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Original Article

Cochlear Implant Single-Unit Audio Processors in Young Children

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BACKGROUND: RONDO 2 is a lightweight, compact, wirelessly charged, and fully integrated single-unit speech processor. Single-unit processors provide an effective and convenient alternative to behind-the-ear processors for adults. Therefore, the aim of this study was to investigate if RONDO 2 is suitable for and did not compromise the hearing performance of young children in everyday life.

METHODS: Thirteen children aged <4 years were fitted with the RONDO 2 speech processor at the first activation of the cochlear implant. They were evaluated with the LittlEARS® Auditory Questionnaire, LittlEARS® Early Speech Production Questionnaire, and the Speech, Spatial, and Qualities of Hearing Scale 12 pre-implantation. In addition to these measures, they were evaluated with the Audio Processor Satisfaction Questionnaire post-implantation. Duration of daily use and troubleshooting data were acquired. Evaluation occurred at 4 time points: before implantation and 1, 3, and 12 months post-initial activation.

RESULTS: Ten out of 13 children continued using RONDO 2 after the study. Twelve months after implantation, they used it on average 11.6 hours per day and had an average Audio Processor Satisfaction Questionnaire score of 9.1 out of 10. Average hearing performance scores continuously improved throughout the follow-up period across measures. Twelve months after implantation, the mean scores were 30.1 out of 35 for the LittlEARS® Auditory Questionnaire, 19.9 out of 27 for the LittlEARS® Early Speech Production Questionnaire, and 7.4 out of 10 for the Speech, Spatial, and Qualities of Hearing Scale 12.

CONCLUSION: Participants demonstrated high levels of satisfaction and good hearing performance with RONDO 2, which indicates that this single-unit processor could be a viable and comfortable alternative to behind-the-ear processors in young children, although larger controlled experiments are warranted.

KEYWORDS: Pediatric, cochlear implant, speech processor, audio processor, RONDO, speech perception, speech production

INTRODUCTION

Cochlear implantation has been established as safe and effective management for individuals with severe-to-profound hearing loss who do not derive adequate benefit from optimally fitted hearing aids (HAs). The age at implantation for children with congenital hearing loss has decreased due to the introduction of universal neonatal hearing screening along with the emerging evidence of early implantation benefits,[1] particularly below the age of 12 months.[2,3] This necessitates the selection of cochlear implants (CIs) that are suitable for use in young children.

Technological advancement made miniaturization of speech processors (the external part of a CI) possible, giving rise to single-unit speech processors. Single-unit speech processors are small, compact, can be hidden discretely under the hair, and are fully integrated. They are cable-free, which could be an advantage from the maintenance point of view.

A single-unit speech processor with a single microphone (RONDO 1) was found to provide 50 experienced adult CI users with high levels of satisfaction in addition to levels of speech perception that were comparable to those provided by the behind-the-ear (BTE)

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OPUS 2 speech processor in both quiet and noise.[4] Mertens et al[5] did not find an effect of RONDO's microphone on outcome measures, which included speech perception in noise. However, Wimmer et al[6] found that RONDO provided speech perception in noise comparable to OPUS 2 in 12 adult CI users when noise was presented from the front or from either side of the head, but not when noise was presented from the back. They also found worse speech perception when noise was presented from the back with the RONDO processors placed further away from the ear, which indicated the importance of the speech processor's position.[6] Furthermore, many adult CI users preferred the single-unit RONDO to the BTE processor after the users were given enough time to adapt to it.[4,5] Taken together, these findings indicate that the single-unit RONDO processor does not compromise performance and comfort compared to the BTE processors in adults. However, it remains unclear if RONDO is suitable for use in young children.

The primary aim of this feasibility study was to determine if RONDO 2 single-unit speech processors were suitable and comfortable for young children. This was done by analyzing the duration of daily CI use, troubleshooting data, and speech processor satisfaction. The secondary aim of this study was to evaluate hearing performance with RONDO 2 over a 12-month follow-up period using a battery of questionnaires.

MATERIAL AND METHODS

Inclusion and Exclusion Criteria

The inclusion criteria were as follows:

- Age at implantation < 4 years.
- Unilaterally or bilaterally implanted.
- Prelingual sensorineural hearing loss.
- Normal developmental and motor milestones.
- Fitted with RONDO 2 speech processor since initial CI activation.
- Written consent provided by parents and willingness to attend all sessions.

The exclusion criteria were as follows:

- Cochlear malformation.
- Auditory neuropathy spectrum disorder.
- Recurrent infection at the implantation site that interfered with the use of the device.
- Absence or malformation of the cochlear nerve.
- Other disabilities.
- History of incomplete electrode insertion.
- History of revision CI surgery.

MAIN POINTS

- Single-unit processor (RONDO 2) could be used by young children under the age of 4 years.
- Most children, even as young as 14 months old, continued to use the RONDO 2 and scored high on the APSQ scale, indicating wearing comfort and high satisfaction with the processor.
- RONDO 2 could be a viable and comfortable alternative to behind-the-ear processors.

Participants

The study obtained an ethical approval from King Saud University College of Medicine (E-19-4165) and participants' parents gave informed consent before the start of any study-related procedures. The CI recipients were recruited from a tertiary care hospital. Both unilaterally and bilaterally implanted children were included because we did not expect this condition to have any effect on the outcome measures.

Test Battery

Troubleshooting data for all parts of the external CI device were collected from the clinical records after each visit to the clinic. Daily use hours were collected using the Audio Processor Satisfaction Questionnaire (APSQ), which is a 15-item questionnaire developed to assess CI recipients' satisfaction with the speech processor. The APSQ is subdivided into 3 subscales: comfort, social life, and usability.[7] The LittlEARS® Auditory Questionnaire (LEAQ) consists of 35 yes/no questions and was designed to evaluate the auditory development of children in the preverbal phase.[8] The LittlEARS® Early Speech Production Questionnaire (LEESPQ) is a 27-item questionnaire designed to assess the early development of speech in children under the age of 18 months.[9] The Speech, Spatial, and Qualities of Hearing scale 12 (SSQ12) is the shorter 12-item version of the SSQ and was designed to measure hearing disabilities across several domains.[10]

Procedures

All questionnaires were completed by parents or caregivers. The LEAQ, LEESPQ, and SSQ12 were completed before the first fitting (V1). Troubleshooting data (the number of dedicated troubleshooting visits per device) were collected and the APSQ and LEESPQ were completed 1 month (V2), 3 months (V3), and 12 months (V4) after the first fitting. The LEAQ and SSQ12 were completed only 3 and 12 months after the first fitting.

Normative and Comparison Data

The normative data of the age-specific LEESPQ scores of 362 German children[9] and 198 Saudi Arabian children with normal hearing (NH) < 18 months old,[11] and the normative data of the age-specific LEAQ scores of 218 German children with NH < 24 months old[12] were used for the analyses.

The number of dedicated troubleshooting visits per device in the first 3 months and in the first 12 months after the first fitting of the CIs were collected from the 23 BTE speech processors of 16 young children. The children were implanted before the age of 4 years. The data were used for making a comparison.

Statistical Analysis

Analysis was conducted to assess the following:

1. If there was a significant difference in the SSQ12 and APSQ scores at the 3 different time intervals.
2. If the LEAQ and LEESPQ results of the participants were different from the results of children with NH.

Children were stratified into 2 groups according to their chronological age: those who were younger than 18 months at implantation and those who were older than 18 months at implantation. This stratification was chosen because age at implantation affects hearing progress.[3]

The Kolmogorov–Smirnov test and the Shapiro–Wilk test were used to check the data distribution to determine whether a parametric or a non-parametric test had to be applied. Depending on the data distribution, the Student's *t*-test or Wilcoxon signed-rank test was used to test for a difference between the test intervals. The significance level was set to $P \leq .05$. IBM Statistical Package for the Social Sciences Statistics version 25.0 (IBM SPSS Corp.; Armonk, NY, USA) was used to perform the statistical analyses.

RESULTS

Participants' Demographics and Device Use

Thirteen pediatric CI recipients were recruited; 3 retracted from the study and asked to use the SONNET 2 instead. One of them switched from the RONDO 2 to the SONNET 2 speech processor because a sibling had a SONNET 2 and the parents preferred to unify the speech processor and accessories for both children. The parents of the other 2 children (16 months and 20 months old) reported frequent detachment of the RONDO 2 despite an adequate magnet strength of 3. When the magnet strength was increased to 4, it caused redness and irritation. In the clinic, the RONDO 2 with the magnet strength of 3 was stable for both children, but parents reported the processor fell off during excessive head movements at home.

Ten children continued to participate in the study, 4 of whom were simultaneously bilaterally implanted and 6 were unilaterally implanted. The mean age was 30.6 months (range 14-44 months); mean duration of HA use before CI use was 6.4 months (range 4-12 months). The average daily use of the RONDO 2 1 year after implantation was 11.6 hours with a range of 6-14 hours (see Table 1).

Ten out of 13 children (77%, or 14 out of 18 ears) continued to use the RONDO 2 speech processor after the conclusion of the study. The parents of these children, even the parents of the youngest, 14-month-old child in the study, did not report any incidents of the device falling off the head.

Device troubleshooting data showed an average of 0.67 dedicated troubleshooting/device in 3 months post-CI for a total of 15 devices (for participants with data up to 3 months) which is less than the average of 1.22 troubleshooting/device in 16 children who received their CI before 4 years of age and were using a BTE speech processor. But due to coronavirus disease 2019, most troubleshooting was done locally at vendors' offices rather than the CI center; hence, later troubleshooting data could not be accurately collected.

Table 1. Summary of the Daily Use Results

		Average Wearing Hours/Daily 3 Months Post Activation	Average Wearing Hours/Daily 1 Year Post Activation
N	Valid	10	10
	Missing	0	0
Mean		10.5	11.6
Minimum		3	6
Maximum		12	14

Outcome

Audio Processor Satisfaction Questionnaire

The average total and subscale APSQ scores increased throughout the follow-up period and reached their maximum 12 months after implantation (see Table 2 and Figure 1). However, these differences were not statistically significant. "Usability" was the subscale with the highest final mean score (9.62 out of 10), followed by the "Social life" (9.43) and "Wearing comfort" (8.23) subscales.

Speech, Spatial, and Qualities of Hearing Scale 12

The average total and subscale SSQ12 scores improved throughout the follow-up period and reached their maximum 12 months after implantation (see Table 3 and Figure 2). The Friedman test revealed a significant improvement in the average total and subscale scores over the tested intervals (all *P*-values ≤ .002). Nine out of 12 pairwise comparisons were significantly different (Table 4). "Qualities" was the subscale with the highest final mean score (8.39 out of 10), followed by the "Spatial" (8.07) and "Speech" (6.40) subscales.

LittlEARS® Early Speech Production Questionnaire

The mean LEESPQ score before implantation was 7.9 (range: 4-12) and the mean LEESPQ score 12 months after implantation was 19.9 (range: 13-23). The highest score (25/27) was achieved by the youngest child 3 months after implantation (Table 5).

Table 2. Summary of the APSQ Results

	Total Score			Wearing Comfort			Usability			Social Life		
	V2	V3	V4	V2	V3	V4	V2	V3	V4	V2	V3	V4
N valid	6	10	10	9	10	10	10	10	10	6	10	10
N missing	4	0	0	1	0	0	0	0	0	4	0	0
Mean	7.92	8.66	9.10	7.38	7.90	8.23	9.03	9.45	9.62	7.49	8.59	9.43
Median	8.43	8.59	9.36	7.50	7.55	8.33	9.25	9.75	10.00	8.70	8.40	9.88
SD	1.53	0.57	1.04	1.35	0.81	1.46	1.12	0.64	0.88	2.94	0.88	1.11
Minimum	5.40	7.87	6.43	4.50	7.20	5.50	6.60	8.40	7.20	1.80	7.40	6.40
Maximum	9.31	9.69	10.00	8.80	9.75	10.00	10.00	10.00	10.00	9.75	10.00	10.00

The APSQ scores range from 0 ("I do not agree at all") to 10 ("I fully agree") with higher scores indicating better outcomes. Missing data indicate that the "Not applicable" box was checked.

APSQ, Audio Processor Satisfaction Questionnaire; V2, visit 2, 1 month after implantation; V3, visit 3, 3 months after implantation; V4, visit 4, 12 months after implantation.

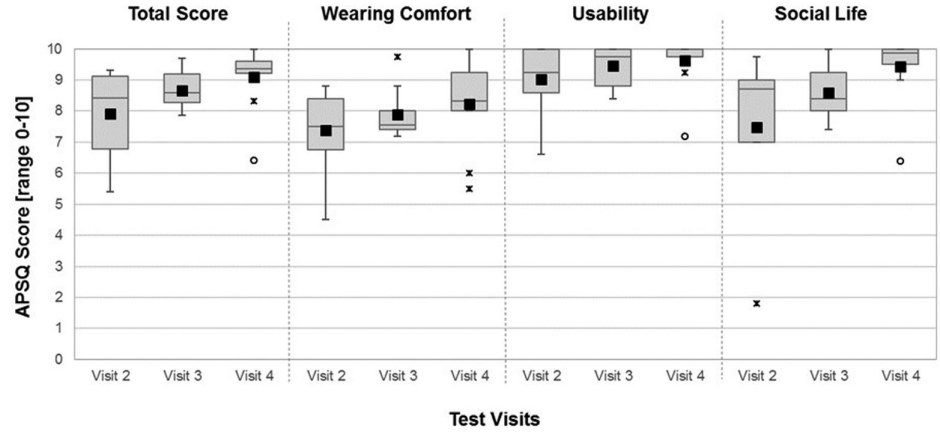

Figure 1. The distribution of the APSQ total scores and the subscale scores at visit 2 (1 month after implantation), visit 3 (3 months after implantation), and visit 4 (12 months after implantation). Black squares—mean values, horizontal lines—median values, asterisks—outliers, circles—extreme outliers. APSQ, Audio Processor Satisfaction Questionnaire.

Table 3. Summary of the SSQ12 Results

	Total Score			Speech			Spatial			Qualities		
	V1	V3	V4	V1	V3	V4	V1	V3	V4	V1	V3	V4
N valid	10	10	9	10	8	9	10	10	9	10	7	9
N missing	0	0	1	0	2	1	0	0	1	0	3	1
Mean	0.06	5.61	7.41	0.06	5.1	6.40	0	5.43	8.07	0.1	5.77	8.39
Median	0	6.17	7.50	0	5.33	6.40	0	5.67	8.30	0	5.5	8.70
SD	0.12	1.57	0.68	0.19	1.12	1.14	0	2.35	1.36	0.32	2.55	0.75
Minimum	0	2.67	6.30	0	2.8	4.80	0	1.67	6.00	0	3	7.00
Maximum	0.3	7.22	8.80	0.6	6.75	8.60	0	9	10.00	1	9.67	9.30

The SSQ12 scores ranged from 0 ("not at all able to do so") to 10 ("perfectly able to do so"), with higher scores indicating better outcomes. Missing data indicate that the "Not applicable" box was checked.
SSQ12, Speech, Spatial, and Qualities of Hearing Scale 12; V1, visit 1, before implantation; V3, visit 3, 3 months after implantation; V4, visit 4, 12 months after implantation.

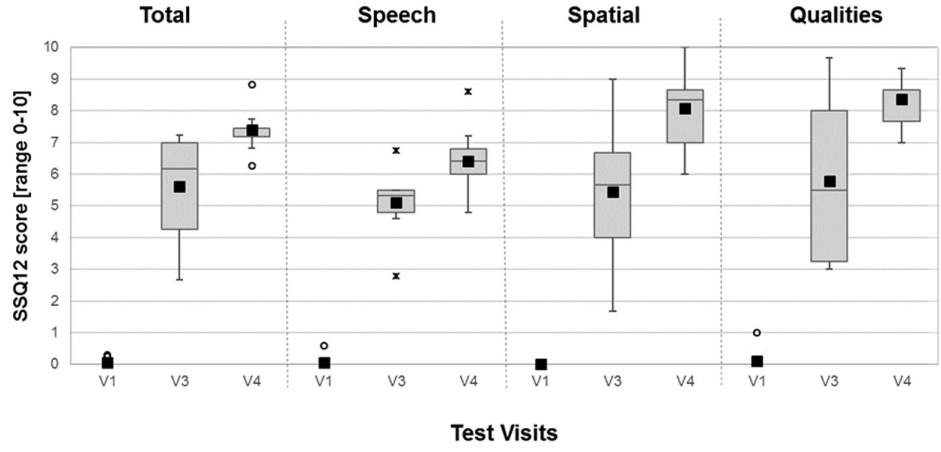

Figure 2. The distribution of the SSQ12 total scores and the subscale scores at visit 1 (pre-implantation), visit 3 (3 months after implantation), and visit 4 (12 months after implantation). Black squares—mean values, horizontal lines—median values, asterisks—outliers, circles—extreme outliers. SSQ12, Speech, Spatial, and Qualities of Hearing Scale 12.

LittlEARS® Auditory Questionnaire

The mean LEAQ score before implantation was 4.67 (range: 0-12) and the mean LEAQ score at 12 months after implantation was 30.1 (range: 21-35). The highest score (35/35) was achieved by the youngest child 3 months after implantation and 2 children 12 months after implantation (Table 6).

Comparison of the LittlEARS® Early Speech Production Questionnaire and the LittlEARS® Auditory Questionnaire Scores to the Norm Curves of Children with Normal Hearing

Children were divided into 2 groups according to their age at implantation:

Table 4. Pairwise Comparisons of Pre- and Post-Implantation SSQ12 Scores

	V1 vs. V3		V1 vs. V4		V3 vs. V4	
	Z	*P*	*Z*	*P*	*Z*	*P*
Total	2.803	.005*	2.675	.007*	2.549	.011*
Speech	2.524	.012*	2.668	.008*	2.103	.035
Spatial	2.805	.005*	2.670	.008*	2.547	.011*
Qualities	2.366	.018	2.692	.007*	2.201	.028

V1, visit 1; V3, visit 3; V4, visit 4.
*Statistically significant after Bonferroni correction ($P = .05/3 = .017$).

Table 5. Individual LEESPQ Total Scores

Participant	Age* (M)	V1	V2	V3	V4
1	14	9	10	25	22
2	15	4	8	17	21
3	17	7	4	11	17
4	24	7	8	14	19
5	35	9	17	16	22
6	36	5	11	15	13
7	36	12	12	16	23
8	42	6	13	16	23
9	43	9	17	19	19
10	44	11	12	21	20

M, months; V1, visit 1; V2, visit 2; V3, visit 3; V4, visit 4.
*Age at implantation. Maximum possible LEESPQ score is 27.

Table 6. Individual LEAQ Total Scores

Participant	Age* (M)	V1	V3	V4
1	14	1	35	34
2	15	0	26	30
3	17	8	22	21
4	24	7	8	29
5	35	12	23	35
6	36	3	21	25
7	36	3	25	32
8	42	3	18	35
9	43	6	32	32
10	44	0	31	28

M, months; V1, visit 1; V3, visit 3; V4, visit 4.
*Age at implantation. Maximum possible LEAQ score is 35.

- <18 months at implantation (n = 3, mean age: 15 months, range: 14-17 months);
- >18 months at implantation (n = 7, mean age: 37 months, range: 24-44 months).

To enable a comparison to the norm curves of children with NH, the LEESPQ and LEAQ scores of the implanted children were plotted according to their hearing age, that is, visit 1 corresponded to a hearing age of 0 months, visit 2 corresponded to 1 month (for the LEESPQ only), visit 3 corresponded to 3 months, and visit 4 corresponded to 4 months. The progress of the younger group was generally faster with a steeper slope than in the older group. At every visit, all children in both groups exceeded the minimum LEESPQ score achieved by German and Saudi children with NH (lower limit of the 95% confidence interval) (Figure 3). Twelve months after implantation, 2 out of 3 children in the younger group achieved LEESPQ scores above the average score of German and Saudi children with NH. In the older group, 4 out of 7 children achieved LEESPQ scores above the average score of German children with NH, and 6 out of 7—above the average score of Saudi children.

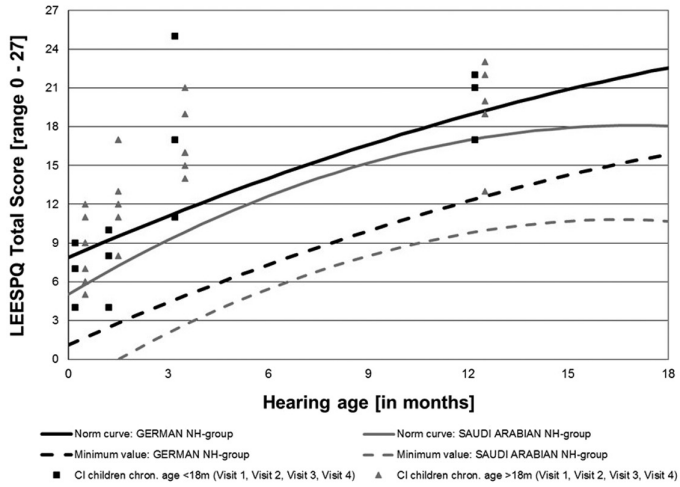

Figure 3. The individual LEESPQ total scores of implanted children and the norm curves of children with normal hearing (NH) over time. The scores are represented as black squares for implanted children < 18 months (n = 3) and as gray triangles for children > 18 months (n = 7). The scores are compared with the norm curves (standardized expected values, solid curves) and with the minimum values (lower 95% confidence interval, dotted curves) of the age-specific speech production abilities of German children with NH (n = 362, black curves) for the younger age group and of Saudi children with NH (n = 198, grey curves) for the older age group. Note: visit 1 corresponds to a hearing age of 0 months, visit 2 corresponds to 1 month, visit 3 corresponds to 3 months, and visit 4 corresponds to 12 months.

The LEAQ scores improved in both age groups 3 and 12 months after implantation (Figure 4). After implantation, all children exceeded the minimum LEAQ score achieved by German children with NH. Twelve months after implantation, 2 out of 3 younger children and all older children had LEAQ scores above the average for children with NH.

DISCUSSION

This feasibility study was designed to evaluate if the single-unit sound processor RONDO 2 was suitable to use in a small group of children under 4 years. It also looked at how their hearing performance changed after implantation. Most children, even as young as 14 months old, continued to use the RONDO 2 and scored high on the APSQ scale, indicating wearing comfort and high satisfaction with the processor. Good hearing outcomes corroborated this finding.

In general, RONDO 2 was suitable to use in children. The average APSQ total score was 9.1 out of 10, which is comparable to the mean scores per item reported by Billinger-Finke et al,[7] which ranged between 7.1 and 9.2. RONDO 2 required less troubleshooting than BTE devices (0.67 versus 1.22/device) possibly because BTE devices have extra parts that need to be fixed or exchanged, for example, a

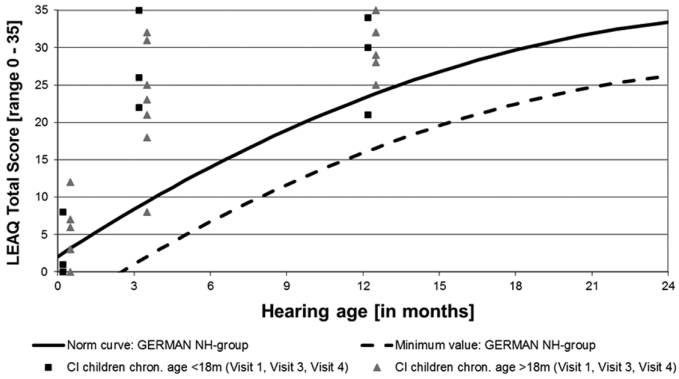

Figure 4. The individual LEAQ scores of implanted children and the norm curves of children with normal hearing (NH) over time. The scores are represented as black squares for implanted children < 18 months (n = 3) and as gray triangles for children > 18 months (n = 7). The scores are compared with the norm curves (standardized expected values, solid curves) and with the minimum values (lower 95% confidence interval, dotted curves) of the age-specific speech production abilities of German children with NH (n = 218, black curves). Note: visit 1 corresponds to a hearing age of 0 months, visit 3 corresponds to 3 months, and visit 4 corresponds to 12 months.

coil or a battery pack frame. It should be noted that troubleshooting was usually required when problems with the cable occurred at home. A dedicated troubleshooting session at the center was not required and, therefore, not included in the data reported for BTE devices in this study. Three children discontinued the study and substituted the RONDO 2 with a SONNET 2. One of these children had their processor replaced to match their sibling's processor and not due to device-associated problems.

The single-unit speech processor appears to be securely attached to the head, given that 11 out of 13 children reported no problems with stability. Nine children had magnet strength 3 and 1 child had magnet strength 2 with no complaint of skin pain or redness. The 2 children who complained about the device falling off reported that it was stable on their heads in the clinic and that they did not require magnet strength 4. The complaint about the device falling off was associated with excessive movement, which could cause problems even with the coil and cable of a BTE device and affect cable lifetime.

Twelve months after implantation, the average daily use of the device was 11.6 hours. For 8 of the 10 children, the daily use was 12 hours per day, which indicated consistent use. The child who only used it for 3 hours per day had behavioral issues rather than device-related problems. Later the child became a consistent user. The average use in our sample was higher than the 8 hours set by Low et al[13] for their classification of regular users.

Although the costs of batteries or replacement cables and coils were not explicitly addressed in this study, RONDO 2 could alleviate some of the costs related to batteries and accessories in the long run. This could be added value to the CI recipient and to the CI center.

Apart from being comfortable to use, sound processors should also enable CI users to improve their listening experience. Therefore, we used 3 different questionnaires to determine if the hearing performance of children developed adequately with RONDO 2. The SSQ12 total score and all subscale scores were significantly better at V4 than V1 and comparable with the values reported by Low et al[13] in long-term bilaterally implanted CI users.

The mean LEAQ score of 30.1 with RONDO 2 12 months post-implantation is comparable to the mean score of 31.6 reported by Obrycka et al[14] that was calculated at the same time interval, while the mean score of 4.67 at activation in our study is lower than the mean score of 9.3 reported in their study. This, in addition to the fact that after 3 months the scores of 8 out of 10 children exceeded those achieved by 9-month-old children with NH, demonstrated excellent auditory development with RONDO 2 in these young children. The 3 children who were implanted below the age of 18 months approached normal LEAQ scores within 3 months of CI use and had a steeper slope than the group implanted at an older age. This is a developmental trend which is consistent with the developmental trends observed in previous studies[3,14] which reported faster development when children were implanted at a younger age.[3,15] After 3 months, 1 child did not achieve an average LEAQ score of 3-month-old German children with NH. This child had used their CI for only 3 hours a day until then but improved afterward.

The LEESPQ scores showed good progress in our study, too. Similar to the LEAQ results, the progress of the younger group was faster with a steeper slope than in the older group. The 3 children in the younger group reached the average scores of Saudi children with NH. Three months after implantation, all 7 children in the older group exceeded the scores of German and Saudi children with NH at 3 and 6 months, respectively, and 2 of them exceeded the average achieved by Saudi children at 18 months. Only 1 child in the older group did not reach the average score of either German or Saudi NH children, this child was initially an inconsistent user.

RONDO 2 has an omnidirectional microphone and is positioned further behind than the BTE, which affects speech perception in noise, as demonstrated by Wimmer et al.[6] They reported that the omnidirectional nature of the RONDO 1 microphone could hinder speech perception when noise is presented from the back. This could compromise binaural hearing in bilaterally implanted individuals, people with asymmetric hearing loss, and people with single-sided deafness, therefore making it difficult to further explore binaural hearing in such a young population in our short-term study. A longitudinal study comparing binaural hearing with RONDO 2 and BTE speech processors might shed more light on that subject. The low sample size and short follow-up duration after the device activation are among the limitations of this study.

This feasibility study demonstrated that the single-unit speech processor RONDO 2 could be used by young children under the age of 4 because participants were extremely satisfied with it and demonstrated adequate auditory progress. RONDO 2 could be a viable and comfortable alternative to BTE processors, although larger controlled comparative studies are needed.

Ethics Committee Approval: This study was approved by Ethics Committee of King Saud University College of Medicine University (Approval No: E-19-4165, Date: August 5, 2019).

Informed Consent: Written informed consent was obtained from the participants' parents who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – S.S., A.H., A.A.; Design – Fa.A., Fi.A.; Supervision – A.H., A.A.; Resources – At.A., S.A.; Materials – At.A., S.A., S.S.; Data Collection and/or Processing – At.A., S.S.; Analysis and/or Interpretation – Fa.A., Fi.A.; Literature Search – Fi.A., S.A.; Writing – S.S., Fi.A., Fa.A., S.A.; Critical Review – A.A., A.H.

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