

COMPARING BEHIND-THE-EAR AND SINGLE-UNIT COCHLEAR IMPLANT AUDIO PROCESSORS IN 83 NEWLY IMPLANTED SUBJECTS

Contributions:
A Study design/planning
B Data collection/entry
C Data analysis/statistics
D Data interpretation
E Preparation of manuscript
F Literature analysis/search
G Funds collection

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Abstract

Background: The RONDO is a single-unit device that merges both the OPUS 2 behind-the-ear audio processor and the coil into a single housing. The study aims to assess the perceived auditory abilities and opinions of newly implanted subjects using the OPUS 2 and/or the RONDO in everyday life.

Material and methods: We studied 83 newly implanted subjects who received the RONDO and OPUS 2 and were free to use whichever processor they preferred or a combination of the two. User satisfaction was evaluated after at least 4 weeks of use (after the first fitting) using the device-specific RONDO questionnaire.

Results: Results showed that 77% of subjects were satisfied with the RONDO in general, and 92% of subjects either preferred to use the RONDO or liked both audio processors equally while wearing eyeglasses. Overall, 91% of subjects would recommend the RONDO to other CI users. RONDO was significantly ($p < 0.05$) preferred at home, for cultural events, or when wearing glasses; OPUS 2 was preferred for sport or while wearing a cap.

Conclusions: The RONDO was associated with a high degree of user satisfaction among newly implanted CI users and offers CI users further options in terms of wearer comfort and cosmetic appearance. Thus, CI users can, if they wish, switch from the OPUS 2 to the RONDO without affecting their hearing ability or speech understanding.

Key words: questionnaire • comfort • audiometry • sound quality • cochlear implants • audio processor

PORÓWNANIE ZAUSZNYCH I JEDNOCZĘŚCIOWYCH PROCESORÓW MOWY IMPLANTU ŚLIMAKOWEGO U 83 PACJENTÓW Z NIEDAWNO WSZCZEPIONYM IMPLANTEM

Streszczenie

Wstęp: RONDO to jednoczęściowe urządzenie, które w jednej obudowie łączy zarówno zauszny procesor OPUS 2, jak i cewkę. Badanie ma na celu ocenę zdolności słuchowych oraz zadowolenia pacjentów z niedawno wszczepionym implantem, korzystających w życiu codziennym z OPUS 2 i/lub RONDO.

Materiał i metody: Przebadaliśmy 83 pacjentów z niedawno wszczepionym implantem, którzy otrzymali dwa procesory: RONDO i OPUS 2 i mogli używać dowolnego procesora lub kombinacji tych dwóch. Zadowolenie pacjentów oceniano po co najmniej 4 tygodniach użytkowania procesora (po pierwszym dopasowaniu implantu) za pomocą kwestionariusza RONDO dla danego urządzenia.

Wyniki: Wyniki wskazują, że 77% badanych było ogólnie zadowolonych z procesora RONDO, a 92% badanych wołało używać RONDO lub było zadowolonych w równym stopniu z obu procesorów mowy podczas noszenia okularów. Ogólnie 91% badanych poleciłoby procesor RONDO innym użytkownikom implantów ślimakowych. Procesor RONDO był istotnie ($p < 0,05$) preferowany do używania w domu, podczas wydarzeń kulturalnych lub podczas noszenia okularów; procesor OPUS 2 był preferowany do uprawiania sportu lub w czapce.

Wnioski: Procesor RONDO był kojarzony z wysokim stopniem satysfakcji wśród pacjentów z niedawno wszczepionym implantem ślimakowym, którym oferuje wiele opcji mających na celu zwiększenie komfortu noszenia i estetyczny wygląd. Użytkownicy implantu ślimakowego mogą, jeśli chcą, zmienić procesor OPUS 2 na procesor RONDO, co pozostaje u nich bez wpływu na zdolności słuchowe lub rozumienie mowy.

Słowa kluczowe: kwestionariusz • komfort • audiometria • jakość dźwięku • implanty ślimakowe • procesor mowy

Background

Cochlear implantation has become increasingly popular as a treatment option for people with severe-to-profound hearing loss; it results in many benefits including improved auditory perception, speech understanding, music perception, and quality of life [1–5]. Improving technologies have resulted in the design and production of newer, more comfortable, and more discreet audio processors. For newly implanted cochlear implant (CI) users, and for experienced CI users with compatible CI systems, there are now traditional behind-the-ear (BTE) devices and the more recently developed single-unit off-the-ear audio processors.

Two popular audio processors include the RONDO off-the-ear and the OPUS 2 BTE from MED-EL GmbH (Innsbruck, Austria). These two audio processors have identical electronic components and use the same audio processor platform [6]. If acoustic stimulation is needed, RONDO cannot be used because there is no EAS version. The RONDO single-unit device merges the OPUS 2 audio processor, coil, and battery pack into a single housing unit. However, despite the similarities, there is a potential performance difference between both audio processors, a difference associated with placement of the microphone. The microphone is located above the pinna in the OPUS 2, but is located directly above the implant receiver coil and further behind the ear when using the RONDO, similar to the position of a bone-anchored hearing device [7,8].

When a new processor is available comparisons are carried out after upgrading patients. Usually, comparisons are done in clinical settings and/or the new processor is given to the patient after a fitting and comparisons are based on the before/after results of tests or questionnaires (e.g. [9–11]).

Mertens et al. measured the subjective and objective outcomes across 10 CI users with single sided deafness using the OPUS 2 and RONDO [12]. Their results showed that long-term OPUS 2 users could be upgraded to the RONDO without compromising speech performance, aided hearing thresholds, sound localisation, objective speech quality, or hearing abilities. Furthermore, user feedback showed a clear improvement in usability, comfort, and maintenance when using the RONDO, with 80% of subjects preferring the new single-unit device.

Spiric et al. compared the speech perception abilities of 22 children with prelingual hearing loss that were upgraded from the TEMPO+ or the OPUS 1 to the RONDO [13]. The results from this study showed that speech understanding in quiet and in noise significantly improved after the

upgrade to the RONDO. In 2017, Dazert et al. compared the hearing performances of 50 adults using the OPUS 2 and the RONDO across three time intervals (i.e. at point of upgrade, 1 month later, and 6 months later) [14]. No significant differences were observed in the results at any of the follow-up intervals, and the majority of the subjects reported that the sound quality with the RONDO was 'better than' or 'the same as' the OPUS 2.

The aim of the current study is to determine how newly implanted RONDO users assess their own auditory abilities and how they feel about using the RONDO in comparison to the OPUS 2. Newly implanted subjects received both audio processors at the same time and were evaluated using the RONDO feedback questionnaire.

Materials and methods

Subjects were recruited for this study across more than 10 clinics in France (Paris, Lyon, Montpellier, Grenoble, Lille, and Bordeaux). The inclusion criteria for this study included: (i) being a newly implanted CI user; (ii) be 18 years of age or older; (iii) having French as mother tongue; and (iv) having had a standard surgery that followed the recommendations outlined by MED-EL for cochlear implantation. This study was approved by the Ethics Committee of Rennes University Hospital (CHU) in Rennes, France (Study no. 15.65; 20 September 2015). All subjects gave written informed consent prior to the study.

As part of the study, subjects received both a RONDO and an OPUS 2 at the same time and were free to use whichever processor they preferred, or to use a combination of the two. All subjects completed the RONDO questionnaire after at least 4 weeks of use (after the first fitting). The questionnaire consisted of 35 questions regarding the ease of using the RONDO, how it compares to the OPUS 2, and whether or not they would recommend the RONDO to other people [14].

For each situation, preference of audio processor was compared with a chi-squared test for multiple comparisons followed with the Marascuilo procedure for the 2-by-2 comparison of proportion. The relationship between comfort, sound quality, noisy environment, wind noise and preference was analysed with a chi-squared test. Significance level was fixed at $p = 0.05$.

Results

A total of 83 adults were recruited for this study with a mean age of 56 years (range 21 to 88 years; standard deviation

±16.4 years). The subjects consisted of 48 females (mean age 54 years; standard deviation ±17.2 years) and 35 males (mean age 58 years; standard deviation ±15.3 years).

Results from the questionnaire showed that 77% of newly implanted subjects were satisfied with the RONDO in general, and if they had to make a choice, then 65% of subjects would prefer to use the RONDO on a daily basis. Some 91% of users would recommend the RONDO to other CI users.

Subjects were asked to indicate the location of their audio processor. As shown in Figure 1, 40% of subjects said that their audio processor was in position 3; 36% in position 1; 13.4% in position 3; 9.4% in position 2; and 1.2% in position 5. Some 66% said they used both processors throughout the study, 21% only used the RONDO, and 13% only used the OPUS 2. The results are separated into two groups: (i) all subjects and (ii) subjects that used both audio processors.

As shown in Table 1, 92% of all subjects either preferred to use the RONDO or liked both audio processors equally while wearing eyeglasses, 78% while attending cultural events, 78% for use at home, 75% for use with an assistive learning system, 57% when working in the office, 43% while wearing a cap, and 38% while playing sport. Results for subjects that chose to use both audio processors during this study are also shown in Table 1. Based on chi-squared or Monte Carlo statistical methods for multiple comparisons and the Marascuilo method for post hoc comparisons (with $p = 0.05$), a significant preference for using the RONDO was found at home ($p < 0.05$), at cultural events ($p < 0.05$), and while wearing glasses ($p < 0.0001$). On the other hand, a significant preference for use of the



Figure 1. Possible positions of the RONDO audio processor

OPUS 2 was found while playing sports ($p < 0.0001$) and wearing a cap ($p < 0.0001$).

Figure 2 shows the results obtained from subjects that used both audio processors (Fig. 2a) and all subjects (Fig. 2b) in terms of their preference in noisy environments, for sound localisation, wind noise reduction, and sound quality. Some 65% of all subjects reported that sound quality with the RONDO was the same as the OPUS 2, and 29% reported a better sound quality with the RONDO. There were 93% who reported that their ability to communicate in a noisy environment was the same or better with the RONDO, 95% reported that sound localisation was the

Table 1. Preference of audio processor in various situations. The number of subjects who answered each question is given in brackets. Figures in columns 1 and 2 are for all subjects in the study, while those in columns 3 and 4 are for subjects who used both audio processors. * represents $p < 0.05$; *** represents $p < 0.0001$

Situation (all subjects)	Preference (all subjects)	Situation (users of both)	Preference (users of both)	Statistical significance
Office (47)	43% OPUS 2 40% RONDO 17% both	Office (31)	45% OPUS 2 29% RONDO 26% both	
Home (78)	22% OPUS 2 51% RONDO 27% both	Home (55)	20% OPUS 2 44% RONDO 36% both]**
Sport (55)	62% OPUS 2 31% RONDO 7% both	Sport (37)	70% OPUS 2 19% RONDO 11% both]****]***
Cultural event (59)	22% OPUS 2 53% RONDO 25% both	Cultural event (37)	16% OPUS 2 43% RONDO 41% both]**
Glasses (69)	9% OPUS 2 70% RONDO 22% both	Glasses (47)	2% OPUS 2 66% RONDO 32% both]****]***
Phone use (49)	41% OPUS 2 37% RONDO 22% both	Phone use (31)	39% OPUS 2 26% RONDO 35% both]****
Assistive listening (28)	43% RONDO 32% both 25% OPUS 2	Assistive listening (18)	28% OPUS 2 28% RONDO 44% both	
Wearing a cap (51)	57% OPUS 2 31% RONDO 12% both.	Wearing a cap (35)	66% OPUS 2 17% RONDO 17% both]****]***

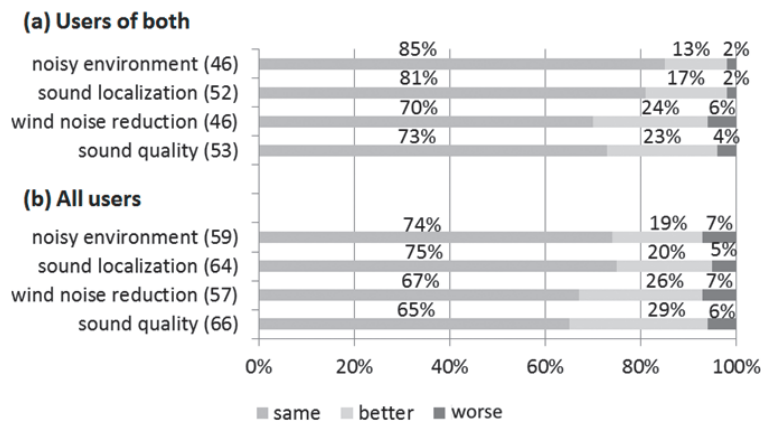


Figure 2. Comparison of the RONDO with the OPUS 2; in terms of: use in noisy environments; degree of sound localization; wind noise reduction; and subjective sound quality. (a) For subjects that used both processors during the study. (b) For all subjects. The numerals in brackets are the number of subjects that answered the question. The percentages are the fraction of subjects who stated that both processors performed equally (*same*), who thought the RONDO performed better than the OPUS 2 (*better*), or that the RONDO performed worse than the OPUS 2 (*worse*) for each listening condition.

Table 2. Answers to questions specific to the RONDO questionnaire. The number of subjects who answered each question is given in brackets

Questions	Answers
How much time do you spend wearing the RONDO every day? (70)	100% of RONDO only users used the RONDO for >6 h/day, and 73% used the RONDO for >9 h/day
How often do you feel pressure on the skin when using the RONDO? (69)	67% – never 17% – after 5-8 h 9% – after 1-4 h 6% – after >8 h 1% – after <1 h
Do you experience any skin irritations or reactions when using the RONDO? (69)	68% – no, 32% – yes 77% of those with skin reactions reported that they only lasted a few minutes
How often does the RONDO accidentally fall off? (67)	46% – never 51% – several times/week 1.5% – each day 1.5% – several times/day
When does the RONDO accidentally fall off? (36)	75% – removing clothing 25% – doing sport 22% – moving head 14% – using phone 47% – other
Have you experienced any technical problems with the RONDO? (70)	63 (90%) – no 7 (10%) – yes
Have you ever found mold on the RONDO? (70)	97% – never 3% – rarely
How often does dirt gather on the RONDO? (69)	93% – never 4% – rarely 1.5% – sometimes 1.5% – often
Rate your satisfaction of the following items: (0 = not satisfied at all; 5 = very satisfied)	
RONDO hair clip (60)	30 (50%) rated ≤ 2
RONDO clothes clip (27)	13 (48%) rated ≥ 4
RONDO slipcover (37)	27 (73%) rated ≥ 4
RONDO mini battery pack (14)	6 (43%) rated ≥ 4
Quality of the RONDO T-coil (18)	14 (78%) rated ≥ 4
RONDO T-coil necklace (10)	7 (70%) rated ≥ 4
Talking on the phone with the RONDO (44)	16 (36%) rated ≥ 4
Using the RONDO in general (67)	53 (79%) rated ≥ 4
Which audio processor would you choose? (64)	42 (65%) – RONDO
Would you recommend the RONDO to other CI users? (70)	64 (91%) – yes

same or better, and 93% reported that wind noise reduction was the same or better with the RONDO. Table 2 shows the results obtained from items relating to the practical use of the RONDO in everyday life. Some 73% of subjects that chose to use the RONDO used it for more than 9 h per day (Table 2). Over 65% of subjects reported never feeling pressure, skin irritation, or reactions from the RONDO. There were 12 subjects who experienced pressure on the skin after 5–8 h of wearing the RONDO, 6 after 1–4 h, 4 after more than 8 h of use, and only 1 subject experienced pressure after less than 1 h of use. There were 11 RONDO users and 6 OPUS 2 users who reported skin irritation that lasted only a few minutes and occurred rarely, with only 2 RONDO users and 2 OPUS 2 users experiencing irritation for longer than a few days. Some subjects reported that the RONDO accidentally fell off, particularly when removing an item of clothing or while playing sport, which was sometimes solved with the use of a stronger magnet.

In terms of comfort in use (Figure 3), 51% of all subjects rated the OPUS 2 as ≥8 on a scale on which 0 represents uncomfortable and 10 represents very comfortable, and 71% of all subjects rated the RONDO as ≥8. Some 68% of subjects reported that the batteries in their OPUS 2 audio processor lasted for more than 3 days, while 86% of RONDO

users had a battery lifetime of more than 3 days. Some 89% of users reported that the RONDO was easy to put on and take off, and 51% reported that unlocking and opening the battery case was also easy. Over 70% of subjects were satisfied with the protective slipcover for the RONDO, 78% were satisfied with the quality of the integrated T-coil, and 70% liked the T-coil necklace for connecting to external devices (Table 2).

Additional results from all users can be found in Table 3, as well as results for subjects that preferred to use the RONDO and subjects that preferred to use the OPUS 2. In terms of how comfortable the RONDO was to wear, 67% of subjects who used both systems ($n = 64$) scored 8 or higher on a scale between 0 (uncomfortable) and 10 (very comfortable), with 65% of users preferring to use the RONDO in comparison to the OPUS 2. Based on chi-squared analyses, two variables were identified as being statistically significant in terms of the user's preference of audio processor. These variables were comfort ($p = 0.00014$) and sound quality ($p = 0.008$), meaning that users that scored ≥8 in terms of comfort for the RONDO and a better sound quality with the RONDO in comparison to the OPUS 2 were, overall, more likely to prefer using the RONDO and, when given the choice, would choose to use the RONDO instead of the OPUS 2.

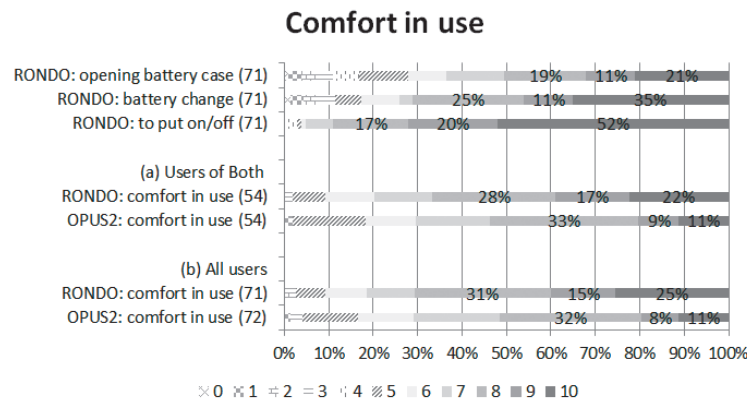


Figure 3. Comparison of RONDO with OPUS 2 in terms of comfort. (a) For subjects that used both processors during the study. (b) For all subjects. The numerals in brackets are the number of subjects who answered the question, and the percentages are the fraction of subjects who rated comfort as ≥8.

Table 3. Summary of answers to questions specific to the RONDO device questionnaire. * represents statistical significance

Question	Answer	Preference:OPUS 2	Preference: RONDO	All users	p-value
How comfortable is the RONDO? (0 = uncomfortable; 10 = very comfortable)	<8	14	7	21	0.00014 *
	≥8	8	35	43	
	Total	22	42	64	
Sound quality using the RONDO is...	better than using the OPUS 2	1	14	15	0.008 *
	same or worse than using the OPUS 2	17	21	38	
	Total	18	35	53	
Noisy environments using the RONDO are...	Better than using the OPUS 2	1	14	15	0.052
	Same or worse than using the OPUS 2	17	21	38	
	Total	18	35	53	
Wind noise experienced with the RONDO is...	Better than using the OPUS 2	1	14	15	0.194
	Same or worse than OPUS 2	17	21	38	
	Total	18	35	53	

Discussion

This study investigated the hearing and speech perception abilities of CI users using the OPUS 2 and/or the RONDO. Other studies have compared off-the-ear units of another brand with behind-the-ear processors. Similar results were found with equivalent speech understanding in quiet and noise, although both types of sound processors had different microphone locations [15,16]. As previously discussed in the literature, hearing in everyday listening situations cannot be adequately assessed using standard speech tests alone [11,17–19].

In a study reported from a different CI manufacturer [(20) testing in a sound booth revealed some differences between processors in spatially separated noise, but participants did not report any functional differences in their real-world speech-in-noise experience.

In our study, we did not perform speech tests in the clinic. Instead, we evaluated subjective speech perception and hearing performance in real-life listening situations with a questionnaire. We believe this provides us with a more realistic representation of CI use in comparison to the results obtained from routine clinical tests. Therefore, the study focused on the self-perceived auditory abilities of new CI users in everyday life. Furthermore, due to the different positions of the microphone (i.e. located above the pinna with the OPUS 2 and above the implant receiver coil with the RONDO), we felt that the use of a subjective questionnaire would provide a better insight into the hearing abilities of these CI users than could be achieved with a routine clinical test.

Subjective questionnaires, such as the RONDO device-specific questionnaire, can provide valuable information in terms of how subjects perceive their CI device and how it affects their hearing abilities in everyday life. Therefore, newly implanted subjects were asked to complete a questionnaire after 4 weeks of CI use. At the start of the study, subjects were given both OPUS 2 and RONDO audio processors and were free to use whichever one they preferred or to use a combination of the two. As expected, the results showed that these CI users perceived benefits from using the single-unit RONDO device which included increased comfort and usability. Over 70% of CI users stated that the RONDO was very comfortable, which is in agreement with results previously reported by Dazert et al. [14], Mertens et al. [12], and Távora-Vieira et al. [21]. Mauger et al. [20] also reported similar findings with audio processors from a different CI manufacturer. Importantly, subjects reported improved comfort in wearing eyeglasses with the RONDO due to the positioning of the RONDO further back from the pinna. It is believed that similar findings could be obtained with single-unit audio processors from different manufacturers and across different product generations/models in comparison to equivalent BTE devices.

Results from the RONDO questionnaire found that the majority of CI users (65%) rated the self-perceived sound

quality as equal between the RONDO and the OPUS 2, with more users preferring the sound quality of the RONDO than the OPUS 2 (i.e. 29% preferred the RONDO versus 6% that preferred the OPUS 2). This showed that the position of the microphone on the RONDO did not have a negative impact on sound quality. Other improvements that were observed with the RONDO include the ability to communicate in a noisy environment, better sound localisation, and reduced wind noise.

Interestingly, the results showed that comfort and sound quality were the main reasons subjects chose to use the RONDO instead of the OPUS 2, with noise perception deemed a less important factor, which accords with the results published by Dazert et al. [14] and Mauger et al. [20] for another brand. Wimmer et al. previously reported that the OPUS 2 could be better than the RONDO in noisy situations [6]; however these measurements were made in a clinical setting and not based on real-life listening situations. While newer models and versions of audio processors are now commercially available, such as the dual microphone SONNET and SONNET 2 from Med-El, this study focused on two previous generation audio processors that have only one microphone, have the same electronic components, and use the same audio processor platform. This allowed for a direct comparison to be made between both audio processors. The SONNET is known to provide CI users with better speech perception in noise [22–24]; however, for the OPUS 2 and RONDO users involved in this study, speech perception in noise was considered less important than comfort or sound quality in terms of their preferred choice of audio processor. Future studies should consider providing CI users with the SONNET or SONNET 2 and a dual microphone single-unit device and compare those results with the results found in this study.

Conclusion

In summary, the majority of subjects were satisfied with the RONDO and over 90% of users would recommend the RONDO to other CI users. Since the RONDO is a single-unit device, it omits the need for a BTE audio processor and offers CI users further options in regards to comfort of wearing and cosmetic appearance. While the microphone position of the RONDO is located further back from the pinna, the RONDO can be very convenient for eyeglass wearers, and users did not report any loss of sound quality. Results from the RONDO device-specific questionnaire showed that users preferred the RONDO to the OPUS 2 in terms of usability, comfort, and maintenance. Therefore, CI adult users can, if they wish, choose between the OPUS 2 and the RONDO without sacrificing hearing or speech intelligibility, sound quality, or comfort.

Conflict of interests

The authors declare a conflict of interest, potential or actual: this study was designed by MED-EL GmbH.

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