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Long-term outcomes of ossiculoplasty using bone cement

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Abstract

Objective. This study aimed to evaluate the long-term results of ossiculoplasty using bone cement.
Method. Forty patients (24 females and 16 males; mean age: 34.1 ± 11.8 years; range, 9–54 years) with chronic otitis media with perforation but without cholesteatoma who had undergone incudostapedial rebridging ossiculoplasty using bone cement were evaluated retrospectively. Pre-operative and post-operative audiograms were evaluated. Bone conduction, air conduction and air–bone gaps were calculated according to international guidelines.
Results. There was a mean reduction in pre-operative and post-operative air conduction (12.30 ± 11.98 dB), and this result was significant ($p = 0.0001$). There was a mean reduction in pre-operative and post-operative bone conduction (4.30 ± 6.69 dB), and this result was significant ($p < 0.0001$). The pre-operative air–bone gap was 27.65 dB and decreased to 19.65 dB during follow-up ($p = 0.0001$). No adverse reactions or complications were observed.
Conclusion. Bone cement is reliable for the repair of incudostapedial-joint defects.

Introduction

The causes of middle-ear diseases of the ossicular chain include chronic ear diseases, trauma and congenital ossicular anomalies. When treating chronic ear disease, the main aims are to avoid irreversible disease and improve auditory function. The incus is the ossicle that is the most vulnerable to damage in chronic diseases of the middle ear.[1] Reconstruction of the incudostapedial joint can be achieved in several ways. The use of bone cement to maintain incudostapedial continuity has increased in recent years.

Bone cement is often used for implant fixation in various types of orthopaedic or trauma surgery and for dental applications.[2] Bone cement consists of powder and liquid mixed at certain ratios. This mixture hardens within minutes through an exothermic process. In Ketac Cem Radiopaque Permanent Glass Ionomer Luting Cement (3M, Maplewood, Minnesota, USA), glass powder, polycarboxylic acid and pigments are used as the powder, and water, tartaric acid and preservative agents are used as the liquids. The mixing time is 2.5 minutes, and the hardening is completed in 5–10 minutes. When the bone cement hardens, it no longer reacts with the surrounding liquids.

In this study, we evaluated the results of our clinical experience with bone cement repair of ossicular discontinuity between the incus and stapes.

Materials and methods

Patients who underwent incudostapedial rebridging ossiculoplasty between June 2006 and June 2010 were evaluated retrospectively.

The collected data comprised patients' age, sex, primary diagnosis, surgical procedure, side of surgical procedure, surgical outcome, and pre- and post-operative audiograms. Patients who had a disease-free or cleansed middle ear and mastoid, no cholesteatoma, and an intact ossicular chain apart from discontinuity within the incus long process and the head of stapes were included.

The study started with 51 patients, but 11 patients were lost at follow up. Therefore, 40 patients (24 females and 16 males; mean age: 34.1 ± 11.8 years; range, 9–54 years) took part in the present study. Patients visited our clinic at least five years after incudostapedial rebridging ossiculoplasty. All patients underwent tympanoplasty through post-auricular incision for chronic otitis media with perforation but without cholesteatoma. Temporalis muscle fascia was applied as a graft material in patients with chronic otitis media, and auricular cartilage was used to prevent direct contact between the bone cement and the tympanic membrane.

Procedures

Post-auricular approaches were used to expose the middle ear. Bone cement was formed by mixing liquid and powder as described in manufacturer instructions. Pre-operative and post-operative pure tone audiometric scores were used to calculate the air–bone gap

Main Article

Dr B Demir takes responsibility for the integrity of the content of the paper

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(ABG), and hearing gain was calculated at frequencies of 0.5, 1, 2 and 4 kHz. According to the recommendation of the American Academy of Otolaryngology Head and Neck Surgery Committee on Hearing and Equilibrium guidelines, an ABG of less than 20 dB post-operatively was used as the criterion for successful ossiculoplasty.[3]

Statistical analyses

Data were analysed using SPSS® (version 16) statistical software. Pre-operative and post-operative bone conduction and air conduction were compared using the paired *t*-test. For comparison of the hearing results of independent groups, the Kruskal–Wallis and chi-square tests were used. A *p*-value of less than 0.05 was considered statistically significant. Results are given as the mean ± standard deviation (SD).

Results

A total of 24 right ears and 16 left ears underwent incudostapedial rebridging ossiculoplasty. The mean ± SD duration after incudostapedial rebridging ossiculoplasty was 62.4 ± 5.1 months (range, 61–74 months). The pre-operative ABG of patients who underwent incudostapedial rebridging ossiculoplasty was 15–50 dB. The mean ± SD ABG was 27.6 ± 7.6 dB.

The mean pre-operative air conduction was 47.9 ± 13.6 dB, and the post-operative air conduction was 35.6 ± 15.4 dB at 62.4 months (mean) after incudostapedial rebridging ossiculoplasty. The mean reduction between pre-operative and post-operative air conduction was 12.3 ± 11.9 dB. There was a significant difference between pre-operative and post-operative air conduction ($p < 0.05$).

The mean pre-operative bone conduction was 20.2 ± 8.1 dB. The mean post-operative bone conduction was 15.9 ± 9.4 dB at 62.4 months (mean) after incudostapedial rebridging ossiculoplasty. The mean reduction between the pre-operative and post-operative bone conduction was 4.3 ± 6.6 dB. These results were significantly different ($p < 0.05$).

The pre- and post-operative conduction thresholds at high frequencies (1, 2, 3 and 4 kHz) were measured. The mean change for high frequencies showed an improvement of 4.6 dB (± 7.3 dB). These results were significantly different ($p < 0.05$).

The mean pre-operative ABG was 27.6 dB and decreased to 19.6 dB after 62.4 (± 5.1) months (mean) since incudostapedial rebridging ossiculoplasty ($p < 0.05$) (Table 1). A post-operative ABG of 0–10, 10–20 and 20–30 dB was seen in 12, 21 and 7 patients, respectively. This would demonstrate that 33 patients had a post-operative ABG of less than 20 dB.

For male patients, the mean pre-operative and post-operative ABG was 23.6 dB and 19 dB, respectively. For female patients, the mean pre-operative and post-operative ABG was 30.3 dB and 20 dB, respectively. These results showed no significant difference between pre-operative and post-operative ABG in terms of gender ($p < 0.05$).

For female patients, the mean pre-operative air conduction was 50.5 ± 15.9 dB, and the mean post-operative air conduction was 39.7 ± 15.8 dB. The mean pre-operative bone conduction was 20.2 ± 8.9 dB, and the mean post-operative bone conduction was 19.6 ± 9 dB. There was a significant difference between pre-operative and post-operative air conduction ($p < 0.05$) but not bone conduction ($p > 0.05$).

Comparison between the pre-operative and post-operative values in male and female patients showed no significant difference in air or bone conduction ($p > 0.05$). However, comparison of post-operative results for male and female patients showed male patients to have significantly better results ($p < 0.05$).

Discussion

Various methods are used for reconstruction of the incudostapedial joint. Total ossicular replacement prostheses or partial ossicular replacement prostheses, autologous bone and cartilage, combined prostheses, or cortical bone grafts have been used for many years. Ossiculoplasty using bone cement can be also employed to reconstruct the ossicular chain in chronic otitis media.[4]

Several methods have been described for reconstruction of the incudostapedial joint, each with its advantages and disadvantages. Definitive hearing results, cost-effectiveness and easy application are the main advantages of this method.[4] Another advantage of ossiculoplasty using bone cement is that it maintains the anatomy and physiology of the ossicular chain.[5] Hearing results using bone cement are good. Ossiculoplasty using bone cement maintains the natural anatomy and physiology of the ossicular chain, but it also results in better hearing and has high success rates.

In our study, the ABG fell to 19.6 dB at follow up. Babu and Seidman performed ossiculoplasty using bone cement on 18 patients, and successful results were obtained for 17 of them.[6] Celenk *et al.* performed incudostapedial rebridging ossiculoplasty in 50 patients and achieved an ABG of less than 20 dB in 78 per cent of the patients.[5] Ozer *et al.* performed ossiculoplasty using bone cement in 15 patients and achieved successful hearing results in 9 patients after 1 year.[4]

The resonance frequency of the middle ear differs for air and bone conduction stimuli. Although airway stimulation averages between 0.8 and 1.2 kHz, the mean shifts towards high frequencies during bone path stimulation (between 1.5 and 2 kHz).[7] There are also differences in the transmission of air and bone conduction stimuli. In air conduction, the sound pressure in the ear canal is primarily transmitted through the tympanic membrane and the ossicular chain to the cochlea. However, bone conduction involves multiple pathways, including distortional, inertial-ossicular and osseotympanic pathways.[8] Therefore, the post-operative air and bone threshold corrections may not be parallel. The improvements in bone conduction pathway thresholds depend on the extent to which bone chain movement can be achieved. However, in our study both bone and air conduction improved in a similar way. The improvement of the conduction thresholds at high frequencies can be interpreted as a sign of the resonance frequency being caught, indicating that the ossicular configuration is approaching normal. The mean change in conduction thresholds showed an improvement of 4.6 dB (± 7.9 dB) in our study. This suggests that bone cement provides a transmission close to the original in bone conduction. The difference in ABG between the genders was not expected in terms of pathology. There is no study found in the literature that shows significant differences in the air–bone range in terms of gender.

Ossiculoplasty using bone cement is inexpensive because one box of cement provides the material for many patients. Application of bone cement is simple, but certain requirements must be met for incudostapedial rebridging ossiculoplasty using bone cement. If using bone cement for ossiculoplasty, there should be no blood or haemorrhage in the middle ear.[9] The mucosa overlying the head of stapes and remnant of the long process of incus must be removed

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Table 1. Long-term outcomes of ossiculoplasty using bone cement

	Air conduction			Bone conduction			ABG		
Age	Pre-op	Post-op	*P*-value	Pre-op	Post-op	*P*-value	Pre-op	Post-op	*P*-value
34.1 ± 11.8	47.9 ± 13.6	35.6 ± 15.4	<0.05	20.2 ± 8.1	15.9 ± 9.4	<0.05	27.6 ± 7.6	19.6 ± 9.6	<0.05

All values are mean ± standard deviation. ABG = air–bone gap; Pre-op = pre-operative; Post-op = post-operative

to expose the 'pure' bone surfaces needed for adhesion of the glass ionomer bone cement.

Due to the potential neurotoxicity of glass ionomeric cement, contact with neural structures, perilymph or dura should be avoided.[4,10] In the event of contamination, bone cement should be aspirated instantly and multiple attempts at aspiration and irrigation of the middle-ear cavity with serum is essential to extract the bone cement.[11] Reconstruction with bone cement should be undertaken at its most appropriate stiffness to avoid contamination. Small pieces of sponge can be used to prevent cement being transmitted to middle-ear structures.[11]

Although bone cement has a neurotoxic effect by increasing inflammation and the formation of granulation tissue, Kum and Kulacoglu reported that it does not give rise to permanent dysfunction of facial nerves.[10] The heat produced in the preparation of bone cement is perhaps another disadvantage of bone cement. Our research team has not observed heat-related problems or neurotoxicity to facial nerves. It has also been reported that use of relatively large amounts of bone cement to repair large craniotomy defects can cause neurotoxic effects and even death due to aluminium toxicity.[12] Although less bone cement is used for ossiculoplasty than to repair craniotomy defects, the risk of aluminium toxicity should be considered.

Hydroxyapatite bone cement is another type of glass ionomer, but it is more expensive than glass ionomer bone cement. However, hydroxyapatite bone cement does not lead to significant neurotoxic properties, aluminium toxicity or formation of granulation tissue.[13] Hydroxyapatite bone cement carries a lower risk of inner-ear damage than other prostheses.[14] The disadvantages of hydroxyapatite bone cement are high cost, difficulty of preparation and placement, and drying time.[15] This cement remains forgeable for 3–4 minutes before placement and can harden completely in 5 minutes.[15]

Bone cement is not associated with the graft take rate.[11] Cement ossiculoplasty can be applied before or after placement of a temporalis fascia graft, but we prefer ossiculoplasty after grafting. We have performed tympanoplasty using the over–underlay method with standard sponges and auricular cartilage to hinder the connection between bone cement and the tympanic membrane. This is particularly important in patients with Eustachian-tube dysfunction.

One of the most important factors affecting the long-term consequences of ossiculoplasty is persistent disease such as cholesteatoma, atelectasis and Eustachian-tube dysfunction.[5] The absence of these persistent diseases in our patients showed the success of our method. Furthermore, extrusion or absorption of prosthetic material may be a long-term complication, particularly as a result of Eustachian-tube dysfunction,[5] but this was not observed in our study. The distance between stapes and the long process of the incus should be evaluated carefully for bone-cement application. The 'ideal' patient for ossiculoplasty using bone cement will have a gap of less than one-third of the incus long arm. Ossiculoplasty can be applied for lengths of up to two-thirds of the incus long process.[5]

- Incus long process defects are a common cause of ossicular discontinuity
- Bone cement ossiculoplasty is a reliable method for repairing incus long process defects
- Hearing gain is maintained in the long term after using bone cement to manage incus long process defects

The retrospective nature and absence of audiograms at one year after incudostapedial rebridging ossiculoplasty were the main limitations of our study. Nevertheless, this was the first study showing the long-term results of ossiculoplasty using bone cement.

Conclusion

Incudostapedial rebridging ossiculoplasty using bone cement is a safe and reliable method that gives good long-term hearing results.

Competing interests. None declared

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