REVIEW



Implantable Devices in Otolaryngology: Pediatric Application of Active Bone Conduction Devices

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Accepted: 3 June 2024 / Published online: 11 June 2024

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Abstract

Purpose of Review This review offers insights into Active Transcutaneous Bone Conduction Implants (ATBCI) for pediatric patients with hearing loss, emphasizing the latest discoveries.

Recent Findings ATBCI showcase substantial enhancements in hearing and speech clarity, especially in the high-frequencies, compared to passive devices. In the pediatric population, special attention should be taken to anatomical considerations such as temporal bone thickness and the proximity of vital structures.

Summary ATBCI provide a promising treatment option for patients who have contraindications to, or side effects with, previous bone conduction implants. ATBCI are safe for implantation in children, however the need for comprehensive preand intra-operative assessment remains important.

Keywords Pediatric hearing loss \cdot Conductive hearing loss \cdot Bone conduction \cdot Bone anchored \cdot Active conduction \cdot Single sided deafness

Introduction

Treating children affected by conductive hearing loss (CHL), mixed hearing loss (MHL), or single-sided deafness (SSD) using conventional non-surgical hearing aids often presents significant challenges. Factors such as atresia of the external ear canal, occurring at an incidence of 1:10,000 to 1:20,000, impede sound transmission to the cochlea, diminishing the efficacy of traditional aids [1]. Moreover, patients with conditions like microtia, chronic otitis media, cholesteatoma, branchio-oto-renal spectrum disorder, Crouzon syndrome, Klippel-Feil syndrome, Pfeiffer syndrome, and other congenital malformations of the middle or external ear may also find limited benefit from conventional solutions (Table 1) [2]. To bypass middle ear limitations and directly stimulate the cochlea, bone-anchored hearing aids (BAHA) and bone conduction implants (BCI) have emerged, offering alternatives [3]. Active transcutaneous bone conduction implants (ATBCI), the latest BCI variant, have been increasingly

used in both adult and pediatric patients in the last decade [4]. However, their application in pediatric cases has stirred controversy, notably due to anatomical factors like immature bone structure [5–7]. This controversy partly underpins the United States approval of ATBCI exclusively for patients aged 12 and older [8]. Currently available as Bonebridge BCI 602 (MEDEL, Austria) and Osia (Cochlear, Sydney, Australia), this review delineates the distinctions between ATBCI and traditional devices, addressing anatomical considerations, overall outcomes, complication rates, surgical techniques, and controversies pertinent to ATBCI's role in treating pediatric hearing loss.

Background

Historically, the primary treatment options for pediatric patients with CHL, MHL, or SSD with contraindications to traditional hearing aids were BAHA or a middle ear implant such as the Vibrant Soundbridge (MEDEL, Austria). The middle ear implant, approved for children in 2009, enables direct stimulation of middle ear ossicles, transmitting vibrations to the cochlea but is associated with frequent surgical trauma and implant displacement [2, 9]. Consequently, it is less commonly used for treating CHL, MHL, and SSD.

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Percutaneous BAHA devices with an externally fixed abutment transmitting vibrations through the skin to stimulate bone conduction, has led to frequent skin irritation and infections [10, 11]. This tends to occur more frequently in children than in adults. Cosmetic dissatisfaction and a high overall complication rate (58.8%) were the driving forces to the development of transcutaneous bone conduction implants [9]. Transcutaneous devices avoid skin penetration, transmitting external vibrations to an internally implanted device through intact skin [12].

Passive transcutaneous devices transmit sound vibrations from an external processor through the skin to a titanium implant on the skull bone, lacking active electronic components in the implant itself. Despite effectiveness, they demonstrate inferior audiologic outcomes compared to active devices due to sound attenuation by scalp and soft tissue [13]. Active transcutaneous bone conduction implants (ATBCI), including Bonebridge (2012) and Osia (2019), comprise an external receiver and an active implantable component producing direct vibrational energy [14]. Launched in 2019, Bonebridge BCI 602 had a reduced transducer thickness of 4.5 mm compared to the 8.7 mm thickness of Bonebridge BCI 601 [2]. In addition, Bonebridge BCI 602 minimized drilling depth, overcoming anatomic limitations in pediatric patients [2]. Bonebridge uses a bone conduction floating mass transducer communicating wirelessly via electromagnetic induction, while Osia relies on a piezoelectric transducer utilizing a digital radiofrequency link. The piezoelectric transducer is unique to previous bone conduction implant technology in that it consists of a crystalline material that is chemically bonded [15]. The crystalline material allows transmission of vibrations that more closely match the incoming electrical signal [15]. Osia's piezoelectric transducer demonstrates benefits in higher frequency hearing by allowing transmission of vibrations that more closely match the incoming electrical signal [15–17].

Studies confirm that ATBCI offer improved outcomes over passive transcutaneous devices, especially in high frequency audiologic outcomes in pediatric patients [10]. Moreover, reduced size and thickness in newer active devices decrease necessary bone removal and surgery duration, alleviating anatomic and surgical concerns, making them more favorable than passive devices for pediatric patients [9, 10]. Additionally, complication rates appear similar between passive and active BCI in children [18].

Indications for Bonebridge and Osia in pediatric patients include many conditions leading to severe unilateral or bilateral CHL, MHL, or SSD (Table 1).

In the United States, Bonebridge BCI 602 and Osia are approved for patients aged 12 and older [19, 20]. Criteria vary for Bonebridge, patients must have bone conduction thresholds exceeding 45 dB, while Osia criteria are more
 Table 1 Indications for Active Transcutaneous Bone Conduction

 Implants. Abbreviations: ATBCI – Active Transcutaneous Bone Conduction

 duction Implants

Indications for ATBCI	
Aural atresia	
Chronic suppurative otitis media	
Microtia	
Cholesteatoma	
Branchio-oto-renal spectrum disorder	
Crouzon syndrome	
Klippel-Feil syndrome	
Pfeiffer syndrome	
Other congenital malformations of the middle ear	
Canal wall down mastoid cavity	

intricate [19]. For CHL, patients must have bone conduction thresholds of at least 55 dB averaged across frequencies of 500, 1000 2000, and 3000 Hz [19]. For SSD, patients must have contralateral bone conduction thresholds of at least 20 dB [19].

Anatomic Considerations

Surgical planning for ATBCI in pediatric patients requires certain considerations due to their intricate anatomy. Both the Bonebridge and Osia devices require transducer components implanted within the temporal bone, sometimes near the external auditory canal and dural venous sinus [2, 21]. According to manufacturers of the Bonebridge BCI 602, the recommended placement of the coil of the device is within the sinodural angle, at an angle of approximately 45 degrees posterosuperiorly [22]. In addition, the flexibility of the Bonebridge device allows the coil to bend approximately 90 degrees laterally in either direction [6]. The transducer can also bend at a depth of 30 degrees medially to allow for additional flexibility [6]. Factors such as temporal skull bone thickness, proximity to the dura and sigmoid sinus, as well as skin thickness and prior mastoid surgeries, are critical considerations similar to passive and percutaneous devices [2, 23]. Pediatric patients typically possess thinner mastoid bones than adults, which continue to develop until puberty, reaching a maximum thickness of approximately 30-35 mm [2, 24]. While implantation of BCI in patients with prior radical mastoidectomy or mastoid surgeries may have been difficult in patients with previous bone conduction implants, the reduced drilling depth required by Bonebridge and Osia might enable implantation in many of these cases [25].

Children with external or middle ear pathologies often exhibit reduced mastoid bone thickness, necessitating pre-operative planning using computed tomography (CT) imaging to determine the optimal location of implantation at maximal cortical bone thickness (23). The Bonebridge BCI 601, with a drilling depth of 8.7 mm, was unsuitable for implantation in some children, prompting the introduction of Bonebridge BCI 602 and Osia with shallower implantation requirements at 4.5 and 3 mm respectively (Fig. 1) [2].

Excessive drilling depth leading to dural exposure is sometimes necessary, but violation of the dura or sinus during surgery could cause complications like bleeding, thrombosis, subdural hematoma, cerebrospinal fluid leak, intracranial hypertension, meningitis, cerebritis and inferior hearing outcomes [25, 26]. However, some studies suggest that controlled compression of the dura might not significantly affect hearing outcomes, and in some cases, non-osseous stimulation of the dura might even enhance audiologic results. Regardless of the impact of dural compression on audiologic outcomes, it is important to locate the dura and sigmoid sinus pre- and intra-operatively to prevent injury, complication, or excessive compression. In pediatric patients with reduced mastoid bone thickness compared to adults, exposure of the dura may be necessary. Adjunct devices such as lifts for the Bonebridge system allow reduced drilling depth in cases where compression of the dura must be avoided [2]. If the dura is exposed, it is of the authors' expert opinion that any epidural bleeds must be meticulously cauterized to avoid epidural hematomas.

Fig. 1 Bonebridge and Osia devices compared side by side with implant placement and depth of drilling depicted on the lower part of the figure. The top part of the figure shows where on the mastoid the implant can be placed with the dotted line indicating possible skin incisions

Soft-tissue thickness, vital for BAHA and percutaneous devices, is also an important consideration for transcutaneous devices. Reduced soft-tissue thickness in children might increase the risk of cutaneous complications from percutaneous devices due to vibration and heat [2, 16]. However, the transcutaneous nature of newer active devices like Bonebridge and Osia reduces the likelihood of skin-related issues. Nevertheless, concerns about skin thickness potentially interfering with the device's link between the sound processor and transducer remain speculative, with some studies suggesting a threshold of over 9 mm as a potential interference point [16]. Other studies have suggested a soft-tissue thickness of less than 8 mm is necessary to allow for retention of the connection between the transducer and external processor [19]. The reduced scalp thickness in pediatric patients makes the transcutaneous options advantageous in this population.

Surgical Techniques

Differences in device size and shape, as well as manufacturer recommendations, influence the surgical approaches for Bonebridge and Osia. Surgical planning considers the implantation site, which can vary based on pre-operative or intra-operative evaluations. Evaluation for retrocochlear



or central auditory disorders is vital, and pre-surgery magnetic resonance or CT scans are recommended [18].

Skin incisions for the Bonebridge or Osia can be variable based on the patient's anatomy and surgeon's preference. Figure 1 shows some possible incisions. To avoid placing the transducer directly beneath the incision, various incision types are considered: anterior, posterior, between the receiver and transducer, or in complex orientations, based on prior surgeries or complex anatomy [19]. Anterior incisions are convenient and aesthetically preferable but might compromise future auricular reconstruction, whereas posterior incisions might preserve the possibility of reconstruction [19]. Care is taken to preserve vascular structures for potential future reconstructions [19].

For Bonebridge, the preferred placement is the sinodural angle, although retrosigmoidal placement is considered if space is limited or prior mastoid surgery is evident, with an associated higher risk of dural compression [27]. In cases of abnormal sigmoid sinus anatomy or anticipated auricular reconstruction, a middle fossa placement might be indicated [27]. The Bonebridge BCI 602 shares a similar implantation procedure to its predecessor but benefits from a reduced transducer size, decreasing the need to compromise the dura [2]. Preoperative CT aids in identifying anatomical contraindications and optimal mastoid thickness for implantation [2]. A bed of at least 4.5 mm deep within the mastoid cortical bone is typically created [2]. The Bonebridge BCI 602 manufacturer's kit contains a Coil-Sizer (C-Sizer) and a Flat-Transducer-Sizer (Flat-T-Sizer) that allow approximation of the depth and thickness of the coil and transducer [22]. If the surgeon decides to avoid exposure of the dura or sigmoid sinus, lifts may be employed that reduce drilling depth by 1 mm [22].

The Osia 2 system, available in 3- and 4-mm depths, requires pre-operative CT to determine the most suitable size based on bone thickness [19]. Similar to Bonebridge, pre-operative CT aids in identifying the ideal cortical bone thickness for implantation, along with anatomical complexities and distances to the dura [19]. Implantation over the tegmen is recommended for patients with thicker cortical bone, minimizing the chance of mastoid air cells or iatrogenic cavity entry [16]. Bed preparation of at least 3 mm or 4 mm depth, depending on the implant size, is essential, measured before device implantation, followed by securing the device with self-tapping screws [28].

Skin incisions are closed in the typical fashion of most ear surgeries. Multilayer closure with absorbable sutures in the fascia layer, deep dermal epidermal layers per surgeon preference. No pressure dressing is needed, however typically patients will receive a glasscock dressing.

Audiologic Outcomes

Both Bonebridge and Osia demonstrate significant improvements in various subjective and objective audiologic measures in pediatric patients. Direct comparison literature between Bonebridge and Osia in terms of audiologic outcomes and complication rates is lacking. One study on Bonebridge implants in twenty pediatric patients showed a mean air conduction pure tone audiogram improvement of 65.7 ± 24.3 dB pre-operatively to 19.6 ± 8.2 dB post-operatively [29]. In addition, mean speech recognition threshold improved from 63 ± 24 dB to 23.7 ± 12.7 dB and mean word recognition score improved from $57.8 \pm 36\%$ to $89.3\% \pm 10.1\%$ [29]. A study on Bonebridge BCI 602 in fourteen patients under twelve, including three under five, showed an average bone conduction threshold increase of 30.0 ± 5.2 dB, with a median speech recognition score of 87.5% (range: 70-100%) for 13 patients and 50% for one patient [2]. Another study in 22 patients under eighteen revealed an increase in average word recognition score from 12.1% to 87.3% and improved hearing in both quiet and noise environments [9, 30]. Studies conducted with Osia revealed analogous improvements. A study in 14 patients aged 7 to 16 showed an average bone conduction threshold increase of 26.2 ± 2.5 dB and a separate study in 16 pediatric patients exhibited a mean functional gain in hearing of 43.2 ± 10.2 dB post-Osia implantation, with enhancements in speech understanding as per various speech audiometry tests [28].

Theoretical superiority in audiologic outcomes of active devices over passive ones is plausible. This is supported by some available comparative outcome data directly contrasting passive and ATBC implants in children. A single study compares Bonebridge BCI 601 and the BAHA Attract passive transcutaneous device in pediatric patients with CHL [13]. Both devices produced comparable improvements in hearing at lower frequencies (250 Hz, 500 Hz, 1000 Hz, and 2000 Hz), but Bonebridge exhibited notably better pure tone audiometry measurements at higher frequencies (4000 Hz and 8000 Hz) [13]. While both devices showed similar complication rates, Bonebridge demonstrated more significant hearing improvements in higher frequencies [13]. Table 2 outlines studies with reported audiologic outcomes of ATBCI.

Complications

Evidence indicates that complications associated with ATBCI appear minimal, with rates comparable to previous devices. A study involving 6 children who received

Table 2 Summary o	f studie	s outlining outcomes	and complications of t	he Bonebric	lge and Osia systems				
Author	Year	Device implanted	# of participants	Age range	Post-surgical follow-up (mo)	Daily Compliance	Mean aided threshold	Speech Recognition Scores (median)	Complications
Willenborg et al. [2]	2023	Bonebridge 602	14	3–11	NR	NR	30.9±5.2 dB	87.50%	Minor: 1 (7.1%) seroma, recovered without interven- tion Major: 1 (7.1%) wound infection requiring revision surreerv
Bae et al. [8]	2022	Bonebridge 601	ø	3-4	Patient 1: 62 Patient 2: 62 Patient 3: 59 Patient 4: 57 Patient 5: 54 Patient 6: 29	NR	28.3 dB	NR	Major: 1 (16.7%) abducens nerve palsy with intrac- ranial hypertension requiring removal
Cywka et al. [9]	2021	Bonebridge 602	22	5-18	All patients: 1, 6	NR	28.8 dB	12.1% to 82.7%	None
Shoman et al. [13]	2022	Bonebridge 601 and passive BAHA	18 Bonebridge and 8 BAHA	5-16	All patients: 3, 6, 9, 12	All patients compli- ant daily	Bonebridge: 37.2 dB at 500– 2000 Hz, 28.9 dB at 4000–8000 Hz BAHA: 39.0 dB at 500–2000 Hz, 16.7 dB at 4000–8000 Hz	NR	None
Ngui and Tang [18]	2018	Bonebridge 601	6	11–18	All patients: 6	NR	31–61 dB at 0.5–4 kHz	67.6% improve- ment	Minor: 1 (13.3%) mild surgical site infection, recovered within 1 week
Posta et al. [16]	2022	Osia	40	5-12	NR	NR	NR	NR	NR
Florentine et al. [28]	2022	Osia	14	7–16	Average: 5.3±3.7	NR	26.2±2.5 dB	NR	Minor: 1 (7.1%) seroma, 1 (7.1%) edema over surgi- cal site; recovered without interven- tion
You et al. [19]	2022	Osia	28	10-17	Average: 7.1 ±4	3/16 patients reported difficulty with daily use of implant due to processor con- nectivity; these issues resolved with changes to the processors	21.2±4.3 dB	94.80%	Minor: 1 (3.6%) seroma, resolved with conservative treatment

601: Major: retroauricular emphysema,

Speech Recognition Complications

Mean aided

Daily Compliance

follow-up (mo)

Post-surgical

range

Age

of participants

Device implanted

threshold

Scores (median)

RR

25.0 dB with 601

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6-19

Bonebridge 601

2022

Šikolová et al. [20]

and 602

and 28.0 dB with

602

resolved with revi-

sion surgery

None

NR

Average decrease in

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All patients: 6

10 - 16

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Bonebridge 601

2015

Hassepass et al.

SRT 50% in two patients: 24.5 dB Bonebridge implants reported no major post-operative complications, with only one patient experiencing a mild surgical site infection that resolved within a week after antibiotic treatment [18]. In another instance with 3 children implanted with Bonebridge, a small peri-auricular hematoma appeared in one patient after four weeks. This was likely due to the patient's resumption of saxophone play, but the hematoma resolved within three weeks through conservative treatment alone [30, 31]. A study with 22 children who received Bonebridge implants found no short- or long-term complications during follow-ups [9]. However, one study involving six patients under five years old who underwent Bonebridge 601 implantation reported one patient experiencing post-procedural lethargy, subsequent left abducens nerve palsy, and intracranial hypertension, which resolved upon device removal [8, 9]. It is important to note however, that this patient had a skull thickness of only 3.62 mm and the Bonebridge 601 requires a drilling depth of at least 8.7 mm. It is possible that implantation of Bonebridge 602 using a lift or implantation of Osia 2, with respective drilling depths of 3.5 mm and 3 mm, would have prevented entering the intracranial space and associated complication. Additionally, research suggests that the thinner transducer of Bonebridge 602 is associated with decreased complication rates compared to Bonebridge 601 [29]. Osia implantations exhibited similarly low complication rates, with one out of fourteen patients reporting only a minor post-operative skin infection that resolved spontaneously in several days [19]. Comparatively, percutaneous devices showed an overall complication rate of 58.8% versus 23.9% for ATBCI devices in pediatric patients [9]. Table 2 outlines studies with reported complication outcomes of ATBCI.

Controversies and Areas of Further Research

ATBCI are presently sanctioned for patients aged 12 and older in the US [8]. However, in Europe and various Asian countries, these implants are approved for patients aged five and above [8]. Concerns regarding implantation in children younger than five predominantly revolve around the thinner mastoid bone thickness [8]. Studies in this age group have shown promising outcomes with few complications [8]. In a study involving six children below the age of five, skull thickness in the retro-sigmoid region ranged from 3.32 mm to 6.63 mm [8]. These children received the first-generation Bonebridge BCI 601 implants, and while surgical care was taken to avoid sigmoid sinus compression, one patient experienced increased intracranial pressure necessitating device removal [8]. The newer and smaller Bonebridge BCI 602 and Osia devices mitigate

	Year
(continued)	
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NR Not Reported

these complications by providing more shallow drilling depth requirements, less than that of the thinnest skull thickness in the aforementioned study.

While some studies suggest that controlled compression and non-osseous stimulation of the dura might not significantly affect outcomes, it is important to locate the dura and sigmoid sinus pre- and intra-operatively to prevent excessive compression, injury, and intracranial complications. In addition, since the rates of dural compression between younger and older children and the tolerability threshold of dural compression remain unclear, it is best practice to avoid entry into the intracranial space when possible by utilizing the newer ATBCI technologies to reduce drilling depths and avoid dural compression altogether [8].

Data suggests that ATBCI significantly enhance hearing at higher frequencies, and they may have an impact at more normal range hearing frequencies too [2, 13]. Although the clinical relevance was deemed small, a study involving 14 pediatric patients with Bonebridge 602 implants demonstrated a statistically significant decrease in boneconduction thresholds at 2000 and 4000 Hz [2].

Conclusions

This review provides an overview of the latest evidence regarding ATBCI in pediatric patients. Research indicates that implanting these devices in children is safe and effective. The distinct anatomical considerations in children, particularly mastoid bone thickness, necessitate careful pre- and intra-operative assessments. Although a standardized minimum measure is yet to be defined, factors such as mastoid thickness and its proximity to the dura and sigmoid sinus warrant consideration. ATBCI have demonstrated substantial enhancements in hearing and word recognition, particularly exhibiting superior improvements in high-frequency hearing when compared to passive devices.

Author Contributions Vivian Kaul had the idea for the article, Patrick Gaffney and Jumah Ahmad performed the literature search and data analysis, and Patrick Gaffney and Jumah Ahmad drafted and/or critically revised the work. Shaina Gong and Vivian Kaul contributed the medical illustration figure. Vivian Kaul was the senior editor and proofed the many drafts and final product.

Declaration

Conflict of Interest The authors declare no conflict of interests.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors, therefore informed consent is not necessary.

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