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ORIGINAL ARTICLE

Preservation of low frequency hearing in partial deafness cochlear implantation (PDCI) using the round window surgical approach

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Abstract

Conclusion. Successful hearing preservation is possible in individuals with excellent low frequency hearing. This is possible due to the partial insertion of an atraumatic electrode using an atraumatic round window surgical technique. *Objectives*. This paper describes the round window surgical technique used to preserve excellent low frequency hearing in patients receiving partially inserted MED-EL cochlear implant electrodes. Results of preserved low frequency hearing in partial deafness cochlear implantation (PDCI) are reported. *Patients and methods*. The surgical approach is described in detail. Ten subjects received a partial insertion of a standard electrode, using the round window approach. Pure tone audiometry was conducted in the implanted and non-implanted ear preoperatively, at implant fitting and then at 1, 3, 6 and 12 months after initial device fitting. *Results*. Results show hearing preservation in 9 of the 10 subjects. One subject lost all hearing 2 weeks after cochlear implantation. Hearing has remained essentially stable up to the 1 year postoperative period. Eight of the nine subjects use the cochlear implant together with their natural low frequency hearing; one subject uses a hearing aid in the implanted ear to amplify the low frequencies.

Introduction

Cochlear implants are a preferred medium for the (re)habilitation of individuals with severe to profound hearing impairment. Open-set speech understanding has now become realistic for the majority of post-lingually deafened adults [1–3] and for children [3–6].

Considerable improvement in cochlear implant technology has resulted in a relaxation of selection criteria [3]. As more positive results of implantation are demonstrated, there is considerable emphasis on implanting individuals who are not only totally deaf, but also those with residual hearing in the low frequencies [4,7–9]. Moreover, recent studies showed that residual hearing can be preserved after cochlear implant placement [10,11]. Further extension of selection criteria was proposed [2,11]. These authors suggested that the use of a hearing aid and a cochlear implant in the same ear in patients with mild to severe hearing loss in the low frequencies and severe to profound hearing loss in the high frequencies can result in hearing and speech perception that is better than with either device alone. This concept is called electric-acoustic stimulation (EAS) [2,11]. Results in these patients show that EAS is of significant benefit, and a strong synergistic effect of using both devices is particularly noticeable in speech testing in noise. Complete hearing preservation following surgery using an atraumatic electrode inserted to a depth of 360° was reported in 85.7% cases [12]. In another report, complete hearing preservation was reported in 86% of cases [13]. In both cases, a modification of the soft surgery procedure [13] was used.

This study aimed to investigate whether using the MED-EL COMBI 40+ standard electrode and utilizing the round window surgical technique would result in any loss of low frequency hearing in the implanted ear.

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Patients and methods

Surgical technique

The MED-EL COMBI 40+ electrode is partially inserted into the cochlea using the round window surgical technique. Insertion depth is determined by the subject's audiogram, but is usually limited to eight electrodes inserted.

The surgical procedure for PDCI consists of the following steps: (1) antrotomy; (2) posterior tympanotomy to allow for visualization of the round window niche (Figure 1); (3) puncture of the round window membrane (Figure 2); (4) approaching the scala tympani directly through the round window membrane (with partial insertion of the electrode array) (Figure 3); (5) electrode fixation in the round window niche with fibrin glue (membrane must be partially uncovered to preserve its mobility) (Figure 4); (6) fixation of the device in the well created in the temporal bone.

Firstly, as in all cochlear implant surgeries, an antromastoidectomy is performed, followed by an atticotomy and posterior tympanotomy to visualize the round window niche. The posterior tympanotomy is usually bigger than that of a standard cochlear implant insertion tympanotomy, providing a better view and allowing for a proper angle of insertion into the scala tympani. In many cases, an anterior tympanotomy needs to be performed for better visualization. This combined approach is used to visualize the round window membrane, and together with a minimal puncture of the membrane, it allows creation of optimal conditions for insertion, and insertion of the electrode, with one or two movements, into the scala tympani. It may be necessary to remove the bony overhang to get a clear view of the round window membrane, being careful to avoid the middle ear structures. The round window is gently punctured in its lower part. There should be no suctioning of fluid at the

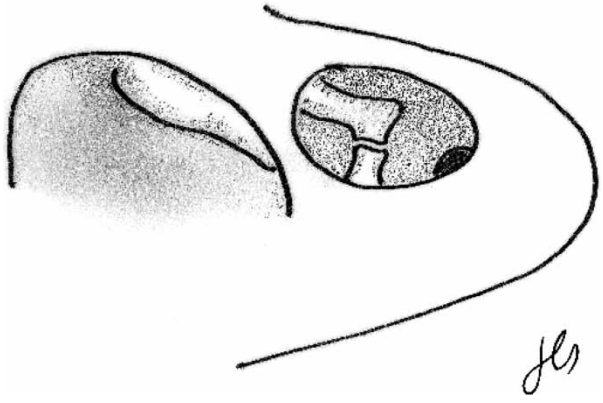

Figure 1. Posterior tympanotomy to allow for visualization of the round window niche.

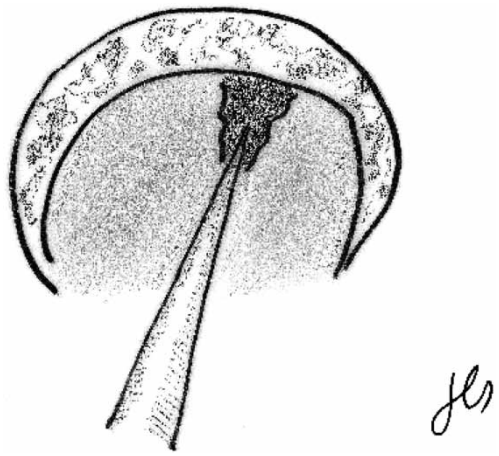

Figure 2. Puncture of the round window membrane.

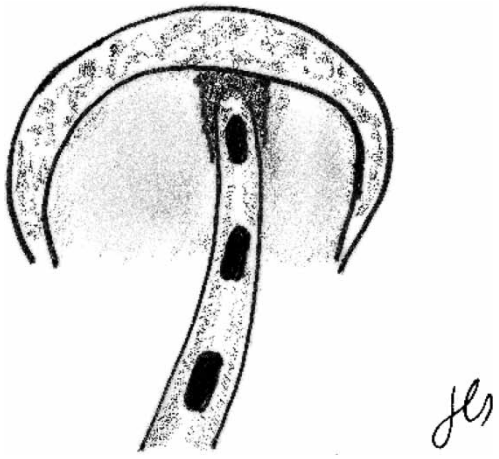

Figure 3. Approaching the scala tympani directly through the round window membrane (with partial insertion of the electrode array).

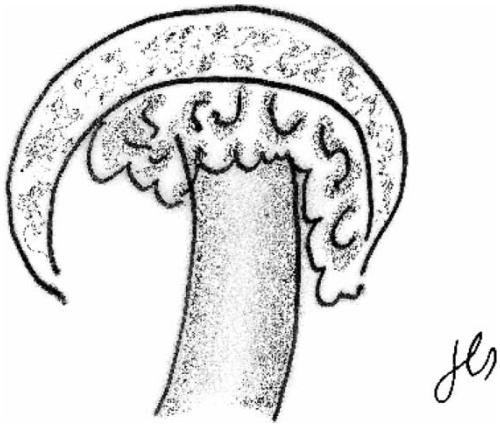

Figure 4. Electrode fixation in round window niche with fibrin glue.

site of the round window puncture. At this point, eight channels of the standard electrode should be delicately inserted with angle of insertion about 75°. Insertion must be in one direction only, and the electrode seals the puncture in the membrane during insertion.

A good view from the external auditory meatus to the round window assists with the appropriate precision required. The time between the puncture of the round window membrane and insertion of the electrode should be kept to a minimum. The electrode is fixed in the round window niche with Fibrin® glue which, when absorbed after some time, does not influence the mobility of the remaining part of the round window membrane. The membrane should be partially uncovered to preserve its mobility. Finally, the implant is fixed in the well of the temporal bone and the wound is closed. To preserve the low frequency hearing and prevent risk of infection, a course of steroids is prescribed postoperatively for a period of 1 month. Antibiotics are also administered at the opening of the skin flap and 1 week post-surgery.

The round window technique, originally used in cochlear implantation, was abandoned because of concerns that the angle of insertion may lead to trauma of the osseous spiral lamina, due to the stiffness of electrodes at that time. Our surgical team decided to use the round window surgical approach in an attempt to limit loss of residual hearing that might be caused by creating a cochleostomy. Potential problems with a cochleostomy may include: perilymph loss and acoustic trauma due to drilling, especially at the thickest part of the promontory. There may also be presence of bone dust, which could lead to the formation of new bone within the cochlea. There is a chance to cause osseous spiral lamina injury, as perilymph is toxic to the hair cells and there may be damage due to infection, as the wound heals with fibrous tissue. We also decided on the round window approach, as this is a more technically straightforward technique providing good landmarks for the surgeon and the surgeon can be confident of correct insertion of the electrode into the scala tympani.

Subjects

Ten patients with partial deafness were implanted using the round window technique; seven women and three men. The mean age at implantation was 39.1 years (range 26–64 years). The first subject was implanted on the 12 July 2002 and this surgery was transmitted live on the internet. Table I provides a brief description of each subject. Six subjects have unknown aetiology, two had meningitis in childhood, one has a familial hearing loss and one loss is ototoxic. Any subjects with a progressive hearing loss are excluded from PDCI. Progressive hearing loss is defined as a 10 dB shift at two consecutive frequencies or a 15 dB shift at one frequency over a period of 1 year. Four subjects have six active electrodes; two have seven active electrodes and four have eight active electrodes (depth of insertion was based on the subject's audiogram).

Audiological testing

Pure-tone testing was performed using a Siemens SD5 audiometer calibrated according to standards established by the American National Standards Institute (ANSI). The maximum output of the audiometer is 130 dB HL, and a standard clinical procedure was used for threshold determination [14]. Testing was performed in an IAC soundproofed booth under Sennheiser HDA 200 headphones.

Statistical analysis

Graphical analyses and descriptive measures, such as average and median calculations, were employed. Additionally, inferential statistics were

Table I. Characteristics of each patient.

Subject	Age at cochlear implant (years)	Age at diagnosis	Aetiology	Ear implanted	Number of inserted contacts
KT	26	6 years	Unknown	Left	7
GD	50	18 years	Familial	Right	8
ZS	46	5 years	Unknown	Left	8
KJ	64	31 years	Ototoxic	Left	7
SB	48	Teens	Unknown	Left	8
MJ	26	15 years	Unknown	Right	6
MP	29	4 years	Meningitis	Left	6
BS	28	8 months	Meningitis	Left	8
MM	32	28 years	Unknown	Right	6
LT	42	Childhood	Unknown	Left	6

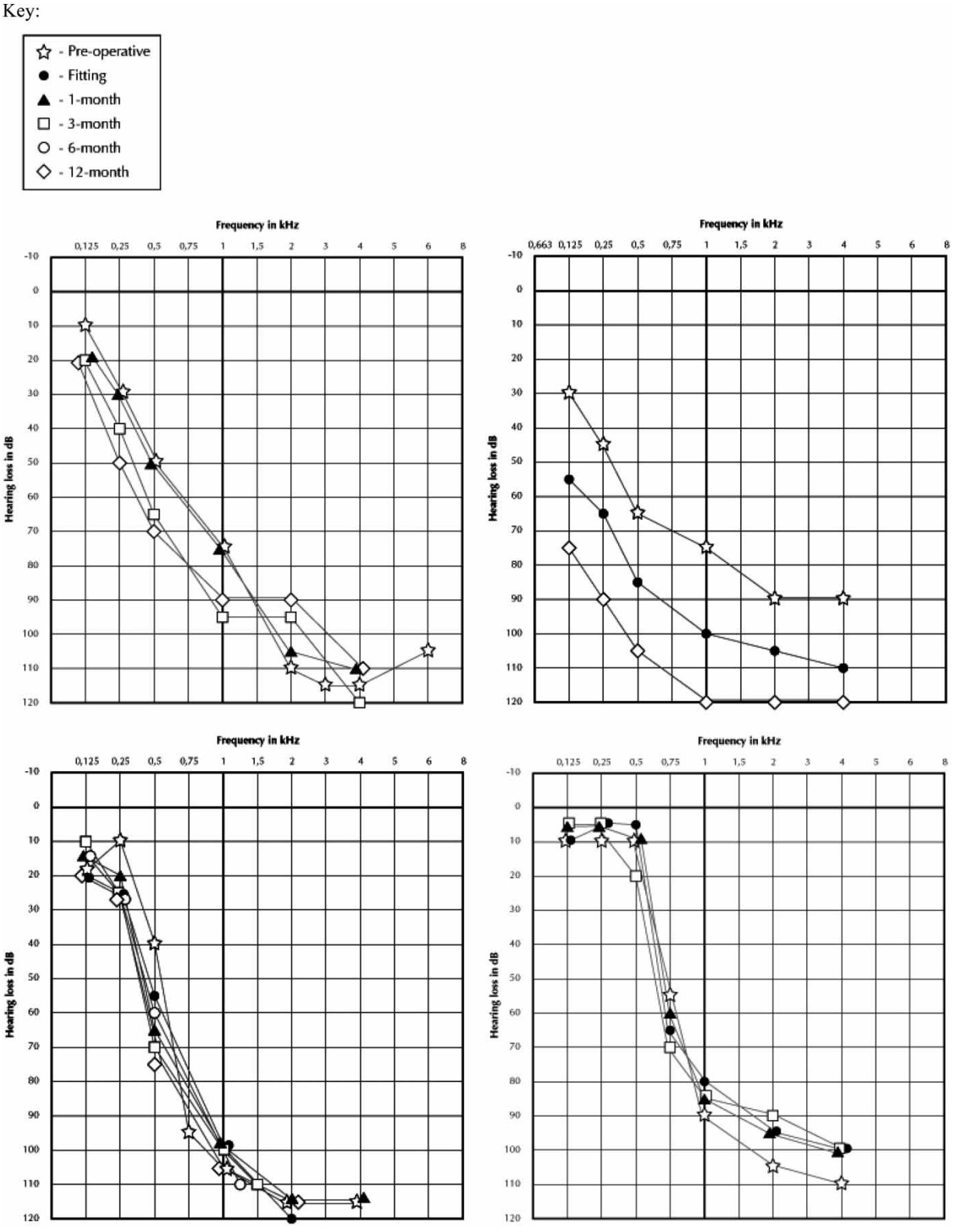

Figure 5 (*Continued*)

also employed and an ANOVA with measurement repetition to analyse the development of scores over time for different frequencies was used. Since this study deals with the preservation of hearing, we analysed whether there is a significant increase or decrease in scores from the test carried out preoperatively compared to the postoperative test intervals. Using ANOVA we also analysed both the

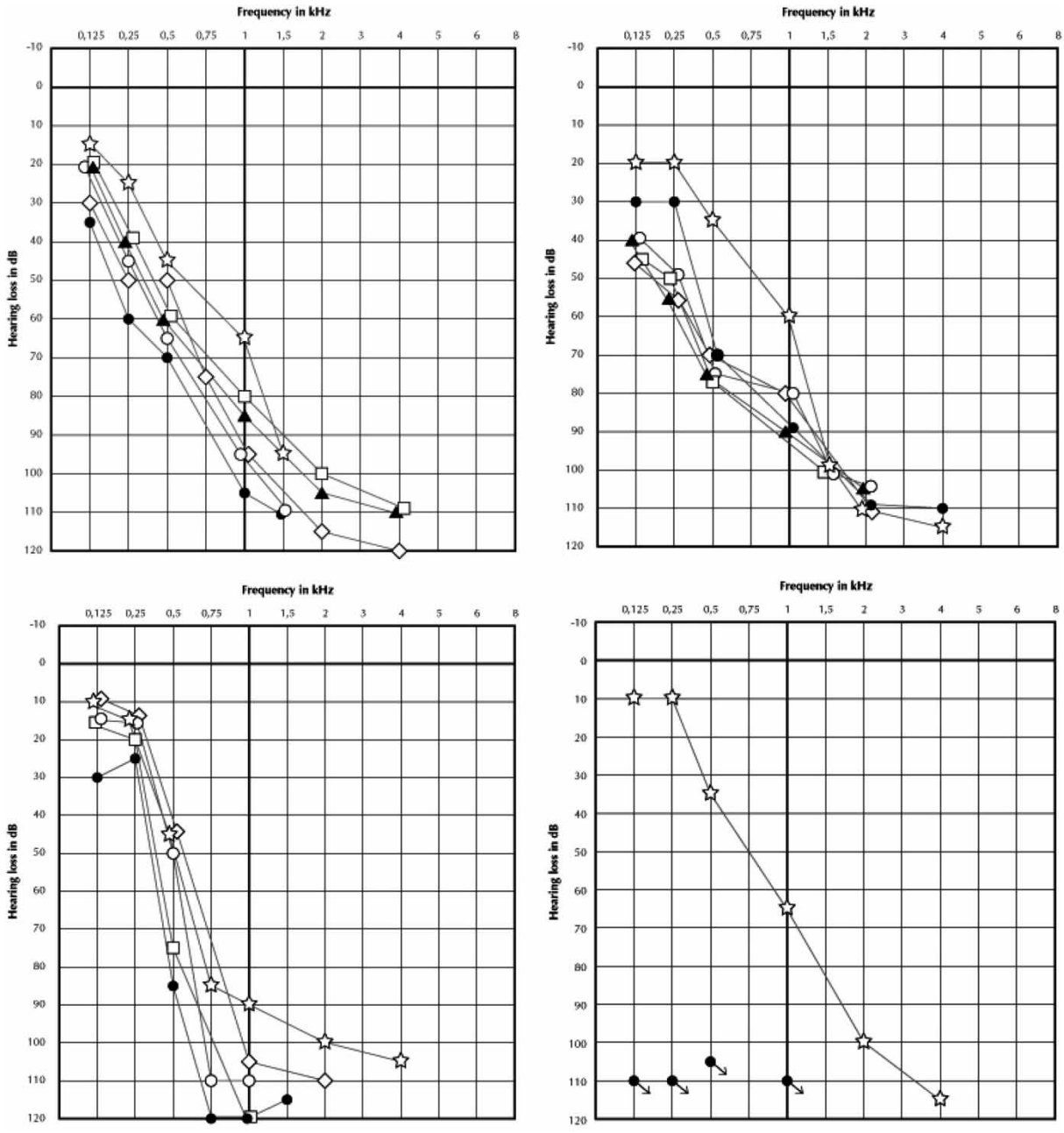

Figure 5 (*Continued*)

overall impact of time on the results and also the pairwise results, i.e. analyses include a direct comparison of scores between single points in time. We made these analyses for both the implanted and non-implanted ears. To be able to directly compare the scores between the implanted and non-implanted ears for all frequencies, the Mann-Whitney U test for independent samples was employed. Additionally, we compared test results of patients between different test intervals employing Wilcoxon signed ranks test for dependent samples.

Results

Surgical outcomes

No problems were encountered intraoperatively and easy partial electrode insertion was achieved in all cases. The original surgical aim was to insert eight channels; this was achieved in four of the subjects. In four cases six channels were inserted; the surgeon inserted fewer electrodes, based on the patients' audiograms, in an attempt to preserve the good middle frequency hearing. In two other cases seven channels were inserted; the eighth channel was

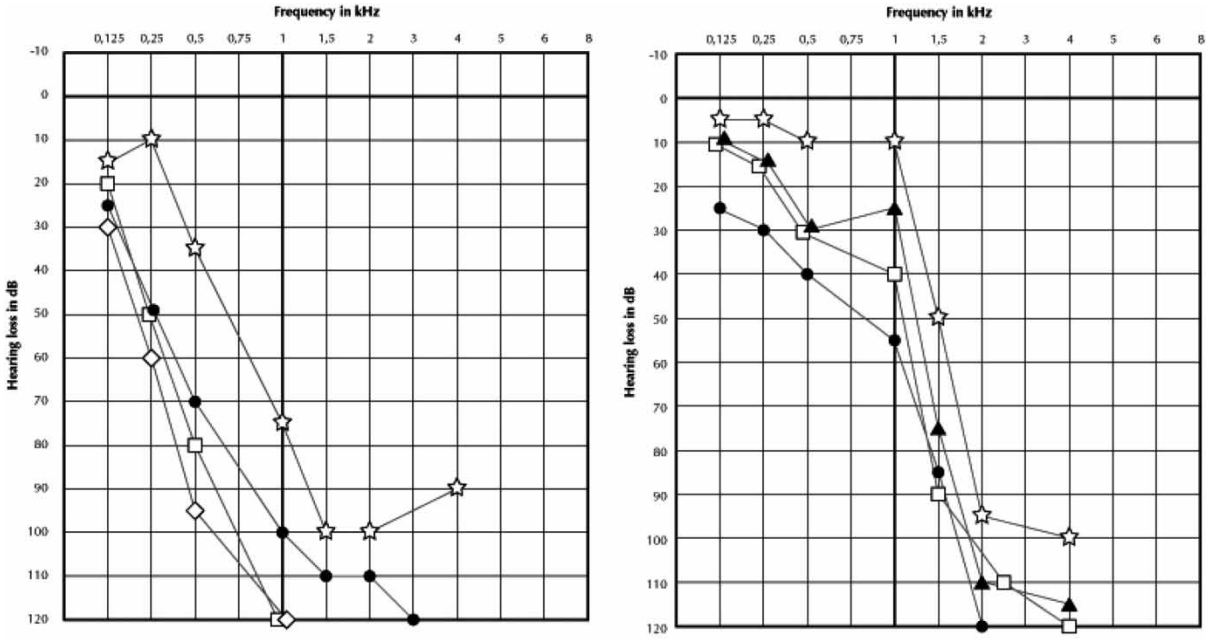

Figure 5. Individual subject audiograms for each test interval.

situated just within the round window niche and does not provide auditory stimulation.

Hearing preservation

Considering the fact that attenuator steps of 5 dB are employed, a minimum of ± 5 dB measurement error is introduced. As tolerances contained in ANSI standards range from ± 3 to 5 dB of designated sound pressure levels, the standard error can potentially expand to ± 10 or 15 dB HL, depending on the listener's actual physiologic sensitivity [15]. Thus, we only consider patients having a negative threshold difference of >10 dB as ones who lost a certain degree of hearing following the cochlear implantation. Hearing was preserved to some degree in 9 of 10 cases. Subject no. 10 lost all low frequency hearing within 2 weeks after surgery, there is no evident reason for this loss.

Table II shows the average decibel for all frequencies across each test interval. The following frequencies were not statistically assessed as the sample size was too small: 750 Hz, 1500 Hz, 2000 Hz, 3000 Hz, 4000 Hz and 6000 Hz (these frequencies were not always assessed). The half-octaves were not tested in all instances and the higher frequencies were not included as there was often no hearing at the limits of the audiometer.

Results reported are for nine subjects, the data from the subject who has lost all hearing have been excluded. Significant changes over time were noted for the following frequencies: 125 Hz ($p = 0.027$), 250 Hz ($p = 0.026$) and 500 Hz ($p = 0.001$). When comparing the differences between each test interval, a significant drop of 13.8 dB in hearing was noted at 125 Hz ($p = 0.031$), 17.9 dB at 250 Hz ($p = 0.016$), 23.3 dB at 500 Hz ($p = 0.016$) and 17.5 dB at 1000 Hz ($p = 0.094$) when comparing preoperative and first fitting audiograms. This means an average change of 17.4 dB after surgery. Thereafter, no significant differences were noted when comparing first fitting to 1 month, 1 month to 3 months, 3 months to 6 and 6 months to 12 months; except for a significant change of 4 dB for 250 Hz ($p = 0.063$) between 6 and 12 months.

Figure 5 details the hearing status for each individual subject over the test period. All except two of the subjects have reached the 12-month test interval; the other two are at the 3-month test interval. One subject lost all hearing as a result of the surgery. Three subjects lost hearing, as evidenced at the first fitting assessment, but then hearing improved afterwards. Three subjects' hearing remained essentially the same, and two lost some hearing, even after the first fitting.

The hearing status of the non-implanted ear was also assessed. Hearing remained stable across all frequencies, when comparing each test interval. The only difference was recorded at 125 Hz, where there was a significant difference ($p = 0.063$) of 8 dB at the 12-month interval compared with the 6-month interval.

Table II. Average decibel measurements for each statistically assessed frequency from each test interval.

	125 Hz	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz
Preoperative	15	18.3	36.7	75.6	103.1	106.3
Fitting	28.6	36.3	60	91.4	110.7	111
1 months	23	33.3	59.7	84.1	105.1	109.2
3 months	22.8	34.6	62.8	87.2	103.4	112
6 months	28.9	44.6	70.4	101.7	105.9	108.7
12 months	32.9	48.6	71.4	103.6	110.8	113.3

Discussion

The results shown indicate that with careful delicate surgery and a limited electrode insertion, hearing can be preserved in the majority of patients with a ski-slope hearing loss, who gain limited benefit from a hearing aid. This preservation allows subjects access to low frequency hearing, which can benefit their speech perception outcomes.

Our results compare rather favourably to reported results. In studies reviewing preservation of residual hearing in severe to profoundly hearing-impaired individuals with significant remaining low frequency hearing, two studies demonstrated a significant loss of hearing in all subjects after implantation [7,16], while another study reported a loss of residual hearing in roughly half of 40 implanted patients [15].

In six subjects where a shorter electrode was inserted (6 mm and 10 mm), hearing was preserved in all cases [17]. However, the insertion depth was less than in our study and hearing preservation in shorter insertion can be expected, as the more apical regions may not be directly exposed to trauma from the electrode. A further report by the same study group [18], reporting on 11 subjects (3 with a 6 mm electrode and 8 with a 10 mm electrode) showed preservation of hearing within 10–15 dB, when comparing preoperative and 1-month postoperative audiograms. It would be interesting to view the stability of this preservation over time, as this seems to be a consideration in hearing preservation, as can be seen in the individual audiograms from our study.

Our results tend to agree with those reported using the same electrode with partial insertion, and later a modified shorter version of the electrode to allow full insertion with 12 channels. Here a different surgical technique was applied [13], but both studies achieved similar insertion depths. Most recent results from this group show [13] that partial preservation was maintained in 12/14 (86%) of subjects over a period of 3 months after implantation. Six subjects with data 1 and 2 years postoperatively show essentially stable audiograms. Two of their subjects lost hearing immediately.

The cause of this immediate loss of hearing is unclear. This is not reported on in the above studies, and there was no clear indication for the cause of hearing loss in our case. What is important to view is stability of hearing over time. In our study, there is a significant drop in hearing post-surgery in some cases, there is slight decrease over time, but audiograms are essentially stable up to 1 year after implantation, and any drop in hearing is not significant. This is an important variable to consider when discussing hearing preservation in a population with significantly more low frequency hearing than the traditional cochlear implant group. The stability of results seen in this study contrasts results of another study where postoperative residual hearing was recorded in 24.5% of subjects, and over time this dropped and in later months only 16.3% had preserved hearing [19]. We would still need to investigate our pool of subjects over a longer period of time to assess true stability of hearing after surgery.

The loss of some hearing after implantation will need to be explained. It does not appear to be an underlying progressive loss, as results of hearing in the non-implanted ear remain stable over the entire period, with only some loss in one frequency over this time period. This progressive loss was also negated in another EAS study [13], where they reported that progression of the underlying pathology of hearing was not observed up to the 2-year postoperative period.

It should be noted that there is some difference between the group of subjects implanted in our study and the groups reported on in other EAS studies [2,11–13]. In our study, subjects had better low frequency hearing, allowing them access to natural hearing of low frequency information after cochlear implantation, whereas the other study group required amplification of the low frequencies with hearing devices. The important point here is that when using an electrode array that is atraumatic in nature [20] and a surgical technique which has been demonstrated to be atraumatic in most cases in histological studies [21], hearing can be preserved in cases with excellent low frequency hearing.

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