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A MAUDE database analysis on the new generation of active bone conduction hearing implants

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Abstract

Objective: To analyze medical device reports (MDR) submitted to the Food and Drug Administration's (FDA) Manufacturer and User Device Facility Experience (MAUDE) database to identify adverse events (AEs) in patients implanted with novel active bone conduction hearing implants (BCIs).

Methods: We conducted a search of the FDA MAUDE database on the newest generation of BCIs. Data were collected concerning device malfunctions, patient injuries, factors triggering these incidents, and the subsequent actions taken.

Results: In total, 93 (16.7%) device malfunctions and 465 (83.3%) patient injuries with 358 subsequent interventions were identified, resulting in 558 AEs. Although the absolute AE number per device cannot be identified, the following trends were detected: Among the 494 AEs associated with OSI200, 55 (11.1%) reported device malfunctions and 454 (88.9%) cited patient injuries. Out of the 64 AEs linked to BCI602, 28 (59.4%) were associated with malfunctions, whereas 26 (40.6%) involved patient injuries. The most frequently reported particular AEs for the OSI200 were infection ($n = 171$, 34.6%), extrusion of the device ($n = 107$, 21.7%), and pain ($n = 51$, 10.3%). Conversely, no device output ($n = 20$, 31.3%) and loss of osseointegration ($n = 7$, 10.9%) were the most reported AEs for the BCI602. Various AEs led to 214 explanations and 77 revision surgeries. Sixty-seven AEs reported conservative treatment.

Conclusion: The current study provides an overview of the most commonly reported complications with new active BCIs. Although providing an overview, given the limitations of the FDA MAUDE database, our results have to be interpreted with caution.

Level of Evidence: 4.

KEYWORDS

BCI602, bone-anchored hearing aids, complications, MAUDE database, OSI200

1 | INTRODUCTION

Bone-anchored hearing aids (BAHAs) are a pivotal solution for patients with conductive hearing loss (CHL), mixed hearing loss (MHL), or single-sided deafness (SSD), especially in individuals with congenital abnormalities or multiple surgeries where traditional hearing aids are not applicable.[1] Although the earliest available forms of BAHAs relied on a percutaneous connection, in 2012, the bone conduction hearing implant (BCI) 601 (MED-EL, Innsbruck, Austria) was introduced and shifted the design to a transcutaneous approach.[2] With the device fully implanted beneath the skin, the infection, revision, and explantation rates subsided.[3] Subsequently, in 2019, the OSI100 implant (Cochlear Ltd., Sydney, Australia) entered the market as another fully implantable option, utilizing a piezoelectric transducer for sound transmission, in contrast to the BCI601's floating mass transducer (FMT).[4]

Contemporary advancements have seen manufacturers refine these devices to address the limitations of their predecessors, employing distinct geometric and functional strategies. The Bonebridge BCI602 (MED-EL, Innsbruck, Austria), introduced in 2019, presents a thinner FMT enabling implantation in patients with limited bone availability.[5] Released in the same year, the Cochlear™ Osia® OSI200 system (Cochlear Ltd., Sydney, Australia) has adopted a monolithic design, aiming to mitigate feedback and streamline the surgical process.[6] Preliminary outcomes indicate low complication rates, but there remains a lack of data on possible adverse effects, necessitating ongoing evaluation of device safety and efficacy.

The Manufacturer and User Facility Device Experience (MAUDE) database by the US Food and Drug Administration (FDA) is an essential repository for such evaluations, capturing reports of adverse events associated with medical devices.[7] The MAUDE database encompasses both mandatory and voluntary submissions and is instrumental for the FDA in overseeing device safety, facilitating timely interventions.[7] Analysis of the MAUDE database can reveal both common and rare side effects, informing manufacturers and contributing to the body of research on otologic devices.[6–10] Despite the significance of this database, to our knowledge, only a single study has analyzed active bone conduction implant malfunctions and adverse events.[11] Unfortunately, this publication did not account for the differing release dates of the Bonebridge and Osia systems nor distinguish between device generations, which could skew comparative analyses.[11]

Although still not being able to correlate the total number of implantations with the quantified MDRs due to the nature of the MAUDE database, the current study aims to fill this gap by comprehensively assessing adverse events and device malfunctions associated with the latest generation of bone conduction hearing implants. By analyzing MDRs submitted to the MAUDE database from 2019 to 2023 for the OSI200 and the BCI602, we intend to reveal the challenges and potential risks associated with these novel devices, thus enabling clinicians and patients to make informed decisions.

2 | METHODS

2.1 | Search strategy

MAUDE database was accessed via the Total Product Life Cycle (TPLC) database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm). To exclusively identify the new generation of active bone-anchored hearing aids, we employed the following search terms: for the OSI200, the search terms were "COCHLEAR OSIA OSI200 IMPLANT" for the "Brand Name" and "OSI200" for device model number. For the BCI602, "BONEBRIDGE" for "Brand Name" and "BCI602 BONE CONDUCTION IMPLANT" for "Device Model Number." The database was queried for all results from December 1, 2019 to July 24, 2023.

2.2 | Data extraction

The Excel download tool (Microsoft Corporation, 2018. Microsoft Excel, Available at: https://office.microsoft.com/excel) of the TPLC database was used to export MDRs. We included all reports for the OSI200 and BCI602. Exclusion criteria were duplicate report entries, reports unrelated to OSI200 and BCI602, and lack of information regarding the event (no device malfunction and no patient injury reported). Reports that met the inclusion criteria were stratified by device type. The event description was reviewed, and data were collected on timing of events, device malfunction, patient injury, inciting events, and subsequent interventions. The majority of the MDRs detailed multiple adverse events. When an MDR specifically stated the outcome of a subsequent intervention, we categorized it as "additional information."

2.3 | Categorization

Adverse events were categorized into device malfunctions and patient injuries. Each report included a maximum of one primary device malfunction and up to two recorded patient injuries. The inciting events for adverse events were identified as magnetic resonance imaging (MRI) and trauma. Device malfunctions were stratified into specific categories, encompassing distorted audio perception, insufficient magnet strength, magnet dislodgement, loss of osseointegration, malposition, no benefit, limited benefit, no device output, static noise, no auditory sensation, and vibration. Patient injuries were stratified to include discomfort, pain, skin irritation, swelling, hematoma, wound dehiscence, extrusion, infection, necrosis, ulceration, and wound-healing problems. Rare patient injuries occurring fewer than three times were consolidated under the umbrella category "other." Subsequent interventions for adverse events included explantation, revision surgery, and conservative management. When multiple subsequent interventions were reported, we prioritized the more invasive intervention in the following order, progressing from least to most invasive: conservative management, revision surgery, and

explantation. Additional information encompassed reimplantation, problem resolution, and implant in situ. Patient consent for this study was waived, given its exclusive reliance on publicly available datasets. The de-identified nature of the data from the MAUDE database ensures participant privacy. The collected data were summarized and organized in an Excel spreadsheet (Microsoft Corporation, 2018. Microsoft Excel, Available at: https://office.microsoft.com/excel).

3 | RESULTS

The search query revealed 791 MDRs for the OSI200 and 61 MDRs for the BCI602, resulting in a total of 852 MDRs. Subsequently, 422 MDRs (49.5%) were excluded, with 383 MDRs (90.8%) identified as duplicates and 39 MDRs (9.2%) lacking sufficient information. A total of 430 MDRs (50.5%) met the inclusion criteria, with 379 MDRs associated with the OSI200 and 51 MDRs with the BCI602, which formed the dataset utilized for analysis. Figure 1 shows a flow chart of the MDR identification, inclusion and exclusion process.

3.1 | Total cohort

Table 1 shows all identified adverse events categorized by device type, totaling 558 incidences. Among these, 93 (16.7%) were device malfunctions, whereas 465 (83.3%) were patient injuries. Specifically, among the 494 adverse events associated with the OSI200, 55 (11.1%) were reported as device malfunctions, whereas 439 cases (88.9%) resulted in patient injuries. The most frequent adverse events for the OSI200 included infection ($n = 171$, 34.6%), extrusion ($n = 107$, 21.7%), and pain ($n = 51$, 10.3%). Within the BCI602 cohort, 26 (40.6%) of the 64 adverse events were linked to patient injuries

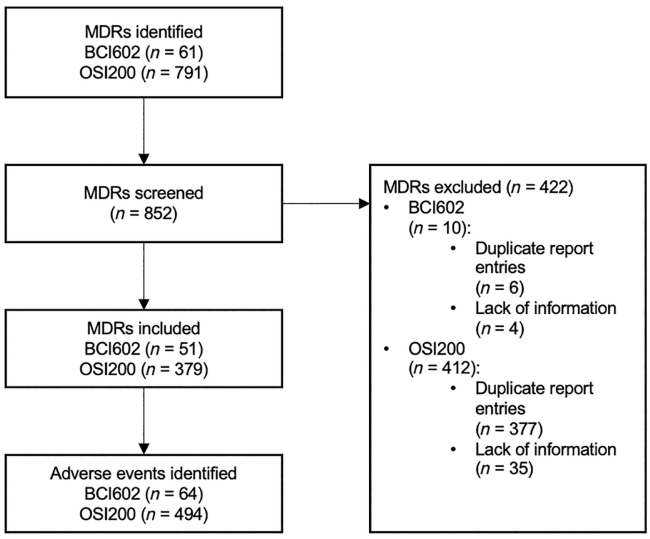

FIGURE 1 Flowchart of medical device report (MDR) identification, inclusion and exclusion. BCI, bone conduction hearing implant.

and 38 (59.4%) were attributed to device malfunctions. The most common issues reported for the BCI602 were no device output ($n = 20$, 31.3%), loss of osseointegration ($n = 7$, 10.9%), wound dehiscence ($n = 6$, 9.4%), and pain ($n = 6$, 9.4%).

3.2 | Device malfunction

In the OSI200 group, the most common malfunction was magnet dislodgement ($n = 11$, 20.0%), followed by limited benefit ($n = 9$, 16.4%), no device output ($n = 8$, 14.5%), and insufficient magnet strength ($n = 8$, 14.5%). In the BCI602 cohort, device malfunctions included no device output ($n = 20$, 52.6%), loss of osseointegration ($n = 7$, 18.4%), and limited benefit ($n = 4$, 10.5%). Notably, occurrences of magnet dislodgement, mispositioning, lack of benefit, nonauditory sensations, and vibration were exclusive to the OSI200 reports, whereas distorted audio perception was mentioned only in BCI602 reports.

3.3 | Patient injuries

In the OSI200 group, prevalent patient injuries were infection ($n = 171$, 39.0%), extrusion ($n = 107$, 24.4%), and pain ($n = 51$, 11.6%). For the BCI602, prominent patient injuries included pain ($n = 6$, 23.0%) and wound dehiscence ($n = 6$, 23.0%), followed by infection ($n = 5$, 19.2%). Notably, patient injuries such as infection, necrosis, ulceration, and wound-healing problems were exclusively reported with the OSI200, but it should be kept in mind that the absolute number of implanted devices is unknown, which could have contributed to this finding. Rare incidents were summarized under the "other" category. For the OSI200, two (0.8%) instances of granuloma growth and one (0.4%) soft tissue growth under the implant, one (0.4%) bone overgrowth, and one (0.4%) postoperative bleeding were reported. Additionally, two (0.8%) OSI200 implants were explanted due to patient preferences. In the BCI602 group, rare patient injuries included one case (1.6%) of cerebrospinal fluid fistula, one (1.6%) air bubble under the FMT, one (1.6%) meningitis, and one (1.6%) postoperative growth of cholesteatoma.

3.4 | Interventions according to primary adverse events

Table 2 shows interventions categorized by type of adverse event. Among the 358 primary adverse events with reported subsequent interventions, 344 were linked to the OSI200, whereas 14 were associated with the BCI602. Among the subsequent information for the OSI200, 202 (58.7%) explantations and 75 (21.8%) revision surgery were reported. Infection emerged as the leading cause for explantation ($n = 76$, 37.6%), followed by revision surgery ($n = 20$, 26.7%) and conservative treatment ($n = 36$, 53.7%). For the BCI602, 12 (85.7%) and two (14.3%) explantations and revision surgeries were reported, respectively. Interestingly, the most

TABLE 1 All events and interventions by device type.

Categories	*n* (% total)	OSI200 (% total)	BCI602 (% total)
Device malfunction			
Distorted audio perception	3 (100%)	0 (0%)	3 (100%)
Insufficient magnet strength	10 (100%)	8 (80%)	2 (20%)
Magnet dislodgement	11 (100%)	11 (100%)	0 (0%)
Loss of osseointegration	14 (100%)	7 (50%)	7 (50%)
Malposition	4 (100%)	4 (100%)	0 (0%)
No benefit	2 (100%)	2 (100%)	0 (0%)
Limited benefit	13 (100%)	9 (69%)	4 (31%)
No device output	28 (100%)	8 (29%)	20 (71%)
Static noise	4 (100%)	2 (50%)	2 (50%)
No-auditory sensation	2 (100%)	2 (100%)	0 (0%)
Vibration	2 (100%)	2 (100%)	0 (0%)
Patient injury			
Discomfort	8 (100%)	7 (88%)	1 (13%)
Pain	57 (100%)	51 (89%)	6 (11%)
Skin irritation	8 (100%)	8 (100%)	0 (0%)
Swelling	20 (100%)	17 (85%)	3 (15%)
Hematoma	15 (100%)	15 (100%)	0 (0%)
Wound dehiscence	47 (100%)	41 (87%)	6 (13%)
Extrusion	108 (100%)	107 (99%)	1 (1%)
Infection	176 (100%)	171 (97%)	5 (3%)
Necrosis	2 (100%)	2 (100%)	0 (0%)
Ulceration	3 (100%)	3 (100%)	0 (0%)
Wound-healing problem	10 (100%)	10 (100%)	0 (0%)
Other	11 (100%)	7 (64%)	4 (36%)
Total			
	558 (100%)	494 (89%)	64 (11%)

Note: Category "other" comprised one cerebrospinal fluid fistula ($n = 1$), air bubble under the floating mass transducer ($n = 1$), meningitis ($n = 1$) and postoperative growth of cholesteatoma ($n = 1$) for the BCI602 and granuloma growth ($n = 2$), soft tissue growth under the implant ($n = 1$), bone overgrowth ($n = 1$), postoperative bleeding ($n = 1$), and explanted due to patient preferences ($n = 2$) for the OSI200. Abbreviation: BCI, bone conduction hearing implant.

prevalent reason for BCI602 explantation was loss of osseointegration ($n = 3$, 25%). The BCI602 revision surgeries were attributed to one (50%) loss of osseointegration and one (50%) extrusion of the device. Overall, conservative management was the least reported subsequent intervention, comprising 67 interventions, all exclusively reported for the OSI200.

3.5 | Cause for device malfunction

Table 3 presents a summary of root causes of device malfunction for both implant generations. Overall, 27 (4.8%) adverse events reported root cause of malfunction. Notably, MRI emerged as the predominant reported cause of adverse events, constituting a total of 16 (59.3%) incidences, whereas trauma contributed to 11 (40.7%) adverse events. Upon closer examination, MRI predominantly led to device malfunction, encompassing magnet dislodgement in nine (56.3%) cases, distorted audio perception in two (12.5%) cases, and insufficient magnet strength in two (12.5%) cases. In contrast, trauma was associated with device malfunction in five (45.5%) cases and patient injury in six (54.5%) cases. Specifically, we found that six of 16 (37.5%) MDRs reported MRI magnet strength, with four (16.7%) for the BCI602 and 2 (20%) for the OSI200. A 3 Tesla MRI caused two cases of insufficient magnet strength in the BCI602 and one magnet dislodgement in the OSI200. A 1.5 Tesla MRI caused one static noise and one magnet dislodgement in the BCI602 and OSI200, respectively.

3.6 | Additional information

A total of 145 (33.7%) reports provided information regarding the subsequent events following an intervention, 141 of the OSI200 and

TABLE 2 Intervention by primary adverse event and device type.

		OSI200			BCI602		
Categories	*n* (% total)	Explantation (% total)	Revision surgery (% total)	Conservative treatment (% total)	Explantation (% total)	Revision surgery (% total)	Conservative treatment (% total)
Device malfunction							
Distorted audio perception	1 (100%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)	0 (0%)
Insufficient magnet strength	8 (100%)	1 (13%)	5 (63%)	2 (25%)	0 (0%)	0 (0%)	0 (0%)
Magnet dislodgement	9 (100%)	1 (11%)	8 (89%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Loss of osseointegration	11 (100%)	6 (55%)	1 (9%)	0 (0%)	3 (27%)	1 (9%)	0 (0%)
Malposition	4 (100%)	2 (50%)	2 (50%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
No benefit	2 (100%)	2 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Limited benefit	9 (100%)	9 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
No device output	7 (100%)	6 (86%)	0 (0%)	0 (0%)	1 (14%)	0 (0%)	0 (0%)
Static noise	3 (100%)	2 (67%)	0 (0%)	0 (0%)	1 (33%)	0 (0%)	0 (0%)
No-auditory sensation	2 (100%)	1 (50%)	0 (0%)	1 (50%)	0 (0%)	0 (0%)	0 (0%)
Vibration	2 (100%)	2 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Patient injury							
Discomfort	3 (100%)	3 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Pain	33 (100%)	22 (67%)	3 (9%)	7 (21%)	1 (3%)	0 (0%)	0 (0%)
Skin irritation	6 (100%)	4 (67%)	1 (17%)	1 (17%)	0 (0%)	0 (0%)	0 (0%)
Swelling	4 (100%)	1 (25%)	2 (50%)	1 (25%)	0 (0%)	0 (0%)	0 (0%)
Hematoma	12 (100%)	1 (8%)	9 (75%)	2 (17%)	0 (0%)	0 (0%)	0 (0%)
Wound dehiscence	24 (100%)	14 (58%)	5 (21%)	3 (13%)	2 (8%)	0 (0%)	0 (0%)
Extrusion	63 (100%)	39 (62%)	15 (24%)	8 (13%)	0 (0%)	1 (2%)	0 (0%)
Infection	134 (100%)	76 (57%)	20 (15%)	36 (27%)	2 (1%)	0 (0%)	0 (0%)
Necrosis	2 (100%)	1 (50%)	0 (0%)	1 (50%)	0 (0%)	0 (0%)	0 (0%)
Ulceration	3 (100%)	0 (0%)	0 (0%)	3 (100%)	0 (0%)	0 (0%)	0 (0%)
Wound-healing problem	10 (100%)	6 (60%)	2 (20%)	2 (20%)	0 (0%)	0 (0%)	0 (0%)
Other	6 (100%)	3 (50%)	2 (33%)	0 (0%)	1 (17%)	0 (0%)	0 (0%)
Total							
	358 (100%)	202 (56%)	75 (21%)	67 (19%)	12 (3%)	2 (1%)	0 (0%)

Abbreviation: BCI, bone conduction hearing implant.

four of the BCI602 (Table 4). In 214 explantations, 36 (16.8%) reported reimplantation. Among 77 revision surgeries, 62 (80.5%) mentioned a postoperative outcome, with 11 cases (17.7%) reporting to have successfully addressed the issue, whereas 51 reports (82.3%) indicated the implant remained in situ. Regarding additional information after 67 conservative treatments, nine (13.4%) MDRs reported problem resolution, and 38 (56.7%) MDRs noted that the implant remained in situ.

4 | DISCUSSION

This study is the first to analyze adverse events specifically related to the BCI602 and OSI200 hearing implants, which represent the latest transcutaneous bone-anchored hearing aid generation, using data extracted from the MAUDE database. Our analysis highlights distinct reporting patterns in device malfunctions and patient injuries. Although most reports mention subsequent interventions, only a fraction of the reported MDRs provide detailed event descriptions.

The present study revealed a high frequency of patient injuries related to the OSI200 device, with a notable predominance of infection reports. The BCI602 exhibited a trend toward device malfunctions rather than patient injuries. As stated above, it is important to note that the absence of comprehensive data on the total number of implanted devices prevents accurate incidence calculations for both infections and malfunctions associated with either device. Thus, any comparative analysis should be approached with caution.

TABLE 3 Reported cause for device malfunction and device type.

		OSI200		BCI602	
Categories	***n* (% total)**	**MRI (% total)**	**Trauma (% total)**	**MRI (% total)**	**Trauma (% total)**
Device malfunction					
Distorted audio perception	2 (100%)	0 (0%)	0 (0%)	2 (100%)	0 (0%)
Insufficient magnet strength	2 (100%)	0 (0%)	0 (0%)	2 (100%)	0 (0%)
Magnet dislodgement	9 (100%)	9 (100%)	0 (0%)	0 (0%)	0 (0%)
Loss of osseointegration	1 (100%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)
No device output	5 (100%)	0 (0%)	0 (0%)	1 (20%)	4 (80%)
Static noise	1 (100%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)
Patient injury					
Skin irritation	1 (100%)	0 (0%)	1 (100%)	0 (0%)	0 (0%)
Wound dehiscence	2 (100%)	0 (0%)	1 (50%)	0 (0%)	1 (50%)
Extrusion	1 (100%)	1 (100%)	0 (0%)	0 (0%)	0 (0%)
Infection	3 (100%)	0 (0%)	2 (67%)	0 (0%)	1 (33%)
Total					
	27 (100%)	10 (37%)	4 (15%)	6 (22%)	7 (26%)

Abbreviations: BCI, bone conduction hearing implant; MRI, magnetic resonance imaging.

In fact, current literature reflecting large-scale studies of BCI602 and OSI200 implantations indicate a comparable distribution of adverse events across both devices. The biggest available cohort study of the BCI602 by Sprinzl et al. observed two bacterial infections and one swelling, resulting in a total adverse event rate of 9%.[5] All events were well manageable, with no subsequent explantation.[5] Comparable results were concluded in the meta-analysis by Magele et al. on the BCI601, with a total adverse event rate of 9.4%.[12] Of those, 7.7% accounted for minor complications, ranging from itching at the implant site to infection, whereas 1.7% were major complications like chronic infections, which led to explantation or revision surgery.[12] A recent meta-analysis comprising 314 patients implanted with the Osia System, observed an overall wound infection rate of 1.92% and wound-related complications rate of 0.07%.[13] The authors observed no incidence of hypertrophy, pain and device extrusion.[13] In addition, a study by Cowan et al. describes no major adverse events in a 24-month follow-up period.[14] These results are in line with the present findings, where infections, wound dehiscence and pain accounted for over 1/2 of OSI200 related patient injuries. However, discrepancies can be observed with regards to device malfunctions. Although device malfunction was the primary MDR for the BCI602, device malfunctions are rarely reported in the current literature.[5,15,16]

The discrepancy in the types of adverse events reported for the OSI200 and BCI602 may be influenced by reporting practices rather than actual device performance. On the one hand, physicians' perceptions of what constitutes a reportable adverse event can significantly influence reporting behavior.[17] A qualitative interview study by Gagliardi et al. revealed that adverse events which are seen as expected parts of practice, or those that clinicians believe they can manage by switching devices or employing workaround strategies, may be underreported.[18] On the other hand, the MAUDE database, managed by the FDA, predominantly compiles adverse event reports that originate from the United States.[11] The OSI200, being widely available in the United States, is subject to a broader spectrum of clinical applications and patient populations, thus exposing it to a greater diversity of clinical scenarios and potential for patient injuries.[19] Conversely, the BCI602, mainly distributed in Europe, may be used in more controlled settings or specific populations, possibly resulting in a higher reporting of device malfunctions.[5,20]

Interestingly, we identified discrepancies between MAUDE database outcomes and current meta-analyses on both implant generations. Specifically, rare adverse events such as device malfunction leading to explantation, magnet dislodgement or postoperative growth of cholesteatoma were not documented in recent meta-analyses.[13,21] This underscores the importance of large, objective databases like MAUDE for capturing a comprehensive range of potential complications, providing a fuller understanding of the safety profile of new implants.

The strength of the MAUDE database is the identification of rare side effects. In particular, a case of meningitis was reported for the BCI602. Correspondingly, Harris et al. documented a patient who experienced meningitis after BCI602 implantation.[22] During drilling of the bone bed for the FMT, a dural violation occurred, requiring intraoperative repair and leading to the development of an intracranial abscess.[22] Because the BCI602 uses a FMT, it is possible that the dura may be exposed during bone bed drilling.[5] In cases of lower bone availability, the use of lifts remains a viable option. Recent publications demonstrate that lifts enable successful implantation in this patient group, yielding equally favorable hearing outcomes.[23,24]

Infection was the most prevalent cause of patient injuries regarding all reported adverse events. The use of preoperative and postoperative antibiotics in clean otologic surgery is still controversial.

TABLE 4 Patient injury and device problems with subsequent information and reported outcomes.

		OSI200				BCI602			
Subsequent intervention	*n* (% total)	No information (% total)	Reimplantation (% total)	Problem resolved (% total)	Implant in situ (% total)	No information (% total)	Reimplantation (% total)	Problem resolved (% total)	Implant in situ (% total)
Explantation	214 (100%)	169 (79%)	33 (15%)	0 (0%)	0 (0%)	9 (4%)	3 (1%)	0 (0%)	0 (0%)
Revision surgery	77 (100%)	14 (18%)	0 (0%)	11 (14%)	50 (65%)	1 (1%)	0 (0%)	0 (0%)	1 (1%)
Conservative management	67 (100%)	20 (30%)	0 (0%)	9 (13%)	38 (57%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Total	358 (100%)	203 (57%)	33 (9%)	20 (6%)	88 (25%)	10 (3%)	3 (1%)	0 (0%)	1 (0%)

Abbreviation: BCI, bone conduction hearing implant.

Although no general antibiotic administration is recommended to date,[25] recent studies underscore the lack of consensus among practicing otolaryngologists.[26] In the present study, we observed a high rate of explantations following wound infections. A recent systematic review recommends a single shot of antibiotics preoperatively in cochlea implant surgery, despite limited supporting evidence, due to the high financial and health risks.[25] Due to equally high costs of explantation in case of bone conduction implant infection, single shot antibiotics could be a viable option to prevent postoperative infections.

Although both implants are transcutaneous, they differ significantly in function, design, and market presence. Notably, we observed that extrusions were the second most commonly reported patient injury in the OSI200 group. Regarding the new monolithic design of the OSI200, the risk for extrusion through mechanical stress through the skin could be elevated. However, this adverse event is rarely described in the literature. The study by Crowder et al. describes three case of device extrusion through the skin.[11] Because the cohort does not differentiate between OSI200 and the OSI100, the side effects cannot be attributed to a specific implant generation. Moreover, a recent study mentioned device protrusion but not extrusion.[14] Nonetheless, surgeons and health care providers should be aware of this potential side effect, and future research should investigate the actual risks associated with it.

The BCI602 and the OSI200 are both MRI conditional up to 1.5 Tesla. However, we observed MRI as the most common root cause for device malfunction. Multiple prior studies analyzed the MRI-implant interactions and their influence on possible follow-up examinations.[27,28] Until now, problems after MRI have only been reported anecdotically.[29] Because MAUDE does not provide precise reasons, examiner error could contribute to MRI related adverse events, as MRI compatibility is dependent on meeting manufacturer-defined conditions.[29] However, this can be mitigated through enhanced patient and provider awareness of otologic implant compatibility, particularly in light of the growing utilization of MRI in clinical routine diagnostics. Future research should prioritize the identification of potential vulnerabilities and the enhancement of MR safety in otologic implants.

4.1 | Limitations

In addition to the aforementioned limitations, there are further points that need to be considered regarding the utilization of the MAUDE database. These include the potential for underreporting and the inability to establish causality. Furthermore, the FDA database operates as a passive surveillance system, which introduces the risk of incomplete, inaccurate, untimely, unverified, or biased data submissions. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency of device use. In most cases, further investigation is necessary to understand the cause of the adverse event.

5 | CONCLUSION

In conclusion, this study presents the first comprehensive analysis of the MAUDE database concerning adverse events associated with the BCI602 and OSI200 implants. It offers an overview of the most frequently reported complications during the initial years of hearing rehabilitation. Despite its limitations, the MAUDE database provides value by enhancing our understanding of otologic device implantation, allowing us to uncover potential side effects that may not have been captured in current studies.

CONFLICT OF INTEREST STATEMENT

L.D.L. receives research funding from Decibel Therapeutics and Amgen and has worked as an independent consultant for Gerson Lehrman Group and Conclave Capital. D.R. is receiving grants from MED-EL outside the submitted work. No other disclosures were reported.

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