a supportive matrix under the regenerating epithelial layer of a perforation, which prevents the movement of reparative cells and nutrients into the perforation margins [13-15].

Hyaluronic Acid EpiDisc® plays a key role by stimulating the migration of the epithelial cells over the fat tissue in the HAFGM technique, and it also prevents dehydration of the perforation margins [15]. The fat graft has potent revascularization activity. Several studies have shown that the angiogenesis of fat tissue precedes the adipogenesis [12-16]. These characteristics are connected to the strong secretory action of fat cells, which produces a lot of proteins and metabolites. By adding HA EpiDisc® to the FGM procedure, Saliba [12] obtained a flat TM, which could not be accomplished by the FGM procedure alone for large TM perforations [16, 17].

Temporalis fascia is the most widely used autogenous material for myringoplasty. However, there should be a large incision, preparation of a tympanomeatal flap, and disconnection of the TM and malleus to perform this technique.

No difference of success was found between the three groups for each of the two grades of perforation. This finding indicates that the fat myringoplasty techniques can be performed successfully also for the larger perforations, and so can avoid the obstacles of the TF technique mentioned above.

There are some difficulties regarding the closure of anterior perforations with the TF technique. These are an inefficient graft support, defective anterior view, and poor vascular supply [2, 4, 5, 7, 8]. Ayache et al. [7] and Kim et al. [9] reported that the perforation site was not an important factor for the success of the FGM procedure. Fat myringoplasty techniques overcome the difficulties of anterior TM perforation closure successfully [5, 9]. Fat myringoplasty techniques require no support at the plane of the anterior annulus (Figure 3). In this study, we found out that the success rates of the FGM and HAFGM proce-

dures were higher than for the temporalis fascia technique. This finding clearly shows that the fat myringoplasty techniques are superior to the TF technique for anterior perforations.

There has been a long debate on using the fat plugging techniques for the closure of large perforations of the TM. Recently, some studies suggested that these techniques can be used safely for large TM perforations [5, 8, 9]. This study also showed the efficacy and safety of fat myringoplasty techniques. However, FGM alone is not satisfactory for large perforations due to the bad audiological outcomes, despite the good success rates of perforation closure [5, 8, 9]. The HAFGM technique overcomes the obstacles of FGM alone by providing a flat TM.

This study showed that the HAFGM technique is superior to FGM alone for large perforations of TM. For small-sized perforations, there are no statistical differences between FGM and HAFGM, both in terms of the success rates and the audiological results. As a result, we propose using HAFGM for large perforations and FGM alone for small perforations. The TF technique is also a successful and well-defined technique for TM perforations but, in our opinion, the technical difficulties make it a secondary choice, particularly for small-sized perforations.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Ankara Numune Training and Research Hospital 19.8.2015/15-573.

Informed Consent: Written informed consent was obtained from patients or patients' parents who participated in this study.

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