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.
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 (PTA4) 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 (50 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 PTA4 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 PTA4 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 otolaryngologic 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).

**Auditory 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, PTA4 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 \( \pm 10 \) 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, PTA4 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 PTA4 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; 3× revision after radical mastoidectomy | No | MIPS | 9            | Power |
| 7       | 39                   | F   | Left         | Bilateral | congenital defect outer ear (craniofacial malformation) | No | No | MIPS | 9            | Power |
| 8       | 59                   | F   | Left         | Bilateral | COM | Antromastoidectomy; 2× tympanoplasty | No | MIPS | 9            | Power |
| 9       | 30                   | M   | Right        | Unilateral | COM; cholesteatoma | Radical mastoidectomy; revision after radical mastoidectomy | No | linear incision without skin thinning | 9 | Power |
| 10      | 60                   | M   | Right        | Bilateral | COM | 2× Myringoossiculoplasty; | No | MIPS | 9            | 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 Power |
| 12      | 54                   | M   | Right        | Bilateral | COM; cholesteatoma | Myringoossiculoplasty; radical mastoidectomy; 3× revision after radical mastoidectomy | No | MIPS | 9 | Ponto 3 Power |
| 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 Power |
| 15      | 22                   | M   | Left         | Bilateral | COM | 4× Myringoossiculoplasty | No | MIPS | 9 | Ponto 3 Power |
| 16      | 44                   | F   | Right        | Bilateral | COM | 2× Myringoossiculoplasty | No | MIPS | 9 | Ponto 3 Power |

COM indicates chronic otitis media; F, female; HA, hearing aid; HL, hearing loss; M, male; MIPS, Minimally Invasive Ponto Surgery.
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 audiological outcomes and subjective benefits compared to the unaided condition. Audiometric results confirmed no deterioration in AC and BC thresholds.

| 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 | 90 | 80 | 110 | 85 | 80 | 75 | 70 | 70 | 70 | 85 | 85 | 85 |
| | 2,000 Hz | 90 | 100 | 75 | 80 | 110 | 75 | 95 | 80 | 80 | 75 | 70 | 75 | 70 | 85 | 85 | 85 | 85 |
| | 4,000 Hz | 100 | 110 | 80 | 80 | 100 | 95 | 110 | 100 | 85 | 90 | 80 | 90 | 110 | 80 | 95 | 95 | 95 |
| BC | 500 Hz | 55 | 35 | 35 | 25 | 20 | 30 | 30 | 30 | 40 | 45 | 35 | 35 | 40 | 45 | 45 | 55 | 40 |
| | 1,000 Hz | 60 | 45 | 35 | 40 | 50 | 35 | 35 | 50 | 55 | 40 | 45 | 35 | 45 | 45 | 45 | 55 | 40 |
| | 2,000 Hz | 50 | 55 | 50 | 55 | 55 | 60 | 45 | 50 | 45 | 50 | 45 | 45 | 50 | 60 | 50 | 50 | 50 |
| | 4,000 Hz | 55 | 65 | 60 | 70 | 45 | 65 | 65 | 70 | 55 | 60 | 55 | 65 | 57 | 60 | 70 | 75 | 75 |
| Nonimplanted ear AC | 500 Hz | 95 | 20 | 10 | 70 | 105 | 70 | 35 | 25 | 10 | 75 | 70 | 25 | 15 | 85 | 85 | 85 |
| | 1,000 Hz | 90 | 15 | 45 | 70 | 100 | 90 | 55 | 30 | 5 | 25 | 55 | 25 | 25 | 80 | 30 | 25 | 25 |
| | 2,000 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 |
| | 2,000 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.
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 was better than in the unaided condition. Speech recognition tests in noise are valuable for assessing auditory benefits after implantation. In either our matrix test,
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 experienced 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 ≥245 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.

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