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MAIN ARTICLE

Comparison of Carina active middle-ear implant with conventional hearing aids for mixed hearing loss

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Abstract

Objective: To compare the auditory outcomes of Carina middle-ear implants with those of conventional hearing aids in patients with moderate-to-severe mixed hearing loss.

Methods: The study comprised nine patients (six males, three females) who underwent middle-ear implantation with Carina fully implantable active middle-ear implants to treat bilateral moderate-to-severe mixed hearing loss. The patients initially used conventional hearing aids and subsequently received the Carina implants. The hearing thresholds with implants and hearing aids were compared.

Results: There were no significant differences between: the pre-operative and post-operative air and bone conduction thresholds ($p > 0.05$), the thresholds with hearing aids and Carina implants ($p > 0.05$), or the pre-operative (mean, 72.8 ± 19 per cent) and post-operative (mean, 69.9 ± 24 per cent) speech discrimination scores ($p > 0.05$). One of the patients suffered total sensorineural hearing loss three months following implantation despite an initial 38 dB functional gain. All except one patient showed clinical improvements after implantation according to quality of life questionnaire (Glasgow Benefit Inventory) scores.

Conclusion: Acceptance of Carina implants is better than with conventional hearing aids in patients with mixed hearing loss, although both yield similar hearing amplification. Cosmetic reasons appear to be critical for patient acceptance.

Key words: Middle Ear Implant; Hearing Aids; Mixed Hearing Loss

Introduction

Conventional hearing aids are currently the main tools used in the rehabilitation of moderate-to-severe hearing loss worldwide.[1] Despite the improvements in conventional hearing aid technology in the last few decades, there are still some limitations, such as insufficient gain, acoustic feedback, distortion of spectral shape and phase shifts, non-linear distortion, occlusion effects, cosmetic problems, poor transduction efficiency, recruitment and reduced dynamic range, and incorrect perception of pitch and sound localisation.[2]

Middle-ear implant technology has been developed to overcome such problems.[3] Middle-ear implants bypass the external ear canal, and directly stimulate the ossicular chain or middle-ear windows. These devices may be either fully or semi-implantable, depending on the location of the microphone and power source. The critical components of implantable hearing aids are the signal transducer and the mechanism that connects this signal transducer to the ossicles or windows.[4] The major limitations of middle-ear implants are: the need for surgery, device extrusion, increased charging times, device lifetime issues, magnetic resonance imaging incompatibility and cost.[2] Currently, two types of fully implantable middle-ear implant are available for use: the Esteem® and Carina® implants.[1]

The fully implantable active middle-ear Carina implant contains an electromagnetic transducer.[5] All components of the Carina device are implanted under the scalp skin, which helps to overcome many of the problems experienced during swimming, showering, sports activities and working in dusty environments. In addition, it has cosmetic advantages.

This study aimed to compare the clinical and audiological results of the Carina with those of conventional

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hearing aids in the treatment of moderate-to-severe mixed hearing loss.

Materials and methods

Nine patients who underwent middle-ear implantation with Carina fully implantable devices in the Otorhinolaryngology Department at Gazi University, between July 2010 and March 2012, were retrospectively included in the study. There were 6 males and 3 females, with ages ranging from 33 to 57 years (mean, 46 years). All of the patients had bilateral moderate-to-severe mixed hearing loss and previous experience with conventional hearing aids for at least three months. Implantation was performed on the right and left sides in four and five patients, respectively.

Pure tone and speech audiometry was performed pre- and post-operatively to evaluate the air and bone conduction thresholds and speech discrimination scores. Post-operative assessment was performed at least three months after the activation of the Carina implant.

A quality of life questionnaire, the Glasgow Benefit Inventory, was administered post-operatively. The inventory yields a total score and three subscale scores: general, social support and physical health. There are 18 questions and each is scored from 1 to 5. Scores between 1 and 100 show an improvement in quality of life, whereas scores between −100 and −1 indicate a regression.

Surgical techniques

In five patients, the transducer was placed on the incus body (Figure 1). Three of these patients had previously undergone canal wall up surgery to treat chronic otitis media, one had undergone stapedotomy with Teflon™ piston placement to treat otosclerosis, and one had congenital external ear canal atresia.

In two patients, the transducer was placed on the oval window. One of them had a canal wall down mastoidectomy and the other had a canal wall up mastoidectomy. The transducer was placed on the round window in one patient who underwent canal wall down mastoidectomy. In the last patient, as the oval and round windows were both ossified, the implant transducer was placed on the cochlear endosteum in the area corresponding to the round window region.

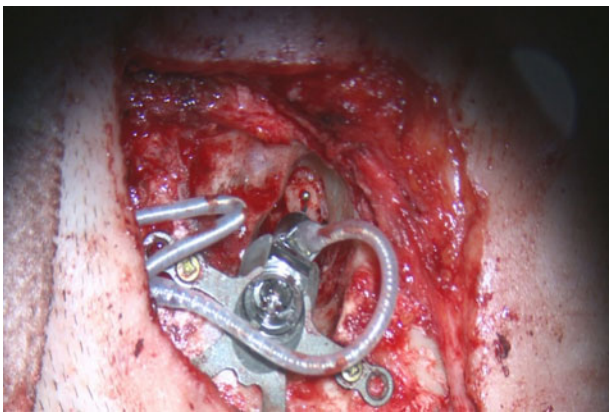

FIG. 1

Implanted Carina device with the transducer placed on the incus body.

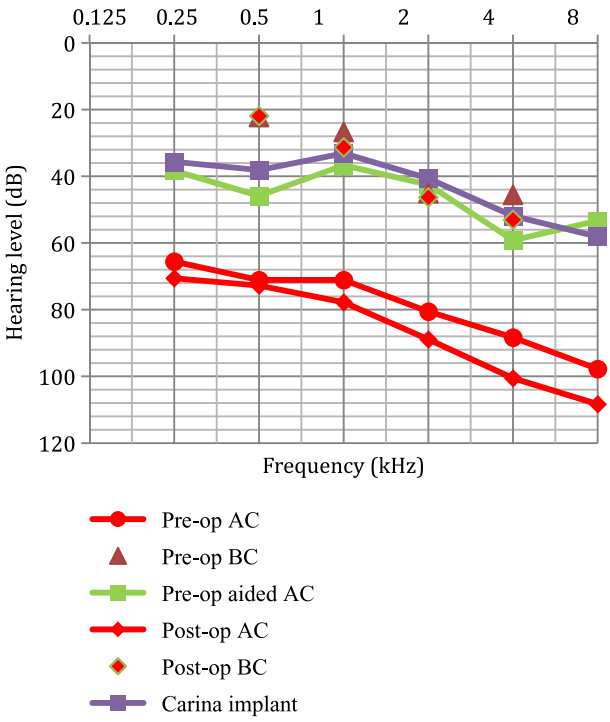

FIG. 2

Mean pre-operative and post-operative audiological results from the nine patients. Pre-op = pre-operative; AC = air conduction; BC = bone conduction; post-op = post-operative

In the patients who had a canal wall down mastoidectomy, a blind sac closure of the ear was performed and the skin was simply closed over the cavity without any obliteration material. The microphone was placed beneath the mastoid tip in all patients.

Statistics

Statistical analysis was performed using the SPSS statistical software package, version 17.0 (SPSS, Chicago, Illinois, USA). The descriptive statistics were presented as means±standard deviations. The Wilcoxon signed-rank test was used to compare pre-operative and post-operative audiological results. In all of the tests, $p < 0.05$ was considered to be statistically significant.

Results

The mean pre-operative and post-operative pure tone audiometry results are shown in Figure 2. Pre-operatively, mean air and bone conduction thresholds were 79.10 ± 11.18 dB (range, 65.56–97.78 dB) and 34.86 ± 10.53 dB (range, 22.22–45.56 dB), respectively. Post-operatively, the mean air conduction threshold was 86.48 ± 14.13 dB (range, 70.56–108.33 dB), whereas the mean bone conduction threshold was

TABLE I
POST-OPERATIVE GLASGOW BENEFIT INVENTORY SCORES

Pt no.	Total	General	Social support	Physical health
1	36.11	45.83	0	33.33
2	55.55	62.5	66.66	16.66
3	44.44	58.33	16.66	50
4	44.44	50	16.6	50
5	11.11	33.33	0	50
6	44.44	50	33.33	33.33
7	−16.66	−33.33	0	33.33
8	36.11	50	0	16.66
9	50	58.33	66.66	0

Pt no. = patient number

38.09 ± 12.23 dB (range, 21.88–53.00 dB). There were no significant differences between the pre-operative and post-operative air and bone conduction thresholds ($p > 0.05$).

Pre-operatively, the mean aided air conduction threshold was 45.97 ± 8.01 dB (range, 36.67–53.33 dB). The mean implanted air conduction threshold was 42.92 ± 9.02 dB (range, 33.13–58.13 dB). There was no significant difference between the thresholds achieved with hearing aids and the Carina implant ($p > 0.05$).

No significant difference was found between the pre-operative and post-operative speech discrimination scores (mean values were 72.8 ± 19 per cent and 69.9 ± 24 per cent, respectively; $p > 0.05$).

There was no significant difference in mean functional gain between incus attachments and middle-ear window attachments ($p > 0.05$).

All of the patients, apart from one, showed clinical improvements according to the quality of life questionnaire (Glasgow Benefit Inventory) after implantation (Table I). The exception was patient number seven, who had a history of stapedectomy and Teflon piston application, and in whom the transducer was placed on the incus body. Despite an initial 38 dB functional gain, this patient suffered total sensorineural hearing loss (SNHL) three months after implantation.

The patients did not have any complaints about sound quality with the implanted microphones, and they did not suffer any sensitivity to body noise.

Discussion

Implantable hearing aids have been used in the treatment of moderate-to-severe hearing impairments. They can be used for sensorineural, conductive or mixed hearing loss. An active middle-ear implant can be coupled to the middle-ear ossicles, the windows or the endosteum of the inner ear.[6–8]

The fully implantable middle-ear Carina implant was primarily developed for the treatment of moderate-to-severe SNHL. Jenkins and colleagues reported their short-term and long-term results with the Carina device used for the amplification needs of adults with SNHL.[9–11] In their description, the tip of the transducer was attached to the incus via insertion into a laser-drilled hole. According to Jenkins *et al.*, the Carina implant is a safe and clinically effective middle-ear prosthesis for the treatment of SNHL.

The Carina implant has subsequently been used for the treatment of conductive and mixed hearing loss. Previous studies have shown the usefulness of middle-ear ossicles and windows for stimulation; hence, the transducer of the Carina device may be placed on the round or oval windows, and on the incus.[6–8] Lefebvre *et al.* applied the Carina implant to the round window in six patients suffering from mixed hearing loss without any adverse effects and with an average functional gain of 26.2 dB.[12] Martin *et al.* reported an average functional gain of 29 dB and improved speech reception by placing the Carina transducer on the round window.[13] In our study, the transducer was placed on the incus body in five patients, and on the middle-ear windows (round or oval window) in four patients. No statistically significant difference was found between incus and window applications ($p > 0.05$).

The Carina implant can also be used in cases of congenital aural atresia. Tringali *et al.* implanted the Carina device in a patient with Treacher Collins syndrome and this yielded a 29 dB functional gain.[14] Siegert *et al.* implanted five congenital aural atresia patients and reported an average functional gain of 36 dB.[15] These results are comparable to our results for the one patient with congenital aural atresia.

Active middle-ear implants can be inserted during or after stapedectomy. Venail *et al.* fitted semi-implantable hearing aids to four patients during or after stapes surgery.[16] They reported improvements in hearing and quality of life with middle-ear implants in otosclerosis patients. In one of our patients who was implanted with a Carina device after stapedectomy, there was an initial 38 dB functional gain; however, this patient suffered total SNHL a few months after implantation.

In the present study, the Carina implant was used for the treatment of mixed hearing loss. There was no statistically significant difference between the conventional hearing aids and the Carina implant with regard to hearing amplification and speech discrimination; however, patient compliance and acceptance were better with the Carina implant compared to conventional hearing aids. This is supported by the findings of the Glasgow Benefit Inventory.

- **Middle-ear implants were designed to overcome audiological and clinical gain issues of conventional hearing aids**
- **In this study, the clinical and audiological outcomes of the Carina middle-ear implant were similar to conventional hearing aids**
- **The Carina implant is better accepted compared with conventional hearing aids, especially regarding cosmetic concerns**

In conclusion, acceptance of the Carina implant is better than with conventional hearing aids, although both yield similar hearing amplification. Cosmetic reasons appear to be critical for patient acceptance.

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