

Hyaluronic Acid Fat Graft Myringoplasty

An Office-Based Technique Adapted to Children

Issam Saliba, MD, FRCSC; Patrick Froehlich, MD

Objectives: To evaluate hyaluronic acid fat graft myringoplasty (HAFGM) for different tympanic membrane perforation (TMP) sizes and to compare its success rate with that of the underlay and overlay techniques.

Design: Prospective study.

Setting: Tertiary care pediatric center.

Patients: Two hundred eight children aged 4 to 16 years (mean age, 11.84 years) with TMPs.

Interventions: The HAFGM is a new technique for TMP repair in an outpatient pediatric population using local anesthesia. All the patients in groups 1 (underlay) and 2 (overlay) were operated on using general anesthesia, whereas group 3 (HAFGM) was operated on at the outpatient office using local anesthesia.

Main Outcome Measures: Postoperative status of the eardrum, hearing improvement, and incidence of complications.

Results: Patients with TMP were divided into 3 groups: group 1 had 75 patients; group 2, 65; and group 3, 73. The global success rate was 87% in group 3, with no difference with the remaining 2 groups. Successful closure of different TMP sizes was the same for the 3 groups. Postoperatively, air-bone gap improvement was better for group 3. No bone conduction threshold worsening was noted. The mean duration of the operative procedure was 65, 74, and 18 minutes for groups 1, 2, and 3, respectively ($P = .02$). Mean postoperative follow-up was 20.7, 17.5, and 14.6 months for groups 1, 2, and 3, respectively. Identification of the anterior perforation rim is mandatory to perform HAFGM.

Conclusions: The HAFGM did not require hospitalization for pediatric patients. It had the advantage of being feasible in children using local anesthesia. Its success rate was comparable with that of conventional techniques.

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Author Affiliations: Division of Otorhinolaryngology–Head and Neck Surgery, Montreal University (Drs Saliba and Froehlich), and Departments of Otolaryngology and Neurotology (Dr Saliba) and Pediatric Otolaryngology (Dr Froehlich), Sainte-Justine University Hospital Center, Montreal, Quebec, Canada; and Université Lyon 1, Hospices Civils de Lyon, Hôpital Femme Mère Enfant, Lyon, France (Dr Froehlich).

TYMPANIC MEMBRANE PERFORATIONS (TMPs) are common in childhood and usually follow episodes of acute otitis media, ventilation tube insertion, or trauma. Perforations that do not heal spontaneously may require surgical repair, particularly when associated with recurrent infections or hearing loss. Closure of uncomplicated TMPs is usually a straightforward procedure with a good success rate. The success rate in adults is higher than that in children.¹ Reasons cited for this finding include poor Eustachian tube function, a higher incidence of upper respiratory tract infections, and greater technical difficulty in performing surgery on smaller anatomy.²

Repair of the TMP without elevating the annulus and entering the middle ear is a commonly performed procedure in pediatric otolaryngology.³ This procedure in-

cludes the use of an autologous fat graft, a paper-patch, an absorbable gelatin (Gelfoam; Pharmacia & Upjohn Co LLC, Kalamazoo, Michigan) patch, and hyaluronic acid (HA) ester films.

The first attempt to use fat in TMP closure is attributed to Ringenberg.⁴ This method of small TMP repair was confirmed by Sterkers⁵ in 1964 with the use of compressed abdominal fat and was later reconfirmed by Terry et al⁶ and Gross et al.⁷ This graft was especially useful in repairing perforations due to transtympanic tube removal in children.⁸ The success rate of fat graft myringoplasty (FGM) for small perforations varies from 76% to 92%.^{6,9,10} Failure rates for larger perforations are high.^{6,9-11}

On the other hand, no significant difference was found between the recovery rate of FGM and paper-patch myringoplasties for small perforations. In larger

perforations (>30% of the membrane surface area), FGM and paper-patch myringoplasties have been found to be ineffective.¹²

Hyaluronic acid is a component of the extracellular matrix of many tissues in the body,¹³ making it highly biocompatible. Hyaluronic acid is frequently used in ophthalmologic surgery and in the treatment of lacrimal drainage system diseases.¹⁴ Stenfors¹⁵ concluded that covering the defect of tympanic membrane (TM) with 1% HA repeated every second to third day has been shown to accelerate the closure of perforation size. However, Prior et al¹⁶ concluded that repair of TMPs with HA ester films alone is not recommended because the success rate for their first 5 patients was 0%. Their study, however, was aborted at this point.

Hyaluronic acid FGM (HAFGM) is an association of HA with FGM. The surgical technique was reported by one of us (I.S.) in 2008 in adults.¹⁷ It is a new technique for TMP repair in an outpatient pediatric population performed using local anesthesia. In this study, we aimed to evaluate HAFGM in children with different TMP sizes to compare the success rate of HAFGM with that of the underlay and overlay techniques and to assess hearing improvement 1 year postoperatively.

METHODS

The following inclusion criteria were used in this prospective study conducted between January 1, 2007, and December 31, 2010, at a tertiary care pediatric center: children 4 to 18 years old (1) with perforations present for at least 6 months; (2) without evidence of active chronic otitis media, cholesteatoma, or retraction pocket formation; (3) without suspected ossicular abnormalities on microscopic examination; and (4) with functional hearing in the contralateral ear. Excluded were children with purulent discharge, suspected ossicular disease (ie, erosion, discontinuity, or fixation of the ossicular chain), suspected cholesteatoma, and an unidentified anterior rim of the perforation. The size of the perforation and the level of hearing loss were not considered exclusion criteria.

PATIENTS

The population was divided into 3 groups depending on the parent's choice of myringoplasty technique: underlay technique (group 1), overlay technique (group 2), and HAFGM technique (group 3). All the patients and parents received a full description (ie, surgical technique, risks, complications, and advantages) of the HAFGM procedure and of the underlay and overlay techniques. The parents discussed the procedure with the patient and signed the informed consent form. The temporalis fascia or the tragal perichondrium was the graft used for the underlay and overlay techniques. All the patients in groups 1 and 2 were operated on while under general anesthesia, whereas group 3 (HAFGM) patients were operated on under local anesthesia in the outpatient setting.

Patients in whom the anterior rim of the perforation was not identified and was hidden by the anterior wall bulging of the external auditory canal were excluded from the 3 groups to eliminate any bias because no drilling of this bulging was performed for the HAFGM group.

The size of the perforation was estimated as a percentage¹⁸ and was graded using Saliba's TMP classification reported in 2008^{17,18}: grade I, small (for perforations <25% of the TM surface); grade II, medium (for perforations 25%-50% of the TM surface);

grade III, large (for perforations >50%-75% of the TM surface); and grade IV, total (for perforations >75% of the TM surface).

HA OTOLOGIC LAMINA

We used the 8-mm-diameter disc of a transparent otologic lamina composed of HA ester (EpiDisc; Medtronic Xomed, Jacksonville, Florida). It has microperforations that allow permeability that facilitates drainage of exudates at the surgical site.

HAFGM TECHNIQUE

Fat was harvested for at least twice the size of the perforation through a 5-mm incision below the mastoid tip and behind the sternocleidomastoid muscle. After the perforation's margins were deepithelialized circumferentially, absorbable gelatin pieces were placed into the middle ear through the perforation to support the fat graft. The fat graft was then inserted through the perforation as an hourglass-shaped plug. The lateral fat bulging should not be too high. Care should be taken to attain intimate contact between the transparent otologic lamina, the fat graft, and the TM remnant. The transparent otologic lamina should overlap all the intact epithelium edge around the perforation. When the malleus handle was denuded by the perforation, it was carefully surrounded by the fat graft pieces. Depending on the TM perforation size, 1 or 2 HA transparent otologic lamina are placed over the fat graft. In the case of total perforation, the HA transparent otologic lamina cover the fat graft and the medial edge of the external auditory canal skin near the annulus. The HA is then covered with pieces of absorbable gelatin soaked with ofloxacin to pack the ear canal. It is recommended to avoid excessive pressure on the HA transparent otologic lamina. No other ear dressing was required. Patients were discharged immediately after the procedure. The HAFGM surgical technique (Saliba's technique) was described in detail in a previous study.¹⁷

OUTCOME MEASURES

The variables examined include patient age, sex, otologic symptoms, and previous surgery on the affected side; perforation side, location, and size; and the duration of surgery. In addition, the collected data include postoperative complications, time of follow-up, and hearing test results. Patient hearing was measured before and after repair of the eardrum perforations. Any bone conduction decrement of 10 dB or greater would be considered a significant sensorineural hearing loss and reported in the results. The mean values of the preoperative and postoperative air conduction and bone conduction thresholds at the frequencies 500, 1000, 2000, and 4000 Hz served to calculate the pure-tone average and the air-bone gap (ABG) closure.

A photoendoscopic image of each TMP was taken immediately before the procedure and at postoperative months 2, 4, 6, and 12. This allowed us to study the evolution of TM healing. Successful closure and graft failure rates were based on the status of the TM at the most recent visit, a minimum of 12 months postoperatively. Hearing improvement was assessed using the audiogram results obtained 4 and 12 months postoperatively. The first postoperative appointment was scheduled at 2 months, or sooner if there was a complication. Follow-up was conducted 4 to 6 months and 12 months after the procedure and then yearly.

STATISTICAL ANALYSIS

A variance analysis with repeated measures and χ^2 tests was performed for statistical analysis. A $P < .05$ was considered statistically significant.

Table 1. Patient Age and Sex and Tympanic Membrane Perforation Side

Characteristic	Group 1 (Underlay) (n=75)	Group 2 (Overlay) (n=65)	Group 3 (HAFGM) (n=73)	P Value
Age, mean (SD), y	11.54 (3.39)	12.51 (3.15)	11.62 (3.54)	.25
Sex, %				
Male	47.6	48.1	60.9	.23
Female	52.4	51.9	39.1	
Side, %				
Right	46.0	59.6	56.5	.30
Left	54.0	40.4	43.5	

Abbreviation: HAFGM, hyaluronic acid fat graft myringoplasty.

Table 2. Myringoplasty Results When Age Was Assessed as a Categorical Variable

Age, y	Result	Tympanic Membrane Perforations, No.			P Value
		Group 1 (Underlay) (n=75)	Group 2 (Overlay) (n=65)	Group 3 (HAFGM) (n=73)	
<11	Success	23	19	25	.10
	Failure	5	1	1	
11-18	Success	41	37	39	.70
	Failure	6	8	8	
P value	NA	.12	.10	.93	NA

Abbreviations: HAFGM, hyaluronic acid fat graft myringoplasty; NA, not applicable.

Table 3. Site and Size of Tympanic Membrane Perforations

Characteristic	Tympanic Membrane Perforations, No.			P Value
	Group 1 (Underlay) (n=75)	Group 2 (Overlay) (n=65)	Group 3 (HAFGM) (n=73)	
Site ^a				
Posterosuperior	24	13	24	.31
Posteroinferior	37	36	44	.51
Anterosuperior	19	17	17	.60
Anteroinferior	27	37	42	.007
Size				
Grade I	35	20	31	.09
Grade II	22	25	29	
Grade III	7	11	9	
Grade IV	11	9	4	

Abbreviation: HAFGM, hyaluronic acid fat graft myringoplasty.

^aPatients may have tympanic membrane perforations affecting multiple sites.

RESULTS

This prospective study included 208 children. Only 5 patients, all from group 3, had a bilateral perforation. Group 1 included 75 TMPs; group 2, 65; and group 3, 73. Age (range, 4-16 years), sex, and side of TMP were not statistically significantly different among the 3 groups (**Table 1**). We assessed age as a categorical variable; patients were grouped as follows: younger than 11 years and 11 to 18 years old. No statistically significant difference was found between the 2 age categories in each group or among the 3 groups (**Table 2**).

Otologic symptoms in the preoperative period were not statistically significantly different among the 3 groups. Patients reported hearing loss, otorrhea, otalgia, ear full-

ness, and tinnitus. Numerous previous surgical procedures in the affected ear were reported: transtympanic tube, myringoplasty, canal wall up mastoidectomy, and ossicular chain reconstruction. No difference among the 3 groups was noted ($P = .87$).

Under microscopic vision, TM was virtually divided into 4 quadrants—posterosuperior, posteroinferior, anterosuperior, and anteroinferior—to facilitate localization of the TMP site (**Table 3**). The size distribution was not statistically significant among the 3 groups (Table 3). The number of large and total perforations was relatively lower than the number of small and medium perforations in the 3 groups, without any significant difference among them.

The global success rate of TMP closure was not statistically significant comparing the underlay (85.7%),

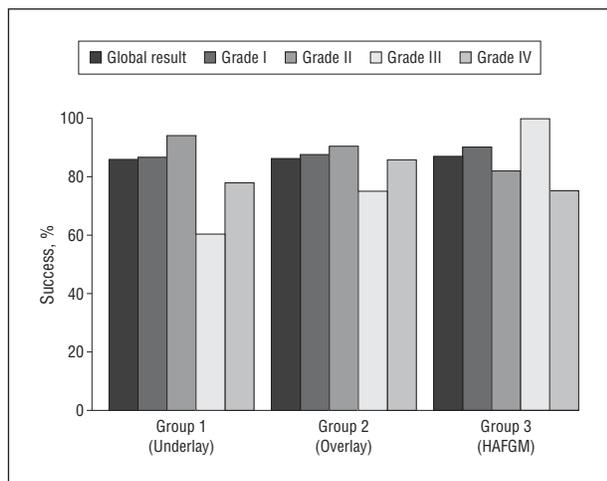


Figure 1. Success rates described by tympanic membrane perforation size. HAFGM indicates hyaluronic acid fat graft myringoplasty.

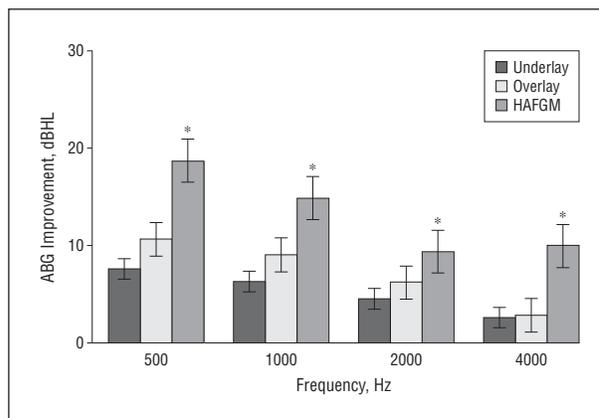


Figure 2. Mean postoperative air-bone gap (ABG) improvement at 4 frequencies. *A statistically significant difference. dBHL indicates decibels hearing level; HAFGM, hyaluronic acid fat graft myringoplasty. Error bars represent SD.

Table 4. Preoperative and 12-Month Postoperative Hearing Results

Criterion	Value, Mean (SD), dBHL		P Value
	Preoperative	Postoperative	
Group 1 (underlay)			
PTA	22.42 (11.59)	19.38 (12.60)	.04
BC threshold	6.32 (9.47)	7.41 (8.90)	>.05
ABG	16.04 (10.34)	12.01 (10.94)	.01
SDS	97.71 (2.46)	96.66 (0.82)	>.05
Group 2 (overlay)			
PTA	29.24 (18.15)	21.48 (15.57)	<.001
BC threshold	10.33 (13.16)	8.94 (12.77)	>.05
ABG	18.99 (10.09)	11.82 (8.55)	<.001
SDS	94.28 (2.55)	96.02 (0.85)	>.05
Group 3 (HAFGM)			
PTA	23.41 (8.18)	11.68 (6.18)	<.001
BC threshold	3.77 (6.40)	4.9 (6.10)	>.05
ABG	19.61 (9.13)	6.76 (7.04)	<.001
SDS	96.64 (2.38)	98.31 (0.79)	>.05

Abbreviations: ABG, air-bone gap; BC, bone conduction; dBHL, decibels hearing level; HAFGM, hyaluronic acid fat graft myringoplasty; PTA, pure-tone average; SDS, speech discrimination score.

overlay (86.5%), and HAFGM (87.0%) techniques. Comparing perforation grades, no significant difference in the success rate was observed among the 3 techniques performed on the small, medium, large, or total perforations ($P > .05$), and no difference in success exists among the 4 TMP grades in each group ($P = .55$) (**Figure 1**). In addition, the previous ear operations did not affect the success rate of myringoplasty in any of the 3 techniques. Furthermore, no significant differences in success rates were observed when posterior perforations were compared with either anterior or anteroposterior perforations in each group and between groups ($P > .05$).

Failure cases occurred mainly in the first 4 postoperative months in the 3 groups ($P = .90$). No causes of failure were identified except 1 case of infection in each of groups 1 and 3. Complications were more frequent in

group 1 ($P = .03$). Whereas TM cholesteatoma pearls arise more frequently after an overlay technique, we found only 1 case of cholesteatoma in group 2 and 2 cases in group 1. This white spot on the TM should raise suspicion for cholesteatoma. Early diagnosis and treatment are imperative to allow easy removal and to avoid middle ear involvement. Surgery was performed in all 3 of these patients through a transcanal approach using local anesthesia in the outpatient department, and the cholesteatoma pearl was peeled from the TM. After removal, the medial layer of the TM was intact, and no further action was taken. Histopathologic analysis confirmed a cholesteatoma. On follow-up, otoscopic examination results were normal, with no signs of recurrence. In addition, 4 cases of TM retraction developed after the underlay technique. There were no graft lateralizations or blunting.

Hearing results 12 months postoperatively are given in **Table 4**. The ABG was significantly improved after surgery in the 3 groups. However, the postoperative ABG and pure-tone average were significantly better after HAFGM than after the underlay ($P = .02$) or overlay ($P = .03$) technique. The postoperative ABG improvement by frequency is represented in **Figure 2**. No difference was found postoperatively among groups 1 (96.6%), 2 (96.0%), and 3 (98.3%) for the speech discrimination score or for the bone conduction threshold. Thus, no sensorineural hearing loss was found in any patients.

Surgical procedures were followed up for more than 12 months in the 3 groups. The mean postoperative follow-up was 20.7 months for group 1, 17.5 months for group 2, and 14.6 months for group 3. The mean duration of the operative procedure was 65 minutes for group 1, 74 minutes for group 2, and 18 minutes for group 3 ($P = .02$).

COMMENT

Three main interests lie in the HAFGM: its success rate, its feasibility using local anesthesia, and its safety. In addition to the high success rate comparable with

that of the underlay and overlay techniques, HAFGM in Sainte-Justine University Hospital Center, Montreal, Quebec, Canada, is processed using local anesthesia in a mean of 18 minutes at the outpatient clinic department. There is no need for sedation. Although the fat graft fills the middle ear and slightly bulges through the TM, it progressively disappears until postoperative month 12. The TMP closure is stable after month 4, as is the hearing test with a maximum follow-up of 48 months.

Ringenberg^{4,19} studied the properties of fat tissue in otology. He compared 3 sites of swab—abdomen, buttock, and earlobe—and concluded that the earlobe allows better epithelial and mucosal tympanic growth because it is more dense. Ear lobule fat is not enough to fill the perforation hole of grade II or greater. We used fat in the region below the mastoid tip and behind the sternocleidomastoid muscle through a 5-mm incision, with special care to harvest a sufficient sample of fat that was at least twice the size of the perforation. If temporalis muscle fascia is an inert support for the tympanic closure, the fat graft presents a big revascularization activity confirmed by the serial otoscopic photograph we took postoperatively. This early revascularization is probably the physiologic explanation for the tympanic growth. Studies^{20,21} about vascularization of the fatty tissue showed that angiogenesis precedes adipogenesis. Moreover, this adipose tissue promotes cicatrization and revascularization of nonvascularized areas.^{20,21} These properties are intimately due to the secretory activity of adipose cells, producing a lot of proteins and metabolites.²² Successful FGM closure was common in small TMPs, whereas graft failure rates were higher for perforations exceeding 30% of the pars tensa.²³ By adding HA to FGM, we observed in this series a high success rate independent of the perforation size and site and comparable with that of the underlay and overlay techniques. The HA transparent otologic lamina is believed to have a role in the healing regulation pattern of the fibrous layer, preventing dehydration of the perforation margins.^{17,24,25} The HAFGM also stimulates epithelial cells, accelerating centripetal migration of the epithelial layer over the temporary support of fat in the HAFGM technique. This occurs during the angiogenesis phase and before the adipogenesis time. This association of HA with FGM provides a benefit expressed by the high success rate for all TMP sizes. Two months after the procedure, the HA transparent otologic lamina was clinically completely dissolved in 80% of patients.

The reported myringoplasty success rate varies from 60% to 99% in adults and from 35% to 94% in children.¹ The HAFGM joins the underlay and overlay techniques in its efficacy and safety, presenting an 87% global success rate. Although closure occurred in 100% of grade III perforations operated on using HAFGM, the results are comparable among the 3 techniques; regarding the size of the perforation and its effect on the success rate of tympanoplasty, there is, again, a difference of opinion. In a different study discussing myringoplasty independently from the technique used, it was found that perforations greater than 50% had poorer results,^{26,27}

but other studies contradict this statement, stating that the success of tympanoplasty has no correlation with perforation size.²⁸⁻³⁰ In the present series, the number of large and total perforations is lower than the number of small and medium perforations in the 3 groups, and there is a trend toward significance, with the HAFGM group having less total perforation (grade IV) compared with the other 2 groups, but the global result of large and total perforations is comparable among the 3 techniques, and no difference was found among the 4 grades of perforation.

Age and the timing at which myringoplasty should be performed are the most debated subjects in the literature today, presenting age as an important factor determining the successful outcome of myringoplasty. Many physicians are opposed to performing the procedure on young children and prefer postponing the surgery; their main arguments rely on the assertion that children have a higher susceptibility to upper respiratory tract infections, persistent Eustachian tube dysfunction, and technical difficulties; consequently, this showed an increased predisposition for middle ear infections. They advocate delaying the surgery until a certain age, which can vary from 10 to 14 years, to allow a more favorable surgical terrain.³¹ It has also been argued that a perforation in the eardrum is equivalent to a ventilation tube.³² We assessed age as a categorical variable, and although no age effect was identified on success rate regardless of the technique used, the number of patients in each age category is not large enough to confirm that age is not a prognostic factor. Other researchers have achieved excellent success rates with myringoplasty regardless of patient age and advocate surgery as early as possible. Careful attention to Eustachian tube function will likely increase the rate of an intact TM with improvement in hearing, but age in itself should not be an indication for or contraindication to treatment.^{33,34}

As reported in the literature,³⁴ age was not found to be a prognostic factor for the HAFGM success rate or for the underlay and overlay techniques. The site and the size of the TMP do not affect the success rate of HAFGM. However, patients with anterior wall bulging of the external auditory canal were excluded to eliminate bias because no drilling was performed in the HAFGM group. The HAFGM technique is limited by this inconvenience because it is performed in the office of the outpatient department. Underlay and overlay cases were performed in the operating room under general anesthesia.

The TM vibrates at the same frequency as the incoming sound and, in turn, causes the ossicular chain to vibrate at that same frequency. Postoperative hearing improvement is statistically significant in the 3 performed techniques. However, we noticed a significantly higher ABG gain in the HAFGM group at 0.5-, 1-, 2-, and 4-kHz frequencies. Laser interferometry to compare the vibration characteristics of repaired TM by the HAFGM, underlay, and overlay techniques could explain this phenomenon. At the first postoperative year, the operated TM does not show new sclerotic areas but rather a normal TM appearance with a small, thin, fatty



Figure 3. Left (A) and right (D) tympanic membrane perforations in the same patient repaired by the hyaluronic acid fat graft myringoplasty technique showing the fat graft remnant 2 months (B and E) and 12 months (C and F) after surgery.

stain in the epithelial thickness reflecting the signature of the HAFGM technique (**Figure 3**). The improvement in the ABG for the 3 groups shows a high quality of TM recovery and serves as evidence that a small fatty thickness in the eardrum does not affect the hearing result.

Hyaluronic acid is a nonototoxic material.³⁵ Sensorineural hearing loss reported in patients who had undergone tympanoplasty procedures has not been noticed in any study on FGM, including the present series.^{4,6,8,36} Hyaluronic acid FGM does not involve manipulation of the middle ear structures and, compared with traditional myringoplasty, carries a low risk of iatrogenic otologic trauma. Absorbable gelatin inserted into the middle ear to support the fat graft does not seem to affect the result of conductive hearing loss at the fourth postoperative month. Hearing tests at 1 year postoperatively were similar to those performed at 4 months. These pieces of absorbable gelatin are important to prevent medialization of the fat graft and to prevent adherence development between the medial side of the TM and the promontory. The HAFGM does not need any support at the level of the anterior annulus, where the graft may lose TM contact with traditional underlay myringoplasty, or an epithelial dissection on the anterior external auditory canal wall and on the anterior TM remnant as in the overlay myringoplasty. All these factors leave HAFGM with minimal complications: TM medialization, lateralization, blunting, and cholesteatoma pearls did not occur in any patient in this HAFGM pediatric series.

Because this population was divided into 3 groups depending on the parent's choice of myringoplasty technique, this study was not a randomized controlled trial, and, therefore, a selection bias may play a role.

In conclusion, HAFGM is a cost-effective alternative in TMPs of all sizes in all quadrants if complete visualization of the margin is possible, including revision cases. It provides the basic requirements for TM grafting, with its own favorable characteristics.

Because of its substantial operational advantages, HAFGM can be suggested as a first choice for the reconstruction of a dry TMP in a pediatric population. It is performed under local anesthesia as an outpatient office procedure; there is no need for sedation, and it also yields a high success rate, better than that of FGM alone or HA

alone. Results are comparable with those of the underlay and overlay myringoplasty techniques.

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Correspondence: Issam Saliba, MD, FRCSC, Department of Otolaryngology, Sainte-Justine University Hospital Center, 3175, Côte Sainte-Catherine, Montreal, QC H3T 1C5, Canada (issam.saliba@umontreal.ca).

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