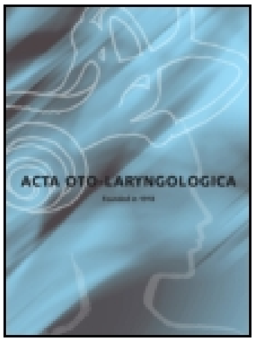

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ORIGINAL ARTICLE

Bone conductive implants in single-sided deafness

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Abstract

Conclusion: Bone conduction implants (BCIs) have been shown to partially restore some of the functions lost when binaural hearing is missing, such as in subjects with single-sided deafness (SSD). The use of a single BCI needs to be recommended by a clinician based on thorough counselling with the SSD subject. *Objectives:* To perform an overview of the present capabilities of BCIs for SSD and to evaluate the reliability of the audiological evaluation for assessing speech recognition in noise and sound localization cues, which are major problems related to the loss of binaural hearing. *Methods:* Nine subjects with SSD who received BCI implants underwent a preoperative audiological evaluation that included sound field speech audiometry, word recognition score (WRS) testing and sound localization testing in quiet and in noise. They were also tested for the accuracy of their directional word recognition in noise and their subjective perceptions of their hearing difficulties using the APHAB questionnaire. *Results:* The mean maximum accuracy of word discrimination was 65.5% in the unaided condition and 78.9% in the BCI-aided condition. Sound localization in noise was better with the BCI than in the unaided condition, especially when the stimulus and noise were presented on the same side as the implanted ear. The accuracy of directional word recognition showed an improvement with the BCI with respect to the unaided condition on the BCI side, with either the stimulus in the implanted ear and the noise in the contralateral ear or with both the stimulus and noise presented to the implanted ear.

Keywords: *Binaural hearing, bone conduction implant, single-sided deafness, speech recognition in noise, sound localization*

Introduction

Bone conduction implants (BCIs) have been used for the rehabilitation of conductive and mixed hearing losses over the last 30 years with a high degree of success. It was, therefore, not surprising that their use in subjects affected by unilateral profound hearing loss (single-sided deafness or SSD) has, in the first years of this century, been proposed to overcome some of the problems related to the loss of binaural hearing [1]. Today, different types of BCIs are available and can be selected according to different parameters. Two of them involve the presence of an incision through the permanent skin hole and are therefore considered percutaneous. They consist of an internal, osseointegrated implanted screw [2] assembled with an abutment, plus an external component that is snugly coupled to the internal component containing the actuator, signal processor and battery. Three of the current BCI devices instead perform the bone stimulation through intact skin and are therefore called transcutaneous. Two of the devices use an internal magnetic component fixed to the skull with screws that also require osseointegration to provide appropriate bone stimulation to the cochlea, but their external components, including the actuator, signal processor and battery, vary because they are made by different manufacturers. The third transcutaneous BCI device differs from the previous two in that the actuator is placed inside the internal component, allowing it to deliver an active vibratory movement to stimulate the cochlea without the need for osseointegration.

The present study focused on the different clinical and audiological factors related to the different BCI

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Table I. Demographics of the subjects with single-sided deafness (SSD) who underwent bone conduction implant (BCI) implantation.

Patient no.	Gender	Age (years)	Cause of SSD	SP type	Contralateral hearing
1	M	65	Meningitis	Divino	Normal
2	M	57	Stapedectomy	BP100	Mild conductive HL
3	F	54	PB cholesteatoma	Divino	Mild conductive HL
4	F	37	PB cholesteatoma	Divino	Normal
5	F	74	Sudden deafness	Divino	Normal
6	M	52	PB cholesteatoma	BP100	Mild conductive HL
7	M	54	Sudden deafness	BP100	Mild sensorineural HL
8	M	57	Sudden deafness	BP100	Mild sensorineural HL
9	M	59	CPA surgery	Divino	Mild sensorineural HL

CPA, cerebello-pontine angle; HL, hearing loss; PB, petrous bone; SP, sound processor.

devices for the rehabilitation of SSD and on the personal experiences of a group of SSD subjects who used two generations of sound processors from the same manufacturer.

Material and methods

Fourteen subjects affected by SSD underwent BCI surgery at our Implanting Center between 2004 and 2012. Three of them were explanted a few years later; one experienced spontaneous explantation and two were non-users due to unsatisfactory outcomes. Therefore, only nine subjects, whose demographics are shown in Table I, were included in the present study. Three subjects had normal contralateral hearing, three subjects had a mild conductive hearing loss and three had a mild sensorineural hearing loss in the contralateral ear. All subjects underwent a preoperative audiological evaluation, consisting of sound field speech audiometry and word recognition score (WRS) and sound localization testing in quiet and in noise. Testing was also performed to determine the accuracy of their directional word recognition in noise. Finally, subjective perceptions of hearing difficulties were assessed using the APHAB questionnaire. Surgery was performed without complications and, in the three subjects with sequels from cholesteatoma surgery, at the same time as the surgical revision. The BCI was activated 2 months after surgery, and the SP model (Divino or BP100; see Discussion) was selected according to the generation available at the time of surgery, with the omnidirectional microphone chosen for both of them. At different times after surgery, after at least 6 months of use, all of the subjects underwent an audiological evaluation using the same audiological battery as before the surgery along with a subjective evaluation of satisfaction. The sound and speech localization cues, in quiet and noise (SNR +10), were compared between the unaided and the BCI-aided conditions.

The tests were performed in soundfield in a soundproof booth with the patient sitting in the centre at the same distance (1 meter) from four loudspeakers positioned at 45r) from t sitting in the d betweimuth 45°, 135°, 225° and 315° in the azimuth horizontal plane and at the level of the patient's head (Figure 1). The sounds were presented at 80 dB HL, with the noise composed of white noise when testing spatial localization and babble noise when testing the accuracy of the perception and localization of a verbal message. When scoring sound localization in quiet and in noise, 1 point was given for each correct answer (correct identification of the sound source) and 1 point was deducted for each wrong answer (mistake in the identification of the sound source). When directional speech perception in noise was investigated, the accuracy of word recognition for words coming from different loudspeakers was taken into account. The accuracy was expressed as a percentage based on identification of the correct word and its source. The speech material consisted of lists of phonetically balanced, bisyllabic words that were familiar to the patients [3]. All of the stimuli that were presented in quiet were presented twice from each loudspeaker at random, with no information given on their sequence, so that four sound stimulations were delivered to each side, with a final score ranging from –4 to + 4. The right ear was investigated by the 225° and 315° loudspeakers, while the left one by the 45° and 135° loudspeakers. For noise testing, four listening situations were possible: (a) stimulus in the implanted ear, noise in the contralateral ear; (b) stimulus and noise in the implanted ear; (c) noise in the implanted ear, stimulus in the contralateral ear; and (d) stimulus and noise in the contralateral ear. Thus, two combined associations can be distinguished: *a* and *c*, with the masking noise separated from the stimuli, and *b* and *d*, with the masking noise on the same side as the stimuli. The scores for sound localization in noise ranged from –2 to +2 for each side.

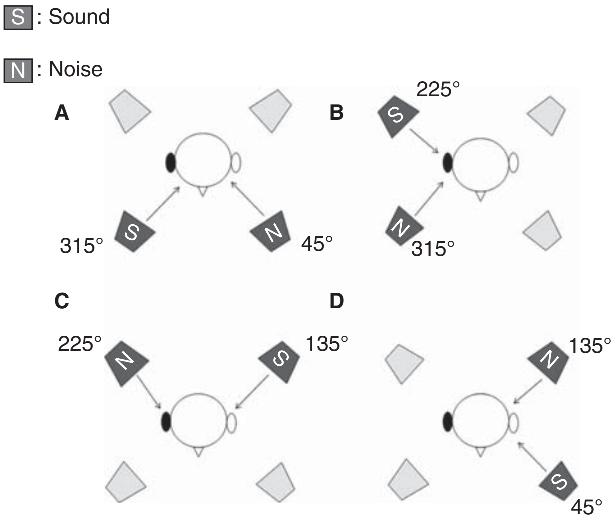

Figure 1. The setting for the directional audiometry is shown. Four different situations can be individuated on the basis of which loudspeaker, placed at 45°, 135°, 225° and 315°, delivers sound and noise stimulations: (A) sound to the front bone conduction implant (BCI) side, noise to the front non-implanted side; (B) sound and noise to the BCI side; (C) sound from the rear to the non-implanted ear, sound from the rear BCI side; (D) sound and noise to the non-implanted ear.

Evaluation of the subjects quality of life was performed using the APHAB questionnaire [4]. The unaided versus the BCI-aided conditions were compared.

The statistical evaluation was performed using the Student's t test with the numerical values for sound directionality in quiet and in noise, and the mean accuracy, as a percentage of directional word recognition in noise, for the unaided and the BCI-aided conditions. The verification of the confidence interval was directly calculated to ensure that the differences between the mean values were not due to chance.

Results

WRS

In quiet, the mean maximum accuracy of word discrimination was 98.8% in the unaided condition and 100% in the BCI-aided condition. This was not statistically significant ($p > 0.05$). In noise, the mean maximum accuracy of word discrimination was 65.5% in the unaided condition and 78.9% in the BCI-aided condition, with a non-significant gain of 13.4% ($p > 0.05$) (Figure 2).

Sound localization in quiet

The mean score on the implanted side was –1.90 in the unaided condition and –1.00 in the BCI-aided condition, which was not statistically significant ($p = 0.4$). On the contralateral side, the mean score was 3.10 in the unaided condition and 3.70 in the BCI-aided condition, which was not statistically significant ($p = 0.2$) (Figure 3).

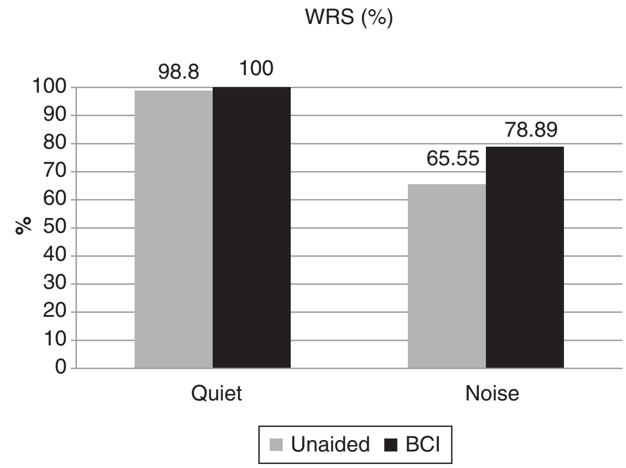

Figure 2. Mean percentage of word recognition in quiet and noise, in the unaided and bone conduction implant (BCI)-aided conditions.

Sound localization in noise

On the implanted side in *situation a*, the mean score was –1.80 in the unaided condition and –1.20 in the BCI-aided condition; in *situation b*, the mean score was –0.80 in the unaided condition and 0.20 in the BCI-aided condition; in *situation c*, the mean score was 1.80 in the unaided condition and 1.40 in the BCI-aided condition; and in *situation d*, the mean score was 1.60 in the unaided situation and 1.40 in the BCI-aided condition (Figure 4a). On the contralateral side, *situation c* corresponds to *situation a* of the implant side, *situation b* corresponds to *situation d* of the implant side, *situation a* corresponds to *situation c* of the implant side and *situation d* corresponds to *situation b* of the implant side (Figure 4b). The comparison of the scores from the two conditions did not show statistical significance ($p > 0.05$).

Accuracy of directional word recognition (%) (Figure 5)

In *situation a*, the accuracy was found to be 75.5% in the unaided condition and 90% in the BCI-aided condition. In *situation b*, this was 78% in the unaided condition and 90.5% in the BCI-aided condition. In *situation c*, the accuracy was 87.5% in the unaided condition and 89% in the BCI-aided condition. In *situation d*, the accuracy was 91.5% in the unaided condition and 94% in the BCI-aided condition.

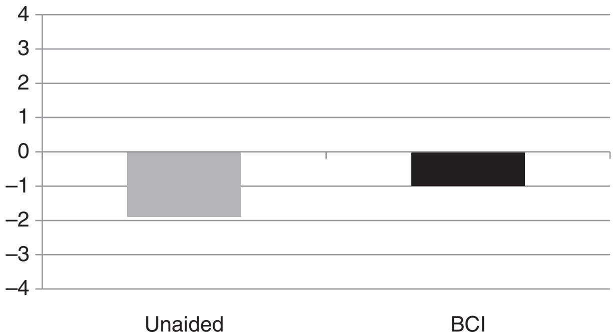

Figure 3. Score for sound localization in quiet, on the bone conduction implant (BCI) side (range from –4 to + 4).

In *situations a* and *b*, a near-significant difference was found in these values between the two conditions, with less than 7% probability that this difference would be due to chance.

APHAB questionnaire

The BCI-aided condition showed a decrease (or improvement) in the mean total score and in the mean partial scores of all of the subscales, except for the aversiveness of sounds (Figure 6).

Discussion

Two percutaneous BCIs are available at the present time: the BAHAs (Cochlear, Mölnlycke, Sweden) and the Ponto® (Oticon Medical, Copenhagen, Denmark). The BAHA® has been used for over 30 years and has been upgraded with increasingly sophisticated sound processors (SPs) (the Compact, Divino, Intenso, Cordelle, BP100 and BP110). Some refinements have recently been proposed for the implanted

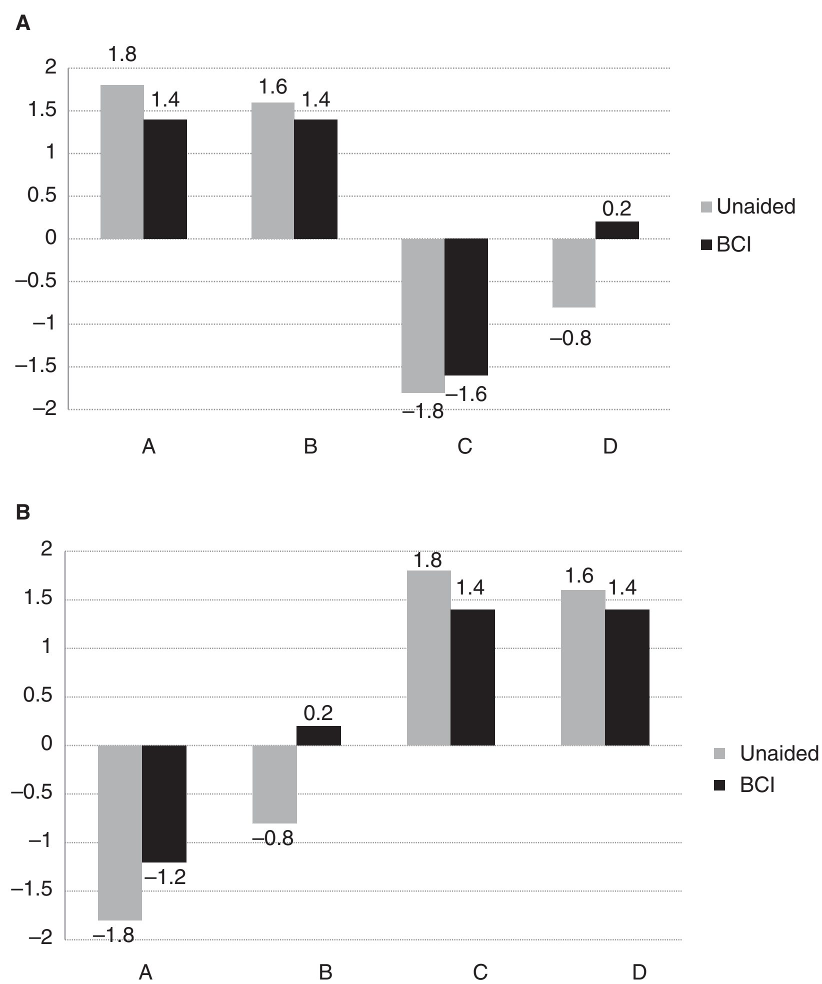

Figure 4. (a) Mean accuracy score of sound localization of the bone conduction implant (BCI)-implanted side in the four different listening situations (min –2, max +2). (A) Stimulus on the implanted ear, noise in the contralateral ear; (B) stimulus and noise on the implanted ear; (C) noise on the implanted ear, stimulus in the contralateral ear; (D) stimulus and noise in the contralateral ear. (b) Mean accuracy score of sound localization of the non-implanted ear in the four different listening situations (min –2, max +2). (A) Stimulus on the implanted ear, noise in the contralateral ear; (B) stimulus and noise on the implanted ear; (C) noise on the implanted ear, stimulus in the contralateral ear; (D) stimulus and noise in the contralateral ear.

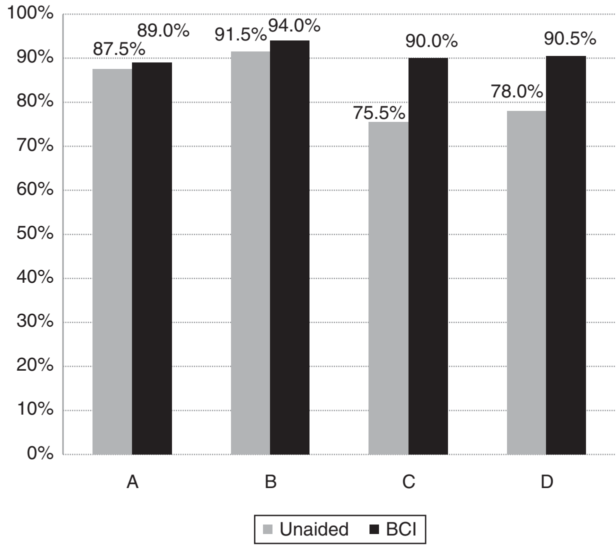

Figure 5. Mean percentage values of accuracy of directional word recognition in the four different listening situations, in the bone conduction implant (BCI)-implanted ear and in the unaided ear. (A) Stimulus on the implanted ear, noise in the contralateral ear; (B) stimulus and noise on the implanted ear; (C) noise on the implanted ear, stimulus in the contralateral ear; (D) stimulus and noise in the contralateral ear.

component, such as the Dermalock system, which uses a hydroxyapatite coating around the fixture [5]. The Ponto (R) was introduced a few years ago with different SPs (Pontopower, Pontoplus) and with refinements to the internal component that make it wider and forged for better and faster osseointegration. The surgical procedure for both of these

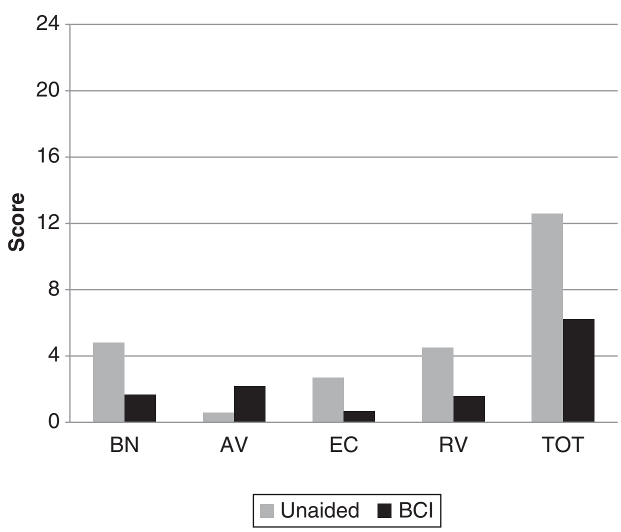

Figure 6. Mean subscale scores of the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire for the unaided and bone conduction implant (BCI)-aided conditions. AV, aversiveness of sound; BN, background noise; EC, ease of communication; RV, reverberation; TOT, total.

percutaneous devices is similar and can be performed under local or general anaesthesia. Although free flaps or manual and dermatome-assisted pedicle flaps were used in the beginning, a linear skin incision is currently preferred with the offside placement of the skin hole. Another additional modification involves the subcutaneous tissue around the area of the fixture that is currently generally spared while utilizing longer abutments of up to 11 mm [6]. It is well known that the percutaneous systems are likely to produce some drawbacks in terms of postoperative complication rates and being aesthetically unappealing when the SP is not worn.

Due to the relatively high rate of complications, the need for periodic and never-ending controls and the annoying imperfection of the percutaneous abutment, the major manufacturers have started to issue BC devices that do not need to penetrate the skin, but that instead work through intact interposed skin via a magnetic coupling. After some preliminary unsuccessful experiences, Sophono (Boulder, Colorado, USA) issued the Alpha1 and Alpha2. They are passive devices made of an internal magnetic plaque screwed into the skull, and an external component that contains an external magnet, actuator, signal processor and battery. The surgical procedure can be performed under general or local anaesthesia in less than 30 min. A very low rate of postoperative complications has been reported, with the most common problem being the eventual sufferance of the interposed skin due to the need to have a solid magnetic coupling between the internal and external magnet [7]. Around 3 years ago, Medel (Innsbruck, Austria) released an active transcutaneous device, the Bonebridge®. Its internal component is placed inside the mastoid cavity, either pre- or retro-sigmoidally, and contains an internal magnet with an antenna. The active actuator is a small canister called the BB-FMT (floating mass transducer) that is screwed into the skull but does not need to be osseointegrated. The surgical procedure lasts approximately 1 h, usually without serious complications. It is mandatory, however, before planning the implantation of the Bonebridge, to perform a radiological evaluation of the space in the temporal bone to determine the placement that is best able to accommodate the 3 × 8.6 mm internal component. Recently, Cochlear released its passive transcutaneous device, the BAHA Attract®. The external component of this device is similar to that of the percutaneous system but with a magnet, and the internal component has a round magnetic plaque that is screwed over the osseointegrated fixture. The surgical procedure lasts approximately 1 h and usually does not involve serious postoperative complications.

We turn now to audiological considerations. Since the initial observations reported by Fowler in 1960 [8], the auditory condition of hearing with one ear only, hence without binaural function, was stressed to have been underestimated in the past. In fact, binaural hearing function may provide important listening features, such as sound localization (head shadow) and the ability to separate and select verbal messages from the background signal (squelch). To overcome the loss of these functions due to SSD, the so-called CROS (contralateral route of offside signal) hearing aid (HA) was an appropriate solution in the past. This device obliges the hearing-impaired subject to also wear a device in the contralateral ear that is connected with a wire or wirelessly to the real HA. Although several reports have described the benefit of the CROS HA with respect to the unaided condition [9], not all of the SSD subjects remained fully satisfied, especially when hearing in noise was considered. When the first BCI was introduced into clinical practice for SSD, several studies investigated their performance compared to the CROS HA. In reality, the BCI would not restore binaural hearing but, by inducing a phase difference in bone conduction stimulation in the normal-hearing cochlea, it exceeds the disadvantages imposed by the head shadow effect, enhancing the monaural function of the healthy side [10]. Although speech discrimination in noise has been shown to be greatly improved compared with the CROS HA, no great differences were found in terms of improvement for sound localization. The advantage of the CROS HA remains, however, the fact that its users may avoid a surgical procedure that although simple and of short duration, can represent a threat to some patients. This issue is particularly important when considering that one of the major groups of SSD subjects is those who became deaf after vestibular schwannoma surgery [11]. It is important to remember that after the US Food and Drug Administration (FDA) clinical clearance for BCIs for SSD in 2002, some otoneurosurgical centres were offering patients undergoing translabyrinthine removal of a vestibular schwannoma the possibility of implanting a BCI in the same surgical session, leaving it inactive, or dormant, until all of the problems related to the schwannoma surgery were resolved. In this regard, only anecdotal reports have been furnished, but it would seem likely that most of the subjects would prefer to have the additional procedure performed during the same session under general anaesthesia, while they would be clearly reluctant to undergo an additional though less invasive procedure. The other important factor is the impossibility of testing subjects preoperatively unless they already had a profound hearing loss caused by the presence of a vestibular schwannoma.

The other possible alternative prescribed for only SSD is a non-surgical device that stimulates the cochlea through direct bony contact using an intra-mouth device over the posterior teeth. This device is called the Soundbite (Sonitus Medical, San Mateo, California, USA). It also requires that an additional tool be placed in the normal-hearing ear. The Soundbite has been reported to provide good results when improvement of speech perception in noise is considered [12].

In recent years, the challenge of rehabilitation for SSD has relied on the use of a cochlear implant (CI). This new CI indication was for only cases of disabling tinnitus [13], but it was then applied more extensively in the adult and paediatric populations for SSD. Because the aim of the present study is to consider only BCI devices, the advantages and disadvantages of a CI for SSD will not be taken into account or discussed.

When considering the literature on the application of BCIs in SSD subjects, most reports took into account the two major limitations that these subjects have due to the loss of binaural hearing function, i.e. reduced speech discrimination in noise and difficulty with sound localization. The first studies, in particular, considered cases of SSD with normal contralateral hearing thresholds, but little attention was paid to the functional gain of the pure-tone audiometry results or to speech reception or recognition in quiet because the latter is mostly influenced by the 'ceiling effect', that is, the maximum level due to the positive influence of the normal-hearing contralateral ear. In the present study this latter biasing factor was overcome in two-thirds of the study group because the contralateral ear was affected by a conductive or sensorineural hearing loss. This is why our findings regarding WRS in quiet showed a significant improvement with the BCI compared with the unaided condition. On the contrary, when testing the same patients in noise, the improvement to the percentage of intelligible words was demonstrated to be not significant. As far as sound localization in quiet is concerned, an improvement in the ipsilateral and contralateral sides was noted, although this was not significant. When spatial sound localization in noise was taken into consideration, it was found to be improved, although not significantly, in the BCI-aided side when the stimulus and noise were either separated (*situation a*) or associated (*situation b*). When the stimulus was delivered to the contralateral side, either separated from or associated with the noise, the localization ability was shown to deteriorate, although not significantly. This finding is in agreement with what has been reported previously, namely that the best situation for using a BCI for SSD is one where the sound is delivered to the BCI side and the noise is delivered to the contralateral ear [14,15], although Saliba et al. [16] demonstrated the opposite. It is also important to note that the BCI may cause a further artificial shadow that masks the noise due to perceptive inputs coming from the diseased side [14] and that the spatial separation of the words from the noise would also create a decrease in masking that improves verbal intelligibility (10 dB in normal-hearing subjects) [17]. Another important result worth discussing is the improvement obtained with the BCI in the accuracy of correct answers to words and not to simple sounds coming from different azimuth degrees that have defined the ipsilateral and contralateral fields in our protocol. The accuracy improved in all listening situations but with significance in only those that defined the BCI side, namely when words were presented to the BCI side and the masking babble noise was either associated or separated. This may also be because the SNR is diminished when sound is delivered to the implanted side [18]. This trend overlaps the outcome for sound localization in noise but also shows a more significant functional improvement with respect to sound localization and simple word recognition in noise. It is possible to hypothesize that when using words instead of simple sounds for testing localization in noise, verbal perception would be influenced by different multisensory inputs that allow for the combination of spectral acoustic cues and spatial information [18]. Moreover, the ability to separate or associate sound and noise also plays an important role in the separation of the stimulus from background noise in all possible directions, especially when using a BCI with an omnidirectional microphone, as was the case in our study. Interestingly, the improvement in speech localization on the contralateral, non-implanted side as well may be attributed to the monaural effect of the contralateral ear via different modalities, such as artificial shadow and level differences between air and bone conduction or the possibility of improving the reception and analysis of the spectral signals.

It is common to observe that audiological details, when not tested in noise, could not fit with the real advantage perceived by BCI-implanted SSD subjects. This is why most studies include questionnaires testing for satisfactory outcomes and quality of life before and after implantation [19]. The satisfaction rate of the patients in the present study was high when tested with the APHAB questionnaire. The only negative finding was the score for aversiveness of sound, which in agreement with Lin et al. [15], caused patients to prefer the unaided condition rather than the BCI. This paradoxical aspect could be explained by the BCI fitting strategy applied for SSD, which involves increased high-frequency and decreased low-frequency gain to improve listening in noise. However, this can lead to uncomfortable loudness for high-frequency noises.

The present study has shown that the only test that substantiates the advantages of a BCI in SSD subjects compared to the unaided condition is directional speech perception in noise, which was shown to improve when the stimulus sound was on the BCI side and independent from the noise source. This was observed in both the implanted and contralateral ears, especially when the latter also had some degree of hearing loss. Therefore, according to Hol et al. [20], it is possible to explain the BCI' positive effect on SSD through an enhancement to monaural function, similar to what has been shown to occur when a normal-hearing subject changes from a binaural to monaural listening modality.

It is possible to conclude that at the present time, based on the different devices currently available for direct cochlear stimulation, the BCI still represents a good solution for restoring some of the functions lost with the elimination of binaural hearing in SSD subjects. The choice of the best BCI will be determined by the clinician, who will discuss the clinical advantages and disadvantages (surgical procedure, integrity of the skin, need for continuous checks, etc.) of the devices with the candidate after collecting all qualitative and quantitative data derived from a thorough audiological assessment. Whether a CI will overcome most of the limitations found with the BCI and supplant them for SSD treatment is yet to be determined and may become the subject of future research.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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