Adverse Events Associated with Full Middle Ear Implant: A MAUDE Study

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Abstract

Objective: Identify the rates of adverse events, the root cause of device malfunction, and adverse event resolution from an FDA-approved middle ear implant reports.

Methods: MAUDE reports from January 1, 2014, to August 1, 2024, were searched for. 138 reports were analyzed for adverse events, including patient-related and device-related.

Results: There were 190 unique adverse events. 121 (63.7%) were patient-related, while 69 were device malfunctions (36.3%). Out of the 121 patients with adverse events, 48% presented with hearing disturbances, 31% presented with wound dehiscence, and 14% presented with post-operative infections. 29% of the device malfunctions were due to battery insufficiency, 24.6% electrical feedback or intermittency, 14.5% impeded connectivity, and 13% malfunctioned with no identified root cause. 21% of the reports were resolved by explant, 15.4% required revision, 14.5% had sound processor replacement, 12.7% battery replacement, and 11.8% device replacements.

Conclusion: This study presents the adverse effects of an FDA-approved middle ear implant, as reported in MAUDE. Due to MAUDE's database limitations, we cannot draw definitive conclusions. However, we provide a reference for the common reasons behind MAUDE adverse event reporting. MAUDE reporting needs to be standardized to elevate the quality of reports for

Introduction

Millions of people worldwide suffer from some degree of sensorineural hearing loss, which impairs signal transduction to the auditory processing center of the brain and reduces quality of life.[1] While conventional hearing aids have historically been the initial choice, surgically implanted hearing devices have become a favorable option due to non-compliance with CHAs.[2,3] The Esteem sensor, an entirely implantable middle ear device, converts mechanical vibrations into electrical signals, thereby facilitating normal physiologic amplification and sound processing.[4] The MAUDE database, supplied by the FDA, reports adverse events from patients, practitioners, and manufacturers for medical device surveillance in the United States.[5] Despite its value, no published studies have evaluated the adverse effects of fully implantable middle ear devices. Our study, therefore, aims to classify adverse events and assess reported data for the Esteem implant from January 1, 2014, to August 1, 2024.

Methods

We conducted a retrospective review of the U.S. Food and Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) database. All reports related to a fully implantable middle ear device were queried between January 1, 2014, and August 1, 2024. A total of 138 reports were identified.

The reports were exported into a Microsoft Excel spreadsheet for data management and analysis. Each report was independently reviewed in full by two investigators (AK and PD). Reports were categorized according to:

- **Type of adverse event** (patient-related vs. device-related),
- **Specific adverse event classification** (e.g., hearing impairment, wound dehiscence, infection),
- **Root cause of device malfunction**
- **Reported resolution** (e.g., explant, revision, replacement).

Methods Cont.

If discrepancies were encountered during classification, a census was reached upon discussion. When necessary, ambiguous entries were assigned to the "unspecified" or "other" categories.

All events were accounted for, and frequencies were calculated to describe the distribution of adverse events, device malfunctions, and management strategies. No patient-identifying information is included in the MAUDE database; institutional review board (IRB) approval was not required.

Results

Device Malfunctions

As shown in ***Table 3.*** Of the 138 reports, 69 (36.3%) described device malfunctions. The most common causes were battery insufficiency (29%), electrical feedback or intermittency (24.6%), impeded connectivity (14.5%), and malfunctions without a clearly identified root cause (13%). Less frequent issues included miscellaneous malfunctions (7.2%), device damage (4.3%), improper device output (4.3%), and material defects (2.9%).

Patient Adverse Events

As shown in ***Table 1***. A total of 121 patient-related adverse events were reported. Nearly half (48.8%) involved hearing impairment, followed by wound dehiscence (25.6%) and postoperative infection (14%). Additional events included miscellaneous complications (5.8%), outcomes with no patient consequence (4.1%), and pain/discomfort (1.7%).

Resolution of Adverse Events

As shown in ***Table 2.*** among 110 reports with documented outcomes, the most frequent resolutions were explant (21.8%), revision surgery (15.4%), sound processor replacement (14.5%), battery replacement (12.7%), and device replacement (11.8%). Less common management strategies included other interventions (7.2%), unresolved cases (5.4%), sound processor explant (5.4%), and revision procedures not otherwise specified (2.7%). A small number of cases lacked resolution updates (2.7%).

Total Patient adverse events	Total number of cases
Hearing impairment	59 (48.8%)
Wound dehiscence	31 (25.6%)
Post-op infection	17 (14%)
Misc (Unspecified mental or emotional or behavioral problem; fistula; vertigo, dizziness, vertigo and discomfort, loss of consciousness, nerve damage)	7 (5.8%)
No consequence to the patient	5 (4.1%)
Pain, discomfort	2 (1.7%)
Total	121

Table 1. Patient-Related Adverse Events Reported in MAUDE

How was it resolved	number of cases
Explant	24 (21.8%)
Revision	17 (15.4%)
SP replacement	16 (14.5%)
Battery Replacement	14 (12.7%)
Device Replacement	13 (11.8%)
Other (Battery removed, sensor lead replaced, sensor and SP replaced, device explanted, reprogrammed, not specified, SP and driver replaced, unresolved (scheduled revision)	8 (7.2%)
Unresolved	6 (5.4%)
SP Explant	6 (5.4%)
No resolution update	3 (2.7%)
Revision procedure	3 (2.7%)
Total	110

Table 2. Reported Management and Resolution of Adverse Events

Device Malfunction	Reason	Number of cases
Adverse event without device issue	No hardware issue after troubleshooting (31), Patient health issue (4), adverse event cause not reported/ identified (5), patient smoking, device improper use, damaged semicircular canal	44 (39%)
Battery Insufficiency	premature battery depletion with no identified cause (12), perpetual feedback (3), excessive usage or external environment (2), Faulty configuration, lack of battery supply chain during COVID-19	20 (29%)
Electrical Feedback/ Intermittency issue	Low impedance (6), Feedback due to undetermined cause (4), Feedback due to ingress (2), SP improperly secured, unspecified, SP abrasion, damaged by manufacture, hardware/ assembly issue, driver lead failed during revision	17 (24.6%)
Impeded connectivity	Detached driver (6), detached driver after battery change (2), Migrated sensor (1), SP migration	10 (14.5%)
Device malfunction without identified device use or root cause of the malfunction	Low sensor capacitance, SP damage with middle ear tissue growth, twisted leads, lead exposure, driver damage, SP exposure, scuffing of adhesive, contaminated transducer	9 (13%)
Misc	Low readings (UC), Max gain dropped (UC), driver underperformance (UC), max gain dropped to 5/5 from 40/40 (UC), Lead in contact with tympanic membrane, SP removed for wound dehiscence patient trauma	5 (7.2%)
Device damaged	iatrogenic: During battery replacement (3),	3 (4.3%)
improper device output	unreadable/bellow acceptable range capacitance	3 (4.3%)
Material Defect	Driver lead severed, breach in lead insulation	2 (2.9%)
Total		113 (69 device related)

Table 3. Causes of Device Malfunction in MAUDE Reports of a Fully Implantable Middle Ear Device

Conclusions

Most adverse events were patient-related (hearing impairment, wound dehiscence, infection), while common device malfunctions included battery insufficiency and electrical feedback. Management most often required explant, revision, or component replacement. MAUDE reporting lacks standardization; hence, incidence cannot be determined, but these findings highlight key areas for device improvement and patient counseling.

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References