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ORIGINAL ARTICLE

Outcomes of Stapedotomy Using Hyaluronic Acid Gel Versus Gelfoam as a Sealing Material

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ABSTRACT

Background: The ideal substance to seal the vestibulotomy site after stapes surgery is a topic of debate. Otology surgeons have historically sealed the oval window with a variety of materials. These consist of blood clots, vascular grafts, adipose tissue, gelatin sponge (Gelfoam), and perichondrium.Objectives: The present work aims to evaluate hearing outcomes and post-operative vestibular symptoms when hyaluronic acid gel (HAG) or gel foam is used as a sealing agent in stapedotomy. **Methods:**This randomized comprehensive clinical trial was performed on 58 patients in Zagazig University hospitals, all complaining of hearing loss. The cases were divided equally into Group (1) hyaluronic acid gel and Group (2) Gelfoam. All study populations were subjected to whole history taking, full ear-nose-throat (ENT) and otoscopic examination, routine laboratory investigations, pure tone and speech audiometry, stapedial reflex, tympanogram, and CT scanning.**Results:** Non-significant differences were found between groups for pre and post-operative tinnitus. There was a statistically non-significant variance between both groups regarding pre and post-operative ABG. Statistically significant differences were found between pre- and post-operative vertigo in each group ($p<0.001$), with non-statistically significant variation between both groups.**Conclusions:**This study revealed that using either HAG or Gel foam to seal the stapedotomy, hearing results, and post-operative tinnitus might be the same. However, post-operative vertigo was comparable with the upper hand for HAG to decrease post-operative vertigo. As a result, HAG is advised as a secure sealing, easily used material following otosclerosis stapedotomy.

Keywords: Stapedotomy, Hyaluronic Acid, Sealing Material.

INTRODUCTION

Otosclerosis is abnormal boneremodeling in the middle ear. Stapes fixation occurs when improperly deposited spongy bone replaces the standard dense endochondral layer of the bony otic capsule in the labyrinth. Otosclerosis typically causes conductive deafness with a typical tympanic membrane [1].

External hearing aids are available to people with tiny ABG, those without command, and those who cannot undergo surgery. People with severe or total hearing loss may be candidates for a cochlear implant. The primary option for treating stapes is surgery. However, according to the case's specifics and the degree of hearing loss, very few additional surgical procedures, such as middle ear or cochlear implants or bone-anchored implants, may be required [2].

Patients clinically presented with hearing loss and, less commonly, vertigo and tinnitus. Most cases of otosclerosis present with

bilateral hearing loss. The Rinne and Weber tests, audiometry, and CT imaging evaluate patients. Treatment included medical or surgical management [1].

The finest sealing material for vestibulotomy sites during stapes surgery is still questionable. Multiple substances have been used in otology operations to seal the oval window. Fat tissue, gelatin sponge (gel foam), perichondrium, vein graft soft connective tissue, and blood clots were included [3].

An investigation by Incesulu and Hausler [4] described fibrosis as the main disadvantage of the fascia, vein, and perichondrium grafts.

Lesinski [5] pointed to the contracture of the new membrane, which may result in lateralization and migration of the prosthesis beyond the stapedectomy or stapedotomy fenestration.

Novel substances, such as hyaluronic acid gel (HAG), have recently become suitable agents in the field of otology [4].

Angeli et al. [6] modified the stapedotomy technique by presenting HAG to the oval window niche before stapes footplate fenestration.

The present work aims to evaluate hearing outcomes and post-operative vestibular symptoms when HAG or gel foam is used as a sealing material in stapedotomy.

METHODS

Patients:

This randomized comprehensive clinical trial was performed on 58 patients in Zagazig University hospitals; the cases were divided equally into two groups: Group (1) hyaluronic acid gel and Group (2) Gelfoam. 7 (24.14%) male and 22 (75.86%) female in group 1, and 10 (34.48%) male and 19 (65.52%) female in group 2. the mean age ranged from (19-50) and (22-49) for group 1 and group 2, respectively. All of them were complaining of hearing loss. Verbal and written informed consent was obtained from all participants after explaining the procedure and medical research. The research was conducted under the World Medical Association's Code of Ethics (Helsinki Declaration) for human research. This study was carried out after the approval of the Institutional Review Board (IRB) (ZU-IRB#9632/24-7-2022).

Cases with the following criteria were included: cases with clinical otosclerosis who were candidates for primary stapes surgery, good general health condition, age range (19-50) years old, males and females with Air bone gap (ABG) of (60)dB > ABG>(20)dB and bone conduction threshold(0-20)dB.

Cases with the following characteristics were excluded: pregnant or lactating patients. Individuals who underwent partial stapedectomy in which vein graft is used as sealing material or total stapedectomy and/or revision stapedotomy was excluded, or stapedotomy for any other reason than otosclerosis as a part of ossicular reconstruction to reestablish ossicular chain continuity and improve the air conduction thresholds in patients who have conductive hearing loss due to ossicular erosion, blunt or penetrating trauma causing disarticulation, congenital malformations or congenital absence of ossicles. The patient was not fit for surgery.

Methods:

All study populations underwent complete history taking, full ear-nose-throat (ENT) and otoscopic examination, and routine laboratory investigations.

Pure tone audiometry

There was a loss in air conduction, more for lower frequencies. Bone conduction was normal. Carhart`s notch was found in 20 ears and 15 ears in group 1 and group 2 respectively, ABG(30-40)dB with mild CHL found in 4 ears((4/29=13,79%) and 6 ears(6/29=20,69%), and moderate CHL with ABG(41-55)dB found in 25 cases (25/29=86,21%) and 23cases (23/29=79,31%) in group1 and 2 respectively.

Speech audiometry:

All of them showed normal discrimination (90-100%).

Stapedial reflex:

Absent stapedial reflex was detected in all patients.

Tympanogram:

In group 1, there were 22 ears with type A and 7 ears with type AS, and in group 2, there were 25 ears with type A and 4 ears with type AS.

CT scanning:

CT's role in otosclerosis is identifying otospongiotoc foci or anatomical obstacles

like hanging facial nerves. HRCT and CBCT are the imaging modalities of choice but are not required for diagnosis. They can improve diagnostic probability by excluding anatomical abnormalities like hanging facial nerve and malleus fixation, assessing for any ossicular discontinuity, and even measuring the otospongiotic focus.

CT scanning of temporal bone axial and coronal sections. Every CT was examined carefully to exclude any middle ear pathology and superior semicircular canal dehiscence. All cases had normal temporal CT scans.

Procedure:

Under General Anesthesia:

A per-meatal approach was used, and the posterosuperior tympanometry flap was elevated.

Curetting of scutum was done for adequate exposure, and the mobility of the malleus, incus, and stapes was assessed.

The incudostapedial joint was separated, and the stapedial tendon was sectioned. Removal of the posterior crura of the stapes by micro scissors. The footplate became visible; the next step was down fracture and removal of the remaining stapes superstructure. Fenestration of the footplate by perforator at the posterior half of the footplate was done.

Medtronic (The Causse Fluroplastic large loop piston with LID=0,8mm & SD=0,6mm and L=4,5mm) was inserted in the fenestration and crimped to the incus. The movement of the prosthesis was assessed by gentle elevation of the manubrium of the malleus.

HAG (HYALO 4 gel) and gel foam were used in 29 patients to seal the fenestration around the stapes at the end of the piston. The flap was restored to its position, and the inner pack was soaked with antibacterial material (Terramycin eye ointment).

Gently and smoothly, a waking from anesthesia was done, and a cough was avoided.

Postoperative:

The patient was observed for one-day post-procedure and checked vital signs, vomiting, and vertigo, and then discharged. All patients were given antibiotics and analgesics. The patient with vertigo was given anti-vertigo drugs. After one week, the patients returned to the clinic for Follow-up vertigo, tinnitus, and nausea.

The inner pack was removed after two weeks, and local antifungal and combined antibiotics with steroid ear drops were prescribed for 5 days. An otoscopic examination was done, and Tunning Fork assessed hearing to evaluate the Rinne test, which was positive for all patients on the operated side. Asked about tinnitus, vertigo, and nausea. All patients were exposed to middle ear function tests as Puretone audiometry 3 months postoperative to evaluate ABG.

Statistical Analysis:

Statistical analysis:

Descriptive statistics were employed to assess the cases' demographic and illness characteristicsusing IBM Corp.'s SPSS software Version 22 (Armonk, NY, USA).. For categorical data, percentages and frequencies were employed, whereas continuous variables were computed using means and standard deviations. The Shapiro-Wilk test and Q-Q plots were performed to confirm the data's normal distribution. Chi-square was used to compare categorical data. P-values <0.05 were considered statistically significant.

RESULTS:

The mean age in the group (1) was 34.24 years and 35.28 years in the group (2); females represented 75.86% for the group (1) and 65.52% for the group (2), RT ear was operated for 68.97% in group (1) and 58.62% for the group (2), CT scan was normal, negative Pre-operative Rinne test and for all studied cases. All of the studied cases had pre-operative normal TM except the ear (3.45) in group (2), which had mild retracted TM in pars flaccida (Table 1).

Hearing loss was the leading complaint for all cases, and it improved (100%) in both groups post-operative. Clinical success (defined as an ABG below 20/25 dB) (Table 2).

There was a statistically non-significant difference between both groups for pre-operative and post-operative tinnitus, as detected by subjective VAS score (Table 3).

No pre-operative vertigo was detected in any of the cases. Still, there was a statistically significant difference between pre and post-operative vertigo for both groups, and a statistically non-significant difference was found between group 1 and group 2 as Post-operative vertigo with 17ear (58.62%)in group 1 and 11ear(37.39%)for group 2 without Post-operative vertigo. Statistically significant differences were found between pre and post-operative vertigo in each group ($p<0.001$), with non-statistically significant variation between group 1 and group 2 (Table 4).

There was a statistically non-significant difference between both groups regarding pre and post-operative ABG. ABG improvement post-operative was ≤ 10db in 12ear (41.38%) and 11ear (37.93%), ≤ 20db in 9ear (31.03%) and 11ear (37.93%), and ≤ 30db in 8ears (27.59%) and 7ears (24.14%) for group 1 and group 2 respectively. Two ears (6.9%) in group 1 were complicated by perforated TM that healed spontaneously during the first month (Table 5).

Table(1): Baseline characteristics of patients

Variable	**Group 1(n=29)**	**Group 2(n=29)**	***p*-value**
Age (years) [a]	34.24±6.77 (19-50)	35.28±7.29 (22-49)	0.75
Gender [b]			
Male	7 (24.14)	10 (34.48)	0.282
Female	22 (75.86)	19 (65.52)	
Side [b]			
Right	20 (68.97)	17 (58.62)	0.293
Left	9 (31.03)	12 (41.38)	
Family history [b]			
Yes	1(3.45)	1 (3.45)	0.754
No	28 (96.55)	28 (96.55)	
Tympanic membrane (TM) [b]			
Normal TM	29 (100)	28 (96.55)	0.5
Mild retracted TM	0	1 (3.45)	
CT scan			
Normal	29 (100)	29 (100)	NA
Pre-operative Rinne test			
Negative	29 (100)	29 (100)	NA

Table 2: Pre-operative hearing loss and post-operative hearing among the studied groups

Variable	Group 1(n= 29)	Group 2(n=29)	*p*-value
Presence of pre-operative hearing loss	29 (100)	29 (100)	NA
Improved post-operative hearing	29 (100)	29 (100)	NA

Table 3: Pre- and post-operative tinnitus among the studied groups

Variable	Group 1(n= 29)	Group 2(n=29)	*p*-value
Pre-operative tinnitus			
Yes	4 (13.79)	6 (20.69)	0.365
No	25 (86.21)	23 (79.31)	
Post-operative tinnitus			
Yes	2 (6.9)	2 (6.9)	0.694
No	27 (93.1)	27 (93.1)	
***p*-value**	0.335	0.126	

Table 4: Pre- and post-operative vertigo among the studied groups

Variable	Group 1(n= 29)	Group 2(n=29)	*p*-value
Pre-operative vertigo			
No	29 (100)	29 (100)	NA
Post-operative vertigo			
Yes	12 (41.38)	18 (62.07)	0.094
No	17 (58.62)	11 (37.39)	
***p*-value**	< 0.001**	< 0.001**	

** $p < 0.001$.

Table 5: Pre- and post-operative audiological investigation among the studied groups:

Variable	Group 1 (n= 29)	Group 2 (n=29)	*p*-value
Pre-operative audiological investigation			
Mild CHL-ABG (30-40) db-SRT above40-SDT above 80%-	4 (13.79)	6 (20.69)	0.365
Moderate CHL-ABG (41-55) db-SRT above50SDT above 90% -	25 (86.21)	23 (79.31)	
Post-operative audiological investigation			
Total HL-SRT NR-SDT 0%-	0	0	0.893
ABG ≤ 10db-SRT40-SDT100%	12 (41.38)	11 (37.93)	
ABG ≤ 20db-SRT above 20-SDT100%-type A	9 (31.03)	11 (37.93)	
ABG ≤ 30db-SRT35-SDT100%	8 (27.59)	7 (24.14)	
***p*-value**	0*	0*	

* $p < 0.001$.

CHL: Conductive Hearing Loss, ABG: Air-Bone Gap, db: decibels, SRT: Speech-Reception hreshold, SDT: Speech Detection Threshold, HL: Hearing Loss

DISCUSSION:

Otosclerosis is a common cause of conductive hearing loss in adults; surgery is the definitive treatment of choice. To improve hearing results and reduce postoperative problems, the oval window is constantly sealed with an autologous tissue graft around the stapes prosthesis [7].

Certain otologists believe soft tissue should be used for sealing fenestrations during stapedotomies. Sealing tissue protects the inner ear against fistulae, pressure changes, and infection. A literature review reveals that many surgeons adhere strictly to this policy and practice. The ideal substance to seal the vestibulotomy site after stapes surgery is a matter of debate. In otology surgery, various materials have proven effective in sealing the oval window. Fat tissue and perichondrium were included. For stapedotomy, otolaryngologists can customize HAG as a sealing material [3].

N acetyl-D-glucosamine and glucuronic acid are found in the disaccharide units that comprise the glycosaminoglycan known as HA. Its viscosity nature, polymeric qualities, and polyelectrolyte characteristics determine its physiological characteristics. HA is a common substance found in all biofluids and tissues. Although HA makes up a significant portion of the extracellular matrix in human synovial fluid, brain tissue, cartilage, vitreous humor, and skin, HA grades are produced via biotechnology techniques. Hydrogel polymer cross-linked, hygroscopic networks are formed to achieve HA [8].

A review by Abi Zeid Daou et al. [9] clearly presented HA in otology. The main points of this review were that HA is safe and biocompatible and degrades in the middle ear without causing inflammation. It also said there is no appreciable ototoxicity and that utilizing HA following a stapes procedure lessens vestibular discomfort. HA could provide entertainment by keeping perilymph from departing the inner ear and blood from entering it. Improving the pace and duration of healing from tympanic membrane perforations has been one of the most popular applications of HA in otology. Recent research has demonstrated promising results for HA-enriched grafts and topical HA in managing tympanic perforations.

Kiefer et al. [10] stated the low-frequency hearing conservation with an adjustment of the cochlear implantation procedure that uses HG to seal the cochleostomy and make the intracochlear electrode easier to glide.

Scarpa et al. [11] demonstrated that hearing results and the frequency of vestibular complications are similar regardless of the type of sealant used; therefore, the surgeon's preference should be taken into consideration when selecting a sealing material, as there is currently insufficient evidence that one sealant is superior to another.

In the experimental model, Bagger-Sjöbäck [12] exhibited no injury to the inner ear sensory components after administering 1% sodium hyaluronate gel to the accessible inner ear through the oval window.

We included 29 cases in the HAG group. The age distribution was 34.24 ± 6.77 (19-50) years. Seven (24.14%) were male, and 22 (75.86%) were female. Operated patients with right ears were 20 (68.97%) and 9 (31.03%) with left ears.

These basic demographics were closely related to another study by Faramarizi et al. [3], which recommended HAG as a safe sealing material post-stapedotomy for otosclerosis of 73 patients in the HAG group with mean age 36.3 ± 8.9 that ranged from 16 to 58 years. Female patients represented 45(61.6%) and there were 28(38.4%) male patient. Operated ears represented 43(58.9%) right ear and 30(41.1%) left ear.

In another study, Angeli et al. [6] analyzed HAG used as an extra sealing compound in stapedotomy. A significant case-control study evaluated cases that received stapedotomies in two groups following the ring superstructure of the stapes by an argon laser. The case group underwent a modified operation where the oval window niche was filled with 0.2 mL of HAG. Then, the footplate was drilled through, and after the insertion of the prosthesis, the fat was used as a primary sealing material in 27 ears for 22 patients. The age was distributed as 47±56 (12-79). There were 16 females and 16 males; however, in the normal group (32 ears), HAG was not used, but fat was used for sealing.

In the present study, there were 2 (6.9%) patients complained of Post-operative tinnitus from 4 (13.79%)patient with Pre-operative tinnitus in 29 operated patient, 12 (41.38%) patients with Post-operative vertigo lasted for 2-4 weeks after surgery, 12 (41.38%) patients with ABG ≤ 10db, 9 (31.03%) patients with ABG ≤ 20db, 8 (27.59%) patients ABG ≤ 30db without any dead ear. Two ears (6.9%) were complicated by perforated TM that healed spontaneously during the first month.

These findings were closely related to Angeli's [6] study, as After one week, postoperative vertigo and nystagmus were identified in 11% of sealed with HG and 38% without HG. Furthermore, after 5 weeks, vestibular complaints were evident in 4% of cases in the HG group, 13% in the control group, 85% of cases with ABG <10, and 15% of cases with ABG 11-20.

In a randomized trial, Farmarizi et al. [3] found ABG closure was ≤ 10 in 22 (30.1) ear, 11–20 in 41(56.2) ear, 21–30 in 7 (9.6) ear, > 30 in 3 (4.1) ear. Additionally, the cases achieved improved ABG closure within 10 dB and a postoperative ABG within 20 dB in 86.3% of ears in the HAG group.

The current study differs from Angeli et al. [6] and is in altered stages. Initially, HAG did not induce a vestibulotomy; instead, a clear, sharp, and more adequate view for drilling the footplate was obtained. Secondly, additional adipose tissue was not used as a sealing material. Finally, from the Farmarizi et al. [3] study, only the oval window niche was filled with HAG, but the entire middle ear cavity was clear.

Moving to the gel foam group, there were 29 patients represented, 10 (34.48%) males and 19 (65.52%) females, with a mean age of 35.28±7.29 (22-49). The operated ears were 17 (58.62) right ear and 12 (41.38) left. These demographics were closely related to other studies:

A retrospective study was undertaken on 418 cases of stape operation. There were 215 cases in the Gel foam group and 203 in the control group that failed to seal. The cases' average age was 47, with a female predominance (65.6%). [13].

In a retrospective study, Surmelioglu et al. [14] used a small amount of gel foam as a sealing material for 36 cases of stapedotomy. Cases were separated into two groups. Cases in Group I were operated on using an endoscope, while cases in Group II were operated on with a microscope. In that study, 46 instances were seen, with 29 males and 17 females. In 25 individuals, a stapedotomy was carried out on the right ear, while 21 patients had it done on the left.

Faramarzi et al. [15] conducted a prospective, double-blind, randomized clinical experiment comparing gel foam and fat as sealing materials for stapedotomies. A total of 176 primary stapedotomies were examined. Fat from the ear lobule was employed in 86 ears, while Gel foam was utilized in 90 ears. Patients in the gel foam group were 40 (46.0%) male, and the mean age was 35.1± 10.6.

During the 3-month follow-up duration in the gel foam group in this study,18 (62.07%) patients complained of post-operative vertigo, and 2 (6.9) patients from post-operative tinnitus after 1 week but after 5 weeks were free. The Post-operative audio logical investigation was 11 (37.93%) patients with ABG ≤ 10db, 11 (37.93%) patients with ABG ≤ 20db, and 7 (24.14%) patients with ABG ≤ 30db, without sensory neural hearing loss and dead ears.

The current study's above data were supported by other studies; Bawazeer et al. [13] During that study period, 11.6% of patients complained of postoperative vertigo, and the average postoperative air-bone gap in the Gel foam group was 4.6 dB. After a 50-month follow-up, there were no significant variations in vestibular or audiological results with stapes operation with or without Gel foam in the middle ear.

In a retrospective study by Surmelioglu et al. [14], the preoperative air-bone gap averaged 36.9 ± 6.8 dB in group I and 35.1 ± 6 dB in group II. The average postoperative air-bone gap was 9.3 ± 7.1 dB in group I and 13.5 ± 9.7 dB in group II, with no complications. The average follow-up period was 15.8 months.

In the Faramarzi et al. [15] study, the postoperative ABG results in the gel foam group were ABG ≤10 for 51(56.7) ear, 11 - 20 for 28(31.1) ear, 21 - 30 for 6(6.7)

ear and 5(5.6) ears with ABG >30. There were no cases of sensory neural hearing loss and dead ears.

The current study showed that the range of age in group1 was (19-50) and (22-49) group2, females represented (75.86) for group 1 and (65.52) for group 2, RT ear was operated for (68.97) in group 1 and (58.62) for 2. CT scan was normal for all cases. Hearing loss was the leading complaint for all cases, and it improved (100%) in both groups post-operative. All studied cases had pre-operative normal TM except for the ear (3.45), which had mild retracted TM. Both groups had a statistically non-substantial difference for pre and post-operative tinnitus. No pre-operative vertigo was detected in any of the cases. Still, there was a substantial variation between pre and post-operative vertigo for both groups, and a statistically non-significant difference was found between group 1 and group 2 as Post-operative vertigo with 17ear (58.62) in group 1 and 11ear(37.39)for group 2 without Post-operative vertigo. There was a statistically non-significant difference between both groups regarding pre and post-operative ABG. ABG improvement post-operative was ≤ 10db in 12ear (41.38) and 11ear (37.93%), ≤ 20db in 9 ear (31.03%) and 11ear (37.93%) and ≤ 30db in 8 ear (27.595) and 7 ear (24.14%) for group 1 and group 2 respectively. The studied groups had highly substantial differences regarding pre-and post-operative audiological investigation (p0.05). There was no significant difference between groups concerning Tympanic Membrane perforation (p >0.05).

CONCLUSIONS:

This study revealed that using either HAG or Gel foam to seal the stapedotomy, hearing results, and post-operative tinnitus might be the same. However, post-operative vertigo was comparable with the upper hand for HAG to decrease post-operative vertigo. As a result, HAG is advised as a secure sealing, easily used material following otosclerosis stapedotomy.

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Ethics approval and consent to participate

Approval of the research ethics committee was obtained from the Faculty of Medicine Suez Canal University under No. 5669.

All procedures and data management are runby the code of ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans [22].

Conflictsof Interest

The authors report no conflicts of interest.

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