International Journal of Audiology 2013; 52: 838–848

informa
healthcare

Original Article

European multi-centre study of the Nucleus Hybrid L24 cochlear implant

Thomas Lenarz*, Chris James[$,^], Domenico Cuda[††], Alec Fitzgerald O'Connor[‡‡], Bruno Frachet[+], Johan H.M. Frijns[##], Thomas Klenzner[†], Roland Laszig[‡], Manuel Manrique[¶¶], Mathieu Marx[$], Paul Merkus[$$], Emmanuel A.M. Mylanus[^^], Erwin Offeciers[++], Joerg Pesch[#], Angel Ramos-Macias[§§], Alain Robier[¶], Olivier Sterkers[§] & Alain Uziel[**]

[*]*MHH, Hannover, Germany,* [†]*HNO-Klinik Universitätsklinikum Düsseldorf, Germany,* [‡]*Universitaetsklinik Freiburg, Germany,* [#]*Cochlear GMBH, Hannover, Germany,* [$]*Hôpital Purpan, CHU Toulouse, France,* [^]*Cochlear France, Toulouse, France,* [+]*Hôpital Avicenne, Paris, France,* [¶]*Hôpital Bretonneau, Tours, France,* [§]*APHP, Hôpital Beaujon, Service ORL & Inserm UMR-5867, Université Denis Diderot Paris 7, France,* [**]*Hôpital Gui de Chauliac, Montpellier, France,* [††]*Guglielmo da Saliceto Hospital ASL, Piacenza, Italy,* [‡‡]*St. Thomas's Hospital, London, UK,* [##]*Leids UMC, Leiden, Netherlands,* [$$]*VU Medisch Centrum Amsterdam, Netherlands,* [^^]*UMC St. Radboud, Nijmegen, Netherlands,* [++]*AZ St. Augustinus, Antwerp, Belgium,* [¶¶]*University Clinica Universitaria de Navarra, Pamplona, Spain, and* [§§]*Hospital Materno Infantil de Gran Canaria, Las Palmas de Gran Canaria, Spain*

Abstract

Objectives: To investigate the preservation of residual hearing in subjects who received the Nucleus Hybrid L24 cochlear implant. To investigate the performance benefits up to one year post-implantation in terms of speech recognition, sound quality, and quality of life. *Design:* Prospective, with sequential enrolment and within-subject comparisons. Post-operative performance using a Freedom Hybrid sound processor was compared with that of pre-operative hearing aids. *Study sample:* Sixty-six adult hearing-impaired subjects with bilateral severe-to-profound high frequency hearing loss. *Results:* Group median increase in air-conduction thresholds in the implanted ear for test frequencies 125–1000 Hz was <15 dB across the population; both immediately and one year post-operatively. Eighty-eight percent of subjects used the Hybrid processor at one year post-op. Sixty-five percent of subjects had significant gain in speech recognition in quiet, and 73% in noise (≥ 20 percentage points/2 dB SNR). Mean SSQ subscale scores were significantly improved ($+1.2$, $+1.3$, $+1.8$ points, $p<0.001$), as was mean HUI3 score ($+0.117$, $p<0.01$). Combining residual hearing with CI gave 22–26 %age points mean benefit in speech recognition scores over CI alone ($p<0.01$). *Conclusions:* Useful residual hearing was conserved in 88% of subjects. Speech perception was significantly improved over preoperative hearing aids, as was sound quality and quality of life.

Key Words: Cochlear implant; sensorineural hearing loss; electric-acoustic stimulation; bimodal stimulation; residual hearing

Patients with profound bilateral high-frequency sensorineural hearing loss (HL) are considerably limited in their receptive communication performance. Conventional acoustic amplification has been shown to be ineffective or even detrimental to speech recognition scores for frequencies where thresholds exceed 60–90 dBHL (Ching et al, 1998; Hogan & Turner, 1998; Vickers et al, 2001; Summers, 2004) or where there are non-functioning inner hair cells in a so called "dead region" (Vickers et al, 2001). Current therapeutic options to improve speech recognition include frequency transposition/compression processing in acoustic hearing aids, which aims to transfer speech information in a non-functioning frequency region to a functioning frequency region (Simpson et al, 2006; Gifford et al, 2007; Robinson et al, 2009), or replacement of ineffective high-frequency acoustic hearing by electrical stimulation via a cochlear implant (CI).

Frequency transposition has the potential to provide benefit in cases where there is sufficient residual frequency bandwidth up to approximately 1500 Hz (Simpson et al, 2006) with residual hearing sensitivity in this range <60 dB HL. Conversely CI candidacy generally applies to patients with a maximum of 30–50% correct speech recognition score in quiet regardless of the configuration of the audiogram. In typical "borderline" cases we see patients with a range of audiogram configurations. For example, the audiogram can be more or less flat with 80–95 dB HL in the range 250–1000 Hz. Alternatively the audiogram may be steeply sloping with in some cases only mild or moderate HL up to 500 Hz and profound HL for higher frequencies. Thus there is no apparent overlap between the beneficial operating range for frequency transposition/compression hearing aids and the range of residual hearing found in even borderline candidates for CI. It is important to note that

Correspondence: Chris James, Cochlear France SAS, 3 Impasse Chalard, 31100, Toulouse, France. E-mail: cjames@cochlear.com

(Received 29 October 2012; accepted 30 April 2013)

ISSN 1499-2027 print/ISSN 1708-8186 online
DOI: 10.3109/14992027.2013.802032

Abbreviations

CI	Cochlear implant
EAS	Electric-acoustic stimulation
HL	Hearing loss
HRQL	Health-related quality of life
NS	Not statistically significant
Post-op	Post-operative
RM ANOVA	Repeated measures analysis of variance
SNR	Signal-to-noise ratio
SP	Sound processor
SRT	Speech reception threshold
%age points	percentage points

frequency transposition will not restore high-frequency sensations as such.

Extending CI indications further we can imagine cases with residual hearing up to 1000 Hz where speech energy starts to have greater information content, especially for monosyllables (Fletcher & Galt, 1950). Pre-operative speech recognition scores may still be well below 100% correct in these cases. However the cost/benefit for CI may be limited because the incremental benefit from CI may be too small and/or patients are not able to achieve high scores using a CI alone or in combination with any remaining low-frequency residual hearing due to various factors (e.g. Blamey et al, 1996). Due to the relatively high absolute cost of cochlear implantation in many reimbursement environments it is necessary to not only measure speech recognition or other auditory performance gains but also health-related quality of life (HRQL) gain such that the treatment may compared to other medical procedures. It is clear from previous studies (UKCISG, 2004a, 2004b; Hawthorne et al, 2004) that unilateral cochlear implantation may provide an adequate level of life-years-adjusted HRQL benefit when considering conventional borderline candidates, however it is unknown at this stage whether this carries over to cases with substantial low-frequency residual hearing.

Where residual hearing levels are significant in contra-lateral non-implanted ears, patients can also receive additional benefit from "bimodal" listening (Armstrong et al, 1997; Ching et al, 2004; Dorman et al, 2008). This appears to improve sound quality, music perception (Dorman et al, 2008; Kong et al, 2005; El Fata et al, 2009), and speech recognition, particularly in noise (Armstrong et al, 1997; Ching et al, 2004; Dorman et al, 2008; Kong et al, 2005).

More recently ipsilateral combination of electrical and acoustic hearing (electric-acoustic, EAS, or "Hybrid" stimulation) has been the focus with benefits for speech recognition and sound quality (Von Ilberg et al, 1999; Gantz & Turner, 2003; Fraysse et al, 2006; Lenarz et al, 2009) especially when the best-aided so-called "combined" condition is tested; that is using the CI plus bilateral residual hearing with hearing aids. Typically Hybrid candidates have symmetrical bilateral profound high-frequency sensorineural hearing loss with only mild or moderate hearing loss in the low-frequencies. Thus a parsimonious solution for Hybrid patients is to provide low-frequency stimulation via residual hearing (with/without amplification depending upon the hearing loss) and complement this with mid- and high-frequency speech information via a CI. As such Hybrid (e.g. Nucleus) or EAS (MedEl) sound processors (SP) have been conceived that allow the user to wear a single integrated device in the implanted ear along with a hearing aid (if still necessary) in the contra-lateral ear.

Access to low-frequency harmonics via residual acoustic hearing appears to improve the representation of certain speech cues such as F1 (Qin & Oxenham, 2006; Mok et al, 2006) compared to CI alone. The increased salience of voice pitch (F0) in acoustic hearing may allow the target talker voice to be better segregated from the noise background (Turner et al, 2004; Qin & Oxenham, 2006; Büchner et al, 2009; Zhang et al, 2010). Certainly the low-frequency range up to and including 500 Hz (Qin & Oxenham, 2006; Büchner et al, 2009; Zhang et al, 2010) provides the majority of benefit when listening in the presence of a competing talker or talkers; but even residual hearing up to 250–300 Hz appears to provide some benefit (Qin & Oxenham, 2006; Büchner et al, 2009; Zhang et al, 2010). The complementary benefits of residual hearing and CI appear to apply in both contralateral and ipsilateral configurations (Turner et al, 2004; James et al, 2006) both for speech, and also for music (Gfeller et al, 2006; El Fata et al, 2009).

In order to benefit from ipsilateral electric-acoustic stimulation a pre-requisite is to preserve residual hearing after introduction of the electrode array. The Nucleus Hybrid L24 CI was developed with an optimal combination of electrode length and number of channels with a new straight, lateral wall, electrode array. The electrode array has 22 electrodes spread over 15 mm with an anticipated insertion depth of 16–17 mm (Lenarz et al, 2006; Briggs et al, 2006) to obtain a maximum angle of about 270° corresponding to approximately 2000 Hz (Greenwood, 1990; Stakhovskaya et al, 2007; Escudé et al, 2006; Lenarz et al, 2009). The electrode was designed to be inserted via the round window. A winglet is attached to the electrode lead to avoid rotation of the electrode carrier inside the scala tympani, and consequently that electrode contacts may face away from the modiolus. In addition the winglet can be used to help secure the electrode lead.

Results of a preliminary single-centre trial with twenty-four Hybrid L24 recipients were promising, with median threshold increases for the implant ear at 1–2 months post-op of 10 dB for frequencies up to 1000 Hz (Lenarz et al, 2009).

The aim of the current study was to evaluate the preservation of residual hearing, initially and up to one year post-implantation, in a larger number of patients recruited from a number of centres and surgeons. Audiometric thresholds and speech perception tests in quiet and in noise were administered for each subject preoperatively and postoperatively in their best-aided condition. In addition, self assessment of hearing ability and quality of life questionnaires were administered: the speech, spatial and qualities of hearing scale (Gatehouse & Noble, 2004), and the health utilities index mark 3 (Feeny et al, 2002; Horsman et al, 2003) .

Additional speech tests were administered in different combinations of electrical and acoustical stimulation in order to evaluate the functional benefit of residual hearing in either, or both ears.

Methods

Subjects

Sixty-six subjects were recruited prospectively from 16 CI centres; mean 4.1 (range 2–17, SD 3.8) subjects per centre. Data from 8/17 of the subjects from the lead author's centre had been included in the analysis of residual hearing at one month post-op in Lenarz et al, 2009. These subjects were followed up to one year in the current analysis.

Inclusion criteria

Subjects were 18 years of age or older with post-linguistic onset of severe to profound high-frequency sensorineural hearing loss;

≥80 dB HL for frequencies >1500 Hz and mild to moderate sensorineural hearing loss; ≤60 dB HL for frequencies <500 Hz. In addition thresholds could fall up to 10 dB outside these limits for up to two frequencies. There were no audiometric restrictions for contralateral ears. The estimated duration of hearing loss was <30 years. The inclusion criteria defined that subjects should have limited open-set word recognition even with well-fitted hearing aids; defined as aided (appropriately fitted hearing aid) word recognition scores (mean of two lists) between 10% and 50% inclusive in the ear to be implanted and ≤60% in the contralateral ear, when presented in quiet at 65 dB SPL. Subjects had experience with high power hearing aids for a minimum of six weeks prior to enrolment. Seven subjects (Figure 2, left) had pre-operative word scores in quiet for the CI ear >50% which may have been due to improved hearing-aid fitting after initial inclusion or differences between the standard test level (i.e. 70 dB for some languages/centres) and the criterion level of 65 dB SPL. The same effect may have applied to the non-implant ear in some cases, in addition to potential summation between ears, such that pre-operative "both ears" scores exceeded 60% correct in twelve cases (Figure 2, right).

Exclusion criteria

Patients were not included who showed signs of ossification or any other cochlear anomaly that might prevent complete insertion of the electrode array, as confirmed by medical examination and imaging. Patients with congenital severe to profound hearing loss or signs of retrocochlear or central hearing impairment, active middle-ear infections or tympanic membrane perforation were excluded. As well, additional handicaps or psychological complaints that would prevent participation in evaluations, or unrealistic expectations regarding the possible benefits, risks, and limitations of the procedure or device disqualified patients from participating.

Surgery

All surgeons were trained in the round-window technique described by Lenarz et al, 2009. A surgery questionnaire was used to help verify deviations from the recommended technique. Corticosteroids were administered systemically, starting just prior to surgery, 1 to 4 mg/kg depending upon centres' specific protocols. Surgical technique followed the usual "posterior-tympanotomy" approach used for CI surgery, followed by excavation of the receiver-stimulator bed. The anterior lip of the round window niche was removed to expose the round window membrane. A 22 gauge needle was used to open a hole in the round window membrane through which the electrode array was inserted up to the stopper (silicon shoulder). Fascia was packed around the entry of the electrode into the round window membrane to seal the scala tympani. A niche was made in the posterior tympanotomy, between chorda tympani and facial nerve to allow the winglet to be used to aid fixing the electrode in place. In many centres subjects were also given oral corticosteroids up to three days post surgery.

Sound processor programming and hearing aids

Device activation was performed approximately one month after surgery. Early recruited subjects' CIs were initially activated with a standard Freedom SP and they used a separate, commercially-available, in-the-ear (ITE) hearing aid for amplification in the CI ear. Later, separate hearing aids were replaced with a receiver-in-the-ear RITE acoustic component connected to a Freedom SP. For this configuration customized CustomSound "Hybrid" software was used to program the acoustic component. The acoustic signal path consisted of an eight-band compression system with a total bandwidth of 2000 Hz, thus providing great flexibility when fitting to the threshold profile. DSL (desired sensation level) linear targets were used as a starting point for programming gain and MPO. Acoustic channels were de-activated where thresholds exceeded 90 dB HL. This system was functionally equivalent to the now commercially available Nucleus Freedom Hybrid SP which uses an ear-hook level connecter to the acoustic component.

For the CI path, the lower boundary of the lowest-frequency channel (i.e. to the most apical active electrode) was set as close as possible to the frequency where threshold just exceeded 80 dB HL. Thus the aim was to provide complementary acoustic and electric coverage of the complete frequency range in a "non-overlapping" fashion as in the MAP-C program described by Fraysse et al (2006). The choice of this configuration ensured that amplification would be sufficient in the acoustic range, with aided thresholds ensured by the CI above this range (25–35 dB SPL). Thus the pure-tone audiogram determined which range of frequencies corresponded to "useful" residual hearing and which should be mapped to the implant (Simpson et al, 2009). Previous experience with patients implanted with Contour electrodes showed either a strong preference for this configuration, or no particular preference between overlapping versus non-overlapping configurations.

By default the four most basal electrodes were deactivated, as had been found in the previous trial with the device, to avoid facial and non-auditory stimulation (Lenarz et al, 2009). Threshold T and comfortable C levels were measured at 900 pps for each electrode and ACE with 8 maxima was used for sound coding. Adjustments to gain and MPO, pulse rate and maxima were made in order optimize sound quality and comfort.

Most subjects continued to use their existing acoustic hearing aids in non-implant ears; the performance of these was verified by a local audiologist, but no particular method was specified to fit them.

Procedures

Air-conduction thresholds for pure tones were measured during the pre-operative visit and one month post-operative visit when the CI was activated, followed by visits at three and six months, and one year (i.e. 12–14 months post-op). Speech recognition scores were obtained at intervals, but are presented here for the one year (primary end point) interval only. Tests were performed according to local languages and procedures, both in quiet and in noise. Pre-operatively scores were obtained for the ear to be implanted alone (other ear plugged) and in the best-aided condition. Post-operatively scores were obtained for the implanted ear alone (combining electric and acoustic hearing, or "hybrid" hearing) and in the best-aided (so-called "combined") condition. In many cases scores were also obtained for CI alone (both ears plugged) and CI plus contra-lateral ear (CI ear plugged).

Word tests were used in all seven languages for speech recognition in quiet, with speech levels 60–70 dB SPL according to local procedures. Lists of disyllabic words were used in France (Fournier lists, 20 items), Italy (GN Resound 2000, 20 items) and Spain (University of Navarra, Adult, 25 items). Lists of monosyllabic words were used in Belgium (NVA, 40 items), Germany (Freiburg monosyllables, 20 items), the Netherlands (NVA, 20 items) and United Kingdom (AB words, 20 items).

For testing in noise most centres used a fixed SNR of 10 dB. However in German, Spanish, and Dutch centres adaptive SNR tests were used. Sentence lists were used in all centres.

SSQ and HUI mk3 questionnaires were administered pre-operatively and at nine months to one year post-operatively. Fewer data points were available for these comparisons due to the addition of these in an amendment after the start of the study.

Statistical analyses

Group mean, median, and median changes in pure-tone thresholds were calculated for each audiometric test frequency for the group at each follow-up interval (Fraysse et al, 2006). Only pre-operative thresholds within audiometer limits were used in calculations of pre- to post-op changes. Post-operative thresholds above audiometer limits were imputed at 999 dB HL in calculations (>85 dB HL @ 125 Hz, >110 dB HL @ 250 Hz, >120 dB HL @ ≥ 500 Hz). This allowed easy identification of aggregate levels indicating "no response".

Speech recognition scores were compared in a single-subject repeated measures design such that the effects of inter-subject differences and inter-language differences were largely controlled for: Percent correct scores and SNR thresholds were compared in two ways. Firstly raw scores for the different visits/conditions were subjected to repeated-measures (RM) analysis of variance (ANOVA), with additional post-hoc comparisons. Non-parametric tests were used where data were not normally distributed or not equivariant. Secondly, proportions of scores with a difference between conditions/intervals of at least 20 %age points or 2 dB SNR were calculated. 20 %age points or 2 dB SNR were considered both clinically and statistically significant by the current authors when comparing a given individual's scores at different intervals (for reference see also UKCISG, 2004a).

The study was performed in accordance with ISO 14155 (2003). Local ethical approval was obtained for all study sites, and all subjects gave informed consent.

Results

Population demographics

Subjects were aged 21 to 81 years at implantation, mean 53.46 (SD 12.71) years. Seventy-nine percent of subjects were female; 53% were implanted in their right ear. The mean duration of severe/profound high-frequency hearing loss in the implant ear was 13.4 (SD 12.2) years, range 0–58. Five percent of subjects had a congenital component of hearing loss, 83% had progressively lost their hearing.

Causes of deafness were unknown in 54% of subjects, familial in 19%, ototoxic drugs in 6%. In the remaining: for two subjects otosclerosis, then for single cases measles, Ménière's disease, noise, vestibular nerve section (non-implant ear), purpura fulminans, sepsis and Pendred syndrome. Prior to surgery 58% of subjects reported that they experienced tinnitus in the ear to be implanted; 56% suffered from bilateral tinnitus. Prior to implantation 77% of subjects wore bilateral hearing aids, 10% were unilaterally aided, and 13% wore no hearing aids. 83% of subjects wore a hearing aid in the ear to be implanted.

Prior or current medical problems were reported by 37/66 subjects. Principle co-morbidities are reported in Table 1. In addition to those listed there were single cases with multiple limb amputation, operated-for brain tumour, operated-for vestibular schwannoma, and sectioned vestibular nerve.

Table 1. Prior or current co-morbidities of significant prevalence (% of those 37/66 reporting co-morbidity).

Health problem	*Prevalence*
Gynecological	19%
Hypertension	19%
Thyroid	16%
Appendix	14%
Cardiologic	14%
Nasopharyngeal	14%
Asthma	11%
Hypercholesterolemia	11%
Severe trauma	8%

Missing data

One subject withdrew after one month follow-up due to non-device-related health problems. A further four subjects withdrew after six months follow-up. Thus threshold data were missing at the one year primary endpoint for a total of five subjects. A number of speech recognition measurements were logically missed out by investigators due to the absence of residual hearing in either one or both ears. Where missing at one year, 6-month speech recognition scores were used if available for CI ear and best-aided pre to post-operative comparisons. Due to clinic time constraints, some conditions such as bimodal and/or CI-alone were missed out in many cases. Paired pre/post-op data were available for 64/66 subjects for the implant ear and 55/66 for the best-aided condition.

Hearing preservation

A summary of pre-operative and post-operative air-conduction thresholds is shown in Figure 1 for implant ears of 66 subjects at 1 month post-operative follow-up (upper left), and 61/66 subjects with one year follow-up (upper right). Thresholds in non-implant ears were available for 44/66 subjects (Figure 1, lower).

Eighty-nine percent of low-frequency hearing thresholds (125, 250, and 500 Hz) were preserved within ≤ 30 dB at 1-m/initial fitting. The data shown in Figure 1 (upper) indicates that some progression of hearing loss occurred over time in the implant ear. Threshold increases ≤ 10 dB were considered as hearing "completely conserved", and ≤ 30 dB as "partially or completely conserved". The proportions of cases by visit are shown in Table 2, for the most sensitive frequency of 500 Hz. At one month, 61% of cases had increases ≤ 10 dB, and 89% ≤ 30 dB. At one year these proportions had reduced to 43% ≤ 10 dB, and 74% ≤ 30 dB. A separate analysis was performed removing those cases (N = 5) without complete one-year follow-up; the resulting percentages were similar. Thresholds for the lowest frequencies 125 and 250 Hz were better conserved than those for 500 Hz (Figure 1 upper right, median change 10 dB versus 20 dB). There was no systematic loss of hearing over time across the population for non-implant ears (Figure 1 lower).

Speech recognition: Overall benefit

Pre- to post-operative speech recognition scores for words presented in quiet are shown in Figures 2 & 3, and for words in sentences presented in noise in Figures 4 & 5.

There were significant correlations between pre- and post-op scores for the implant ear (Figure 2 left) and for best-aided/both ears conditions (Figure 2 right). Seventy percent of cases improved

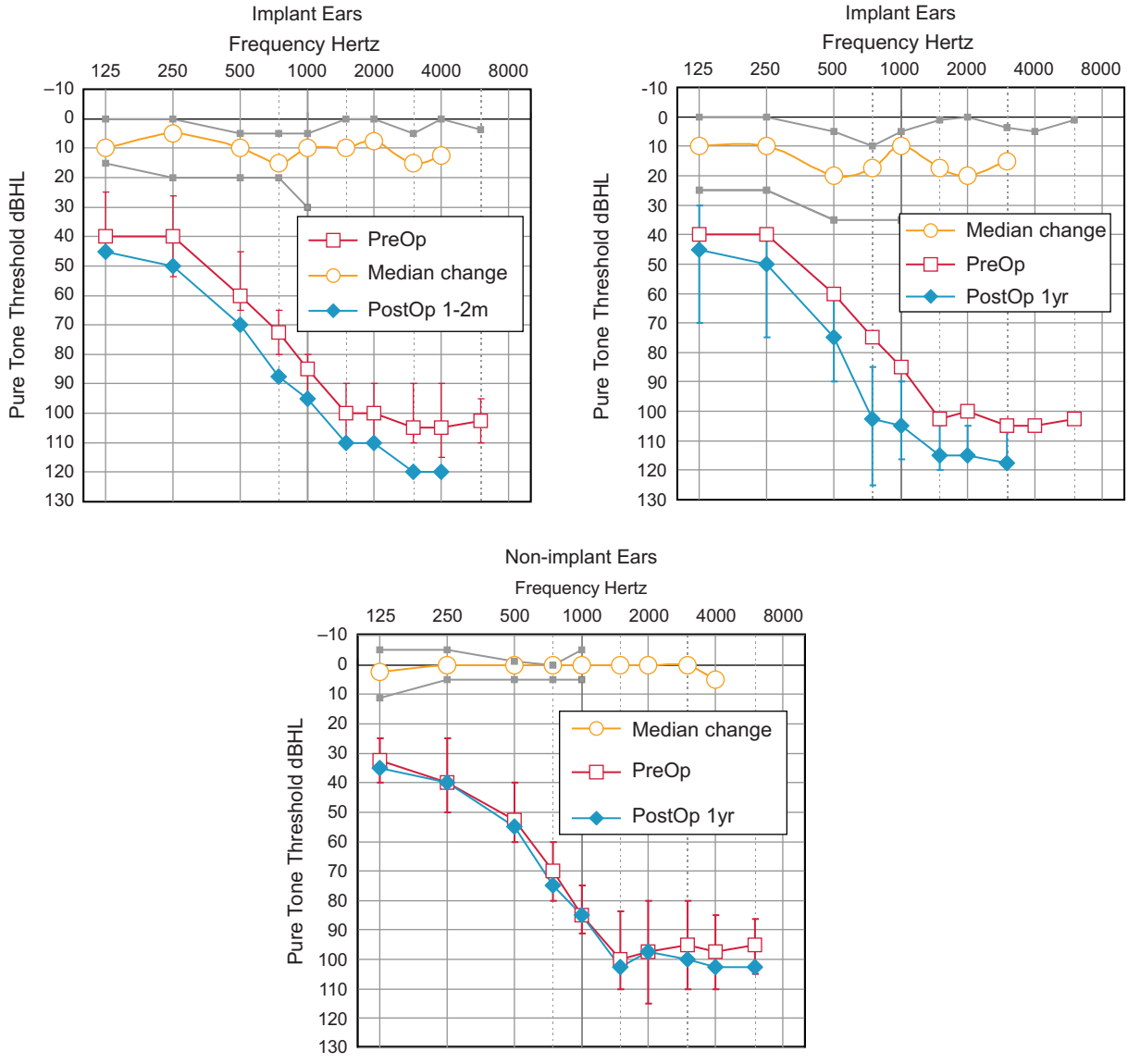

Figure 1. Median pure-tone air-conduction hearing threshold levels: Implanted ears at 1–2 months post-op (upper left, N = 66), and one year post-op (upper right, N = 61), and non-implant ears (lower, N = 48) one year post-op. Median pre- to post- differences are shown (circles-solid lines) with inter-quartile ranges (small points lines).

by ≥ 20 percentage points on speech recognition in quiet for the CI ear, and 65% for both ears (Figure 1 right, increase > 20 %age points limited in two cases because pre-op scores were > 80%).

There were 16/61 cases (26%) where 500 Hz thresholds increased by > 30 dB in the implant ear by one year. This group included four cases where scores worsened in quiet by ≥ 20 %age points for the CI ear. For the remainder, 4/16 had considerable gains in speech scores (55–65 %age points) and 8/16 either a slight decrement or slight gain in score.

Group data are summarized in Figure 3. A one-way RM ANOVA (interval-condition) was performed on recognition scores; all differences in mean scores between intervals/conditions were highly significant ($p < 0.001$, post-hoc Holm-Sidak). Mean benefit in quiet was 32 %age points for the CI ear, and 28 %age points for the best-aided condition.

Separate one-way RM ANOVAs (interval-condition) were performed on ranked scores (Friedman test) obtained with the 44 subjects tested in fixed 10 dB SNR. Increases in median scores were 42 %age points for the CI ear and 38 %age points for both ears/best aided (significant differences, $p < 0.05$, Tukey, Figure 4).

In some centres adaptive SNR speech in noise tests were used. For cases missing pre-operative data, these were imputed to a conservative SRT of 7.24 dB SNR where the test was performed but did not converge (e.g. rather than an arbitrary value of 20 dB as is sometimes used). This level was determined from the data of Lenarz et al (2009), from regression analysis. 7.24 dB SNR corresponded to Hybrid candidates obtaining 50% correct on the German Freiburg word test in quiet; it therefore gave a conservative upper limit on pre-operative SNR. The group data are presented in Figure 5. A one-way RM-ANOVA (interval-condition) was performed on ranked SRTs (Friedman test). Increases in median SRT were 6.1 dB for the implant ear and 6.5 dB for best aided (significant differences, $p < 0.05$, Tukey).

Table 2. Proportions of subjects with increases in thresholds at 500 Hz of ≤ 10 dB and ≤ 30 dB for different intervals, and proportions with < 90 dB HL. Data were similar when comparing N = 61 at all intervals. Changes in thresholds at 125 and 250 Hz were largely correlated with those at 500 Hz.

Post-op interval	*N*	*Increase ≤ 10 dB*	*Increase ≤ 30 dB*	*< 90 dB HL*
One month/initial fitting	66	61%	89%	98%
+3 months	65	58%	88%	97%
+6 months	64	55%	81%	92%
+9 months	64	39%	77%	88%
+1 year	61	43%	74%	88%

Overall, 73% of subjects improved their speech recognition score in noise by ≥ 20 %age points or ≥ 2 dB SNR. At one year post-op, 88% of cases combined electric and residual acoustic hearing in the implant ear (i.e. used Hybrid stimulation) which was also the proportion who retained thresholds < 90 dB HL at 500 Hz.

Speech recognition: Combining CI with residual hearing

In all noise conditions post-op there were no significant differences in scores/SNR using both ears/best aided versus using the implant ear alone with residual hearing (Figures 2–5). In order to further elucidate the probable benefits of using residual hearing in either/both ears for speech recognition, separate analyses were performed on data where a complete set of listening conditions ear/device combinations had been tested for a given subject. Hearing aids were removed and ears plugged with a noise-protecting foam ear plug and circumaural ear defenders to exclude using residual hearing in one or both ears. Speech recognition data were available for 54/66 subjects tested in quiet, 24/66 tested in fixed 10-dB SNR, and 34/66 with adaptive SNR tests. Group results are shown in Figures 6–8.

Separate 2-way RM ANOVAs (Implant ear/both ears, pre-op/CI/Hybrid) were performed on percent correct scores. A one-way RM ANOVA was performed on ranks (Friedman) for adaptive SNR SRTs. All mean differences were statistically significant (at least $p < 0.05$) except as indicated (NS).

Scores for the CI used alone (CI – implant ear) were extremely heterogeneous with a mean difference of 20 %age points in quiet versus using pre-operative hearing aid (Pre op – implant ear), and slightly less in noise.

Summarizing the results in Figures 6–8, the analyses indicated that residual hearing in either ear combined with CI significantly improved speech recognition compared to CI alone, either in quiet or in noise. The benefit was on average about 20 %age points or 2 dB SNR (CI – implant ear versus Hybrid – implant ear ≅ CI – both ears). For the best-aided condition (Hybrid – both ears), often termed "combined", there was a slight improvement (5–7 %age points, NS) for performance in quiet or in 10 dB-SNR noise over using residual hearing in either ear with CI. It should be remembered that these data represent a feature of our prospectively studied population and that we did not "select" *a priori* subjects with well preserved residual hearing as is often the case in experimental studies. Indeed for 12% of subjects, scores for CI conditions were equal to those for the corresponding Hybrid condition (implant ear, or both ears).

Speech spatial qualities (SSQ) scale

Subjects rated listening situations on a 0–10 point scale (Gatehouse & Noble, 2004). Pre-operative and post-operative (eight months to one year) group results are given in Figure 9. Separate paired-t tests were performed for each subscale; 40 pre-op/post-op subject-matched pairs were available for analyses. Mean differences in ratings pre- to post-op were 1.2, 1.3, and 1.8 for speech, spatial, and quality subscales respectively (all differences significant, $p < 0.001$).

Health utility index

Twenty-nine subjects completed HUI mk3 questionnaires pre-operatively, just prior to implantation, and 38 post-operatively by the one-year visit. Mean pre- and post-op scores are shown in Figure 10. The difference between mean pre-op and mean post-op multi-attribute HUI3 scores was + 0.117 (t-test, $p < 0.01$, effect size Cohen's $d =$ 0.67). As expected the largest benefit was seen for "hearing" single-attribute score. Of subjects with paired data (N = 27), 59% had an improvement in HUI3 score of > + 0.03; defined as "clinically important", according Horsman et al (2003).

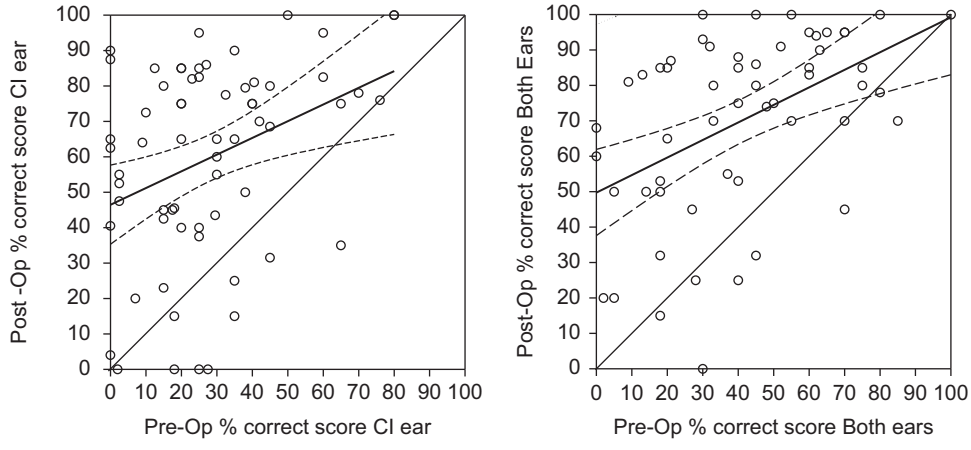

Figure 2. Post-operative versus pre-operative word recognition scores in quiet for implant ear alone (left panel, N = 64), and best aided listening (right panel, N = 55). Linear regressions of data ($p \leq 0.005$) are shown (solid lines) with 95% confidence intervals (long dash).

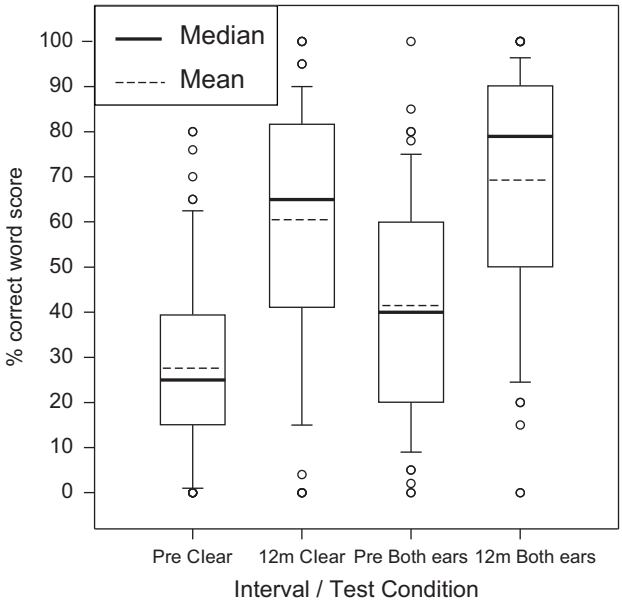

Figure 3. Group data for speech recognition in quiet by visit and condition (N = 64 CI ear, N = 55 Both ears). Horizontal mid-lines are group median (solid line) and mean (dashed line) scores; box limits 25th/75th percentiles, and whiskers 10th/90th percentiles.

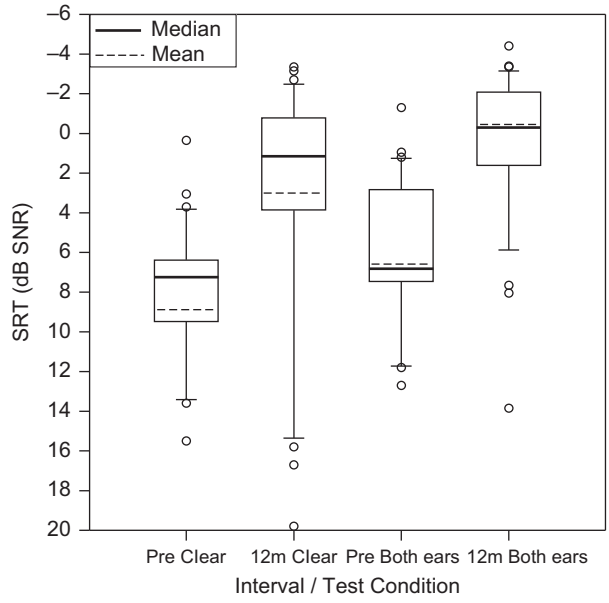

Figure 5. Group data for speech recognition in noise for adaptive SNR SRT tests (N = 30), by visit and condition. Horizontal mid-lines are group median (solid line) and mean (dashed line) scores; box limits 25th/75th percentiles, and whiskers 10th/90th percentiles.

Interrelations among performance measures

Speech recognition scores were highly correlated between different test conditions (CI/both ear, quiet/noise) at any given interval. As reported above there were very significant correlations (i.e. $p < 0.01$) between pre- and post-op speech recognition scores for words presented in quiet, however this was not the case for scores for 10 dB SNR (implant ear, $r = 0.299$, $p = 0.122$, best-aided, $r = 0.415$, $p = 0.035$). Furthermore there was only one very significant inter-measure correlation; post-operative best-aided speech scores were correlated with post-operative SSQ quality subscale scores ($r = 0.395$, $p < 0.01$).

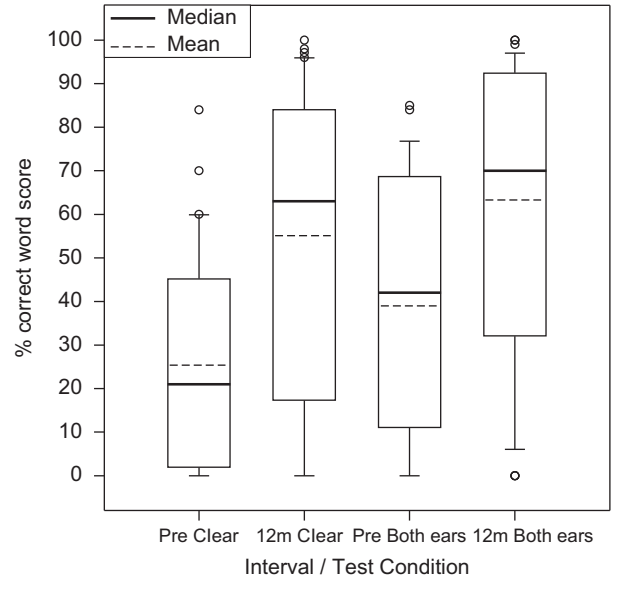

Figure 4. Group data for speech recognition in fixed 10 dB SNR noise (N = 28), by visit and condition. Horizontal mid-lines are group median (solid line) and mean (dashed line) scores; box limits 25th/75th percentiles, and whiskers 10th/90th percentiles.

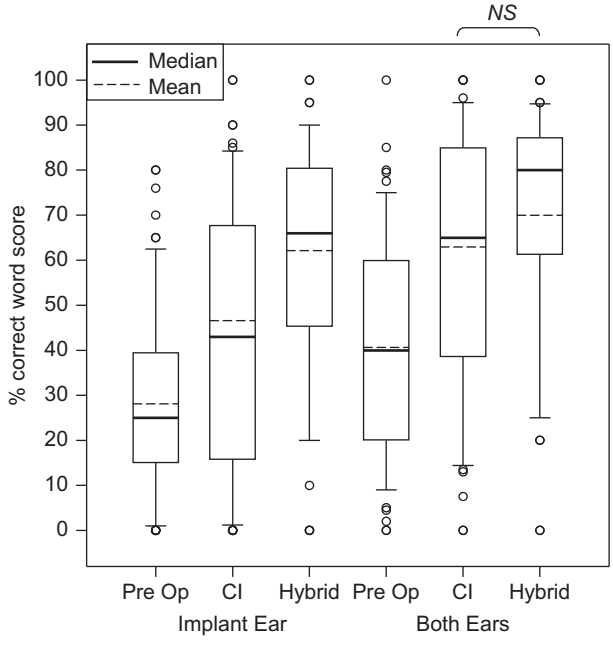

Figure 6. Group data for speech recognition in quiet by listening condition for a set of patients with complete data (N = 54). Horizontal mid-lines are group median (solid line) and mean (dashed line) scores; box limits 25th/75th percentiles, and whiskers 10th/90th percentiles. All differences except that marked NS were statistically significant ($p < 0.05$).

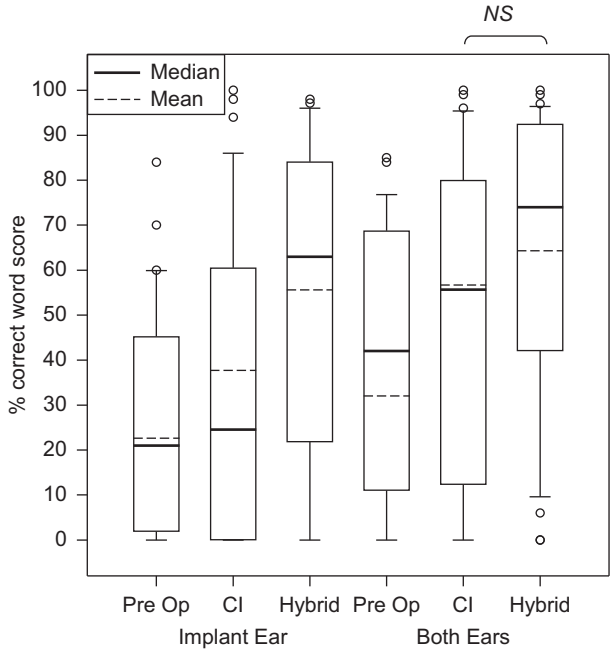

Figure 7. Group data for speech recognition in fixed 10 dB SNR (N = 24) by listening condition for a subset of patients with complete data. Horizontal mid-lines are group median (solid line) and mean (dashed line) scores; box limits 25th/75th percentiles, and whiskers 10th/90th percentiles. All differences except those marked NS were statistically significant ($p < 0.05$).

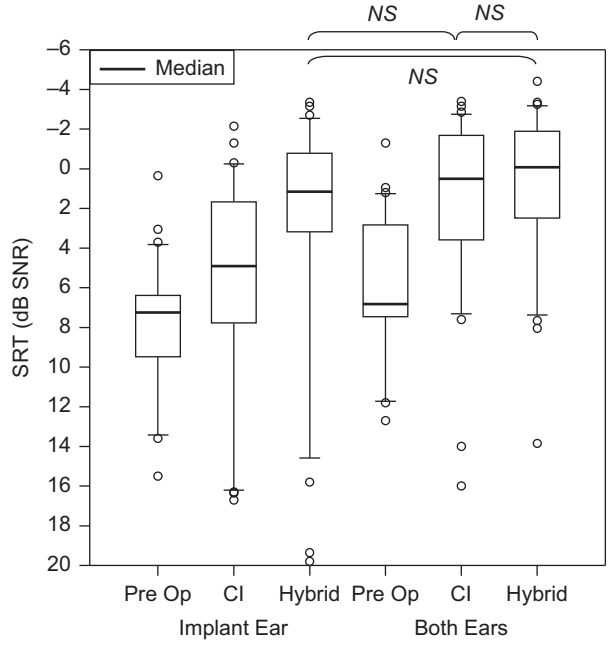

Figure 8. Group data for speech recognition in noise for adaptive SNR SRT tests by condition for a subset of subjects with complete data (N = 34). Horizontal mid-lines are group median scores; box limits 25th/75th percentiles, and whiskers 10th/90th percentiles. NS: Differences in medians not statistically significant ($p \geq 0.05$).

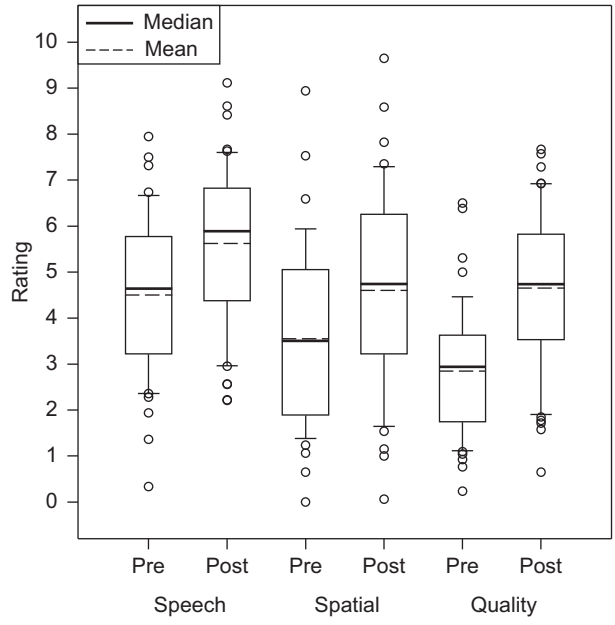

Figure 9. Group ratings for each SSQ subscale (speech/quality N = 40, spatial N = 37). Horizontal mid-lines are group median (solid line) and mean (dashed line) scores; box limits 25th/75th percentiles, and whiskers 10th/90th percentiles. Mean differences pre/post on each subscale were statistically significant ($p < 0.001$).

Discussion

The Nucleus Hybrid L24 electrode array was principally designed to optimize conservation of residual hearing after implantation. In our study residual hearing at 500 Hz was partially preserved (increase ≤ 30 dB) initially in 89% of subjects with one month follow-up (Table 2) with some degradation over time with ≤ 30 dB threshold increase in 74% of subjects at one year. Eighty-eight percent of subjects were using Hybrid stimulation in the implant ear at one year with pure-tone thresholds < 90 dB HL at 500 Hz. Thus a large majority of subjects could still combine useful residual hearing with the cochlear implant in the implanted ear by using a Freedom Hybrid SP with an acoustic sound amplification component.

Preservation of residual hearing implies that there was little or no trauma to the cochlea due to introduction of the electrode array. Low-trauma in itself may provide better performance from a cochlear implant (Finley et al, 2008) and will also conserve the inner ear for future treatment strategies (e.g. regeneration of hair cells).

Pre-operatively the population studied had a substantial receptive communication deficit as born out by their limited open-set speech recognition performance. When using the Nucleus Hybrid L24 cochlear implant in combination with residual hearing in one or both ears, speech recognition performance was substantially (≥ 20 %age points) improved for 65% of subjects for listening in quiet (Figure 2), and for 73% of subjects (≥ 20 %age points or ≥ 2 dB SNR) when listening in noise (Figure 3). The proportion of subjects obtaining substantial benefit for speech recognition in quiet is similar to that reported in the literature for standard cochlear implant recipients. For example, in the UK unilateral study (UKCISG, 2004a) proportions of subjects with non-zero pre-operative sentence recognition in quiet scores ("MHUs") who obtained ≥ 20 %age points benefit were 64% or 77% depending upon the configuration of hearing loss; zero score for the implant ear, or non-zero score for the implant ear. From this

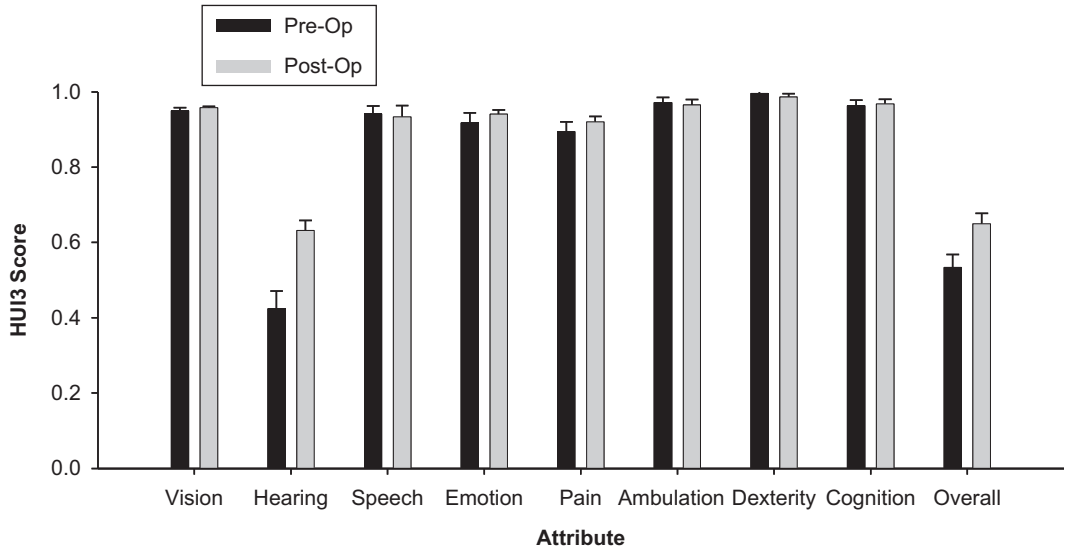

Figure 10. Group mean pre- (N = 29) and post-op (N = 38) HUI3 scores for single-attribute and "overall" multi-attribute heath utility functions. Error bars are standard errors of means.

point of view the Hybrid L24 CI can be considered as effective a treatment for our group of subjects as standard cochlear implantation is in standard CI candidates, as far as improving receptive communication ability. The average improvement in score after about one year's use for words presented in quiet was 28 %age points, and for speech in noise at 10 dB SNR was 38 %age points. This represents a substantial gain in speech understanding, particularly in noise. The results of this study confirm that the Nucleus Hybrid CI device is an effective treatment for patients with severe-to-profound levels of high-frequency sensorineural hearing loss. For example, at one year post-operatively 65% of subjects scored greater than 50% correct on word tests in quiet (Figure 2, left), or on average 65% correct (Figure 3) which would allow for basic use of the telephone. Furthermore 59% of subjects with pre- and post-op HUI3 scores obtained clinically important (>0.03) gain in health related quality of life score.

As mentioned above, there is always some risk of losing residual hearing in the implanted ear due to introduction of an electrode array. In this study 74% of subjects retained residual hearing within 30 dB of pre-operative levels over time, and roughly half retained hearing within 15 dB. These results are similar to the previous single-centre study with the Hybrid L24 (Lenarz et al, 2009) where median threshold increase was 10 dB.

Other types of cochlear implant, usually with longer electrode arrays, have been evaluated in similar populations of subjects with substantial low-frequency residual hearing. Improvements in speech recognition scores using the 16-mm Nucleus Hybrid CI were similar to those obtained with other "standard" CI devices, usually with longer electrode arrays (UKCISG, 2004a). However preservation of residual hearing in the present study was generally better than often reported in the literature for longer electrodes/greater insertion depths in terms of median loss across the population (15 dB at one year, e.g. Skarzynski et al, 2012) but worse compared to the best results in terms of the percentage occurrence of large losses >30 dB. This may be attributed to the heterogeneity of the current population studied (i.e. co-morbidities) and the large number of surgeons/centres involved compared to single-centre results often reported in the literature. Nevertheless despite a residual risk of losing residual hearing in this population, overall use of the Hybrid L24 provided nearly the same chance of improving speech recognition scores significantly when compared to conventional CI candidates (UKCISG, 2004a) with reportedly much lower levels of residual hearing and speech recognition function. In our population with substantial levels of low-frequency residual hearing we showed that the Hybrid L24 device provided significant improvements in subjective sound perception (SSQ scores, Figure 9) and significant improvements in HRQL score (HUI3, Figure 10) over the use of hearing aids.

The majority of the population studied could be compared to borderline candidates for conventional CIs in terms of their low pre-operative speech recognition scores; however two-thirds of subjects had substantial levels of low-frequency residual hearing (i.e. 500 Hz threshold ≤ 60 dB) and thus cannot be directly compared to conventional candidates.

The remaining third (i.e. 500 Hz threshold >60 dB) could be considered as borderline candidates for conventional CI, and it is questionable whether the Hybrid cochlear implant system is the most suitable device for them. Given their higher degree of pre-operative hearing loss, the probability of maintaining useful levels of residual hearing over time is reduced. These cases may be better off using a longer or "full" electrode array in combination with their contralateral and usually better-hearing ear.

The usefulness of residual hearing when combined with electrical stimulation via a CI has been reported in a number of studies and has been shown to improve speech recognition performance, particularly in competing background noise and sound quality, including the appreciation of music (e.g. Armstrong et al, 1997; Kong et al, 2005; El Fata et al, 2009). It can be seen from Figures 6–8 that combining residual hearing from either ear with the CI provided significant improvements in speech recognition scores. The simulated "bimodal" and CI alone conditions presented here did not account for the signal bandwidth processed by the CI using MAP-C which was generally reduced compared to a standard CI. This may have acted to accentuate the difference in score between using CI alone or in combination with either/both ears (~20 %age points). Conversely

the incomplete exclusion of acoustic information by ear plugs and ear defender (estimated to be ~ 30 dB in the low frequencies) may have reduced the size of these differences.

As a general principle, the aim of cochlear implantation is to provide benefit in terms of improvements in speech recognition. Thus, a pre-requisite for benefit should be limited pre-operative speech recognition performance using well-fitted hearing aids where the type of audiogram allows. However there were significant linear correlations between pre- and post-operative speech recognition scores (see Results and, e.g. Figure 2) and thus benefit in this respect was roughly constant across different levels of pre-operative performance and even subjects with $>50\%$ correct scores could still obtain >20 %age points benefit. The best prognostic factor for poor performance with CI is a long duration of severe-to-profound hearing loss (Blamey et al, 1996). Thus caution should be applied when treating patients with significant pre-operative speech recognition scores who are known to have hearing loss of long duration (e.g. >30 years or since birth or early childhood) since these patients may receive little or no benefit from cochlear implantation and there is a risk of losing some or all residual hearing.

For the 16 subjects whose 500 Hz thresholds increased by >30 dB, 4/16 still obtained a large gain in speech recognition score for the implant ear (55–65 %age points) although the remainder either had no change (8/16) or a reduced score. As mentioned above no significant gain in speech recognition performance after cochlear implantation was also previously reported in the UK unilateral CI trial (UKCISG, 2004a) for approximately 30% patients with non-zero pre-operative scores. In the present study the combination of loss of residual hearing, which had provided non-zero pre-operative speech scores, combined with no benefit from the cochlear implant, could result in negative benefit. It may be the case that in choosing the "worse" ear to be implanted, as in our study, that we may have potentially limited the outcome with CI for some subjects.

The specific benefit provided by the design of this device over other CI devices is the ease of introduction of the electrode array; it is easy to insert into the cochlea via the round window membrane, thus removing the trauma produced by drilling a cochleostomy hole and assuring that the electrode is inserted into the scala tympany. The reduced thickness and controlled flexibility of the Hybrid L24 compared to other devices appears also to allow largely atraumatic insertion into the cochlea. Overall insertion of the Hybrid L24 in this study via the round-window was rated either "very easy", "easy", or "acceptable" in 83% of cases.

During the study there were three adverse events reported which may have related to the device or surgery; these were prickling pain below the eye/sinusitis, middle-ear infection, and dizziness. All were resolved. In addition, in two cases the receiver stimulator needed to be re-positioned due to poor fixation, and in one case X-ray confirmed partial extrusion of the electrode array. There was no noticeable impact on performance for these cases.

Conclusions

Hearing conservation using the Nucleus Hybrid L24 cochlear implant, inserted via the round window was studied in 66 subjects with significant low-frequency residual hearing. Low-frequency residual hearing was well conserved up to one year; thresholds increases at 500 Hz were ≤ 30 dB for 74% of subjects. Speech recognition scores in quiet were significantly improved (≥ 20 %age points) for 65% of subjects, and for 73% of subjects in noise. Mean speech, spatial, and quality subscale ratings were significantly improved by 1.2 to 1.8 points. Mean health related quality of life HUI3 score significantly improved by 0.117. Thus subjects received substantial benefit in terms of performance, subjective perception, and quality of life. Residual hearing combined with the Nucleus Hybrid L24 CI; either in the same ear using a Hybrid sound processor, or using the contralateral ear, significantly improved speech understanding in quiet and in noise.

Acknowledgements

The authors acknowledge the hard work of the unlisted members of clinical teams, and the subjects recruited to the study. We thank the journal's reviewers for their helpful comments.

Declaration of interest: This study was sponsored by Cochlear AG, Basel, Switzerland. CJ and JP are employees of Cochlear Corporation, the manufacturer of the device studied. The remaining authors report no conflicts of interest.

References

Armstrong M., Pegg P., James C.J. & Blamey P. 1997. Speech perception in noise with implant and hearing aid. *Am J Otol*, 18(6 Suppl.), S140–1.

Blamey P., Arndt P., Bergeron F., Bredberg G., Brimacombe J. et al. 1996. Factors affecting auditory performance of postlinguistically deaf adults using cochlear implants. *Audiol Neurootol*, 1(5), 293–306.

Briggs R.J.S., Tykocinski M., Xu J., Risi F., Svehla M. et al. 2006. Comparison of round window and cochleostomy approaches with a prototype hearing preservation electrode. *Audiol Neurootol*, 11 Suppl. 1, 42–8.

Büchner A., Schüssler M., Battmer R.D., Stöver T., Lesinski-Schiedat A. et al. 2009. Impact of low-frequency hearing. *Audiol Neurootol*, 14 Suppl. 1, 8–13.

Ching T., Dillon H. & Byrne D. 1998. Speech recognition of hearing-impaired listeners: Predictions from audibility and the limited role of high-frequency amplification. *J Acoust Soc Am*, 103(2), 1128–40.

Ching T., Incerti P. & Hill M. 2004. Binaural benefits for adults who use hearing aids and cochlear implants in opposite ears. *Ear Hear*, 25, 9–21.

Dorman M.F., Gifford R.H., Spahr A.J. & Mckarns S.A. 2008. The benefits of combining acoustic and electric stimulation for the recognition of speech, voice, and melodies. *Audiol Neurootol*, 13, 105–12.

Escudé B., James C.J., Deguine O., Cochard N., Eter E., et al. 2006. The size of the cochlea and predictions of insertion depth angles for cochlear implant electrodes. *Audiol Neurootol*, 11 Suppl. 1, 27–33.

El Fata F., James C.J., Laborde M-L. & Fraysse, B. 2009. How much residual hearing is "useful" for music perception with cochlear implants? *Audiol Neurootol*, 14 Suppl. 1, 14–21.

Feeny D., Furlong W., Torrance G.W., Goldsmith C.H., Zhu Z. et al. 2002. Multi-attribute and single-attribute utility functions for the health utilities index mark 3 system. *Med Care*, 40(2), 113–28.

Finley C.C., Holden T. Holden L.K., Whiting B.R., Chole R. et al. 2008. Role of electrode placement as a contributor to variability in cochlear implant outcomes. *Otol Neurotol*, 29(7), 920–8.

Fletcher H. & Galt R.H. 1950. The perception of speech and its relation to telephony. *J Acoust Soc Am*, 22(2), 89–151.

Fraysse B., Macías A.R., Sterkers O., Burdo S., Ramsden R. et al. 2006. Residual hearing conservation and electroacoustic stimulation with the nucleus 24 contour advance cochlear implant. *Otol Neurotol*, 27(5), 624–33.

Gantz B.J. & Turner, C.W., 2003. Combining electric and acoustical hearing. *Laryngoscope*, 113, 1726–1730.

Gatehouse S. & Noble W. 2004. The speech, spatial and qualities of hearing scale (SSQ). *Int J Audiol*, 43(2), 85–99.

Gfeller K.E., Olszewski C., Turner C., Gantz B. & Oleson J. 2006. Music perception with cochlear implants and residual hearing. *Audiology & neuro-otology*, 11, Suppl. 1, 12–5.

Gifford R.H., Dorman M.F., Spahr A.J. & McKarns S.A. 2007. Effect of digital frequency compression (DFC) on speech recognition in candidates for combined electric and acoustic stimulation (EAS). *J Speech Lang Hear Res*, 50(5), 1194–202.

Greenwood D.D. 1990. A cochlear frequency-position function for several species: 29 years later. *J Acoust Soc Am*, 87(6), 2592–605.

Hawthorne G., Hogan A., Giles E., Stewar, M., Kethel L. et al, 2004. Evaluating the health-related quality of life effects of cochlear implants: A prospective study of an adult cochlear implant program. *Int J Audiol*, 43(4), 183–92.

Hogan C.A. & Turner C.W., 1998. High-frequency audibility: Benefits for hearing-impaired listeners. *J Acoust Soc Am*, 104(1), 432–41.

Horsman J., Furlong W., Feeny D. & Torrance G. 2003. The health utilities index (HUI): Concepts, measurement properties, and applications. *Health Qual Life Outcomes*, 1, 54.

Von Ilberg C.A., Kiefer J., Tillein J., Pfenningdorff T., Hartmann R. et al. 1999. Electric-acoustic stimulation of the auditory system. New technology for severe hearing loss. *ORL J Otorhinolaryngol Relat Spec*, 61(6), 334–40.

James C.J., Fraysse B., Deguine O., Lenarz T., Mawman D. et al. 2006. Combined electroacoustic stimulation in conventional candidates for cochlear implantation. *Audiol Neurootol*, 11 Suppl. 1, 57–62.

Kong Y., Stickney G.S. & Zeng F.-G., 2005. Speech and melody recognition in binaurally combined acoustic and electric hearing. *J Acoust Soc Am*, 117(3 Pt 1), 1351–61.

Lenarz T., Stover T., Buechner A., Paasche G., Briggs R. et al. 2006. Temporal bone results and hearing preservation with a new straight electrode. *Audiol Neurootol*, 11 Suppl. 1, 34–41.

Lenarz T., Stöver T., Buechner A., Lesinski-Schiedat A., Patrick J. et al. 2009. Hearing conservation surgery using the Hybrid-L electrode. Results from the first clinical trial at the Medical University of Hannover. *Audiol Neurootol*, 14, Suppl. 1, 22–31.

Mok M., Grayden D., Dowell R.C. & Lawrence D. 2006. Speech perception for adults who use hearing aids in conjunction with cochlear implants in opposite ears. *J Speech Lang Hear Res*, 49(2), 338–51.

Qin M.K. & Oxenham A.J. 2006. Effects of introducing unprocessed low-frequency information on the reception of envelope-vocoder processed speech. *J Acoust Soc Am*, 119, 2417–26.

Robinson J.D., Stainsby T.H., Baer T. & Moore B.C.J. 2009. Evaluation of a frequency transposition algorithm using wearable hearing aids. *Int J Audiol*, 48(6), 384–93.

Simpson A., Hersbach A.A. & McDermott H. 2006. Frequency-compression outcomes in listeners with steeply sloping audiograms. *Int J Audiol*, 45(11), 619–29.

Simpson A., McDermott H., Dowell R.C., Sucher C. & Briggs R.J.S. 2009. Comparison of two frequency-to-electrode maps for acoustic-electric stimulation. *Int J Audiol*, 48(2), 63–73.

Skarzynski H., Lorens A., Matusiak M., Porowski M., Skarzynski P.H. et al. 2012. Partial deafness treatment with the nucleus straight research array cochlear implant. *Audiol Neurootol*, 17(2), 82–91.

Stakhovskaya O., Sridhar D., Bonham B.H. & Leake P.A. 2007. Frequency map for the human cochlear spiral ganglion: implications for cochlear implants. *J Assoc Res Otolaryngol*, 8(2), 220–33.

Summers V. 2004. Do tests for cochlear dead regions provide important information for fitting hearing aids? *J Acoust Soc Am*, 115(4), 1420–3.

Turner C.W., Gantz, B.J., Vidal C., Behrens A. & Henry B.A. 2004. Speech recognition in noise for cochlear implant listeners: Benefits of residual acoustic hearing. *J Acoust Soc Am*, 115(4), 1729–35.

UKCISG. 2004a. Criteria of candidacy for unilateral cochlear implantation in postlingually deafened adults I: Theory and measures of effectiveness. *Ear Hear*, 25(4), 310–335.

UKCISG 2004b. Criteria of candidacy for unilateral cochlear implantation in postlingually deafened adults II: cost-effectiveness analysis. *Ear Hear*, 25(4), 336–60.

Vickers D.A., Moore B.C.J. & Baer T., 2001. Effects of low-pass filtering on the intelligibility of speech in quiet for people with and without dead regions at high frequencies. *J Acoust Soc Am*, 110(2), 1164–75.

Zhang T., Dorman M.F. & Spahr A.J. 2010. Information from the voice fundamental frequency (F0) region accounts for the majority of the benefit when acoustic stimulation is added to electric stimulation. *Ear Hear*, 31(1), 63–9.