

## Feasibility of an implanted microphone for cochlear implant listening

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**Abstract** This study aimed at evaluating the feasibility of an implanted microphone for cochlear implants (CI) by comparison of hearing outcomes, sound quality and patient satisfaction of a subcutaneous microphone to a standard external microphone of a behind-the-ear sound processor. In this prospective feasibility study with a within-subject repeated measures design comparing the microphone modalities, ten experienced adult unilateral CI users received an implantable contralateral subcutaneous microphone attached to a percutaneous plug. The signal was pre-processed and fed into their CI sound processor. Subjects compared listening modes at home for a period of up to 4 months. At the end of the study the microphone was explanted. Aided audiometric thresholds, speech understanding in quiet, and sound quality questionnaires were assessed. On average thresholds (250, 500, 750, 1k, 2k, 3k, 4k and 6 kHz) with the subcutaneous microphone were 44.9 dB, compared to 36.4 dB for the external mode. Speech understanding on sentences in quiet was high, within approximately 90% of performance levels compared to hearing with an external microphone. Body sounds were audible but not annoying to almost all subjects. This feasibility study with a research device shows significantly better results than previous studies with implanted microphones. This is attributed to technology enhancements and

careful fitting. Listening effort was somewhat increased with an implanted microphone. Under good sound conditions, speech performance is nearly similar to that of external microphones demonstrating that an implanted microphone is feasible in a range of normal listening conditions.

**Keywords** Implantable microphone · Cochlear implant · Totally implantable hearing device · Subcutaneous microphone · Speech performance

### Introduction

As of today, cochlear implants are still semi-implantable. In the current system architecture, the sound processing electronics, battery and microphone(s) are worn externally in the form of a behind-the-ear (BTE) device that transmits power and stimulation data via inductive coupling to the implanted part. The latter contains the electronics to decode the data stream and to generate corresponding amplitude-modulated stimulation pulses, typically biphasic and monopolar, which are delivered to the auditory nerve via a set of intracochlear Platinum contacts on the electrode array.

Since more than a decade, there is a desire for a totally implantable cochlear implant (TICI). Anticipated advantages of such a system are significant. In terms of safety, a TICI device would allow users to detect dangers and auditory warnings continuously, 24 h a day, 7 days a week. Usability would be substantially improved as a TICI device would function well in wet, humid, dusty and dirty conditions and the user would be able to engage in daily activities without restrictions. Potentially the device could be more reliable, since components are no longer exposed

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to daily wear and tear. Users would also benefit from a reduced stigma associated with wearing visible externals such as the coil and cables [1–3].

There are many technological challenges associated with the development of a TICI device, such as an implantable battery that meets lifetime and safety requirements. One that may clearly impact hearing performance is the implanted microphone. Commercially available totally implantable middle ear devices, containing an implantable microphone, have demonstrated that it is feasible to capture sound inside the body [1].

Subcutaneous microphones are known to be less sensitive than external microphones, especially in the high frequencies and inadvertently capture body noises such as breathing, swallowing, own voice, etc. This effectively lowers the signal-to-noise ratio of the source signal. In the field of cochlear implants, a first pilot study was conducted in Melbourne in 2005. Three patients were implanted with a Tirkandi research device containing a subcutaneous microphone mounted in the implant housing [2].

Speech understanding results with the subcutaneous microphone were modest. CNC word scores at 60 dB SPL halved in invisible hearing mode compared to hearing performance with an external microphone. Subjects were also distracted by the presence of body sounds. Still the subjects were pleased with the ability to hear day and night and are in fact still active users of their devices today. One of them uses invisible hearing during approximately 1/3 of the day. Their performance has been stable across the years [3].

A second pilot study was conducted with the more advanced subcutaneous microphone technology from the Carina device of Otologics (Boulder, CO, USA) in 2010, at the time still an independent manufacturer of the totally implantable Carina middle ear implant [4].

The research device was not an integrated TICI device. The focus of this study was the Carina subcutaneous microphone and its associated sound processing. Therefore, an assembly was built consisting of the Carina microphone capsule connected to a percutaneous plug connector developed for research on cochlear implants used in different studies [5].

Through the connector the microphone signals were made available externally, pre-processed by a digital sound processor (DSP) and then routed to the auxiliary input of a nucleus freedom sound processor. Four subjects participated in this pilot study in Denver [4].

Subjects could switch between external hearing and invisible hearing. The results confirmed improvements in perception of body noises compared to the Tirkandi study [2].

Two of the four patients rated their sound quality on the abbreviated profile of hearing aid benefit (APHAB)

questionnaire [6] very similar in external and invisible mode, and speech scores showed a decrease at softer presentation levels (from 70 to 50% CNC words at 60 dB, respectively).

More research is needed on the use of this microphone technology for cochlear implant use to better understand the potential of this technology towards TICI use. In the meantime, several new technologies have become available to improve hearing in noisy situations in classical hearing aids such as advanced gain management and single channel noise reduction [7].

The purpose of this study was to extend the study of Jenkins and Uhler, with higher patient numbers and improved state-of-the-art sound enhancement technologies to add to the body of knowledge on feasibility of implanted microphones for cochlear implants.

## Materials and methods

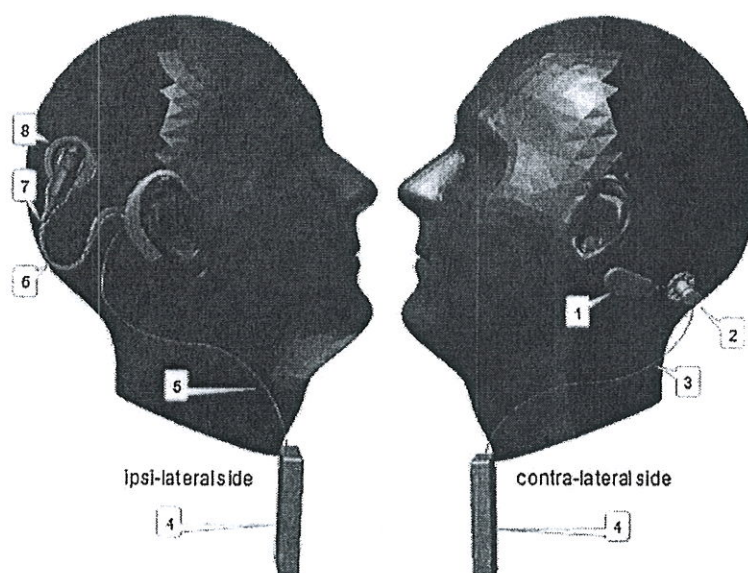
### Investigational device

The investigational device architecture shown in Fig. 1 is identical to the one used in the Denver study [4]. An implantable microphone, identical to the Carina middle ear implant, was connected through a four-wire lead to a percutaneous plug. The microphone assembly was implanted at the recommended implantation site by the company (inferior of the temporalis muscle, superior to the sternocleido-mastoid, and posterior to the external auditory canal). A difference to the Denver study is that the microphone was placed contralaterally to the CI side. All microphone assemblies were produced and sterilized in a single batch.

The percutaneous plug provides external access to the microphone signals. These were fed into a sound processor performing body noise cancellation, noise reduction and spectral shaping. In fact this processor was a standard Carina implant not including the actuator, mounted in housing and worn around the neck (Carina-in-a-box). The enhanced signal was then sent to the auxiliary input of the CI sound processor. By switching between standard microphone and auxiliary input, in-subject comparisons could be made between external and invisible listening mode.

In comparison with the Denver study, newer Carina components, identical to the current commercial hardware and firmware, were available for the sound capture and sound pre-processing in our study. In this new application the firmware was configured as a linear hearing aid. The Carina microphone fitting software was a custom research application written in Matlab (Mathworks, Natick, USA). Our first four participants reported continuous background

**Fig. 1** Investigational device configuration: (1) implanted Carina microphone, (2) percutaneous plug, (3) percutaneous plug cable, (4) Carina-in-a-box processor, (5) sound processor accessory cable, (6) CI sound processor, (7) coil cable, (8) coil



noise that could not be eliminated through the firmware and fittings but was subsequently alleviated by a hardware change. At the same time the fitting software and firmware were upgraded with different algorithms for body noise cancellation, expansion and amplification. This second version of the Carina hardware and software was used by the six subsequent subjects.

The CI sound processor (and remote assistant) used during the study was the latest generation, commercially available system at the time of testing in Belgium. For the first six subjects, this was the Nucleus 5 system (with CP810 sound processor with a slightly modified firmware incorporating a research version of the SNR-NR noise reduction algorithm) from Cochlear Ltd (Sydney, NSW, Australia) [8].

For the last four subjects, the Nucleus 6 system (with CP910 sound processor) was available. All research hardware and software was built and verified for use with human subjects according to Cochlear Ltd investigational device procedure.

### Study design

The primary objective was to evaluate the clinical efficacy of the implanted subcutaneous microphone in combination with a cochlear implant, in terms of microphone sensitivity, speech understanding in quiet, perception of body noises and patient satisfaction.

A repeated-measures design with within-subject comparison was used. After implantation, a 2-month healing period was observed prior to activation of the implanted microphone. During this period, the subjects received their

sound processor and their map was checked. They were instructed to use during the study an everyday map (ACE strategy at 900 pulses per second, nine maxima, with adaptive dynamic range optimisation (ADRO) and automatic sensitivity control (ASC enabled) with standard directionality pattern). Also a baseline audiological evaluation with this map was performed.

At month 2 the subcutaneous microphone was activated, subjects were counseled on the use of the external Carina components, a program was fitted and further tuned 2 weeks later. Subjects were instructed to listen approximately 50% of their time in invisible mode.

In the following three evaluation sessions (between month 2, 5 and 6, in general one per month) study endpoints were measured with the standard microphone and the subcutaneous microphone. For audibility free-field audiometric thresholds at 8 frequencies (250, 500, 750, 1k, 2k, 3k, 4k and 6 kHz) were collected.

For speech testing the MBAA2 corpus (Université de Montpellier) was chosen [9].

This corpus consists of 36 lists of 15 French everyday sentences, clearly pronounced by a female speaker. Every list consists of approximately 100 words with sentence length varying between 2 and 15 words. Sentence materials were preferred over the CNC words used in prior studies, because multiple sound cleaning algorithms (e.g. body noise cancellation, microphone noise reduction, automatic gain control) are adaptive in nature and, therefore, function more realistically on continuous speech materials than on short words. Sentences were presented in free-field using a research software (SPIN—speech in noise testing, Cochlear Technology Centre, Mechelen, Belgium) driving

the audiometer. Scoring was performed at word level. Performance was evaluated at four presentation levels: 45, 55, 65 and 75 dB SPL. The extended range was chosen to evaluate hearing performance in invisible mode over the full range of everyday sound conditions.

All audiological evaluations took place in the clinic in a soundproof booth. To evaluate sound quality in everyday life, subjects were asked to complete the comparative APHAB questionnaire and a study specific questionnaire, prior to coming to the clinic, typically after a 1-month take-home period.

After completion of the three evaluation sessions, the subcutaneous microphone and percutaneous plug were explanted in the hospital.

### Subject population

Since this is a feasibility study, subject inclusion was not driven by a formal power calculation. Earlier pilot studies on totally implantable cochlear implants were limited to four subjects [2, 4].

Here ten adult postlingual French-speaking subjects participated. They were recruited from the clinical population of two Belgian university clinics: UCL Brussels and CHU Liège. Their demographic data are shown in Table 1. They had experience with their unilateral Nucleus CI for at least 24 months. Subjects with an increased risk for skin infections were excluded from the current study.

Due to slow recruitment three groups were formed with a somewhat modified investigational device:

Group 1 First four subjects, recruited from UCL Brussels using Nucleus 5

Group 2 (Two subjects from Brussels) with Nucleus 5 and the improved external Carina hardware and firmware described above

Group 3 (Four subjects from Liège) used the Nucleus 6 sound processor and the improved external Carina hardware and firmware described above

Ethical approval for the original protocol, and the subsequent amendments supporting the hardware and software changes, was obtained for the study under registration number B403201214375 from the Belgian Ministry of Health.

### Statistical analysis

Statistical analysis was performed in Matlab version 7.13.0.564 using the statistics toolbox version 7.6. Multi-factorial ANOVA was used to test for significant changes. Significance levels for a factor were set at 5% and Bonferroni corrections were applied in post hoc pair-wise comparisons.

### Results

The microphone was implanted in all ten subjects at the inferior to temporalis muscle, superior to the sterno-cleido-mastoid and posterior to the external auditory canal. No intraoperative complications were noted. During the course of the study several subjects reported skin irritation around the site of the percutaneous plug. All incidences were easily treated with corticoid and antibiotic cream.

Overall subjects adhered well to the study schedule. Two subjects (S05 and S06) had to interrupt their participation due to health issues, unrelated to the investigational device. They completed the remaining evaluation sessions afterwards.

Two subjects (S06 and S07) did not comply with the request to listen in invisible mode for approximately 50% of the time because of lack of time and practical reasons.

**Table 1** Subject demographics

|     | Age (years) | Gender | Duration of severe HL (years) | Etiology       | Duration of CI use (years) | CI side | Group | Skin thickness (mm) |
|-----|-------------|--------|-------------------------------|----------------|----------------------------|---------|-------|---------------------|
| S01 | 50          | ♂      | 12                            | Ototoxic drugs | 13                         | R       | 1     | 9                   |
| S02 | 70          | ♂      | 11                            | Genetic        | 30                         | L       | 1     | 7                   |
| S03 | 36          | ♀      | 28                            | Genetic        | 9                          | R       | 1     | 4                   |
| S04 | 30          | ♂      | 1                             | Cogan syndrome | 10                         | L       | 1     | 6                   |
| S05 | 64          | ♀      | 46                            | Genetic        | 10                         | L       | 2     | 8                   |
| S06 | 50          | ♀      | 1                             | Genetic        | 11                         | L       | 2     | 8                   |
| S07 | 41          | ♀      | 3                             | Unknown        | 4                          | L       | 3     | 4                   |
| S08 | 30          | ♀      | 8                             | Unknown        | 4                          | R       | 3     | 10                  |
| S09 | 26          | ♀      | 5                             | Unknown        | 7                          | L       | 3     | 6                   |
| S10 | 26          | ♀      | 7                             | Unknown        | 2                          | R       | 3     | 8                   |

In terms of device fitting, our approach was to fit the implanted microphone and the associated sound processing as an additional accessory and to avoid changing the CI map. Linear gains were set to optimally match the signal from the implanted microphone to the signal coming from an external microphone in standard mode. In terms of the microphone fitting, activation of the body noise cancellation (BNC) function was essential. In vivo bone conduction threshold measurements showed that the BNC algorithm attenuated body noises by more than 20 dB. All subjects requested the activation of expansion and single channel noise reduction.

### Access to sound

Figure 2 shows the free field pure tone audiometric (PTA) thresholds for each subject and the overall group. The PTA is averaged across test frequencies (250, 500, 750, 1k, 2k, 3k, 4k and 6 kHz) and across the evaluation sessions (month 3, 4 and 5).

A four-factor fixed-effects ANOVA analysis was conducted with factors Mode (external or subcutaneous microphone), Session (month 3, 4 or 5), Frequency (eight test frequencies) and Group (1, 2 or 3, see Table 1). Factors Mode [ $F(1,142) = 228.9$ ], Frequency [ $F(7,138) = 6.03$ ] and Group [ $F(2,141) = 52.2$ ], were highly significant ( $p < 0.01$ ). Effect sizes were 25.0, 4.6 and 11.4% for group 1, 2 and 3, respectively.

On average thresholds with the subcutaneous microphone were 44.9 dB, compared to 36.4 dB for the external mode.

The Group effect is linked to the hardware and software improvements performed after thorough analysis of the

group 1 data. PTAs improved to on average 34.5 dB for groups 2 and 3.

Although the Frequency factor was significant, tonal audiograms were essentially flat with deviations up to 3 dB only, including for those frequencies beyond the microphone resonance, which is approximately located around 3500 Hz.

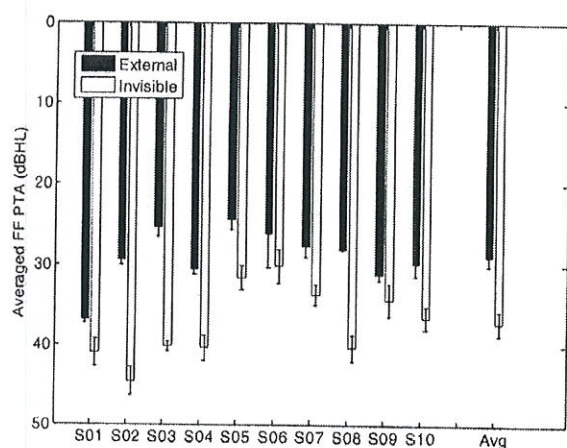
### Speech understanding performance

Figure 3 shows the individual speech in quiet results at conversational level (65 dB SPL) averaged over the three evaluation sessions, for standard and subcutaneous microphone modality. For the first evaluation session (month 3) some data points (S1, S2, S4 and S6) could not be collected due to time constraints. For some of the subjects, ceiling of the speech scores is observed on these sentence materials.

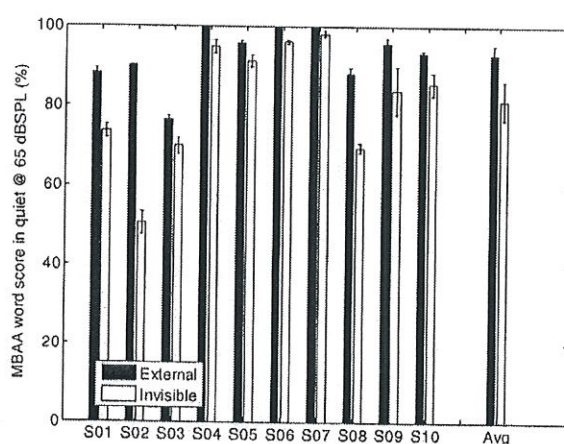
A three-factor fixed-effects ANOVA analysis was conducted with factors Mode (external or subcutaneous microphone), Session and Group (defined as before).

Factors Mode [ $F(1,60) = 11.62$ ] and Group [ $F(2,58) = 9.36$ ], were highly significant ( $p < 0.01$ ). Respectively, 13.1 and 21.2% of the variability was explained by these factors.

Speech performance with the subcutaneous microphone on this sentence test was good (84.04% average word score). This was somewhat lower (by 9.5%) than in external mode. Several subjects performed in invisible hearing mode almost as well as in external mode. In some subjects (e.g. S02 and S08) the difference was greater. For these subjects it was difficult to find reliable and stable amplification settings because either they could not



**Fig. 2** Free field aided thresholds, averaged over the eight test frequencies and over the three evaluation sessions. Group average data are shown on the right. Error bars represent the standard error of the mean



**Fig. 3** Individual word scores at 65 dB SPL in Quiet averaged across three evaluation sessions

reliably report on loudness differences or we experienced some connectivity issues with the percutaneous plug that may have led to a variable attenuation.

Figure 4 shows the average speech scores across different presentation levels. The same speech materials were used. The performance difference between the implanted microphone and the external microphone at soft to medium speech levels is larger than at conversational and loud levels.

The three-factor ANOVA analyses were repeated for all presentation levels. The factor Session was never significant. The factors Mode and Group were highly significant at 45, 55 and 65 dB SPL and significant at 75 dB SPL. Post-hoc comparisons with Bonferroni corrections for the factor Group showed that group 1 performance was always significantly worse than group 2. Performance of groups 2 and 3 was not statistically different.

For the factor Mode, effect size increased with decreasing presentation level (a performance difference of 46.1% at 45 dB, 23.8% at 55 dB, 13.1% at 65 dB and 7.1% at 75 dB).

One hypothesis was that skin flap thickness above the microphone measured before the skin incision and local anesthesia infiltration (see Table 1) may be a contributing factor to the performance difference with a subcutaneous microphone. The skin thickness was varying between 4 and 10 mm. A linear correlation analysis was performed of the final speech scores at 65 dB SPL. S02 and S08 were excluded from this analysis for the reason stated above. A significant and very strong correlation was then found between performance decrement and skin flap thickness ( $r = 0.829$ ,  $p = 0.011$ ). On average 2% word score was lost for every millimeter skin flap beyond 4 mm when using an implantable microphone.

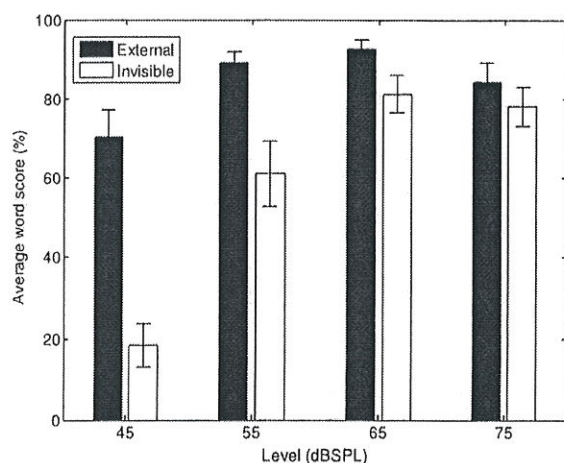


Fig. 4 Word score averaged across sessions and subjects for four presentation levels

## Sound quality

Sound quality questionnaires were to be completed monthly at home. Unfortunately compliance was low. Only in half of the cases the questionnaires were returned. S06 never completed the questionnaires and is excluded from this part of the analysis.

Figure 5 shows an overall view on the sound quality ratings. The top-right shows the average APHAB (abbreviated profile of hearing aid benefit). Given the many missing data, non-parametric paired tests were performed on the last available data point per subject.

Subjects report more sound quality issues with the implantable microphone. The Wilcoxon signed rank test showed a statistically significant difference on the three subscales Ease of Communication ( $p = 0.0156$ ), Background Noise ( $p = 0.0156$ ) and Reverberation ( $p = 0.0156$ ) for the two microphone conditions. There is no significant difference on the subscale averseness ( $p = 0.327$ ). In general, group 1 subjects tended to be more similar in their ratings for the two conditions compared to the subjects of group 2 and 3.

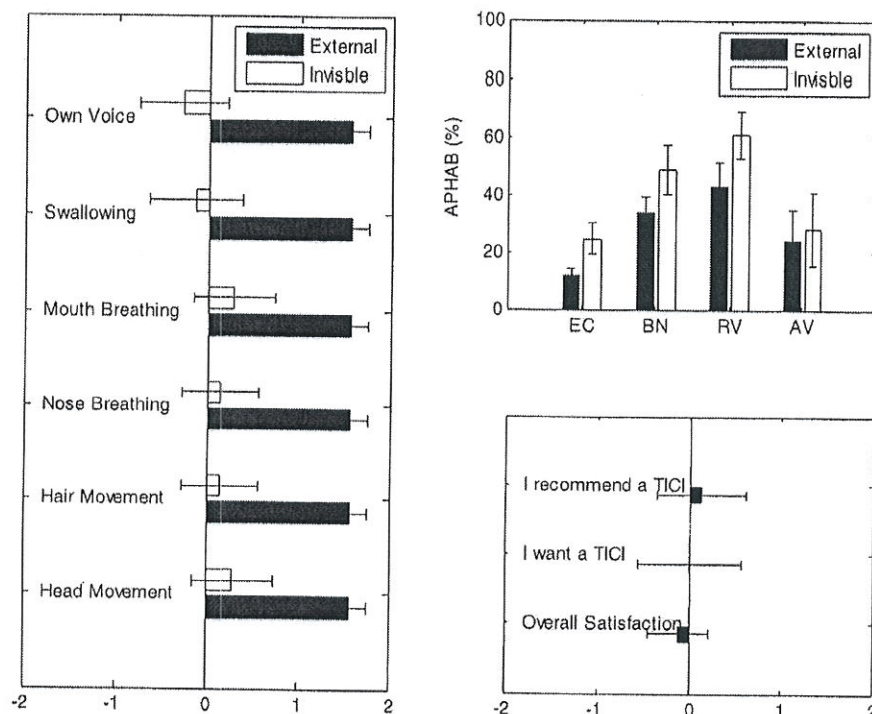
The left panel shows the average level of satisfaction with the implantable microphone regarding hair and head movement and breathing through the nose and mouth. On average the scores are rather neutral, neither satisfied nor dissatisfied. Swallowing and own voice are categories where subjects remain on average somewhat dissatisfied.

The right bottom panel shows the average response to the question how satisfied they were in general regarding their hearing performance with the implantable microphone. Overall satisfaction is slightly negative. Subjects of group 1 tended to be more satisfied than the subjects of group 2 and 3. Overall, in terms of hearing performance, the feedback regarding a fully implantable cochlear implant using the Carina microphone was mixed. Half of the participants would want a totally implanted CI with an implantable microphone on condition that it is a fully integrated. Five out of eight participants would recommend a totally implanted CI to others.

When asked for the motivation for the poorer scores in a final interview, most subjects stated that the overall sound quality was similar to external microphone, but their ratings were influenced by the quality of their own voice. Although they grew accustomed to the difference, it remained sounding distorted. The poorer hearing performance also played a role as they needed to concentrate more in challenging listening conditions. Residual body noise was not a big issue. It was audible but not particularly annoying, except for S04, part of group 1, who kept finding the noise too loud and disturbing.

Subject 07 with long wavy hair constantly heard the movement of the hair while moving around. In the lab,

**Fig. 5** Sound quality rating group data (average and standard error). *Left* ( $N = 7$ ), comparative data on six aspects of sound quality. Scores ranging from very dissatisfied or fully disagree ( $-2$ ) to very satisfied or fully agree ( $+2$ ). *Top-right* ( $N = 8$ ) APHAB scores on ease of communication (EC), background noise (BN), reverberation (RV) and averseness (AV). *Bottom right* ( $N = 8$ ), overall satisfaction with the implantable microphone and attitude towards a future TICI device



sitting still, S07 was a star performer. But in everyday conditions, the hair noise was reported to be loud. The body noise cancellation algorithm could not act on this broadband external sound. The subject stopped using the implantable microphone at home and only participated to the lab evaluations. To a lesser extent, hair movement was also brought up by S08 and S09.

## Discussion

There were several limiting factors associated with this feasibility study on the use of the Carina implantable microphone for cochlear implant listening. The configuration of the investigational device and the sound processing was complex which may have deteriorated the signal quality.

Also usability of the investigational device was rather poor. The percutaneous connector is inconveniently located. The device was bulky, not very aesthetic and impractical. Fortunately, subjects did not consider this to be too burdensome, resulting in all completing the design study.

Third, the microphone was implanted contra laterally to the cochlear implant.

Last, the small sample size in this feasibility study does not allow drawing far reaching conclusions on efficacy. There were also some missing data points, although we

believe these have not influenced the conclusions in terms of significance of the microphone modality or other factors.

Still this feasibility study resulted in meaningful insights. First the investigational device design, based on a percutaneous plug, worked well. Device-related adverse events, such as skin irritation, occurred but were mild. The clinical teams could treat all issues with standard medication.

The implanted microphone provided good access to softer sounds. Free-field audiometric thresholds of  $\pm 35$  dB were achievable which is consistent with clinician expectation [10] and in line with thresholds obtained with the Carina middle ear implant [11, 12].

Sentence understanding under good listening circumstances with the implanted microphone exceeded 80%. This is within approximately 90% of performance levels listening with the external microphone. This result trends to exceed the outcomes of the earlier studies [2, 4] where the speech intelligibility was halved. Contributors to this improved performance are careful fitting and access to latest technology. It is also likely the choice of test materials may have played a role. Previous studies used English CNC word lists to quantify speech intelligibility. Since this study took place in French-speaking part of Belgium, different materials were needed. We opted for continuous speech materials due to the adaptive nature of the sound pre-processing algorithms. In hindsight it would have been

interesting to include short word lists. This option was considered but dropped because the audiological evaluation sessions were already intense.

Sound quality is an area where more research is needed. With the current signal cleaning functions, the loudness of body-generated sounds was comfortable. Hair noise and perception of own voice remain a concern for some recipients. The quality is intrinsically different as the own voice is also heard through bone conduction. Without processing the recipient's voice is too loud. The body noise cancellation function is essential in bringing own voice loudness in balance with external speech, but it may also cause audible distortions.

When listening conditions are more challenging, performance with a subcutaneous microphone in this study degraded more than for an external microphone. There is room for further optimization of the sound processing to improve hearing outcomes in soft and noisy circumstances.

Overall, this study has demonstrated that CI users can achieve good hearing outcomes in ideal listening environments. State-of-the-art sound processing can deal effectively with internal noise and body sounds. For listening in more noisy complex listening conditions, the recipient of a future TICI device would benefit from the option of using an external sound processor with dual microphone capability to provide an optimal sound input through input processing algorithms to improve the signal-to-noise ratio.

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#### Compliance with ethical standards

**Conflict of interest** Filiep Vanpoucke, Joris Walraevens and Anke Plasman are employed by Cochlear Technology Centre, Belgium. The remaining authors have no conflict of interest.

**Funding** Funding for this study has been received from Cochlear Ltd., Sydney, Australia.

**Ethical approval** Ethical approval for the original protocol, and the subsequent amendments supporting the hardware and software changes, was obtained for the study under registration number B403201214375 from the Belgian Ministry of Health. This research involved human participants.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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