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The Effects of Glass Ionomer Bone Cement Fixation of the Stapes Prosthesis on Audiological Outcomes and Prosthesis Dislocation Incidence

Stapes Protezinin Cam İyonomer Kemik Çimentosu ile Fiksasyonunun Odyolojik Sonuçlara ve Protezin Yerinden Çıkma İnsidansına Etkileri

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ABSTRACT Objective: The aim of this study is to retrospectively evaluate the effects of bone cement stabilization of the stapedotomy prosthesis with respect to audiological results and incidence of prosthesis dislocation. **Material and Methods:** A retrospective analysis of 32 cases that were operated using the same surgical technique. Surgeries were done by the same surgeon under general anesthesia. Preoperative and postoperative audiograms between Group 1 and Group 2 were compared. Demographic data, the surgical status of the contralateral ear, surgical technique, bone cement fixation status, length of the prosthesis, and intraoperative complications were analysed. Pure tone average (PTA) gains, air-bone gap (ABG) improvements, and 8 kHz hearing level changes were calculated. **Results:** Out of 32 stapedotomies, 13 cases had bone cement stabilization. There was no age (p=0.388) or sex (p=0.704) difference between the groups. Both groups had significantly improved PTAs (p<0.001) and decreased ABG (p<0.001) values. But there was no difference between the groups (p=0.701). Also, there was no difference of 8 kHz hearing levels (p: 0.656). Three prosthesis dislocations were seen in the "no bone cement" Group 1 versus no dislocations in the "bone cement" Group 2. This difference was not significant (p=0.253). **Conclusion:** Bone cement stabilization of the stapedotomy prosthesis is a safe technique. Bone cement stabilization did not affect audiological outcomes and may offer a reduction in the incidence of prosthesis dislocation. However, studies with larger patient series and longer follow-up periods are needed.

Keywords: Bone cements; stapes surgery; glass ionomer cements

ÖZET Amaç: Bu çalışmanın amacı, stapedotomideki protezin kemik çimentosu stabilizasyonunun odyolojik sonuçlar ve protez yerinden çıkma insidansı üzerindeki etkilerini retrospektif olarak değerlendirmektir. **Gereç ve Yöntemler:** Aynı cerrahi teknikle opere edilen 32 olgunun retrospektif olarak analizi yapıldı. Bu ameliyatlar aynı cerrah tarafından genel anestezi altında yapılmıştır. Ameliyat öncesi ve ameliyat sonrası odyogramlar Grup 1 ile Grup 2 arasında karşılaştırıldı. Demografik veriler, karşı taraftaki kulağın cerrahi durumu, cerrahi teknik, kemik çimentosunun fiksasyon durumu, protez uzunluğu ve intraoperatif komplikasyonlar analiz edildi. Saf ses ortalaması [pure tone averages (PTA)] kazançları, hava-kemik aralığı [air-bone gap (ABG)] iyileştirmeleri ve 8 kHz işitme seviyesi değişiklikleri hesaplandı. **Bulgular:** Otuz iki stapedotomiden 13'ünde kemik çimentosu stabilizasyonu sağlandı. Her iki grup arasında yaş (p=0,388) ve cinsiyet (p=0,704) açısından farkı yoktu. Her iki grupta da anlamlı olarak PTA (p<0,001) düzeldi ve ABG (p<0,001) değerleri azaldı. Ancak gruplar arasında fark yoktu (p=0,701). Ayrıca 8 kHz işitme seviyeleri arasında fark yoktu (p: 0,656). "Kemik çimentosu olmayan" (Grup 1) grupta 3 protez yerinden ayrılması görülürken, "kemik çimentosu" (Grup 2) grubunda hiç ayrılma görülmedi. Ancak bu fark anlamlı değildi (p=0,253). **Sonuç:** Stapedotomide protezin kemik çimentosu ile stabilizasyonu güvenli bir tekniktir. Kemik çimentosu stabilizasyonu odyolojik sonuçları etkilemedi ama protezin yerinden çıkma insidansında bir azalma sağlayabilir. Ancak daha geniş hasta serilerinde ve daha uzun takip sürelerini içeren çalışmalara ihtiyaç vardır.

Anahtar Kelimeler: Kemik çimentosu; stapes cerrahisi; cam iyonomer sementler

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Otosclerosis is a progressive disorder of the otic capsule leading to conductive, mixed, or sensorineural hearing loss.[1] Treatment options include medical treatment, surgery, and/or hearing aids.[1,2] Although surgery doesn't stop the disease progression, enables better energy transfer into the inner ear and provides a second mobile window.

In the past, fenestration techniques and footplate mobilizations have been performed. These techniques are largely abandoned due to their morbidity and higher recurrence rates.[1] Stapedectomy and stapedotomy are reported to have similar success rates but the latter have better high-frequency hearing results and lower complication rates.[3] The surgical technique of stapedotomy is continuously evolving to decrease morbidity, invasiveness, and complications. The use of lasers and endoscopic visualization have been some of the recent advances.[4,5]

One of the most common causes of hearing deterioration and revision surgery after a successful stapes surgery is the dislocation or loosening of the prosthesis.[6,7] It is well known that a tight stapes prosthesis fixation would result in a more efficient sound energy transfer and better audiological outcomes.[8] Recent studies have reported that stabilization of the prosthesis with bone cement has favorable hearing results in both primary and revision stapes surgeries.[6,9,10] Also, bone cement stabilization may have the potential to decrease the prosthesis dislocation risk in the long term.

Our aim in this study is to compare the audiological results and prosthesis dislocation incidence of stapedotomy with or without bone cement stabilization.

MATERIAL AND METHODS

This study was approved by Başkent University Institutional Review Board (date: January 4, 2023, no: KA 22/357) and supported by Başkent University Research Fund. A retrospective analysis of adult patients that were undergone stapedotomy between 2017 and 2022 was conducted. Patients with uncontrolled systemic diseases, prior ipsilateral middle ear or stapes surgeries, and otologic diseases other than otosclerosis were excluded. Patient records were analyzed in terms of demographic data, the surgical status of the contralateral ear, preoperative audiograms, surgical technique, bone cement fixation status (bone cement "Group 2" and no-fixation "Group 1"), length of the prosthesis, intraoperative complications, postoperative audiogram, and follow-up duration.

SURGICAL TECHNIQUE

Surgeries were done by the same surgeon under general anesthesia with an operating microscope. The ear canal was injected with 1% lidocaine 1 with 1:100,000 adrenaline. The tympanomeatal flap was elevated using a Rosen incision. 2 cases needed an endaural approach. A limited atticotomy was done with micro-bur until enough exposure was reached. Bone dust was collected for later sealing. After the mobility of the ossicles was checked and stapes fixation was detected, the incudostapedial junction was separated and the stapedius tendon was cut. The stapes superstructure was carefully removed. The distance between the long process of incus (LPI) and the footplate was measured and a 0.6 mm Teflon prosthesis was cut accordingly. The footplate was fenestrated carefully with 0.6 and then 0.8 mm manual perforators. The loop of the prosthesis was dilated with a pick. The prosthesis was gently inserted and the mobility was checked. After the prosthesis was placed, the stability of the prosthesis was tested by palpation. Bone cement (Ketac Cem Easy Mix; 3M ESPE, Starnberg, Germany) stabilization was done if the stability of the prosthesis was suspected with a drop of bone cement applied inferior to the loop. Bone dust was used for sealing followed by a few pieces of resorbable gelatin foam. The flaps were returned to their places.

AUDIOLOGICAL ANALYSIS

Preoperatively all patients had a 25 dB or greater conductive hearing loss in frequencies 500 Hz to 2 kHz with negative Rinne at 512 Hz. Air thresholds were measured between 0.125 and 8 kHz. Bone thresholds and air-bone gaps (ABG) were measured at 0.5-4 kHz. Postoperative audiograms were done at least 6 weeks after surgeries. Earlier tests were excluded due to possible conductive losses by non-resorbed gelatin foam.

STATISTICAL ANALYSIS

SPSS (Version 22.0, IBM Corp., Armonk, NY USA) was used. To evaluate the normality of distribution

Shapiro-Wilk test was used. For comparison of the use of bone cement groups Mann-Whitney U test was used. Fisher's exact test was performed for categorical variables. The level of statistical significance was considered $p<0.05$ in all data.

RESULTS

Thirty two patients were operated between February 2017 and June 2022 were included. Bone cement fixation cases were from 11.2019 onwards. There was no age (p=0.388) or sex (p=0.704) difference between the groups. Piston length was significantly longer (p: 0.019) in Group 2 (Table 1). The patients in Group 2 had incidentally higher preoperative pure tone averages (PTA) and ABGs (Table 2) which may be linked to delayed hospital admission and treatments due to the coronavirus disease-2019 pandemic.

No major complications were encountered. In two cases, small tympanomeatal flap perforations happened and were repaired intraoperatively. Chorda tympani was cut in one case.

TABLE 1: The demographic data, mean piston length and follow-up durations of stapedotomy prosthesis not fixated (no-fixation) (Group 1), and bone cement fixated (bone cement) (Group 2).

	No-fixation (Group 1)	Bone cement (Group 2)
Age (at surgery)	42.8	46.3
Sex (male/female)	6/13	3/10
Side (right/left)	11/8	8/5
Piston length (millimeters)	4.47	4.61
Follow-up duration (months)	39.7	13.8

TABLE 2: Preoperative and postoperative audiological results of no-fixation (Group 1) and bone cement groups (Group 2).

		No-fixation(dB) (Group 1)	Bone cement (dB) (Group 2)
PTA	Pre-operative	48.42	62.5
	Post-operative	23.82	39.48
	gain	**24.6**	**23.02**
ABG	Pre-operative	25.74	33.75
	Post-operative	4.92	13.65
	closure	**20.82**	**20.1**

PTA: Pure tone averages; ABG: Air-bone gaps.

The mean follow-up duration of Group 1 was longer than Group 2 (Table 2). No dislocations were seen in Group 2. Three prosthesis dislocations were seen in Group 1 with a mean follow-up of 13.3 months before hearing deterioration was documented. These cases were surgically explored, dislocations were identified and new pistons were inserted and fixated with bone cement. Although no dislocations were seen and successful hearing results were obtained after revisions, these cases were removed from the follow-up data of this study after their revisions. With our limited number of cases and shorter follow-up duration of the bone cement group, the difference in the prosthesis dislocation incidence was not significant (p=0.253).

Both bone cement (Group 2) and no-fixation (Group 1) groups had significantly improved PTAs ($p<0.001$) and decreased ABGs ($p<0.001$). The average ABG closure and PTA gain were similar between the groups. There was no difference between groups in terms of PTA increase (p=0.701) and ABG closures (p: 0.501) (Table 2). Also, there was no difference between the groups in terms of the 8 kHz threshold gains (p=0.656).

Seventeen of 19 (89.5%) no-fixation patients and 6 of 13 (46.1%) bone cement patients had less than 10 dB postoperative ABG. None of the no-fixation patients had more than 15 dB postoperative ABG. Five patients of the bone cement group (38.5%) had more than 15 dB postoperative ABG. Ten of 19 (52.6%) no-fixation patients and 11 of 13 (84.6%) bone cement patients had more than 20dB PTA gain.

DISCUSSION

No curative medical therapy exists for otosclerosis.[2] Some medical therapies have been tried before. For example, sodium fluoride and bisphosphonates, but according to current literature, surgery is accepted as the gold standard.

The surgical technique of otosclerosis has been improving for more than a century. Surgical techniques that increase success and decrease morbidity and recurrences are being developed. As a rule, better energy transfer means better hearing. Therefore,

assuming no secondary pathologies of ossicles or tympanic membrane are present, the connection between the prosthesis and the LPI would determine the hearing result. A connection that is not loose but also has a limited articulation potential to convert the complex motion of the incus to a linear piston-like movement would be the holy grail.

Having a tight fixation with a manually crimped titanium loop prosthesis is risky in the long run. Overtight crimping might lead to resorption or necrosis of the LPI, leading to prosthesis loosening or dislocation.[9] Shape-memory alloy (Nitinol) prostheses that have laser-activated loop closure mechanisms can be considered as a solution to this.[11] Commonly used Teflon pistons also have shape memories. The loop is dilated before installation and expected to close soon after insertion with minimal tightness.

Stabilization of the prosthesis with bone cement is intended for filling all of the gaps between the loop and the LPI. Although bone cement doesn't strongly adhere to the polymeric material of the prosthesis, mechanical stabilization is possible. Since dislocations commonly occur towards the inferior, a drop of bone cement applied to the distal end of the LPI would prevent most of the dislocations.[6,9] Applying to both sides of the loop or bridging over the loop could even give better stabilization. But it should not be forgotten that increasing the weight of the ossicular chain could deteriorate high-frequency hearing. Therefore in this study, bone cement was only applied inferior to the loop. In our study, 8 kHz threshold gains of bone cement and no fixation groups were compared to see if there was a high-frequency loss. But no difference was noted.

There are many different bone cement formulations such as Aqua Meron (San Pablo City, Laguna, Philippines), KetacCem (Neuss, Germany), AquaCem (Charlotte, Kuzey Carolina, ABD), OtoMimix (Shinjuku, Tokyo, Japonya). OtoMimix® is a hydroxyl-apatite cement that is primarily used as a bone filler and depends on mechanical adhesion to the bone it is applied on.[12] The others are glass-ionomer cement that has inorganic glass crystals and a polymerizing component, such as polyacrylate or polymethacrylate. Polymerizing agent of glass-ionomer cements chemically bond to tissue as well as a mechanical adhesion. In this study, we preferred Ketac™Cem.

The causes of revision stapedotomy include loose prosthesis, LPI necrosis-mainly due to overtight wire loop prostheses, or dislocations.[6] Bone cement application may prevent loose prostheses and dislocations. If bone cement stabilization is planned, the surgeon may depend on the bone cement for ensuring a tight fixation and avoid overtightening. That way LPI necrosis could also be prevented which would require revisions with malleovestibular prostheses or total ossicular replacement prosthesis on a vein graft etc. In our study, no-fixation group had 3 dislocations with a mean follow-up duration of 13.3 months. No dislocations or conductive-type hearing deterioration was seen in the bone cement group. But the number of bone cement patients and shorter follow-up duration hindered a significant difference. Longer follow-ups with larger study groups could reveal significant results in the future.

Success criteria for stapes surgeries are many and different criteria may give varying results with the same set of records.[13] Widely used success criteria include ABG<10dB, ABG<15dB, and PTA gain >20dB. Quality of life questionnaires tailored for stapes surgeries such as SPOT-25 may also be helpful if the test is validated to the language and pre-operative scores are present for direct comparison.[14] Both no-fixation and bone cement groups had successful audiological results and bone cement stabilization did not cause a significant difference. PTA gain and ABG closure were similar in both groups. Since pre-operative PTA and ABG values of the bone cement group were higher, ABG<10 and <15 dB results seem to be lower in the bone cement group. On the other hand, this preoperative difference favored the bone cement group in terms of the PTA gain >20 dB percentage.

CONCLUSION

Bone cement stabilization of the stapedotomy prosthesis is a safe technique. The addition of bone cement does not affect audiological outcomes and may offer a reduction in the incidence of prosthesis dislo-

cation. However, studies with larger patient series and longer follow-up periods are needed.

Source of Finance

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Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

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