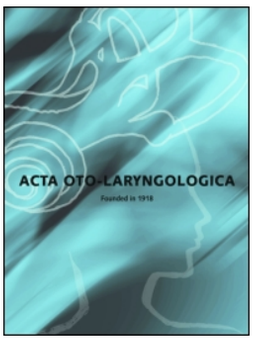

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RESEARCH ARTICLE

Transitions in auditory rehabilitation with bone conduction implants (BCI)

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ABSTRACT

Background: The bone conductive implants (BCI) are nowadays a reliable alternative for rehabilitation of specific forms of hearing loss, i.e. conductive, mixed or single sided deafness (SSD).
Aims/Objective: To analyse the various factors in play when considering an auditory rehabilitation with a bone-conductive device (BCI).
Materials and Methods: The clinical charts of subjects who underwent BCI application at the same Implanting Center from 2005 to 2018 were retrieved analysing also the reason for eventual explantation and the alternative option (transition) for hearing rehabilitation.
Results: Nine BAHA Compact, 4 BAHA Intenso, 21 BAHA Divino, 3 BAHA BP100, 4 Ponto, 2 Sophono, 5 Bonebridge, 5 BAHA5 Attract; 11 BAHA5 Connect were used in 12 unilateral COM; 16 bilateral COM; 3 unilateral cholesteatoma; 6 bilateral cholesteatoma; 2 unilateral otosclerosis; 5 bilateral otosclerosis; 9 congenital malformations; 6 major otoneurosurgical procedures; 5 sudden deafness. Explantation was necessary for five subjects.
Conclusions: Middle ear pathology and sequels from surgery represent the most common reason for BCI implantation, both in unilateral and in bilateral cases. Transition from one implantable device to another one can be predictable, mostly when explantation is necessary.
Significance: The role of BCI for rehabilitation in middle ear pathology may be extremely important.

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Middle ear surgery; hearing loss; bone conduction implants

Introduction

Middle ear surgery, in principle, aims for the simultaneous resolution of both pathological and functional issues related to the causative pathology. When a middle ear disease is present, it initially causes a decline in the conductive mechanism of hearing, as shown by the presence of a mild-to-moderate air-bone gap in pure tone audiometry. Although this type of hearing loss is less disabling than purely sensorineural hearing loss, a conductive loss that affects both ears can also compromise communication skills and quality of life [1].

The most frequent permanent causes of conductive hearing loss are related to chronic otitis media (COM) with or without cholesteatoma, ear malformations and otosclerosis. While surgery and its functional outcomes are quite standardised and reproducible for complicated COM, in cases of ear malformations, functional recovery may require more than a single surgical procedure, which can result in an uncertain functional outcome. Therefore, in some of these cases, subsequent auditory rehabilitation is required, primarily using a conventional hearing aid (cHA), such as bone-conduction glass-held HA.

Since their first introduction in the clinical field in the late 1970s [2], bone conduction implants (BCI) have been considered a possible alternative solution, initially for the rehabilitation of conductive hearing loss. Thereafter, in light of technological innovations in sound processors (SP), the initial indications have been extended to mild/moderate forms of mixed hearing loss, with bone conduction threshold levels of 35 dB or better. In fact, in some forms of COM and, mostly, otosclerosis, it is not unusual to observe a decrease in the BC threshold over time, for which even the use of a conventional bone- or air-conduction HA could become inadequate.

The aim of the present retrospective study was to analyse the experience with the use of different types of BCIs at a single institution during the last fifteen years. In particular, by retrieving data from a specific database, several factors were taken into consideration, including the initial reasons for selecting a BCI and the need for any eventual changes in alternative solutions.

Material and methods

From 2005 to 2018, 64 subjects (29 males, 35 females; aged 15–86 years) from an entire patient population of 161 subjects treated with a surgically implanted device at a tertiary university referral implantation centre underwent BCI implantation surgery for the rehabilitation of conductive, mild-to-moderate mixed or single-sided (SSD) hearing loss.

The patients' gender, age and type of device are listed in Table 1.

The following brands of BCI were used: BAHA ® (Cochlear, Melbourne, Australia), Ponto ® (OticonMedical, Copenhagen, Denmark), Alpha 1 ® (Sophono, Medtronic,

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Table 1. Demographic data of the study sample, including year of implantation and type of bone conduction implant.

	No
Gender	
29 males, 35 females; 12–85 years	
Year of implantation	
2005–2018	64
Type of device	
BAHA ®	53
SOPHONO ®	2
PONTO ®	4
BONEBRIDGE ®	5

Minneapolis USA) and Bonebridge ® (Medel, Innsbruck, Austria). According to the year of implantation, the subjects received the most current and suitable system with the latest-generation SP available from each company.

According to our protocol, all the subjects underwent a thorough preoperative evaluation that included a simulation trial session using a fitted, headband-worn SP tailored to the individual's functional needs [3]. Surgery was performed according to the best-practice procedure recommended by each company. In this regard, the greatest differences were related to implantation with the BAHA ® device because the incision underwent various technical evolutions ranging from the initial rectangular, pedicled flap with total subcutaneous removal to a linear incision with subcutaneous removal and the most recent procedure, a linear incision without subcutaneous removal and the placement of a longer abutment.

Reasons for modifying the original choice, i.e. for transitioning to a different option, were examined for both percutaneous and transcutaneous BCI systems.

Results

In total, 64 BCIs were implanted, always unilaterally, for unilateral and bilateral hearing loss. The type and generation of device SP depended on the year of implantation and the availability of the device at the implantation centre. The SPs were distributed as follows: 2004–2006 (9 BAHA ® Compact; 4 BAHA ® Intenso); 2006–2010 (21 BAHA ® Divino); 2010–2012 (3 BAHA ® BP100); 2013–2014 (4 Ponto ®); 2013–2015 (2 Sophono ®); 2012–2015 (5 Bonebridge ®) (BB); 2015–2018 (5 BAHA5 ® Attract; 11 BAHA5 ® Connect). In total, 52 percutaneous and 12 transcutaneous systems were implanted.

The underlying pathologies (Table 2) included 28 cases of COM (12 unilateral, 16 bilateral), 9 cholesteatomas (3 unilateral, 6 bilateral), 7 cases of otosclerosis (2 unilateral, 5 bilateral), 9 congenital malformations (1 unilateral, 8 bilateral), 6 unilateral skull base procedures and 5 cases of unilateral idiopathic sudden deafness; in the latter 11 subjects, the BCI was applied as an SSD protocol [4,5].

Among the postsurgical cases, 44 subjects had previously undergone conventional middle ear surgery for the underlying pathology: 28 for COM, 9 for COM with cholesteatoma and 7 for otosclerosis. A single traditional middle ear procedure was performed in 17 COM subjects; the remaining

Table 2. Pathologies underlying conductive or mixed hearing loss.

Pathology	Unilateral	Bilateral
COM	12	16
CCOM	3	6
Otosclerosis	2	5
Ear malformations	1	8
SSD	5	
Post skull base procedures	6	

COM: chronic otitis media; CCOM: chronic otitis media with cholesteatoma; SSD: single-sided deafness.

Table 3. Time interval (in years) between the last middle ear surgery (MES) and BCI implantation.

<1 year	1–5 years	5 years	10 years	NO MES
11	12	10	12	19

Table 4. Number of previous conventional middle ear procedures (MES).

NO MES	1	2–3	>3
19	13	10	22

Table 5. Transitions involving BCI and the causative factors.

Original BCI	Transition	No	Cause
pBCI	tBCI	1	Skin dehiscence
1 OW-VSB	tBCI	1	Hardware failure
BB	pBCI	1	Retroauricular pain
pBCI	–	1	Extrusion
pBCI	–	1	Skin overgrowth
BAHA DIVINO	BAHA5	1	Deterioration of bone conduction threshold
BAHA DIVINO	BP100	2	Deterioration of bone conduction threshold
BAHA COMPACT	INTENSO	1	Deterioration of bone conduction threshold

–: no transition.

COM patients, including cholesteatoma cases, had undergone multiple surgeries: 10 subjects underwent 3 surgeries or fewer and 10 subjects underwent 4 surgeries or more (Table 3). The time lapse from the last middle ear surgery was <1 year in 11 subjects; 1–5 years in 12 subjects; >5 years in 10 subjects and >10 years in 11 subjects (Table 4). Twenty subjects, including the nine with ear malformations, had not undergone previous middle ear surgery. In six cases, hearing loss was an unavoidable sequela of major skull base procedures and led to an SSD condition. No surgery was previously performed in the five cases of SSD caused by idiopathic sudden deafness episodes.

Transitions from the original option to a different solution involved all types of devices (Table 5). Three subjects with a percutaneous device required explantation: 1 case because of skin dehiscence that prompted the implantation of a transcutaneous device; 1 case because of skin overgrowth for which no other option was selected; and 1 case due to a delayed loss of osteointegration and loss of the fixture with no further options. In four subjects, the decrease of the bone conduction threshold required an upgrade to a more powerful SP. With transcutaneous devices, minor skin irritation/redness was resolved by temporarily reducing the wearing time and switching to a weaker magnet. In one case, the transcutaneous device was removed due to painful symptomatology and replaced with a percutaneous device.

Discussion

The presence of middle ear pathology or sequelae from conventional middle ear surgery for variable degrees of conductive or mixed hearing loss most often represent a local contraindication for wearing a cHA. Therefore, under these circumstances, the use of an alternative solution may be required. The timing of implantation and the selection of the appropriate implantable device depend on different factors that are *in primis* linked to their actual availability at an implantation centre. For example, all the possible solutions that could be proposed for conductive or mixed hearing loss, including a conventional HA, BCI or an active middle ear implant (AMEI), should be taken into consideration. For the two implantable solutions, the decision would depend on the availability of the device but also on other factors, including the specific surgical experience of the centre itself and the reliability of the device in the long term. In this latter regard, BCIs have been the only implantable solution available for many years. They have been applied worldwide, generating many reports with long-term follow-up outcomes that have confirmed their efficacy. AMEIs were introduced in the mid-2000s; consequently, they have had a shorter existence and have generated fewer and shorter follow-up reports. In addition, their application may require specific skills, so that only selected centres are implanting them. Given these premises, it is reasonable to assume that, especially in an otologic centre without prior AMEI experience, BCIs would be the first logical choice.

The BCI group in the present study showed an uneven distribution among the four types of devices, and percutaneous systems (pBCI) were more prevalent than transcutaneous systems (tBCI), namely, BAHA Attract ® [6], Sophono ® [7] and BoneBridge ® [8]. This finding is primarily related to the fact that tBCIs have only recently been made available in clinical practice. The advent of the tBCI was welcomed with the hope of overcoming some negative issues related to pBCI, such as the need for daily care, the unaesthetic screw exposure and the potential skin complications; however, at least for the passive tBCI (Sophono ®, BAHA Attract ®), a slightly inferior functional performance due to the interposed skin attenuation should be expected, especially at the high-frequency level. Personal limited experience with tBCI indicates that in only one case, the adoption of such a system (Sophono ®) was necessary to address skin problems that occurred after a previously positioned pBCI (BAHA ®), while the other tBCI was selected and applied as the first choice, mostly for aesthetic reasons.

Since the start of the BCI programme at our implantation centre, many patients were considered candidates for this type of rehabilitation, including those with unilateral and bilateral cases of cholesteatomatous (CCOM) and noncholesteatomatous COM, otosclerosis, ear malformations and SSD. Following an economics-related policy of device supply, only one ear was implanted, even in the presence of a bilateral functional need. Despite this fact, the BCI-implanted population has been shown to achieve a high level of satisfaction with other types of implantable solutions [9]. The factor that determined ear selection was the side with a higher bone conduction threshold, from which a better functional performance could be expected. Among the subjects who had undergone previous operations, the number of previous procedures did not seem to influence the patient's choice. Multiple surgeries were generally related to CCOM and were less likely in cases of otosclerosis or ear malformations. In cases of otosclerosis specifically, none of the subjects had undergone any prior middle ear surgical attempt (canalplasty with ossicular reconstruction), and they preferred a BCI for their auditory rehabilitation. A unilateral BCI was obviously adopted in the SSD cases. In some tBCI subjects, some issues with the magnetic contact were noticed, especially during the initial period after implant activation [10]; in some others, skin redness over the internal magnet site was observed and required a reduction of the daily wearing time; finally, one subject (fitted with a BoneBridge ® with retrosigmoid placement) asked to be explanted due to retroauricular pain that resolved after surgical removal of the BCI, which prompted a request for a pBCI.

Because our findings were not derived from a randomised trial, it is not possible to draw any conclusions regarding the hypothesis that BCI could be the best rehabilitative option to offer and/or whether affected subjects would prefer it to, for instance, classical middle ear surgical revision. To answer this question, one would need to perform a retrospective analysis of all cases in which classical middle ear surgery was performed before and after the availability of BCI and with a similar observational time. What seems to be important, however, is that, as routinely occurs at our implantation centre, all potential BCI candidates receive thorough information on the existence of a rehabilitative option that, with respect to the classical middle ear procedures, also offers the non-insignificant advantage of preventing any further hearing deterioration, as may sometimes occur during revision middle ear surgery. It is also our conviction that the routine adoption of a preoperative headband test with a fitted SP could encourage the patient to accept this implantable auditory solution.

Despite an overall successful BCI experience, a few subjects experienced some issues that required a change from the original plan; in some cases, this change included explantation and/or another solution, such as returning to cHA, adopting a more powerful BCI system, or placing an active middle ear implant (AMEI). The transition process, therefore, encompasses not only the first option motivated by the underlying pathology but also the postimplantation period.

It is possible to conclude that transition is a phenomenon that affects several aspects of BCI implantation, from selection in accordance with the underlying pathology to the possible need for solutions other than the original option. This possibility should always be thoroughly discussed with the potential candidate during preoperative counselling.

Disclosure statement

No potential conflict of interest was reported by the authors.

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