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The Benefit of Bimodal Hearing and Beamforming for Cochlear Implant Users

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Keywords

Cochlear implants · Sensorineural hearing loss · Bimodal hearing · Front-end processing · Beamforming

Abstract

Introduction: Cochlear implantation is the standard treatment for severe to profound hearing loss. While cochlear implant (CI) users can communicate effectively in quiet environments, speech understanding in noise remains challenging. Bimodal hearing, combining a CI in one ear and a hearing aid (HA) in the other, has shown advantages over unilateral electrical hearing, especially for speech understanding in noisy conditions. Beamforming is a technique used to improve speech understanding in noise by detecting sound direction and enhancing frontal (speech) sounds while attenuating background noise. One specific beamformer, Stereozoom, combines signals from microphones in both ears to create a focused beam toward the front resulting in a binaural beamformer (BB), in order to improve speech intelligibility in noise for bilateral and bimodal CI users. Methods: A prospective crossover study involving 17 bimodal CI users was conducted, and participants were tested with various device configurations (CI, HA, CI + HA)

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This article is licensed under the Creative Commons Attribution 4.0 International License (CC BY) (http://www.karger.com/Services/ OpenAccessLicense). Usage, derivative works and distribution are permitted provided that proper credit is given to the author and the original publisher. with and without BB. Speech recognition testing with the Dutch/Flemish matrix test was performed in a soundattenuated booth with diffuse noise to simulate realistic listening conditions. Results: The results showed a statistically significant benefit of bimodal hearing over the CI configuration and showed a statistical significant benefit of BB for the CI and CI + HA configuration. The benefit of BB in the HA configuration was not statistically significant probably due to the higher variance. The benefit of BB in the three configurations did not differ statistically significant. Conclusion: In conclusion, bimodal hearing offers advantages for speech understanding in noise for CI users. BB provides a benefit in various device configurations, leading to improved speech intelligibility when speech comes from the front in challenging listening environments. © 2024 The Author(s).

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Plain Language Summary

Cochlear implantation is the standard treatment for severe to profound hearing loss. While cochlear implant (CI) users can communicate effectively in quiet environments, speech understanding in noise remains challenging. Bimodal

Correspondence to: Hendrik Christiaan Stronks, h.c.stronks@lumc.nl hearing, combining a CI in one ear and a hearing aid (HA) in the other, has shown advantages over unilateral electrical hearing, especially for speech understanding in noisy conditions. We analyzed the effect of the addition of the HA to the CI in this paper. There are also other processing techniques available to improve speech understanding in noise for this population. In this paper, one of these techniques, beamforming, is studied in different configurations. Therefore, 17 participants with a CI in one ear and a HA in the other ear are included. They performed a speech test for different configurations with and without beamforming to be able to analyze the effect of beamforming.

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Introduction

Cochlear implantation is the standard treatment for severe to profound hearing loss. With a cochlear implant (CI), the degenerated hair cells in the cochlea are bypassed through direct electrical stimulation of the auditory nerve cells. CI users often can communicate and understand speech in quiet situations, but speech understanding in noise remains challenging [1]. Listening with a CI on one side and a hearing aid (HA) on the other, using both electrical and acoustical inputs, is called bimodal hearing. A prerequisite for this device configuration is sufficient residual hearing in the non-implanted ear. Bimodal listening has advantages over electrical hearing alone, notably for speech understanding in noise [2–4]. Residual hearing can add low acoustic frequencies to the CI signal that normally are not available through electric hearing because of the restricted insertion depth of CI electrode arrays [5]. A HA can also add temporal fine structure, which is discarded by the CI because of envelope-driven speech-coding strategies [6]. Another advantage of bimodal hearing is increased environmental awareness because of listening with a device on each side of the head instead of unilaterally [4, 7].

Beamforming is a technique used to improve speech understanding in noise, in which the direction of sound is detected by comparing the phase of signals from spatially separated microphones. Noise from the back is typically attenuated, whereas frontal preferential (speech) sounds are passed unaltered [8]. Beamforming thus serves as a spatial filter and can be used on one device (monaural) or two devices combined (binaural). This technique has been used for decades in HAs [9] and has been introduced into CI systems in the last decade [10-12]. One frontal beamformer, Stereozoom[™] (Sonova AG, Stäfa, Switzerland), combines signals from the two microphones in a device in one ear and merges them with signals from two microphones on a hearing device in the other ear. In bimodal users, the outputs from a CI and HA thus can be combined into one signal, resulting in a binaural beamformer (BB). The signals from both ears result in a relatively narrow beam to the front [13]. Figure 1 illustrates the polar pattern of the BB compared with the current default microphone setting of Advanced Bionics devices, Real Ear Sound, obtained with a KEMAR head simulator. Real Ear Sound directs a beam to the front for frequencies higher than 1,500 Hz and simulates the localization ability of the pinna in that way [14]. BB has proved efficient for bilateral and bimodal CI users for speech understanding in noise when speech comes from the front [1, 13].

In this study, we distinguished bimodal benefit from binaural benefit. We defined bimodal benefit as that arising from the addition of the HA ear to the CI ear and binaural benefit as the bimodal benefit relative to the better hearing ear. Stronks et al. [6], measured as pure-tone thresholds, found no significant correlation between bimodal benefit and residual hearing in the HA ear. Here, we correlated the binaural benefit with the speech recognition threshold (SRT) difference in noise between the HA and CI ears. We expected to find a higher binaural benefit in noise when both ears had comparable SRTs. When the performance of both ears differed considerably, the addition of a second modality to the better hearing ear was expected to have less impact.

Our second aim was to assess the benefit of BB on the speech intelligibility of the CI and HA ears separately and together. The SRT benefit of BB theoretically reflects signal-to-noise ratio reduction, so that the three configurations assessed here (CI, HA, and CI + HA) were expected to yield a similar benefit.

Materials and Methods

Study Design and Participants

A prospective crossover study was performed in which only the participants were unaware of the speech-processing condition being tested. Of 18 bimodal CI users (eight women, ten men) recruited from the Leiden University Medical Center, one was ultimately excluded from the analysis because of missing data. At recruitment, all participants had at least 6 months of experience with their CI and were already using their HA on the



Fig. 1. Polar pattern of the default microphone setting (dashed blue line) and binaural beamformer (BB) (red line).

non-implanted side. Other inclusion criteria were a clinical consonant-vowel-consonant phoneme score of at least 80% in quiet at a 65 dB SPL presentation level when using their CI only, and an average pure-tone audiometric threshold equal to or better than 80 dB of hearing loss across 125, 250, and 500 Hz (pure-tone average $[PTA]_{125-500}$) for the HA ear. The PTA₁₂₅₋₅₀₀ was based on a clinical audiogram performed on the first day of testing (Fig. 2), as opposed to the in situ audiogram, audiogram performed with stimuli that are generated by the HA, that was used for fitting purposes only. Participant demographics, including PTAs and consonant-vowel-consonant scores, can be found in Table 1. All participants signed informed consent before entering the study. This study was approved by the Medical Ethics Committee Leiden, The Hague, Delft (METC number P20.018).

Fitting of CI and HA

Study participants received a research HarmonyTM speech processor (Advanced Bionics LLC, Valencia, CA, USA) for speech testing that was fitted using their own clinical CI settings, including threshold and maximal comfortable stimulus levels. On the non-implanted side, participants received a research HA (Phonak Audéo M90-312, Stäfa, Switzerland). The HA was fitted using Phonak Target (version 6.2.5; Sonova, Stäfa, Switzerland) guided by an in situ audiogram (Phonak AudiogramDirectTM) and a feedback test obtained directly from the participant's HA and by using the Adaptive Phonak Digital Bimodal fitting formula (Advanced

Hardware

To allow for wireless binaural streaming between the Harmony CI (which lacks Binaural VoiceStream TechnologyTM) and the contralateral HA (capable of wireless streaming), the Harmony CI processor was hardwired to a second Audéo M90-312 HA. This HA was worn on the implanted side and took over the sound capture and front-end processing from the Harmony speech processor. It also was fitted using the Phonak Digital Bimodal fitting formula. The coupling was established with a custom-made adapter that included an audio transformer (Neutrik NTE1, Schaan, Liechtenstein) and a spindle potentiometer (Vishav, Malvern, PA, USA) to transform the pulsewidth-modulated output of the HA into an analog signal. This analog signal was compatible with the auxiliary input of the Harmony processor, which was clipped to the participant's clothing. This proximity did not affect the incoming sound signal because the microphones of the CI speech processor were not deployed.

We chose the Harmony processor instead of a state-of-theart CI processor capable of wireless binaural streaming because we wanted to test experimental front-end paradigms involving measurements outside of the work presented here. The hardware configuration was not expected to affect results because the adapter output was calibrated to produce the same broadband output as a Harmony T-MicTM. Calibration was performed using a HA model that was functionally similar to the one used for the study (Audéo Marvel M13-T HA), with white noise being played back to the HA or the T-Mic of the Harmony processor inside an ACAM[™] audiometry measurement box (Acousticon Inc., Raleigh, NC, USA). Corresponding output levels were determined by streaming of the signal after adaptive gain control (set to linear, sensitivity 0) from the Harmony speech processor using a BEPSnet 1.14 environment (Advanced Bionics, Valencia, CA, USA). The resistor value was adjusted to yield the desired attenuation for an Audéo Marvel with a 15-dB flat insertion gain using the external fitting formula.

Test Environment

Speech recognition testing was performed in a soundattenuated audiometric booth with eight loudspeakers (Control 1; JBL Corp., Los Angeles, CA, USA) to create a diffuse noise field. The dimensions of the booth were $3.4 \times 3.2 \times 2.4$ m ($l \times w \times h$), and the eight loudspeakers were symmetrically distributed in two planes below and above the listener (Fig. 3; see Soede et al. [16] and Stronks et al. [6] for more details). Each loudspeaker was calibrated individually with a sound meter (Rion NA-28; Rion Co. Ltd., Tokyo, Japan) to establish a sound level of 60 dBA around the listener's head. Background noise consisted of an 8-talker babble with a long-term average sound level of 60 dBA based on the male 2-talker babble of the International Collegium of Rehabilitative Audiology [17]. This babble noise consisted of temporally modulated broadband noise with spectral characteristics resembling a male voice. The right and left channels of the original signal each consisted of a different single talker. To generate an 8-talker babble noise, each file was presented through four speakers yielding eight

Bionics LLC, Valencia, CA, USA) [15]. Other front-end processing algorithms were turned off (e.g., SoundRelaxTM, NoiseBlockTM, and WindBlockTM).



Fig. 2. Clinical pure-tone audiograms of the study participants (gray lines) with the median (black line). The red square indicates the area of exclusion based on residual hearing.

signals. The offset of those eight signals was semi-randomly varied to create uncorrelated noise streams. A detailed description of the 8-talker babble noise can be found in Stronks et al. [6].

One additional loudspeaker (MSP5A monitor speaker; Yamaha Corp., Japan) was placed approximately 1 m in front of the centrally seated participant in the booth. This loudspeaker delivered speech stimuli at a height of 1.2 m. The participant was asked to face the loudspeaker throughout the test and to minimize head movements.

Speech Recognition Testing

Speech recognition was measured using the SRT, i.e., the speech level at which 50% of the words could be correctly repeated, using the Dutch/Flemish matrix test. This speech material consists of 13 lists with 20 sentences each, voiced by a female Flemish speaker [18]. For every test condition, a random list was assigned, and each list was used only once or twice per session. The test was executed adaptively in a MATLAB program (R2017b; MathWorks, Inc., Natick, MA, USA) based on the procedure of Dyballa et al. [19]. Participants were asked to repeat the sentence out loud, and correctly repeated words were scored manually by the experimenter. Guessing was allowed, and no feedback was given to the participant. A test and re-test were performed for six configurations (CI, HA, CI + HA, CI + BB, HA + BB, and CI + HA + BB), and two practice measurements, one in quiet and one in noise, were added to reduce potential within-session learning effects [6, 20]. Thus, there were 14 measurements per participant, tested in a random order for each participant except for the practice measurements at the beginning of the session. When testing configurations without CI (i.e., HA and HA + BB), the external CI coil was disconnected from the participant. In this procedure, the



Fig. 3. Measurement setup, with one loudspeaker for speech (orange) and eight loudspeakers for the homogeneous noise field (gray).

behind-the-ear unit of the HA of the implanted side was left in place to ensure that the BB algorithm could use the two binaural signals. Likewise, when the CI and CI + BB configurations were tested, the behind-the-ear unit of the non-implanted side was in place, and an earplug was used to occlude the HA ear.

Statistical Analysis

RStudio 2022.02.3 (PBC, Boston, MA, USA) was used for statistical analysis. To assess for any effect of BB on SRTs for all three device configurations, a linear mixed model (LMM) was constructed with the nlme package in RStudio. The LMM can be seen as an extended analysis of variance test with the possibility of adding random factors [21]. Participant identification number was included as a random variable, and microphone setting (BB on or off) and device configuration (CI, HA, or CI + HA) were included as categorical fixed-effect factors. Two fixed-effects covariates were included in the model: session number (to account for a potential learning effect) and PTA₁₂₅₋₅₀₀ of the non-implanted ear. Trial number was excluded because an earlier study showed no effect [6]. To evaluate whether the device configuration affected BB performance, an interaction factor (microphone setting × configuration) was introduced into the LMM. SRT was set as the outcome variable, and an intercept was included for both the fixed and random effects. We used a LMM with different variances per device configuration because F-tests indicated that the variances differed significantly in the HA configuration. A significance level of $\alpha = 0.05$ was used, and other settings of the LMM were left at the default. The LMM can be described by the following formula:

(1) LMM: SRT = intercept + (microphone setting) + (configuration) + (microphone setting × configuration) + (b* $PTA_{125-500}$) + (a*session).

We also evaluated whether the binaural benefit depended on the SRT difference between ears using robust regression analysis, which minimizes the effect of outliers. Binaural benefit was defined as the SRT difference between the CI + HA configuration and the

| Subject | Sex | Age | CI side | CI use, vears | Duration of deafness, years | PTA ₁₂₅₋₅₀₀ , dB | Etiology | Clinical CVC |
|---------|-----|------------|---------|------------------|--------------------------------|--------------------------------|-------------------------|----------------|
| 501 | F | 66 | R | 7 | 10 | 60 | Unknown progressive | 85 |
| S02 | F | 67 | R | 7 | * | 65 | DFNA9 | 96 |
| S03 | F | 69 | R | 5 | 24 | 35 | Unknown progressive | 85 |
| S04 | F | 65 | R | 6 | ** | 22 | Unknown progressive | 84 |
| S06 | М | 54 | L | 6 | 14 | 43 | Unknown progressive | 93 |
| S07 | F | 66 | R | 11 | * | 63 | Usher syndrome | 93 |
| S08 | F | 71 | L | 7 | * | 53 | DFNA22 | 86 |
| S09 | М | 58 | L | 9 | ** | 42 | Usher syndrome | 98 |
| S10 | М | 77 | R | 1 | 5 | 43 | Unknown progressive | 89 |
| S11 | М | 70 | L | 1 | * | 53 | DFNA9 | 91 |
| S12 | F | 62 | R | 1 | 7 | 30 | Unknown | 86 |
| S13 | М | 80 | R | 1 | 34 | 48 | Unknown | 96 |
| S14 | М | 76 | L | 2 | 13 | 52 | Unknown progressive | 87 |
| S15 | М | 63 | L | 1 | ** | 45 | DFNA9 | 95 |
| S16 | F | 65 | R | 2 | 7 | 53 | Waardenburg syndrome | 98 |
| S17 | М | 67 | L | 1 | 7 | 65 | DFNA9 | 90 |
| S18 | М | 72 | R | 0.5 | 18 | 55 | Unknown progressive | 92 |
| | | Mean 68 | | Mean 4 | | Median 50 | | Median 90.5 |

Table 1. Participant demographics

*Unknown. **Still able to make phone calls at the time the CI was implanted. CVC, consonant-vowel-consonant.

better hearing ear (SRT_{CI+HA} – SRT_{BetterEar}). The better hearing ear was defined as the ear with the best SRT when measured solely with their device in noise. The SRT difference between ears was defined as the magnitude of the difference between both ears (abs(SRT_{HA} – SRT_{CI})). Because both the abscissa and ordinate contained an identical factor/element (i.e., SRT_{BetterEar}), the data were mathematically coupled, which artificially introduces a correlation [22]. To decouple the data [23], we correlated the binaural benefit to the magnitude of the SRT difference between the ears with BB switched on (abs(SRT_{HA+BB} – SRT_{CI+BB})).

Results

The SRTs of the CI and CI + HA configurations with default microphone settings are plotted in Figure 4, where lower SRTs represented better performance. The estimated mean benefit of the CI + HA configuration relative



Fig. 4. Scatterplot of the SRTs of the CI and the CI + HA configurations showing a bimodal benefit of 2.4 dB (p < 0.005) in the default microphone setting (R, gray dots) and a benefit of 2.0 dB (p < 0.005) with BB enabled (open circles).

Bimodal Hearing and Beamforming Benefit for CI Users

| | | Fixed parameter estimates of the LMM with SRT as dependent variable | | | | | |
|--|---|---|--|--|---|---|--|
| Parameter | | LMM factor type | Estimate | Std. error | DF | t | p value |
| Intercept HA ¹ CI + HA ¹ BB ¹ Configuration M CI + HA ² B HA ² B Session PTA ₁₂₅₋₅₀₀ | lic setting B ² B ² | Main effect Main effect Main effect Interaction Interaction Fixed covariate Fixed covariate | 2.88818 2.9269 -2.4253 -2.7235 0.38861 1.57378 -0.7042637 0.0140134 | 1.95885 0.88569 0.40492 0.48240 0.57375 1.25391 0.1344613 0.0373611 | 180 180 180 180 180 180 180 15 | 1.474 3.305 -5.989 -5.646 0.667 1.255 -5,238 0.677 | 0.142 0.0011 0.000 0.000 0.4991 0.211 0.000 0.710 |

Table 2. Parameter estimates of the LMM with SRT as the dependent variable

¹CI with default microphone setting as reference. ²CI with omni \times CI with default microphone setting as reference.

to the CI configuration obtained from the LMM was statistically significant, with a difference of 2.4 dB (p < 0.005; Table 2). When BB was enabled, the CI + HA configuration had a statistically significant benefit of 2.0 dB (p < 0.005; not shown).

Figure 5 shows the relation between the binaural benefit and the absolute difference in performance between ears, calculated with and without BB activated. In three study participants, the HA ear was the better performing ear (open circles). For the other participants, CI ear was their best performing ear (closed circles). A robust regression analysis showed no significant correlation for calculation of the difference between the ears either with or without BB (without BB: t = -0.427, $r^2 = -0.053$, p = 0.67; with BB: t = -0.517, $r^2 = -0.056$, p = 0.61).

As Figure 6 shows, there was a significantly greater variance of the SRT in the HA configuration than in the CI and CI + HA configurations (Bonferroni-corrected, pairwise F-tests, p < 0.05). Variances of CI and CI + HA did not differ significantly (p = 0.66). To investigate whether the increased variance in the HA configuration was caused by the repeatability of the measurements, we statistically compared the withinparticipant standard deviation of the test and re-test for all participants with standard microphone settings. Within-participant standard deviations of 1.6 dB and 3.0 dB were found for the CI and HA configurations, respectively. Repeatability was 4.5 dB for CI and 8.4 dB for HA. According to Bland and Altman [24], these results indicate that in 95% of all measurements, repeated measures were expected to differ by 4.5 dB in CI and by 8.4 dB in HA.



Fig. 5. Binaural benefit plotted against the magnitude of the SRT difference between both ears. Orange dots: BB enabled. Black dots: BB disabled. Open circles: HA ear with better SRTs than the CI ear.

Figure 6a shows the effects of BB on SRTs in the three device configurations. According to the LMM analysis, BB significantly improved SRTs in both the CI and the CI + HA configurations but had no statistically significant effect on the HA configuration (CI, p < 0.005; CI + HA, p < 0.005; HA, p = 0.322; see Table 3). Session number had a statistically significant effect on the SRTs (p < 0.005), but PTA₁₂₅₋₅₀₀ did not. Figure 6b shows the benefit of BB in all three configurations (CI, HA, and CI + HA), defined as the difference between the SRTs of the device configuration with



Fig. 6. SRTs obtained with different device configurations with and without BB. **a** SRTs in default (R) microphone settings and with BB enabled. **b** The same data plotted as benefits of BB relative to the default microphone setting.

BB and without BB. The higher the value in Figure 6b, the greater the BB benefit. BB had the highest estimated mean benefit for the CI configuration (2.7 dB), whereas BB had a benefit of 1.2 dB for the HA configuration and 2.3 dB for the CI + HA configuration (Table 3). The benefits of BB (HA, CI, and CI + HA configurations) did not differ significantly according to the LMM (p > 0.05 for all three configurations; see interaction factor in Table 2).

Discussion

In this study, speech-in-noise testing was performed for three device configurations (CI, HA, and CI + HA) with and without binaural beamforming. CI + HA had a statistically significant benefit of 2.4 dB over CI. This benefit was comparable to that found in our earlier studies [4, 6], but Vroegop et al. [1] reported a higher benefit of 3.1 dB for a CI + HA configuration over a CI configuration in a listening condition with babble noise. It is difficult to compare the current results with some previously published findings because of different outcome measures (i.e., percentage correct instead of SRTs) [7]. The benefit of BB in the CI and CI + HA configurations seen in the current work was comparable to that of binaural beamforming found in earlier studies performed with the same noise setup [20, 25]. Those studies showed an improved SRT of 1.4 dB and 2.9 dB for the CI + HA configuration with binaural beamforming in babble noise. The detected benefit, however, is lower than a previously reported 4.7 dB and 3.4 dB [1, 13]. Those studies used noise field setups in which noise sources were not deployed in front of the participants. In

contrast, our setup was more challenging for beamforming because the noise was equally loud in all directions, including from the front where the speech was originating. This difference likely will have resulted in a smaller benefit of BB than seen in some other studies. Future work should examine the influence of different setups with and without noise sources from the front or sides to elucidate the contribution of differing noise configurations to BB benefits.

We did not find a correlation between the binaural benefit ($SRT_{CI+HA} - SRT_{BetterEar}$) and the difference in SRTs between the two ears. Illg et al. [26] described a negative correlation between bimodal benefit (the addition of HA to CI) and hearing threshold level at 125 and 250 Hz, but did not find a correlation between bimodal benefit and PTA_{500-4,000}. Stronks et al. [6] also did not find a correlation between bimodal benefit and PTA₁₂₅₋₅₀₀. Thus, neither PTA nor a difference in performance between ears seems to offer prognostic value for bimodal or binaural benefit. In our hospital, most unilateral CI users are fitted with a HA in the other ear, independently from the performance of that ear and even when little residual hearing remains.

We found a significantly higher variance of SRTs in the HA configuration than in the CI and CI + HA configurations (Fig. 6). A plausible explanation for this observation is that the CI ear in most participants was the better hearing ear, and listening with only the HA was unusual for them. BB showed a statistically significant SRT benefit in the CI and CI + HA configurations, but not with HA only. The effect of BB on the HA configuration was beneficial but not significant, probably because of the higher variance and thus lower statistical power in the HA configuration. When BB is **Table 3.** Estimated marginal means ofthe BB benefit, based on the LMM

| Estimated marginal means of the benefit of BB | | | | | | | |
|---|---------------|------------------------------|------------|--------|---------|--|--|
| Setting a | Setting b | Mean SRT benefit a–b, dBA | Std. error | t | p value | | |
| CI + HA R | CI + HA BB | 2.33 | 0.3114 | -7.497 | 0.000 | | |
| HA R | HA BB | 1.15 | 1.1575 | -0.993 | 0.322 | | |
| CI R | CI BB | 2.72 | 0.4824 | -5.646 | 0.000 | | |

turned on with the CI configuration, it can be seen as contralateral routing of signals. However, a previous study in our laboratory showed no statistically significant effect from contralateral routing of signals in a homogeneous babble noise field with speech from the front [25], and the effect we found here in the three different configurations is plausibly the effect of BB. The magnitude of BB benefit did not differ significantly among the configurations. Although an absence of significance does not prove an absence of effect, this finding nonetheless is in agreement with our hypothesis that BB has an identical effect in all device configurations that is equal to signal-to-noise ratio improvement.

Conclusion

A bimodal configuration for patients with residual hearing in the non-implanted ear can be beneficial, even when one ear outperforms the other. In general, we found a significant benefit of BB in a homogeneous 8-talker babble noise field. We conclude that BB has a positive effect on understanding speech in noise when speech comes from the front. The outcomes of BB effects on the different configurations are in line with our hypothesis that these effects would not differ significantly among the CI, HA, and CI + HA configurations.

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Statement of Ethics

This study protocol was reviewed and approved by the Medical Ethics Committee Leiden, The Hague, Delft (METC protocol Number P20.018). All participants in this study provided written informed consent before participation, and the study was conducted ethically in accordance with the World Medical Association Declaration of Helsinki.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

Nienke C. Langerak contributed to study design, data collection, analyses, and draft writing. H. Christiaan Stronks obtained ethical approval for the study, designed the study, performed analyses, and critically revised the work. Jeroen J. Briaire and Johan H. M. Frijns supervised the project and revised the manuscript. All authors read and approved the final manuscript.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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