

implant (CI) is considered a safe and viable solution with good outcomes in terms of speech perception and quality of life, even in older adults (17–19). Recently, Mosnier et al. (20) investigated the effect of hearing rehabilitation through cochlear implantation on cognition in 94 older, profoundly hearing-impaired adults. The authors established that intervention by means of cochlear implantation was associated with improvements in preoperatively impaired cognitive capabilities after 6 and 12 months of CI use. Since then, five other research groups have investigated the cognitive outcomes after cochlear implantation in older adults, with the majority confirming the results of Mosnier et al. (20,21–24). Only Sonnet et al. (25) did not find any significant changes in cognition after 1 year of CI usage.

The present study aims to elaborate on earlier work by investigating the cognitive evolution up to 1 year after cochlear implantation among severely hearing-impaired older adults by means of a cognitive test battery specifically adjusted for the hearing-impaired. This cognitive test battery is the Repeatable Battery for the Assessment of Neuropsychological Status for Hearing-impaired individuals (RBANS-H) (26). In addition, the change in speech perception in quiet and in noise, and in health-related quality of life, self-perceived hearing disability and sound quality, and anxiety and depression is examined after implantation.

MATERIALS AND METHODS

Study Protocol

The present study reports on the preliminary results up to 1 year after implantation of a 10-year follow-up cohort study.

The protocol of the study is described in detail in Claes et al. (26) and only a short summary is given below.

Participants

Twenty consecutive, older participants (12 men and 8 women) with a postlingual bilateral severe hearing impairment were enrolled in the study and unilaterally implanted with a CI. Every participant met the Belgian criteria for reimbursement of the CI. The median age at implantation was 71.5 years (range, 54.8–84.8 yr). The number of years of formal education ranged from 7 to 16 years (median: 10 yr). Before implantation, six of the participants (30%) used bilateral hearing aids, nine unilateral (45%) (six right, three left), and five participants (25%) did not use hearing aids at all. More information on the demographics can be found in Table 1. The speech processor was activated approximately 4 weeks after implantation and the processor settings were optimized during regular programming sessions. In addition, a post-activation auditory rehabilitation program was offered to every CI recipient. This program consists of individual training sessions with a speech therapist 1 hour a week for at least 3 months. During these sessions, speech perception tasks are given to improve communication skills with the CI. Although this rehabilitation program is strongly recommended, three of the 20 participants (15%) did not enter the program.

Primary Outcome Measurement: RBANS-H

The primary outcome measurement is the change in cognitive performance across the three test moments; preoperatively and at 6 and 12 months after implantation. Cognition was assessed by means of the RBANS-H (26). The RBANS-H is a modification of the RBANS (27), and was especially developed to examine cognition in individuals with a hearing impairment. This cognitive test battery consists of 12 subtests and assesses five cognitive domains, namely immediate

TABLE 1. Characteristics of the 20 participants

Sex	Duration of Hearing Loss (yr)	Cause of Hearing Loss	HA Use Preop.	Formal Education (yr)	Age at Implantation (yr)	Side of Implantation	Cochlear Implant and Electrode	Speech Processor	Contralateral HA Use Postop.	Rehabilitation?	
1	m	15	Trauma	Bilateral	11	71.5	Left	Concerto flex28	SONNET	No	No
2	f	11	Unknown	Bilateral	16	71.4	Left	Concerto flex28	SONNET	Yes	Yes
3	f	47	DFNA9	Bilateral	8	76.0	Left	Concerto flex28	SONNET	Yes	Yes
4	f	20	DFNA9	No	13	70.7	Left	Concerto flex28	RONDO	N/A	No
5	m	30	Unknown	Right	9	84.8	Right	Synchrony flex28	SONNET	N/A	Yes
6	f	18	Unknown	Bilateral	11	72.1	Right	Synchrony flex28	SONNET	No	Yes
7	m	50	Unknown	Bilateral	8	77.0	Right	Synchrony flex28	SONNET	No	Yes
8	f	30	Trauma	Right	10	69.1	Right	Synchrony flex28	SONNET	N/A	Yes
9	m	38	Unknown	Bilateral	10	54.8	Right	Synchrony flex28	SONNET	No	No
10	m	40	Unknown	No	9	83.9	Left	Synchrony flex24	SONNET	N/A	Yes
11	m	45	Unknown	Left	12	76.7	Left	Synchrony flex28	SONNET	N/A	Yes
12	m	10	Unknown	Right	10	70.1	Left	Synchrony flex28	SONNET	Yes	Yes
13	f	55	Ototoxicity	Left	7	67.3	Right	Synchrony flex28	SONNET	Yes	Yes
14	f	35	Otosclerosis	No	9	65.8	Right	Synchrony flex28	SONNET	N/A	Yes
15	m	10	Unknown	No	14	57.1	Left	Synchrony flex28	SONNET EAS	N/A	Yes
16	m	16	Unknown	Right	10	77.8	Right	Synchrony flex28	SONNET	N/A	Yes
17	f	18	Unknown	Right	8	80.4	Left	Synchrony flex28	SONNET	No	Yes
18	m	45	Unknown	Right	10	63.9	Right	Synchrony flex28	SONNET	N/A	Yes
19	m	4	Unknown	Left	8	62.8	Left	Synchrony flex24	SONNET	N/A	Yes
20	m	0.3	Trauma	No	13	76.5	Right	Synchrony flex28	SONNET	N/A	Yes

f indicates female; HA, hearing aid; m, male; N/A, not applicable.

TABLE 2. Description of RBANS-H domains and subtests

Domain	Subtest	Description
Delayed memory	(1) List learning	A list of 10 unrelated words is presented audiovisually to the participant and he or she is asked to recall as many words as possible after each of four learning trials.
	(2) Story memory	A short story of two sentences is presented audiovisually to the participant and he or she has to retell the story as accurately as possible after each of two learning trials.
Visuospatial/constructional	(3) Figure copy	The participant has to copy a geometric figure, while this figure remains on display.
	(4) Line orientation	A semi-circular, fan-shaped pattern of 13 lines is shown to the participant. The lines are identical, except for their orientation. Below this pattern are two lines that match the orientation of two of the lines from the pattern. The participant is instructed to identify those two matching lines.
Language	(5) Picture naming	Ten line drawings of objects are to be named by the participant.
	(6) Semantic fluency	The participant has to list as many exemplars as possible from a given semantic category, e.g., fruits and vegetables, within 1 minute.
Attention	(7) Digit span	The participant is instructed to repeat a string of digits, presented audiovisually, in the same order. The length of the strings increases by one on each trial, starting from two up to nine digits.
	(8) Coding	A form with symbols is given to the participant. He or she has to fill out the corresponding number below each symbol, using the key on top of the page. The time limit is 90 seconds.
Delayed memory	(9) List recall	The participant is asked to recall as many words as possible from the list of words learned earlier in the list learning subtest.
	(10) List recognition	Twenty words, of which 10 are targets and 10 are distractors, are presented audiovisually to the participant. The participant has to indicate whether each word was on the original list or not.
	(11) Story recall	The participant is asked to retell the story learned earlier from memory.
	(12) Figure recall	The geometric figure shown earlier in the figure copy subtest has to be drawn from memory as accurately as possible.

memory, visuospatial/constructional, language, attention, and delayed memory (Table 2). The subdomain scores and the total score are age-corrected standard scores, scaled to a normal distribution with a mean of 100 and a standard deviation of 15. In contrast to the original RBANS, the RBANS-H provides a PowerPoint presentation presenting the written instructions to the participant on an external screen, along with the standard oral instructions. In addition, simultaneous auditory and visual stimulation is provided in four of the 12 subtests, for which the items are presented solely orally in the original RBANS. These four subtests are list learning, story memory, digit span, and list recognition. A detailed description of the modified RBANS-H can be found in Claes et al. (26). RBANS-H alternate forms A and B were used in the present study.

Secondary Outcome Measurements

Best-aided speech audiometry in quiet and in noise was performed at each of the three evaluations. The NVA-lists developed by the Nederlandse Vereniging voor Audiologie (NVA) (Dutch Society for Audiology) were used to assess speech perception in quiet (28) and the Leuven Intelligibility Sentences Test (LIST) (29) was performed to quantify speech perception in noise. The best-aided situation preoperatively was either unaided or with unilateral or bilateral hearing aid(s) and postoperatively either with unilateral CI or with unilateral CI and contralateral hearing aid. In addition, four questionnaires were administered at every assessment. 1) The Nijmegen Cochlear Implant Questionnaire (NCIQ) measures health-related quality of life in CI users (30). In the present study, the NCIQ scores were calculated according to the corrected code book, published in the corrigendum (31). 2) The Speech, Spatial and Qualities of hearing Scale—12 (SSQ12) (32) assesses hearing disabilities. 3) The Hearing Implant Sound Quality Index—19 (HISQUI19) (33) quantifies the self-

perceived level of auditory benefit experienced by hearing implant users in everyday listening situations. 4) The Hospital Anxiety and Depression Scale (HADS) evaluates states of anxiety and depression (34).

Ethics

This study was conducted in accordance with the recommendations of the ethics committee of the Antwerp University Hospital/University of Antwerp. The protocol was approved on June 15th, 2015 (protocol number: 15/17/181). All participants gave written informed consent in accordance with the Declaration of Helsinki before participation. The study is registered at Clinical Trials (ClinicalTrials.gov) on June 9, 2016. The protocol identifier is NCT02794350.

Statistics

IBM SPSS Statistics version 24 (IBM Corp., New York, NY) was used for the statistical analyses. Linear mixed models (LMM) were run across the three measurements for the RBANS-H total score and subdomain scores, NCIQ total score and subdomain scores, SSQ12 total score, HISQUI19 total score, and HADS anxiety and depression scores. When a significant result was found using an alpha level of 0.05, pairwise comparisons were performed to investigate in which of the three pairs a significant difference was present (preoperatively <> 6 months postoperatively; 6 months postoperatively <> 12 months postoperatively; preoperatively <> 12 months postoperatively). Bonferroni correction was applied to correct for multiple testing within the pairwise comparisons (*p*-value multiplied by three). For the speech recognition scores in quiet (percentage correct) and the speech reception thresholds (SRTs) in noise, Friedman's tests and Wilcoxon pairwise comparisons with Bonferroni correction were used to account for the non-parametric distribution of these variables.

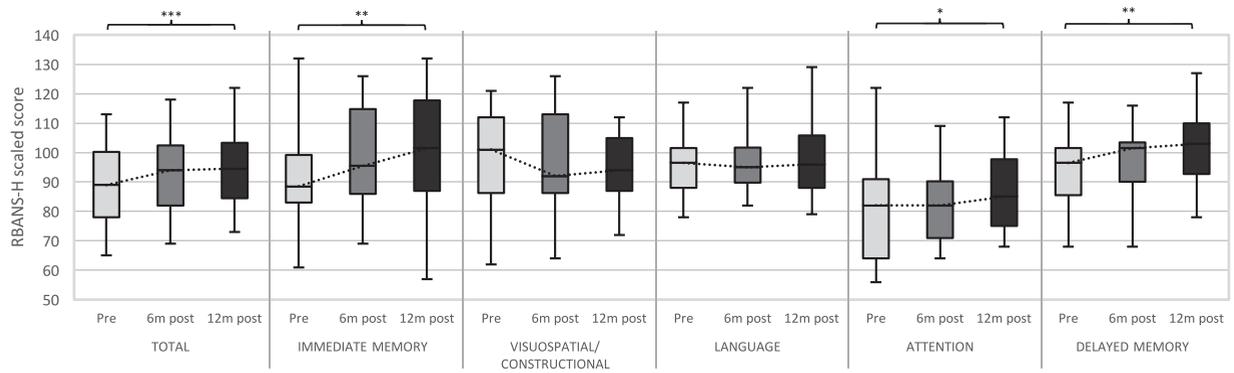


FIG. 1. The RBANS-H total scores and subdomain scores. The boxplots represent the minimum, 1st quartile, median, 3rd quartile, and maximum of the RBANS-H total scores and subdomain scores before implantation (pre) and at 6 and 12 months after implantation (resp., 6m post and 12m post) ($n = 20$). The dotted line connects the median scores. Higher scores indicate better cognition. * indicates $p < 0.05$, ** indicates $p < 0.01$, *** indicates $p < 0.001$, and **** indicates $p < 0.0001$.

RESULTS

Primary Outcome Measurement: RBANS-H

The mean RBANS-H total score was $89.6 (\pm 15.2)$ before implantation and changed to $93 (\pm 12.8)$ and $95.3 (\pm 13.7)$ at respectively 6 and 12 months after implantation (Fig. 1). The change in RBANS-H total score across the three measurements was significant (LMM: $p < 0.001$). Pairwise comparisons with Bonferroni correction indicated that only the change between the preoperative RBANS-H total score and the 12-months total scores was significant ($p < 0.001$) (mean change: $5.7 [\pm 7.8]$).

Additionally, the change of the five subdomain scores was explored. Immediate memory improved significantly (LMM: $p = 0.005$) from a mean score of $91.4 (\pm 16.3)$, to $98.4 (\pm 17.9)$ and $101.4 (\pm 19.3)$ across the three test intervals. Only the change between the preoperative and the 12-months postoperative evaluation was significant ($p = 0.005$) (mean change: $10.0 [\pm 14.5]$). The visuospatial/constructional and language index scores remained stable across the measurements. The attention index scores changed significantly with mean scores improving from $82.1 (\pm 21.0)$ to $83.9 (\pm 15.2)$ and $88.1 (\pm 13.8)$ (LMM: $p = 0.047$). Again, only a significant improvement was observed between preoperative and 12-months postoperative scores ($p = 0.050$) (mean change: $6.0 [\pm 11.5]$). Finally, the fifth domain, delayed memory, also presented a significant improvement. The mean scores changed from $94.1 (\pm 13.2)$ preoperatively, to $97.6 (\pm 12.1)$ and $101.5 (\pm 14.2)$ at 6 and 12 months postoperatively (LMM: $p = 0.002$). Pairwise comparisons with Bonferroni correction revealed only a significant change between the delayed memory score before implantation and at 12 months after the implantation ($p = 0.002$) (mean change: $7.4 [\pm 9.1]$).

In short, significant change was demonstrated after 12 months of CI usage for overall cognition, and for the immediate memory, attention, and delayed memory

domains. When correction for multiple testing was applied across the LMMs of the five subdomain scores, only the change in attention did not remain significant.

Secondary Outcome Measurements

Audiometric Assessment

Both at 6 and 12 months postimplantation, all 20 participants used the speech processor each day and all day long. Four of the nine participants (44%) who could continue to use the contralateral hearing aid, actually did (Table 1).

The median best-aided speech recognition score in quiet was 18% (range, 0–85%) before implantation and improved to respectively 79% (range, 39–94%) and 75% (range, 42–88%) at 6 and 12 months after implantation (Fig. 2A). Friedman's test revealed that the speech scores in quiet significantly changed across the three time points ($\chi^2(2) = 21.494$, $p < 0.0001$). Wilcoxon post hoc comparisons with Bonferroni correction pointed out that speech recognition in quiet significantly improved at 6 months after the implantation ($Z = -3.865$, $p < 0.001$) and remained stable between 6 and 12 months postoperatively ($Z = -1.350$, $p = 0.531$).

Preoperatively, 17 of the 20 participants (85%) could not perceive the LIST sentences correctly at the highest, i.e., easiest, signal to noise ratio of +20 dB SNR (median SRT: +20.00 dB SNR; range, +5.00 to +20.00 dB SNR) (Fig. 2B). In contrast, at 6 and 12 months after implantation all but one participant (95%) could finish the test at a speech-noise ratio lower than +20 dB SNR. The median SRT at 6 months postoperatively was +6.00 dB SNR (range, 0.00–20.00 dB SNR) and at 12 months postoperatively +4.33 dB SNR (range, 0.00–20.00 dB SNR). Overall, a significant change in SRT was found ($\chi^2(2) = 30.658$, $p < 0.0001$). More specifically, the SRT decreased, i.e., improved, significantly at 6 months ($Z = -3.825$, $p < 0.001$) and remained stable at 12 months postoperatively ($Z = -1.219$, $p = 0.669$).

