

# Do complications of percutaneous osseointegration justify a switch to transcutaneous devices? A retrospective longitudinal study on complications

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 OPEN ACCESS

PEER REVIEWED

ORIGINAL RESEARCH

DOI: 10.51445/sja.auditio.vol7.2023.0089

Received: 15 . 09 . 2022

Reviewed: 05 . 12 . 2022

Accepted: 16 . 03 . 2023

Published: 02 . 11 . 2023

Edited by:

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How to cite

Núñez-Gutiérrez, M., Castro-Jiménez, J., Fernández-Nogueras Jiménez, F., Espinosa-Sánchez, J.M., García-Valdecasas, J. (2023).

Do complications of percutaneous osseointegration justify a switch to transcutaneous devices? A retrospective longitudinal study on complications. *Auditio*, 7, e89.

<https://doi.org/10.51445/sja.auditio.vol7.2023.0089>

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<https://journal.auditio.com/>

Publicación de la Asociación Española de Audiología (AEDA)  
Published by the Spanish Audiological Society (AEDA)

## Abstract

**Introduction:** Percutaneous bone conduction implants are the standard osseointegration model used to provide an alternative treatment option for conductive and mixed hearing loss. In recent years, the indications for these implants have increased, despite concerns about their use because of local complications.

The aim of this study was to describe the complications of percutaneous osseointegrated devices implanted at our hospital.

**Material and methods:** A retrospective longitudinal study was conducted in 57 consecutive patients who received a Baha®-type percutaneous bone conduction implantation. The main clinical indications were chronic otitis media and ear malformations. Local peri-implant complications were described using the Holgers classification.

**Results:** After a mean follow-up of 12 months (range: 4-48 months), 26.31% of patients had some type of peri-implant soft tissue complication. Only one patient (1.75%) had major reactions requiring removal of the implant. Complications in the paediatric age group were notably higher, affecting 42.85% of the children.

**Conclusions:** The local complication rate in our study was at the lower end of the range described in the literature, which reports a very wide range of rates, even reaching 70%. Most complications are minor and resolve with topical antibiotic treatment. However, the rate is higher in children.

## Keywords

Percutaneous bone conduction implant, local complications, Holgers, BAHA, Baha®.

### Clinical Implications

Major peri-implant skin reactions are rare. Switching to transcutaneous osseointegration is not justified for this reason alone. The most appropriate bone-anchored device should be selected on a patient-by-patient basis, considering primarily the audiological indication and hearing loss at high frequencies in particular, since the use of passive transcutaneous devices may hinder discrimination. The surgical team's experience and financial considerations must also be taken into account.

## Introduction

In recent years, bone conduction implants have received increasing acceptance and interest (Lavilla *et al.*, 2019). They are an effective treatment option in patients with conductive, mixed or profound sensorineural hearing loss with normal contralateral hearing and are increasingly used for both current and new indications (Lavilla Martín de Valmaseda *et al.*, 2019; Yuen *et al.*, 2009).

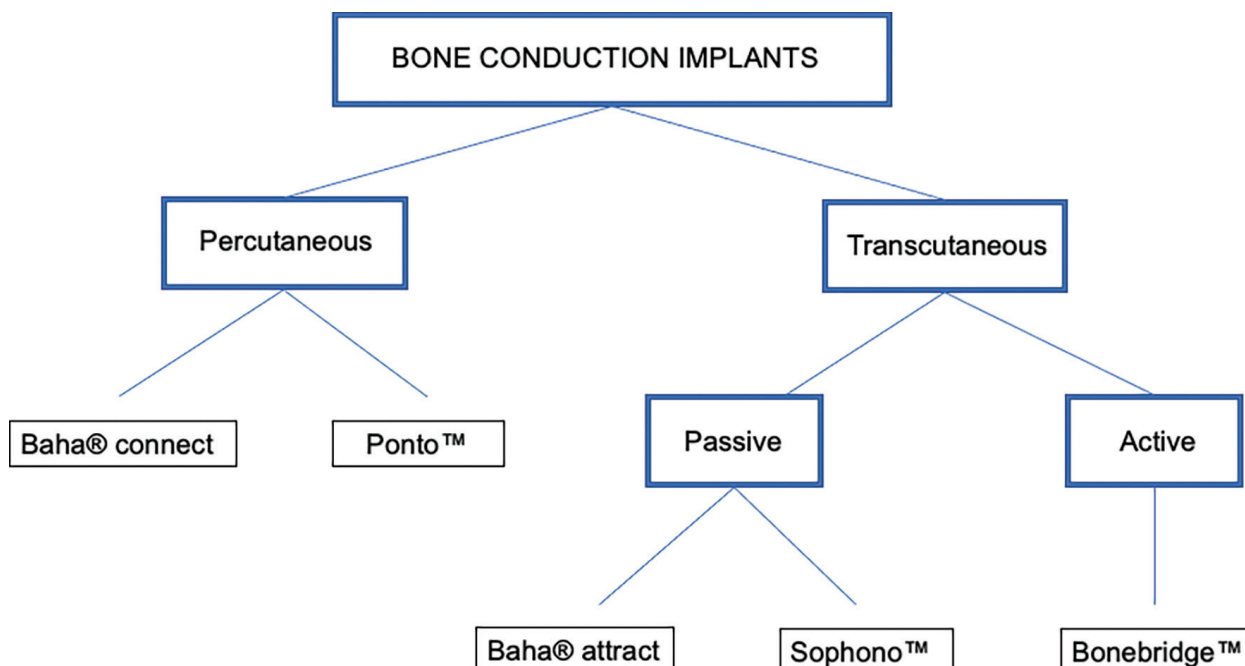
Bone conduction implants are semi-implantable medical devices consisting of an external processor, a microphone and an amplifier. They transmit sound to the cochlea, allowing intracochlear fluids to vibrate, bypassing the outer and middle ear (Lavilla Martín de Valmaseda *et al.*, 2019). The difference between percutaneous and transcutaneous bone conduction implants lies in the way the external processor and the implant are connected (Figure 1). Percutaneous systems have a direct connection between the two, whereby the implant emerges through the skin, while transcutaneous systems

involve communication through intact skin. Transcutaneous conduction systems are divided into passive or skin-drive devices (where vibrations are transmitted through intact skin by magnets) and active or direct-drive devices (where vibrations are generated directly by the implant; Lavilla Martín de Valmaseda *et al.*, 2019).

Passive transcutaneous devices consist of a titanium implant that is placed under the skin, with a baseplate that protrudes under the skin. Sound is transmitted through the intact skin from a passive transducer to the baseplate, whereas active transcutaneous devices are characterised by the vibration being generated directly by the implant after receiving the correctly processed sound (Reinfeldt *et al.*, 2015).

Osseointegration, as previously described in the literature is a phenomenon whereby bone tissue grows when it is in contact with a titanium implant, forming a structural and functional connection between the bone and the implant surface that allows sound transmission. (Brånemark *et al.*,

Figure 1. Types of bone conduction implants



2001; Tjellström *et al.*, 1981). Low-frequency sounds mainly travel through the frontal transmission pathway, but the high-frequency pathway is less well defined (Dufour-Fournier *et al.*, 2022). Bone conduction implants have subsequently been developed that require no titanium-component osseointegration (Bonebridge™; Zernotti and Sarasti, 2015).

Percutaneous bone conduction implants are the standard osseointegration model that provides excellent audiological results (especially at high frequencies), despite some cosmetic concerns. Percutaneous devices may be superior to transcutaneous devices due to the skin damping that occurs in this type of device of up to 5-20 dB for frequencies of 1 to 4 KHz (Verstraeten *et al.*, 2009). Transcutaneous devices provide a better cosmetic solution, which has led to increased use in recent years. Some authors have reported a lower rate of local complications using transcutaneous devices, which also appears to favour their use (Ellsperman *et al.*, 2021). Even so, the force required to hold the magnet in place and achieve good sound transmission can irritate the skin and percutaneous tissues, leading to necrosis in the worst cases (Chen *et al.*, 2017). The most frequent major complications of passive transcutaneous implants are seroma, haematoma, local infection and skin ulcers, which occur in 5.2% of all patients (Cooper *et al.*, 2017).

Surgical techniques in bone conduction device implantation have evolved over the last few decades. Currently, most procedures are performed as single-stage surgery under local or general anaesthesia, using a wide variety of incision approaches (Calon *et al.*, 2018). In paediatric patients, who have thinner cranial bone, osseointegration must occur before inserting the processor; and therefore, a two-stage procedure can be considered (Roman *et al.*, 2011; Verheij *et al.*, 2016). The conventional surgical procedure involves thinning the skin around the implant with the aim of ensuring adequate skin contact with the bone tissue while decreasing the risk of skin overgrowth and local infections (Cass and Mudd, 2010). To try to minimize local complications, new surgical techniques have been developed such as the linear incision technique without soft tissue reduction (den Besten *et al.*, 2016), the punch-only technique, and minimally invasive Ponto surgery (MIPS; Johansson *et al.*, 2017).

Skin condition and cranial thickness may influence the development of skin complications after percutaneous osseointegrated device implantation surgery. Patients with thin or fragile skin or a history of

skin diseases such as psoriasis or eczema may be at increased risk for skin irritation, pressure ulcers and post-operative infection (Calon *et al.*, 2018). Another risk factor for device failure in paediatric patients is low socioeconomic status (Kraai *et al.*, 2011).

In addition, greater skull thickness is considered more amenable for implantation, as it provides greater stability and reduces the risk of implant migration. Preoperative assessment and careful selection of eligible patients may help reduce the risk of complications and achieve more satisfactory results. Some authors suggest routine preoperative CT scans and specific radiological protocols (Brenner *et al.*, 2007).

The aim of this study was to describe the complications of percutaneous osseointegrated devices implanted at our hospital.

## Methods

We conducted a retrospective longitudinal study in 57 consecutive patients who received a Baha® Connect percutaneous bone conduction implantation device at a tertiary hospital between January 2015 and December 2021. The external processor was selected according to bone conduction threshold hearing level, and ranged between 45-, 55-, and 65-dB HL for the Baha® 5, Baha® 5 Power and Baha® 5 SuperPower processors, respectively. All evaluated patients underwent a complete audiological evaluation including otomicroscopy, pure-tone audiometry, and speech audiometry. They also underwent preoperative testing in the clinic using an adapted device with an elastic testband for an average of two hours.

The surgical technique used was a U-shaped incision with the implant placed outside the incision. After performing the incision and dissecting the subcutaneous cellular tissue, the periosteum was elevated, a countersink created in the bone bed and the baseplate was placed in situ; the baseplate size was chosen according to the thickness of the skin and subcutaneous cellular tissue. The baseplate was exteriorised outside the incision by punch technique. The incision was sutured, and a healing cap was then attached and covered with antibiotic ointment-impregnated gauze with bacitracin, neomycin and polymyxin B.

All surgery were performed under general anaesthesia combined with infiltration of a local anaesthetic with a vasoconstrictor agent. Complications were graded according to the classification described by Holgers classification, which stratifies peri-implant skin complications (Table 1; Ellsperman *et al.*, 2021).

**Table 1.** Holgers classification

Grade	Skin reaction	Treatment
0	None	Remove debris
1	Redness	Local treatment
2	Redness + moistness	Local treatment
3	Redness + moistness + granulation tissue	Revision surgery
4	Severe reactions	Removal

## Results

The initial sample consisted of 63 patients, of whom a total of six were excluded (three were lost to follow-up and three still had a Softband-adapted Baha® device). The final sample had 57 patients with a mean age of  $49.80 \pm 20.02$  years, 56.89% of whom were female. The mean age of the adult subgroup was  $55.26 \pm 15.80$  years. Of the total, seven patients (12.28%) were younger than 15 years and had a mean age of  $10.42 \pm 3.30$  years. The mean follow-up was 12 months (range 4-48 months) and consisted of regular visits to the hearing clinic once weekly for the first two weeks, then monthly until six months and then every six months for most patients, although the schedule varied according to each patient's progress. The Holgers classification was recorded at each visit if the patient was grade 1-4. The sound processor was programmed at the clinic at the postoperative month 1 visit.

About 80% of local peri-implant complications occurred in the first two months after surgery. However, three adult patients without medical histories of note had recurrent infections during the first years after surgery. The average follow-up period varies widely in the literature, ranging from three to 61 months in the systematic review by *Mohamad et al.* (2016).

**Table 2** shows the clinical indications for device implantation. **Tables 3 and 4** specify the clinical indications for the paediatric and adult population subgroups, respectively, in the sample. Patients with chronic otitis media reported frequent episodes of otorrhoea that either prevented the use of conventional hearing aids or limited their performance. No patients who received an implant in the sample were using a CROS (Contralateral Routing of Signals) device for unilateral profound sensorineural hearing loss.

**Table 2.** Clinical indications for percutaneous bone conduction device placement in the study sample

Diagnosis	n = 57
Chronic simple/cholesteatomatous otitis media	42
Congenital malformations of the pinna and external auditory canal	10
Otosclerosis with poor response to surgery	4
Poor adaptation to hearing aid	1

**Table 3.** Clinical indications for percutaneous bone conduction device placement in the paediatric subgroup

Diagnosis	n = 7
Congenital malformations of the pinna and external auditory canal	6
Chronic cholesteatomatous otitis media	1

**Table 4.** Clinical indications for percutaneous bone conduction device placement in the adult subgroup

Diagnosis	n = 50
Chronic simple/cholesteatomatous otitis media	41
Congenital malformations of the pinna and external auditory canal	4
Otosclerosis with poor response to surgery	4
Poor adaptation to hearing aid	1

Of the total patients studied, 15 (26.31%) had some type of local complication. Most of these complications (93.33%) were minor (Holgers grades 1 and 2; **Table 5**). Complications in the paediatric subgroup were notably higher. Of the seven children who received implants, three (42.85%) had some type of complication. Two were classified as Holgers grade 1 and the third, who had tissue overgrowth on the implant requiring replacement, as Holgers grade 4 (**Figure 2**). One paediatric patient had spontaneous implant extrusion and another had extrusion following local trauma. In the adult subgroup, the complication rate was 24%, and all complications were classified as minor (Holgers 1 and 2). There were no major local complications graded as Holgers 3 or 4 (**Figure 3**).

**Table 5.** Peri-implant soft tissue complications categorised by Holgers grade, entire study population

Skin complications	Treatment	Number of patients (%)
Holgers 0	None needed	42 (73.68%)
Holgers 1	None needed	3 (5.26%)
Holgers 2	Topical antibiotic + weekly revisions	11 (19.29%)
Holgers 3	Revision surgery	0 (0.00%)
Holgers 4	Implant removal	1 (1.75%)

Of the patients with local complications, two were diagnosed with irritative eczema and one with psoriasis, with no other skin diseases. According to the CT studies, all patients complied with the 2.5-mm minimum thickness required for baseplate placement and therefore it was not considered a determinant for the occurrence of local complications in our sample (Tjellström et al., 2001).

### Discussion

Our study had a low rate of local complications (26.31%) from percutaneous bone conduction implantation, and most complications (93.33%) were minor. However, the rate increased to 42% in the paediatric subgroup. A systematic review of Ponto® percutaneous

bone conduction devices, published by Lagerkvist et al. (2020), described a local adverse reaction rate of Holgers  $\geq 2$  in 15% (133/863) of patients, although not all studies reported this information. The same systematic review found no life-threatening complications, coinciding with the data obtained in a systematic review by Schwab et al. (2020), covering a total of 234 articles, in which the incidence of adverse events was described using the ratio of events-to-ears (REE) parameter and analysed the REE separately for five categories (device-related, skin-related, surgery-related, patient-related and not specified). A total of 204 different types of adverse events were found. For Baha® Connect devices, the most frequent adverse events were Holgers grade 1 (REE 0.07), Holgers grade

Figure 2. Skin complications in the paediatric subgroup

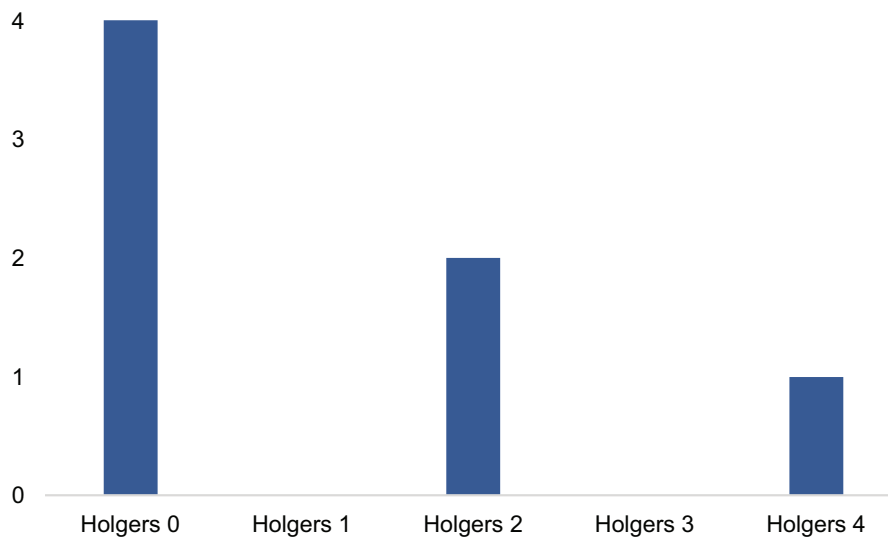
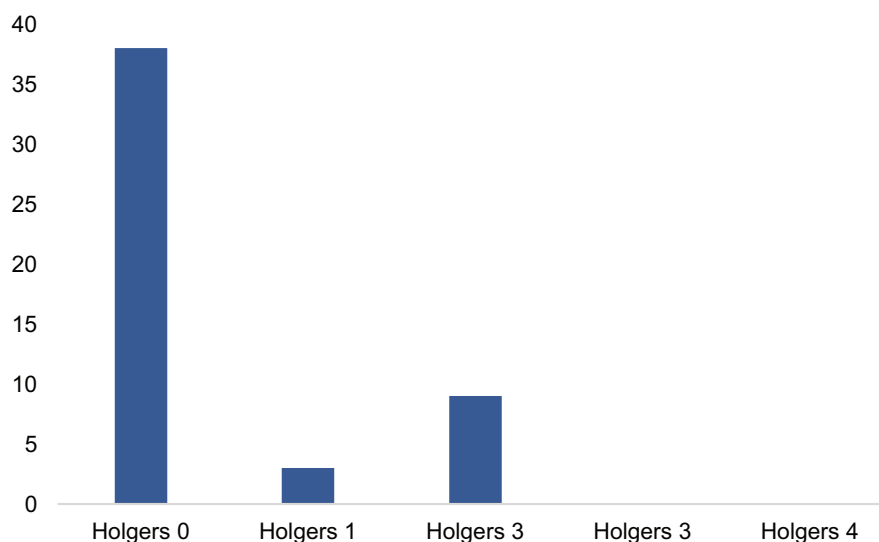


Figure 3. Skin complications in the adult subgroup





2 (REE 0.05) and skin revision surgery due to overgrowth (REE 0.04). The data analysis showed that the complication rate was very low in both devices and that adverse events were not comparable because they were qualitatively different. The results reported in the systematic review corroborate the findings in our study, in which the most frequent complications were Holgers grades 1 and 2 (82.35%).

A meta-analysis by [Kiringoda and Lustig \(2013\)](#) found that the most common complications reported were local skin complications. After reviewing 21 articles, the complication rate in adult and mixed populations was found to range from 2.4% to 38.1% for Holgers grades 2-4 and from 0.4% to 4.8% specifically for Holgers grade <4 complications. A single study in paediatric patients reported an overall complication rate of 89% and Holgers  $\geq 2$  in 77.8% of 27 patients ([Kraai et al., 2011](#)). Other studies report implant extrusion rates in the paediatric population ranging from 5.3% to 26% ([Dun et al., 2012](#)). [Roman et al. \(2011\)](#) found that the most frequent complications in the paediatric age group were fixture loss and the development of skin complications, with fixture loss occurring in 14% of the overall study population and in 71% in the group of children under 5 years of age. These results are consistent with a retrospective study published by [de Wolf et al. \(2008\)](#) that found implant loss in 16.3% (21/129) of the paediatric population, mostly occurring during the first year after surgery.

In studies by [den Besten et al. \(2015\)](#) and [Dun et al. \(2012\)](#), skin diseases and profound learning disabilities were found to be risk factors for the development of skin complications; in contrast, female gender was considered to be a negative or protective risk factor. We did not study risk factors in our sample. [Siau et al. \(2016\)](#) described the main reasons for patients refusing Baha® implantation. Of 98 patients who were found suitable for this procedure, only 38.8% underwent surgery. Anxiety over surgery was reported by 45% and cosmetic concerns by 30%. Cosmetic concerns are one of the main reasons why transcutaneous devices are popular, since they maintain skin surface integrity. However, these devices are not free of complications ([de Souza et al., 2022](#)).

Although passive transcutaneous devices result in a lower rate of skin complications, the magnetic force required to hold the external device in place and ensure good sound transmission can cause pain and local irritation, leading to ischaemic necrosis in the worst cases ([Chen et al., 2017](#); [Ellsperman et al., 2021](#)).

A systematic review by [Cooper et al.](#) reported a 13.1% rate for minor skin complications, which resolved with the use of a weaker magnet ([Cooper et al., 2017](#); [Ellsperman et al., 2021](#)). The systematic review published by [de Souza et al., \(2022\)](#) described a total of 192 adverse events related to 901 transcutaneous device implantations (21.3%), 84.3% of which were classified as minor and 16.1% as major. The rate of minor complications for transcutaneous implantation is around 20%, which is similar to the complication rate for percutaneous implantation.

The aim of the tissue-preservation U-shaped incision technique with external implant placement that we used in our study is to avoid complications such as bacterial overgrowth, which can lead to local complications. A retrospective study published by [Strijbos et al. \(2022\)](#) compared the linear incision technique with tissue preservation (LITT-P) with the minimally invasive star-shaped incision (SSI). No intraoperative complications were reported, but the rate of skin complications was lower with the LITT-P technique (17 vs. 21 for Holgers grade 1, and 10 vs. 16 Holgers grade 2). These results are consistent with the systematic review by [Mohamad et al. \(2016\)](#) of 30 studies that compared complication rates by surgical technique used. Fewer complications were reported with the linear incision than with the dermatome technique ([Mohamad et al., 2016](#); [Tamarit Conejeros et al., 2009](#)). In our study, we used the same surgical technique in all patients, so we were unable to compare complication rates.

The cost of bone conduction devices varies depending on the specific model, device complexity, processor type and accessories included ([Olsen et al., 2011](#)). Cost does not influence the onset of skin complications, but we believe that this aspect should be taken into account when selecting a device, especially in public health care institutions. Complication rates vary by surgical technique, surgeon experience and patient predisposing factors ([den Besten et al., 2015](#); [Ellsperman et al., 2021](#); [Kiringoda and Lustig, 2013](#)). The percentage of major complications is low; and therefore, changing device-type indications due to the risk of complications is unwarranted ([Ellsperman et al., 2021](#)). Tissue-preservation techniques, such as the one used in our study, are safe, with a low incidence of postoperative infection in short- and long-term follow-ups ([Verheij et al., 2016](#)).

Limitations of our study include a heterogeneous sample population, small size and lack of a risk factor

analysis. Comparing different surgical techniques (minimally invasive ponto surgery [MIPS] versus skin flap incisions) and analysing complication rates by bone conduction device both require broader studies with larger study populations. We are; therefore, considering designing a multicentre study.

## Conclusions

The choice of osseointegrated device should depend on its amplification capability, cost, and complications reported at the health care institution. The rate of major complications is very low. Changing from percutaneous to transcutaneous device implantations solely to avoid local complications is unjustified.

## Acknowledgements

The authors are grateful to Dr. José Luis Castillo for his advice on methodological aspects.

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### Conflict of interest

The authors declare no conflict of interest.

### Ethical approval and informed consent

This study was conducted in accordance with the principles of the Declaration of Helsinki. All patients enrolled in the study signed the relevant informed consent form.

### Author contributions

MNG: Data acquisition. Research. Data analysis and interpretation. Writing of the original draft. JCJ: Data acquisition. Data analysis and interpretation. Research. FFN: Data acquisition. Material resources. Research. Supervision. JME: Writing (review and editing). Validation. JGV: Conceptualization. Research. Data analysis and interpretation.

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