Therapeutic algorithm for soft tissue hypertrophy associated with percutaneous bone-anchored hearing implants

Original Article

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Resumo

Objectives: The present work aims to make a brief reflection about cutaneous complications of percutaneous bone anchored implants, with special focus on isolated soft tissue hypertrophy, establishing a treatment algorithm.
Study design: This is a retrospective study, in which children who underwent unilateral BAHA, with a minimum follow-up of 5 years and with detailed clinical records, were included. The following data were collected: age, sex, surgical indications, laterality, audiological evaluation, surgical technique and postoperative complications.
Results: Of the 53 children included, 49.1% developed skin complications at some point in the 5 years after the intervention. In 28.3% of the children, peri-implant skin hypertrophy was described, in which the application of the Holgers classification was considered unfeasible. For these cases, treatment algorithm is presented.
Conclusions: Peri-implant skin hypertrophy is one of the most frequently reported complications, so the development of a uniform and standardized therapeutic strategy is essential.

Keywords: osseointegrated implants; BAHA; skin hypertrophy

Introduction

Bone-anchored hearing implants are bone conduction devices that were initially introduced by Tjellstrom and Carlsson in Gothenburg, Sweden, in the 1970s[1].

The bone-anchored hearing aid (BAHA) system consists of an external sound processor coupled to a bone-anchored titanium screw by a small percutaneous post.

The sound processor acts as a vibration transducer that transmits sound to the cochlea via bone conduction, thus overcoming the limitations of the external and/or middle ear that are compromised[2]. This direct and percutaneous connection

between the processor and temporal bone mitigates the effect of interpositioned soft tissues in sound transmission and provides an additional audio gain of 10–15 dB, especially in the high-frequency range, compared with transcutaneous stimulation[3,4].

However, the interface between the implant and adjacent skin and soft tissues can become chronically inflamed and/or infected, with the possibility of progressing to serious complications. Recurrent infection, excessive growth of soft tissues, and implant instability or extrusion have been reported in the literature with a variable frequency[5]. Thus, maintaining a healthy skin/post interface, especially in children, remains a long-term challenge in the management of skin conditions and a key factor in the successful adherence and adaptation to the device.

Despite recent significant surgical and technological advances in the design, function, and technical BAHA implantation, complications involving peri-implant skin and soft tissues continue to arise.

Holgers et al. proposed a system that classifies peri-implant skin conditions from grades 0 to 4 according to increasing severity as: no irritation, mild redness, redness and exudation without granulation tissue, redness and exudation with granulation tissue, and surgical revision required[6].

However, not all skin reactions can be precisely categorized using this system, especially those involving isolated skin overgrowth, and novel classification systems have been proposed that are more inclusive and descriptive of the entire spectrum of skin reactions[7,8].

The present study aimed to clarify the most frequent skin complications identified in children with bone-anchored implants who were followed up for a minimum of five years, and to create a treatment algorithm.

Material and Methods

This was a retrospective study that included children who received percutaneous bone-anchored implants between January 2008 and December 2014 at CHUPorto.

Children and adolescents aged 18 years or less at the time of surgery who received a unilateral implant (children who received bilateral implants were excluded because of the higher inaccuracy of their records and specification of laterality), with a minimum follow-up period of five years after implant placement, detailed clinical records, and informed consent from their legal guardians, were selected to participate in the study.

We collected information about age, sex, surgical indications, medical and surgical history, results of preoperative audiological assessment and computed tomography of the temporal bone, the applied surgical technique, and the development of postoperative complications.

The pre- and postoperative auditory thresholds considering their pure tone average (PTA) were determined as average tone thresholds at 500, 1000, 2000, and 4000 Hz.

All surgeries proceeded in a single stage under general anesthesia, using the linear technique with a punch biopsy that was similar to that described by Wolf et al. 9 and adapted by Gordon and Coelho10. It consists of a vertical incision of about 3 cm, elevation of the periosteum, and placement of the implant as recommended by the manufacturer. A 5-mm skin biopsy perforator is used to place the implant immediately anterior to and outside the vertical incision.

Skin complications were documented using photographic records and progression was evaluated using the Holgers classification.

Fifty-three children with a mean age of 10.47 ± 3.44 years (range: 4–17 years) were included in the study. Twenty-six patients were girls and 27 were boys. Malformations of the external and middle ear were the main surgical indicator (64.2%), followed by chronic otitis media with persistent otorrhea (17.0%) and post-mastoidectomy status (13.2%). Among 53 implanted BAHA devices, 40 and 13 were implanted on the right and left sides, respectively.

Data were statistically analyzed using SPSS® v 20 (IBM Inc., Armonk, NY, USA). Values with p

< 0.05 were considered significantly different. This study was approved by the Ethics Committee of the Centro Hospitalar Universitário do Porto, and all the legal guardians signed the informed consent form.

Results

Table 1 summarizes the demographic data, surgical indication, laterality, and pre- and postoperative auditory thresholds.

The mean preoperative and postoperative free-field PTA values significantly differed at 51.1 ± 18.13 vs. 19.6 ± 5.79 dB, with a mean audio gain of 31.5 ± 7.20 dB ($p < 0.05$; paired sample t-tests). The complications arising during follow-up comprised peri-implant inflammatory or infectious processes, skin hypertrophy, and loss of fixation. Overall, 49.1% and ~ 17% of the children developed some type of skin complication and non-hypertrophic peri-implant skin reactions, respectively, during the five years after implantation (Figure 1).

Among the skin reactions, 33.4%, 33.4% and 44.4% were categorized under grades 1, 2, and 3, according to the Holgers classification. Only one implant had to be surgically removed to control local infection after medical treatment failed (Holgers classification grade 4).

Overgrowth of the peri-implant skin and soft tissue was the primary clinical feature in 28.3% of the participants. We placed these participants in a separate group, as the Holgers classification was not considered applicable to them (Figure 2). Some patients initially developed concomitant signs of inflammation or infection, but after stabilization, a hypertrophic scar had the most clinical impact (difficulty in coupling the processor with subsequent maceration and perpetuation of the skin damage) and was the best predictor of resistance to medical

Figure 1
Peri-implant erythema, scabs, and exudate

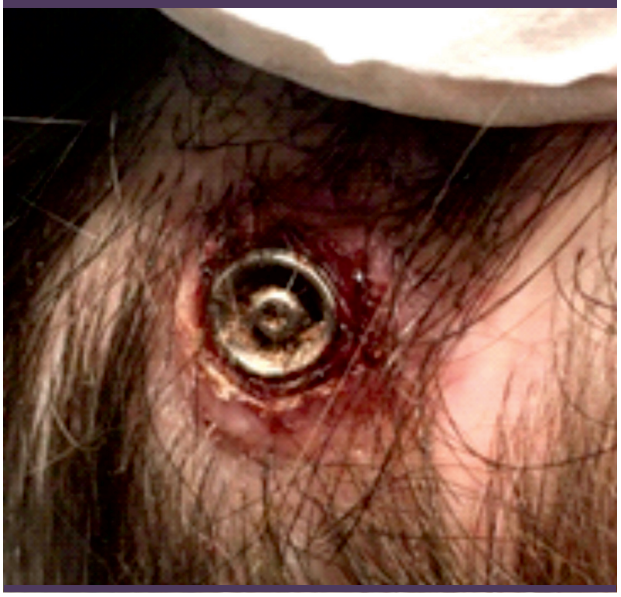
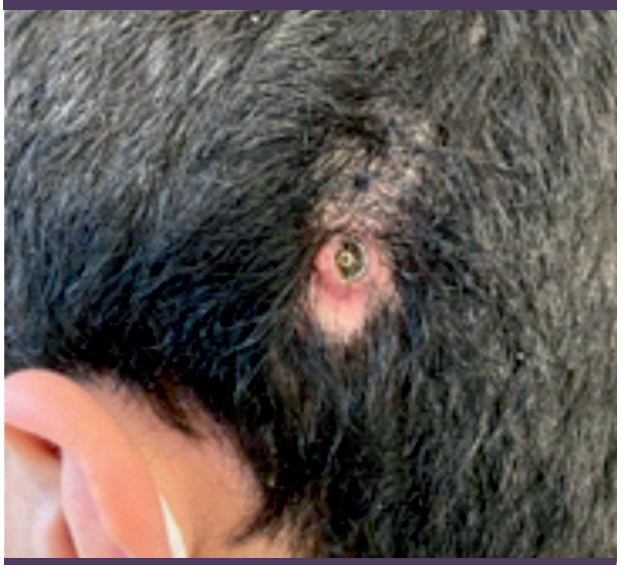


Table 1
Demographic data, surgical indicators, surgical laterality, and pre- and postoperative auditory thresholds.

Demographic, surgical, and audiological data	
Mean age (range)	10,47 (4-17)
Sex n (%)	
Female	26 (49,1)
Male	27 (50,9)
Surgical indications n (%)	
Malformations of external and middle ear	34 (64,2)
Chronic otitis media with persistent otorrhea	9 (17,0)
Post-mastoidectomy status	7 (13,2)
Unilateral sensorineural hypoacusis	3 (5,6)
Laterality n (%)	
Right	40 (75,5)
Left	13 (24,5)
Auditory thresholds (PTA; means ± SD) dB	
Preoperative	51,1 ± 18,13
Postoperative	31,5 ± 7,20

PTA, pure tone average; SD, standard deviation

Figure 2
Skin overgrowth covers the implant without significant signs of inflammation



treatment. Five of these patients required revision surgery. Loss of implant fixation/bone-anchorage failure developed in five patients. In two (3.8%) patients, complications resulted from loss of bone anchorage in the context of recurrent skin and soft tissue reactions that destabilized the implant, and finally led to its loss. Complications in the other three patients were secondary to trauma (5.6%) and thus not considered as being associated with the skin. No other complications developed.

Thus, 29 (54.7%) of the 53 children included in the study developed some type of postoperative complication among which 89.7% involved peri-implant skin and soft tissues. Table 2 summarizes the skin complications.

Table 2
Postoperative skin complications

Postoperative skin complications	
Skin complications n(%)	26 (49.1)
Peri-implant skin hypertrophy n (%)	15 (28,3)
Non-hypertrophic peri-implant skin reaction n (%) Holgers grades 1 2 3 4	9 (17.0) 3 (33.4) 4 (44.4) 1 (11.1) 1(11.1)
Implant instability n (%)	2 (3.8)
Skin necrosis n (%)	0 (0.0)
Number of skin complications n (%)	27 (50.9)

Discussion

Although the Holgers classification is widely applied, it is insufficient for some aspects of clinical practice. One of the main complications associated with the bone-anchored implants identified herein was skin hypertrophy, without associated signs of inflammation/infection. None of the categories and grades in the Holgers classification are appropriate to describe this complication.

Fontaine et al. in 2014 also found that skin overgrowth was the most common complication[11]. The Holgers classification, in addition to being a user-friendly tool, has also served as a guide to treatment; for example, topical treatment and surgical revision for Holgers grades 2 vs. 4, respectively. However, these treatments are not standardized, and intra-grade variability in responses to treatment is high when this classification is applied.

Kruyt et al., in 2017, proposed a new scale of evaluation and classification of skin complications associated with percutaneous and transcutaneous bone conduction implants[12]. However, the inclusion of subjective self-reported parameters, such as pain, increases the likelihood of the classification

being less rigorous and more variable, rendering it less objective and reproducible. In addition, it hinders appropriate application for children. Although the content is comprehensive, cumulative scores are difficult to rapidly and intuitively apply in the fast-paced context of everyday clinical practice.

The new Coutinho classification system developed during 20218 is more intuitive and aims to overcome the difficulties associated with current classification systems. It is also easy to use for geriatric populations without loss of accuracy. This classification is not a scale, but rather a categorical evaluation that should be applied to each observation and in all follow-up consultations in which significant changes are evident.

In addition to introducing the concept of hypertrophy with signs of inflammation (category C) and of skin hypertrophy without inflammation, that is, isolated skin hypertrophy (category D), the Coutinho classification emphasizes the importance of specifying the level of the skin at the interface between the skin and the post, which may be below the post (C1 and D1), at the same level as the post (C2 and D2), or above the post, covering it partially or totally (C3 and D3). The Coutinho classification is as follows.

Type A: redness
Type B: redness with exudates and/or scabs
Type C: redness with exudates and/or scabs, with granulation tissue and/or skin hypertrophy (C1, C2, C3)
Type D: skin hypertrophy (D1, D2, D3)
Type E: implant loss (E1: extensive skin reaction requiring post removal; E2: spontaneous implant loss associated with extensive skin reaction)
Type F: skin necrosis.

The aim of this classification is to develop treatment algorithms standardized for each category. Here, we propose a treatment algorithm for skin hypertrophy associated with percutaneous bone-anchored hearing implants, that is, categories C and D of the Coutinho classification.

Figure 3 is a flow chart that establishes guidelines for peri-implant skin hypertrophy in bone-anchored implants.

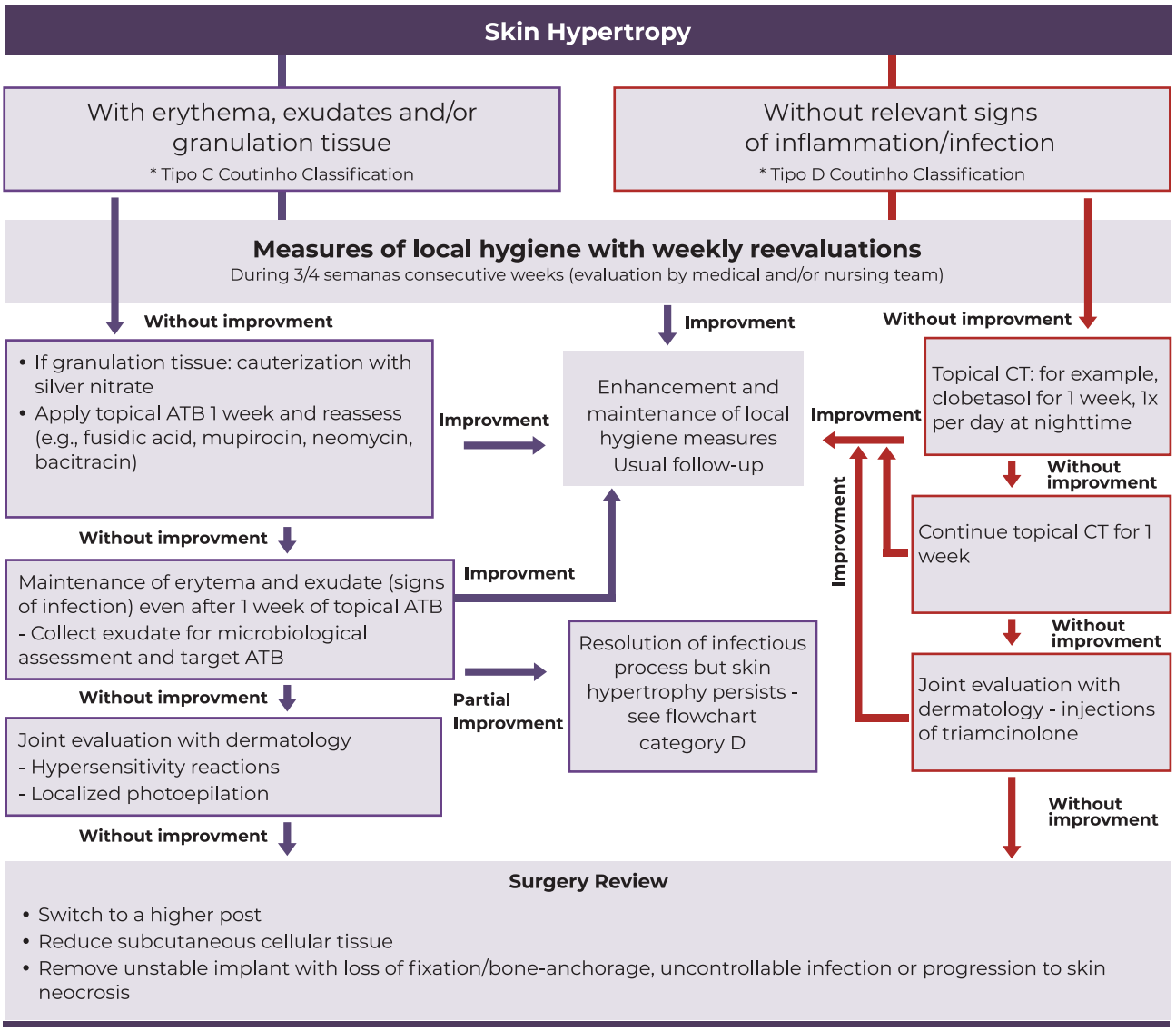
Skin hypertrophy might initially be associated with an inflammatory process, skin erythema and maceration, which almost inevitably progresses to mucous exudates and scab formation (Coutinho classification category C). However, skin hypertrophy might be isolated, without associated signs of inflammation/infection (Coutinho classification category D).

In both situations, local hygiene is essential, with weekly visits and observation by an experienced team until the condition is resolved, which is usually within one month. Local hygiene consists of cleaning the exudate and scabs with saline and applying povidone-iodine. Parents should be instructed to conduct routine daily hygiene care comprising cleaning with saline and thoroughly drying the skin around the post.

If skin homeostasis around the implant is not reestablished and signs of infection persist, topical antibiotics should be started against the most prevalent bacterial isolates *Staphylococcus epidermidis, S. capitis, S. hominis, and Streptococcus pneumoniae*[13,14]. Collecting exudates using a swab for microbiological analysis might be needed if the condition is unresponsive to empirical antibiotic therapy. The collection site is important to specify so that antimicrobial agents with topical formulations can be assessed. Evaluation by a dermatologist might provide added value not only to evaluate potential skin hypersensitivity/allergies to implant components, but also to consider other treatment strategies such as photoepilation when hair follicles near the implant significantly contribute to the perpetuation or recurrence of the infectious process, although this option is limited for pediatric patients[15].

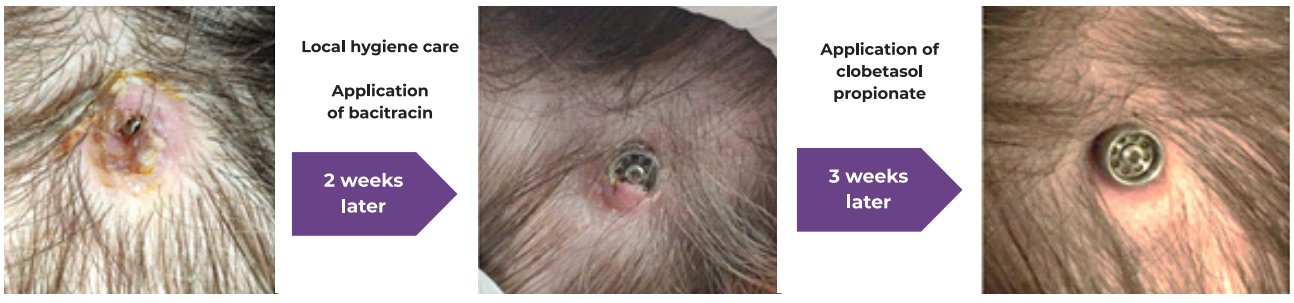
Skin hypertrophy sometimes occurs around implants without associated signs of inflammation/infection, and this hinders and can even prevent placement of the processor. Under such circumstances, the

Figure 3
Algorithm for treating skin hypertrophy associated with percutaneous bone-anchored hearing implants.



Legend: ATB, antibiotic therapy; CT, corticosteroid

Figure 4
Effects of treatment algorithm and lesion progression.



initial treatment consists of using topical corticosteroids for one week, followed by reevaluation[16,17]. If unsuccessful, injections of triamcinolone acetonide might be effective18. Figure 4 shows a patient who was treated using the proposed treatment algorithm and progression until resolution.

More invasive measures might ultimately be required such as surgical revision to reduce subcutaneous cellular tissue and the placement of higher implants. Implants should be removed if the infectious process is severe or when skin necrosis occurs, but this is quite rare.

Conclusion

Skin hypertrophy with or without associated signs of inflammation is the main complication of bone-anchored implants. Therefore, developing treatment algorithms that are standardized and aimed at each category is fundamental to being able to compare results of targeted treatments. We developed such an algorithm for treating skin hypertrophy associated with percutaneous bone-anchored hearing implants. Further studies are required to determine the feasibility and results of systematic application of our proposed algorithm.

Conflicts of Interest

The authors declare that there is no conflict of interests regarding the publication of this paper.

Data Confidentiality

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

Protection of humans and animals

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the 2013 Helsinki Declaration of the World Medical Association.

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Availability of scientific data

There are no datasets available, publicly related to this work.

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