



## Case Report

# A Novel Way of Stimulation of the Inner Ear via Labyrinthotomy with Fully Implantable Active Middle Ear Implant, Carina

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The aim of this case report is to demonstrate the effectiveness of Carina for the treatment of mixed hearing loss by stimulation of the inner ear via the endosteum of the cochlea.

The left ear of a 55-year-old man with bilateral mixed hearing loss was implanted with Carina. Due to absence of middle ear ossicles and oval and round windows, the transducer was coupled with the endosteum of the cochlea. A significant improvement was observed in the pure tone average after Carina application. Carina and a conventional hearing aid yielded similar amplification in the low frequencies (250 Hz to 1 kHz). The functional gain with Carina was better than that with the conventional hearing aid in the middle (2 kHz) and high (4 and 6 kHz) frequencies, by 15dB, 5dB, and 25dB, respectively. Speech reception threshold in the free field was 80 dB HL without the hearing aid, 60 dB HL with the hearing aid, and 50 dB HL with Carina. Two-syllable speech discrimination scores increased to 40% and 56% in noise and quiet, respectively. According to International Outcome Inventory for Hearing Aids questionnaire, the patient scored 24 with the hearing aid and 32 with Carina.

Stimulation of the inner ear with Carina through the endosteum of the cochlea seems to be an efficient and alternative way to amplify hearing.

**KEY WORDS:** Carina, hearing loss, fully implantable device, chronic otitis media

## INTRODUCTION

Occlusion of the ear canal, chronic ear canal irritation, and limited amplification in the high frequencies are the drawbacks of conventional hearing devices <sup>[1]</sup>. Active middle ear implants can be used in the presence of these drawbacks. Carina (Otologics) is a fully implantable active middle ear implant with an electromagnetic transducer, which can be coupled to ossicles or windows in the middle ear <sup>[2]</sup>. Herein we report a case in which the Carina transducer was coupled to the endosteum of the cochlea as a new method of application.

## CASE REPORT

A 55-year-old man with bilateral severe mixed hearing loss was admitted. The right ear was operated on for cholesteatoma for four times. A canal wall down mastoidectomy was performed in this ear. The left ear was operated on for chronic otitis media. There was an intact canal with an intact tympanic membrane graft. He was using a conventional hearing aid in the left ear until 1 year previously, when he had sudden deterioration of hearing in this ear. Then, he could not benefit from the conventional hearing aid because of acoustic feedback. He was communicating verbally with some limited lip reading.

After counselling with the patient, it was decided to perform implantation of the fully implantable active middle ear Carina on the left ear. Under general endotracheal anaesthesia, the previous mastoidectomy cavity was revised, and the middle ear was exposed by elevating the tympanomeatal flap. There was no cholesteatoma in the middle ear or mastoid cavity. There was no ossicle or ossiculoplasty prosthesis in the middle ear. In addition, there was no visible stapes footplate or round window, which was attributed to congenital absence or ossification of the windows. A posterior tympanotomy was made. The otic capsule was drilled in the area corresponding to the round window until the endosteum was reached. The bone was drilled with diamond burrs, which were 1 mm and 0.5 mm in diameter. The drill was set to 5000 rounds per minute. Under high magnification of the microscope, diamond burrs and needle were used successively until the endosteum of the cochlea was exposed. Care was exercised not to perforate the endosteum. Once the soft and fluctuating structure of the endosteum was palpated with a needle, drilling was discontinued. The endosteum was exposed in almost 0.5 to 1 mm in diameter for the Carina transducer tip to fit.

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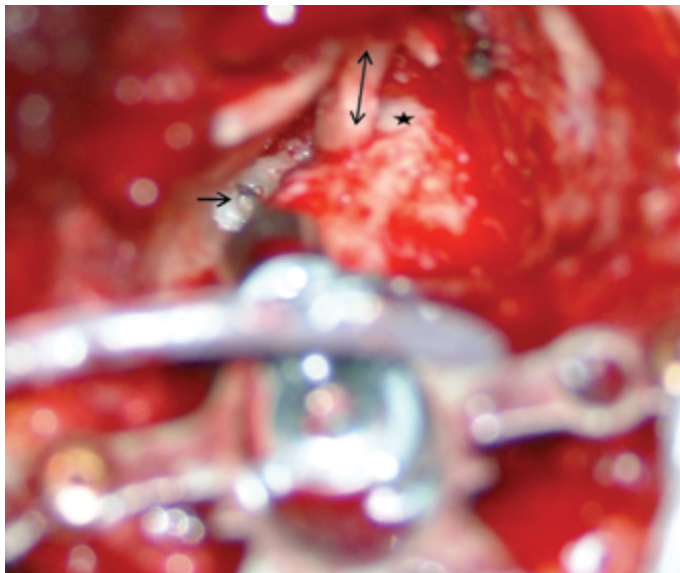
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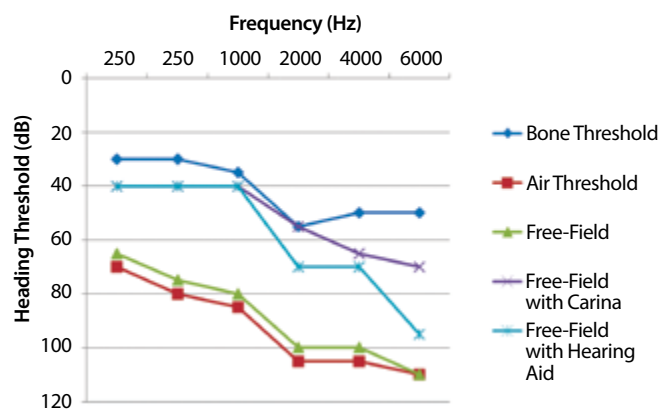
The endosteum was not torn or incised. After an uneventful exposure of the endosteum, the transducer tip (ball type) was placed on the endosteum, and the area around the transducer tip was sealed with soft tissues. The other components of the Carina implant were placed in the standard way. The attic area was supported with a piece of cartilage to prevent possible retraction of the ear drum (Figure 1).

The postoperative period was uneventful, and the patient was discharged after 1 day. The initial fitting was performed 6 weeks after the operation, and audiological findings after 6 months of follow-up are presented.

The preoperative and postoperative audiological assessments are summarised in Figure 2. The thresholds of aided with conventional hearing aid and free field with hearing aid were the same and only free field with hearing aid thresholds are shown in Figure 2. On pure tone audiometry, masking was performed, especially while assessing bone conduction. Without activation of Carina, the pre- and postoperative air and bone conduction thresholds of the patient were



**Figure 1.** Intraoperative view of Carina that was fitted to the endosteum, →: Carina fitted to the cochlear endosteum; ↔: tragal cartilage that was used to reconstruct the outer ear canal; \*: lateral semicircular canal



**Figure 2.** Preoperative and postoperative audiological evaluations of the patient

similar. After activation of the implant, the pure tone average at the frequencies of 0.5, 1, 2, and 4 kHz increased to 50 dB, which was 56.25 dB with the conventional hearing aid. Similar audiometric results were obtained with Carina and the conventional hearing aid in the low frequencies (250-1000 Hz). The functional gain with Carina was better than with the conventional hearing aid in the middle (2 kHz) and high (4 and 6 kHz) frequencies, which was 15 dB, 5 dB, and 25dB, respectively (Figure 2).

Two-syllable speech discrimination (SD) scores were evaluated with and without switching on, both in quiet and noise. The signal-to-noise ratio was 10 dB. Preoperatively with the conventional hearing aid, two-syllable SD scores of the patient were 48% and 32% in quiet and noise, respectively. Postoperatively, with Carina switched off, the two-syllable SD scores were 40% and 28% in quiet and noise, respectively. After Carina was switched on, the SD scores increased to 56% and 40% in quiet and noise, respectively. There was no significant difference between the hearing aid and Carina regarding SD scores of the patient ( $\chi^2$  test,  $p > 0.05$ ). Speech reception threshold in the free field was 80 dB HL without the hearing aid, 60 dB HL with the hearing aid, and 50 dB HL with Carina.

The patient was also evaluated with the the international outcome inventory for hearing aids questionnaire. The preoperative unaided and aided scores were 3 and 24, respectively. Postoperatively, the score was 8 without switching on the implant, and 32 after switching on (Table 1). There was no significant difference between the hearing aid and Carina regarding the IOI-HA scores of the patient ( $\chi^2$  test,  $p > 0.05$ ).

**DISCUSSION**

Problems related to cosmetics, psychology, external ear canal occlusion and hygiene, acoustic feedback and sound distortion, and hearing loss in the high frequencies may lead to difficulty in hearing aid use [3]. Then, an active middle ear implant or bone anchored hearing aids may be used to overcome these problems. The expectations of the patient, anatomy of the ear, type and severity of the hearing loss, and pathology in the ear affect the method of amplification for hearing loss. An active middle ear implant is usually advocated when the bone conduction threshold exceeds 40 dB [1]. The active middle ear implant Carina was selected for this patient according to their demand for an invisible implant as well as the severity of the hearing loss. In addition, IOI-HA responses were more favourable for the Carina than the hearing aid, even if this difference did not reach statistical significance. This may also be a justification for using Carina.

Bone conduction hearing aids should be another alternative option for improving hearing for this patient. Bone anchored hearing aid (BAHA) fixture placement is relatively rapid and simple. Hearing results are usually excellent for BAHA, with an expected air-bone gap of only 16-18 dB HL [4]. However, the cosmetic result is not ideal, with a visible metal abutment and a snap-on hearing aid. BAHA complications include occasional loss of the fixture from infection, and fairly common surgical site infections with flap thickening that may require revision surgery [4]. The patient must also be careful to avoid trauma to the BAHA site, which may result in loss. Despite BAHA being recommended to the patient, he did not want to use BAHA because of cosmetic reasons.

**Table 1.** IOI-HA Scale Evaluation Results

IO-IHA Scale	Hearing Aid	Middle Ear Implant
<b>1. Think about how much you used your present hearing aid(s) over the past two weeks. On an average day, how many hours did you use the hearing aid(s)?</b>		
(1) none		
(2) less than 1 hours a day		
(3) 1 to 4 hours a day		
(4) 4 to 8 hours a day		
(5) more than 8 hours a day	+	+
<b>2. Think about the situation where you most wanted to hear better, before you got your present hearing aid(s). Over the past two weeks, how much has the hearing aid helped in that situation?</b>		
(1) Helped not at all		
(2) Helped slightly		
(3) Helped moderately	+	
(4) Helped quite a lot		+
(5) Helped very much		
<b>3. Think again about the situation where you most wanted to hear better. When you use your present hearing aid(s), how much difficulty do you STILL have in that situation?</b>		
(1) Very much difficulty		
(2) Quite a lot of difficulty		
(3) Moderate difficulty	+	
(4) Slight difficulty		+
(5) No difficulty		
<b>4. Considering everything, do you think your present hearing aid(s) is worth the trouble?</b>		
(1) Not at all worth it		
(2) Slightly worth it		
(3) Moderately worth it		
(4) Quite a lot worth it	+	
(5) Very much worth it		+
<b>5. Over the past two weeks, with your present hearing aid(s), how much have your hearing difficulties affected the things you can do?</b>		
(1) Affected very much		
(2) Affected quite a lot		
(3) Affected moderately	+	
(4) Affected slightly		
(5) Affected not at all		+
<b>6. Over the past two weeks, with your present hearing aid(s), how much do you think other people were bothered by your hearing difficulties?</b>		
(1) Bothered very much		
(2) Bothered quite a lot		
(3) Bothered moderately	+	
(4) Bothered slightly		
(5) Bothered not at all		+
<b>7. Considering everything, how much has your present hearing aid(s) changed your enjoyment of life?</b>		
(1)Worse		
(2) No change		
(3) Slightly better	+	
(4) Quite a lot better		
(5) Very much better		+

IOI-HA: the international outcome inventory for hearing aids

Active middle ear implants are safe and efficient in moderate to severe sensorineural hearing loss in adults [2]. The transducer of Carina can be coupled to an ossicular prosthesis or it can be placed on the round window [5-7]. However, the anatomy and anatomic structures are usually changed in patients who have had multiple ear surgeries, and preoperative imaging may not always give accurate information about the anatomy. Therefore, the surgeon should be ready to change the strategy during the operation. This was the case in our patient. The initial plan was to perform an oval window application. However, in the end an endosteum application was used due to anatomic limitations.

Although congenital absence of the oval window is possible [8], absence of both oval and round windows is a rare intraoperative finding, which may be congenital or acquired due to ossification and new bone formation. Vestibulotomy or labyrinthotomy is a surgical option for prosthesis placement in the absence or closure of the oval window [9]. Similarly, in the present case, the inner ear was stimulated through the endosteum of the otic capsule in the area corresponding to the round window.

It is important to evaluate the status of the middle ear and mastoid air cells before middle ear implantation. The volumes of middle ear and mastoid air cells are particularly important before the implantation of the MET or Carina. Kontorinis et al. [10] measured the distance between the dura and the superior-posterior wall of the external auditory canal (dura-meatal distance) on the incus projection level. As a result, when the dura-meatal distance is less than 5 mm, MET or Carina implantation is not recommended, and when the dura-meatal distance is smaller than 8 mm, the surgery introduces a high risk of complications [10]. If the patient has a history of surgery because of chronic otitis media with or without cholesteatoma, as our patient had, preoperative computed tomography evaluation is particularly important for evaluating recurrent cholesteatoma [11].

In conclusion, stimulation of the inner ear by Carina through the endosteum of the cochlea seems to be an efficient and alternative way to amplify hearing.

**Informed Consent:** Written informed consent was obtained from patient who participated in this study.

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