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Percutaneous Bone-Anchored Hearing Implant: Is It Clinically Useful in Korean?

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ABSTRACT

Background: The aim of this study is to investigate the clinical effectiveness of Ponto in Korea, a recently released percutaneous bone-anchored hearing implant.

Methods: 16 patients with single-sided deafness (SSD) and mixed or conductive hearing loss who underwent Ponto implantation from December 2018 to September 2020 were enrolled in the study. Puretone audiometry, the Korean version of the Hearing in Noise Test (K-HINT), sound localization test (SLT), and Pupillometry were performed pre- and three months post-operation. Standardized questionnaires, the Hearing Handicap Inventory for the Elderly (HHIE) and Speech, Spatial and Qualities of Hearing Scale (SSQ), were administered.

Results: The mean age of subjects was 55.5 (range, 48–67) years. Four males and 12 females participated in the study. The mean puretone average was 73.17 dB hearing level (HL) before surgery and significantly improved to 36.72 dB HL three months after surgery. The mean word recognition score improved from 26.0% to 90.75% after implantation. In the case of K-HINT, there was a significant difference in summation ($Z = -2.250$, $P = 0.024$) and head shadow effects ($Z = -3.103$, $P = 0.002$). There was no significant difference in root mean square error degree (RMSE) and hemifield identification scores for SLT testing. Pupillometry was performed to measure listening effort and the results revealed that the degree of pupillary dilatation decreased under the condition of quiet, 0 dB signal to noise ratio (SNR) and 3 dB SNR. The total score for HHIE decreased significantly ($Z = -3.130$, $P = 0.002$) while the SSQ score increased significantly ($Z = -2.216$, $P = 0.027$).

Conclusions: The Ponto bone-anchored hearing system showed significant clinical benefit in Korean patients with conductive and mixed hearing loss and SSD.

Keywords: Bone Conduction Devices; Ponto; Speech Recognition in Noise; Sound Localization; Pupillometry

INTRODUCTION

Bone conduction devices (BCDs) combine the concepts of osseointegration and bone conduction stimulation for hearing rehabilitation in patients with conductive or mixed hearing loss. Although the surgery is mandatory, these BCDs can be a good rehabilitation option for patients with single-sided deafness (SSD) or who do not receive benefits from

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Data Sharing Statement

Data sharing statement is provided in **Supplementary Data 1**.

Disclosure

The authors have no potential conflicts of interest to disclose.

Author Contributions

Conceptualization: Koh SM, Cho YS, Moon IJ.
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conventional hearing aids (HAs). The United States Food and Drug Administration approved the use of the Bone-anchored hearing aids (Baha) for conductive and mixed hearing loss in 1996 and for SSD in 2002.¹

BCDs can be divided into active and passive devices depending on the way sounds are transmitted. Passive devices include percutaneous and transcutaneous devices.² The Baha® (Cochlear Bone Anchored Solutions AG, Mölnlycke, Sweden) and Ponto® (Oticon Medical AB, Askim, Sweden) are percutaneous implantable osseointegrated hearing system. The transmission of sound to the bone is accomplished via an osseointegrated titanium fixture surgically implanted in the temporal bone. Although this method is helpful for sound transmission, the percutaneous abutment connection system has cosmetic issues and regular surgical site care is necessary.³ These factors often cause inflammation and skin infections which can be problematic.⁴

Recently, a magnetic transcutaneous bone conduction implant system with intact skin interposed between two magnets have been introduced and widely used.⁵ Unlike previous percutaneous bone-anchored hearing implants, this transcutaneous system reduces the need for soft tissue reduction at the implant, improving concerns regarding skin irritation, inflammation, overgrowth, and pain.^{6,7} However, cases of skin necrosis have often been reported due to the strength of the magnet⁸ and sound transmission has not been as good as that of the percutaneous bone-anchored system.⁹

A new BCD, Ponto, has been developed and introduced in 2009. The system provides a wide range of abutments for different skin thickness, decreasing the need for soft tissue reduction during surgery. Besides, tissue preservation surgical techniques, including the Minimally Invasive Ponto Surgery procedure, can possibly decrease skin problems after surgery. Previous studies reported that the use of BCDs improved speech perception in noise, especially the head shadow effect. However, no significant improvement was observed for sound localization testing.^{10,11} Although Ponto has been studied for maximum output and gain, there is no objective and comprehensive study of its clinical effectiveness, especially in Asian countries.¹² This study investigates the clinical effectiveness of the recent sound processor for a BCD, Ponto, through objective (speech perception in quiet and noise and sound localization) and subjective measures (questionnaires).

METHODS

Subjects

This is a prospective single-institution study. Inclusion criteria were age between 18 and 70 years with conductive hearing loss (average bone conduction threshold below 65 dB with air-bone gap over 25 dB on the implant side) or SSD (average air conduction threshold over 55 dB with air-bone gap less than or equal to 15 dB on the implant side and average air conduction threshold less than or equal to 25 dB on the non-implant side). Exclusion criteria included patients with cognitive impairment and patients who were unable to complete a pupillometry test due to ophthalmic diseases. From December 2018 to September 2020, a total of 20 patients underwent Ponto implant surgery performed by a single surgeon. Out of the 20 patients, 16 patients were enrolled in the study and completed all test batteries before and three months after surgery. Ten of 16 patients had mixed hearing loss, 3 of 16 patients had conductive hearing loss on the implant side and three patients had SSD.

Device fitting

Six weeks after surgery, subjects visited Samsung Medical Center to activate the Ponto device. The device was programmed by experienced audiologists using the manufacturer programming software, Genie Medical fitting software, based on the bone conduction thresholds of each participant before surgery. Participants returned to the facility after three months for their follow up appointments.

Test batteries

Auditory and speech perception abilities were evaluated objectively through unaided and aided threshold testing, word recognition test, the Korean version of the Hearing in Noise Test (K-HINT), and sound localization test (SLT). Listening effort was also measured using a pupillometer. Subjective evaluation was completed by administering the Hearing Handicap Inventory for the Elderly (HHIE) and the Speech and Spatial Qualities of Hearing Scale (SSQ) questionnaires before surgery and three months after the first fitting appointment.

Unaided and aided threshold testing was performed with the subject sitting 1m in front of the speaker in a double-walled, sound-treated booth. A word recognition score (WRS) was obtained at most comfortable level using 50 monosyllabic words from the Korean Standard – Sentence Lists for Adults. The monosyllabic words were phonetically balanced. K-HINT was performed using HINT pro (HINT pro 7.2, Bio-logic® System; Natus Medical Inc., Pleasanton, CA, USA) to assess speech performance in noise. K-HINT consists of 12 sentence lists that contains 20 sentences per list. Subjects were asked to repeat the sentences back to the tester. Background noise was presented constantly at 65 dB. Masking effects were evaluated with noise being presented in front of the listener (0° azimuth) and from lateralized positions relative to the poor and better ear (90° and 270° azimuth).¹³ The presentation level of the sentences decreased by 4 dB if the subject repeated the sentences correctly and increased by 4 dB if the subject repeated the sentences incorrectly. Average scores were calculated after completing K-HINT twice. K-HINT was performed in three conditions: 1) summation effect; 2) squelch effect; and 3) head shadow effect. Both speech and noise were presented from the front (F_sF_N) for the summation effect condition. For the squelch effect condition, among the speakers located on both sides ($\pm 90^\circ$), speech was presented to the better hearing side and noise was presented to the poor hearing side (NH_sHL_N). Lastly, for the head shadow effect condition, among the two speakers ($\pm 90^\circ$), speech was presented to the poor hearing side and noise was presented to the better hearing (HL_sNH_N) side.

All participants completed SLT using a 13-loudspeaker array. The loudspeakers were placed at 15° intervals from -90° azimuth to +90° azimuth. Each subject sat in a chair at the center of the arc with their ears at a height equal to the loudspeaker array. The loudspeakers were numbered from 1 to 13 and the stimulus was presented randomly at 62, 65, and 68 dB. The participants were instructed to report the speaker number which they thought the target speech was presenting. Root-mean square error (RMSE) and hemifield identification scores (percent-correct scores) were calculated.¹⁴

Pupillometry was also performed using REDn Scientific™ (SensoMotoric Instruments Inc, San Francisco, CA, USA) to measure listening effort objectively. It is reported in previous literature that pupil diameter increases when individuals exert greater effort to solve hard problems.¹⁵ Therefore, many studies have evaluated the degree of pupil dilatation in order to measure cognitive load in listening effort and reported a significant correlation between pupil dilation and listening effort.^{16,17} The pupillometer uses infrared video-based tracking technology to measure the size of the pupil. The spatial resolution of the pupillometer was

0.03 mm. The location and size of the pupil were automatically recorded at 50 Hz and a PC connected to the pupillometer stored the data with time stamps, indicating the start of the trials and the stimuli, the prompt signal, and the response of the participant. For the first five seconds, the pupil size at baseline was set. Then, the participants were asked to answer questions in quiet. After presenting noise for three seconds (multi-talker babble noise, 65 dB sound pressure level) the participants were asked to answer questions that were presented at 0 dB and 3 dB signal to noise ratio (SNR). Finally, the amount of pupil dilation or contraction was measured based on the pupil size at baseline with blinks and saccades removed. The peak dilated pupil diameter with respect to the reference pupil diameter was calculated.

Subjective evaluation was carried out with two standardized questionnaires: HHIE and SSQ. These questionnaires were administered before and three months after Ponto implantation. The Wilcoxon signed-rank test was used to examine statistical significance between pre- and post-operation questionnaire scores.

Ethics statement

This study was approved by the Institutional Review Board at Samsung Medical Center following the Declaration of Helsinki (IRB File No. 2020-10-057). Written informed consent was obtained from all participants.

RESULTS

The age range of the participants was 48 to 67 years old with the median value of 55.5 years old. Among the 16 participants, four were men (25%) and 12 were women (75%). Mean air and bone conduction thresholds across 500, 1,000, 2,000, and 4,000 Hz were 73.17 dB hearing level (HL) and 24.58 dB HL, respectively (**Fig. 1**). Nine patients (56.3%) wore the device in the right ear and seven patients (43.7%) wore the device in the left ear.

Statistical difference was observed between pre- and post-operation unaided and aided threshold and word recognition testing. The mean unaided threshold was 73.17 dB (standard deviation [SD] = 14.17) HL prior to surgery and significantly improved to 36.72 dB (SD = 10.50) HL at three months post-operation ($P < 0.05$). Additionally, there were significant differences in all frequencies before and after surgery (**Fig. 2**). In terms of WRS, the average WRS significantly improved from 26.0% (SD = 40.13) to 90.75% (SD = 7.33, $P = 0.039$) after three months of Ponto implantation.

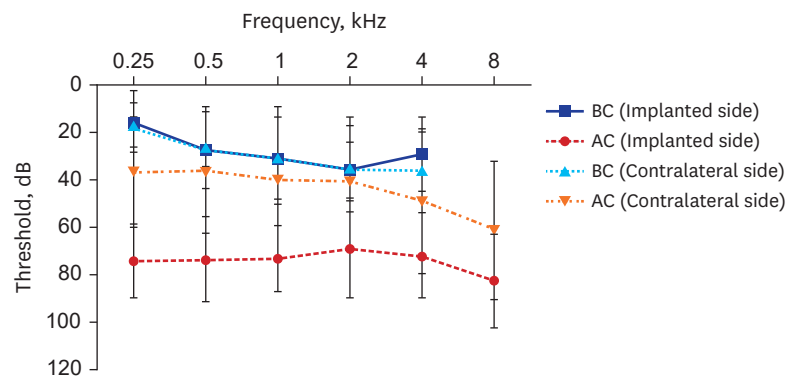


Fig. 1. Average preoperative puretone thresholds on the implant and non-implant side.

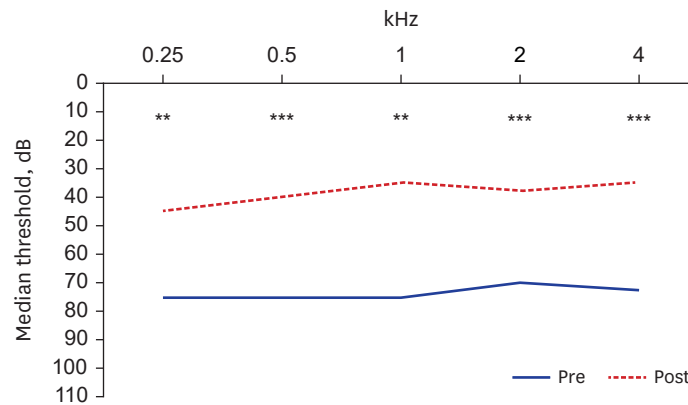


Fig. 2. There were significant differences before and after surgery at 250 Hz ($Z = -3.417, P = 0.001$), 500 Hz ($Z = -3.530, P < 0.001$), 1,000 Hz ($Z = -2.694, P = 0.007$), 2,000 Hz ($Z = -3.522, P < 0.001$), and 4,000 Hz ($Z = -3.419, P = 0.001$). Statistically significant differences are indicated with an asterisk (** $P < 0.01$, *** $P < 0.001$).

In the case of K-HINT, the summation, squelch, and head shadow effects were analyzed by changing the direction of the speaker presenting target speech and noise. The speech reception thresholds under 8-talker babble noise of 65 dBA before and after surgery were not significantly different ($Z = -1.086, P = 0.278$). However, there was a significant difference in the summation ($Z = -2.250, P = 0.024$) and head shadow effect ($Z = -3.103, P = 0.002$) conditions before and after surgery for speech recognition threshold (**Fig. 3**).

For SLT, there was no significant difference in RMSE ($Z = 0.230, P = 0.820$) and hemifield identification scores (**Table 1**). The degree of pupillary dilatation decreased in quiet ($Z = -0.314, P = 0.753$), 0 dB SNR ($Z = -1.014, P = 0.310$), and 3 dB SNR ($Z = -0.734, P = 0.463$), but no statistical significance was observed between the conditions. The total HHIE scores decreased after Ponto implantation ($Z = -3.130, P = 0.002$). To be more specific, the scores

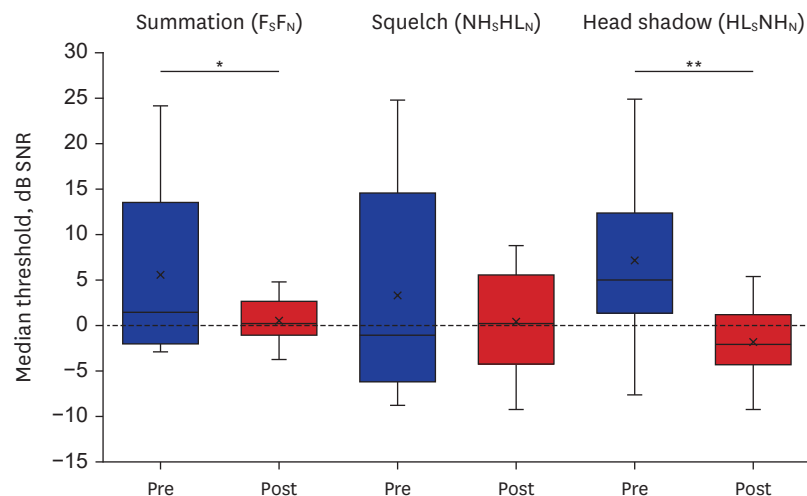


Fig. 3. Median differences between speech perception on K-HINT for three different speech in noise test conditions. Horizontal lines within the bars represent the median value. Bars represent interquartile ranges and error whiskers represent the highest and lowest points. K-HINT = Korean version of the Hearing in Noise Test, F_sF_N = speech and noise were presented from the front, NH_sHL_N = speech was presented to the better hearing side and noise was presented to the poor hearing side, HL_sNH_N = speech was presented to the poor hearing side and noise was presented to the better hearing. Statistically significant differences are indicated with an asterisk (* $P < 0.05$, ** $P < 0.01$).

Table 1. Sound localization results

Variables	No.	Median	Quartile	Z	P
RMSE				0.230	0.820
Pre (°)	15	3.9	2.4–4.4		
Post (°)	15	3.3	2.2–5.0		
HIT rate				-0.336	0.737
Pre (%)	15	15.7	9.6–24.5		
Post (%)	15	16.4	11.5–24.5		

RMSE = root mean square error, HIT = hemifield identification.

 Statistically significant differences are indicated with an asterisk (* $P < 0.05$, ** $P < 0.01$).

Table 2. SSQ and HHIE result

Questionnaires	No.	Median	Quartile	Z	P
SSQ					
Total				-2.216	0.027*
Pre	16	4.9	3.75–5.88		
Post	16	6.2	5.1–7.4		
Speech				-2.457	0.014*
Pre	16	4.75	2.83–7.4		
Post	16	7.6	5.83–8.1		
Spatial				-2.330	0.020*
Pre	16	3.55	2.75–6.05		
Post	16	6	3.65–7.25		
Quality of hearing				-1.321	0.187
Pre	16	5.7	3.97–6.88		
Post	16	5.7	5.1–7.4		
HHIE					
Total				-3.3130	0.002**
Pre	16	42	20.5–75.5		
Post	16	15	5–31.5		
Emotional				-3.3126	0.002**
Pre	16	27	14.5–45		
Post	16	11	2.5–17		
Social				-2.445	0.014*
Pre	16	21	6.5–29.5		
Post	16	5	2–17.5		

SSQ = Speech, Spatial and Qualities of Hearing Scale, HHIE = Hearing Handicap Inventory for the Elderly.

 Statistically significant differences are indicated with an asterisk (* $P < 0.05$, ** $P < 0.01$).

in the emotion ($Z = -3.126$, $P = 0.002$) and social ($Z = -2.445$, $P = 0.014$) domains statistically significantly decreased. The total SSQ scores increased ($Z = -2.216$, $P = 0.027$). SSQ scores in the domain of speech ($Z = -2.457$, $P = 0.014$) and spatial ($Z = -2.330$, $P = 0.020$) statistically significantly improved. However, the score in the quality of hearing domain did not show any statistical significance ($Z = -1.321$, $P = 0.187$) (Table 2).

Postoperative complications included five minor complications and one major complication. The minor complications included irritation and mild inflammation of the skin which recovered entirely after using antibiotics for one to two weeks. For the major complication, one patient's abutment became loose after six weeks. The patient underwent revision surgery and was excluded from the study.

DISCUSSION

Age-related hearing loss is common in South Korea. The general prevalence of subjective hearing loss was 12.0% and 44.7% of elderly people (> 70 years old) reported hearing

loss.¹⁸ Accordingly, the hearing rehabilitation market is growing rapidly. In particular, bone conduction hearing aids have recently been improved in terms of performance with the development of technology and surgical techniques and the devices have been evaluated as a good means of compensating for conductive and mixed hearing loss and SSD. In a cross-sectional, nationwide, and population-based survey in Korea, the prevalence of unilateral hearing loss including SSD was 5.55% and the prevalence of SSD (worse ear > 70 dB) was 1.74%. However, hearing aid adoption rate in patients with unilateral hearing loss was only 1.56%.¹⁹ Thus, the role of BCD for proactive rehabilitation in this specific clinical population is becoming important.

Pros and cons of various types of bone conduction hearing aids should be considered prior to surgery. Transcutaneous type of BCD has gained popularity and there have been many studies regarding this type of BCD. However, there have been few studies on the recently developed percutaneous type device, Ponto, especially in terms of objective assessments of its clinical effectiveness.

The transcutaneous bone conduction device has also been studied in Korea.²⁰ According to this study, a transcutaneous type bone conduction device (Cochlear™ Baha® Attract System with Baha® 5 sound processor) was used. There is no exact value, but the postoperative puretone threshold was close to bone conduction threshold of the better ear before surgery and WRS was improved approximately 30%. This is similar to our study in which threshold was significantly improved from 73.17 dB HL to 36.72 dB HL at three months after surgery and in the case of speech perception which was significantly improved from 26.0% to 90.75%, which gave better results in our study.

The authors found a significant improvement in both summation and head shadow effects following Ponto surgery. This improvement is especially important in patients with asymmetric hearing loss or SSD. However, no differences were observed in the squelch effect condition. A possible explanation for this result is that noise which can be ignored without the device can be transferred to the better hearing side interfering with sound processing in the auditory system.

In addition to the binaural benefit of Ponto implantation, this is the first study to objectively and subjectively investigate listening effort with Ponto. The degree of pupil dilatation decreased overall, although statistical significance was not observed. However, the questionnaire results showed the reduction of subjective listening effort. This result is in line with results from another study that analyzed listening effort exerted by the bone-anchored hearing system. The pupil dilatation decreased statistically significantly after BCD use, especially in a noisy environment.²¹ This reduction of subjective listening effort may be due to the improvement in audibility and this can be another benefit of Ponto implantation.

Comparing the HHIE and SSQ scores before and after the implantation, patients showed significantly improved subjective hearing, especially in the emotional and speech portion of the hearing scale as well as decrease in their hearing handicap. Improvement in binaural listening ability, subjective listening effort, and audibility may have affected satisfaction following implantation.

To reduce skin complications after surgery, we have strictly followed the minimally invasive surgical principles, especially concerning minimal or no soft tissue reduction.

Our complication rates were similar to those reported in other literature.^{22,23} One major complication, explantation, occurred at six weeks post-operation due to osseointegration failure. To avoid osseointegration failure, both continuous irrigation during drilling and maintaining the axis of drill burr during drilling seem to be important. Other than this major complication, skin problems after implantation were minimal.

Despite the fewer skin complications with transcutaneous system, percutaneous devices have higher maximum output than transcutaneous devices.²⁴ For the transcutaneous system, sound needs to get transmitted through the skin, resulting in losses of up to 7 dB for sound transmission.²⁵⁻²⁷ In addition, since percutaneous devices do not have a magnet implanted inside, they have an advantage regarding magnetic resonance imaging (MRI) compatibility which is especially important for the elderly than transcutaneous devices with internal magnet and external spacer magnets.

Although percutaneous devices have demonstrated successful outcomes, one should be aware of some drawbacks.^{28,29} Firstly, the implant site for percutaneous coupling requires lifelong care otherwise patients might experience adverse skin reactions. Secondly, patients might lose their devices due to infection or lack of osseointegration. Dun et al.³⁰ assessed more than 1,000 percutaneous BCDs and reported that 8.3% of the implants (94 implants) were lost or removed due to infection and lack of osseointegration for adults. Thus, it is crucial to consider skin complications, MRI compatibility, and device output during device selection.

In conclusion, percutaneous stimulation through a recently introduced BCD, Ponto, is beneficial for Korean patients with conductive and mixed hearing loss and SSD. In particular, it significantly improves speech perception in noise by overcoming the head shadow effect.

SUPPLEMENTARY MATERIAL

Supplementary Data 1

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