

Combined Electric and Acoustic Stimulation of the Auditory System: Results of a Clinical Study

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Key Words

Hearing impairment · Cochlear implant · Hearing aids ·
Electric and acoustic stimulation · Deafness

Abstract

Combined electric and acoustic stimulation (EAS) of the auditory system is a new therapy for patients with severe to profound high- and mid-frequency hearing loss but remaining low-frequency hearing. In a prospective study, 13 patients with low-frequency hearing of better than 60 dB below 1 kHz were implanted with a MED-EL COMBI 40+ cochlear implant. Pure tone thresholds as well as monosyllabic word scores and Hochmair-Schulz-Moser sentences in quiet and in noise were measured with hearing aids, cochlear implant alone and in the combined stimulation mode (EAS) in the same ear. Hearing could be partially preserved in 11 out of the 13 patients. All patients scored significantly higher with cochlear implant alone than with hearing aids. Seven patients scored higher in the EAS mode than with cochlear implant alone for sentences in noise, 4 remained unchanged, and 2 could not use EAS. Synergistic effects of EAS were most prominent for hearing in noise with increases of up to 72% as compared to cochlear implant alone.

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Introduction

Hearing loss is common in western societies. It has been estimated that about 16% of the German population suffers from hearing impairment, and more than half of them would benefit from amplification [Zenner, 1998]. The majority of these hearing impairments are due to a sensorineural hearing loss, most often presenting as a high-frequency hearing loss. Whereas in moderate degrees, hearing loss can be compensated by means of acoustic amplification with hearing aids, at higher degrees, acoustic amplification becomes less effective or can even have adverse effects on speech understanding [Ching et al., 1998; Hogan and Turner, 1998].

A distinct group of patients presents with rather well-preserved low-frequency hearing of 20–60 dB up to 750 Hz and severe to profound hearing loss of more than 60 dB at 1 kHz and above. Based on analysis of our clinical database, including more than 20000 audiograms of patients coming to our clinic, approximately 2% of patients met the criteria for this group. Monosyllabic word understanding in this specific subgroup does generally not exceed 30–40% in their best-aided condition with hearing

This article is dedicated to Christoph von Ilberg, pioneer and driving force in the development of combined EAS, in honour of his 70th anniversary.

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aids. Functionally, this subgroup may be characterized as presenting with partial mid- to high-frequency deafness. The remaining low-frequency hearing, however, can be regarded as useful, since it is able to convey information on prosodic features, fundamental frequency and first formant frequency of speech sounds. The quality of sound is perceived as natural and therefore, it can be of great subjective value for the patients. However, speech understanding most often remains unsatisfactory in many of these patients, as important information on second and third formants as well as high-frequency fricative sounds cannot be transmitted. Since acoustic amplification seems to be of little benefit, electric stimulation by means of cochlear implants might present as an alternative treatment for this group of patients. Cochlear implants are able to transmit information via direct electric stimulation of the auditory nerve fibers, independent of the function of the hair cells. Technological improvements, advanced signal processing and stimulation paradigms have resulted in a continuous and important improvement of performance with cochlear implants over the last decade. At present, speech understanding of numerous adult cochlear implant patients exceeds that of patients with severe or severe-to-profound hearing loss using acoustic amplification [Brimacombe et al., 1994; Kiefer et al., 1998; Klenzner et al., 1999] with average monosyllabic word scores above 40% and sentence scores of more than 80% being reported for adult postlingually deaf patients using current cochlear implant systems [Gstoettner et al., 2000; Helms et al., 1997]. Consequently, indication criteria have been extended to patients with profound and severe-to-profound hearing loss and limited speech understanding with conventional acoustic amplification [Fraysse et al., 1998]. However, cochlear implantation is generally accompanied by a loss of acoustic hearing in a large percentage of implanted subjects [Brimacombe et al., 1994], and patients with preoperative low-frequency hearing are at risk to lose the benefits of residual acoustic hearing and to experience a change of sound quality in the low-frequency region. In addition, it is not possible to predict with a high degree of certainty, whether a specific individual patient will be able to obtain results well above the preoperative level of 30–40% monosyllabic words, as the variability of outcome after cochlear implantation is rather large. Therefore, it is difficult to counsel patients whether hearing aids or cochlear implants are the better alternative.

To be able to solve this dilemma, the concept of electric-acoustic stimulation (EAS) has been developed as a new therapeutic strategy for these patients [von Ilberg et al., 1999] and first results have been reported [Kiefer et

al., 2002; Gantz and Turner, 2003]. EAS is based on compensation for the loss of sensory cells by means of electric stimulation in the mid- to high-frequency range in combination with acoustic stimulation of the remaining low-frequency areas of the cochlear receptor in one and the same ear. It may potentially benefit an important number of patients.

Successful preservation of remaining acoustic hearing after cochlear implantation is a prerequisite for the use of combined EAS. In general, cochlear implantation itself entails a complete loss of residual cochlear function in the majority of implanted patients [Brimacombe et al., 1994]. However, animal experiments have shown that implantation of electrode carriers in the cochlea with preservation of functional structures, at least apical to the position of the electrode carrier, is possible [Xu et al., 1997]. Subsequent clinical studies reported that hearing preservation could also be achieved in human cochlear implantation [Skarzynski et al., 2002]. Using a modified surgical technique, we were able to preserve hearing within 20 dB of the mean preoperative values in 12 out of 14 subjects and within 10 dB in 9/14 subjects [Kiefer et al., 2004a]. The aim of this study was to evaluate results with EAS over a period of time and to investigate the possible synergistic effects of the combined EAS in a prospective longitudinal study. The study protocol was approved by the ethics committee board of the University of Frankfurt, Germany. Patients with sufficient hearing in the low-frequency region underwent cochlear implantation. The depth of the electrode carrier was limited to the regions of hearing loss of more than 65 dB in order to prevent damage to apical regions of the cochlea that still had sufficient function. Subjects whose postoperative thresholds for acoustic stimuli remained sufficiently low were fitted with a speech processor for the cochlear implant and a hearing aid on the ipsilateral ear.

Methods

Cochlear Implant System

Patients were implanted with the MED-EL COMBI 40+ cochlear implant system. The system has 12 stimulation channels and an overall stimulation rate of 18180 pulses per second, equally distributed over all active channels. The electrode carrier of this implant system has been designed for atraumatic insertions. It is straight and very flexible, electrode contacts are slightly recessed, giving a smooth surface. In the regular COMBI 40+, the contacts are spaced 2.4 mm apart and are distributed over a total length of 26.4 mm. Including the distance of 1 mm from the tip to the first contact, the last electrode is situated at 27.4 mm from the tip. For limited insertion depths, this distance is not ideal, as some of the contacts will remain outside the cochlea and are not available for stimulation. Therefore,

Table 1. Demographic data of subjects

ID	Age at implantation years	Length of hearing impairment	Etiology	Implant	Depth of insertion mm	Side
K.H.	50	30	idiopathic	C40+	24	right
S.S.	40	15	aminoglycosides	C40+	20	right
M.B.	46	15	hereditary progressive	C40+	19	right
B.D.	64	10	idiopathic	C40+M	19	right
O.M.	57	22	hereditary progressive	C40+	22	right
P.I.	42	20	idiopathic	C40+M	20	left
D.I.	46	20	idiopathic	C40+	19	right
E.Z.	31	21	idiopathic	C40+M	21	left
U.R.	33	25	Ushers syndrome	C40+M	20	left
S.L.	48	28	idiopathic	C40+	20	right
K.W.	77	10	encephalitis	C40+M	20	right
W.R.	64	12	skull trauma	C40+M	21	right
E.M.	76	46	idiopathic	C40+M	21	right

the electrode carrier was modified during the course of the study and spacing of electrode contacts was reduced to 1.9 mm resulting in a total active length of 20.9 mm. Including 1 mm distance from the tip to the first contact, the last contact is situated at 21.9 mm. This electrode array was implanted in 4 subjects. All 13 subjects used the TEMPO+ speech processor (BTE technology). Subjects with remaining postoperative hearing in the implanted ear were also fitted with a digital high-power ITE hearing aid (table 1).

Surgical Methods

The surgical methods used for implantation will only be described briefly, as they are published in detail elsewhere [Kiefer et al., 2004a]. After retroauricular incision, a mastoidectomy/posterior tympanotomy approach was drilled; the cochlea was opened very carefully, using the guidelines of the soft surgery technique [Lehnhardt, 1993]. The endothelium was carefully incised and a drop of triamcinolone solution (Volon A[®], 40 mg/ml, crystal solution) was applied onto the open cochleostomy. Then, the electrode was inserted up the intended insertion depth. The individual insertion depth was defined using the corner frequency of the audiogram and the frequency distribution map according to Greenwood [1990]. The cochlea was immediately sealed with a circular flap from temporalis fascia and fibrin glue. A single dose of intravenous 500 mg prednisolone (SOLU-Decortin[®]) was applied prior to the opening of the cochlea. Peri- and postoperative antibiotics (cefuroxime) were given intravenously for 3 days.

Subjects

The study has been conducted at two centers, the University Clinic of Frankfurt and the University Clinic of Vienna. Inclusion criteria were post- or perilingual deafness and hearing loss in the ear to be implanted of less than 60 dB HL in at least two of the frequencies 125, 250 and 500 Hz and more than 60 dB HL at 1 kHz and above. Monosyllabic word understanding at 70 dB in the best-aided condition had to be less than 40%. In most subjects, the best-aided condition was obtained with bilateral hearing aids.

Thirteen subjects have been included so far (table 1). Mean age at implantation was 51, ranging from 33 to 77 years. The etiology was idiopathic in 7 cases and hereditary in 2 patients, one of whom suf-

fered from Ushers syndrome. Further causes were antibiotic treatment with aminoglycosides, encephalitis and skull trauma. Subjects had a mean duration of hearing impairment of 21 years from the time of initial onset of hearing loss; individual duration ranged from 10 to 46 years. Preoperatively, subjects used different kinds of high-power hearing aids that were adequately fitted and maintained. Two subjects had stopped using their hearing aid prior to the operation, because they felt it did not improve their hearing abilities. These 2 subjects both had thresholds of 20–30 dB up to 500 Hz and very steep declines of threshold at 1 kHz.

Audiological Measurements

Pure tone thresholds were measured under headphones using a Hortmann Audiometer CA 540/2 audiometer, calibrated to EN ISO 389 standards. The audiometer output was limited to 110 dB HL. In case of no response up to the limit to the audiometer, a nominal value of 115 dB was assigned for the purpose of calculation.

Preoperative pure tone thresholds for all subjects as well as mean values are represented in figure 1. Hearing was present at levels that could adequately be amplified in the low-frequency range up to 500–1000 Hz, whereas above 1 kHz few subjects had measurable hearing. Therefore, average thresholds were calculated including only the frequencies of 125, 250, 500, and 1000 Hz. Aided thresholds were assessed, but have to be interpreted carefully, as some subjects used digital hearing aids where the automatic noise suppression prevented the correct measurement of aided thresholds.

Subjects were asked to report any vibrotactile sensations. Responses to such sensations were not regarded as hearing responses and were excluded from the calculations. In 3 subjects, audiometric thresholds obtained under headphones were verified with insert earphones, which reduce the possibility of vibrotactile responses. For all 3 subjects, responses with insert earphones corresponded within ± 5 dB to responses under headphones.

For speech understanding, the Freiburg test for monosyllabic words and numbers was applied under headphones for each ear individually at 70, 80 and preoperatively at a maximum of 90 dB; in addition, patients were tested in a free-field condition with hearing aids at 70 and 80 dB HL monaurally and binaurally. Sentence understanding was assessed with the Hochmair-Schulz-Moser (HSM) sen-

tence test in quiet and in noise. Tests were performed in free-field conditions with signal and noise coming from the front (S_0N_0) in the optimal condition, in most cases with bilateral hearing aids. Patients were seated at a 1-meter distance of the loudspeakers. Fixed signal-to-noise ratios of 10 dB S/N (and in some cases additionally 15 dB S/N) were used. One list of 20 words was tested in each condition; the test was scored for the number of correct words in the sentence.

Postoperatively, pure tone thresholds were determined as described above and the Freiburg test for monosyllabic words and numbers was applied in a free-field condition at 70 dB in the following conditions: (1) ipsilateral hearing aid alone; (2) cochlear implant alone; (3) cochlear implant + ipsilateral hearing aid; (4) cochlear implant + contralateral hearing aid, and (5) cochlear implant + bilateral hearing aid (if possible).

HSM sentences were tested in conditions 1, 2 and 3, and if time allowed also in conditions 4 and 5 as described above. To eliminate contributions of the acoustic hearing in the cochlear implant only conditions, the ipsi- and contralateral ears were closed with an ear-plug and additional circumferential isolating earmolds. These measures result in attenuation of at least 50 dB in the frequency range of 125 Hz to 5 kHz, as tested with normal hearing subjects. Thus, as minimal hearing loss in our group of subjects was 20 dB, resulting in an overall threshold of at least 70 dB HL, a significant contribution of acoustic hearing in the implant alone conditions can be excluded. The t test for repeated measures was used for statistical comparison of the different conditions. Results were considered significant at a level of $p < 0.05$.

Fitting of Cochlear Implants

The frequency range that can be transmitted acoustically is mainly determined by the pure tone audiogram of the individual patient, whereas information that can be represented electrically depends on the fixed electrode position inside the cochlea as well as on the designation of frequency bands to the different electrodes that can be varied within the technical limits of the implant system.

Surgically, it was intended to place the most apical electrode in the region in which thresholds are steeply sloping downwards, exceeding values of 65 dB, called the corner frequency. Three different situations may be considered. The frequency range presented via electrical stimulation may be overlapping with the remaining acoustic range, adjacent to it, or a gap between the two may exist. In the default settings, the cochlear implant system processes acoustic information in the frequency range from 300 Hz up to 5.5 kHz, divided into frequency bands, called channels. Patients implanted with a COMBI 40+ electrode had 7–8 active electrodes available; in patients with a C40+M electrode, 9–11 electrodes could be activated. During the initial fitting period of 2–8 weeks, the full frequency range of 300 Hz to 5500 Hz was programmed, until stable thresholds were reached. In this period, patients used their cochlear implant alone. After postoperative fitting of hearing aids, patients were instructed to use cochlear implants and hearing aids in parallel. For the cochlear implants, 3 different maps were programmed. The first map used the full frequency range, the second map was programmed with a lower frequency boundary of 650 Hz, and a third map introduced a gap with a lower frequency border of 1000 Hz. Subjects were allowed to use all 3 maps for 2–3 weeks. At the end of this period, consonant and vowel tests were performed with all 3 maps to determine the optimal electric frequency range. The frequency range for further fitting and testing was chosen on the basis of these test results and subjective preference of the patients.

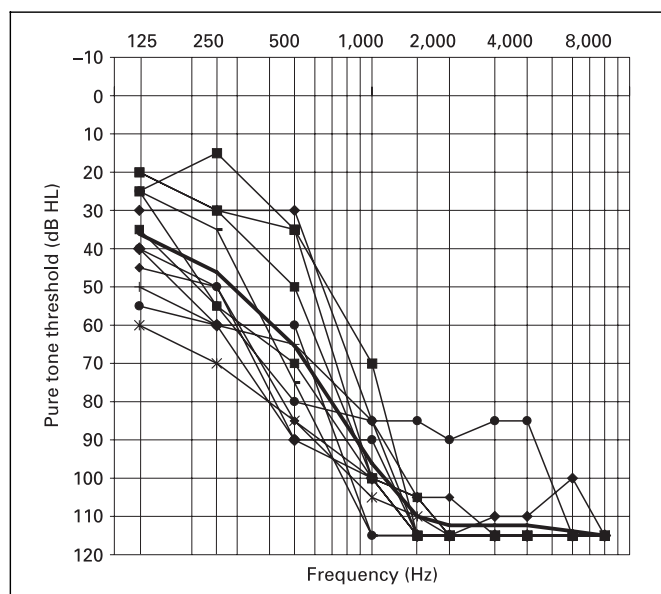


Fig. 1. Preoperative pure tone thresholds in the ear that was chosen for implantation, individual audiograms and mean values (bold line).

Fitting of Hearing Aids

Postoperatively, digital in-the-ear hearing aids were fitted. It was soon recognized that standard fitting procedures implemented as default procedures in the software had unsatisfactory results, as they gave high levels of amplification in the mid- and high-frequency region, where, in fact, acoustic stimulation was neither possible nor desired in the subjects in this study, and insufficient amplification in the low-frequency range, where acoustic hearing was still present. Therefore, initial amplification for the different frequencies was set to half of the hearing loss, e.g. 20 dB amplification for a hearing loss of 40 dB at 500 Hz, using a nonlinear compression model. Amplification was mainly provided in the frequency range of 125 Hz up to 1 kHz, where useful acoustic hearing was present. Fitting was controlled by loudness scaling and individual adjustments were made as necessary.

Results

Pure Tone Thresholds

Preoperative pure tone thresholds as well as the mean values are represented in figure 1.

At the frequency of 250 Hz, 5 subjects showed thresholds of 35 dB or less, and 7 subjects had thresholds of 50 dB or less. Postoperative thresholds as measured at 3 months after surgery are shown in figure 2. Hearing was preserved within 0–10 dB in 8/13 subjects, and within 11–20 dB in 3/13 subjects; in 2/13 subjects, hearing was

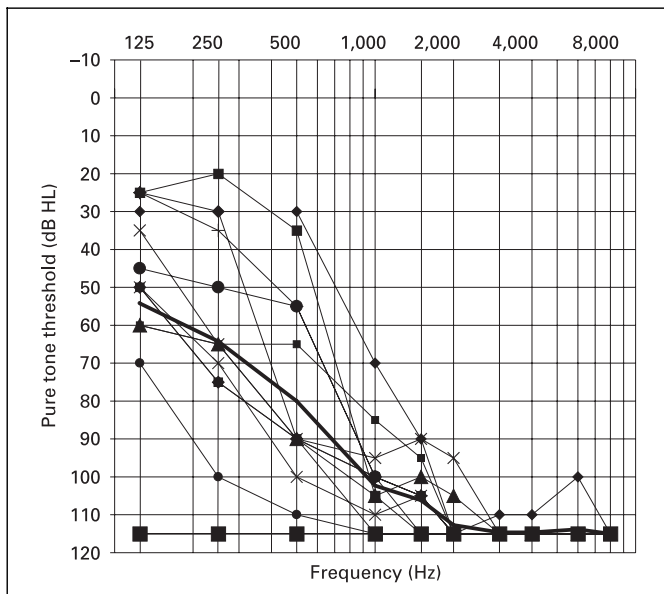


Fig. 2. Postoperative pure tone thresholds in the implanted ear, 3 months after implantation, individual audiograms and mean values (bold line). Symbols for each subject are as in figure 1.

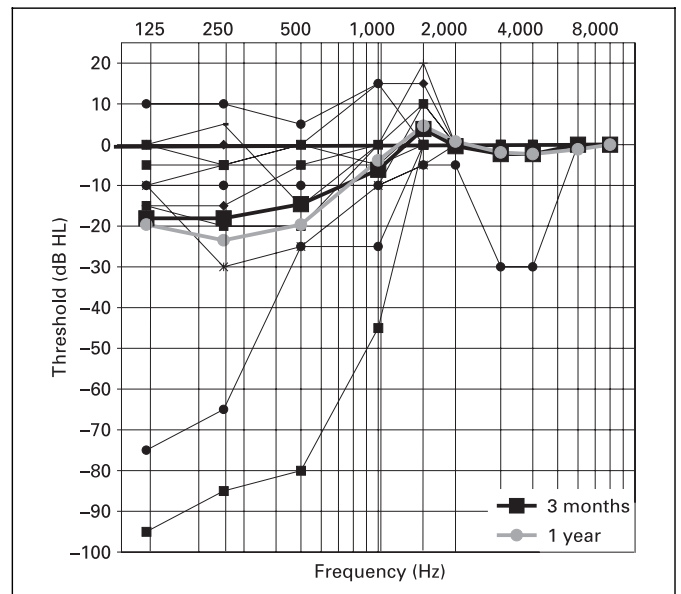


Fig. 3. Difference between pre- and postoperative thresholds for individual subjects and mean values 3 months (black bold line) and 1 year (grey bold line) after surgery.

completely lost in the implanted ear. Thus, hearing could at least be partially preserved in 11/13 subjects. Mean threshold values increased by 18, 18, 15 and 6 dB at the frequencies 125, 250, 500 and 1000 Hz 3 months after implantation. Figure 3 shows the difference of thresholds in relation to the preoperative hearing at 3 months and 1 year postoperatively. Data 1 year after implantation show a progression of hearing loss of 5 dB in two frequencies during further postoperative course (fig. 3). Contralateral hearing loss progressed by 2.5 dB during this period. Even high levels of hearing, e.g. 30 dB at 500 Hz, could be maintained in some subjects after implantation. Mean preoperative thresholds in the frequencies from 125 to 1000 Hz were 61 dB HL; postoperatively, they increased to 75 dB.

Speech Audiometric Results Monosyllabic Word Scores

Pre- and postoperative monosyllabic word scores were measured preoperatively with hearing aids and postoperatively at the time intervals of 3 months, 6 months, 1 year and 2 years. Data reported here are for the ear ipsilateral to the implanted ear. For practical reasons, some patients could not be measured at all intervals. However, data at the preoperative and 1-year postoperative interval could be obtained from all patients in the study and can be used

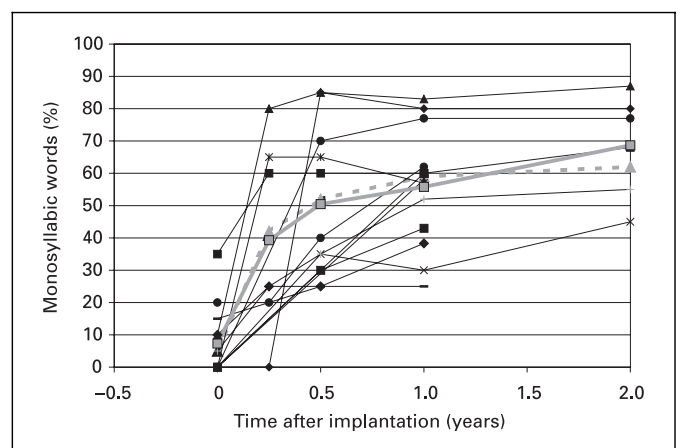


Fig. 4. Monosyllabic words with hearing aids (preoperative, time = 0) and postoperative values with cochlear implant alone (70 dB). Solid bold line: mean value; solid dashed line: mean of reference data.

for statistical comparison. Figure 4 shows the postoperative data obtained with cochlear implant alone (preoperative scores were obtained with hearing aid).

Apart from the single subjects' data, this graph also shows the mean values of the study group (bold, solid line), as well as the mean performance of a multicentric reference group of adult postlingually deaf patients

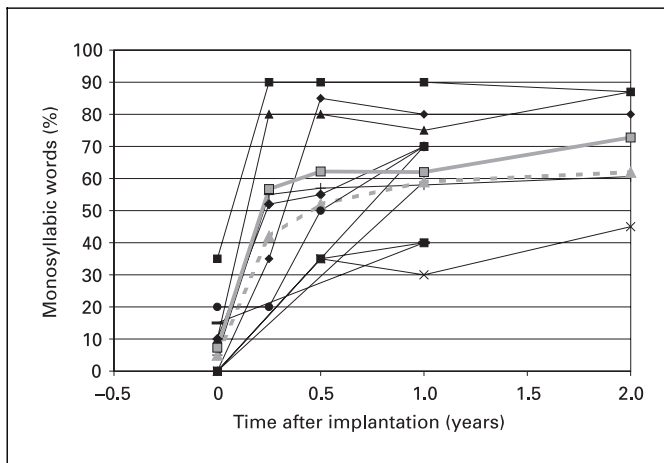


Fig. 5. Monosyllabic words with hearing aids (preoperative, time = 0) and postoperative values with combined EAS (70 dB). Solid bold line: mean value; solid dashed line: mean of reference data.

(dashed, bold line), using a similar cochlear implant system (MED-EL COMBI 40) [Helms et al., 1997]. Average performance of the study group before implantation was 7% (SD \pm 11%, maximum 35%). After 1 year of implant use, the average score with cochlear implant alone increased to 56% (SD \pm 17%; fig. 4). Results with cochlear implant alone were significantly better than with hearing aids (t test, $p < 0.01$). This postoperative score with cochlear implant alone is in the same range as results obtained in the reference group.

Monosyllabic word scores in the EAS condition (cochlear implant + hearing aids on the ipsilateral ear) are shown in figure 5. Average performance after 1 year increased to 62% (SD \pm 17%), compared to 54% with cochlear implant only (2 patients, who lost hearing, are excluded). With $p = 0.059$, this difference was not statistically significant. A benefit of EAS versus the cochlear implant only condition after 1 year was found in 6 patients with a maximum benefit of 35%. Two patients could not use the EAS condition since they lost hearing postoperatively, 1 patient scored 8% worse in the combined condition, 4 patients scored identically under both conditions. Patients with high levels of postoperative hearing better than 60 dB were more likely to have a benefit with combined EAS.

Four patients were able to integrate the contralateral acoustic input and increase their performance versus the cochlear implant only condition (2 patients, who lost their hearing postoperatively) or against the EAS condition (2 further patients). Including these values, the average per-

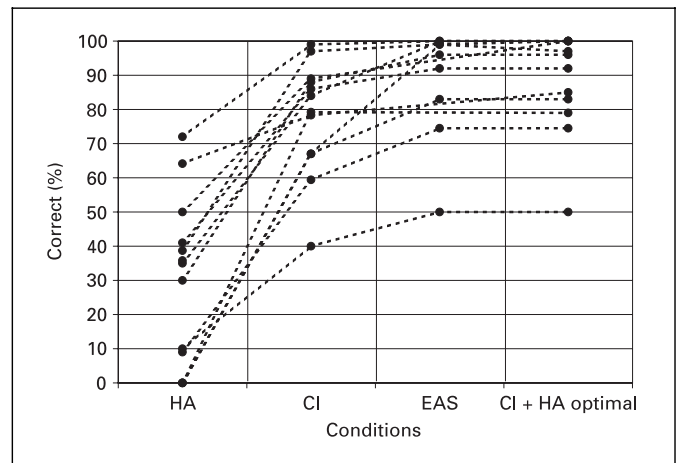


Fig. 6. HSM sentence scores in quiet for the conditions with hearing aid (HA), cochlear implant (CI) alone, EAS, and in the optimal condition with cochlear implant and hearing aid ipsi-, contra- or bilateral, 1 year after implantation.

formance in the optimal condition increased to 67% (SD \pm 16%) correct. The difference to cochlear implant alone was statistically significant at a level of $p < 0.01$.

Sentences in Quiet and in Noise

HSM sentences were tested in quiet (signal at 70 dB HL) and at a signal-to-noise ratio of +10 dB (signal 70 dB, noise 60 dB). Data at the 1-year interval from 12 patients can be reported. Data with hearing aid alone are preoperative scores. Performance with cochlear implants was significantly higher (mean 78%) than with hearing aids (mean 32%, $p < 0.01$). In quiet, mean scores in the EAS condition were 8% higher than those with cochlear implant alone ($p < 0.05$). Differences ranged from -2% up to +32% (fig. 6). At a signal-to-noise ratio of 10 dB, a larger mean gain between the cochlear implant and the EAS conditions of 23% was found (fig. 7), ranging from -2% up to +72% ($p < 0.01$). In this condition, 7/12 subjects demonstrated a significant benefit in the combined EAS mode, 3 patients showed no difference, and in 2 patients testing with EAS was not possible due to loss of hearing. However, these 2 patients were able to integrate the contralateral acoustic input.

Frequency Allocation to Electrode Contacts

In all except 1 patient, the overlapping frequency map allocating the full frequency range from 300 Hz to 5.5 kHz to the electrodes gave the best results and was chosen by the patient. One patient obtained her best result with a map with a frequency range of 650 Hz to 5.5 kHz.

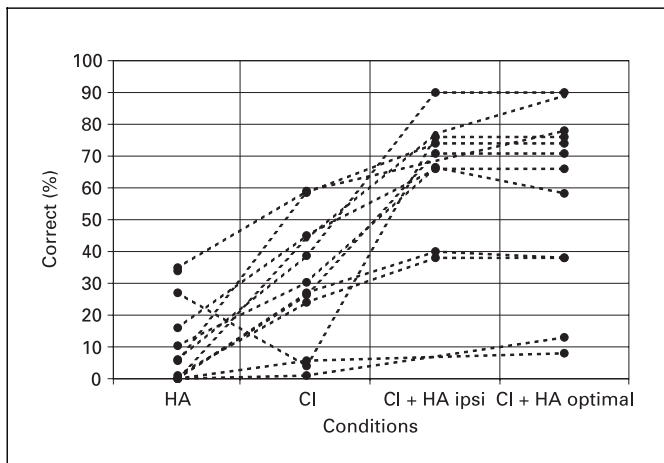


Fig. 7. HSM sentence scores at a signal-to-noise ratio of 10 dB for the conditions with hearing aid (HA), cochlear implant (CI) alone, EAS, and in the optimal condition with cochlear implant and hearing aid ipsi-, contra- or bilateral, 1 year after implantation.

Data of Single Patients

In the following section, data of 2 single patients are presented in more detail. These patients are of interest because they were able to integrate both electric and acoustic stimulation to a great extent, patient S.S. with the use of a hearing aid, whereas patient S.L. was able to use her acoustic hearing without hearing aids. Both patients differ in the relative amount they made use of electric and acoustic information.

Subject S.S. was implanted at the age of 40 with a standard MED-EL COMBI 40+ cochlear implant; insertion depth of the electrode was 20 mm. She presented with severe to profound high-frequency hearing loss for 15 years after treatment with aminoglycoside antibiotics. Her pre- and postoperative audiograms are shown in figure 8a. Hearing in the implanted ear remained stable over 3 years. Patient S.S. used a Resound DX in-the-ear hearing aid. Monosyllabic word scores with the hearing aid were 35% preoperatively as well as at 3 months and 1 year postoperatively and 38% at the 2-year interval. Performance with cochlear implant alone increased from 60% at 3 months postoperatively to 68% at the 2-year interval. In the combined EAS mode, monosyllabic word scores of 85–90% were obtained (fig. 8b). Sentence understanding in quiet was 72% for hearing aid, 98% for cochlear implant only and 100% for EAS. At a signal-to-noise ratio of 15 dB, performance with hearing aid diminished to 10% and 74% with cochlear implant, whereas performance in the EAS mode was well preserved at 100%. At a more adverse signal-to-noise ratio of 10 dB, a further

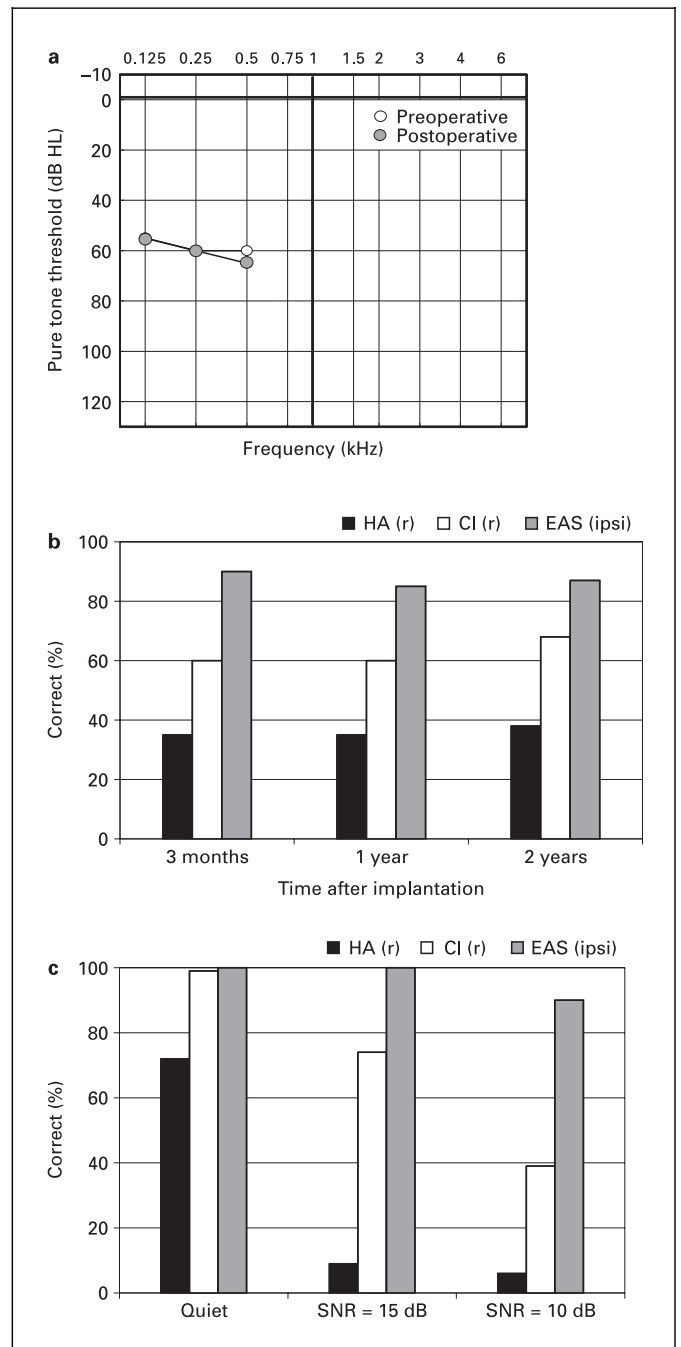


Fig. 8. **a** Single subject data (S.S.): pre- and postoperative pure tone thresholds. **b** Single subject data (S.S.): monosyllabic word scores with hearing aid (HA), cochlear implant (CI) alone, and EAS at different intervals postoperatively. **c** Single subject data (S.S.): HSM sentence scores in quiet and in noise (a signal-to-noise ratio of 15 and 10 dB) with hearing aid, cochlear implant alone, and EAS, 1 year postoperatively.

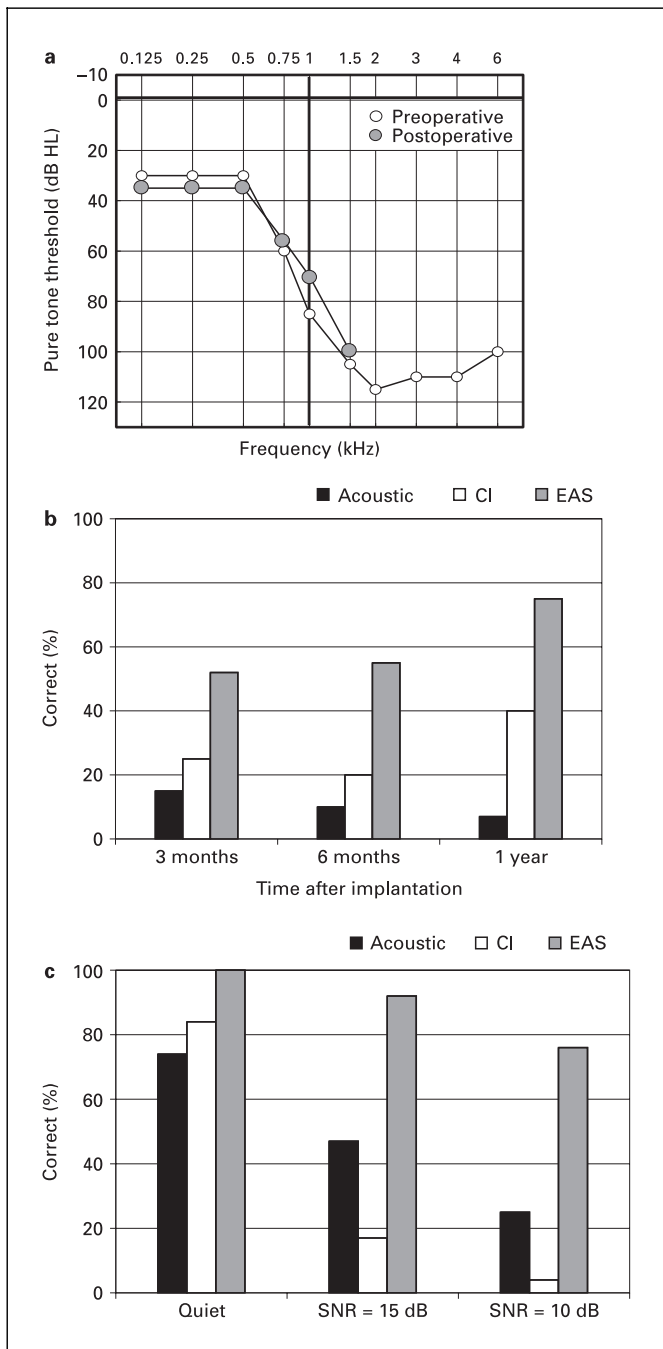


Fig. 9. **a** Single subject data (S.L.): pre- and postoperative pure tone thresholds. **b** Single subject data (S.L.): monosyllabic word scores with hearing aid (HA), cochlear implant (CI) alone, and EAS at different intervals postoperatively. **c** Single subject data (S.L.): HSM sentence scores in quiet and in noise (a signal-to-noise ratio of 15 and 10 dB) with hearing aid, cochlear implant alone, and EAS, 1 year postoperatively.

decrease of the performance with cochlear implant to 38% could be observed, whereas performance with combined EAS remained at a high level of 90% (fig. 8c). A clear synergistic effect between both modes of stimulation could be demonstrated. The combination of both modes of stimulation in EAS renders speech understanding remarkably insensitive to the destructive interference of noise.

Subject S.L. was implanted at the age of 48. Hearing loss of unknown etiology was slowly progressive over 28 years, affecting both high and mid frequencies. Preoperatively, the subject did not use hearing aids in everyday life, since she experienced no subjective benefits. A probatory fit of hearing aids confirmed the lack of benefit. All pre- and postoperative scores reported here were tested without hearing aids. Subject S.L. was implanted on her right ear with a COMBI 40+M electrode; insertion depth was 20 mm. Pre- and postoperative audiograms are shown in figure 9a. Hearing was preserved near preoperative levels except for the high-frequency range at 2 kHz and above. It remained stable throughout the 2-year follow-up period. Monosyllabic word scores with hearing aid were 15% and decreased to 10% at the 6-month and 1-year intervals. Performance with cochlear implant alone increased only slowly to 40% at 1 year and remained somewhat below average performance. Monosyllabic word scores with combined EAS increased from 50% at 3 months to 75% at 1 year (fig. 9b). Sentences in quiet showed 70% with hearing aid, 85% with cochlear implant alone and 100% in the combined EAS mode. In noise, performance with cochlear implant fell to 18% at a signal-to-noise ratio of 15 dB and 5% at 10 dB; understanding with hearing aid diminished to 50% (15 dB S/N) and 30% (10 dB S/N). Again, understanding in the combined mode was preserved at high levels of 90% at 15 dB S/N and 75% at 10 dB S/N, respectively (fig. 9c). The synergistic effect of the combined stimulation was more marked than for speech understanding in quiet. The addition of both stimulation modes results in a robust performance under adverse noise conditions. In contrast to the previous patient, speech understanding with hearing aid is predominant as compared with cochlear implant alone. The relatively low performance with cochlear implant alone may be attributed to the fact that this subject always uses the combined stimulation mode and is trained to listening to cochlear implant only in formal training sessions, as her well-preserved low-frequency hearing allows for natural, unaided acoustic stimulation.

Discussion

The intention of this study was to evaluate the feasibility and outcomes of combined EAS of the auditory system in a prospective study involving patients with remaining low-frequency hearing.

When combining electric and acoustic stimulation, we have to be aware of the differences between both modalities of stimulation and it is not clear, what effect they would have on perception, i.e. if acoustic and electric stimulation was synergistic or antagonistic when presented simultaneously. It is known that acoustic and electric stimulation produces very different responses at the level of the auditory nerve, both in terms of tonotopic selectivity and in terms of temporal responses like phase locking and adaptation. Single nerve fiber responses of the auditory nerve in response to acoustic stimulation show phase coupling to periodic signals, but with a certain stochastic pattern of action potentials [Kiang et al., 1965; Klinke and Hartmann, 1997], whereas a strong phase locking with highly synchronous activity is observed for electrical stimulation [van den Honert and Stypulkowski, 1987]. Tuning curves of single nerve fibers in response to acoustic stimuli are sharply tuned to a characteristic frequency with filter characteristics of more than 50 dB/mm along the basilar membrane [Hartmann and Klinke, 1990], at least at lower presentation levels, whereas tuning curves for electric stimulation of the auditory nerve are shallow with filter characteristics of 4–13 dB/mm for bipolar stimulation [Hartmann et al., 1982]; there are large differences between electric and acoustic dynamic ranges.

Results of animal studies have suggested that tuning properties of single nerve fibers in response to acoustic stimulation are essentially unchanged in the presence of sinusoidal electric stimulation [Tillein et al., 2003] at low and medium levels of extracochlear electric stimulation. At higher levels of intracochlear stimulation, auditory nerve fibers respond primarily to electric stimulation and responses to acoustic stimulation can be suppressed by the electric stimulation. Although animal experiments reveal insight into the detailed activation patterns in the auditory nerve and more central levels of the auditory system, only human subjects can teach us about the processing and subjective perception of speech and other sounds in EAS. The combination of two modalities may have a synergistic effect on speech understanding or on the contrary, detrimental interference may occur. Specific conditions, e.g. by varying the frequency ranges of EAS in relation to each other have to be taken into account to achieve possible synergistic effects.

In the present study, we could show that patients with sufficiently preserved postoperative hearing were able to integrate both acoustic and electric stimuli and use the combined EAS.

In all patients, performance with the cochlear implant alone was already significantly above the results obtained preoperatively with hearing aids; the mean performance was comparable to average adult cochlear implant users of a similar cochlear implant system. Depending on the exact condition, 6 or 7 of 13 patients scored higher in the EAS mode, especially in conditions with noise interference. Overall, mean results with EAS were clearly above average performance with a similar device. In individual patients with postoperative residual hearing of better than 60 dB up to 500 Hz, benefits of more than 70% in the EAS mode as compared to cochlear implant alone could be observed. This finding indicates a strong synergistic effect of combined EAS in individual patients and does not seem to be related to test-specific properties like ceiling effect but to represent a true advantage of EAS.

Subjectively, patients were able to integrate and merge the acoustic and electric stimuli into a united hearing impression, although they were able to differentiate the characteristics of EAS if presented separately.

In our study concept, the insertion depth was intentionally limited to prevent damage of the intact apical cochlear structures. The depth of insertion was determined by the frequency in the preoperative tone audiogram, in which the threshold curve crossed the line of 60 dB. We assumed that in these basilar region, little or no useful hearing was present. Using the function described by Greenwood [1990], we estimated the distance from the round window for the tonotopic representation of this frequency along the basilar membrane. The overall length of the organ of Corti is reported to be 32–35 mm with great interindividual variability [von Békésy, 1960; Otte et al., 1978; Úlehlová et al., 1987]; the length of the scala tympani has a mean of 28.5 mm, measured in an axis in the middle of the scala tympani [Thorne et al., 1999]. Individual variances of cochlear dimensions and the position of the cochleostomy in relation to the round window have to be taken into account. Thus, the exact position of the electrode tip with respect to the frequency allocations based on depth of insertions can only be estimated with a certain amount of variance. In this study, all except 1 patient had their best results with frequency representation for electrical stimulation that overlapped with the acoustic range. Detailed studies including some of our subjects have revealed an advantage for an overlapping frequency map in 2 subjects, for 1 subject, adjacent ranges were benefi-

cial, and another subject showed no differences in the results for both conditions [Wilson et al., 2002]. We have indications by pitch matching experiments that the apical electrode stimulates frequencies lower than would correspond to the actual position of the electrode on the basilar membrane. This can be due to the fact that ganglion cell bodies that code for deep frequencies are clustered around a position corresponding to $1\frac{3}{4}$ turn, thus cell bodies of ganglion cells encoding for deeper frequencies might be stimulated by electrodes in the second turn of the cochlea. In addition, current spread along the scala tympani may also result in stimulation of more apical structures. Overlapping electric and acoustic frequency representation seems to be at least not detrimental for speech understanding. In cat experiments, Tillein et al. [2004] found that the characteristic features of acoustic stimuli are well-preserved in the presence of electric stimuli and vice versa. However, depending on relative levels, some masking may occur, and a double representation may thereby increase the transfer of information.

In the intention to preserve cochlear function as far as possible for combined EAS, a reasonable balance between the number of distinguishable electrical channels for stimulation of neural elements on the one hand and minimal trauma on the other hand has to be found. Deeper insertion has the advantage of a higher number of electrical channels, but the risk of damage to remaining apical cochlear structures will probably become greater. Simulations of combined electric and acoustic hearing in normal listeners with insertion depths of 19 and 17 mm produced significantly better speech understanding than more shallow depths [Dorman et al., in press]. In case of loss of acoustic hearing following surgery, these simulations indicated that with a 19-mm insertion, performance was as good as that of a patient with 4–6 effective channels of stimulation, comparable to average cochlear implant users. The effects of losing low-frequency hearing were severe for insertion depths of 15 mm or less. At 15 mm, performance was far less than that of an average implant patient and was no better than what was achieved with 500 Hz residual hearing. For depths of 13 and 11 mm, the loss of acoustic hearing resulted in performance that was worse than that achieved with 500 Hz residual hearing. These results support an insertion depth of 17–19 mm and are in accordance with results presented here. Subjects in the present study obtained results with cochlear implant alone that match those reported in a larger multi-center study with a similar cochlear implant system [Helms et al., 1997], providing evidence that a medium insertion depth of around 20 mm can yield good results

using a cochlear implant alone, although stimulation of apical parts of the cochlea by deep insertion in patients with little or no useful residual hearing seems to be advantageous [Hochmair et al., 2003]. However, even in patients, in whom long-term hearing should not be stable but may show progression over time, or in whom hearing might be lost peri- or postoperatively, performance with the cochlear implant alone will probably be satisfactory in the majority of patients. Gantz and Turner [2003] have reported results on combined EAS using insertion depths of 6 and 10 mm in 6 patients. Whereas enhancement of speech understanding with an insertion depth of 6 mm was not satisfactory, a 10-mm insertion depth resulted in doubling of monosyllabic word scores as compared with the use of hearing aids alone and a benefit of combined EAS in comparison to the use of cochlear implant alone. No loss of hearing exceeding 15 dB was reported. However, numbers are still too small to compare relative risks in relation to the depth of insertion.

Hearing loss, although only partial, is still problematic in our series of patients. Significant loss of hearing postoperatively in an ear with preexisting hearing loss limits the possible use of EAS. Therefore, it will be of great importance to find further ways to avoid peri- or postoperative hearing loss. The cochleostomy is of great importance in this regard. In histological studies, trauma to basal cochlear structures, e.g. fractures of the lamina spiralis ossea or rupture of the basilar membrane, has been a frequent finding [Adunka et al., 2004]. Special attention to the correct placement of the cochleostomy should be given, alternative access via the round window membrane might be an alternative. The use of CO₂ or erbium-YAG lasers has not been advantageous in animal experiments [Kiefer et al., 2004b]. Electrode design is crucial for combined EAS to reduce trauma to cochlear structures. In the future, additional protection of cochlear structures during and after the surgery, e.g. by means of pharmacological substances, may be helpful. Long-term stability of hearing after implantation is another important issue for the use of EAS. In our series of patients, a slight progression of hearing loss of 5 dB in two frequencies throughout the first year has been found. This progression was larger than in the contralateral ear (2.5 dB). It remains to be determined, whether hearing will stabilize in the future course or will continue to decrease, impeding the successful use of EAS.

Combined EAS is feasible and effective in patients with remaining low-frequency hearing. Substituting missing acoustic information by combined EAS has the potential to benefit a large number of patients, in whom acous-

tic amplification remains unsatisfactory, but traditional cochlear implantation with deep insertion of the electrode carrier and high risk of hearing loss is not justified. Large synergistic effects can be observed especially in conditions with interfering noise, where patients using cochlear implant alone still have large difficulties in understanding, even with modern implant technology and speech coding strategies. Natural perception of sounds as provided by the acoustic stimulation is appreciated by the

patients and may also be helpful for identifying melodies in music with a higher quality than can be achieved with cochlear implant alone. Further research is necessary to investigate the short- and long-term results, develop appropriate selection criteria, increase the reliability of hearing preservation and improve the applied technology in order to open the combined EAS to a larger number of patients.

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