OPEN

The Oticon Ponto System in Adults With Severe-to-Profound and Mixed Hearing Loss: Audiologic Outcomes and Patient Satisfaction

*†‡Piotr Henryk Skarzynski, §Beata Dziendziel, §Elzbieta Wlodarczyk, and ||Henryk Skarzynski

*Teleaudiology and Screening Department, World Hearing Center, Institute of Physiology and Pathology of Hearing, Kajetany, Poland; †Heart Failure and Cardiac Rehabilitation Department, Faculty of Medicine, Medical University of Warsaw, Poland; ‡Institute of Sensory Organs, Kajetany, Poland; §Rehabilitation Clinic, World Hearing Center, Institute of Physiology and Pathology of Hearing, Kajetany, Polnad; and ||Otorhinolaryngosurgery Clinic, World Hearing Center, Institute of Physiology and Pathology of Hearing, Kajetany, Poland

Objective: To measure audiologic outcomes and self-assessed satisfaction with the Ponto system in a group of patients who had severe to profound and mixed hearing loss.
Study Design: Retrospective case review.
Setting: Tertiary referral center.
Patients: Sixteen patients aged 21 to 74 years with severe-to-profound and mixed hearing loss (bone conduction thresholds, ≥45 dB HL).
Interventions: Ponto implant surgery.
Main Outcome Measure(s): Pure-tone audiometry, free-field hearing thresholds, effective gain, word recognition score in quiet, and speech reception threshold (SRT) in noise were assessed. Patient-reported outcomes were collected using the Clinical Global Impression Scale, Glasgow Benefit Inventory, and Abbreviated Profile of Hearing Aid Benefit. Information concerning any medical complications was also gathered.
Results: Both word recognition score and SRT were significantly better after 12 months compared with before surgery. At normal speech level (65 dB SPL), 12 of 16 users had speech discrimination ≥70%. However, at the 12-month follow-up, the average effective gain was −6.2 dB. In general, the self-report outcomes showed good satisfaction in most patients. Postoperatively, skin complications were noted in six patients, of whom two underwent reoperation. All patients were still using the Ponto after an average observation time of 2.7 years.
Conclusion: Although skin complications were not uncommon, the Ponto system seems to be an effective method of improving hearing performance and provides subjective satisfaction in real-life situations in patients with severe-to-profound and mixed hearing loss. However, considering the significantly increased bone conduction thresholds and the risk of their further deterioration, long-term follow-up is still needed.
Key Words: Bone conduction—Complications—Hearing loss—Implantation—Oticon Ponto—Quality of life.

Otol Neurotol **43:**987–994, 2022.

INTRODUCTION

Bone-anchored hearing implants (BAHIs) are widely used for hearing rehabilitation of patients with conductive or mixed hearing loss as well as for those with single-sided deafness. There are two percutaneous solutions currently on the market: the BAHA Connect (Cochlear Bone Anchored Solutions AG, Mölnlycke, Sweden) and the Ponto (Oticon Medical AB, Askim, Sweden). BAHIs bypass the middle ear by conveying vibration, generated by an external sound processor, to the inner ear via a skin-penetrating abutment and a screw implanted in the mastoid bone (1). Survival rates of BAHI systems are high, varying from 74% to 98% (2–4). However, complications, such as inflammation of the skin around the percutaneous abutment, pain, and even implant loss, have been reported (2,5).

In the center where we work, transcutaneous solutions are our first choice because they avoid such complications (6–8), although, sometimes, two-stage surgery is needed in patients who have previously undergone radical modified surgery (9,10). However, there is another group of patients with severe-to-profound and mixed hearing loss whose requirements extend beyond transcutaneous solutions. Perhaps, because of resistant chronic otitis, a complex surgical history, or congenital malformation of the ear, use of conventional hearing aids is not possible. Bone conduction hearing aids also have limited applicability when the audiologic indications are poor (11). At this point, there is a need for an alternative percutaneous solution that has a wider indication range and which can compensate for hearing loss involving bone conduction thresholds of up to 65 dB.

Address correspondence and reprint requests to Piotr Henryk Skarzynski, Ph.D., M.Sc., M.D., Mokra 17 Street, 05-830 Nadarzyn, Poland; E-mail: p.skarzynski@ifps.org.pl

The authors disclose no conflicts of interest.

DOI: 10.1097/MAO.0000000000003664

The Ponto BAHI is a relatively new solution (compared with BAHAs) and was introduced on the market in 2009 (12). Since then, effectiveness of the Ponto has been reported in terms of audiologic and self-report outcomes, intraoperative and postoperative adverse events, comparison of various models of implant and sound processor, and different surgical techniques (2,13–18). However, in the latest systematic literature review, Lagerkvist et al. (19) say that the effectiveness of Ponto in patients with severe-to-profound and mixed hearing loss (with bone conduction thresholds greater than 45 dB HL) has not been fully assessed.

This study, therefore, aims to investigate the audiologic effectiveness of the Ponto system in such patients. Because hearing loss has psychosocial consequences and can cause constant emotional tension that cannot be predicted from audiometric data alone, a second aim of this study was to assess the change in hearing and quality of life from the patient's perspective.

MATERIALS AND METHODS

Patients and Study Design

A database consisting of medical records of patients who had undergone a Ponto implantation between July 2015 and September 2020 in our tertiary referral ENT center was carefully examined. The eligibility criteria were as follows:

- age, ≥18 years;
- preoperative severe-to-profound hearing impairment according to the Bureau International d'Audiophonologie recommendations (20);
- preoperative bone thresholds average (at frequencies: 0.5, 1, 2, and 4 kHz) ≥ 45 dB HL;
- a minimum of 12 months follow-up.

The analysis of each patient's treatment and audiologic outcomes was based on full medical documentation. This study was conducted in accordance with the ethical standards of the institutional review board and conformed with the Helsinki Declaration. Because of the retrospective nature of the study, no specific informed consent was obtained from the participants.

Audiometric Testing

Hearing thresholds for air conduction (AC) and bone conduction (BC) were assessed on all patients three times: before surgery and at 1 and 12 months after sound processor activation. The pure tone average (PTA_4) for AC and BC was determined at 0.5, 1, 2, and 4 kHz.

The free-field hearing thresholds, word recognition score (WRS), and speech reception threshold (SRT) in noise were assessed before surgery and 6 and 12 months afterwards. All tests were performed in free-field under unaided and aided condition (i.e., without and with the processor). A loudspeaker was positioned 1 m in front of the subject (S0 azimuth). During the free-field hearing thresholds and WRS tests, the contralateral side was plugged and additionally covered with an over-the-ear phone or masked with 70 dB narrowband noise (if the interaural difference for PTA_4 for AC was over 30 dB). For the matrix test, only double blocks of the nonoperated ear were used.

The free-field hearing thresholds were assessed at 0.5, 1, 2, and 4 kHz. The effective gain was evaluated 12 months after surgery and calculated as the difference between the PTA_4 for BC and the average free-field hearing threshold in the aided condition.

WRS was assessed with the Demenko & Pruszewicz Polish Monosyllabic Word Test performed under unaided and aided configurations in quiet at 50, 65, and 80 dB SPL.

SRT in noise were assessed using the Polish Matrix Sentence Test (21) with signal and noise presented from the front (S0N0). The noise level was fixed at 65 dB SPL and the signal level was changed adaptively. The maximum value of SRT was 15.5 dB (i.e., the point at which there was lack of understanding of speech in noise).

Self-Report Questionnaire

Self-reported patient outcomes were collected using the Clinical Global Impression Scale (CGI-S) (22), the Glasgow Benefit Inventory (GBI) (23), and the Abbreviated Profile of Hearing Aid Benefit (APHAB) (24).

The CGI-S is a short tool used to assess change in a patient's condition. In our study, patients were asked to assess the change in their hearing and the change in their general quality of life 12 months after Ponto sound processor activation in comparison with the state before surgery. The answers consisted of a seven-point scale with the degrees: 1, very much improved; 2, much improved; 3, minimally improved; 4, no change; 5, minimally worse; 6, much worse; 7, very much worse.

The GBI is an instrument to measure patient benefit developed especially for otorhinolaryngologic interventions. The questionnaire consists of 18 items on a five-point Likert scale, which address change in health status after an intervention. The responses range from −100 (maximum negative benefit) to 0 (no benefit) to +100 (maximum benefit). The GBI was filled in once, 12 months after activation of the sound processor.

The APHAB is the most widely used hearing-specific questionnaire among Polish audiology patients. APHAB comprises 24 items divided into four subscales: ease of communication (EC), background noise (BN), reverberation (RV), and aversiveness (AV). The first three subscales (EC, RV, and BN) address speech understanding in various everyday environments, while AV quantifies negative reactions to environmental sounds. APHAB was filled in before implantation and 12 months after sound processor activation. The change in hearing was calculated by subtracting the postoperative result from the preoperative result.

Surgery

All surgical procedures were performed by two senior surgeons. In all cases, a wide Ponto implant, diameter of 4.5 mm and length of 4 mm, was placed in a one-stage surgical procedure under general anesthesia.

Over the last 5 years, different surgical techniques for inserting implants in the temporal bone have been used in our center. For the first five patients operated in 2015, a linear incision technique with peri-implant soft-tissue reduction (skin thinning) was performed as originally described by de Wolf et al. (25). In these patients, a 6-mm abutment length was used. For the next nine patients, a Minimally Invasive Ponto Surgery (MIPS) technique (Oticon Medical, Somerset, NJ) involving a surgical punch technique (4-mm punch) described in previous articles (16,18,26) was used. For these cases, the abutment length was 9 mm. In two patients, a linear incision without soft tissue thinning (first described by Hultcrantz et al. (27)) was done and a 9-mm abutment was used. The reason for perforation was bleeding after the first step of the MIPS technique—punch puncture of the skin and subcutaneous tissue. In such cases, coagulation might impair wound healing, and there was a need to stop bleeding from the emissary vein. Punch puncture was performed with a superior and inferior cut. Bleeding was secured and a drill was used to prepare a place for screws. It was important

to assess the subcutaneous tissue and adjust abutment length accordingly (6, 9, or 12 mm).

Dressing removal was 10 days after surgery. Skin reaction around the implant was assessed for all patients postsurgery according to the Holgers scale (28).

All patients were fitted with an external processor (Ponto Pro Power, Ponto 3 Power, or Ponto 3 SuperPower). The sound processor was activated 6 to 8 weeks after implantation in the case of 11 patients and after 10 weeks in three patients. The other two patients had activation at 10 weeks reoperation.

Statistical Analysis

A Shapiro-Wilk test was used to test the assumption of normality. If the assumption of normality was met, paired-sample *t* tests were conducted to compare preoperative and postoperative results. To assess postoperative GBI results, a one-sample *t*-test was used. The level of statistical significance was set at $p < 0.05$. For statistical analysis, IBM SPSS Statistics v.24 software (IBM Corp, 2016, Armonk, NY) was used.

RESULTS

Study Setting and Patient Selection

There were 38 patients who underwent Ponto implantation during the study period. Of these, 18 met the inclusion criteria. Two patients who were lost from follow-up were excluded. The final study group included 16 patients. Patient information is summarized in Table 1.

Age at implantation ranged from 21 to 74 years with a mean of 50.9 years (standard deviation [SD] = 16.6 yr). In 15 patients, the hearing loss was bilateral, although all patients were implanted unilaterally. In two patients (Patients 5 and 6), the implantation procedure was performed in the better hearing ear because their BC thresholds in the poorer ear were beyond the audiologic indications for BAHIs. The etiology of hearing loss in our group of patients included chronic otitis media (COM), cholesteatoma, and congenital malformations of the middle or outer ear.

Surgical Outcomes and Adverse Events

Intraoperatively, one patient (Patient 4) had emissary vein bleeding after the periosteum was exposed, which was corrected with wax. A somewhat spongy bone was confirmed in two patients (Patients 3 and 6). There were no symptoms in preoperative diagnosis that could pose any problem, but especially in the case of those patients who had middle ear surgery (e.g., canal wall up or canal wall down), the consistency of the bone might be soft. In these patients, the sound processor was activated 10 weeks after implantation.

At dressing removal, good wound healing (Holgers Grade 0 or 1) around the abutment was found in 10 of 16 patients. In four patients (Patients 4, 6, 8, and 15), minor complications such as slight redness and moist tissue without granulation formation (Holgers Grade 2) was observed. After local treatment (and checks at extra visits), these symptoms disappeared within 6 weeks. However, one patient (Patient 8) reported slight numbness of the skin around the abutment and periodic pain that persisted throughout the postoperative follow-up period. Major complications assessed as Holgers Grade 4 were noted in two patients (Patients 7 and 11); because of persistent skin infection around the abutment and a lack of response to treatment, reoperation was required.

In Patient 7, 5 weeks after the initial surgery, inflammatory and granulation tissues were removed. At postoperative extra visits, healing was normal (Holgers Grade 0) and activation was done after 10 weeks. In Patient 11, 6 weeks after the initial surgery, the abutment (without implant) was removed and so was necrotic tissue. After 3 months, the abutment was placed and connected to the implant under local anesthesia. Four weeks later a second revision was performed involving the removal of skin overgrowth. Ten weeks later, activation was done. The patient reported periodic itching and aching skin at the abutment site lasting up to 1 year.

At the 12-month postoperative follow-up, slight redness requiring local treatment (Holgers Grade 2) was noted in three patients (Patients 5, 9, and 16) in whom no complications had previously been reported. All patients were still using the Ponto after an average observation time of 2.7 years (minimum, 1.1 yr; maximum, 4.9 yr).

Audiometry and Speech Tests

Preoperative hearing thresholds for air and bone condition in the implanted and nonimplanted ear for each patient are shown in Table 2.

Preoperatively, PTA_4 for AC thresholds was between 75 and 98.75 dB HL (median [Me] = 83.1 dB HL) and remained stable in all subjects (i.e., there was a threshold shift of less than ±10 dB HL) both at the 1 month follow-up (preoperative versus 1 mo, $t = 2.18$; $p = 0.045$) and at the 12-month follow-up (pre versus 12 mo, $t = 2.45$; $p = 0.027$).

Likewise, PTA_4 for BC thresholds was between 45 and 56.25 dB HL (Me = 46.25 dB) and remained stable in all subjects both at the short-term follow-up (pre versus 1 month, $t = 0.70$; $p = 0.493$) and at the long-term follow-up (pre versus 12 mo, $t = 1.15$; $p = 0.270$).

Average free-field hearing thresholds decreased from 79.2 dB HL (SD = 8.09 dB HL; Me = 78.75 dB HL) to 53.1 dB HL (SD = 5.02 dB HL; Me = 52.5 dB HL) after 6 months and to 54.5 dB HL (SD = 4.72 dB HL; Me = 53.75 dB HL) after 12 months. At both timeframes, the mean thresholds were significantly lower than before surgery (pre versus 6 mo, $t = 15.11$; $p < 0.001$ and pre versus 12 mo, $t = 15.57$; $p < 0.001$). At the 12-month follow-up, the PTA_4 for BC was 48.1 dB, and average free-field hearing with Ponto was 54.5 dB, which indicated an average effective gain of −6.2 dB.

The average WRS results are presented in Figure 1. For all three level settings (50, 65, and 80 dB), WRS increased significantly from (respectively) 0%, 1%, and 16% before surgery to 34%, 70%, and 84% after 6 months and to 32%, 75%, and 88% after 12 months. For both timeframes, average WRS was significantly higher than before intervention (pre versus 6 mo, $t = 11.44$; $p < 0.001$ and pre versus 12 mo, $t = 13.80$; $p < 0.001$).

Average SRT results are presented in Figure 2. Patient 11 was excluded from the analysis because of significant problems remembering words during the test. SRT in noise decreased

TABLE 1. *Patient characteristics*

Patient	Age at Implantation	Sex	Implant Side	HL Side	Cause of HL	Previous Surgery (Implanted Side)	HA Before Surgery	Surgery Technique	Abutment (mm)	Processor Type
1	41	F	Left	Bilateral	congenital malformations of the middle or outer ear; COM; cholesteatoma	Radical mastoidectomy; revision after radical mastoidectomy	Nonoperated ear	linear incision with skin thinning	6	Ponto Pro Power
2	64	F	Left	Bilateral	COM; cholesteatoma	Myringoossiculoplasty; radical mastoidectomy; 3× revision after radical mastoidectomy	No	linear incision with skin thinning	6	Ponto Pro Power
3	65	M	Right	Bilateral	COM; cholesteatoma	Radical mastoidectomy; revision after radical mastoidectomy	Nonoperated ear	linear incision with skin thinning	6	Ponto Pro Power
4	63	F	Right	Bilateral	COM	2× Myringoossiculoplasty	Nonoperated ear	linear incision with skin thinning	6	Ponto Pro Power
5	64	M	Left	Bilateral	COM	2× Myringoossiculoplasty; antromastoidectomy	No	linear incision with skin thinning	6	Ponto Pro Power
6	68	M	Left	Bilateral	COM; cholesteatoma	2× Myringoossiculoplasty; radical mastoidectomy; revision after radical mastoidectomy	No	MIPS	9	Ponto 3 Power
7	39	F	Left	Bilateral	congenital defect outer ear (craniofacial malformation)	No	No	MIPS	9	Ponto 3 Power
8	59	F	Left	Bilateral	COM	Antromastoidectomy; 2× tympanoplasty	No	MIPS	9	Ponto 3 Power
9	30	M	Right	Unilateral	COM; cholesteatoma	Radical mastoidectomy; revision after radical mastoidectomy	No	linear incision without skin thinning	9	Ponto 3 Power
10	60	M	Left	Bilateral	COM	2× Myringoossiculoplasty;	No	MIPS	9	Ponto 3 Power
11	74	F	Left	Bilateral	COM; cholesteatoma	3× Myringoossiculoplasty; radical mastoidectomy; revision after radical mastoidectomy	Nonoperated ear	linear incision without skin thinning	9	Ponto 3 SuperPower
12	54	M	Right	Bilateral	COM; cholesteatoma	Myringoossiculoplasty; radical mastoidectomy; 3× revision after radical mastoidectomy	No	MIPS	9	Ponto 3 SuperPower
13	21	M	Right	Bilateral	COM	2× Myringoossiculoplasty	No	MIPS	9	Ponto 3 Power
14	47	F	Right	Bilateral	COM; congenital defect middle ear; Turner syndrome	2× Myringoossiculoplasty	Bilateral	MIPS	9	Ponto 3 SuperPower
15	22	M	Left	Bilateral	COM	4× Myringoossiculoplasty	No	MIPS	9	Ponto 3 SuperPower
16	44	F	Right	Bilateral	COM	2× Myringoossiculoplasty	No	MIPS	9	Ponto 3 SuperPower

COM indicates chronic otitis media; F, female; HA, hearing aid; HL, hearing loss; M, male; MIPS, Minimally Invasive Ponto Surgery.

TABLE 2. *Preoperative hearing thresholds for air and bone condition in the implanted and nonimplanted ear*

Patient			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Implanted ear	AC	500 Hz	100	95	70	65	55	60	85	75	75	80	85	70	60	85	80	90
		1,000 Hz	105	90	75	75	75	75	90	80	110	85	70	85	65	75	85	85
		2000 Hz	90	100	75	80	110	75	95	80	80	75	70	75	70	70	85	85
		4,000 Hz	100	110	80	80	100	95	110	100	85	90	80	90	110	80	95	95
	BC	500 Hz	55	35	35	25	30	20	30	30	30	30	40	35	25	30	40	45
		1,000 Hz	60	45	35	40	50	35	35	50	55	40	40	45	35	45	55	40
		2000 Hz	50	55	50	55	55	60	45	50	45	50	50	45	45	50	60	50
		4,000 Hz	55	65	60	70	45	65	70	55	50	60	55	65	75	60	70	75
Nonimplanted ear	AC	500 Hz	95	20	10	70	105	70	35	25	10	10	75	10	25	85	15	30
		1,000 Hz	90	15	45	70	100	90	55	30	5	25	55	25	25	80	30	25
		2000 Hz	95	30	80	75	100	105	35	30	5	30	45	30	10	60	25	35
		4,000 Hz	100	45	90	70	100	110	75	45	5	80	70	80	45	65	45	35
	BC	500 Hz	50	15	5	45	60	55	20	20	5	5	40	5	0	40	5	20
		1,000 Hz	50	10	40	40	70	65	40	25	0	20	25	20	5	45	25	20
		2000 Hz	70	25	60	40	70	75	30	25	0	25	15	25	5	40	20	30
		4,000 Hz	65	40	75	35	65	75	65	40	0	75	35	75	30	50	40	30

AC indicates air conduction; BC, bone conduction.

from 14.07 dB signal-to-noise ratio (SNR) (SD = 3.17 dB; Me = 15.5 dB) before surgery to 6.32 dB SNR (SD = 4.99 dB; Me = 7.6 dB) after 6 months and 6.17 dB SNR (SD = 4.38 dB; Me = 6.8 dB) after 12 months, respectively. At both timeframes the average WRS was significantly lower than before intervention (pre versus 6 mo, $t = 7.60$; $p < 0.001$ and pre versus 12 mo, $t = 9.27$; $p < 0.001$).

Patient-Reported Outcomes

The results of 15 of 16 patients were included in the analysis (Patient 1 refused to fill in the questionnaires).

According to the CGI-S questionnaire, 14 of 15 patients reported that their hearing after implantation was much improved or very much improved. Just one patient (Patient 8) reported only minimal improvement in hearing. For the quality of life (QoL) question, 13 of 15 patients reported it was much improved or very much improved; for the other two (Patients 8 and 9), the QoL improved minimally.

The average GBI total score was 38.7 points (SD = 18.8; Me = 36.1) and was statistically significantly higher than 0 ($t = 7.98$; $p < 0.001$). When GBI total score was analyzed for each patient individually, it was found that all patients experienced an increase in QoL after implantation.

Analysis of the average APHAB scores obtained before and 12 months after implantation showed that after Ponto implantation, there was a decrease in the degree of difficulty with everyday speech communication for the first three subscales (Fig. 3). Global scores decreased from 70.2% (SD = 17.6%; Me = 72.4%) before surgery to 34.5% (SD = 16.2%; Me = 27.0%) after 12 months and was statistically significant ($t = 8.63$; $p < 0.001$).

DISCUSSION

Patients with severe-to-profound mixed hearing loss pose a unique challenge for specialists. Because of the significantly increased bone conduction thresholds, sufficient amplification and speech understanding cannot always be assured.

The results of the present study showed that, in general, the Ponto provided favorable audiologic outcomes and subjective benefits compared to the unaided condition. Audiometric results confirmed no deterioration in AC and BC thresholds.

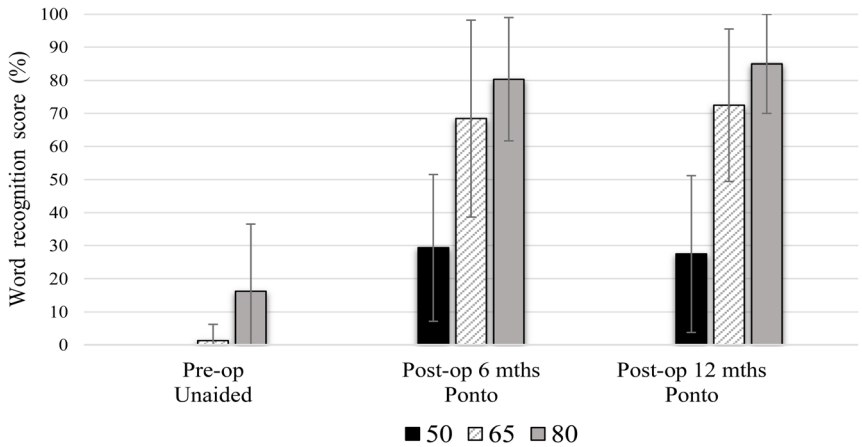

FIG. 1. WRS results at 50, 65, and 80 dB preoperatively, and at 6 and 12 months postoperatively. The error bars represent SDs. SD indicates standard deviation; WRS, word recognition score.

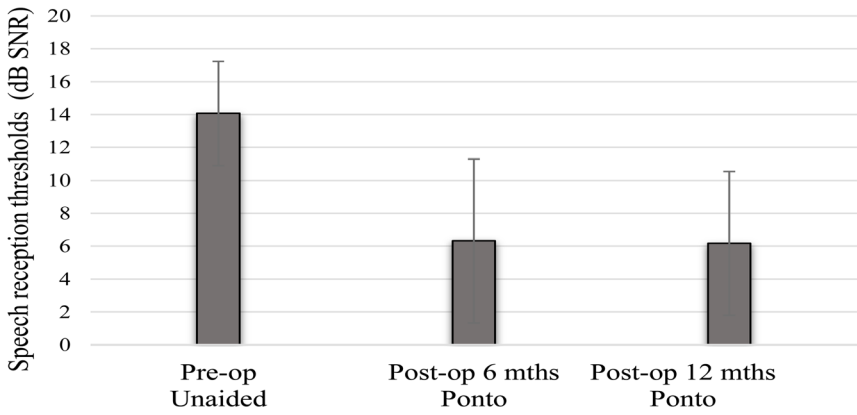

FIG. 2. SRTs in noise preoperatively, and at 6 and 12 months postoperatively. SRT indicates speech reception threshold.

The efficacy outcome of most studies is the gain of the device expressed as "functional gain," which, by definition, is the difference between aided and unaided sound-field thresholds (29). According to previous reports, the functional gain provided by the Ponto has been found to be 29 to 33 dB (1,30–34). However, in mixed or conductive hearing loss, such a measure (functional gain as expressed by the air-bone gap) is not a true reflection of the status of the malfunctioning middle ear. That is, the air-bone gap directly affects the "functional gain" value: the larger the air-bone gap, the higher the "functional gain" of any device that bypasses the middle ear will be (29). Therefore, we evaluated the efficacy of the Ponto in mixed hearing loss in terms of "effective gain." In our study, we obtained a negative gain of 6.2 dB. In comparison, the results of previous studies published by Pérez-Carbonell et al. (35) and Bosman et al. (36) reported a positive gain of approximately 5 dB in groups of patients with severe-mixed hearing loss. Nevertheless, our results are difficult to compare with these results. First, Pérez-Carbonell et al. (35), in a group of six patients, presented the average free-field hearing thresholds over a wide range of tested frequencies, but omitted 2 kHz. Second, Bosman et al. (36) presented the results for average BC thresholds and aided free-field thresholds (calculated for 0.5, 1, 2, 4 kHz) in the device expressed in 25%, 50%, and 75% percentiles. In their group of 10 patients, the Me for BC was 42.8 dB, and 36.8 dB for aided free-field thresholds; however, the average values are not provided. Thirdly, in our study, in nine subjects with asymmetric hearing loss, we used active narrowband noise masking of the nonimplanted ear, which may also affect the results of aided free-field thresholds. Because of the retrospective nature of the study, the limitations of our results should be emphasized.

Be that as it may, significant improvements were observed in the free-field speech test. At the 1-year follow-up, 75% of Ponto users achieved speech discrimination ≥70% in quiet at normal speech level (65 dB SPL). In comparison, before surgery the highest unaided speech discrimination score was only 20%. Similarly, for most patients the SRT in noise values using Ponto were better than in the unaided condition. Speech recognition tests in noise are valuable for assessing auditory benefits after implantation. In either our matrix test,

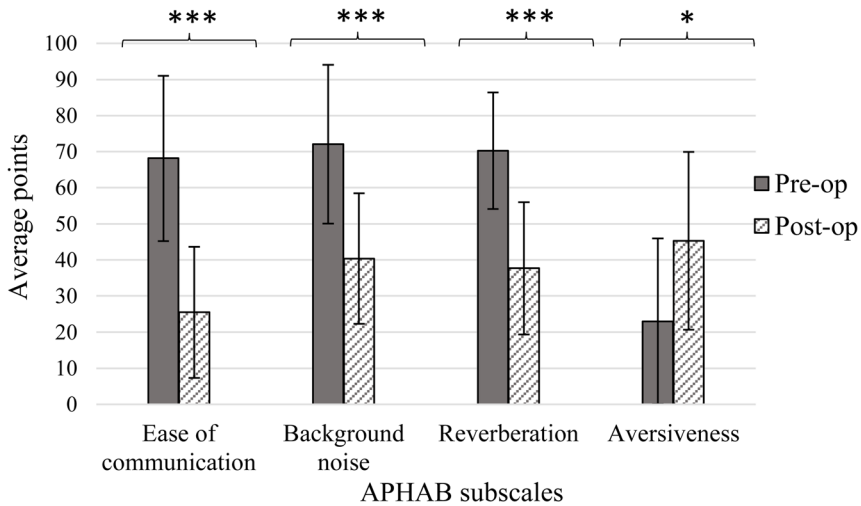

FIG. 3. Average APHAB subscale scores preoperatively and at 12 months postoperatively. The error bars represent standard deviations. ***$p < 0.001$; *$p < 0.05$. APHAB indicates Abbreviated Profile of Hearing Aid Benefit.

as well as with the previously published studies by Pérez-Carbonell et al. (35) and Bosman et al. (36), a fixed noise of 65 dB was used. However, it is worth noting some limitations of such tests in a group of patients with mixed severe to profound hearing loss. First, the presented noise level may not be audible to these patients. Second, in the matrix test the maximum value of SRT is only 15.5 dB (which is interpreted as a total lack of understanding of speech in noise). However, we assume that, in reality, the value of SRT for unaided conditions may be larger.

Assuming that severe hearing loss significantly affects a patient's daily functioning, the major goal of Ponto implantation was to improve the patient's quality of life. In terms of patient-reported outcomes, APHAB demonstrated that there was a significant reduction in hearing loss problems after surgery, especially in quiet. This is supported by the CGI-S results, where over 90% of patients reported much improved or very much improved hearing after surgery. For the GBI results, QoL generally improved in the aided condition compared to before implantation. Previous studies using the GBI questionnaire have shown that Ponto implantation has a positive effect (i.e., score >0) on QoL in over 92% of operated patients (1,33,37–39). The average total GBI score across these studies ranged from 32 to 39, which is in line with our outcomes. We, therefore, conclude that patients with severe-to-profound and mixed hearing loss generally have their QoL increased significantly after Ponto surgery. However, we note that in two patients (Patients 8 and 9), GBI and CGI-S scores showed only a minimal effect of medical intervention on their QoL. In Patient 8, one might hypothesize that the low level of satisfaction could be caused by only a small improvement in speech understanding (WRS = 40% at 65 dB SPL after 1 yr) and constant numbness and periodic pain around the abutment throughout the observation period. Patient 9 had unilateral hearing loss, which probably did not have a negative impact on his QoL before surgery. According to our clinical observations of cases of asymmetric hearing loss, where patients have considerably better hearing in the nonimplanted ear than in the implanted one, such patients tend to be dissatisfied with the hearing gain offered by the implant.

Despite the many design and surgical innovations in percutaneous implants, skin complications are still reported (15). According to Lagerkvist et al. (19), one in seven patients experience a skin reaction requiring treatment (classified as Holgers 2), and 0.4% of patients have skin reactions of Holgers 4 (the highest grading, often requiring removal of the abutment). In our group of 16 patients, based on monthly follow-ups, adverse events occurred in six of them, of which two had a major complication requiring reoperation. In long-term follow-up, minor skin complications occurred in four patients who had never had similar complications. We are not able to fully explain the observed complications. It is important to note that our study included all patients who met the inclusion criteria (which is less than 50% of operated patients). The reported postoperative complications do not seem to be associated with a specific surgical technique.

This study suffers from the weaknesses inherent in retrospective studies. In addition, the short follow-up time makes it impossible to assess the long-term implant survival. On the other hand, the strength of the current study is that it presents audiologic and subjective results in a homogeneous group of patients with severe-to-profound and mixed hearing loss (an average BC threshold of ≥45 dB). The results encourage us to develop a more detailed treatment program in our center for patients with severe-to-profound and mixed hearing loss based on the Ponto system.

CONCLUSION

Although skin complications are not uncommon, the Ponto system seems to be an effective method of improving hearing performance and provide subjective satisfaction in real-life situations in patients with severe-to-profound and mixed hearing loss. However, considering the significantly increased bone conduction thresholds and the risk of their further deterioration, long-term follow-up is still needed, looking both at implant survival and sustained hearing benefits.

REFERENCES

1. Caruso A, Giannuzzi AL, Sozzi V, Sanna M. Bone anchored hearing implants without skin thinning: the Gruppo Otologico surgical and audiological experience. *Eur Arch Otorhinolaryngol* 2017;274: 695–700.
2. Calon TGA, van Tongeren J, Heuft AME, et al. Percutaneous bone-anchored hearing system implant survival after 550 primary implant surgeries. *Clin Otolaryngol* 2018;43:735–9.
3. Dun CA, Faber HT, de Wolf MJ, et al. Assessment of more than 1,000 implanted percutaneous bone conduction devices: skin reactions and implant survival. *Otol Neurotol* 2012;33:192–8.
4. Larsson A, Tjellström A, Stalfors J. Implant losses for the bone-anchored hearing devices are more frequent in some patients. *Otol Neurotol* 2015; 36:336–40.
5. Kiringoda R, Lustig LR. A meta-analysis of the complications associated with osseointegrated hearing aids. *Otol Neurotol* 2013;34:790–4.
6. Ratuszniak A, Skarzynski PH, Gos E, Skarzynski H. The bonebridge implant in older children and adolescents with mixed or conductive hearing loss: audiological outcomes. *Int J Pediatr Otorhinolaryngol* 2019; 118:97–102.
7. Skarżyński PH, Ratuszniak A, Król B, et al. The bonebridge in adults with mixed and conductive hearing loss: audiological and quality of life outcomes. *Audiol Neurootol* 2019;24:90–9.
8. Mylanus EAM, Hua H, Wigren S, et al. Multicenter clinical investigation of a new active osseointegrated steady-state implant system. *Otol Neurotol* 2020;41:1249–57.
9. Król B, Porowski M, Cywka KB, Skarżyńska MB, Skarżyński PH. Mastoid obliteration with S53P4 bioactive glass can make bonebridge implantation feasible: a case report. *Am J Case Rep* 2020;21:e925914.
10. Król B, Cywka KB, Skarżyńska MB, Skarżyński PH. Implantation of the bonebridge BCI 602 after mastoid obliteration with S53P4 bioactive glass: a safe method of treating difficult anatomical conditions—preliminary results. *Life (Basel)* 2021;11:374.
11. Skarzynski PH, Ratuszniak A, Osinska K, et al. A comparative study of a novel adhesive bone conduction device and conventional treatment options for conductive hearing loss. *Otol Neurotol* 2019;40:858–64.
12. Westerkull P. The Ponto bone-anchored hearing system. *Adv Otorhinolaryngol* 2011;71:32–40.
13. Reznitsky M, Wielandt K, Foghsgaard S. Wide diameter bone-anchored hearing system implants: a comparison of long-term follow-up data between tissue reduction and tissue preservation techniques. *Eur Arch Otorhinolaryngol* 2019;276:349–56.
14. Kruyt IJ, Kok H, Bosman A, et al. Three-year clinical and audiological outcomes of percutaneous implants for bone conduction devices: comparison between tissue preservation technique and tissue reduction technique. *Otol Neurotol* 2019;40:335–43.

15. Bezdjian A, Smith RA, Thomeer HGXM, Willie BM, Daniel SJ. A systematic review on factors associated with percutaneous bone anchored hearing implants loss. *Otol Neurotol* 2018;39:e897–906.
16. Kim HHS, Kari E, Copeland BJ, et al. Standardization of the punch technique for the implantation of bone anchored auditory devices: evaluation of the MIPS surgical set. *Otol Neurotol* 2019;40:e631–5.
17. den Besten CA, Monksfield P, Bosman A, et al. Audiological and clinical outcomes of a transcutaneous bone conduction hearing implant: six-month results from a multicentre study. *Clin Otolaryngol* 2019; 44:144–57.
18. Wilson DF, Kim HH. A minimally invasive technique for the implantation of bone-anchored hearing devices. *Otolaryngol Head Neck Surg* 2013; 149:473–7.
19. Lagerkvist H, Carvalho K, Holmberg M, et al. Ten years of experience with the Ponto bone-anchored hearing system-a systematic literature review. *Clin Otolaryngol* 2020;45:667–80.
20. International Bureau for Audiophonology. BIAP Recommendation 02/1: audiometric classification of hearing impairmentst. WHO. Published 1996. http://www.who.int/deafness/hearing_impairment_grades/en/. Accessed July 29, 2020.
21. Ozimek E, Warzybok A, Kutzner D. Polish sentence matrix test for speech intelligibility measurement in noise. *Int J Audiol* 2010;49:444–54.
22. Busner J, Targum SD. The clinical global impressions scale: applying a research tool in clinical practice. *Psychiatry (Edgmont)* 2007;4:28–37.
23. Robinson K, Gatehouse S, Browning GG. Measuring patient benefit from otorhinolaryngological surgery and therapy. *Ann Otol Rhinol Laryngol* 1996;105:415–22.
24. Cox RM, Alexander GC. The abbreviated profile of hearing aid benefit. *Ear Hear* 1995;16:176–86.
25. de Wolf MJ, Hol MK, Huygen PL, Mylanus EA, Cremers CW. Clinical outcome of the simplified surgical technique for BAHA implantation. *Otol Neurotol* 2008;29:1100–8.
26. Gordon SA, Coelho DH. Minimally invasive surgery for osseointegrated auditory implants: a comparison of linear versus punch techniques. *Otolaryngol Head Neck Surg* 2015;152:1089–93.
27. Hultcrantz M. Outcome of the bone-anchored hearing aid procedure without skin thinning: a prospective clinical trial. *Otol Neurotol* 2011; 32:1134–9.
28. Holgers KM, Tjellström A, Bjursten LM, Erlandsson BE. Soft tissue reactions around percutaneous implants: a clinical study of soft tissue conditions around skin-penetrating titanium implants for bone-anchored hearing aids. *Am J Otolaryngol* 1988;9:56–9.
29. Snik A, Maier H, Hodgetts B, et al. Efficacy of auditory implants for patients with conductive and mixed hearing loss depends on implant center. *Otol Neurotol* 2019;40:430–5.
30. Bosman AJ, Snik AF, Hol MK, Mylanus EA. Evaluation of a new powerful bone-anchored hearing system: a comparison study. *J Am Acad Audiol* 2013;24:505–13.
31. Busch S, Giere T, Lenarz T, Maier H. Comparison of audiologic results and patient satisfaction for two osseointegrated bone conduction devices: results of a prospective study. *Otol Neurotol* 2015;36:842–8.
32. Celikgun B, Kalcioglu MT. Assessment of discrimination ability in ipsilateral and contralateral ears with a unilateral bone-anchored hearing system. *Ear Nose Throat J* 2017;96:297–310.
33. Rigato C, Reinfeldt S, Håkansson B, et al. Audiometric comparison between the first patients with the transcutaneous bone conduction implant and matched percutaneous bone anchored hearing device users. *Otol Neurotol* 2016;37:1381–7.
34. Wang Y, Fan X, Wang P, Fan Y, Chen X. Hearing improvement with softband and implanted bone-anchored hearing devices and modified implantation surgery in patients with bilateral microtia-atresia. *Int J Pediatr Otorhinolaryngol* 2018;104:120–5.
35. Pérez-Carbonell T, Pla-Gil I, Morant-Ventura A, et al. First experiences with the Ponto™ SuperPower osseointegrated device. *Acta Otorrinolaringol Esp* 2019;70:358–63.
36. Bosman AJ, Kruyt IJ, Mylanus EAM, Hol MKS, Snik AFM. On the evaluation of a superpower sound processor for bone-anchored hearing. *Clin Otolaryngol* 2018;43:450–5.
37. den Besten CA, Bosman AJ, Nelissen RC, Mylanus EA, Hol MK. Controlled clinical trial on bone-anchored hearing implants and a surgical technique with soft-tissue preservation. *Otol Neurotol* 2016; 37:504–12.
38. Nelissen RC, den Besten CA, Mylanus EA, Hol MK. Stability, survival, and tolerability of a 4.5-mm-wide bone-anchored hearing implant: 6-month data from a randomized controlled clinical trial. *Eur Arch Otorhinolaryngol* 2016;273:105–11.
39. Nelissen RC, Mylanus EA, Kunst HP, et al. A new bone-anchored hearing implant: short-term retrospective data on implant survival and subjective benefit. *Eur Arch Otorhinolaryngol* 2013;270:3019–25.