

ORIGINAL ARTICLE

Preservation of Low-Frequency Residual Hearing after Cochlear Implantation. Is Soft Surgery Effective?

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Objectives: To evaluate the preservation of residual hearing after cochlear implantation and to analyze the effect of soft surgery.

Study Design: Retrospective.

Methods: Fifty-eight patients implanted with a Nucleus Contour cochlear implant electrode were included. Their preoperative hearing threshold was 90 dB or better at 250 Hz and 110 dB or better at 500 Hz. Patients with partial and/or any aberrant insertion of the electrode array, hearing loss due to meningitis, osteogenesis imperfecta and malformations of the cochlea or labyrinth were excluded. Pre- and postoperative thresholds were compared. The change in hearing threshold after implantation in the non-implanted ear was subtracted from the change in hearing threshold in the implanted ear, which was defined as the 'corrected threshold difference'. This 'corrected threshold difference' was compared between two different implantation techniques: classic implantation versus soft surgery implantation.

Results: Median corrected threshold differences for the lower frequencies were 25 dB at 250 Hz and 20 dB at 500 Hz. In the soft surgery group, these differences were 10 dB and 7.5 dB respectively.

Conclusions: The classic surgery as well as the soft surgery implantation technique is good for preservation of residual hearing, however, there is a trend towards a better preservation of residual hearing according to the soft surgery protocol.

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Introduction

The introduction of cochlear implants has made it possible to successfully rehabilitate profoundly deaf adults and children who did not derive any benefit from conventional hearing aids. Implantation in this group produced remarkable speech recognition results. Due to improvements in the performance of patients with cochlear implants the last decades, the inclusion criteria for implantation have gradually been broadened [1]. Besides the indication of profound deafness, patients with some residual hearing have become candidates for cochlear implantation. Research has shown that preoperative residual hearing is a positive predictor of good performance with a cochlear implant [1-3]. However, not all studies confirm this [4, 5]. In the past, loss of residual hearing occurred in the majority of patients after cochlear implantation and did not give any cause for concern [6, 7]. Later, the design of the cochlear implant electrodes was improved and new surgical techniques were developed

to minimize insertion trauma to the cochlea and to preserve any residual hearing [8-11]. Preservation of residual hearing is of special importance for electro-acoustic stimulation (EAS) in patients with a high frequency deafness [12-14]. The main principle of EAS is to stimulate the non-functioning high-frequency areas of the cochlea with a cochlear implant and to preserve the low-frequency portions of the cochlea for acoustic stimulation. Lehnhardt [15] introduced the 'soft surgery' concept for cochlear implantation to avoid as much damage as possible in the inner ear. Five main characteristics of the 'soft surgery' technique are: administration of corticosteroids, drilling until the cochlear endosteum is visible, followed by opening of the endosteum with a sharp needle, refraining from intracochlear suctioning and prevention of intracochlear entry of bone dust and blood. Recently, 'soft surgery' led to preservation of residual hearing in more than about 70% of the patients after cochlear implantation [12-14, 16-19].

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The aim of the present study was to evaluate retrospectively the preservation of residual hearing after cochlear implantation in our clinic and to compare these data with data from comparative studies. Besides, we evaluated the effect of the ‘soft surgery’ protocol on preservation of residual hearing after cochlear implantation.

Materials and Methods

• Audiological assessment

The patients’ records were reviewed retrospectively. In each individual patient, the preoperative audiometric data that met our inclusion criteria were compared to the audiometric data obtained 3 to 6 months postoperatively. These data comprised unaided pure-tone air conduction hearing thresholds obtained from either ears using a standard audiometer (Interacoustics AC40) with TDH49-P headphones. Audiometer output was limited to 110 dB HL at 0.25 kHz and 8 kHz and to 120 dB HL at 0.5 to 4 kHz. Responses to pure tones of 0.25 to 8 kHz were measured, if necessary with adequate masking, using the Hughson-Westlake procedure. In contrast with previous studies, pre-postoperative threshold changes in the implanted ear were compared to threshold changes in the non-implanted ear. In this way, we could determine the preservation of residual hearing and correct the data for possible non-implant-related postoperative changes in hearing loss or physical status of the patient (e.g. stress-related non-optimal cooperation of the patient). To correct the data, the change in hearing threshold in the non-implanted ear was subtracted from the change in hearing threshold in the implanted ear. Below, we refer to this calculated difference in hearing thresholds as the ‘corrected threshold difference’, which represents the level of residual hearing loss after cochlear implantation.

Patient selection

Patients were selected from the database of the Cochlear Implant Centre at the ‘Radboud University Nijmegen Medical Centre’. Only patients implanted with a Nucleus Contour cochlear implant electrode

were included. This cochlear implant type contains the Nucleus 24 Contour (N24RCS), the Nucleus 24 Contour Advance with Softip (N24RCA) and the Nucleus Freedom model with Contour Advance electrode array (CI24RE). Inclusion criteria for the hearing threshold data from individual patients in this study, require preoperative hearing thresholds better than the level of vibrotactility^[20], i.e. 90 dB or better at 250 Hz and of 110 dB or better at 500 Hz. In this way, in some patients, we just included data from one frequency. Furthermore, we excluded all the patients with partial and/or any aberrant insertion of the electrode array and all patients with hearing loss due to meningitis, osteogenesis imperfecta and malformations of the cochlea or labyrinth.

A total of fifty-eight patients met our selection criteria, 22 patients were implanted in a period of 7 years with a N24RCS and 36 patients were implanted with a N24RCA/CI24RE (Table 1). They were all implanted by one of two experienced cochlear implant surgeons. Since the N24RCA and the CI24RE cochlear implant have the same electrode array, we considered this as one group. Patients with asymmetrical hearing loss had been implanted in their poorest ear, while those with symmetrical hearing loss had been implanted in their subjectively poorest ear. ‘Soft surgery’ implantation technique was applied when a significant level of residual hearing was measured preoperatively, i.e. a best-aided hearing threshold of 70 dB HL or better at 250 Hz and 500 Hz and a phoneme score of 20% or better at 65 dB SPL. In this study, 18 patients had been implanted according to the ‘soft surgery’ protocol (Table 1).

Surgical procedure

In all patients, at the induction of anesthesia, single doses of cefazolin and metronidazole were given intravenously. Peroperatively, the facial nerve was monitored closely in all cases. Dependent from the amount of residual hearing, a classic or a ‘soft surgery’ protocol was applied. The classic surgical procedure comprised a standard retroauricular incision, mastoidectomy, posterior tympanotomy and a 1.2 mm cochleostomy to insert the cochlear implant electrode

Table 1. Numbers of implant types used and included in this study

	N24 RCS	N24 RCA/RE	Total
Soft Surgery	-	18	18
Classical	22	18	40
Total	22	36	58

array. Cochleostomy was performed anteriorly and inferiorly to the round window membrane. The 'Advance Off Stylet' insertion technique^[11] was used in both Contour Advanced electrode systems. Before wound closure, implant and neural integrity was checked by means of standard procedures: electrode impedance measurements, stapedius reflex measurements and electrically-evoked compound action potentials ('neural response telemetry'). Postoperatively, a cochlear view X-ray was taken according to Stenvers to verify correct electrode positioning and insertion depth.

In 18 patients with residual hearing, the 'soft surgery' technique had been used to minimize damage to the inner ear. One hour before cochleostomy, these patients were given a single dose of methylprednisolone (1.8 mg per kilogram). Touching the ossicular chain with the drill was avoided at all times. Cochleostomy was performed according to the 'soft surgery' protocol: the endosteum was opened with a sharp needle after drilling had been completed. Intracochlear suctioning was not applied in order to prevent the loss of perilymphatic fluid. As is the case in all cochlear implantation procedures, hyaluronic acid (healon) was used to lubricate the electrode array and to stop the entry of bone dust and blood. After the electrode array had been slowly inserted into the cochlea, the cochleostomy was closed immediately using periosteum and fibrin glue.

Statistical analysis

For calculation purposes, auditory thresholds beyond the upper limit of the audiometer were defined as this upper limit plus 5 dB HL. In accordance with Kiefer et al.^[19] and Balkany et al.^[16], this level was chosen to represent a data point that was poorer than the maximum threshold that could be tested. Statistical analysis was performed using SPSS version 16.0. For comparing the two different surgical procedures in preservation of residual hearing, the Mann-Whitney-U test was used. P-values ≤ 0.05 were considered to indicate significant difference in 'corrected threshold difference' between the two groups.

Results

Almost all patients had profound preoperative hearing loss at the frequencies of 1-8 kHz. In most patients, preoperative thresholds of frequencies lay at or beyond the maximum output of the audiometer (i.e 120 dB, 120 dB, 120 dB and 110 dB for the octave frequencies 1, 2, 4, and 8 kHz respectively), or postoperative

thresholds were measured beyond the maximum output of the audiometer. For this frequency region, only in a small group of patients pre-postoperative threshold differences could be obtained because of ceiling effects. Therefore, the present study is specifically focused on hearing deterioration of the lower frequencies, i.e. 250 and 500 Hz. Of the 58 subjects, data of 33 and 57 patients respectively, were used for statistical analyses.

Median corrected threshold differences for the whole group were 25 dB (range: -5 to 100 dB) at 250 Hz and 20 dB (range: -10 to 75 dB) at 500 Hz.

Soft surgery was applied in 18 patients with a N24RCA/CI24RE cochlear implant. In these patients, the median corrected threshold differences were 10 dB (range: 0 to 45 dB) at 250 Hz (n=11) and 7.5 dB (range: -5 to 45 dB) at 500 Hz (n=18). For the classic surgery protocol in the N24RCA/CI24RE group (n=18), these differences were 20 dB (range: 5 to 100 dB) at 250 Hz (n=9) and 20 dB (range: -5 to 75 dB) at 500 Hz (n=18). Analyzing the difference in preservation of residual hearing after soft surgery and after the classic implantation technique, the Mann-Whitney U test showed a significant better preservation of low frequency hearing in the 'soft surgery' group for 250 Hz (U= 24.0, p=0.05, two-tailed), but not for 500 Hz (U= 107.5, p=0.08, two-tailed).

Analysis of the corrected threshold difference on an individual level showed a preservation of residual hearing within 10 dB HL in 3 patients (27%) in the soft surgery group compared to 2 patients (22%) in the classic surgery group at 250 Hz. At 500 Hz, these numbers are 8 patients (44%) in the soft surgery group, compared to 6 patients (33%) in the classic surgery group. So, on the individual level, less than 50% of the subjects showed pre-postoperative threshold differences of ≤ 10 dB, of which most of these patients belonged to the soft surgery group.

Discussion

In the past, several research groups^[12-14, 16-19] have studied the preservation of residual hearing. Contrastingly, our study was focused on patients with residual hearing in the low frequencies to avoid possible ceiling effects due to immeasurable hearing thresholds for the higher frequencies. Another important difference with other studies is that we corrected for possible (bilateral) non-implant-related threshold changes (e.g. due to measurement conditions, aggravation, progressive hearing loss) by

using the contralateral non-implanted ear as a reference. It should be emphasized that in this study, a ‘true’ threshold difference in the implanted ear was described and defined as the ‘corrected threshold difference’. The use of this ‘corrected threshold difference’ prevented overestimation of the real difference between the preoperative and postoperative thresholds.

The median corrected threshold differences for the whole group in this study appeared to be 25 dB at 250 Hz and 20 dB at 500 Hz. There is no significant difference in preservation of residual hearing between the Nucleus 24 Contour electrode array and the Nucleus 24 Contour Advance with Softip electrode array. Although, the Advance off Stylet technique was used at implantation of the latter electrode array to reduce the risk of damage to the basilar membrane during insertion [11], this study shows that this insertion technique as well as the Softip of the electrode array, did not significantly contribute to the preservation of residual hearing in our population.

Additionally, the ‘soft surgery’ implantation technique was used in 18 patients with preoperative residual hearing, who were implanted with a Nucleus Contour Advance electrode to prevent damage to the cochlea and to preserve residual hearing. Our results showed median ‘corrected threshold differences’ of 10 dB at 250 Hz and 7.5 dB at 500 Hz in the patients who had received ‘soft surgery’, compared to 25 dB at 250 Hz and 20 dB at 500 Hz in the patients who had not. Therefore, it may be concluded that ‘soft surgery’ has the desired effect on hearing preservation and should

be recommended in patients with significant level of preoperative residual hearing.

A remarkable finding in the results on preservation of residual hearing is the great range in median corrected threshold difference. Analyzing the data, it was seen that this range was determined by just one patient in the Contour Advance group with a great loss of residual hearing after cochlear implantation.

Recently, several studies have reported results on the preservation of residual hearing after ‘soft surgery’. To analyze such data, it is important to know which surgical protocol was used, since the protocol of ‘soft surgery’ is not always strictly specified in the literature. The five main characteristics of the ‘soft surgery’ technique, as described here are: administration of corticosteroids, drilling until the cochlear endosteum is visible, opening of the endosteum with a sharp needle, no intracochlear suctioning and prevention of intracochlear entry of bone dust and blood. In reviewing the literature, we noted that the ‘soft surgery’ technique had been applied when the authors mentioned all these 5 characteristic points as part of the surgical protocol. Table 2 shows how ‘soft surgery’ affected the preservation of residual hearing in other studies in the literature [12, 16, 18, 21]. If we compare our results with the results in the literature, it is remarkable that the results on preservation of residual hearing with the soft surgery technique are better than those reported by the others. Table 2 even shows that our data on hearing preservation after the classic implantation technique are comparable with the ‘soft surgery’ data in

Table 2. Literature review of deterioration in hearing thresholds after implantation of Nucleus 24 Contour Advance electrode array using the ‘soft surgery’ technique

Authors, study (number of included patients)	Surgery protocol	Cochlear implant model	Median deterioration in hearing threshold at 250 Hz (dB)	Median deterioration in hearing threshold at 500 Hz (dB)
[Balkany et al., 2006] ¹⁶ (n=28)	Specified as ‘soft surgery’	Nucleus Freedom	15	15
[James et al., 2005] ¹⁸ (n=12)	Specified as ‘soft surgery’	Nucleus 24 Contour Advance	27	33
[Fraysse et al., 2006] ¹² (n=12)	Specified as ‘soft surgery’	Nucleus 24 Contour Advance	20.5	26
[Garcia-Ibanez et al., 2008] ²¹ (n=28)	Specified as ‘soft surgery’	Nucleus 24 Contour Advance	15	15
Verhaegen et al. (n=18)	Specified as ‘soft surgery’	Nucleus 24 Contour Advance	10	7.5
Verhaegen et al. (n=18)	Classic surgery	Nucleus 24 Contour Advance	20.0	20.0

literature. The present results confirm the positive effect of soft surgery on preservation of residual hearing as demonstrated in other studies, however, our data also shows that, at least with respect to the low frequencies, the classical approach might also lead to effective preservation of residual hearing. In addition, the use of corrected changes in thresholds as applied in this study, compared to a straightforward comparison of pre- and post-operative data might have played a role.

Conclusion

Analysis of data on residual hearing loss in patients with severe to profound deafness must take into account: 1. the auditory function of the non-operated ear, 2. the ceiling effect caused by maximum output limitations of audiometers, 3. the vibrotactile limits of the human ear. Taking these into account, our data showed a positive effect of 'soft surgery' implantation technique on the preservation of residual hearing, however, the classical approach might also lead to effective preservation of residual hearing of the lower frequencies.

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