







## ORIGINAL RESEARCH

# Choice of treatment evaluated after trial periods with bone conduction devices and contralateral routing of sound systems in patients with single-sided deafness

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## Funding information

Cochlear

## Abstract

**Objectives:** Patients with single-sided deafness (SSD) may experience difficulties with speech perception in noise, sound localization, have tinnitus and experience a reduced quality of life (QoL). Contralateral routing of sound hearing aids (CROS) or bone conduction devices (BCD) may partly improve subjective speech communication and QoL in SSD patients. A trial period with these devices can help in making a well-informed choice of treatment. Our aim was to evaluate factors influencing the choice of treatment made after a BCD and CROS trial period in adult SSD patients.

**Methods:** Patients were randomized in the: “first BCD, then CROS” or “first CROS, then BCD” trial period group. After the BCD on headband and CROS were tested for 6 weeks each, patients choose for BCD, CROS or no treatment. Primary outcome was the distribution of choice of treatment. Secondary outcomes included the association between the choice of treatment and patient characteristics, reasons for treatment acceptance or rejection, device usage during the trial periods, and disease-specific QoL outcomes.

**Results:** Of 91 patients randomized, 84 completed both trial periods and made their choice of treatment: 25 (30%) BCD, 34 (40%) CROS, and 25 (30%) no treatment. No characteristics were found to be related to choice of treatment. Top three reasons for acceptance or rejection were: device (dis)comfort, sound quality and (dis)advantage of subjective hearing. Average daily device use during the trial periods was higher for CROS than for BCD. Choice of treatment was significantly related with both duration of device usage and greater improvement of QoL after the corresponding trial period.

**Conclusion:** The majority of SSD patients preferred BCD or CROS over no treatment. Evaluating device usage, discussing treatment (dis)advantages and disease-specific

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QoL outcomes after trial periods are to be considered during patient counseling and could facilitate whether to choose one of these treatments.

**Level of evidence:** 1B.

**KEYWORDS**

bone conduction device, contralateral routing of sound, randomized controlled trial, single-sided deafness, trial period

## 1 | INTRODUCTION

Single-sided deafness (SSD) is defined as severe to profound sensorineural hearing loss in one ear and normal to near-normal hearing in the contralateral ear.<sup>1</sup> With only one functional ear, one cannot benefit from the advantages of binaural hearing: summation, squelch and the head shadow effect.<sup>2-4</sup> Therefore, most SSD patients experience difficulties with sound localization and speech perception in noise.<sup>5</sup> Frequently, SSD patients also suffer from disabling tinnitus.<sup>6</sup> As a consequence of the abovementioned hearing difficulties, SSD patients often experience a reduced quality of life (QoL).<sup>7,8</sup>

The bone conduction device (BCD) and contralateral routing of sound hearing aid (CROS) are widely available treatment modalities in most health care settings, whereas in only a few countries cochlear implantation (CI) is a reimbursed treatment strategy for SSD. The less invasive BCD and CROS can compensate for the head shadow effect, improving subjective speech communication and health-related QoL.<sup>9-11</sup> However, no significant improvement has been observed for sound localization abilities or speech perception in noise.<sup>9,10</sup> Moreover, when noise is coming from the impaired side, both devices can hinder speech perception.<sup>9,10</sup>

As both BCD and CROS can partly improve the problems SSD patients experience, it is important to consider the advantages and disadvantages of these devices. Trial periods, first with the BCD worn on a headband and then a conventional CROS hearing aid (or vice versa), can facilitate decision making.

So far, the literature on the outcomes of device trials for patients with SSD has mainly focused on the BCD trial period.<sup>12-19</sup> Less is known about the experience or preference of SSD patients with a CROS trial period or when both devices are sequentially trialed. The few studies<sup>20-25</sup> directly comparing the CROS and BCD trial periods highlight the high variability of the choice of treatment after the trial periods. However, the methodological heterogeneity of these studies hinders the direct comparison of the BCD and CROS trial period outcomes. For instance, the patients' experience can be influenced by a fixed order of the trial periods used in these studies,<sup>20,21</sup> the different duration of trial periods<sup>21</sup> and whether other treatment options are offered (CI, remote microphone or in the ear hearing aid).<sup>22-25</sup>

In literature, reported reasons for treatment acceptance or rejection are diverse and cover objective as well as subjective reasons. The most important reasons for rejection include limited benefit in hearing abilities, physical discomfort, the need for surgery, cosmetic reasons or a better experience with another device.<sup>17-19,26</sup> Currently, there

are no clear patient- or disease-specific characteristics identified to be related to the choice of treatment.<sup>17,19</sup>

Higher level of evidence on the experience of SSD patients with the BCD and CROS trial periods, insights into reasons for treatment acceptance or rejection and identification of patient- or disease-specific characteristics related to the choice of treatment might help to set treatment expectations and counsel future SSD patients. Therefore, as part of a randomized controlled study, we aim to provide these insights and evaluate the reasons behind the choice of treatment after a trial period with BCD and CROS in SSD patients.

## 2 | MATERIALS AND METHODS

The research protocol of this study was approved by the Institutional Review Board of the University Medical Center Utrecht (NL45288.041.13) and is registered with the Netherlands Trial Register ([www.trialregister.nl](http://www.trialregister.nl), NTR4580).

### 2.1 | Study population

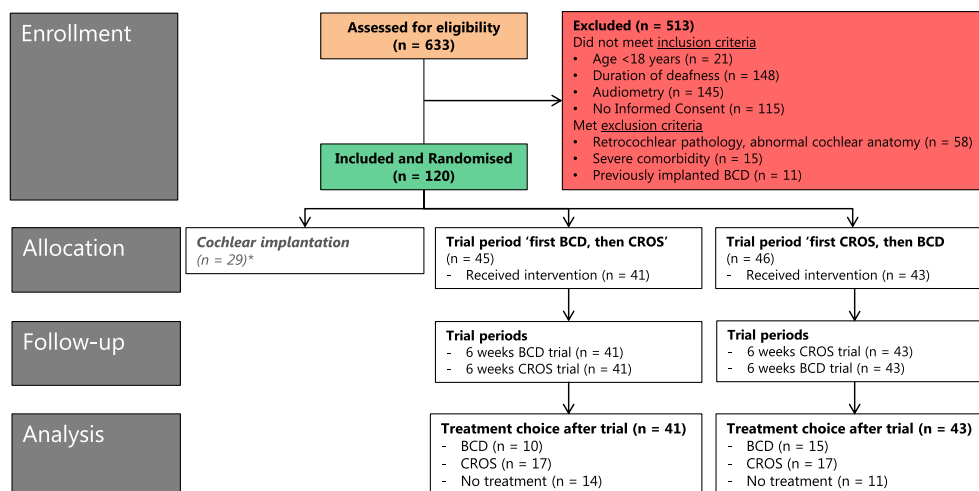
All patients described in this study are participants in an ongoing randomized controlled trial (RCT), the CINGLE-trial (Cochlear Implantation for SINGLE-sided deafness),<sup>27</sup> investigating treatment options for SSD. All participants provided written informed consent prior to study participation between July 2014 and February 2019. Adult patients were eligible for inclusion if they fulfilled the in- and exclusion criteria, including the following:

- pure tone average (PTA) threshold at 0.5, 1, 2, 4 kHz: best ear maximum 30 dB hearing loss, and of the poor ear minimum 70 dB hearing loss, air-bone gap  $\leq$ 10 dB;
- duration of deafness between 3 months and 10 years;
- no previously implanted BCD.

For a detailed description of the CINGLE-trial, we refer to the study protocol.<sup>27</sup>

### 2.2 | Study design

After inclusion, patients were randomized in one of three treatment groups by a web-based randomization tool. The study flow chart is



**FIGURE 1** Flow diagram of the study. \*Data on the cochlear implantation group will not be discussed in the current study. BCD, bone conduction device; CROS, contralateral routing of sound hearing aid

presented in Figure 1. A total of 91 patients were randomized into the two trial period groups ( $n = 45$  to the “first BCD, then CROS” group;  $n = 46$  to the “first CROS, then BCD” group). For the current study, we report on data of the trial period groups obtained at baseline (i.e., the unaided situation), after the BCD trial period and after the CROS trial period. The 29 patients randomized to the CI group will not be discussed in this paper. Recently, short-term outcomes of the CINGLE-trial comparing CI versus BCD, CROS, and no treatment have been published.<sup>28</sup>

### 2.3 | Study procedures

The BCD and CROS were sequentially tested at home for 6 weeks per device. The BCD was tested using the Cochlear™ Baha® on a headband, the CROS was tested using Phonak hearing aids. At the beginning of each trial period, the device was set by an experienced audiologist. After finishing both trial periods (after 12 weeks), patients reported which device they preferred. If they preferred the BCD, the surgical placement of the percutaneous BCD was scheduled. If they preferred the CROS, they were referred to a local hearing aid dispenser to fit their own CROS device. Patients could also opt for no treatment.

### 2.4 | Outcomes

The primary outcome was the distribution of the choice of treatment after the trial periods. Secondary outcomes included the association between the choice of treatment and patient or disease-specific characteristics, the reasons for treatment acceptance or rejection, duration of device usage during the trial periods and disease-specific QoL outcomes.

Patient and disease-specific characteristics (gender, age, SSD etiology, side of deafness, duration of deafness, PTA of the better and poor ear and presence of tinnitus) were collected at baseline. After completing both trial periods (i.e. after 12 weeks), patients reported their choice of treatment (BCD, CROS, or no treatment) in an

evaluation interview. During this interview, reasons mentioned by the patients (one or multiple) for treatment acceptance or rejection were noted. These reasons were divided into five categories of advantages and eight categories of disadvantages. Device usage time during the trial period was gathered using Phonak Target 5.0 and Baha® Fitting Software 4.0.

Three disease-specific QoL questionnaires were completed. The speech, spatial and qualities of hearing scale (SSQ) assesses three domains of hearing in everyday life; a higher score (on a scale of 0–100) reflects less hearing handicap.<sup>29</sup> The abbreviated profile for hearing aid benefit questionnaire (APHAB) has four subdomains: ease of communication (EC), listening in background noise (BN), listening under reverberant conditions (RV), and aversiveness of sounds (AS)<sup>30</sup>; a lower score (on a scale of 0–1) reflects less hearing difficulty. The SSQ and APHAB were completed three times: at baseline, directly after finishing the BCD trial period and directly after finishing the CROS trial period. The Glasgow Benefit Inventory (GBI) was completed twice: directly after finishing the BCD trial period and after finishing the CROS trial period to assess how the trial period has altered QoL. The GBI has three subscales: general, social support and physical health<sup>31</sup>; a higher value (on a scale of –100–100) represents a positive change in health status.

### 2.5 | Statistical-analysis

Kolmogorov–Smirnov and Shapiro–Wilk tests were used to determine the normality of data. Continuous data are presented as mean (SD) or median [range] and categorical data are represented as the number of total. To compare patient and disease-specific characteristics, duration of device usage, and outcomes of questionnaires between treatment groups after the trial periods, the Chi-square test and One-way Anova were used in normally-distributed data. Independent-Samples Kruskal-Wallis and Related Samples Wilcoxon Signed Rank were used in not normally-distributed data. All analyses were performed using SPSS version 25.0 (IBM corp., Armonk, NY, USA).  $P < .05$  (two-sided) was considered to be statistically significant.

**TABLE 1** Patient characteristics per choice of treatment after BCD and CROS trial periods ( $n = 84$ )

|                                 | Choice after trial period |                   |                          | Statistics      |
|---------------------------------|---------------------------|-------------------|--------------------------|-----------------|
|                                 | BCD<br>$n = 25$           | CROS<br>$n = 34$  | No treatment<br>$n = 25$ |                 |
| Gender                          |                           |                   |                          |                 |
| Male                            | 10                        | 21                | 9                        | ns <sup>a</sup> |
| Female                          | 15                        | 13                | 16                       |                 |
| Age at inclusion (years)        |                           |                   |                          |                 |
| Mean (SD)                       | 56.0 (8.4)                | 52.1 (12.0)       | 50.9 (12.8)              | ns <sup>b</sup> |
| SSD etiology                    |                           |                   |                          |                 |
| Unknown                         | 4                         | 5                 | 12                       | ns <sup>a</sup> |
| Iatrogenic                      | 0                         | 0                 | 1                        |                 |
| Sudden deafness                 | 15                        | 18                | 7                        |                 |
| Labyrinthitis                   | 2                         | 5                 | 1                        |                 |
| Infection                       | 0                         | 2                 | 1                        |                 |
| Ménière's disease               | 3                         | 3                 | 1                        |                 |
| Traumatic                       | 1                         | 1                 | 2                        |                 |
| Side of deafness                |                           |                   |                          |                 |
| Left ear                        | 16                        | 18                | 16                       | ns <sup>a</sup> |
| Right ear                       | 9                         | 16                | 9                        |                 |
| Duration of deafness (year)     |                           |                   |                          |                 |
| Median [range]                  | 2.3 [0.3–10.0]            | 1.3 [0.3–10.0]    | 1.9 [0.3–10.0]           | ns <sup>c</sup> |
| PTA better ear (0.5–4 kHz) (dB) |                           |                   |                          |                 |
| Median [range]                  | 12.5 [3.8–28.8]           | 16.3 [5.0–27.5]   | 13.8 [2.5–30.0]          | ns <sup>c</sup> |
| PTA poor ear (0.5–4 kHz) (dB)   |                           |                   |                          |                 |
| Median [range]                  | 92.5 [80.0–116.2]         | 93.8 [73.8–120.0] | 93.8 [70.0–117.5]        | ns <sup>c</sup> |
| Presence of tinnitus            |                           |                   |                          |                 |
| Yes                             | 22                        | 33                | 23                       | ns <sup>a</sup> |
| No                              | 3                         | 1                 | 2                        |                 |
| Trial period group              |                           |                   |                          |                 |
| First BCD, then CROS            | 10                        | 16                | 14                       | ns <sup>a</sup> |
| First CROS, then BCD            | 15                        | 18                | 11                       |                 |

Abbreviations: BCD, bone conduction device; CROS, contralateral routing of sound hearing aid; ns, not significant; PTA, pure tone average; SD, standard deviation.

<sup>a</sup>Chi-square test.

<sup>b</sup>One-way ANOVA.

<sup>c</sup>Independent-Samples Kruskal-Wallis Test.

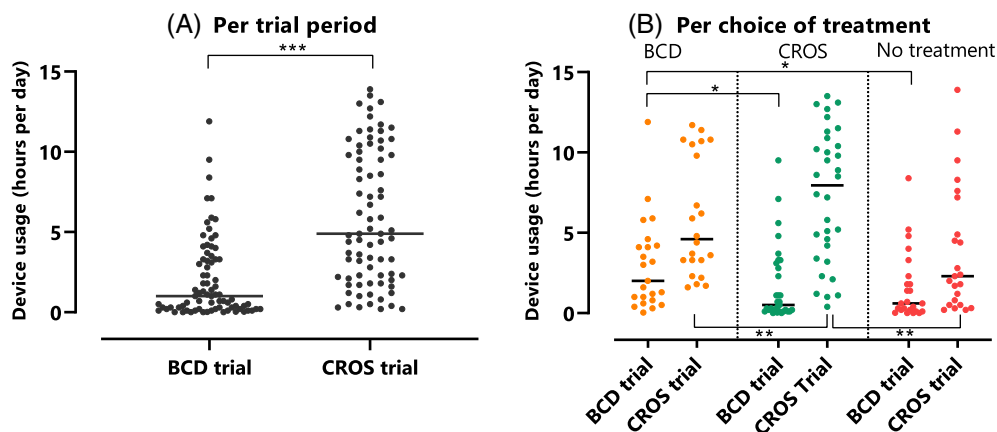
### 3 | RESULTS

#### 3.1 | Patient characteristics and choice of treatment after trial periods

Of the 91 patients randomized to the BCD and CROS trial period groups, 84 patients (92%) completed both the BCD and CROS trial and were included in the analysis. Seven patients did not start or complete the trial periods due to various reasons: one patient rejected to test the devices because of invalidating tinnitus, one patient was implanted with a CI after negotiations with his insurance company, one patient could not complete the trial periods due to health issues

not related to SSD, one patient was disappointed by the randomization result and unwilling to start the trial period, three patients indicated to lack motivation to complete the trial periods for personal reasons.

After finishing both trial periods, 25 out of 84 (30%) patients chose the BCD, 34 (40%) patients chose CROS and 25 (30%) patients chose no treatment. As shown in Table 1, there were no significant associations between the choice of treatment and any of the patient or disease-specific characteristics. Also, there was no significant association between the randomization group (“first BCD then CROS”; “first CROS, then BCD”) with regard to the choice of treatment.



**FIGURE 2** Duration of device usage during trial periods. (A) Duration of device usage in hours per day per trial period. (B) Duration of device usage in hours per day per choice of treatment after trial periods. Horizontal bars represent median values. BCD, bone conduction device; CROS, contralateral routing of sound hearing aid. Statistical difference between groups: \*\*\* =  $p < .001$ ; \*\* =  $p < .01$ , \* =  $p < .05$ .

### 3.2 | Device characteristics and usage data

During the BCD trial period, the first 52 patients (inclusion between 2014 and 2016) tested the Cochlear™ Baha® BP110. From 2017 on, the remaining 32 patients tested the more recently introduced Cochlear™ Baha® 5 Power. During the CROS trial, patients tested the Phonak Audeo Q50-312 T or V50-312 hearing aids. As described before by Peters et al.,<sup>28</sup> there was a significant difference between the number of patients choosing a BCD after testing the Baha® BP110 or Baha® 5 Power on headband: 10 out of 52 patients (19%) chose to proceed with BCD after the Baha® BP110 trial, whereas 15 out of 33 patients (45%) chose the BCD after the Baha® 5 Power trial (Fisher's exact test,  $p = .014$ ).

Duration of device usage during the trial periods was available for 78 out of 84 patients (93%) after the BCD trial and for 77 out of 84 patients (92%) after the CROS trial. Individual device usage data is depicted in Figure 2. The median duration for patients to test the BCD on headband during the trial period was 1.0 (0.0–11.9) hours per day, the median duration for the CROS device was 4.9 (0.2–13.9) hours per day ( $p < .001$ , Wilcoxon Signed Rank test, Figure 2A). Five of 84 (6%) patients indicated that they barely tested the BCD during the trial period and had an average device usage of <0.05 h per day; none of these patients chose the BCD after the trial periods. Patients who chose the BCD tested the BCD significantly longer than patients who chose the CROS or no treatment ( $p = .022$ , Kruskal-Wallis test, Figure 2B). Patients who chose the CROS tested the CROS significantly longer than patients who chose the BCD or no treatment ( $p = .006$ , Kruskal-Wallis test, Figure 2B).

### 3.3 | Reasons for BCD or CROS acceptance or rejection

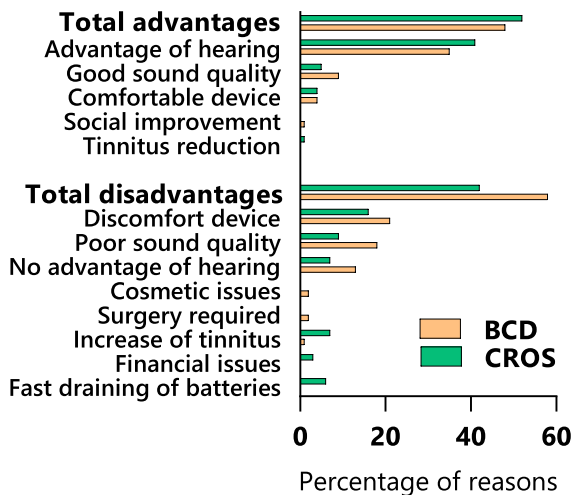
Most patients gave multiple reasons (range 0–3) for BCD or CROS acceptance or rejection, resulting in a total of 378 reported reasons ( $n = 205$  for BCD,  $n = 173$  for CROS). The reported reasons,

**TABLE 2** Categorized disadvantages and advantages for the BCD and CROS trial period

| Disadvantages (n = 243)    |               |               |
|----------------------------|---------------|---------------|
| Category                   | BCD           | CROS          |
| Discomfort device          | n = 52 (21%)  | n = 40 (16%)  |
| Poor sound quality         | n = 43 (18%)  | n = 21 (9%)   |
| No advantage of hearing    | n = 32 (13%)  | n = 18 (7%)   |
| Cosmetic issues            | n = 6 (2%)    | n = 0 (0%)    |
| Surgery required           | n = 5 (2%)    | n = 0 (0%)    |
| Increase of tinnitus       | n = 2 (1%)    | n = 7 (3%)    |
| Financial issues           | n = 0 (0%)    | n = 3 (1%)    |
| Fast draining of batteries | n = 0 (0%)    | n = 14 (6%)   |
| Total disadvantages        | n = 140 (58%) | n = 103 (42%) |
| Advantages (n = 135)       |               |               |
| Category                   | BCD           | CROS          |
| Advantage of hearing       | n = 47 (35%)  | n = 56 (41%)  |
| Good sound quality         | n = 12 (9%)   | n = 7 (5%)    |
| Comfortable device         | n = 5 (4%)    | n = 6 (4%)    |
| Social improvement         | n = 1 (1%)    | n = 0 (0%)    |
| Tinnitus reduction         | n = 0 (0%)    | n = 1 (1%)    |
| Total advantages           | n = 65 (48%)  | n = 70 (52%)  |

Note: See supplemental information 1 for an overview of examples of the different categories. Abbreviations: BCD, bone conduction device; CROS, contralateral routing of sound hearing aid.

categorized in five different groups of treatment advantages (total  $n = 135$ ;  $n = 65$  for BCD,  $n = 70$  for CROS) and eight groups for treatment disadvantages ( $n = 243$ ;  $n = 140$  for BCD,  $n = 103$  for CROS) are summarized in Table 2 and visualized in Figure 3. The top three categories of reasons for device rejection were similar for BCD and CROS: device discomfort, poor sound quality and no advantage of hearing. The top three categories of reasons for treatment acceptance were advantage of hearing, high sound quality and device



**FIGURE 3** Categorized advantages and disadvantages for the BCD and CROS trial period. See supplemental file 1 for an overview of examples of the different categories. BCD, bone conduction device; CROS, contralateral routing of sound hearing aid.

comfort. Examples of reasons for treatment acceptance and rejection are summarized in Supporting information 1.

### 3.4 | Disease-specific quality of life outcomes

Outcomes of the SSQ and APHAB were available for all patients at baseline. After the trial periods, outcomes were available in 80 out of 84 patients (95%) for the SSQ and the GBI, and in 79 out of 84 patients (94%) for the APHAB. Outcomes are summarized in Figures 4, 5 and 6.

#### 3.4.1 | Speech, spatial and qualities of hearing scale

Only the BCD and CROS groups had a significant improvement after both trial periods at the speech and spatial subscales compared to baseline (Figure 4A,B). Also, in patients who chose the BCD the qualities subscale score was significantly improved after the BCD trial compared to baseline. For patients choosing the BCD, the speech and qualities subscale score was significantly higher after their BCD trial compared to their CROS trial. For patients choosing CROS, the speech subscale score was significantly higher than after their CROS trial compared to their BCD trial.

#### 3.4.2 | Abbreviated profile for hearing aid benefit questionnaire

Only the BCD and CROS groups had a significant improvement after both trial periods at all APHAB subscales compared to baseline (Figure 5A,B). For patients choosing the BCD, the EC, BN and RV subscale scores for their BCD trial were significantly higher than for their

CROS trial. For patients choosing CROS, their BN and RV subscale scores were significantly higher after their CROS trial compared to the BCD trial.

#### 3.4.3 | Glasgow benefit inventory

For patients choosing the BCD, the general subscale score after their BCD trial was significantly higher than after their CROS trial (Figure 6A). For patients opting for CROS, the general subscale score after their CROS trial period was significantly higher compared to the score after their BCD trial (Figure 6B).

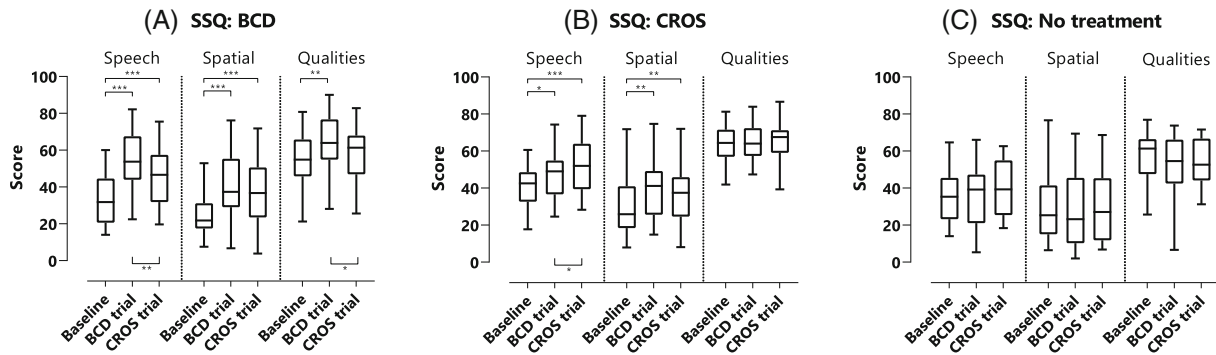
For patients choosing no treatment, there were no significant differences in scores for any QoL questionnaire between their BCD and CROS trial (Figures 4C,5C,6C).

## 4 | DISCUSSION

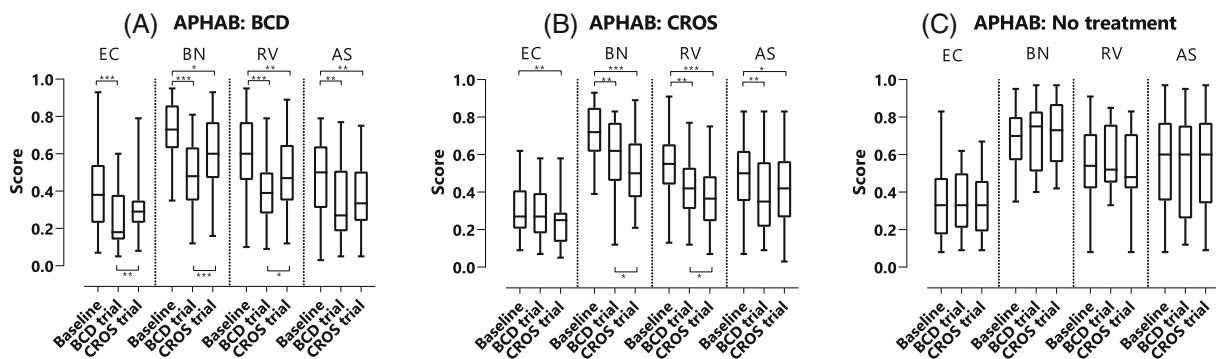
### 4.1 | Interpretation of results

We evaluated the choice of treatment after a 6 week BCD and 6 week CROS trial period as part of a RCT investigating different treatment options for adult SSD patients. Out of 84 patients who completed both trial periods, 70% preferred a BCD (30%) or CROS (40%) over no treatment. Preference for the BCD or CROS was independent of the order in which they were trialed, which is in line with the results of the study by Hol et al.<sup>23</sup>

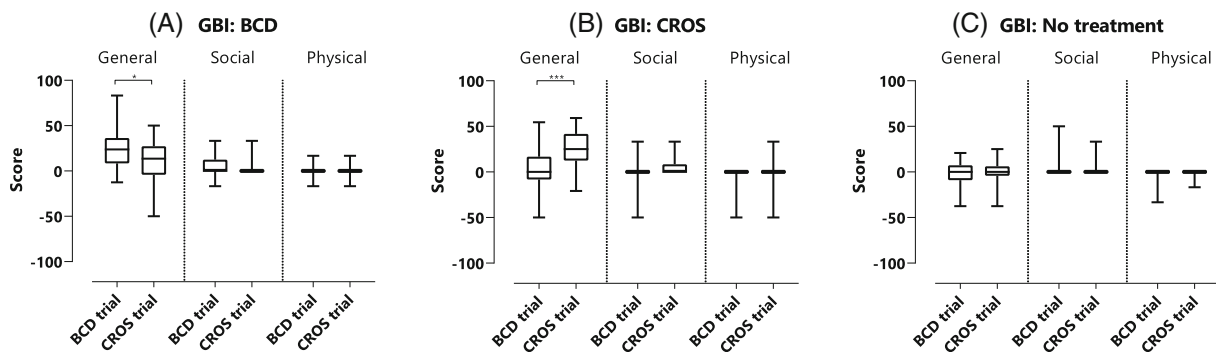
In literature, the percentage of SSD patients choosing the BCD or CROS after a trial period varies among studies. In a systematic review investigating of six studies on the outcomes of the BCD trial period by Wendrich et al., it was demonstrated that 30%–68% of 427 included SSD patients chose a BCD after a BCD trial period.<sup>19</sup> In one of the included studies patients also followed a 2-week CROS trial period after a 2-week BCD trial period resulting in a similar percentage of patients choosing for BCD or CROS as in our study: 30% of 72 patients chose for the BCD and 41% chose CROS after trial periods of 2 weeks each.<sup>20</sup> Different results were reported by the crossover study by Leterme et al.<sup>21</sup>: they directly compared outcomes of a BCD (7 days) and CROS (60 days) trial period in 18 SSD patients, of whom 72% opted for the BCD, 11% for CROS and 17% for no treatment. In other studies<sup>22–25</sup> evaluating the BCD and CROS trial periods, other treatment modalities was offered (i.e., a CI, Remote Microphone or in the ear hearing aid) which hinders comparability with our results. Especially in studies where a CI was offered, the number of patients choosing for BCD or CROS was remarkably lower, e.g. the prospective study by Jakob et al.<sup>24</sup> where 18% out of 89 SSD participants chose BCD, 15% CROS, 37% CI and 22% no treatment. Although our RCT included the possible randomization to the CI group, the number of patients opting for BCD or CROS after the trial periods was comparable to studies investigating trial periods with BCD and CROS (without the possibility of a CI).



**FIGURE 4** The Speech, Spatial and Qualities of hearing questionnaire (SSQ), subscales: speech, spatial and qualities of hearing. (A) SSQ outcomes for patients choosing the BCD after the trial periods. (B) SSQ outcomes for patients choosing the CROS after the trial periods. (C) SSQ outcomes for patients choosing no treatment after the trial periods. BCD = Bone Conduction Device, CROS = Contralateral Routing of Sound hearing aid. Statistical difference between groups: \*\*\* =  $p < .001$ ; \*\* =  $p < .01$ , \* =  $p < .05$ .



**FIGURE 5** The Abbreviated Profile for Hearing Aid Benefit questionnaire (APHAB), subscales: ease of communication (EC), background noise (BN), reverberant conditions (RV) and aversiveness of sounds (AV). (A) APHAB outcomes for patients choosing the BCD after the trial periods. (B) APHAB outcomes for patients choosing the CROS after the trial periods. (C) APHAB outcomes for patients choosing no treatment after the trial periods. BCD, bone conduction device; CROS, contralateral routing of sound hearing aid. Statistical difference between groups: \*\*\* =  $p < .001$ ; \*\* =  $p < .01$ , \* =  $p < .05$ .



**FIGURE 6** The Glasgow Benefit Inventory (GBI), subscales: general, social support and physical health. (A) GBI outcomes for patients choosing the BCD after the trial periods. (B) GBI outcomes for patients choosing the CROS after the trial periods. (C) GBI outcomes for patients choosing no treatment after the trial periods. BCD, bone conduction device; CROS, contralateral routing of sound hearing aid. Statistical difference between groups: \*\*\* =  $p < .001$ ; \*\* =  $p < .01$ , \* =  $p < .05$ .

BCD or CROS preference may be influenced by the duration of the trial periods. In the previous mentioned studies<sup>12-17</sup> the duration differed from 1 h to 8 weeks per device. Differences in the duration of trial periods may be explained by differences in clinical care

standards for patients with SSD among countries, device availability and reimbursement issues or patient logistics. Furthermore, the choice of treatment may be influenced by the specific type of device used. Our study demonstrated that significantly more patients chose to be

implanted with a BCD after a trial period with the Baha® 5 Power (46%) than after a trial period with Baha® BP110 (19%). The more recently introduced Baha® 5 Power is a more powerful device compared to the Baha® BP110. Therefore, when the Baha® 5 Power is used on the headband, the device might better mimic the implanted situation. Also, esthetic reasons may play a role, as the Baha® 5 Power is smaller than the Baha® BP110. Ongoing technical advances for both CROS and BCD devices (e.g., open fitting, power devices, microphone technology, noise and feedback reduction algorithms) can further improve hearing outcomes in SSD patients with these devices, which can also influence the distribution of the preferred treatment when both devices are compared in trial periods.

Hypothetically, the choice of treatment could also be influenced by patient or disease-specific characteristics. However, in line with previous literature,<sup>17,19</sup> we could not identify any patient or disease-specific characteristics related to the choice of treatment after the trial periods. Similar to other studies,<sup>18,19,26</sup> the choice of treatment was mainly driven by subjective factors. The described subjective BCD and CROS advantages and disadvantages in our study were comparable to previous literature reporting on reasons for treatment acceptance or rejection.<sup>18,19</sup>

In agreement with literature,<sup>22,23</sup> there were significant QoL improvements after the BCD and CROS trial periods compared to baseline. The results of our study also indicated that the choice for a BCD or CROS was associated with a greater experienced improvement of QoL after the corresponding trial period. Furthermore, we also showed that patients opting for BCD or CROS tested the device significantly longer during the corresponding trial. This points out that QoL assessments and measuring the duration of device usage could help health care providers and patients to make a well informed decision.

Remarkably, the duration of device usage during the BCD trial period was significantly lower than during the CROS trial period, irrespective of choice of treatment (Figure 2B). The low device usage during the BCD trial period is most probably explained by discomfort caused by the headband and/or cosmetic issues. However, the difference in device usage did not translate into treatment choice after the trial periods (40% CROS and 30% BCD).

## 4.2 | Methodological considerations

Strengths of this study include the random allocation to the intervention trial groups, which ensured equal patient and disease characteristics across groups. Moreover, by the randomization we corrected for the possible order effect of testing first BCD and then CROS, and vice versa. Also, during the trial period, we tested the latest BCD and CROS models, representing the current clinical standard. Finally, we had only few missing data. The most important limitation of our study is the generalizability of results which can be hindered by the fact that study participants were eligible to be randomized to the BCD and CROS trial groups as well as to a CI group. Since BCD and CROS are available as standard clinical care for SSD patients, and CI is not a reimbursed treatment modality in the Netherlands, our study might

represent patients with a higher than average experienced disease burden motivated to get implanted with a CI.

## 4.3 | Future perspectives

The BCD and CROS trial periods are of importance for SSD patients as well as clinicians to set expectations and determine which device fits best. The use of standardized trial periods and improved outcome measures for trial evaluation can help identify factors (e.g., personality, self-image, cosmetic needs, hearing environment) related to the choice of treatment. Standardized registration of duration of device usage during the trial period, evaluation of advantages and disadvantages and QoL outcomes can be helpful in patient counseling. Future research should provide insights into whether these subjective outcome measures are related to objective outcome measures (such as speech perception in noise, sound localization) and if other specific factors are related to choice of treatment.

## 5 | CONCLUSION

After the BCD and CROS trial periods, 30% of patients chose to be implanted with a BCD, 40% chose for CROS, and 30% chose no treatment. No patient characteristics were found to be related to choice of treatment. The top three reasons for BCD or CROS acceptance or rejection were: experienced device (dis)comfort, sound quality and (dis)advantage of subjective hearing. Patients tested the CROS significantly longer than the BCD on headband during the trial periods. The choice for a BCD or CROS was associated with longer duration of device usage and greater improvements of QoL outcomes after the corresponding trial. Therefore, registration of duration of device usage during the trial periods and collecting the device (dis)advantages and QoL outcomes after trial periods can help in patient counseling and facilitate whether to choose one of these treatments.

## FUNDING INFORMATION

This study is partly funded by Cochlear Ltd. as an unrestricted research grant. By research contract, Cochlear Ltd. did not have influence on the study design, data collection, analysis, data interpretation, and publication. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript

## CONFLICT OF INTEREST

There are no competing interests for any of the authors. This study is partly funded by Cochlear Ltd. as an unrestricted research grant. By research contract, Cochlear Ltd. did not have influence on the study design, data collection, analysis, data interpretation, and publication.

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

**How to cite this article:** Wendrich AW, van Heteren JAA, Peters JPM, et al. Choice of treatment evaluated after trial periods with bone conduction devices and contralateral routing of sound systems in patients with single-sided deafness. *Laryngoscope Investigative Otolaryngology*. 2023;8(1):192-200. doi:10.1002/liv2.1002