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Objective and Subjective Measures of Simultaneous vs Sequential Bilateral Cochlear Implants in Adults
A Randomized Clinical Trial

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IMPORTANCE To date, no randomized clinical trial on the comparison between simultaneous and sequential bilateral cochlear implants (BiCIs) has been performed.

OBJECTIVE To investigate the hearing capabilities and the self-reported benefits of simultaneous BiCIs compared with those of sequential BiCIs.

DESIGN, SETTING, AND PARTICIPANTS A multicenter randomized clinical trial was conducted between January 12, 2010, and September 2, 2012, at 5 tertiary referral centers among 40 participants eligible for BiCIs. Main inclusion criteria were postlingual severe to profound hearing loss, age 18 to 70 years, and a maximum duration of 10 years without hearing aid use in both ears. Data analysis was conducted from May 24 to June 12, 2016.

INTERVENTIONS The simultaneous BiCI group received 2 cochlear implants during 1 surgical procedure. The sequential BiCI group received 2 cochlear implants with an interval of 2 years between implants.

MAIN OUTCOMES AND MEASURES First, the results 1 year after receiving simultaneous BiCIs were compared with the results 1 year after receiving sequential BiCIs. Second, the results of 3 years of follow-up for both groups were compared separately. The primary outcome measure was speech intelligibility in noise from straight ahead. Secondary outcome measures were speech intelligibility in noise from spatially separated sources, speech intelligibility in silence, localization capabilities, and self-reported benefits assessed with various hearing and quality of life questionnaires.

RESULTS Nineteen participants were randomized to receive simultaneous BiCIs (11 women and 8 men; median age, 52 years [interquartile range, 36-63 years]), and another 19 participants were randomized to undergo sequential BiCIs (8 women and 11 men; median age, 54 years [interquartile range, 43-64 years]). Three patients did not receive a second cochlear implant and were unavailable for follow-up. Comparable results were found 1 year after simultaneous or sequential BiCIs for speech intelligibility in noise from straight ahead (difference, 0.9 dB [95% CI, −3.1 to 4.4 dB]) and all secondary outcome measures except for localization with a 30° angle between loudspeakers (difference, −10% [95% CI, −20.1% to 0.0%]). In the sequential BiCI group, all participants performed significantly better after the BiCIs on speech intelligibility in noise from spatially separated sources and on all localization tests, which was consistent with most of the participants' self-reported hearing capabilities. Speech intelligibility-in-noise results improved in the simultaneous BiCI group up to 3 years following the BiCIs.

CONCLUSIONS AND RELEVANCE This study shows comparable objective and subjective hearing results 1 year after receiving simultaneous BiCIs and sequential BiCIs with an interval of 2 years between implants. It also shows a significant benefit of sequential BiCIs over a unilateral cochlear implant. Until 3 years after receiving simultaneous BiCIs, speech intelligibility in noise significantly improved compared with previous years.

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Supplemental content

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Various observational studies have shown that individuals who receive bilateral cochlear implants (BiCIs) are better able to localize sounds and perceive speech in noise than are patients who receive a unilateral implant.[1-4] These findings were recently confirmed in a randomized clinical trial (RCT) on the effectiveness of simultaneous BiCIs compared with a unilateral cochlear implant, which showed that participants who received BiCIs benefit in difficult listening situations when speech and noise are spatially separated and in various localization tests.[5] The results remained stable for at least 2 years of follow-up.[6]

Although the rate of deaf adults receiving BiCIs is increasing, the question remains whether simultaneous BiCIs lead to better hearing results than do sequential BiCIs. Systematic reviews suggest that simultaneous BiCIs may result in better postoperative outcomes than sequential BiCIs in children and that a prolonged interval between implants may have a negative effect or, at best, no effect on postoperative outcomes in children.[7,8] Comparative studies on simultaneous vs sequential BiCIs in adults have not been conducted, to our knowledge. The best available evidence to date are the previously mentioned observational studies that show that both simultaneous and sequential BiCIs result in better postoperative outcomes compared with a unilateral cochlear implant.[1-5] The outcomes of the studies are, however, difficult to compare since a great deal of heterogeneity exists between the studies regarding study design, sample size, follow-up duration, and outcome measures.

The primary aim of this study was to compare the results of simultaneous BiCIs with those of sequential BiCIs with a 2-year interval between implants in adults with severe to profound postlingual sensorineural hearing loss. The secondary aim was to evaluate the results of 3 consecutive years of follow-up for the sequential and the simultaneous BiCI groups separately.

Key Points

Question Is there a difference between the hearing results after receiving simultaneous bilateral cochlear implants and the hearing results after receiving sequential bilateral cochlear implants with a 2-year interval between implants?

Findings In this randomized controlled trial including 38 participants, no differences were found on all objective and subjective outcome measures on hearing and quality of life. One year after receiving a second cochlear implant, significant improvements were seen on objective hearing in noise and localization results as well as subjective hearing results in the group that received sequential bilateral cochlear implants.

Meaning Patients who received sequential bilateral cochlear implants with a 2-year interval between implants derive the same benefit of a second cochlear implant as patients who received simultaneous cochlear implants.

Methods

Ethical Considerations

The study was approved by the Human Ethics Committees of all participating centers (University Medical Center [UMC] Utrecht, Maastricht UMC, Radboud UMC, Leiden UMC, and UMC Groningen) (NL2466001808), was registered in the Dutch Trial Register (NTR1722), and conducted according to the Declaration of Helsinki.[9] Written informed consent was obtained from all participants.

Study Design

We conducted a multicenter RCT to compare the hearing results after receiving simultaneous BiCIs with the hearing results after receiving sequential BiCIs in adults with severe to profound bilateral postlingual sensorineural hearing loss. The full protocol is in Supplement 1. We reported data according to the CONSORT statement.[10]

Between January 12, 2010, and September 2, 2012, all participants eligible to participate in this study were discussed, and inclusion and exclusion criteria for each participant were verified.[5] The inclusion criteria were as follows: (1) age of 18 to 70 years; (2) postlingual onset of sensorineural hearing loss; (3) pure-tone average hearing loss of 70 dB or higher in each ear; (4) duration of severe to profound heraing loss of less than 20 years in each ear and a difference in duration of deafness between the 2 ears of 10 years or less; (5) ability to hear with or without hearing aid until 10 years or less; (6) marginal hearing aid benefit, defined as an aided phoneme score of 50% or less at a 65-dB sound pressure level; (7) Dutch as native language; (8) willingness and ability to participate in all scheduled procedures; (9) general health allowing general anesthesia for the duration of potential simultaneous BCIs; (10) Dutch health insurance coverage; and (11) agreement to be implanted with Advanced Bionics implants. The exclusion criteria were as follows: (1) previous cochlear implant; (2) abnormal cochlear anatomy; and (3) chronic ear infections. After providing informed consent, undergoing hearing evaluations, and providing self-reported questionnaires on hearing and quality of life (QoL), participants were randomly allocated to 1 of 2 treatment groups. Using a web-based randomization program, participants were randomized to either simultaneous BiCIs or sequential BiCIs with an interval of 2 years between implants. We used a block randomization per center strategy to obtain an equal distribution between sequential and simultaneous BiCI groups in all centers.

Intervention

All participants were implanted with HiRes90K implants (Advanced Bionics) and used Harmony processors (Advanced Bionics) with high resolution or high resolution 120 processing strategies. Implantation and rehabilitation (≥6 weeks) were performed in the participants' own hospitals, and rehabilitation decisions were based on the surgeon's and audiologist's expertise.

Hearing Evaluation

Hearing tests were conducted using the AB-York Crescent of Sound.[5,11] All tests were performed with BiCIs, except for participants in the sequential BiCI group prior to receiving their second cochlear implant. For these participants, we defined the *participant's preferred situation* as the maximum score reached either with cochlear implant only or cochlear implant plus hearing aid. When comparing follow-up years, we compared the results after receiving sequential BiCIs with the participant's preferred situation.

Primary and Secondary Outcomes

The primary outcome was speech intelligibility in noise from straight ahead, measured with the Utrecht-Sentence Test with Adaptive Randomized Roving levels,[12] which resulted in a speech reception threshold in noise. A speech reception threshold in noise of 30 dB was considered relative silence and was used as a cutoff if participants scored 30 dB or higher on all speech-in-noise tests.

Speech intelligibility in noise from spatially separated sources (SISSS) was an objective secondary outcome. Sentences were presented from 60° to the left (−60° azimuth) or to the right (+60° azimuth) of the participant, and the noise was presented from the opposite side.[13] When sounds come from different directions, participants usually have a best performing situation and a worst performing situation. A participant's best performing situation was defined when speech was presented to the ear with the lowest signal to noise ratio (SNR) and noise to the ear with the highest SNR. In participants' worst performing situations, speech and noise originated from the opposite sides. In the sequential BiCI group, before the implantation of the second cochlear implant, the best performing situation was defined as the situation in which the sound was presented to the implanted ear and the noise to the nonimplanted ear. After BiCIs, the ear with the lowest SNR was defined as the best performing cochlear implant's side. Another objective secondary outcome was maximum speech intelligibility in silence, measured with the Dutch consonant vowel consonant test at varying decibel sound pressure levels. A third objective secondary outcome was localization capabilities in a setup with horizontally placed loudspeakers in an arc around the participant. Numbers were shown on screens, representing the loudspeaker above them. Thirty phrases were presented randomly at 60-, 65-, or 70-dB sound pressure level from one of the loudspeakers. Participants were instructed to face the loudspeaker in front during the procedure. The results were the percentage of correct responses in the following 3 localization conditions: 15° angle azimuth between loudspeakers (−30°, −15°, 0°, 15°, and 30°); 30° angle azimuth between loudspeakers (−60°, −30°, 0°, 30°, and 60°); and 60° angle azimuth between loudspeakers (−60°, 0°, and 60°).

Subjective secondary outcomes were self-reported benefits assessed with different quality of hearing questionnaires. The first was the Speech, Spatial and Qualities Hearing Scale (SSQ), which consists of 3 domains: speech (SSQ1), spatial hearing (SSQ2), and quality of hearing (SSQ3).[14] The second was the Nijmegen Cochlear Implant Questionnaire (NCIQ), which assesses 6 subdomains of hearing,[15] and the third was the visual analog scale (VAS) on hearing.

The QoL questionnaires were the VAS on health, the Health Utilities Index 3,[16] the Dutch EuroQol 5-Dimension questionnaire,[17,18] and the Time Trade-off, calculated as a percentage using the following equation: [(life expectancy − amount of years to give up for perfect hearing)/life expectancy] × 100.[19]

Sample Size Calculation

To detect a clinically relevant difference of 3 dB in SNR between groups on the Utrecht-Sentence Test with Adaptive Randomized Roving levels and a SD of 3 dB, an α level of .05, and a power of 80%, 14 participants per group were needed. To compensate for any loss to follow-up, 5 additional participants were included per group.

Statistical Analysis

Statistical analysis was conducted from May 24 to June 12, 2016. Before analysis, all data were double-checked by 2 independent individuals. Most of the data were not normally distributed. We thus calculated median values and interquartile ranges. We used the Mann-Whitney test to compare the 1-year results from the simultaneous BiCI group with the 3-year results from the sequential BiCI group (1 year after sequential BiCIs). All analyses were 2-tailed, and a $P < .05$ was considered statistically significant. We used the Wilcoxon signed rank test to compare the 3-year results with the 1-year and 2-year results for the simultaneous and sequential BiCI groups separately, and we used Bonferroni correction for multiple testing. Median difference data were reported, including a 95% CI derived from the Hodges-Lehmann estimate in SPSS, version 22 (SPSS Inc).

Missing Data

In case of loss to follow-up in either group, we performed a per protocol (PP) analysis and a last observation carried forward (LOCF) analysis in which missing data were replaced by the participant's last results before dropout. This analysis meant that unilateral scores were used for the sequential BiCI results after 3 years of follow-up in participants unavailable for follow-up.

Results

Participant Characteristics

A total of 19 participants were included in each group. Baseline characteristics are described in **Table 1**. Hearing aid use before implantation was imbalanced between groups (sequential BiCI group, 19 participants; simultaneous BiCI group, 15 participants). Linear regression analysis revealed no confounding role of hearing aid use ($t_{36} = 0.05$; $P = .96$).

Loss to Follow-up and Missing Data

After providing written informed consent, 1 participant in each group withdrew and was replaced by new participants. One of the participants who withdrew had received a diagnosis of Kahler disease, and 1 preferred to be implanted with another brand of cochlear implant. During the second and third year, 2 participants in the sequential BiCI group withdrew because of personal reasons. Another participant was excluded from the sequential BiCI group because of poor results with the first implant and low expectations after sequential BiCIs owing to central deafness caused by rhesus antagonism (**Figure 1**).

At 1 year after implantation, the 15° localization results were missing for 1 participant in the simultaneous BiCI group. At 3

Table 1. Baseline Characteristics

Characteristic	Participants Who Received BiCIs[a] Sequential	Participants Who Received BiCIs[a] Simultaneous
Sex, No.		
Male	11	8
Female	8	11
Age at inclusion, y	54 (43-64)	52 (36-63)
Duration of severe hearing loss, y		
AD	17 (9-33)	16 (11-25)
AS	18 (9-35)	16 (11-25)
First CI	6:13	17:2
Right	6	17
Left	13	2
PTA AD, dB	106 (94-111)	106 (89-119)
500 Hz	90 (75-95)	95 (75-105)
1000 Hz	95 (90-110)	100 (85-115)
2000 Hz	100 (95-115)	110 (90-130)
4000 Hz	120 (110-130)	115 (95-130)
PTA AS, dB	108 (93-114)	108 (89-120)
500 Hz	90 (80-95)	90 (80-100)
1000 Hz	100 (85-110)	100 (90-115)
2000 Hz	110 (100-115)	115 (90-130)
4000 Hz	115 (105-130)	120 (90-130)
Maximum CVC phoneme score with hearing aids, %	44 (29-56)	48 (24-63)
Hearing aid use before CI, No.		
Yes	19	15
No	0	4
Hearing aid use in year 1, No.		
Yes	12	NA
No	7	NA
Hearing aid use in year 2, No.		
Yes	13	NA
No	5	NA
Treatment hospital, No.		
Utrecht	11	8
Maastricht	4	5
Nijmegen	2	3
Leiden	1	2
Groningen	1	1
Cause of deafness, No.		
Hereditary	7	9
Unknown and progressive	9	6
Sudden deafness	0	2
Head trauma	0	1
Meningitis	2	0
Rhesus antagonism	1	0
Sound exposure	0	1

Abbreviations: AD, auriculus dexter; AS, auricula sinistra; BiCI, bilateral cochlear implant; CI, cochlear implant; CVC, consonant vowel consonant; NA, not applicable; PTA, pure-tone average over 1, 2, and 4 kHz.

[a] Data are presented as median (interquartile range) unless otherwise indicated.

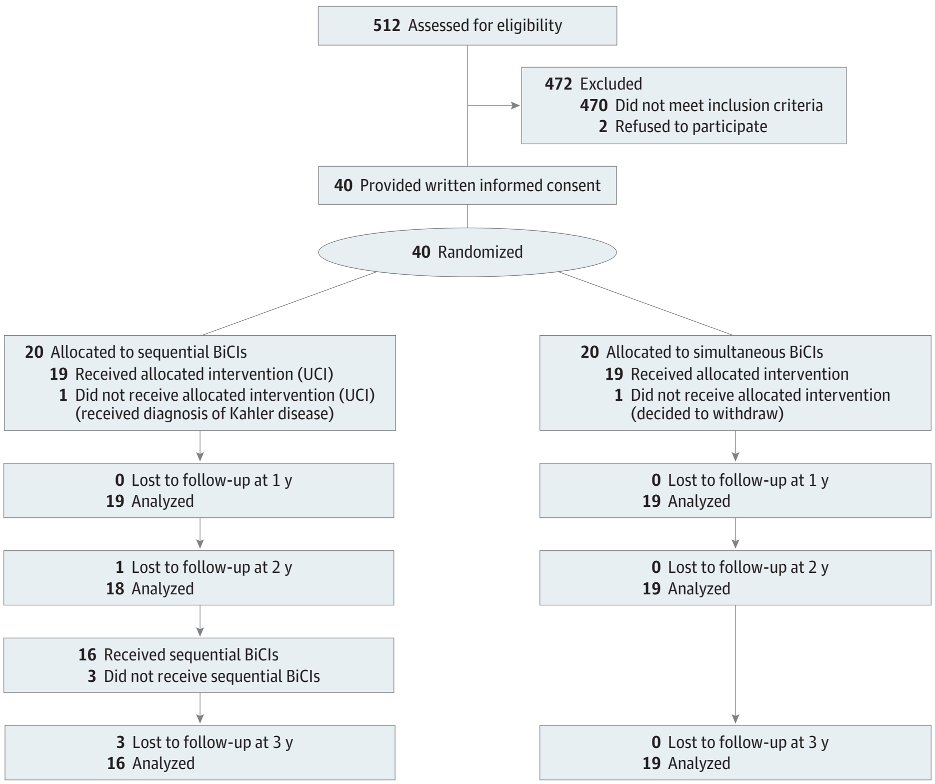
years after implantation, the Time Trade-off result was missing for 1 participant in the sequential BiCI group, and the VAS on health and hearing was missing for another participant in the sequential BiCI group. A cutoff of 30 dB was used for the speech reception threshold for 1 participant in each group.

Simultaneous vs Sequential BiCIs

Objective Results

As shown in the PP data in **Table 2** and **Figure 2**, no significant differences were seen between the 1-year results in the simultaneous BiCI group and the 3-year results in the sequential BiCI

Figure 1. Flowchart of Enrollment



BiCI indicates bilateral cochlear implant; CI, cochlear implant; DoD, duration of deafness; HA, hearing aid; HL, hearing loss; PTA, pure-tone average; SNHL, sensorineural hearing loss; SPL, sound pressure level; and UCI, unilateral cochlear implant. See the Methods section for inclusion and exclusion criteria.

group for all objective outcomes except for the 30° localization task. In the PP and LOCF analyses, the participants in the simultaneous BiCI group performed significantly better than those in the sequential BiCI group (PP: difference, −10% [95% CI, −20.1% to 0%]; LOCF: difference, −13.3% [95% CI, −23.3% to −3.3%]).

Subjective Results

As shown in the PP data in Table 2, **Figure 3**, and the eFigure in Supplement 2, no significant differences were seen in the PP and the LOCF analyses on all subjective results between both groups. The score for the simultaneous BiCI group, although higher on all questionnaires except for 2 subdomains of the NCIQ, were not significantly different from the sequential group scores.

Sequential BiCIs: Comparing Follow-up Years

Objective Results

As shown in Figure 2, participants in the sequential BiCI group performed better 1 year after receiving their second cochlear implant compared with previous years. A significant benefit was seen on the SISSS in the worst performing situation (difference between year 1 and year 3, −6.8 dB [97.5% CI, −10.5 to −3.4 dB]; difference between year 2 and year 3, −7.3 dB [97.5% CI, −13.7 to −1.1 dB]), as well as in the best performing situation (difference between year 1 and year 3, −2.6 dB [95% CI, −4.7 to −0.2 dB]), which lost its significance after correction for multiple testing (−2.6 dB [97.5% CI, −5.2 to 0.3 dB]). In addition, participants in the sequential BiCI group performed better on all localization tests compared with the previous years (15° configuration: difference between year 1 and year 3, 23.3% [97.5% CI, 6.7%-36.7%]; difference between year 2 and year 3, 26.7% [97.5% CI, 13.3%-40.0%]; 30° configuration: difference between year 1 and year 3, 33.3% [97.5% CI, 21.7%-43.3%]; difference between year 2 and year 3, 35.8% [97.5% CI, 25.0%-46.7%]; 60° configuration: difference between year 1 and year 3, 43.3% [97.5% CI, 28.3%-50.0%]; difference between year 2 and year 3, 43.3% [97.5% CI, 31.7%-53.2%]). No differences were seen for speech in noise from straight ahead and speech in silence.

Subjective Results

As shown in Figure 3, participants in the sequential BiCI group scored significantly better on the SSQ after receiving their second cochlear implant compared with previous years (difference on speech subscale between year 1 and year 3, 0.84 [97.5% CI, 0.12-1.48]; difference between year 2 and year 3, 0.64 [97.5% CI, 0.27-2.06]; difference on spatial subscale between year 1 and year 3, 2.01 [97.5% CI, 0.68-3.53]; difference between year 2 and year 3, 2.41 [97.5% CI, 1.45-3.97]; difference on quality subscale between year 1 and year 3, 1.09 [97.5% CI, 0.37-1.73]; difference between year 2 and year 3, 1.10 [97.5% CI, 0.05-1.85]).

On the NCIQ, participants scored significantly higher in year 3 on the social interactions subdomain compared with

Table 2. Comparison Between Simultaneous and Sequential BiCIs for All Outcome Measures[a]

Characteristic	BiCIs, Median (IQR)		Difference (95% CI)	
	Sequential	Simultaneous	PP	LOCF
Objective tests for hearing, dB				
Speech intelligibility in noise from straight ahead	8.0 (5.5 to 12.7)	7.5 (3.8 to 12.2)	0.9 (−3.1 to 4.4)	0.9 (−2.8 to 4.4)
SISSS				
Best performing situation	2.7 (0.1 to 7.8)	5.0 (−1.3 to 8.8)	−0.3 (−5.0 to 4.1)	−0.3 (−4.7 to 4.1)
Worst performing situation	7.3 (4.8 to 12.1)	5.3 (0.3 to 13.1)	1.9 (−4.4 to 6.6)	2.5 (−3.1 to 6.6)
Localization, %				
15°	51.7 (36.7 to 63.3)	53.3 (46.7 to 67.5)	−3.3 (−16.7 to 6.7)	−10.0 (−20.0 to 3.3)
30°	60.0 (53.3 to 72.5)	76.7 (60.0 to 83.3)	−10.0 (−20.1 to 0.0)	−13.3 (−23.3 to −3.3)[b]
60°	91.7 (76.7 to 99.2)	96.7 (86.7 to 100.0)	−3.3 (−13.3 to 0.0)	−6.7 (−13.3 to 0.0)
Maximum CVC phoneme score, %	90.0 (83.5 to 94.0)	88.0 (80.0 to 95.0)	1.5 (−4.0 to 8.0)	2.0 (−4.0 to 7.0)
Subjective hearing				
SSQ				
Speech	4.37 (3.45 to 6.01)	5.94 (3.53 to 6.57)	−0.82 (−2.27 to 0.36)	−0.82 (−2.27 to 0.36)
Spatial	5.18 (3.74 to 7.05)	5.92 (4.33 to 7.24)	−0.46 (−1.72 to 0.85)	−0.52 (−1.79 to 0.76)
Quality	6.08 (5.05 to 6.78)	6.24 (5.82 to 8.00)	−0.71 (−1.76 to 0.46)	−0.63 (−1.76 to 0.46)
NCIQ				
Basic sound perception	86.3 (76.3 to 97.5)	92.5 (72.5 to 95.0)	−2.5 (−10.0 to 5.0)	−2.5 (−10.0 to 5.0)
Advanced sound perception	55.0 (40.0 to 77.5)	60.0 (45.0 to 85.0)	−2.5 (−20.0 to 10.0)	0.0 (−17.1 to 15.0)
Speech production	86.3 (76.3 to 97.5)	92.5 (80.0 to 95.0)	−2.5 (−10.0 to 5.0)	−2.5 (−12.5 to 2.5)
Self-esteem	70.0 (55.6 to 82.5)	75.0 (65.0 to 80.6)	−5.0 (−16.1 to 3.9)	−5.0 (−15.0 to 4.4)
Activity limitations	76.3 (60.0 to 89.4)	75.0 (71.9 to 83.3)	0.0 (−13.9 to 10.0)	0.0 (−10.0 to 11.5)
Social interactions	66.9 (50.6 to 78.8)	63.9 (61.1 to 77.8)	−2.8 (−13.9 to 7.8)	−2.8 (−11.4 to 7.5)
VAS hearing	74.5 (61.3 to 80.0)	80.0 (70.0 to 85.0)	−5.0 (−10.0 to 4.0)	−5.0 (−10.0 to 3.0)
Subjective health				
VAS health	80.0 (71.0 to 90.0)	80.0 (65.0 to 90.0)	0.0 (−9.0 to 10.0)	0.0 (−6.0 to 10.0)
HUI3	0.78 (0.54 to 0.82)	0.78 (0.61 to 0.85)	−0.024 (−0.084 to 0.048)	0.0 (−0.072 to 0.154)
EQ-5D questionnairre				
Utility score	1.0 (0.8 to 1.0)	1.0 (0.8 to 1.0)	0.00 (−0.04 to 0.00)	0.00 (0.00 to 0.00)
Thermometer	80.0 (71.3 to 90.0)	75.0 (70.0 to 95.0)	1.0 (−5.0 to 10.0)	3.0 (−5.0 to 10.0)
Time Trade-off	100 (88.8 to 100)	100 (100 to 100)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)

Abbreviations: BiCIs, bilateral cochlear implants; CVC, consonant vowel consonant; EQ-5D, Dutch EuroQol 5-Dimension; HUI3, Health Utilities Index 3; IQR, interquartile range; LOCF, last observation carried forward analysis; NCIQ, Nijmegen Cochlear Implant Questionnaire; PP, per protocol analysis; SISSS, Speech intelligibility-in-noise from spatially separated sources; SSQ, Speech, Spatial and Qualities Hearing Scale; VAS, visual analog scale.

[a] Legend data contain 1-y results of the simultaneous BiCI group vs 3-y results of the sequential BiCI group.

[b] $P < .05$.

year 1 (difference, 5.5 [97.5% CI, 0.0-13.2]; $P = .02$). The difference between year 2 and year 3 (5.6 [95% CI, 0.3-11.7]) was not significant after correction for multiple testing. For the activity limitations subdomain, the differences between year 1 and year 3 (6.3 [95% CI, 1.5-12.5]) and year 2 and year 3 (7.2 [95% CI, 0.0-13.8]) were also not significant after correction for multiple testing.

As shown in the eFigure in Supplement 2, no significant differences were seen on the results of the QoL questionnaires in the sequential BiCI group. Results of original data and LOCF data did not differ.

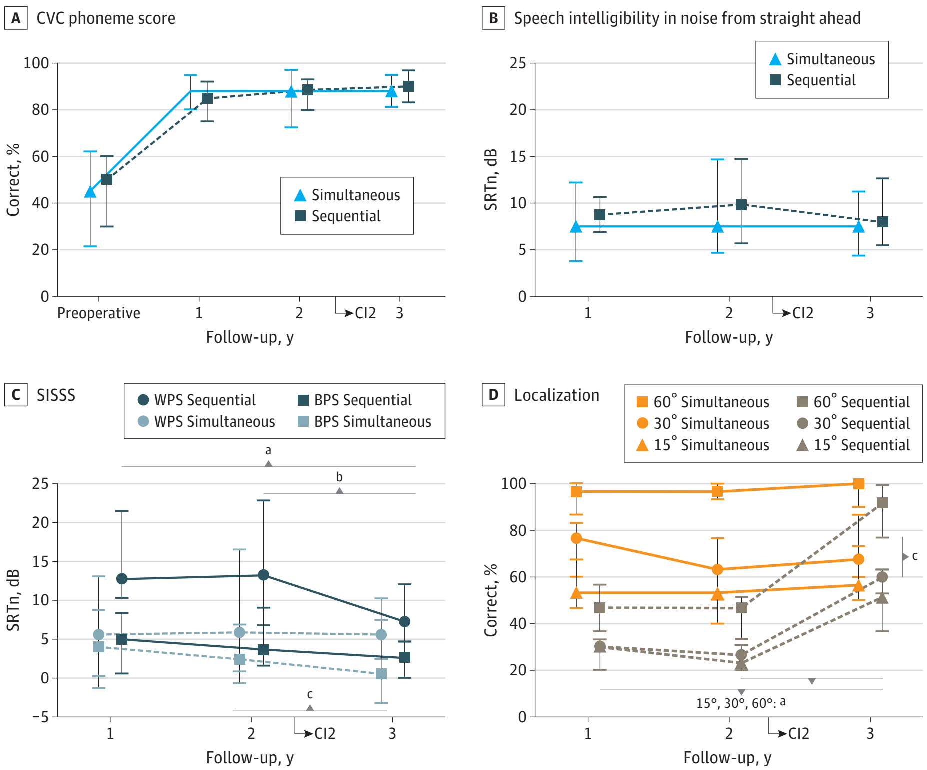
Simultaneous BiCIs: Comparing Follow-up Years

When we compared the 3-year follow-up data with the 1-year and 2-year data for the participants in the simultaneous BiCI group, a significant improvement of -2.50 dB (97.5% CI, -4.85 to -0.01 dB) was seen for the best performing situation on the SISSS between year 1 and year 3. After correcting for multiple testing, we found that a 6.7% increase (97.5% CI, -0.01% to 15.0%) in performance on the 15° localization task between year 2 and year 3 was not significant. No differences were observed for any of the other objective and subjective outcomes (Figures 2 and 3; eFigure in Supplement 2).[5,6]

Discussion

In this study, we present the results of the first RCT, to our knowledge, comparing simultaneous and sequential BiCIs in postlingually deafened adults. In addition, we present the 3-year follow-up results for both study groups separately.

Figure 2. Development Over Time of Objective Outcomes for Simultaneous and Sequential Bilateral Cochlear Implants



A, Consonant vowel consonant (CVC) phoneme score. B, Speech intelligibility-in-noise test from straight ahead. C, Speech intelligibility in noise from spatially separated sources (SISSS). D, Localization. Scores of the per protocol data are presented as median values with an error bar representing the interquartile range. Statistical analyses were performed between the 1- or 2-year data and the 3-year data, applying a Bonferroni correction. The 30° localization capabilities did not significantly decrease during follow-up for the simultaneous BiCI group. BPS indicates best performing situation; CI2, second cochlear implant; SRTn, speech reception threshold in noise; WPS: worst performing situation.

[a] $P < .001$.

[b] $P < .01$.

[c] $P < .05$.

First, the simultaneous BiCI group and the sequential BiCI group performed equally 1 year after receiving BiCIs on all objective and subjective hearing tests, except for the 30° localization task. The sequential BiCI group did not need a longer follow-up to reach the same level of speech perception as the simultaneous BiCI group. So far, studies have solely examined the benefit of BiCIs vs a unilateral cochlear implant, but a comparison between sequential and simultaneous BiCIs has not yet been attempted.[1,2,4] Because it requires auditory stimulation during early ages to achieve effective central auditory development, a critical period exists for pediatric cochlear implantation. Given this critical period, simultaneous BiCIs have advantages over sequential BiCIs in children.[20] Simultaneous BiCIs guarantee the implantation of the better ear and the earlier implantation of the second ear, which may facilitate the development of binaural hearing. In postlingually deafened adults, the auditory system is fully developed, which may explain the similar results between our 2 study groups.

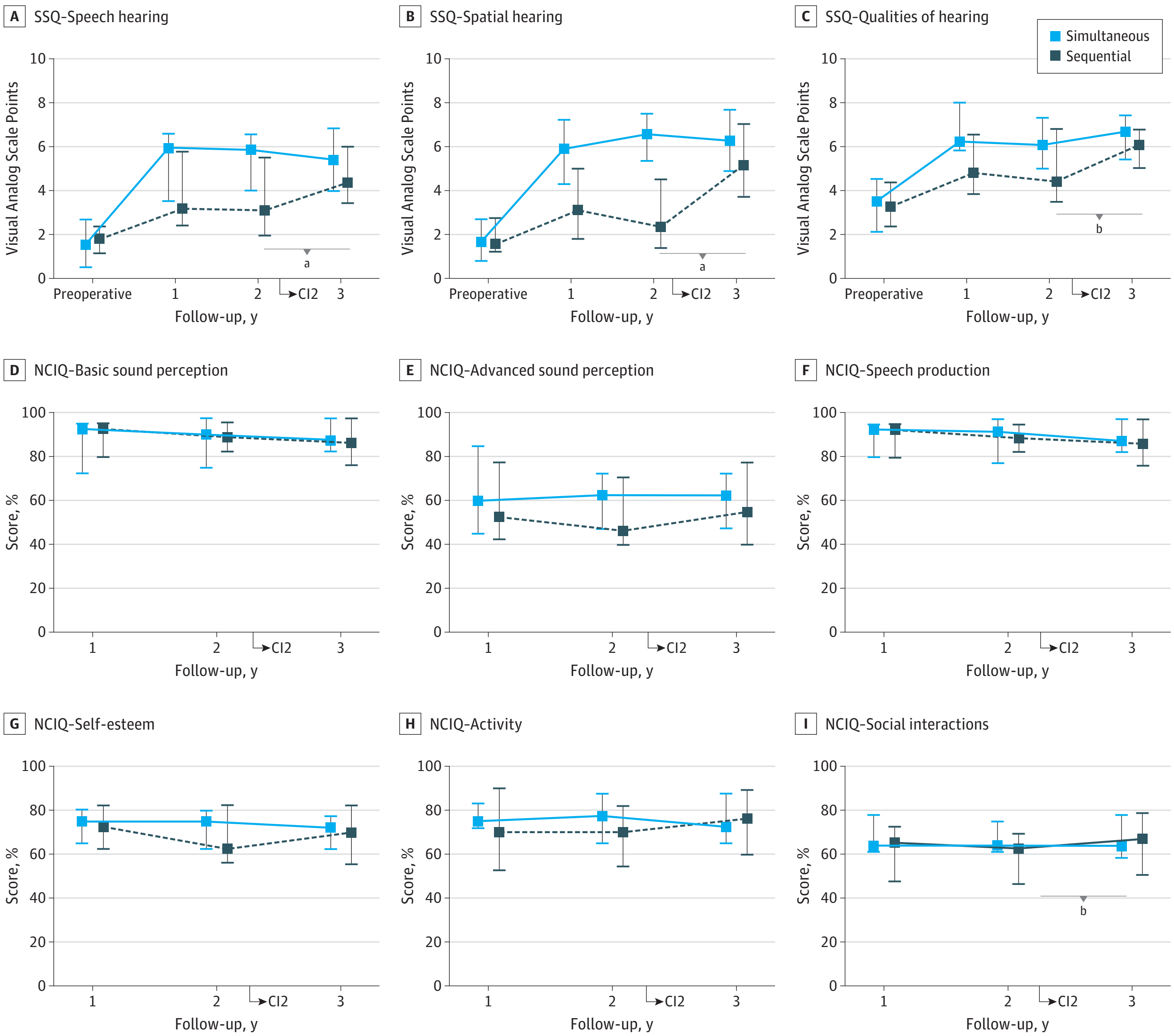
Second, we found that the participants in the sequential BiCI group benefit from BiCIs in the same listening situations as do the participants in the simultaneous BiCI group: difficult listening situations with speech and noise from spatially separated sources in participants' worst performing situation and on several localization tasks. These findings were confirmed by improved scores on questionnaires concerning perception of speech, spatial hearing, and quality of hearing (SSQ) and the social interaction subdomain on the NCIQ.

Two study participants dropped out of the sequential BiCI group for personal reasons. Both participants were satisfied with the results that they obtained with their first cochlear implant, which is in accordance with the significant improvement in QoL found in this study 1 year after a unilateral cochlear implant. However, sequential BiCIs could further improve these participants' spatial hearing capabilities (hearing in noise from spatially separated sources and localization), as shown in this study.

Five earlier studies[21-25] investigated sequential BiCIs compared with unilateral cochlear implants. Two studies[21,25] compared bilateral results with unilateral results after sequential BiCIs by deactivating 1 cochlear implant. This situation, however, is not representative for a unilateral cochlear implant because the patients are used to hearing with 2 cochlear implants and because cochlear implantation causes an insertion trauma that might have a negative effect on residual hearing. Ramsden et al[22] compared unilateral results prior to receiving sequential BiCIs with the results after sequential BiCIs and found significantly improved scores after sequential BiCIs. Improved hearing in quiet and noisy settings 3 months after sequential BiCIs was also seen in a study by Zeitler et al.[24] In accordance with our results, Summerfield et al[23] reported subjective benefits of BiCIs on the SSQ1, SSQ2, and SSQ3 but not on QoL questionnaires in a group of participants receiving sequential BiCIs.

Finally, we saw an increase in speech-intelligibility-in-noise abilities in our simultaneous BiCI group 3 years after

Figure 3. Development Over Time of Subjective Outcomes for Simultaneous and Sequential Bilateral Cochlear Implants



A, Speech, Spatial and Qualities Hearing Scale (SSQ): speech hearing component. B, SSQ: spatial hearing component. C, SSQ: qualities of hearing component. D, Nijmegen Cochlear Implant Questionnaire (NCIQ): basic sound perception component. E, NCIQ: advanced sound perception component. F, NCIQ: speech production component. G, NCIQ: self-esteem component. H, NCIQ: activity component. I, NCIQ: social interactions component. Scores of the per protocol data are presented in median values with an error bar representing the interquartile range. Statistical analyses were performed between 1-, 2-, and 3-year data, applying a Bonferroni correction. CI2 indicates the second cochlear implant.

[a] $P < .001$.

[b] $P < .05$.

implantation. In a study by Eapen et al[26] with 9 individuals who received simultaneous BiCIs and fixed SNRs, hearing-in-noise results improved in the 4 years following implantation. Our simultaneous BiCI group exhibited an improvement in the SISSS results in the best performing situation (difference, -2.50 dB [95% CI, -4.69 to -0.32 dB]). This improvement may result from binaural integration, as measured through one of the binaural hearing effects: the squelch effect.[13]

Strengths and Limitations

To our knowledge, this is the first RCT examining the effect of simultaneous vs sequential BiCIs on various hearing outcomes. The use of this design minimized allocation bias. In addition, the study population was homogenous; for example, onset of hearing loss was not allowed to differ more than 10 years between ears. A longer interval between ears might have caused an unfavorable result in the sequential BiCI group owing to sound deprivation of the longer-deprived ear.[27] Three participants were unavailable for follow-up in the sequential BiCI group. We performed both a PP analysis and an LOCF analysis and found that this loss had no influence on the results. Owing to the multicenter nature of this study, implantation procedures may vary between centers. In addition, the sample size calculation incorporated loss to follow-up; therefore, the study had sufficient power to detect a difference on the primary outcome measure. However, the sample size might have been too small for secondary outcomes such as QoL questionnaires because smaller subjective changes were expected between the 2 groups. In addition, these questionnaires were unable to detect changes in QoL after cochlear implantation because they do not incorporate a specific hearing element. On 2 of these questionnaires (Time Trade-off, EuroQol 5-Dimension), ceiling effects were noted that hindered differentiation between study groups. Finally, this study focused solely on subjective and objective speech perception outcomes and did not incorporate other factors that affect the choice for simultaneous vs sequential BiCIs, such as cost utility and surgical complications (such as bilateral areflexia).[28] We plan to study the differences between the first and second ear implanted in the sequential BiCI group and to investigate whether these participants demonstrate a clinically relevant binaural squelch effect.

Conclusions

In this RCT, we compared the objective and subjective results of simultaneous BiCIs and sequential BiCIs in adults with severe-to-profound hearing loss. This study demonstrates that individuals who receive sequential BiCIs derive the same benefit as those who receive simultaneous BiCIs on speech perception 1 year after receiving their second cochlear implant. Participants who underwent sequential BiCIs had significant improvements in spatial speech-in-noise and localization abilities compared with their unilateral situation before receiving a second cochlear implant. These findings were consistent with the participants' self-reported hearing capabilities. Three years after simultaneous BiCIs, the spatial speech-in-noise abilities of the participants increased for the best performing situation. All other objective and self-reported hearing capabilities remained stable. These findings suggest that simultaneous BiCIs offer long-term stable results in adults with severe-to-profound bilateral sensorineural hearing loss.

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