Article

The Utility of the MAUDE Database for Osseointegrated Auditory Implants

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Abstract

Objective: To determine the utility of Manufacturer and User Friendly Device Experience (MAUDE) database in studying osseointegrated auditory implant (OAI)–related complications.

Methods: The MAUDE database was searched for all reports involving OAIs (ie, Baha, Ponto, Sophono). Complications were classified into 1 or more of 6 categories—implant, abutment, processor, skin, surgery, and other. Subcategories were generated to prevent overgeneralization. Other variables recorded included date of report, number of complications per report, manufacturer, and time from complication to report.

Results: Over the study period, there were 269 complications listed from 238 reports divided into the following categories: implant related (n = 145), abutment related (n = 16), processor related (n = 13), skin and soft tissue related (n = 79), surgery related (n = 11), and other (n = 5). No demographic data were available. There were no discernible trends from the data, and when compared to published literature, MAUDE data appear to under- or misrepresent complications.

Conclusion: The MAUDE database is limited in its design and given fairly disparate reporting quality may not be ideally suited for quantifying risks of OAIs. These findings suggest the necessity for a substantially improved central registry for otologic implants and highlight the need for further research to investigate the root causes of their associated complication

Keywords

BAHA, otology, otolaryngology, complications, miscellaneous, clinical database, osseointegrated implants

Introduction

Osseointegrated auditory implants (OAIs) have proven to be extremely useful in the treatment of patients with conductive, mixed, or single sided sensorineural deafness. First described in 1977 by Tjellström et al[1] and approved by the United States Food and Drug Administration (FDA) in 1996,[2] they function by direct vibration of the cochlear fluid (ipsilateral or contralateral) by a processor coupled via an osseointegrated implant to the mastoid bone.

Despite the excellent auditory outcomes demonstrated over decades, OAIs are not without risks or complications. These adverse events can be either intraoperative or postoperative and can be related to the surgical technique, the implant, the abutment, the processor, postoperative wound healing, or any combination therein. Reported complication rates are disparate. For example, the incidence of skin reactions has been reported from 2.4% to 38% and loss of the implant (for any reason) from 1.6% to 17.4%.[3-5] The presence of such a large discrepancy indicates the need for better and standardized tools for reporting of these complications.

The Manufacturer and User Friendly Device Experience (MAUDE)[6] database was established by the FDA to aid in the reporting and analysis of medical device–related complications. It is the largest openly searchable public database for device-related complications. Entries to MAUDE are broadly classified into 2 general categories—reports from mandatory reporters (manufacturers, importers, device using facilities) and reports from voluntary reporters (physicians and patients). Previous authors have used MAUDE to reveal trends in device complications with variable conclusions regarding its utility. This includes studies on robot-assisted surgical systems, endometrial ablation devices, surgical lasers, automated external defibrillators, lariat devices for left atrial appendages, inferior vena cava (IVC) filters, and cochlear implants (CI), among others.[7-14] Despite the increasing prevalence of OAI, it has never been studied for this patient population.

The purpose of this study was to determine the utility of MAUDE in understanding patterns and trends in OAI-related complications. In addition, this study sought to

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highlight any limitations that may prevent MAUDE from being a useful tool in studying adverse consequences of OAIs.

Methods

The MAUDE database was accessed on January 1, 2015, at the following website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm. All reports were searched for between January 1, 1990, and January 1, 2015. The following search criteria were used: manufacturer (Cochlear, Entific [which later became Cochlear], Oticon, Oticon Medical, Sophono) and device (bone anchored hearing aid, BAHA, Baha, Ponto, Alpha 2 MPO). Complications were classified into 1 of 6 categories: (1) implant related, (2) abutment related, (3) processor related, (4) skin related, (5) surgery related, and (6) other. All records were combined and duplicates removed. Subcategories were generated during review to prevent overgeneralization. The number of complications per report was recorded. Date of complication (DOC) and date of report (DOR) were also recorded for each report. The DOC and DOR that were within 12 months were considered to be within the same year. Reporter type (mandatory or voluntary) was not available.

Results

For the study period, 269 total complications were identified within 238 reports. Two hundred thirteen (90%) reports included 1 complication, 21 (9%) included 2 complications, and 3 (1%) included more than 2 complications, including 1 with 8 complications described. Figure 1 is a summary of the total number of complications by category. The list of subcategories encountered can be seen in Table 1. Figure 2 represents the number of reports by year. The earliest report was January 1, 2003. The year with the fewest number of reports was 2007, with zero reports logged. The year with the highest number of reports was 2014, with 106 reports, representing 44.5% of the total number of reports for the entire study period. Figure 3 shows the duration between DOC and DOR. Eighty reports (33.6%) were logged within 1 month of the associated complication(s). Nineteen reports (8.0%) were logged over 1 year later. Fifty-three reports (22.3%) had no identifiable DOC.

By manufacturer, the number of complications recorded during the study period were: Oticon Medical 140 (52%), Cochlear Ltd (including Entific) 123 (46%), and Sophono 6 (2%). The average number of complications per report did not differ significantly by manufacturer. Cochlear Ltd had the highest number of complications in every category with the exception of implant related (Oticon Medical). No total number of OAIs placed during the study period could be found in MAUDE. As a result, no further manufacturer-related analysis was performed.

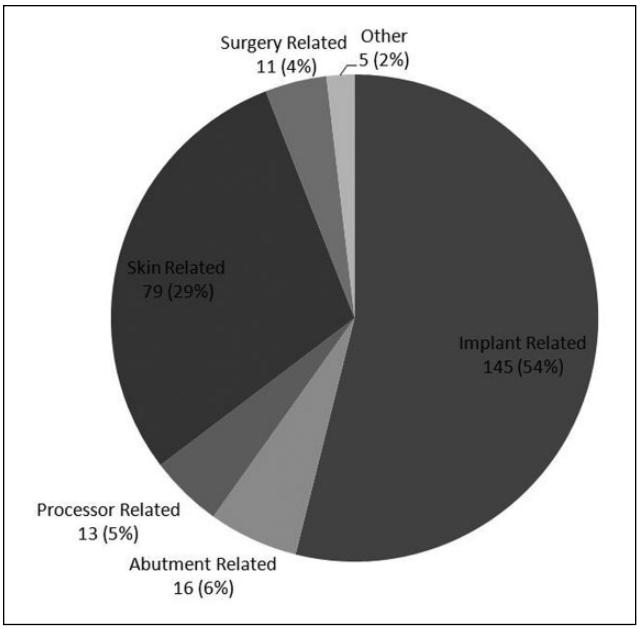

Figure 1. Osseointegrated auditory implant complications by category.

Discussion

Osseointegrated auditory implants, while beneficial by many objective and subjective measures, are surgically implantable devices and therefore not without their share of potential complications. The literature is inconsistent in reporting the nature and incidence of complications associated with OAIs. Variable definitions of complications, threshold for reporting of complications, single center case series, and other biases preclude published research data from serving as the gold standard for the true incidence of OAI-related complications. In a recent meta-analysis, Kiringoda et al[15] studied 20 articles comprising 2134 patients with 2210 osseoimplants. Their results show a wide range of complication rates (Figure 4). Even the relatively strong statistical methods of meta-analysis fall short in clarifying trends in complications for OAIs. This would suggest the need for a well-designed and actively updated central registry.

As a result of the Safe Medical Devices Act of 1990, MAUDE is a public database mandated by the FDA as one of the systems put in place for postmarket surveillance. Manufacturers, importers, and device user facilities are required by law to report devices that result in or contributed to a death or serious injury due to a malfunction.[6,16,17] The FDA warns users that data from MAUDE cannot be used to establish rates of complications,[6] though others have commented on its usefulness in establishing trends.[8,13,14] Our goal was to evaluate MAUDE's usefulness in understanding complications of OAIs.

The major limitation of MAUDE for OAI-related complications is the disparate reporting and overall lack of

Table 1. Adverse events by category.

Category	No. of Reports
Implant related	
Pain	8
Implant loss, initial failure to osseointegrate	35
Implant loss, due to trauma	21
Implant loss, due to revision surgery	3
Implant loss, due to infection	7
Implant loss, etiology unknown	71
Total	145 (53.9%)
Abutment related	
Pain	5
Abutment loss/removal	11
Total	16 (5.9%)
Processor related	
Broken plastic	2
Broken switch	1
Battery leak	1
Processor inoperable	2
Incorrect programming	7
Total	13 (4.8%)
Skin related	
Infection	35
Allergic reaction	1
Hypertrophic scar	2
Seroma	1
Magnet sore/exposure	5
Skin overgrowth	25
Wound failure to resolve	10
Total	79 (29.3%)
Surgery related	
Hematoma	3
Abscess, postoperative	2
Subarachnoid air	1
Misplacement of device	2
Stripped cover screw	1
Surgical maintenance of device	2
Total	11 (4.1%)
Other	
Dizziness	1
Finger wrapped around safety line	1
Failure to disconnect	1
Sterility violation/expiration	2
Total	5 (1.9%)

uniformity, making classification difficult. When a report is made to MAUDE, the reporter enters free text about the event and submits it. The result is a range between vague and useless words to overly detailed and extensive information in any given report. In their analysis of automated external defibrillator complications, DeLuca et al[10] reported that of the 1150 MAUDE reports they reviewed, only 12% were unambiguous, 51% had somewhat clear and useful information, 33% had somewhat vague with key information missing, and 4% of reports had no useful information. They were only able to detect the actual type of failure in 79.4% of all reports. We experienced similar difficulty in classification, which resulted in the initial formation of as many as 19 subcategories within a category (this was subsequently pared down to 7 subcategories).

The current study found implant loss as the most commonly reported complication within the database. This contrasts many other reports where implant loss was fairly uncommon compared to other complications.[4,5] Likewise, in these same studies (and in the senior author's experience), skin reactivity issues are the most prevalent complications seen in OAIs; however, MAUDE reports of skin issues are a distant second place behind implant loss. This difference in the relative incidence of complications between reality and the database is misleading and is likely due to reporting bias. As skin reactions are relatively commonplace, with most easily managed in the office, most surgeons may not consider one sufficiently adverse to necessitate a report to the manufacturer and/or a federal database. Nonetheless, this study found 29% of all reported complications within the database to be skin-related. This may be related to who is reporting the complication.

The MAUDE database does not directly differentiate between mandatory and voluntary reporters. This is a potential major problem as industry and patients may have very divergent ideas of what constitutes a serious adverse event (SAE). Although not specifically identified, reports such as "patient feeling ill to upper respiratory illness and suspects the implant" does not constitute a SAE and was therefore likely entered by a voluntary reporter. The more technically specific reports may have been submitted by industry, though as in the aforementioned example, there is no way to know for sure. We found the majority of reports to be technical in nature, suggesting the majority of reports were filed by mandatory reporters (eg, manufacturer, importer, distributor, hospital). In addition, since no unique case identifiers are included in reports, it is conceivable that both mandatory and voluntary reporters are submitting entries for the same complication (potentially separated by months or longer).

Another of the more substantial shortcomings of MAUDE is its failure to include the total number of OAIs placed (devices placed with and without complications), a popular point that has been made by other studies.[7-14] Without this denominator, only relative comparisons of values within the MAUDE data set can be determined, and prevalence cannot be known. This is of limited value to the researcher, clinician, or patient. Moreover, without the context of total numbers of OAIs placed over a given timeframe, MAUDE searchers (including candidates) could misinterpret the data. Potential candidates may inaccurately conclude that based on the number of reports, one manufacturer has a higher rate of complications than others. In fact, this is simply unknown. It should

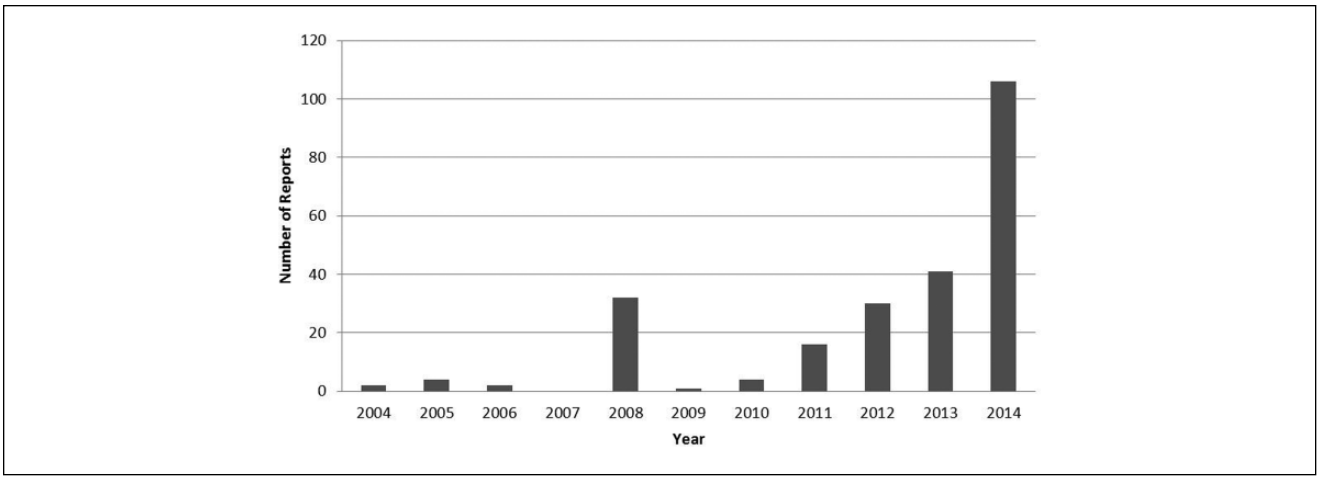

Figure 2. Reports submitted by year.

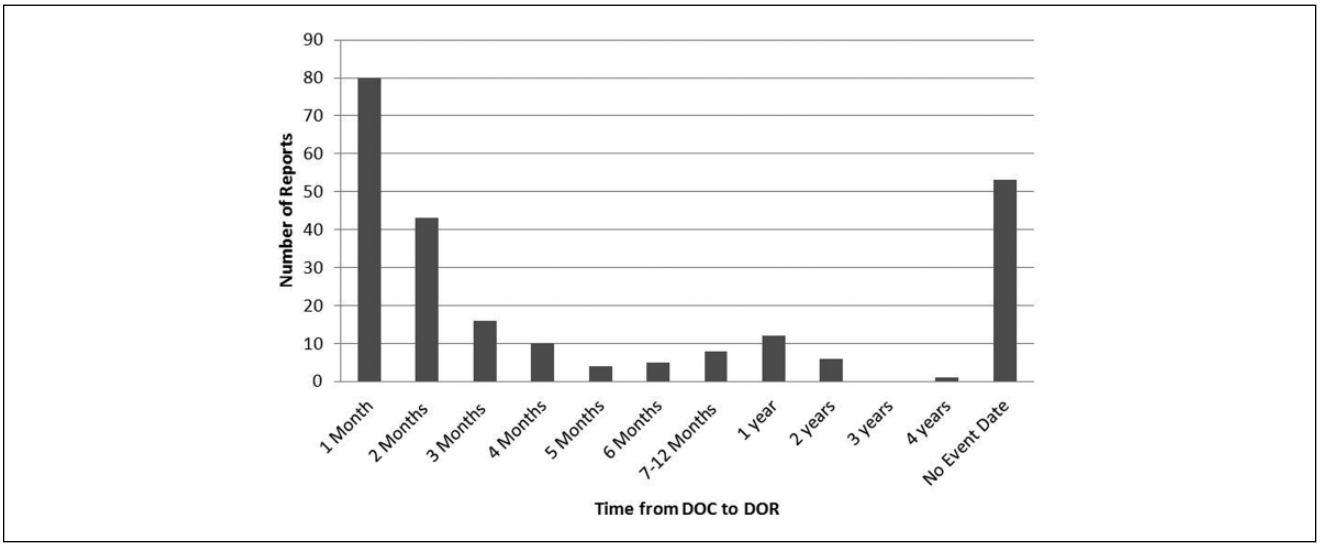

Figure 3. Time interval between date of complication and date of report.

be mentioned that as a tool for this type of investigation, the FDA does indeed acknowledge on their website that "data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices."[6] Moreover, despite disclaimers to the contrary on the MAUDE website, the casual searcher of this database may inaccurately conclude that complications are due to a fault with the product itself—whereas in reality, given the ability for anyone to report "complications," device users themselves may have caused or contributed to the complications.

Manufacturers, who do know the total number of devices implanted, may benefit more from MAUDE. Perhaps one of the few benefits to a given manufacturer is to learn about potential complications seen in competing products. However, while those within the industry may look at MAUDE from time to time, no systematic analyses are performed with this tool (personal communication with each manufacturer).

Although the FDA approved OAIs in 1996, the first report is not found until 2004. With the exception of a reporting spike in 2008, the number of reports between 2004 and 2010 are in the single digits and inconsistent (Figure 2). The reasons for this are unclear as this is in stark contrast to the rising number of implants placed each year (personal communication with each manufacturer). Mandatory reporters are required by law to input the data within 30 days; however, industry representatives may not be aware of a particular complaint or complication for months after it occurs. This likely translates into substantial delays (months or

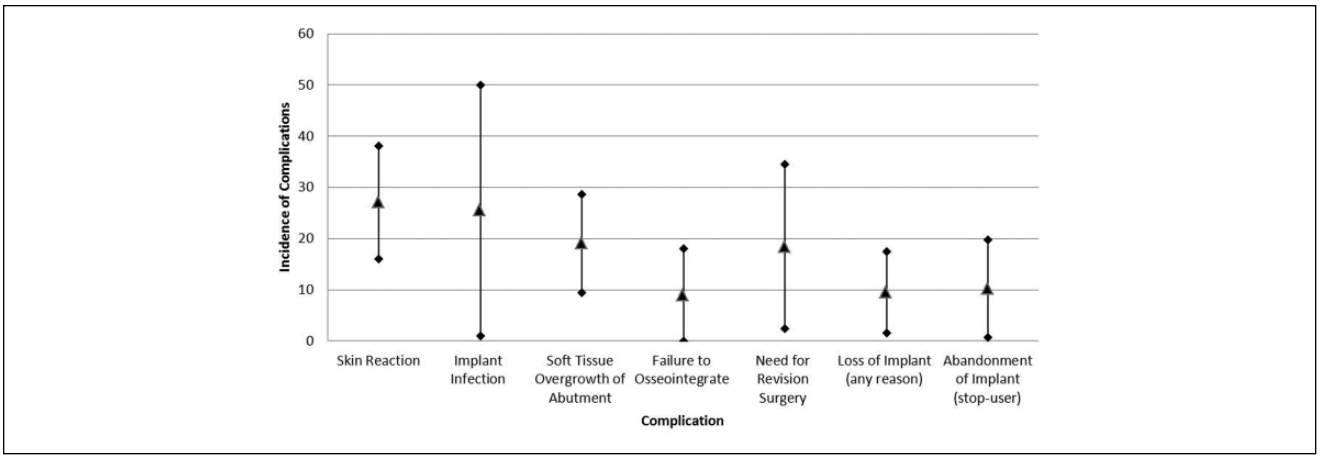

Figure 4. Mean incidences of complications as reported in the literature. The bars represent the degree of variability of complication incidences reported in the literature. Adapted from Kiringoda et al.[15]

years) before a report is even filed (Figure 3). Moreover, every manufacturer may have its own thresholds for what constitutes a SAE, and even these definitions may change over time. Fears of additional regulatory scrutiny may prompt manufacturers to set the bar for reports even lower.

The FDA does have additional access to many more data points than publicly available through MAUDE. They can and have used information from the reports to identify trends and enact change. Whether or not these changes are beneficial or meaningful is a source of controversy and beyond the scope of this article. Nonetheless, the benefit of the publicly searchable arm of this database remains in doubt. In its current form, MAUDE even blocks age, gender, race, specifics on onset and duration of adverse events, or even any clear delineation or standardized definition of what qualifies as a complication. Knowing the ages of the patient affected, while perhaps not necessarily of vital importance for medical devices such as defibrillators or IVC filters, can be important for otolaryngologists who implant OAIs across the full range of life.[14] Moreover, despite the seemingly beneficial option for free text input, in reality, this option currently only serves to further obfuscate.

The ideal searchable repository of suspected medical device–associated complications would prove useful to patients, health care providers, and industry alike. For OAIs, the minimum variables reported should include details of implants and abutments (manufacturer, length, width), age of patient, date of surgery, surgical technique used, and a forced choice of 1 of the 6 complication areas. Additional information can be placed as open text. Furthermore, unique identifiers should be used to avoid duplication of entries (from different reporters). Ultimately, reports should be as detailed as possible, with as many variables available for entry as possible. However, the benefit of a large number of variables must be balanced with the burden of manually inputting those data, particularly for a database that is voluntary for patients and physicians.

Conclusions

A central registry of device-related complications, serious or otherwise, has the potential to benefit candidates, existing patients, surgeons, researchers, audiologists, and manufacturers alike. Yet those publicly available through the MAUDE passive surveillance system fall short in their utility to these same groups, particularly in the case of OAIs.

Declaration of Conflicting Interests

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