Original Investigation

Comparison of Bilateral and Unilateral Cochlear Implantation in Adults
A Randomized Clinical Trial

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IMPORTANCE The cost of bilateral cochlear implantation (BCI) is usually not reimbursed by insurance companies because of a lack of well-designed studies reporting the benefits of a second cochlear implant.

OBJECTIVE To determine the benefits of simultaneous BCI compared with unilateral cochlear implantation (UCI) in adults with postlingual deafness.

DESIGN, SETTING, AND PARTICIPANTS A multicenter randomized clinical trial was performed. The study took place in 5 Dutch tertiary referral centers: the University Medical Centers of Utrecht, Maastricht, Groningen, Leiden, and Nijmegen. Forty patients eligible for cochlear implantation met the study criteria and were included from January 12, 2010, through November 2, 2012. The main inclusion criteria were postlingual onset of hearing loss, age of 18 to 70 years, duration of hearing loss of less than 20 years, and a marginal hearing aid benefit. Two participants withdrew from the study before implantation. Nineteen participants were randomized to undergo UCI and 19 to undergo BCI.

INTERVENTIONS The BCI group received 2 cochlear implants during 1 surgery. The UCI group received 1 cochlear implant.

MAIN OUTCOMES AND MEASURES The primary outcome was the Utrecht Sentence Test with Adaptive Randomized Roving levels (speech in noise, both presented from straight ahead). Secondary outcomes were consonant-vowel-consonant words in silence, speech-intelligibility test with spatially separated sources (speech in noise from different directions), sound localization, and quality of hearing questionnaires. Before any data were collected, the hypothesis was that the BCI group would perform better on the objective and subjective tests that concerned speech intelligibility in noise and spatial hearing.

RESULTS Thirty-eight patients were included in the study. Fifteen patients in the BCI group used hearing aids before implantation compared with 19 in the UCI group. Otherwise, there were no significant differences between the groups' baseline characteristics. At 1-year follow-up, there were no significant differences between groups on the Utrecht Sentence Test with Adaptive Randomized Roving levels (9.1 dB, UCI group; 8.2 dB, BCI group; $P = .39$) or the consonant-vowel-consonant test (median percentage correct score 85.0% in the UCI group and 86.8% in the BCI group; $P = .21$). The BCI group performed significantly better than the UCI group when noise came from different directions (median speech reception threshold in noise, 14.4 dB, BCI group; 5.6 dB, BCI group; $P < .001$). The BCI group was better able to localize sounds (median correct score of 50.0% at 60°, UCI group; 96.7%, BCI group; $P < .001$). These results were consistent with the patients' self-reported hearing capabilities.

CONCLUSIONS AND RELEVANCE This randomized clinical trial demonstrates a significant benefit of simultaneous BCI above UCI in daily listening situations for adults with postlingual deafness.

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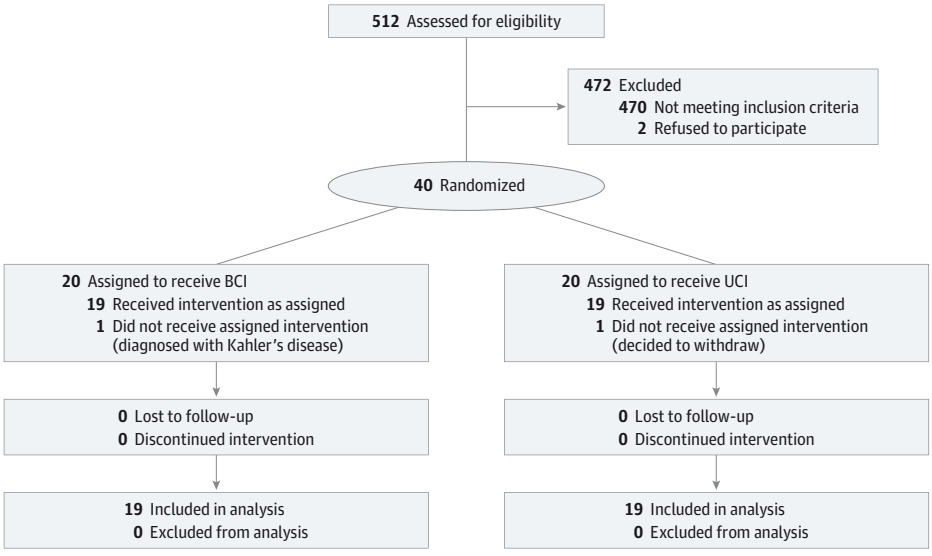
More than 550 million people worldwide have disabling hearing loss (pure-tone average at 500, 1000, and 2000 Hz, ≥35-dB hearing level in the better ear). More than 60 million have severe hearing loss or worse (pure-tone average, ≥65-dB hearing level).[1] For the latter group, a cochlear implant may be provided. Cochlear implantation has proven to be very successful, especially for patients who have well-developed central auditory pathways (ie, in those who received an implant at an early age or who lost their hearing later in life after auditory cortex development).[2] In the Netherlands, cochlear implantation is considered a treatment option if hearing aids do not provide sufficient benefit. This means that the aided speech perception threshold in quiet, and the phoneme score, measured with consonant-vowel-consonant (CVC) words, is 50% or less at a 65-dB sound pressure level (SPL). Since 2012, bilateral cochlear implantation (BCI) has been standard care for children in the Netherlands until the age of 5 years. Adults only receive reimbursement for a second implant when deafness is caused by meningitis, which may lead to ossification of the cochlea. There is an ongoing discussion in the Netherlands about whether BCI should be standard care for adults, as it is in Germany and Scandinavia.[3] Binaural hearing enables one to differentiate sounds of interest from background noise and locate where sounds come from by using different effects of binaural hearing: head shadow, squelch, and summation.[4-7] Several reviewers have analyzed the benefits of BCI compared with unilateral cochlear implantation (UCI). Bilateral cochlear implantation seems beneficial for speech perception in noise, localization of sounds, and improvement of quality of hearing and quality of life; however, reviewers conclude that most studies[8-10] have a low level of evidence. For this reason, Dutch insurance companies have decided that reimbursement of a second cochlear implant in adults cannot be justified. In this article, we present the results of a multicenter randomized clinical trial (RCT) on the benefits of simultaneous BCI compared with UCI in adults with severe bilateral postlingual hearing loss. We present objective hearing test results for hearing in noise and quiet, which also includes sound localization capabilities, and patients' self-reported quality of hearing results.

Methods

Trial Design and Participants

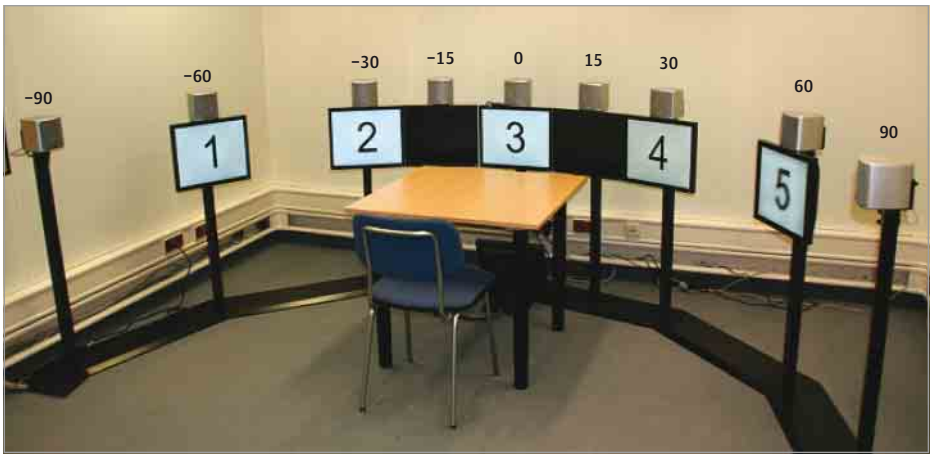
In the Netherlands, cochlear implantation is performed in 8 tertiary referral centers, 5 of which participated in this RCT: the University Medical Centers of Utrecht, Maastricht, Nijmegen, Leiden, and Groningen. The study criteria were verified for each patient eligible for cochlear implantation, in the multidisciplinary cochlear implantation teams, from January 12, 2010, through November 2, 2012 (**Figure 1**). The inclusion criteria were as follows: (1) age of 18 to 70 years; (2) postlingual onset of hearing loss (participants attended mainstream education); (3) duration of severe to profound hearing loss of less than 20 years in each ear and a difference in duration of hearing loss between the 2 ears of less than 10 years; (4) marginal hearing aid benefit, defined as an aided phoneme score less than 50% at a 65-dB SPL; (5) Dutch as native language; (6) willingness and ability to participate in all scheduled procedures outlined in the protocol; (7) general health allowing general anesthesia for the duration of potential simultaneous BCI; (8) Dutch health insurance coverage; and (9) agreement to undergo implantation with Advanced Bionics implants. Exclusion criteria were as follows: (1) previous cochlear implantation; (2) disability that could interfere with the completion of the tests; (3) abnormal cochlear anatomy in one or both ears; and (4) chronic ear infection in one or both ears. The criteria were double-checked by the main investigators in Utrecht before a patient received written information from his or her otolaryngologist and was asked to participate in the study. Baseline hearing tests were performed as part of the standard

Figure 1. Flowchart of Enrollment



This flowchart shows the number of patients eligible for cochlear implantation in whom the study criteria were assessed. The participants were randomly allocated to unilateral cochlear implantation (UCI) or bilateral cochlear implantation (BCI). All were available for follow-up.

Figure 2. The AB-York Crescent of Sound Test Setup



This setup was used to conduct the Utrecht Sentence Test with Adaptive Randomized Roving levels, speech intelligibility test with spatially separated sources, and localization tests. The numbers on the screens represent the answer options, and the numbers above the speakers represent degrees of angle.

cochlear implantation workup and were equal in all centers. They encompassed standard pure-tone audiometry and speech intelligibility in quiet, with and without hearing aids, using standard CVC words. After patients provided written informed consent, self-reported questionnaires on hearing were filled out at the patients' own hospitals before participants were randomly allocated to 1 of 2 treatment groups. This order was chosen because the knowledge of receiving 1 or 2 implants could influence the participant's answers and bias the results. The trial protocol can be found in the Supplement.

Randomization and Masking

The participants were randomized to undergo UCI or simultaneous BCI. The randomization program was designed by an independent data manager and could not be influenced by any of the researchers. We used a block randomization per center strategy to obtain an equal distribution between UCI and BCI in all centers. Masking was not possible because of the nature of the study; one could see on the outside whether a patient had 1 or 2 implants. This study was approved by the human ethics committees of all participating centers and was conducted according to the principles expressed in the Declaration of Helsinki.

Unavailable for Follow-up

One participant, who was randomized to the BCI group, was excluded when diagnosed as having Kahler's disease only a few weeks later (Kahler's disease or multiple myeloma is a cancer in which antibody-producing plasma cells grow in an uncontrolled and invasive [malignant] manner). Another participant, who was randomized to the UCI group, decided to withdraw when his surgery was postponed because of a temporary recall of Advanced Bionics implants. These participants were replaced by new participants. All other patients completed the test sessions for the 1-year follow-up period (Figure 1).

Study Procedures

All participants received HiRes90K cochlear implants (Advanced Bionics) to ensure that they had access to the same technology. In the UCI group, patients chose the ear of implantation, which was usually the ear with the worst hearing. They were allowed to discuss their decision with members of the cochlear implantation team but made the choice themselves. Because the objective of the study was to compare BCI with the next best alternative, the use of a contralateral hearing aid was encouraged in the UCI group. The surgery and rehabilitation took place in the patients' own hospital, and rehabilitation started approximately 6 weeks after surgery. The implant processing strategy was defined in a protocol for all centers. All patients were fitted with Harmony processors (Advanced Bionics) except for 2 (1 in each group) who used Neptune processors (that have an identical processing strategy but a body-worn microphone). Four weeks before testing, they switched to Harmony processors to allow time for acclimatization. All tests were performed with the patients wearing Harmony processors.

Test Procedures at 1-Year Follow-up

One year after surgery all participants were asked to complete the quality-of-hearing questionnaires for the second time. Further spatial hearing tests were performed at the University Medical Center Utrecht by 4 well-trained researchers (Y.E.S., A.v.Z., and A.B.R.) who strictly followed the same protocol. All gathered data were double-checked by an independent person who did not have any other connections to the otorhinolaryngology department.

The Dutch AB-York Crescent of Sound

Speech intelligibility in noise and localization capabilities were tested with the Dutch AB-York crescent of sound.[11,12] The test battery included the following: (1) Utrecht Sentence Test with Adaptive Randomized Roving levels (U-STARR), (2) speech-intelligibility test with spatially separated sources (SISSS), and (3) a sound localization test. The AB-York crescent of sound contains 9 audiovisual stands, 7 positioned at 30° intervals and 2 at 15° intervals on either side of 0° (**Figure 2**). In the U-STARR, Dutch VU-98 sentences were presented at a 65-, 70-, or 75-dB SPL (randomly selected) in speech noise, both coming from straight ahead. The number of keywords correctly repeated per sentence was scored. Sentences were presented with

Table 1. Patient Characteristics

Characteristic	UCI	BCI	*P* Value
Sex, M:F, No.	11:8	8:11	.33
Age, mean (SD) [range], y			
At inclusion	52.5 (12.5) [26-67]	47.7 (15.9) [18-70]	.31
At start of severe hearing loss			
Right ear	30.8 (20.1) [3-55]	30.5 (17.2) [3-63]	.95
Left ear	30.6 (19.8) [3-55]	30.0 (17.5) [3-63]	.92
PTA, mean (SD) [range], dB			
Right ear	106.3 (12) [78-125]	106.1 (16) [80-130]	.65
500 Hz	84 (17.2) [35-115]	93 (21.3) [65-130]	.15
1000 Hz	97 (12.0) [70-115]	101 (17.0) [80-130]	.44
2000 Hz	104 (14.9) [70-130]	108 (17.7) [80-130]	.46
4000 Hz	118 (13.6) [90-130]	109 (18.5) [70-130]	.12
Left ear	107.5 (13) [83-127]	108.3 (18) [77-130]	.67
500 Hz	86 (20.6) [20-115]	93 (20.1) [65-130]	.33
1000 Hz	99 (15.1) [75-130]	103 (17.2) [80-130]	.46
2000 Hz	107 (14.1) [80-130]	111 (19.9) [75-130]	.51
4000 Hz	117 (14.3) [85-130]	111 (22.6) [65-130]	.37
Maximum phoneme score with hearing aids, mean (SD) [range], %	46.2 (20.4) [0-80]	42.1 (27.6) [0-90]	.60
Treatment hospital, No.			
Utrecht	11	8	.89
Maastricht	4	5	
Nijmegen	2	3	
Leiden	1	2	
Groningen	1	1	
Hearing aid use before cochlear implantation, No.			
Yes	19	15	.04[a]
No	0	4	
Cause of deafness, No.			
Hereditary	7	9	.25
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: BCI, bilateral cochlear implantation; PTA, pure-tone average (mean at 0.5, 1, and 2 kHz); UCI, unilateral cochlear implantation.

[a] Significant at $P < .05$.

an initial signal to noise ratio (SNR) of +20 dB (sentence 20 dB louder than noise). If a sentence was scored as correct, the SNR for the next sentence was decreased by increasing the noise level. If a sentence was scored as incorrect, the SNR was increased. The SNR was changed with consecutive steps of 10, 5, and 2.5 dB. The mean SNR of the last 10 sentences was calculated, which resulted in the speech reception threshold in noise. For the SISSS, the same procedure was used as for the U-STARR. The only difference was that the sentences were presented from 60° to the left (−60° azimuth) or to the right (+60° azimuth) of the patient. For the sound localization test, numbers were shown on screens, representing the loudspeakers above them. A phrase was presented from one of the loudspeakers (randomly at a 60-, 65-, or 70-dB SPL), 30 times in total. The results were percentage of correct responses with 60°, 30°, and 15° angles between speakers. All tests were performed monaurally, with either one of the cochlear implants or the hearing aid switched on; bilaterally, using both cochlear implants; or bimodally, with both the cochlear implant and hearing aid switched on. Participants were instructed to face the loudspeaker positioned in front of them and not to turn their head during the tests.

To compare BCI to the next best option, we defined a patient's preferred situation for each patient in the UCI group. This was the daily hearing situation: either wearing the cochlear implant only or wearing a cochlear implant and hearing aid. Results from the BCI group were compared with results of the patient's preferred situations from the UCI group.

When speech and noise come from different directions, one is best able to understand the speech when it is presented to the best-hearing ear and noise to the worst-hearing ear. In the UCI group, this situation occurs when speech is presented to

Table 2. Objective 1-Year Postoperative Outcomes

Outcome	Patient Preferred Situation (With or Without HA)				
	UCI (n = 19)		BCI (n = 19)		
	Mean (SD)	Median (Range)	Mean (SD)	Median (Range)	*P* Value
Residual hearing in the ear without an implant (phoneme score in silence, % CVC words)					
HA users (n = 12)	22.7 (22.7)	22.5 (0 to 65)	...	...	...
Non-HA users (n = 7)	8.3 (21.9)	0 (0 to 58)	...	...	...
Whole UCI group	17.4 (23.0)	0 (0 to 65)	...	...	...
Speech in noise and in silence				...	...
Speech in noise both from straight ahead, SRTn in dB	10.0 (6.3)	9.1 (2.2 to 30)	8.2 (5.3)	8.2 (0.3 to 18.4)	.39
Phoneme score in silence, % CVC words	83.4 (8.9)	85.0 (70 to 98)	86.8 (9.5)	88.0 (67 to 100)	.21
Speech and noise from different directions					
SISSS performing situation, SRTn in dB					
Best	5.9 (7.3)	5.0 (−3.1 to 30.0)	4.1 (5.9)	4.1 (−4.7 to 14.1)	.61
Worst	15.8 (6.3)	14.4 (8.1 to 30.0)	7.1 (7.5)	5.6 (−2.8 to 22.8)	.002[a]
Localization of sounds, % correct					
60°	50.5 (16.5)	50.0 (30.0 to 90.0)	93.7 (7.8)	96.7 (73.3 to 100.0)	<.001[a]
30°	30.9 (10.2)	30.0 (16.7 to 50.0)	71.8 (14.0)	76.7 (43.3 to 96.7)	<.001[a]
15°	29.0 (8.8)	30.0 (20.0 to 50.0)	56.7 (16.3)	53.3 (33.3 to 90.0)	<.001[a]

Abbreviations: CVC, consonant-vowel-consonant words; BCI, bilateral cochlear implantation; HA, hearing aid; SISSS, speech in spatially separated sources; SRTn, speech reception threshold in noise; UCI, unilateral cochlear implantation.

Ellipses indicate data not applicable.

[a] Significant at $P < .05$.

the cochlear implant side and noise to the contralateral side. Patients who underwent bilateral implantation generally also have one side with which they hear better than with the other.

Per participant, we defined this as the best hearing situation and the worst hearing situation. The latter occurs when speech is presented to the worst-hearing side and noise to the best-hearing side.

Outcomes

The primary outcome was the U-STARR. Secondary outcomes were the SISSS, CVC words in quiet, sound localization, and self-reported benefits in everyday listening situations assessed with the Speech, Spatial, and Qualities Hearing Scale (SSQ),[13] Time Trade-off (TTO),[14] a visual analog scale (VAS) for hearing (scale of 0-100), and Nijmegen Cochlear Implant Questionnaire (NCIQ).[15]

On the TTO, participants were asked how many life-years they were willing to give up to live the rest of their lives with perfect hearing. (TTO = [(Life Expectancy − Amount of Years to Give Up for Perfect Hearing)/Life Expectancy] × 100).[14] This question needs good instruction; therefore, we decided not to let patients answer it in their own hospitals preoperatively, but we asked them personally at the 1-year follow-up test moment at the University Medical Center Utrecht.

Sample Size Calculation

To detect a clinically relevant difference of 3 dB in the SNR between groups on the hearing in noise test and an SD of 3 dB, with an α of .05 and a power of 80%, we calculated that 14 patients per group were needed. To compensate for any data unavailable for follow-up, 5 additional patients were included in each group. Three decibels is the magnitude of the summation effect that is typically observed.

Statistical Analysis

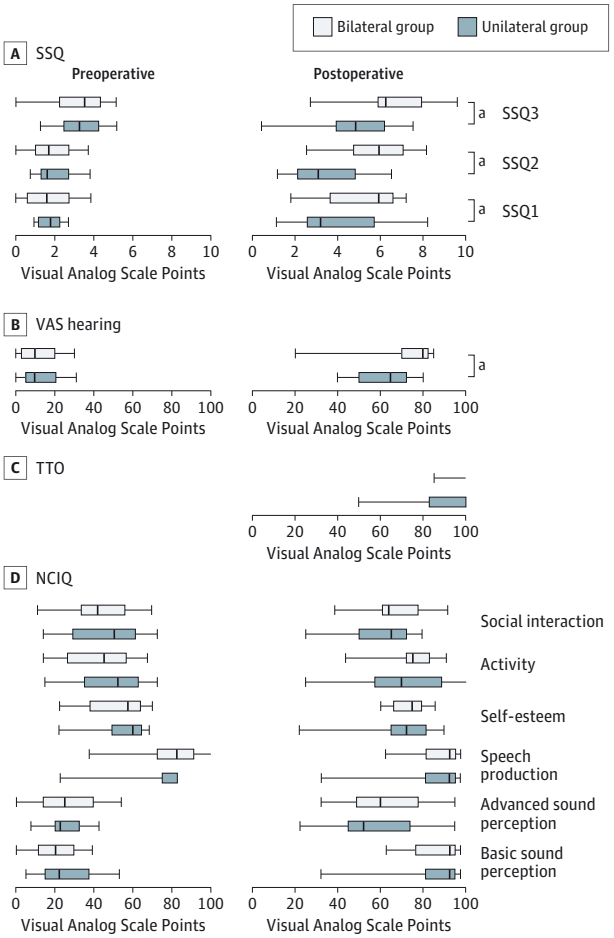
To compare baseline characteristics and preoperative test results, we used the *t* test for numeric, normally distributed data and the χ^2 test for ordinal data. None of the postoperative test results were normally distributed. We therefore present median outcomes and ranges. We used the Mann-Whitney tests for all hearing test results (TTO, VAS, and SSQ) for comparing UCI and BCI data. For the NCIQ, we used the χ^2 test. To compare preoperative with postoperative findings, we used the Wilcoxon signed-rank test. To analyze whether residual hearing had an effect on the outcomes, we calculated Spearman ρ correlation coefficients between the preoperative maximum CVC score (with or without hearing aid) and the U-STARR, SISSS, and localization test results. To make it easier to compare our findings with the literature, in which means (SDs) are usually presented, we added means (SDs).

Results

Patient Characteristics and Objective Results

The baseline characteristics of the 38 included patients are summarized in **Table 1**. Fifteen patients in the BCI group used hearing aids before implantation compared with 19 in the UCI group. Otherwise, no significant differences were found between the groups' baseline characteristics. One year after implantation, hearing had clearly improved in both groups compared with the preoperative situation (**Table 2**). Although no

Figure 3. Quality of Hearing Questionnaires



Preoperative and 1-year postoperative results on 3 quality of hearing questionnaires in 19 patients in the unilateral cochlear implantation (UCI) group and 19 in the bilateral cochlear implantation (BCI) group are shown.
NCIQ indicates Nijmegen Cochlear Implant Questionnaire; SSQ, Speech, Spatial, and Qualities Hearing Scale; SSQ1, speech understanding in silence, in background noise, in resonating environments, and on the telephone; SSQ2, spatial listening; SSQ3, quality of hearing; TTO, time trade-off; VAS, visual analog scale.

[a] Significant difference at $P < .05$.

significant differences were found between groups on the U-STARR and CVC test, clear differences appeared when sounds came from different directions. When speech was presented to the ear without an implant and noise to the ear with an implant (worst hearing situation), the patients who underwent UCI performed significantly worse than the patients who underwent BCI in their worst hearing situations on the SISSS. Patients who underwent BCI had significantly better results on all localization tests (Table 2).

Residual Hearing

In the UCI group, 7 of 19 patients did not use a contralateral hearing aid at 1-year follow-up because they did not experience any benefits from it (Table 2). The objective test outcomes did not correlate significantly with the preoperative maximum CVC score with hearing aid (n = 12) (U-STARR: $P = .60$, SISSS: $P = .24$, localization tests at 15°, 30° and 60°: $P = .42$, $P = .78$, $P = .64$,) or without hearing aid (n = 7) (U-STARR: $P = .29$, SISSS: $P = .09$, localization tests at 15°, 30° and 60°: $P = .17$, $P = .59$, $P = .29$), which means that residual hearing did not influence the results.

Subjective Results

No differences between the UCI and BCI group on the quality of hearing questionnaire results (SSQ, VAS on hearing, and NCIQ) were found preoperatively (**Figure 3**). All participants reported significant improvement on all questionnaires at 1 year postoperatively. At 1-year follow-up, the BCI group had significantly better results on the 3 chapters of the SSQ, VAS on hearing, and TTO than the UCI group. On the NCIQ, the BCI group reported better hearing capabilities than the UCI group but not significantly so (social interaction: $P = .17$; activity: $P = .40$; self-esteem: $P = .25$; speech production: $P = .52$; advanced sound perception: $P = .14$; basic sound perception: $P = .60$) (Figure 3).

Discussion

We present the results of the first RCT, to our knowledge, to investigate the benefits of simultaneous BCI compared with UCI in adults with postlingual deafness. In quiet or when sound was presented to the ear with an implant, patients in the UCI group performed equally well as those in the BCI group. However, in everyday life, sounds come from different directions, and there is usually background noise present. Our study reveals that patients undergoing BCI significantly benefit from their second implant in these situations.

Comparison With the Literature

Most studies published on the potential benefits of BCI vs UCI are nonrandomized cohort studies, and often, patients who underwent BCI were asked to deactivate one implant to assess differences between unilateral and bilateral hearing. This is not representative of actual UCI because the patients were used to listening with 2 implants in daily life. In addition, implantation would have caused insertion damage to the cochlea, deteriorating residual hearing.[8] As in our study, prior studies[16-19] found that bilateral implantation did not improve speech in noise understanding when both were presented from straight ahead,[16-18] although a summation effect has occasionally been found.[19] Dunn et al[20] assessed speech perception in noise, from separated sources, on 60 matched patients, who had undergone simultaneous BCI or UCI.[20] As in our study, the former performed better than the latter. In our study, the patients in the BCI group were able to localize sounds, which was difficult for the UCI group. Several other studies[18,21-25] have found that bilateral implantation makes sound localization possible. The quality of hearing questionnaire results confirmed the objective findings. The BCI group evaluated their own performance in difficult listening situations, as represented in the SSQ, better than the UCI group. They also evaluated their overall hearing as better on the VAS. As in our study, Summerfield

et al[26] reported a significant positive effect of a second cochlear implant in 24 UCI users on the SSQ. Noble and colleagues[23] compared 70 patients fit with one implant and 36 patients fit with bilateral implants (31 simultaneously and 5 sequentially) and also reported significantly better results in the BCI group on the SSQ. On the TTO, our 2 study groups had comparable results, which were similar to the results of Kuthubutheen et al.[27] On the NCIQ, Hinderink et al[15] reported comparable findings of 47 patients with postlingual deafness who underwent UCI. To our knowledge, there is no literature on NCIQ results in patients undergoing BCI. Of interest, no differences were found between the UCI and BCI groups on the NCIQ. All participants had developed speech before losing their hearing, which explains the lack of difference on this subdomain within and between groups. A second implant apparently did not have an additional value on changes in the patients' self-esteem, activity levels, or social interactions. The NCIQ contains questions on hearing in easy and difficult situations but does not focus on spatial hearing like the SSQ does. This might explain why the results in the BCI group are better but not significantly so.

Strengths and Weaknesses

The major strength of our study was that allocation bias was minimized by using an RCT. Furthermore, the study group was homogeneous by setting strict inclusion and exclusion criteria, and none of the patients was unavailable for follow-up after having undergone implantation. In the UCI group, the contralateral cochlea was untreated, and most patients used a hearing aid to exploit that ear's even minimal function. We tested the participants after 1 year of implantation experience, which gave the brain time to adapt to this listening situation. Possible weaknesses of our study were that the patients were treated in 5 different centers and the included numbers of patients per center varied. We attempted to minimize this potential bias by using a per center block randomization strategy. Furthermore, the researchers and caregivers were not masked. However, we used a strict test protocol to minimize differences in testing among researchers.

Conclusions

This is the first report, to our knowledge, of an RCT reporting the benefits of simultaneous BCI over UCI in adults in various listening situations. Although a second cochlear implant did not have an additional value in easy listening conditions, patients who underwent BCI had significantly better hearing results when sounds came from different directions, such as in everyday noisy environments. This finding was demonstrated with objective hearing test results that were consistent with the participants' self-reported hearing capabilities.

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Author Contributions: Drs Smulders and Grolman had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
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Acquisition, analysis, or interpretation of data: Smulders, van Zon, Stegeman, Van Zanten, Rinia, Stokroos, Hendrice, Free, Maat, Frijns, Mylanus, Huinck, Smit, Topsakal, Tange, Grolman.
Drafting of the manuscript: Smulders.
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Additional Contributions: A. Q. Summerfield, PhD, and his group developed the AB-York crescent of sound test setup. M. T. A. van den Aardweg, MD, and D. W. Millin, MD, reviewed the manuscript before submission. No compensation was provided. The anonymized data and study protocol are available from the corresponding author. Readers may contact the corresponding author to request the data. We thank all patients included in this trial.

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Invited Commentary

Getting the Most From Cochlear Implants

Timothy E. Hullar, MD

It is no longer true that cochlear implantation is considered successful if the device simply provides some access between a deaf person and the surrounding auditory world. Our expectations for implants have grown so much that we now aspire for them to create or restore normal or near-normal hearing. As binaural creatures, we intuitively grasp that this goal requires bilateral, rather than unilateral, implantation to achieve the same advantages of sound localization and improved hearing in noise that 2 ears provide to normal listeners.[1]

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In this issue, Smulders et al[2] describe 38 postlingually deafened adults who were randomized to receive either unilateral or bilateral implantation and whose sound localization and hearing in noise performance was measured 1 year following implantation. They found that patients undergoing bilateral implantation were able to localize sound and hear in challenging noisy situations better than patients receiving unilateral implantation. They also found that subjective benefit was generally greater in patients with bilateral implantation, a crucial measure lacking from several previous studies.

This is a relatively well-trodden field: most previous work has reported similar findings.[3] The experimental design used by Smulders et al,[2] however, overcomes some earlier problems. For example, the study compared a group of unilaterally implanted with a group of bilaterally implanted patients, which is more clinically relevant than testing a bilateral implantee who simply removes 1 device.[4] They also allowed unilateral implantees to wear a hearing aid in the unimplanted ear, a significant strength of the study by Smulders et al[2] that reflects recent trends to implant patients with significant residual hearing in 1 or both ears.[5]

The motivation for the study was to satisfy the criteria of insurance companies in the Netherlands, who would not support bilateral implantation in adults without a randomized study being performed. Indeed, overall we have remarkably few randomized clinical trials evaluating the benefits of cochlear implantation. Performing these studies may seem more bothersome than necessary given the dramatic improvements that are so common in implant recipients. However, as cochlear implant candidacy expands to include more people with better hearing (including those with contralateral hear-