A prospective longitudinal quality of life study before and after cochlear implantation in post-lingually deafened adults

Meis, M.[1], Lesinski-Schiedat, A.[2], Plotz, K.[3], Dillier, N.[4], Walger, M.[5], Wechtenbruch, J.[6] & Hessel, H.[7]

[1]Hearing Center Oldenburg
[2]Department of Otorhinolaryngology and Hearing Center Medical University of Hanover
[3]Cochlear Implant Center CIC Oldenburg at the Evanglisches Krankenhaus Oldenburg
[4]Laboratory of Experimental Audiology, ENT Department, University Hospital Zurich, Switzerland
[5]Department of Otorhinolaryngology, Head and Neck Surgery, University Clinics Cologne
[6]Department of Otorhinolaryngology, Head and Neck Surgery, Ludwig-Maximilians-University Munich
[7]Cochlear GmbH, Germany

keywords: Health-related Quality of Life, cochlear implants, NHP, outcome research

Introduction

The construct of health-related quality of life (HRQoL) has become accurately operationalised and validated for medico-psychological as well as for health economical scientific investigations. The HRQoL components include aspects of physical condition, mental health, social integration, and functional competence. In the realm of evidence-based medicine (EBM) it is important to document the improvement of HRQoL in CI patients with high quality research plans, such as prospective cohort studies. In the German speaking part there is a lack of such well documented studies. The present study aims to document hearing related QoL as well as health-related quality of life as perceived by post-lingually deafened adults before and after cochlear implant surgery.

Methods

Sample: In sum n = 53 patients from five CI centers in Hanover, Oldenburg, Zurich, Cologne, and Munich participated in the prospective study. The mean age of the sample was M = 52.0 (SD = 18.1); 63% were female. The participants reported that were since 7.6 yrs. deaf (SD = 8.7) and they had hearing problems since M = 25.8 yrs. (SD=17.9). The number of self reported chronic diseases was M = 0.6 (SD = 0.9) in accordance with the German Health Survey from 1998 (Stolzenberg, 1998). 64% reported no diseases, 21% one disease, and 15% two or more diseases. We compared the sample with a cross-sectional study in Germany from Meis et al. (2006) to ensure that there is no bias concerning the recruited sample, regarding age, gender, deafness in years, number of diseases, years with hearing problems, number of people in household. In comparison to the cross-sectional study with 337 participants (KIND databank, Cochlear™ products), no statistical significant different results occurred.

The causes of hearing loss following ICD-10 was mainly sudden and noise related hearing loss (H91.2 / 22%; H83.3 / 2%), meningitis (G03.9 / 10%), otitis media (H66.9 / 7%), morbus meniere (H81.0 / 5%), perinatal period (P00-P96 / 5%) and other causes (H91.0, H91.9, A00-B99, O00-O99, Q00-Q99, 15%). From 34% of the participants the cause of hearing loss was unknown or missing (data verification is still in progress). 38 patients were implanted with CI's from Cochelar™, 12 patients with MED-EL, and 3 with CI's from the company Advanced Bionics® (detailed description is available) in the period from May 2004 to June 2006.

Study design and procedure: A prospective pre-post design was conducted. The participants completed with or without assistance a questionnaire battery one month before CI surgery ("Baseline"), direct after "Surgery", but before speech processor fitting, and 2-4 ("Post1"), 5-7 ("Post 2"), and 8-10 months after implantation ("Post 3"). The duration of the prospective study was at minimum nine months and at maximum 11 months.

Questionnaires: We used the HörTech Questionnaire CD vers. 1.0© (Kompetenzzentrum HörTech, 2004), including questionnaire modules, such as the Oldenburg Inventory-R (OI-R) with the subscales "Hearing in quiet", "Hearing in noise", and "Localization" to test subjective hearing ability, the Gothenburg Profile (GP) with the sub-scales "Experienced Handicap in social settings" and "Personal reactions to the experienced handicap" (see Ringdahl et al., 1998), and the Nottingham Health Profile (NHP) with the sub-scales "Energy", "Pain", "Sleep", "Emotional Reaction", "Social Isolation", and "Physical Mobility" as a generic Quality of Life module (German version from Kohlmann et al., 1998). Directly after the surgery a reduced set of questions was used, so that for the Gothenburg Profile only data for four points of times are available. Each scale of the three questionnaires reported here, were transformed into 0% to 100% scales.

Data analyses: The data were analyzed with the Software SPSS 12.0. Repeated-measures ANOVA's with Greenhouse-Geisser correction according the General Linear Models (GLM) were used. Possible confounders were controlled via covariates, posthoc tests were analyzed with the BONFERRONI adjustment. Repeated-measures ANOVA were mainly computed with the factor TIME ("Baseline" to "Post 3": four or five time points), SCALE (the different scales), the interaction TIME by SCALE and the interactions TIME by CONFOUNDERS (number diseases, years deafness etc.). The significance level was set as α=5%.

'Experimental mortality' and missing data: One of the participants was bilaterally aided. This case was dropped,

three participants who terminated the study after surgery, and from 10 participants we got only incomplete data sets. According to the GLM repeated measurement models missing data to one time point will lower the n of cases for the whole model.

Results

Subjective hearing ability: The descriptive statistics of the Oldenburg Inventor-R with all three sub-scales over five time points are to be found in Tab. 1; see appendix.

A repeated-measures ANOVA indicated that the factor TIME was highly significant ($F(2.0, 77.1) = 78.2$, $p < .000$, $\eta_p^2 = .67$. Pairwise comparisons revealed that the mean score of subjective hearing ability over all scales at "Baseline" and "Surgery" differ significantly from the other three time points ($p < 0.000$). The improvement over all scales was 28% to 35%. Also the factor SCALE was significant ($F(1.4, 77.1) = 32.0$, $p < .000$, $\eta_p^2 = .46$) and, of special interest, the interaction TIME by SCALE ($F(5.1, 197.0) = 17.0$, $p < .000$, $\eta_p^2 = .31$); for a graphical illustration with the confounder adjusted means see Fig. 1. The improvement of subjective hearing ability was significant stronger for the scale "Hearing in quiet", compared with the two other scales "Hearing in Noise", and "Localization". Here, the improvement increased over 40% from baseline to the last wave. This pattern of result is in line with the descriptive statistics in Tab. 1, indicating that the reduced n of cases and inclusion of control factors did not change the results.

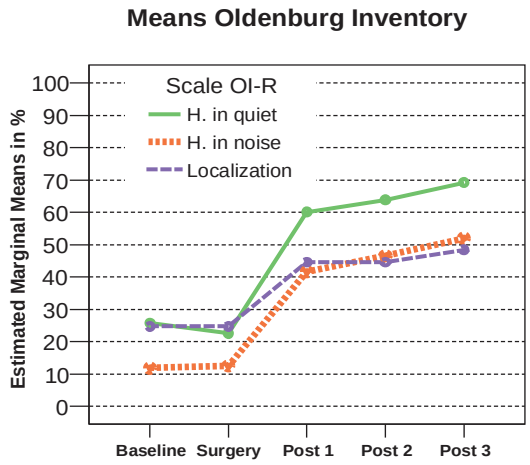

Fig. 1: Estimated Means Oldenburg Inventory-R, Hearing in quiet, Hearing in noise, and Localization from 0-100%. Database: n=39 participants. The lines reflect confounder adjusted means.

The factors duration YEARS OF DEAFNESS, YEARS OF HEARING PROBLEMS, and AGE showed no significant interactions with the factor TIME (all $F<1.0$), indicating that the improvement of subjective hearing ability was not affected by these variables.

Experienced hearing disability and handicap: The descriptive statistics of the Gothenburg Profile with the two sub-scales over five time points are to be found in Tab. 2; see appendix.

The results of the Gothenburg Profile also showed a strong TIME effect. The repeated-measures ANOVA, indicated that the factor TIME was highly significant $F2(2.0, 70.0) = 30.2$, $p < .000$, $\eta_p^2 = .46$. Pairwise comparisons showed that the mean score for both scales of experienced hearing handicap was significant lower only for the comparison "Baseline" vs. the other three waves ($p < 0.000$). The increase of hearing related QoL was 28% (estimated means). The factor SCALE showed also statistical significance ($F(1, 35) = 6.0$, $p < .05$, $\eta_p^2 = .15$), but the interaction TIME by SCALE was not significant ($F(2.8, 99.4) < 1$, $p = 0.80$, $\eta_p^2 = 0.009$); see Fig. 2. The above mentioned factors YEARS OF DEAFNESS, YEARS OF HEARING PROBLEMS, and AGE showed no significant interactions with the factor TIME (all $p > 0.10$).

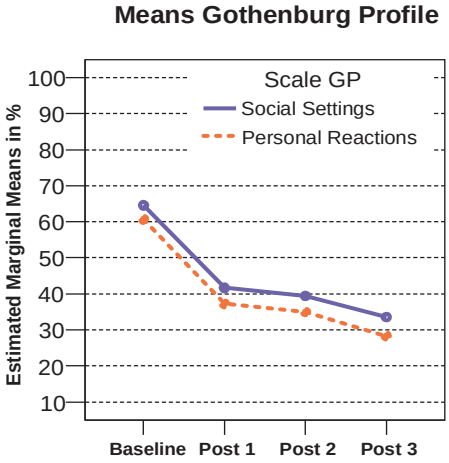

Fig. 2: Estimated Means Gothenburg Profile, Social Settings, and Personal Reactions from 0-100%. Database: n=39 participants. The lines reflect confounder adjusted means.

HRQoL (NHP): The means and standard deviations from the six sub-scales of the Nottingham Health Profile are listed in Tab. 3; see appendix.

As a generic QoL instrument, the NHP scales were checked in a first step whether the factor TIME was dependent from the variables NUMBER OF DISEASES (not related to hearing), YEARS of DEAFNESS, AGE, YEARS OF HEARING PROBLEMS, GENDER, and NUMBER OF PERSONS IN HOUSEHOLD. The first two variables showed statistical relevant relations ($p < .10$). In the following analyses this two variables are included as covariates in the repeated measurement ANOVA's.

The factor TIME was highly significant ($F(3.2, 72.7) = 5.9$, $p = .002$, $\eta_p^2 = .18$). Pairwise comparisons revealed that the mean score of the NHP over all scales at "Baseline" differ significantly from the time points "Post 1" to "Post 3" ($p < 0.05$) and from "Surgery". The time point "Surgery" differs significantly from the time points "Post 1" and "Post 3". The improvement over all scales was nearly 10%. The factor SCALE showed a statistical tendency ($F(2.4, 64.1) = 2.7$, $p = .06$, $\eta_p^2 = .09$). More important for the evidence of disease specific sensitivity, the interaction TIME by SCALE showed statistical significance ($F(6.4, 172.8) = 2.9$, $p < .007$,

$\eta_p^2 = .10$): The scales "Pain", and "Physical Mobility" were not affected by the implantation (for an illustration of the adjusted means see Fig. 3).

Pairwise posthoc tests indicate that for the scales "Social Isolation", "Emotional Reaction", and "Sleep" pre-post effects occurred from "Baseline" to "Post 3" (all $p < 0.05$). For the first two scales we observed the effect that an improvement of HRQoL occurred also from "Baseline" to "Surgery", indicating that is there possibly an anticipation effect in contrast to the scale "Sleep". In the latter scale the strongest contrasts were observable from "Surgery" to the three Post time points.

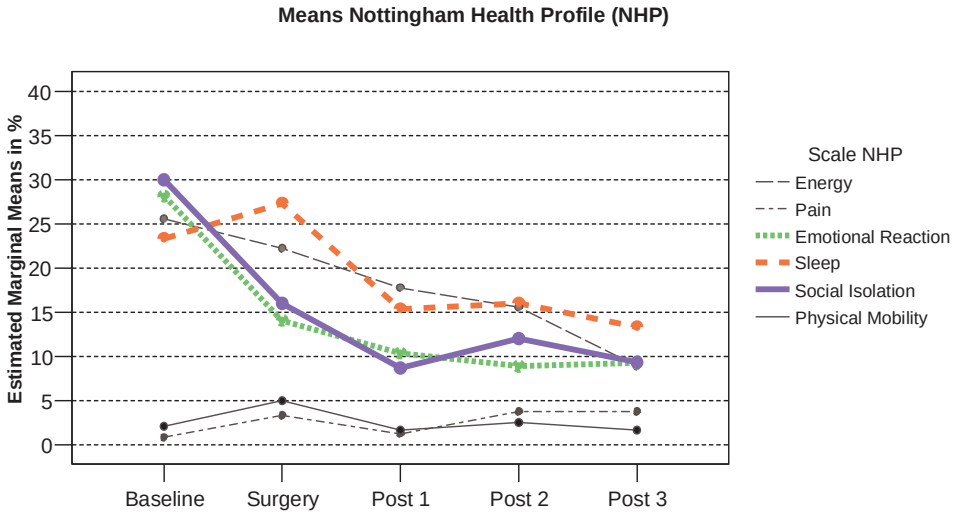

Fig. 3: Estimated NHP, all scales 0-100%. Database n=30 participants. The lines reflect confounder adjusted means.

Summary and Discussion

The study presented here, showed clear evidence of improvement of hearing specific and generic quality of life by means of unilateral cochlear implantation. The patients showed a better subjective self reported hearing ability, especially regarding "Hearing in quiet", and felt less handicapped, isolated, and disabled in everyday life. The study was projected as an observational study in the realm of a normal clinic routine. Unfortunately, the audiological measurements were not comparable across the five clinics to obtain a valid conjoint audiological profile over the five time points, but the data are indicating that with subjective perceived hearing ability HRQoL increases. The effects of HRQoL are striking, especially the decrease of social isolation and negative emotional reaction after the implantation with CI in direction of the German norms (see Hinz et al., 2003).

With the present study it was documented that also HRQoL instruments, such as the NHP, are reliable and valid instruments to measure the outcome in the field of audiology and cochlear implantation and can be used in further studies in the field of evidence based medicine. A fruitful prosecution would be an outcome study reflecting the psychological in combination with a well-documented audiological benefit of a bilateral fitting with cochlear implants.

Acknowledgement

We would like to thank all patients for their collaboration, Tanja Braatz and Berit Jütz for the data management.

References

Hinz A, Klaiber A, Schumacher J, Brähler E (2003) Zur psychometrischen Qualität des Lebensqualitätsfragebogens Nottingham Health Profile (NHP) in der Allgemeinbevölkerung. Psychother Psych Med 53: 353-358.

Kohlmann T, Bullinger M, Kirchberger-Blumstein I (1997) German version of the Nottingham Health Profile (NHP): Translation and psychometric validation. Soz Praventivmed 42(3): 175-185

Kompetenzzentrum HörTech (2004). Fragebogeninventar für die Hörgeräteversorgung Version 1.0, Mai 2004. HörTech gGmbH, Oldenburg

Meis, M., Plotz, K., Dillier, N., Kießling, J., Kinkel, M., Hessel, H. (2006). Bilaterale Versorgung mit Hörgeräten und Cochlea Implantaten: Ergebnisse einer multizentrischen Studie zur (gesundheitsbezogenen) Lebensqualität. 9. Jahrestagung der DGA in Köln.

Ringdahl A, Eriksson-Mangold M, Andersson G (1998). Psychometric evaluation of the Gothenburg Profile for measurement of experienced hearing disability and handicap: applications with new hearing aid candidates and experienced hearing aid users. Br J Audiol. 1998 Dec; 32(6):375-85.

Stolzenberg H. Bundesgesundheitssurvey 1998: Public Use File BGS98: Dokumentation des Datensatzes. Berlin: Robert-Koch-Institut, 2000.

Appendix: Tables 1-3

Oldenburg Inventory-R															
Scale	Baseline			Surgery			Post 1			Post 2			Post 3		
	M	SD	N	M	SD	N	M	SD	N	M	SD	N	M	SD	N
H. in quiet	26.3	17.9	51	25.5	19.7	50	57.8	21.2	46	62.9	19.9	47	67.2	20.0	45
H. in noise	12.2	13.3	51	14.3	15.3	50	39.3	19.3	46	44.8	20.1	47	49.6	22.6	45
Localization	26.5	22.9	51	25.5	21.6	50	45.7	21.1	46	46.0	19.7	47	48.6	22.0	45
Overall	20.5	15.1	51	20.1	16.2	50	48.1	18.2	46	52.7	18.3	47	56.9	19.7	45
Legend: M=mean, SD=Standard deviation, N=number of patients "Baseline": 1 month before surgery, "Surgery": direct after surgery, before speech processor fitting, "Post 1": 2-4 months, "Post 2": 5-7 months, "Post 3": 8-10 months after implantation; *higher* values indicate *higher* subjective hearing ability															

Table 1: Results of the Oldenburg Inventory-R

Gothenburg Profile												
Scale	Baseline			Post 1			Post 2			Post 3		
	M	SD	N	M	SD	N	M	SD	N	M	SD	N
Social Settings	67.7	22.0	51	49.4	22.3	44	44.6	22.1	47	39.0	20.6	43
Personal Reactions	62.6	25.4	51	43.9	25.8	44	39.5	26.3	47	32.8	22.4	42
Overall	65.1	22.8	51	46.1	23.3	44	42.0	23.2	47	36.0	20.5	43
Legend: M=mean, SD=Standard deviation, N=number of patients "Baseline": 1 month before surgery, "Post 1": 2-4 months, "Post 2": 5-7 months, "Post 3": 8-10 months after implantation; *lower* values indicate *higher* hearing specific QoL												

Table 2: Results of the Gothenburg Profile

Nottingham Health Profile															
Scale	Baseline			Surgery			Post 1			Post 2			Post 3		
	M	SD	N	M	SD	N	M	SD	N	M	SD	N	M	SD	N
Energy	25.3	36.0	50	24.2	34.7	51	15.2	32.5	44	14.4	33.3	44	9.3	21.0	43
Pain	5.1	18.6	51	7.2	20.2	50	3.6	15.2	45	6.8	21.7	46	5.8	18.9	45
Emotion. R.	22.7	23.9	48	12.4	17.7	51	7.5	15.5	43	6.3	14.7	46	8.9	16.3	45
Sleep	23.2	27.8	50	27.5	31.5	51	15.6	27.6	45	18.7	26.8	46	13.6	25.1	44
Social I.	27.8	27.5	51	16.1	22.9	51	10.2	14.5	45	10.0	18.7	46	8.0	13.8	45
P. Mobility	6.1	16.5	51	9.8	20.9	51	4.7	16.7	45	5.4	18.9	46	5.4	13.6	44
Legend: M=mean, SD=Standard deviation, N=number of patients "Baseline": 1 month before surgery, "Surgery": direct after surgery, before speech processor fitting, "Post 1": 2-4 months, "Post 2": 5-7 months, "Post 3": 8-10 months after implantation; *lower* values indicate *higher* HRQoL															

Table 3: Results of the Nottingham Health Profile