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Off the ear with no loss in speech understanding: comparing the RONDO and the OPUS 2 cochlear implant audio processors

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Abstract The RONDO is a single-unit cochlear implant audio processor, which omits the need for a behind-the-ear (BTE) audio processor. The primary aim was to compare speech perception results in quiet and in noise with the RONDO and the OPUS 2, a BTE audio processor. Secondary aims were to determine subjects' self-assessed levels of sound quality and gather subjective feedback on RONDO use. All speech perception tests were performed with the RONDO and the OPUS 2 behind-the-ear audio processor at 3 test intervals. Subjects were required to use the RONDO between test intervals. Subjects were tested at upgrade from the OPUS 2 to the RONDO and at 1 and 6 months after upgrade. Speech perception was determined using the Freiburg Monosyllables in quiet test and the Oldenburg Sentence Test (OLSA) in noise. Subjective perception was determined using the Hearing Implant Sound Quality Index ($HISQUI_{19}$), and a RONDO device-specific questionnaire. 50 subjects participated in the study. Neither speech perception scores nor self-perceived sound quality scores were significantly different at any interval between the RONDO and the OPUS 2. Subjects reported high levels of satisfaction with the RONDO. The RONDO provides comparable speech perception to the OPUS 2 while providing users with high levels of satisfaction and comfort without increasing health risk. The RONDO is a suitable and safe alternative to traditional BTE audio processors.

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Introduction

Single-unit processors combine control unit, coil, and the battery pack of a cochlear implant (CI) audio processor into a single device that sits off the ear on the CI site. The integration of the control unit, battery pack, and coil into one external component means the single-unit processor has no cable. The absence of the cable should benefit the user by reducing the number of device parts, making the single-unit processor more simple to wear and more durable. Furthermore, the off-the-ear location has an esthetic advantage over standard audio processors: it can easily be hidden by the wearer's hair and leaves the ear free, as it would be natural. This should make wearing glasses more comfortable.

The electronic components of the RONDO off-the-ear speech processor and the OPUS 2 behind-the-ear (BTE) speech processor (both MED-EL, Innsbruck, Austria) are identical. As an audio processor, the RONDO is responsible for picking up sound from the environment, processing this sound, and then sending it to the implant. Specifically, a microphone (acoustic signals) and/or telecoil (inductive signals) in the RONDO pick up sound and send it to the signal processing application-specific integrated circuit (ASIC). This ASIC, which is the same as the one used in the OPUS 2, digitizes and analyzes the sound signal from the microphone and/or telecoil according to the selected speech coding strategy and converts it into a coded electrical signal that is sent to the coil of the inductive link to the implant.

The OPUS 2 uses, among others, the Fine Structure Processing coding strategy. Fine structure contributes to greater speech perception in noise, particularly in fluctuating noise [1, 2]. However, the microphone position is different between the RONDO and the OPUS 2; in the OPUS 2 it is above the pinna, as the OPUS 2 is worn on the pinna; whereas in the RONDO the microphone is located directly above the implant receiver coil, as the RONDO is worn somewhat behind the pinna [3]. Therefore, the new wearing option offered by the RONDO shifts the microphone further back on the head than it would be with a BTE audio processor. The few studies available to date indicate either that: (1) hearing outcomes with the RONDO are not significantly influenced by the position of the microphone [4] or that (2) speech intelligibility depends on the sound source [3]. When given time (28 days) to become accustomed to the RONDO, many subjects preferred the RONDO to their BTE audio processor [5].

Thus, the present study's primary aim was to clarify what effect the RONDO has on the speech perception of experienced adult CI users. The secondary aim was to determine how RONDO users (1) assessed their own auditory abilities with the RONDO and (2) thought and felt about the speech processor after 6 months of daily use.

Methods

Subjects

To participate in the study, potential subjects had to: be 18 years or older, be fluent in German, use their OPUS 2 for a minimum of 10 h a day, have been an OPUS 2 user for at least 6 months, have had a stable fitting map for at least 3 months, and have a minimum of 10 active electrode contacts.

Testing

Five test centers participated in the study; all followed the same procedures.

Speech perception was evaluated by (1) the Freiburg Monosyllables in quiet test and (2) the Oldenburger Sentence Test in noise (OLSA). Subjects evaluated their auditory abilities in everyday communication situations via the Hearing Implant Sound Quality Index ($HISQUI_{19}$). In addition, subjects evaluated the RONDO via a custom made device-specific questionnaire: the RONDO questionnaire.

Testing was conducted at three intervals. At interval 1, subjects were upgraded to the RONDO and handed over their OPUS 2 to the investigator. The OPUS 2 was stored at the test site during the entire study phase to ensure the exclusive use of the RONDO. Interval 2 was 1 month after interval 1. Interval 3 was 6 months after interval 1. See Table 1 for testing by interval.

Safety of the RONDO/adverse events

The safety of the RONDO was evaluated via adverse event reporting.

Statistical analyses

Patient characteristics and outcome variables are described as mean with standard deviation (SD) and/or median and range (minimum and maximum values). For qualitative data the frequency distribution is shown.

Wilcoxon signed-rank test was used to test for a significant difference between the OPUS 2 and RONDO on the speech performance tests (Freiburg Monosyllables in

Table 1 Tests and questionnaires by interval

	With the OPUS 2	With the RONDO
Interval 1 (0 days)	Freiburg Monosyllables in quiet	Freiburg Monosyllables in quiet
	OLSA sentences in noise	OLSA sentences in noise
	$HISQUI_{19}$	RONDO questionnaire
Interval 2 (1 month)	Freiburg Monosyllables in quiet	Freiburg Monosyllables in quiet
	OLSA sentences in noise	OLSA sentences in noise
		RONDO questionnaire
Interval 3 (6 months)	Freiburg Monosyllables in quiet	Freiburg Monosyllables in quiet
	OLSA sentences in noise	OLSA sentences in noise
		RONDO questionnaire
		$HISQUI_{19}$

quiet and OLSA in noise) and the self-perceived sound quality of everyday listening situations ($HISQUI_{19}$).

All p values are the results of two-sided tests. A p value of ≤ 0.05 was considered significant. The software tool IBM SPSS Statistics 22 (IBM, Armonik, New York) was used for the statistical analyses.

Ethics approval was granted (Ruhr University Bochum, 4555-13). All subjects gave their informed consent in writing before any study-specific procedure was performed. The informed consent procedure was in full accordance with the Declaration of Helsinki and all German requirements.

Results

Subjects

Fifty subjects were enrolled. The mean age at enrollment was 56.1 years (range 18.4–82.6); mean duration of hearing loss in the tested ear was 20.2 years (range 1–61); mean CI use in the tested ear was 4.7 years (range 0.6–15.5), and the mean OPUS 2 experience was 3.2 years (range 0.5–7.5). The average daily use of the OPUS 2 before upgrade, as reported by the subjects, was 14.5 h (range 10–19).

41/50 subjects completed the study and have full datasets available. Of the 9 subjects who dropped out, 7 reported dissatisfaction with the sound quality, the wearing option, the magnet strength or a combination of these issues; 2 dropped out due to health reasons. All subjects for whom data from at least 2 test intervals were available were included in the analyses.

Speech test results

1 of 2: Freiburg monosyllables in quiet

Mean scores with the OPUS 2 (range 62.4–63.4% correct) and with the RONDO (range 60.3–61.9% correct) showed little change across intervals. At no interval were the scores with the OPUS 2 and RONDO significantly different (interval 1: $p = 0.274$; interval 2: $p = 0.565$; interval 3: $p = 0.131$).

2 of 2: OLSA in noise

Mean scores with OPUS 2 (range 2.2–4.1 db SNR) and with the RONDO (range 1.9–4.6 dB SNR) showed little change across intervals. At no interval were the scores with the OPUS 2 and RONDO significantly different (interval 1: $p = 0.349$; interval 2: $p = 0.318$; interval 3: $p = 0.151$).

Subjective tests

1 of 2: $HISQUI_{19}$

Mean $HISQUI_{19}$ scores with the OPUS 2 at interval 1 (87.5) and with the RONDO at interval 3 (86.1) both indicated subjects had a 'moderate' self-perceived sound quality in everyday listening situations. No significant difference was found between scores with the OPUS 2 and with the RONDO ($p = 0.379$).

2 of 2: RONDO device-specific questionnaire

Depending on the interval, 93.3–94.7% of subjects who answered the question reported that the sound quality with the RONDO was 'better than' or 'the same as' with the OPUS 2 (Fig. 1).

Most subjects were generally satisfied with the RONDO: 86.7% of subjects reported being 'very satisfied' or 'satisfied' at interval 2 and 87.8% reported being at 'very satisfied' or 'satisfied' at interval 3. Subjects were similarly likely to report being 'very satisfied' or 'satisfied' with the general wearing comfort of the RONDO: 98% of answering subjects at interval 1, 86.7% at interval 2, and 92.7% at interval 3.

Subjects were likely to recommend the RONDO to other CI users: 75.6% of subjects at interval 2 and 70.7% at interval 3 would 'absolutely' recommend the RONDO; at

the same intervals 15.6 and 19.5% would recommend it 'only with the OPUS 2', and 8.9 and 7.3% would 'rather not' recommend it.

Amongst subjects who used the telephone, 86.7% at interval 2 and 92.3% at interval 3 were 'very satisfied', 'satisfied', or found the RONDO 'acceptable' when making a telephone call. Approximately one-third of the subjects (30.2% at interval 2 and 36.6% at interval 3), however, reported that they never used the telephone.

1 subject at interval 2 and 3 reported being 'somewhat satisfied' with the combination of wearing the RONDO with glasses. All other subjects reported being 'very satisfied' or 'satisfied' (interval 1: 97.6%; interval 2: 97.5%). No subjects reported being 'unsatisfied'.

Most subjects used the RONDO for the most of the waking day: 95.5% at interval 2 and 95.0% at interval 3 reported that they wore the RONDO for 9 or more hours per day. No subjects reported wearing the RONDO for less than 6 h per day.

Adverse events

Five adverse events were reported, four of which were caused by device misuse. In one case, the subject reported redness which required topical treatment with antibiotics and corticosteroids. As no attempt was made to reduce the magnet strength, contrary to what is suggested in the manual, a causal relationship due to user misuse cannot be excluded.

One device or procedure-related adverse event was reported: a subject experienced redness and pain on his/her skin between the audio processor and the implant. This may have been due to the subject having a too powerful magnet. This should be resolved by switching to a less powerful magnet; no information, however, was provided on if this intervention was taken. The subject dropped out of the study.

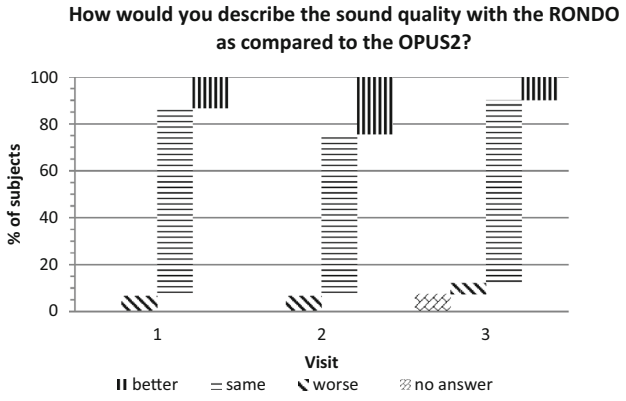

Fig. 1 Answers (in %) to the question: 'How would describe the sound quality with the RONDO as compared to the OPUS 2?'

In addition, subjects were asked to report any irritations experienced with the RONDO. Most commonly itching and skin irritation/redness of the skin was reported; followed by sweating. Those are inconveniencies which are also experienced with the behind-the-ear processors and coils as stated by some users in the device-specific questionnaire. Most importantly, the occurrence rate of those inconveniencies was reported to be low (not more than 1 × per week) in the majority of the cases (12/20) and the duration was either not reported or less than 8 h. In most cases, (6/20) the problem was solved by a magnet change or by drying the device (3/20). In 11/20 cases no countermeasure was reported. No serious adverse events were reported.

Discussion

In the majority of the subjects, the speech understanding results and the self-assessed benefit derived from RONDO use were not significantly different from those with the OPUS 2. This suggests that the microphone position of the RONDO does not negatively impact speech perception outcomes or sound quality in either clinical setting or in everyday listening situations. Furthermore, device-related adverse event reporting suggests that the RONDO is safe and that when problems do occur, they can be addressed by changing the magnet strength. In sum, CI users can, if they choose to, switch from the OPUS 2 to the RONDO without sacrificing speech understanding, sound quality, or exposing themselves to additional safety risk.

The fact that the RONDO offers the same speech perception performance in quiet and in noise as with the comparator BTE device contradicts the findings of Wimmer et al. [3], who found that RONDO users could have reduced understanding in noisy situations. Similar to the current study, Mertens et al. [5] and Távora-Vieira and Miller [6] found that RONDO users' understanding was unaffected by the change in microphone position. It should be noted that the present study had a much higher N than did Wimmer et al. ($N = 12$), Mertens et al. ($N = 10$), or Távora-Vieira and Miller ($N = 5$).

Regarding RONDO users' subjective assessment of sound quality with the RONDO versus sound quality with their BTE device: the majority of subjects in both Mertens et al. [5] and the present study reported that the sound quality was the same or that the RONDO provided superior sound quality to the BTE device. While in the present study subjects were queried about sound quality but not specifically sound quality of speech in noise, like they were in Mertens et al. [5], it can be assumed that 'in noise' was what was assessed since sound quality was assessed in real-life situations and subjects are unlikely to live in anechoic

chambers. Wimmer et al. [3] did not assess subjective response to the RONDO.

Mertens et al. found that after a short time of experience (28 days), 80% of users preferred using the RONDO to their previous BTE device [5]. Although subjects were not asked that question in the present study, results suggest that the subjects were happy with the RONDO: after 6 months of daily use (i.e., at interval 3), 87.8% of subjects were at 'very satisfied' or 'satisfied', 92.7% were 'very satisfied' or 'satisfied' with the general wearing comfort, and 70.7% would 'absolutely' recommend the RONDO. These results showed little variation according to interval.

However, it should be noted that 14% of the subjects discontinued the study prematurely because of dissatisfaction with the sound quality, the wearing option, the magnet strength, or a combination of these issues. This suggests that the RONDO is not be the ideal solution for every potential user and that some users still might prefer a BTE option. This topic should be discussed with the subject before a switch of the processor will be planned.

The safety results suggest that the RONDO does not introduce any new or increased risk level.

Conclusion

The RONDO provides comparable speech perception to the OPUS 2 while providing most users with high levels of satisfaction and comfort without increasing health risk. We can conclude that the RONDO is a suitable and safe alternative to traditional BTE audio processors.

Compliance with ethical standards

Conflict of interest The authors declare no conflict of interest.

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