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Tinnitus reduction after active bone-conduction implantation in patients with single-sided deafness: a prospective multicenter study

Jungho Ha[1] · Moo Kyun Park[2] · Shi Nae Park[3] · Hyong-Ho Cho[4] · Jae Young Choi[5] · Chi Kyou Lee[6] · Il-Woo Lee[7] · Il Joon Moon[8] · Jae Yun Jung[9] · Jinsei Jung[5] · Kyu-Yup Lee[10] · Jeong-Hoon Oh[11,12] · Hong Ju Park[13] · Jae-Hyun Seo[3] · Jae-Jin Song[14] · Hantai Kim[15] · Jeong Hun Jang[1] · Yun-Hoon Choung[1]

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Abstract

Purpose Single-sided deafness (SSD) presents significant challenges for patients, including compromised sound localization, reduced speech recognition, and often, tinnitus. These issues are typically addressed using interventions such as cochlear implantation (CI) and bone conduction implant (BCI). However, evidence regarding the efficacy of BCI in reducing tinnitus in SSD patients remains limited. This study explored the ability of a novel active transcutaneous BCI (Bonebridge BCI602) to alleviate tinnitus in SSD patients.

Study design Prospective cohort multicenter study.

Setting Tertiary referral hospitals.

Methods A prospective multicenter study of 30 SSD patients was conducted. The patients were divided into two groups: those with ($n = 19$) and without ($n = 11$) tinnitus. Audiometric assessments, subjective questionnaires including the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Bern Benefit in Single-Sided Deafness (BBSS), and tinnitus evaluations with the Tinnitus Handicap Inventory (THI) and tinnitogram were conducted before and after BCI surgery.

Results THI scores after surgery were significantly reduced in SSD patients with tinnitus. Subjective satisfaction improved in both the tinnitus and non-tinnitus groups; however, the former group exhibited a significantly greater improvement in the APHAB questionnaire score. According to tinnitograms, the loudness of tinnitus decreased, particularly in patients with ipsilateral tinnitus. Patients with residual hearing had greater reductions in their THI scores. However, three patients without residual hearing had a relative worsening of tinnitus after surgery.

Conclusion The Bonebridge BCI602 effectively reduced tinnitus in SSD patients, particularly in those with residual hearing. Subjective satisfaction improved in both the tinnitus and non-tinnitus groups. These findings demonstrate the therapeutic potential of BCI for managing SSD and associated tinnitus.

Keywords Tinnitus · Bone conduction implant · Active transcutaneous bone conduction implant · Bonebridge · Single-sided deafness

Introduction

Single-sided deafness (SSD) is defined as normal hearing in one ear and severe to profound hearing loss in the other [1]. In adults, acquired SSD is often caused by idiopathic sensorineural hearing loss (SNHL), but other factors, including cholesteatoma, infections, cerebellopontine angle tumors, head trauma, autoimmune conditions, and Meniere's disease, may be involved as well [2]. The estimated prevalence of SSD in the United States is 0.11–0.14% [3].

Patients with SSD suffer not only hearing loss but also dysfunctional binaural hearing, leading to compromised sound localization abilities and reduced speech recognition in noisy environments, with some patients reporting tinnitus [4, 5]. Hearing rehabilitation options for SSD patients mainly include cochlear implantation (CI) to enable binaural hearing, bone conduction implants (BCIs) for sound

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transfer to the contralateral side, and the use of contralateral routing of the signal (CROS) hearing aids [4–9]. BCI and CROS reduce the head shadow effect, resulting in improved speech perception and sound localization [9–13].

Tinnitus occurs in up to 85% of patients with hearing loss [14] and in 66–86% of adult patients with bilateral deafness who undergo CI for conventional hearing restoration [15, 16]. The prevalence of tinnitus in SSD patients is unknown. For SSD patients with tinnitus, CI is a viable and effective option for the treatment of tinnitus, with nearly 90% reporting either tinnitus suppression or improvement [9, 14, 17, 18].

In the few studies that have examined BCI and tinnitus, Tinnitus Reaction Questionnaire (TRQ) and Tinnitus Handicap Inventory (THI) scores in patients with unilateral SNHL or SSD who had undergone BCI significantly improved [19–21]. This prospective multicenter study investigated the effectiveness of BCI as a novel active transcutaneous approach to tinnitus reduction in patients with SSD. The factors influencing tinnitus reduction following BCI were also examined.

Materials and methods

This prospective multicenter study was conducted at 15 institutions in Korea from January 2021 to August 2022. All institutions have audiology laboratories that meet both national (KOSHA Guide H-56–2021) and international (ISO 8253–1) standards. The study received ethical approval from the Institutional Review Board of each participating institution, and all participants provided written informed consent before enrollment.

Participants

The study population included 30 patients, with 1–5 patients at each institution. Participants 19 years of age or older diagnosed with SSD (defined as an air-conductive [AC] threshold $\geq$ 70 dB HL at 0.5–4 kHz in the deaf ear and bone-conductive [BC] threshold $\leq$ 30 dB HL at 0.5–4 kHz in the normal ear) and without expected hearing improvement with conventional hearing aids (indicated by an aided speech discrimination score [SDS] < 30% at 60 dB and unaided SDS < 20% at 100 dB) were eligible for participation. Patients with a potential for hearing recovery within 6 months from the onset of symptoms, such as sudden SNHL, those requiring ototoxic drugs, and patients at risk for exacerbated hearing loss due to systemic conditions were excluded from the study. The 30 eligible patients with SSD were divided into two groups: those with ($n = 19$) and without ($n = 11$) tinnitus. Patients in the tinnitus group were further subdivided according to the changes in tinnitus based on the presence of residual hearing. During the follow-up period, none of the patients experienced postoperative complications.

Profile of device

The Bonebridge BCI 602 (MED-EL Medical Electronics, Innsbruck, Austria), an active transcutaneous BCI device, was used in this study. Its advantages compared to the previous model, the BCI 601, include a decrease in the depth of the self-vibrating bone conduction-floating mass transducer (BC-FMT) from 8.7 mm to 4.5 mm and greater flexibility of the transition portion connecting the receiver to the BC-FMT, allowing it to bend up to 90°.

Audiometric assessment and questionnaire

The BCI was switched on 6 weeks after surgery. Hearing evaluations, which included pre- and postoperative audiometry and SDS, were conducted at 1 month and 3 months thereafter. Unaided SDS for the poorer-hearing ear was measured at 100 dB. Aided pure tone audiometry (PTA) data and SDS at 60 dB were obtained in a sound field, with the normal-hearing ear masked using an earplug and headphone.

Patient subjective satisfaction was assessed by administering the Abbreviated Profile of Hearing Aid Benefit (APHAB) test before surgery, and 3 months after switch-on as well as the Bern Benefit in Single-Sided Deafness (BBSS) test at 3 months after switch-on.

Tinnitus assessment

Tinnitus in the 19 patients in the tinnitus group was evaluated by obtaining a tinnitogram and based on the THI questionnaire both before surgery and 3 months after switch-on. The THI questionnaire consists of 25 items related to functional, emotional, and catastrophic assessments. The THI score is defined as follows: 0–16, no or slight handicap; 18–36, mild handicap; 38–56, moderate handicap; 58–76, severe handicap; and 78–100, catastrophic handicap. In this study, a $\geq$ 20% change in the THI score was defined as an improvement, and a < 20% change was considered worsening tinnitus symptoms.

A tinnitogram is used to determine the characteristics of patients' tinnitus. The test involves "pitch matching" within a frequency range of 0.125–12 kHz at 10 dB above the pure tone threshold for 2–3 s. This process helps identify the sound that most closely matches the patients' tinnitus. Based on the frequency matched, the tester adjusts the sound's volume in 1 dB increments to determine the stimulus intensity

perceived by patients as equivalent to their tinnitus loudness, expressed in dB SL.

Statistical analyses

Significant differences between the two groups were analyzed using a *t*-test or a Mann-Whitney U-test for independent data and a chi-square test or Fisher's exact test for categorical comparisons. Pre- and postoperative data were compared using a paired *t*-test or a Wilcoxon signed-rank test for continuous variables. The data were analyzed using SPSS Statistics for Windows (version 23.0, IBM, Armonk, NY, USA). A p value < 0.05 was considered statistically significant.

Results

Patient demographics

The 30 patients with SSD included 19 (63.3%) with and 11 (36.7%) without symptoms of tinnitus. The tinnitus group consisted of 5 males (45.4%) and 6 females (54.6%), and the non-tinnitus group included 3 males (15.8%) and 16 females (84.2%). Overall, 7 patients (63.6%) in the tinnitus group and 12 (63.1%) in the non-tinnitus group had left-sided deafness. In the tinnitus group, the preoperative average hearing threshold was 107.1 ± 14.9 dB for the ipsilateral side and 18.1 ± 6.9 dB for the contralateral side. In the non-tinnitus group, the thresholds were 108.6 ± 16.4 dB and 15.0 ± 8.2 dB, respectively. The differences between the two groups were not significant. The preoperative SDS in the tinnitus group was 2.2 ± 5.2% for the ipsilateral side and 97.5 ± 4.1% for the contralateral side. In the non-tinnitus group, the corresponding values were 2.3 ± 4.9% and 96.8 ± 8.3%. The differences in the SDS results between the two groups were not statistically significant (Table 1).

Table 1 Patient demographics according to tinnitus in SSD patients

	Total` $n=30$	Non-tinnitus $n=11$	Tinnitus $n=19$	*P*-value
Age	50.9 ± 15.4	56.7 ± 15.3	47.6 ± 14.8	0.119
Gender				0.077
Male	8	5 (45.4%)	3 (15.8%)	
Female	22	6 (54.6%)	16 (84.2%)	
Side				0.979
Right	11	4 (36.4%)	7 (36.9%)	
Left	19	7 (63.6%)	12 (63.1%)	
Pre-op PTA (dB)				
Contralateral ear	29.2 ± 16.1	18.1 ± 6.9	15.0 ± 8.2	0.290
Ipsilateral ear	108.1 ± 15.6	107.1 ± 14.9	108.6 ± 16.4	0.803
Pre-op SDS (%)				
Contralateral ear	97.1 ± 7.0	97.5 ± 4.1	96.8 ± 8.3	0.944
Ipsilateral ear	2.3 ± 4.9	2.2 ± 5.2	2.3 ± 4.9	0.822

SDS, speech discrimination score; SSD, Sing sided deafness; PTA, pure tone audiometry

Audiologic outcomes after BCI

After BCI surgery, the aided hearing thresholds and SDS at 1 month after switch-on were 30.7 ± 9.5 dB and 76.5 ± 20.2%, respectively, in the tinnitus group, and 38.9 ± 13.1 dB and 73.5 ± 20.1% in the non-tinnitus group. At 3 months after switch-on, the aided hearing threshold and SDS were 29.8 ± 9.3 dB and 82.2 ± 15.9% in the tinnitus group and 35.4 ± 12.7 dB and 82.1 ± 16.4% in the non-tinnitus group. The differences between the two groups with respect to aided PTA and SDS were not significant (Fig. 1).

Subjective satisfaction

In the tinnitus group, the results of the APHAB questionnaire indicated significant improvements, based on reductions from 31.8 to 20.9 in the ease of communication, from 37.7 to 21.1 in reverberation, from 58.0 to 17.2 in background noise, and from 42.7 to 26.8 in aversiveness ($p=0.155$, 0.009, 0.001, and 0.012, respectively). In the non-tinnitus group, despite the overall improvement, evidenced by reductions from 36.8 to 20.0 in ease of communication, from 37.7 to 25.4 in the reverberation, from 51.2 to 29.6 in background noise, and from 26.3 to 21.7 in aversiveness, it did not reach statistical significance ($p=0.076$, 0.636, 0.076, and 0.441, respectively) (Fig. 2A). The postoperative BBSS questionnaire scores for the tinnitus and non-tinnitus groups were 27.0 and 30.2 points, respectively. The difference between the groups was not significant ($p=0.589$) (Fig. 2B). A higher level of satisfaction was determined in both groups when the BCI was operational.

Change in tinnitus after BCI switch-on

In the 19 SSD patients with tinnitus, the mean THI score improved from 47.4 ± 30.1 preoperatively to 31.1 ± 27.0 at 3 months after switch-on ($p<0.001$) (Fig. 3A). Before surgery, 4 patients (21.1%) had slight, 6 patients (31.6%) had mild, 1 patient (5.3%) had moderate, 4 patients (21.1%) had severe, and 4 patients (21.1%) had a catastrophic hearing handicap. At 3 months after surgery, the distribution changed to 7 (36.8%), 5 (26.3%), 2 (10.5%), 4 (21.1%), and 1 (5.3%), indicating a slight grade increase and a decrease in the catastrophic grade. However, while a trend was evident, it was not statistically significant ($p=0.053$) (Fig. 3B). In the analysis of THI scores, 13 patients showed an improvement

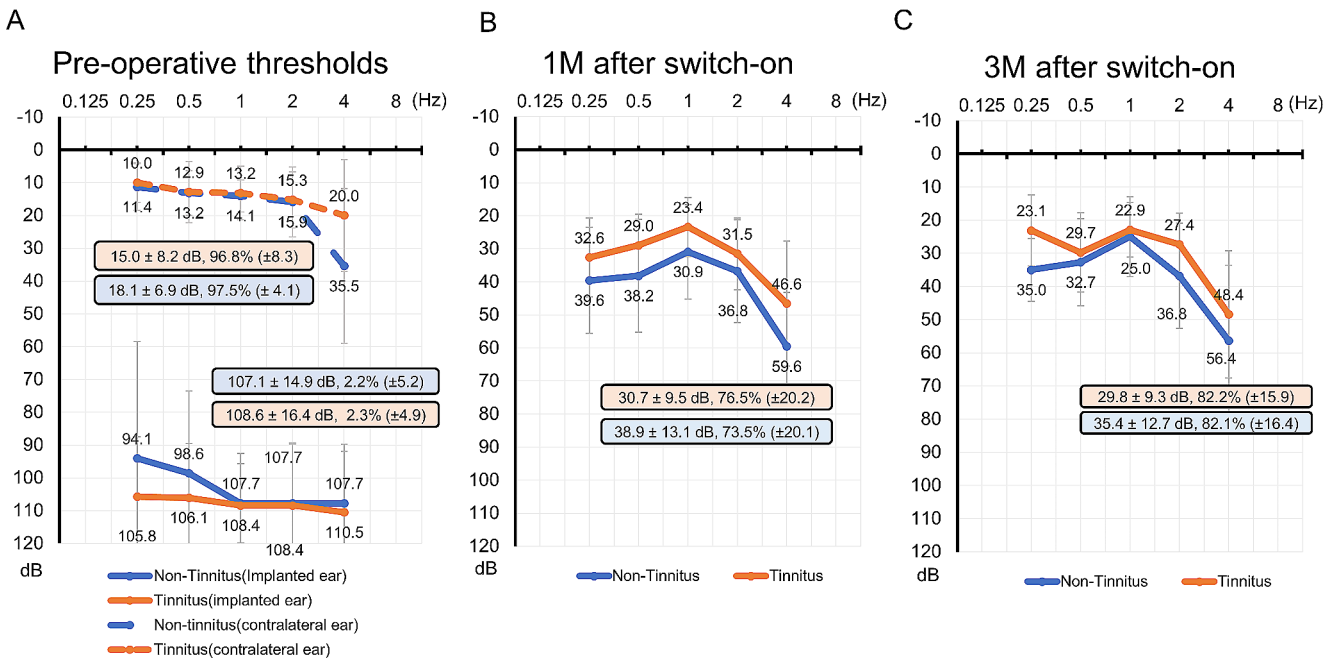


Fig. 1 Hearing outcomes according to the presence of tinnitus. (**A**) Unaided pure-tone thresholds and Speech Discrimination Score. (**B**) Aided pure-tone thresholds 1 month after device switch-on. (**C**) Aided pure-tone thresholds 3 months after device switch-on

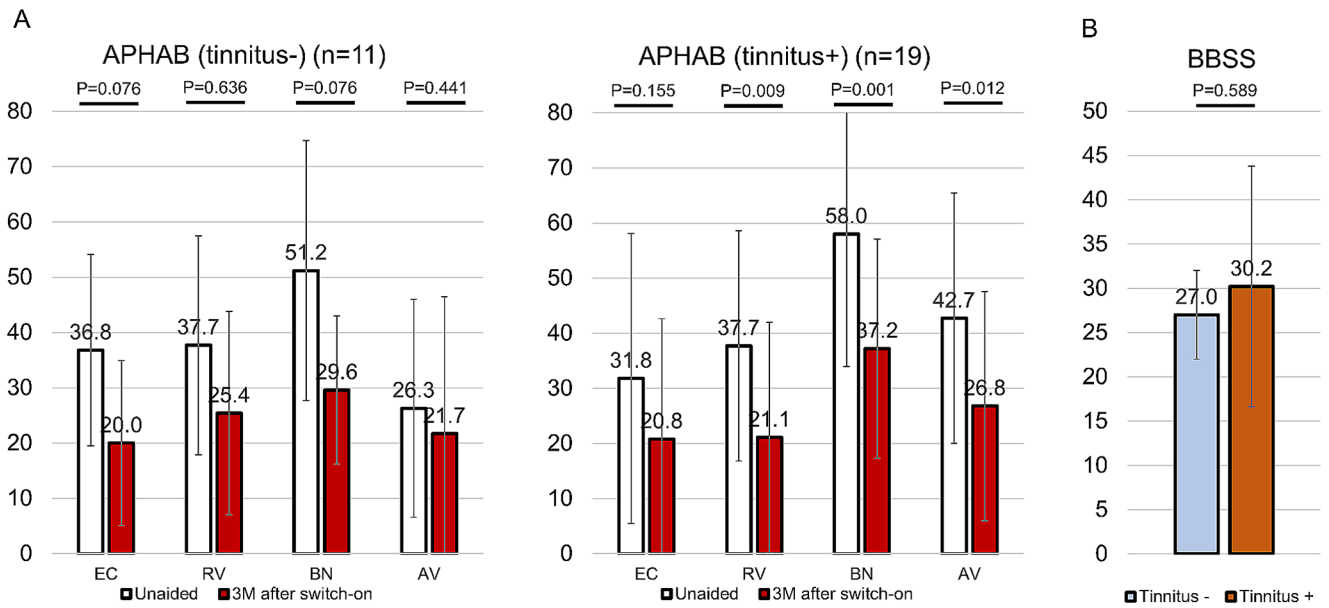
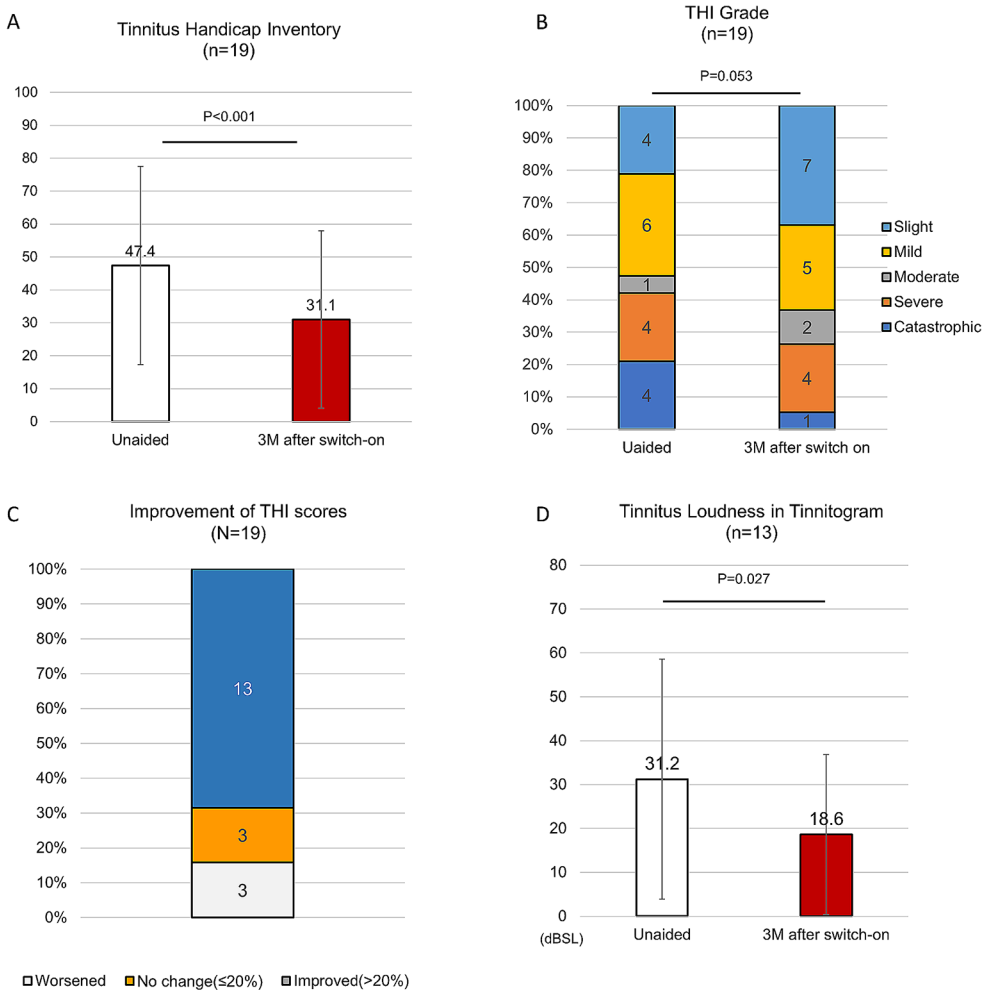


Fig. 2 Subjective outcomes according to the presence of tinnitus. (**A**) APHAB questionnaire scores and (**B**) BBSS questionnaire scores

(≥20% change) but in 3 patients their tinnitus worsened, as their THI scores increased from 32 to 46, 72 to 90, and 58 to 60, respectively (Fig. 3C and Supplementary Table 1). In the tinnitus group, the loudness of tinnitus as determined in the tinnitogram significantly decreased ($p=0.027$) after vs. before BCI surgery, from 31.2 ± 27.4 dB SL to 18.6 ± 18.2 dB SL (Fig. 3D).

Tinnitogram and THI according to tinnitus site

Among the 19 SSD patients with tinnitus, the ipsilateral side was involved in 11 patients (57.9%) and the contralateral side was involved in 7 patients (36.8%); in 1 patient (5.3%) tinnitus was bilateral (Fig. 4A). In the patients with ipsilateral tinnitus, the analysis of loudness showed a statistically significant ($p=0.011$) improvement, with a decrease from 40.8 ± 27.9 dB SL to 22.2 ± 19.6 dB SL (Fig. 4B). In this



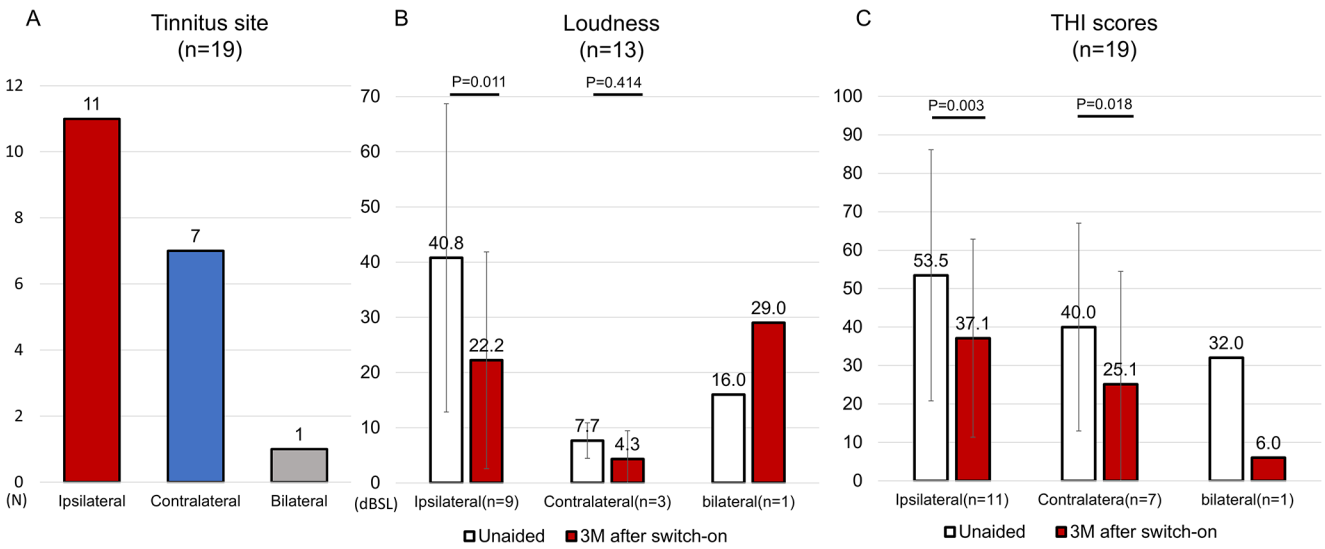


Fig. 3 Changes in tinnitus after BCI surgery. (**A**) THI scores after BCI surgery. (**B**) Grade distribution of THI scores. (**C**) Percentage improvement in the THI scores. (**D**) Reductions in tinnitus loudness according to a tinnitogram

Fig. 4 Tinnitogram and THI scores according to the tinnitus side. (**A**) Tinnitus side. (**B**) Changes in tinnitus loudness according to location as determined via tinnitogram. (**C**) Changes in THI scores according to tinnitus location

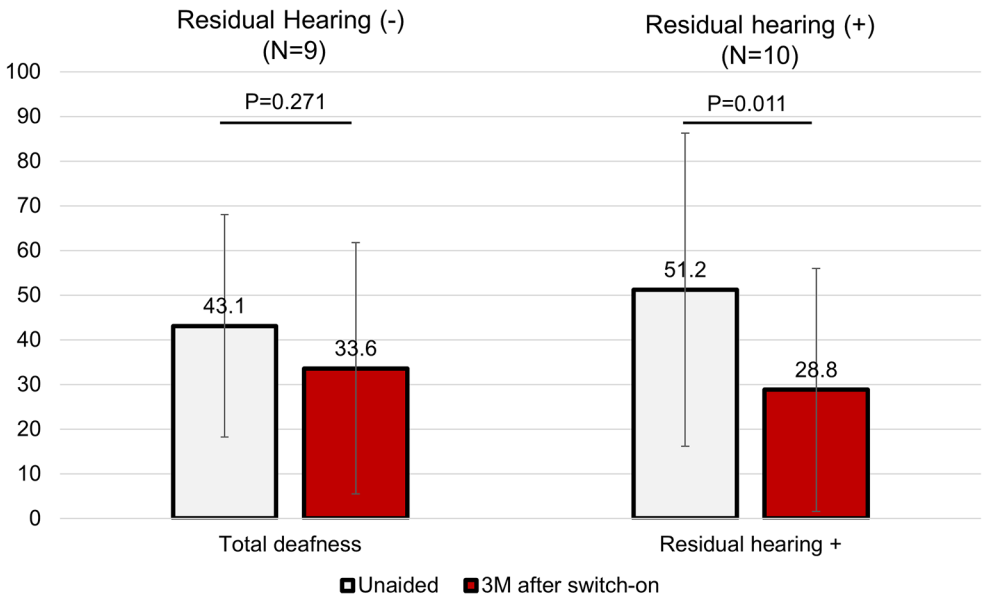


Fig. 5 THI changes according to residual hearing

group, there was also a significant ($p=0.003$) improvement in the mean THI score, which decreased from 53.5 ± 32.6 to 37.1 ± 25.7. A significant improvement ($p=0.018$) in the THI score was also determined in the patients with contralateral tinnitus, based on a decrease from 40.0 ± 27.0 to 25.1 ± 29.4 (Fig. 4C).

THI changes according to residual hearing

Of the 19 patients with SSD and tinnitus, 10 had some degree of residual hearing before BCI surgery, while the remaining 9 had completely scaled-out hearing thresholds. In the latter, there was a tendency for a decrease in the THI score but it was not statistically significant. In the group with residual hearing, however, there was a significant reduction in the average THI score, from 51.2 ± 35.0 to 28.8 ± 27.2, a mean decrease of 22.4 points (Fig. 5). The three patients with tinnitus worsening had no residual hearing (Supplementary Table 1).

Adverse events

There were no adverse events related to the surgery or the study procedures.

Discussion

This study examined the effectiveness of a novel active transcutaneous BCI (Bonebridge BCI 602) in reducing tinnitus in patients with SSD and analyzed the factors influencing tinnitus reduction following BCI surgery. BCI, the CROS hearing aid, and CI are auditory rehabilitation methods for patients with SSD, and their effectiveness has been assessed in several studies [6, 8, 9, 13, 22]. Linstrom et al. reported the outcomes of bone-anchored hearing aid surgery in patients with SSD, including the efficacy of these devices in improving speech recognition in noise (with noise presented in front and speech lateralized to the impaired ear) and subjective measures of benefit over both the short- and long-term [8]. Another previous study demonstrated the effectiveness of the BCI602 device for individuals with SSD, including functional hearing gain and a high level of satisfaction [23]. The BCI602 is well-suited for long-term SSD patients but with limited subjective benefits expected for those with congenital SSD [23].

Tinnitus may adversely affect speech reception in the affected ear, especially in noisy environments [24]. Mertens et al. found that unilateral debilitating tinnitus also reduced speech reception by the non-tinnitus ear in noisy environments, consistent with the common clinical observation of reduced speech reception by healthy ears in such environments among tinnitus patients despite normal hearing [25]. Tinnitus in patients with SSD may therefore impact audiologic outcomes. In this study, the absence of a significant difference among SSD patients with and without tinnitus after BCI surgery with respect to aided thresholds and objective audiologic outcome measurements, such as the SDS, suggests improvement. The aided mean thresholds at 1 and 3 months after device switch-on decreased, albeit not significantly, in SSD patients with tinnitus; thus, even in SSD patients with tinnitus, satisfactory audiologic outcomes can be achieved with BCI.

In both groups, subjective satisfaction, assessed using the BBSS and APHAB questionnaires, increased after BCI surgery. Significant improvements were most notably reflected

in the APHAB questionnaire, with particularly high levels of subjective satisfaction among patients with SSD and tinnitus. Previous studies have also reported effective subjective satisfaction across various domains on the APHAB questionnaire following BCI surgery [26, 27] but subjective satisfaction outcomes in patients with tinnitus have not been determined.

Previous studies have examined the effects of CI surgery in reducing tinnitus in patients with SSD [14, 17, 18, 28]. The mechanisms underlying tinnitus suppression after CI may be related to electrical stimulation of the auditory nerve in the SSD ear [29]. The reestablishment of central auditory pathways and the promotion of neuroplasticity achieved with CI may also influence tinnitus perception. The masking effect following CI activation may likewise contribute to tinnitus reduction [17].

Transmitting sound to the normal-hearing ear through BCI implies a distinct mechanism for suppressing tinnitus, as BCI does not directly provide auditory stimulation to the affected ear. Several studies have reported the efficacy of BCI in mitigating tinnitus. For example, in Kim et al. [30], tinnitus was significantly reduced in patients with asymmetric hearing loss (AHL) but no such effect was obtained in the SSD group. This suggests a sound therapeutic effect of masking as a mechanism. Another study demonstrated significant reductions in tinnitus in patients with severe to profound unilateral SNHL treated with percutaneous osseointegrated auditory implants [20]. In that study, both THI and TRQ scores were significantly improved, with greater improvements in tinnitus occurring in patients with severe than with profound hearing loss. In our study, the THI scores of SSD patients with tinnitus substantially improved, decreasing from 47.4 to 31.1. A score improvement of $>20\%$ was achieved by 68.4% (13/19) of the patients, highlighting the efficacy of BCI surgery in eliciting meaningful tinnitus relief in SSD patients.

Improvements in tinnitus severity in our SSD patients also depended on its location. Among the 19 patients who underwent BCI surgery, 7 reported tinnitus in the normal-hearing ear. Preoperatively, ipsilateral tinnitus was louder than contralateral tinnitus. A significant change in loudness occurred postoperatively in patients with the ipsilateral type. This demonstrates that BCI is effective in improving tinnitus in the ipsilateral affected ear in SSD, as evidenced by changes in THI scores.

Postoperative THI scores were significantly reduced in patients with ipsilateral and contralateral tinnitus. Sound transmission to the contralateral ear might improve tinnitus in the affected ear by the previously mentioned masking effect and due to the bidirectionality of the central auditory pathway. During signal passage from the ipsilateral cochlear nucleus to the contralateral superior olivary nucleus, tinnitus may be reduced both in the unaffected and the affected ear [19, 30], as suggested by the significant reductions in the THI scores of the ipsilateral and contralateral sides. Over the long term, a reorganization of the central auditory pathways may occur, resulting in a late-onset reduction of tinnitus [17].

Additionally, concerning the improvement of tinnitus in either the affected or unaffected ear of SSD patients, BCIs transfer sound to the opposite side, as observed with CROS or bi-contralateral routing of sound (BiCROS) hearing aids; they also deliver sound to the less responsive ear. The bone conduction sound from BCI is simultaneously transmitted to both inner ears. In contrast, CROS might contribute to a relative functional sensory deficit in the less responsive ear, potentially exacerbating tinnitus in the affected ear. In a study by Marx et al., 75 patients with SSD or AHL using CROS or BiCROS hearing aids showed no improvement in tinnitus intensity or severity [31]. Potier et al. explored the impact of using BiCROS with additional amplification in the worse ear on tinnitus improvement in patients with AHL and SSD. They emphasized the previously mentioned masking effect, as well as modifications in central plasticity due to partial hearing restoration; their results suggested that acoustic stimulation of the worse ear could be effective in alleviating tinnitus [32, 33]. Moreover, considering that tinnitus arises from central changes after sensory deprivation due to hearing loss, partial restoration of sensory inputs may help prevent or reverse these tinnitus-related central changes [34]. Therefore, sound delivery to the affected ear is essential, particularly when residual hearing is present.

In this study, worsening of tinnitus was noted in three (15%) female patients, two with ipsilateral tinnitus and one with contralateral tinnitus. All three had scaled-out hearing thresholds. Significant reductions in THI scores, especially in patients with residual hearing, highlight the importance of residual hearing in reducing tinnitus impact in SSD patients. For this group, a more substantial decrease in tinnitus after BCI surgery could be expected, indicating that BCI might be more effective for SSD patients with tinnitus when some residual hearing is preserved.

In summary, our findings suggest that novel active transcutaneous BCI is effective for reducing tinnitus in SSD patients, with positive impacts achieved based on subjective as well as objective measures. Our results contribute to the growing body of evidence supporting the use of BCI as a valuable therapeutic option for patients with SSD and tinnitus.

Conclusions

This study demonstrated the effectiveness of the Bonebridge BCI602 active transcutaneous device in providing functional hearing gain and satisfaction. Tinnitus was reduced in all but three SSD patients, with the largest reduction achieved in those with residual hearing.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00405-024-08780-0.

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Declarations

Ethical approval Ethical approval for this multicenter study was obtained from the institutional review board of each participating institution, including Ajou University Hospital (approval number: AJIRB-DEV-DE3-20-373), Seoul National University Hospital (J-2011-045-1171), Seoul St. Mary's Hospital (KC20DIDI0926), Chonnam National University Hospital (CNUH-2020-365), Yonsei University Severance Hospital (1-2020-0087), Soonchunhyang University Hospital (SCHCA 2020-11-032), Yangsan Pusan National University Hospital (03-2020-017), Samsung Medical Center (SMC2020-10-090-003), Dankook University Hospital (DKUH2020-11-011-005), Kyungpook National University Hospital (KNUH2020-10-024-002), Bucheon St. Mary's Hospital (HC20DIDI0117), Asan Medical Center (2020 – 1852), Korea University Ansan Hospital (2020AS0342), Seoul National University Bundang Hospital (B-2010/640-003) and Konyang University Hospital (KYUH2020-11-014-002). Additionally, the study was registered with the Clinical Research Information Service (approval number: KCT0005517).

Informed consent All participants provided written informed consent before enrollment.

Conflict of interest The authors have no conflicts of interests to declare.

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Authors and Affiliations

Jungho Ha[1] · Moo Kyun Park[2] · Shi Nae Park[3] · Hyong-Ho Cho[4] · Jae Young Choi[5] · Chi Kyou Lee[6] · Il-Woo Lee[7] · Il Joon Moon[8] · Jae Yun Jung[9] · Jinsei Jung[5] · Kyu-Yup Lee[10] · Jeong-Hoon Oh[11,12] · Hong Ju Park[13] · Jae-Hyun Seo[3] · Jae-Jin Song[14] · Hantai Kim[15] · Jeong Hun Jang[1] · Yun-Hoon Choung[1]

✉ Yun-Hoon Choung
yhc@ajou.ac.kr

[1] Department of Otolaryngology, Ajou University School of Medicine, 164 Worldcup-ro, Yeongtong-gu, Suwon, Gyeonggi-do 16499, Republic of Korea

[2] Department of Otorhinolaryngology–Head and Neck Surgery, Seoul National University College of Medicine, Seoul, Korea

[3] Department of Otorhinolaryngology–Head and Neck Surgery, Seoul St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Seoul, Korea

[4] Department of Otolaryngology–Head and Neck Surgery, Chonnam National University Medical School, Chonnam National University Hospital, Gwangju, Korea

[5] Department of Otorhinolaryngology, Yonsei University College of Medicine, Seoul, Korea

[6] Department of Otorhinolaryngology–Head and Neck Surgery, Soonchunhyang University College of Medicine, Seoul Hospital, Seoul, Korea

[7] Department of Otorhinolaryngology–Head and Neck Surgery, Pusan National University College of Medicine, Pusan National University Yangsan Hospital, Yangsan, Korea

[8] Department of Otorhinolaryngology–Head and Neck Surgery, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Korea

[9] Department of Otolaryngology–Head and Neck Surgery, Dankook University College of Medicine, Cheonan, Korea

[10] Department of Otorhinolaryngology–Head and Neck Surgery, School of Medicine, Kyungpook National University, Daegu, Korea

[11] Department of Otorhinolaryngology–Head and Neck Surgery, Bucheon St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Bucheon, Korea

[12] Department of Otolaryngology, Tntn Hospital, Hwasung, Korea

[13] Department of Otorhinolaryngology–Head and Neck Surgery, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea

[14] Department of Otorhinolaryngology–Head and Neck Surgery, Seoul National University Bundang Hospital, Seongnam, Korea

[15] Department of Otorhinolaryngology–Head and Neck Surgery, Konyang University College of Medicine, Daejeon, Korea