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## Clinical Validation of a Sound Processor Upgrade in Direct Acoustic Cochlear Implant Subjects

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**Objective:** The objectives of the investigation were to evaluate the effect of a sound processor upgrade on the speech reception threshold in noise and to collect long-term safety and efficacy data after 2½ to 5 years of device use of direct acoustic cochlear implant (DACI) recipients.

**Study Design:** The study was designed as a mono-centric, prospective clinical trial.

**Setting:** Tertiary referral center.

**Patients:** Fifteen patients implanted with a direct acoustic cochlear implant.

**Intervention:** Upgrade with a newer generation of sound processor.

**Main Outcome Measures:** Speech recognition test in quiet and in noise, pure tone thresholds, subject-reported outcome measures.

**Results:** The speech recognition in quiet and in noise is superior after the sound processor upgrade and stable after long-term use of the direct acoustic cochlear implant. The

bone conduction thresholds did not decrease significantly after long-term high level stimulation.

**Conclusions:** The new sound processor for the DACI system provides significant benefits for DACI users for speech recognition in both quiet and noise. Especially the noise program with the use of directional microphones (Zoom) allows DACI patients to have much less difficulty when having conversations in noisy environments. Furthermore, the study confirms that the benefits of the sound processor upgrade are available to the DACI recipients even after several years of experience with a legacy sound processor. Finally, our study demonstrates that the DACI system is a safe and effective long-term therapy. **Key Words:** Direct acoustic cochlear implant—Long-term performance—Long-term safety—Mixed hearing loss—Otosclerosis—Speech perception in noise.

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Since October 2013 a new type of implantable hearing system, the direct acoustic cochlear implant (DACI), has become commercially available. It was developed to offer a treatment option for individuals with severe to profound mixed hearing loss. By now, fundamental research regarding DACIs from concept and design (1,2) to first clinical results (3), as well as safety and effectiveness (4–6), have been reported. Since the release of the DACI, a new generation of sound processor, the Nucleus CP810 Sound Processor (Cochlear Ltd., Sydney, Australia), has become available for cochlear implants. This new sound processor has shown a

significant improvement in speech recognition in quiet and noise in cochlear implant patients in comparison to the previous processor (7) (Freedom Sound Processor [Cochlear Ltd.]). When the Nucleus CP810 became available for acoustic implants we hypothesized that the new sound processor would provide a similar improvement in acoustic stimulation with the DACI. As the new sound processor has a directional microphone and a dedicated program for speech intelligibility in noise, we aimed to investigate the effect of the sound processor upgrade on the speech perception in noise. A secondary aim of the study was to assess the long-term benefit after several years of DACI use with all subjects being consistent daily users of their DACI system for at least 2 years.

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The authors disclose no conflicts of interest.

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### MATERIALS AND METHODS

#### Subjects

Fifteen adults (12 women, 3 men) with an average age of 66 years (range, 53–77 yr) were included in the study. All subjects were previously implanted monaurally with the Codacs direct acoustic cochlear implant system (Cochlear Ltd., Sydney, Australia, referred to as DACI in this report) between November 2009 and October 2012 at the Hannover Medical School (Germany) during two premarket clinical studies. Ten subjects

TABLE 1. Subject's demographics

Subject No.	Gender	Age at Study Start	Implanted Ear	Etiology	Months Implanted at Study Start	Months Implanted at Final Study Visit
1	Female	73	Right	ECF	22	34
2	Female	71	Left	Otosclerosis	22	40
3	Male	66	Left	Otosclerosis	42	54
4	Female	68	Left	Otosclerosis	35	47
5	Female	60	Left	Otosclerosis	51	64
6	Female	64	Right	Otosclerosis	23	36
7	Male	53	Right	Otosclerosis	26	39
8	Female	72	Right	Otosclerosis	21	35
9	Female	73	Right	Otosclerosis	52	64
10	Female	65	Left	Otosclerosis	17	30
11	Female	77	Right	Otosclerosis	26	38
12	Female	59	Right	Otosclerosis	36	48
13	Female	63	Right	Otosclerosis	47	60
14	Female	56	Right	COM	18	30
15	Male	76	Right	Otosclerosis	41	53
Mean		66			32	45

COM indicates chronic otitis media; ECF, ear canal fibrosis.

were implanted in the right ear and five subjects in the left ear. All subjects had been diagnosed with a severe to profound mixed hearing loss in the ear to be implanted. The etiology was otosclerosis in 13 subjects, while for the remaining two subjects one case of ear canal fibrosis and one case of chronic otitis media were reported. At the start and end of this study, the subjects had used their DACI system on a daily basis for 32 months (range, 17–52 mo) and 45 months (range, 30–64 mo) on average, respectively. The subjects' demographics are presented in Table 1.

### Study Devices

Up to the study start, all subjects had used the Freedom Sound Processor for the Codacs system (Cochlear Ltd.; referred to as Freedom in the remainder of this report). This sound processor did not have any SmartSound (Cochlear Ltd., Sydney, Australia) preprocessing algorithms, i.e., only an omnidirectional microphone was used. During the study subjects were upgraded to the Nucleus CP810 Sound Processor for the Codacs System (Cochlear Ltd.; referred to as CP810 in the remainder of this report). The CP810 is physically the same sound processor as the Nucleus CP810 for Cochlear's cochlear implant systems, but was programmed with different firmware, developed specifically for acoustic sound processing.

### Study Design

The study was designed as a single center, prospective clinical trial at the Hannover Medical School and ran from November 2013 to June 2015. The study duration was 12 months per subject. The study subjects visited the clinic three times during this period.

In this self-controlled case series each subject served as his/her own control. Only complete datasets were included for statistical analysis. In case of outliers and/or low number of complete pairs and/or a non-normal data distribution, non-parametric tests were used. Statistical analysis was performed with the IBM SPSS Statistics Software Package (IBM Corporation, Armonk, NY). Throughout the statistical analysis, a significance level of 5% was adopted.

The study was approved by the ethics committee of the Hannover Medical School (No. 6305–2013). All subjects gave

their written informed consent for voluntary participation before the start of the study. The principles outlined in the Declaration of Helsinki (2013) were followed during the conduct of the study. The study was registered in the database [clinicaltrials.gov](http://clinicaltrials.gov) under number NCT02156167.

The initial visit included a fine tuning of the subject's own Freedom followed by an audiometric test, and a questionnaire, which was completed by the patient. After the tests with the Freedom, the CP810 was fitted to the subjects hearing loss based on the hearing thresholds measured with the implant (Codacs Direct thresholds). Three (3M FU) and 12 (12M FU) months after the sound processor upgrade subjects came back to the clinic for fine tuning of the fitting, audiometric tests, and to complete the same questionnaires as before (3M FU only).

At the 12-month follow-up visit subjects had been using the DACI for at least 30 months. In contrast to previous clinical studies (4,5) focusing on short-term outcomes, long-term results were evaluated in this work.

### Audiometric Tests

Air conduction (AC) and bone conduction (BC) pure tone thresholds were measured at 0.125, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 6, and 8 kHz and 0.5, 0.75, 1, 1.5, 2, 3, and 4 kHz, respectively. In this report, the four frequency pure tone average (4f PTA, average of AC or BC hearing thresholds at 0.5, 1, 2, and 4 kHz) is reported.

For the speech test in quiet the Freiburg monosyllables test (8) was used, which results in a word recognition score (WRS). For the speech-in-noise test the Oldenburg sentence test (OLSA) (9–11) was used to determine the signal-to-noise ratio (SNR) adaptively at which 50% of words in the sentence list were correctly repeated by the subject. An SNR change of 1.4 dB is considered a clinically relevant change (12). The Freedom was tested in two different conditions in the standard program (Everyday), one time with both speech and noise coming from the front ( $S_0N_0$ ) and once with the speech coming from the front and the noise coming from the implanted side ( $S_0N_{90}$ ). The CP810 was tested in the same conditions but in two different programs, the Everyday program and the Noise program. The Everyday program uses a fixed omnidirectionality of the microphones, unlike the Noise program that has a fixed

microphone directionality enhancing signals coming from the front. All tests were performed in an anechoic chamber with an audiometer (CAS AD2117, Audio Data GmbH). For the speech-in-noise tests the loudspeakers were positioned 1 m in front of the subject, and in a  $-90$  degrees or  $+90$  degrees position 1 m away from the head of the subject depending on the side of implantation. The noise level was fixed at 65 dB SPL in all conditions.

### Subjective Self-Reported Outcome Measures

Two questionnaires were used in this study: the abbreviated profile of hearing aid benefit (APHAB) (13), and the health utilities index (HUI) Mark 2/3 (14,15). For the APHAB, a difference of 22% or more in any of the three subscales, or of 31% or more in the aversiveness subscale, or a difference of 10% in the global score, is considered a clinically relevant difference as reported by the developers (13). In the HUI, the utility index is scored on a scale from 0 to 1 with 0 representing poor health (equivalent to death) and 1 representing perfect health. A difference of 0.03 in the overall HUI score is considered as clinically relevant (16). Both questionnaires were completed before the sound processor upgrade, i.e., at the initial study visit and 3 months after the sound processor upgrade.

## RESULTS

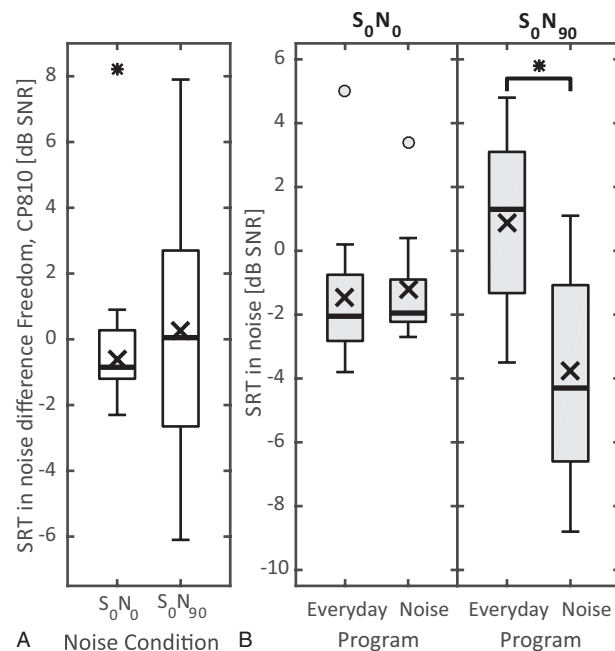
### Sound Processor Upgrade Pure Tone Audiometry

On average the subjects had moderate to severe BC hearing loss (4f PTA: 56.5 dB HL, standard deviation [SD]: 5.3 dB) and an air-bone gap of 36.5 dB (SD 4.7 dB) at the initial visit. These hearing thresholds lie within the inclusion criteria for the DACI. The average AC hearing loss was of profound degree (4f PTA: 93.3 dB HL, SD: 7.7 dB).

### Speech Testing

For comparison of the Freedom to the CP810 processor using the Everyday program, paired speech reception threshold (SRT) in noise data were available for 13 patients at the 3M FU (Fig. 1A). In the  $S_0N_0$  situation the improvement of 0.6 dB SNR (SD 0.9 dB) by the CP810 was significant ( $p=0.033$ , paired Student's  $t$  test, Freedom:  $-0.8$  dB SNR [SD: 2.0 dB], CP810:  $-1.5$  dB SNR [SD: 2.3 dB]). In contrast, for the  $S_0N_{90}$  situation the change of 0.3 dB SNR (SD 3.7 dB) was not significant ( $p>0.05$ , paired Student's  $t$  test, Freedom: 0.6 dB SNR [SD: 2.9 dB], CP810: 0.9 dB SNR [SD: 2.8 dB]). In this condition, the test was found to be particularly difficult by the patients, leading to a pronounced spread of the results. While five patients improved with the CP810, seven had worse results, and one was unchanged.

In Figure 1B the Everyday program is compared with the Noise program of the CP810 at the 3-month follow-up (3M FU). Although there is no significant difference ( $p>0.05$ , Wilcoxon signed ranks test) between the two programs in the condition  $S_0N_0$  in median SRT (Everyday program:  $-1.5$  dB SNR, Noise program:  $-1.2$  dB SNR), there is a pronounced and highly significant ( $p<0.001$ , paired Student's  $t$  test) improvement of



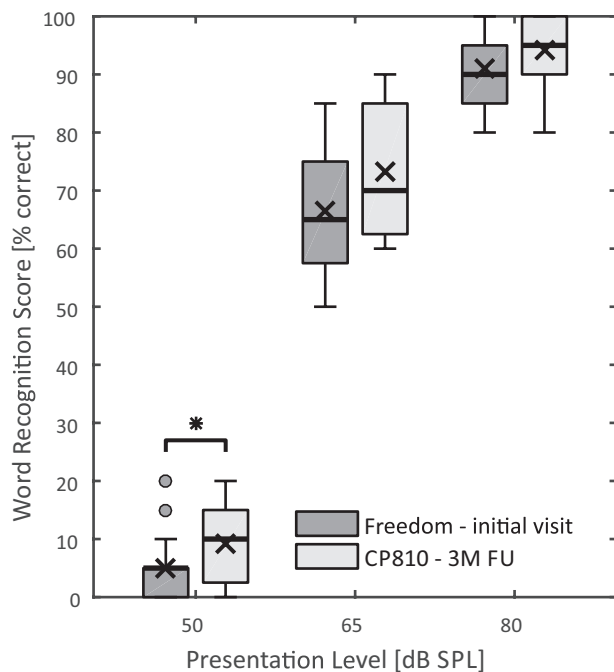
**FIG. 1.** A, Comparison of the SRT in noise with the Freedom and the CP810 both measured with the Everyday program after 3 months (3M FU) in the  $S_0N_0$  (left) and  $S_0N_{90}$  (right) condition. Negative values indicate an improvement with the CP810. The significant ( $p<0.05$ ) difference from baseline is indicated by \*. B, Comparison of the SRT in noise of the two programs (Everyday, Noise) available for the CP810. Measurements were performed at the (3M FU) in two different measurement conditions:  $S_0N_0$  and  $S_0N_{90}$ . Medians are presented by a black line, mean values by a cross and circles indicate outliers ( $>1.5$  times the interquartile range). Significances between groups ( $p<0.05$ ) are indicated by \*.  $S_0N_0$  indicates speech and noise coming from the front;  $S_0N_{90}$ , speech coming from the front and the noise coming from the implanted side; SRT, speech reception threshold.

4.7 dB by the Noise program in the  $S_0N_{90}$  configuration (Everyday program: 0.9 dB SNR, Noise program:  $-3.8$  dB SNR).

Figure 2 shows the WRS in quiet with the Freedom at the initial visit and the CP810 at the 3M FU for three different input levels, all measured in the Everyday program. The WRS improved by 4% (SD 7%), 7% (SD 20%), and 3% (SD 9%) on average at input levels of 50, 65, and 80 dB SPL respectively, after the sound processor upgrade from Freedom to CP810. The change was statistically significant at 50 dB SPL (Wilcoxon signed ranks test,  $p=0.035$ ); however, this is not considered a clinically relevant change.

### Subject-Reported Outcome Measures

The APHAB questionnaire was completed by the subjects at the initial visit and at the 3M FU of the study. The answers in the four subscales ease of communication (EC), background noise (BN), reverberation (RV), and aversiveness (AV), and the global score were compared to assess if the sound processor upgrade had an influence on hearing ability in the daily life of the subjects. The mean APHAB score improved by 1% (SD 4%), 6% (SD 14%), 9% (SD 16%), 9% (SD 18%), and 6% (SD 10%) in



**FIG. 2.** WRS in quiet with Freedom at the initial visit and CP810 at the 3M FU for input levels of 50, 65, and 80 dB SPL. Median and mean are presented by a black line and a black cross, respectively. Circles indicate outliers ( $>1.5$  times the interquartile range). \* indicates a significant difference ( $p < 0.05$ ). WRS indicates word recognition score.

the four subscales EC, BN, RV, and AV and the global score, respectively. The change was not statistically significant in the subscales (Student's  $t$  test,  $p > 0.05$ ) but the mean global score improved statistically significantly after the sound processor upgrade (Student's  $t$  test,  $p = 0.033$ ). However, this change is not clinically relevant as it is below 10%.

The HUI questionnaire was completed by the subjects at the initial visit and at the 3M FU. The HUI2 and HUI3 scores changed by 0.03 (SD 0.14) and  $-0.005$  (SD 0.93), respectively. These changes were statistically not significant (Wilcoxon signed ranks test,  $p > 0.05$ ). Nevertheless, the mean HUI2 score showed an improvement of clinically relevant size with the CP810, indicating that the health value status was rated better with the CP810 than with the Freedom. The results of the subject reported outcome measures are shown in Figure 3.

#### Long-term Results

At the end of the 12M FU, the study subjects had been using their DACI system for 45 months on average and had at least 12 months experience with the CP810. In this section, the results of the current study are compared with the short-term results reported at the end of previous studies (4,5), where the study subjects had only 3 months experience with their Freedom DACI system.

#### SRT in Noise

On average the SRT in noise improved significantly by 1.1 dB SNR (SD 1.6 dB) from 0.4 dB SNR (SD 2.5 dB) to

$-0.7$  dB SNR (SD 1.8 dB) when comparing the initial short-term results (Freedom 3M FU) with the long-term results (CP810 12M FU) in the condition  $S_0N_0$  in the Everyday program (paired Student's  $t$  test,  $p = 0.019$ , Fig. 4A). However, this change is not clinically relevant, as it is below 1.4 dB SNR. The condition  $S_0N_{90}$  could not be compared as this condition was not tested in the initial study.

The speech intelligibility in quiet did not change significantly at any of the three tested levels when comparing the WRS results at CP810 12M FU visit with the results at the end of the previous study (Freedom 3M FU, Wilcoxon signed ranks test,  $p > 0.05$ , Fig. 4B). The mean WRS difference at the three tested levels was  $-2\%$  (SD 19%),  $-4\%$  (SD 15%), and  $1\%$  (SD 9%), respectively. Negative values indicate worse long-term WRS. However, these values are all below 10%, i.e., were clinically irrelevant changes. All but two subjects have a long-term WRS of at least 60% at 65 dB SPL.

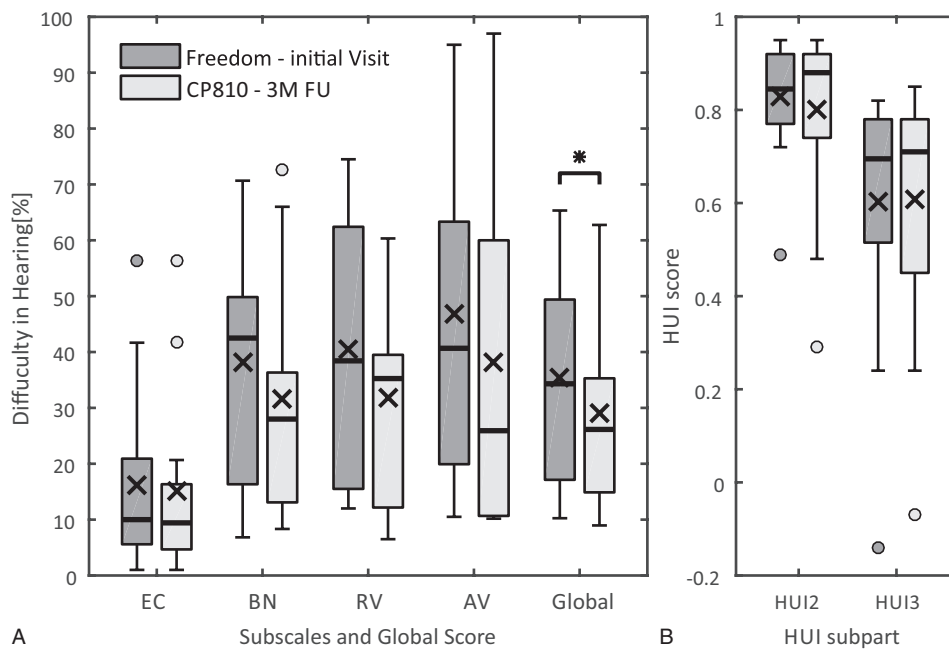
#### Bone Conduction Thresholds

The 4f PTA of the BC thresholds increased by 1.4 dB after long-term DACI use, i.e., it is marginally poorer. The change was not statistically significant at any of the tested frequencies except for 0.75 and 1 kHz, where the BC thresholds increased by 6 and 4 dB, respectively (paired Student's  $t$  test,  $p < 0.05$ ). Analyzing the individual short- and long-term 4f PTA only one subject (subject 3) presents with a BC threshold increase of more than 10 dB (see Fig. 5).

## DISCUSSION

#### Sound Processor Upgrade

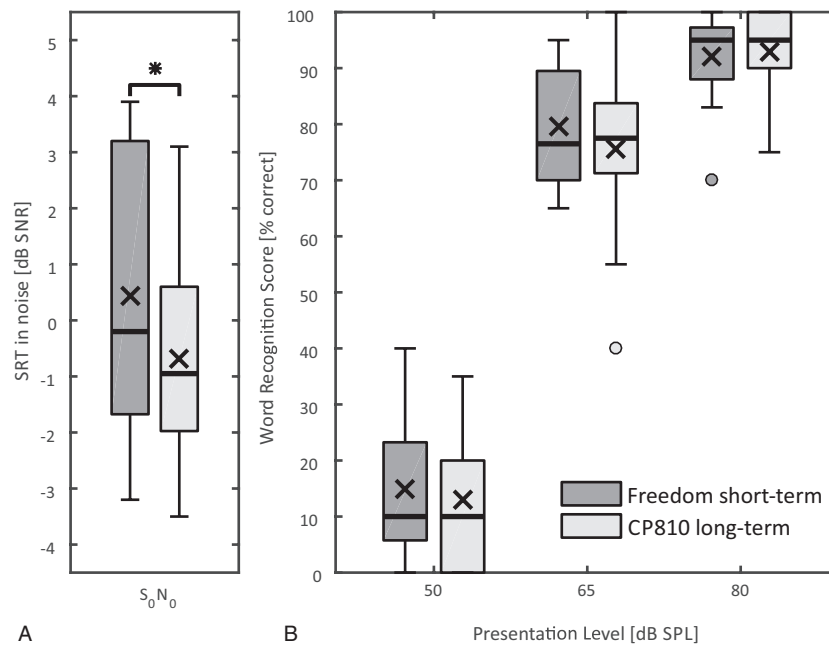
The first investigational DACI patients were implanted at the Hannover Medical School in late 2009, making them ideal study subjects to investigate the effectiveness of the upgrade to a new sound processor offering new preprocessing features. The effectiveness was evaluated with two different sound processors, the Freedom and the CP810. The CP810 allows DACI users to make use of a dedicated Noise program using a directional microphone, which was investigated for the first time in our study for this patient population. Our study results showed an improvement in noise when using the CP810 compared with the Freedom; this improvement was most pronounced and statistically significant when using the Noise program in the condition  $S_0N_{90}$  (Fig. 1B). In a comparative study using the identical sound processor for a group of cochlear implant users, Wolfe et al. (7) found similar results, although a comparison between electric and acoustic stimulation must be limited in its conclusions. They observed significantly improved speech recognition in quiet of 3.1% at 60 dBA with the CP810 compared with the Freedom when both are used in the Everyday program. In the current study, we saw an improvement of 7% at an input level of 65 dB SPL, slightly better than results reported by Wolfe et al. (7) For speech in noise, the cochlear



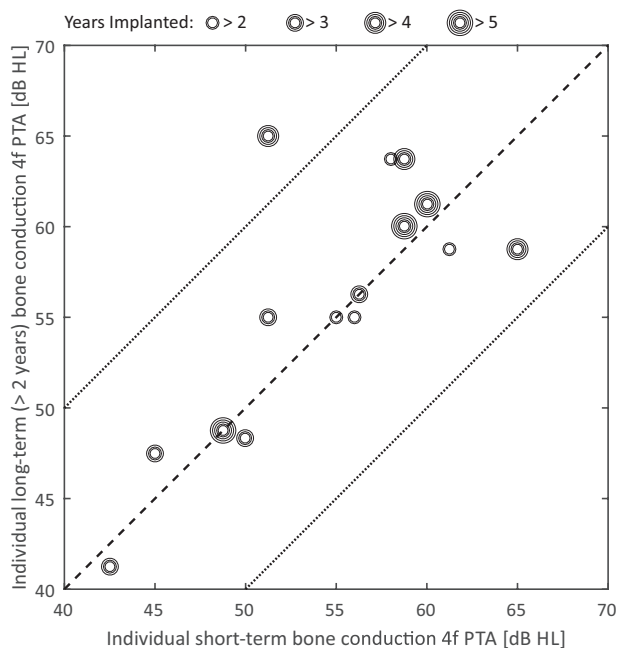
**FIG. 3.** APHAB scores (A) and HUI scores (B) before (dark grey) and after (light grey) the sound processor upgrade. Median and mean are presented by a black line and a black cross, respectively. The circles indicate outliers (>1.5 times the interquartile range), \* indicates a significant difference ( $p < 0.05$ ). APHAB indicates abbreviated profile of hearing aid benefit; HUI, health utilities index.

implant subjects of Wolfe et al. received the greatest benefit from the Noise program in the condition  $S_0N_{90}$ . They showed a relatively small effect on the SRT in noise scores after a sound processor upgrade when using the standard noise program (0.8 dB SNR), and a large effect when comparing the SRT in noise scores, with and

without directional microphones (6.0 dB SNR). This is comparable to our observations in the condition  $S_0N_{90}$ : the effect on the SRT in noise after sound processor upgrade was small in the Everyday program (-0.3 dB SNR) while it was large when comparing the Everyday program with the Noise program (4.7 dB SNR). Razza



**FIG. 4.** SRT in noise (A) and WRS at 50, 65, and 80 dB SPL (B) with Freedom (dark grey) and CP810 (light grey) in the condition  $S_0N_0$  in the Everyday program. Median and mean are presented by a black line and a black cross, respectively. Circles indicate outliers (>1.5 times the interquartile range). \* indicates a significant change ( $p < 0.05$ ). SRT indicates speech reception threshold; WRS, word recognition score.



**FIG. 5.** Individual long-term (12M FU with CP810) BC 4f PTA as a function of the short-term BC 4f PTA 3 months after activation. The different symbol size indicates the different durations of DACI use at the 12M FU (yr after implantation). The *dashed line* represents no change, while the *dotted lines* represent a change of  $\pm 10$  dB HL. BC indicates bone conduction; DACI, direct acoustic cochlear implant.

et al. (17) compared the Freedom with the CP810 in cochlear implant patients, showing a significant effect of the sound processor on the SRT in noise. The CP810 allowed better performance than the Freedom device in either of two preprocessing configurations. The APHAB and HUI scores further support the positive effect of the sound processor upgrade observed by DACI users in real life following the sound processor upgrade. The APHAB showed statistically significant improvements in the global score. However, changes in global HUI2 scores were not statistically significant, although the amount of improvement was in a clinically relevant range. The difference may be due to the lower sensitivity of the HUI2 to hearing quality, as it evaluates general quality of life, in contrast to the APHAB, which focuses specifically on hearing. Subjective outcome measures might have been positively influenced by the smaller size of the CP810 and the ease of manipulation afforded by the remote control.

### Long-Term Results

The DACI presented in this manuscript is a relatively new treatment option for patients with severe to profound mixed hearing loss when conventional amplification is not adequate. It has already been shown to be a safe and effective treatment in the short-term (3 mo to 1 yr post-operative) (4–6). As no long-term (>2 yr) outcome data for DACI recipients was published to date, one of the secondary objectives of the current study was to

collect long-term safety and effectiveness data for DACI patients.

At the end of the current study, the subjects used their DACI for 45 months on average. The SRT in noise improved statistically significantly by 1.1 dB SNR over time when short-term results for Freedom are compared with the long-term results for CP810 (12M FU) in the condition  $S_0N_0$ , using the Everyday program. Also, the WRS were stable over time, i.e., did not change statistically significantly or by a clinically relevant amount. A long-term SRT in noise of  $-0.7$  dB SNR and a mean WRS of 76% at 65 dB SPL can be considered a very good long-term result. All but two subjects had a long-term WRS of more than or equal to 60% at 65 dB SPL, sufficient to follow a conversation in quiet at a distance of 1 m from the speaker (18).

Böheim et al. (19) reported on long-term results with an active middle ear implant (AMEI) connected to the round window in 12 patients with mixed or conductive hearing loss. At the time of the long-term measurement, the patients had been using their AMEIs for 40 months on average, allowing a comparison with our study group at the final study visit (45 mo on average). Performance outcome tests for both the speech in quiet (Freiburg monosyllables) as well as the speech test in noise (OLSA) were the same as used in our study. Böheim et al. (19) reported a WRS of 67% (SD 36%) at an input level of 65 dB SPL 3 months after surgery and a long-term WRS of 65% (SD 30%). The mean decrease of 2% was statistically non-significant and comparable to our mean WRS decrease of 4% (SD 15%), also not significant. In that study the SRT in noise worsened from 3 dB SNR at the 3-month follow-up to 5 dB SNR at the 40-month follow-up; this was reported to be statistically non-significant. A change of 2 dB SNR is, however, clinically relevant (12). In our study the SRT in noise improved from 0.4 dB SNR (SD 2.5 dB) to  $-0.68$  dB SNR (SD 1.8 dB) when comparing the short-term results with Freedom with the long-term results with the CP810, a statistically significant but clinically non-relevant improvement of 1.1 dB (SD 1.6 dB, Fig. 4A).

The long-term WRS data at 65 dB shows two negative outliers (Fig. 4B), which explains why the mean WRS at 65 dB was slightly worse compared with the Freedom data at the 3M FU. Looking at the median, however, the long-term value was 2% better. The two negative outliers scored 55 and 40% at 65 dB SPL input levels. However, they reach 80 and 75% at 80 dB SPL input level, which indicates that they probably need some fine tuning of the fitting to give them more gain at conversational speech level to increase their WRS at 65 dB input level.

The long-term BC thresholds were marginally poorer on average compared with the short-term thresholds. Only one subject presented with an increase of the BC thresholds by more than 10 dB. No reason could be found for this increase. However, as the DACI is very powerful, it can compensate for the additional hearing loss and this subject still received good clinical benefit (WRS of 75% at 65 dB SPL and an SRT in noise of  $-1.3$  dB SNR in the

Everyday program in the condition  $S_0N_0$  at the latest study visit).

### CONCLUSION

The new sound processor for the DACI system provides significant benefits for DACI users for speech recognition in both quiet and noise. The Noise program with the use of directional microphones is of particular value, allowing DACI patients to have less difficulty with conversations in noisy environments. Furthermore, our study confirmed that the benefits of the sound processor upgrade were available to the DACI recipients even after several years of experience with a legacy sound processor. Finally, our study demonstrated that the DACI system is a safe and effective long-term therapy.

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