An Analysis of 33,082 Adverse Events from Cochlear Implant Medical Devices Reported by the FDA's Manufacturer and User Facility Device Experience Database

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Introduction

With the ground-breaking innovation of cochlear implant (CI) technology in delivering auditory signals to the cochlear nerve, there has been an increasing prevalence and demand for CIs in the clinical setting. However, there are reports of infection, device failure, and hearing impairment associated with CIs.

Documenting and understanding device-specific adverse events of cochlear implant devices, such as impedance problems, migration, or leakage, is a topic of clinical importance for ensuring safe technology use and prioritizing complications for further device development.

Therefore, we investigated the medical device reports (MDRs) from the FDA's Manufacturer and User Facility Database (MAUDE) to better understand the scope of adverse events associated with CIs.

Objectives

This study summarizes the medical device reports (MDRs) associated with adverse events for Cochlear Implant Medical Devices as reported by the FDA's Manufacturer and User Facility Device Experience (MAUDE) database.

Methods

n = 35,335 | MDRs Imported from MAUDE

389 MDRs Removed – Incomprehensible Data

n = 34,946 | MDRs Screened for Content

1,864 Studies Excluded – Report Duplicates & Insufficient Info

n = 33,082 | **MDRs Extracted for Analysis**

Unique Variables Assessed	
3	Manufacturers
217	Unique Patient Problems
201	Unique Device Problems

Study Design

Retrospective study of cochlear implant medical devices in Otolaryngology based on MDRs from the FDA's Manufacturer and User Facility Device Experience (MAUDE) database.[1]

Data Collection

Data on adverse events were queried from the FDA's MAUDE database between 01/01/2018 – 01/29/2023 for the 3 largest CI manufacturers: Med-El, Advanced Bionics, and the Cochlear Corporation (or Cochlear Americas).

Preliminary Statistical Analysis

Duplicates and MDRs with incomplete data were removed. Event descriptions, device problems, and correlated patient problems were grouped and analyzed using R – some MDRs had multiple problems listed. All data is de-identified and HIPAA-compliant.

Results

Table 1: Within the FDA's MAUDE database for cochlear implants, the majority of MDRs are associated with devices from Cochlear Limited. MED-EL and Advanced Bionics follow closely with comparable report counts. It's crucial to clarify that these counts are not reflective of the manufacturers' market share in the U.S.[2]

Company & Manufacturer	# of MDRs	% MAUDE Contribution	% US Market Share
Advanced Bionics	9746	30%	20%
Cochlear Limited	13993	42%	60%
MED-EL	9343	28%	17%

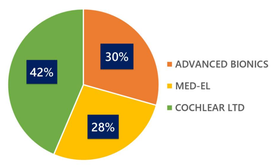

Table 2: A comprehensive analysis of cochlear implant devices categorized by manufacturer, highlighting the frequency of associated MDRs. This breakdown further delves into the predominant device malfunctions and patient problems encountered. Such insights shed light on specific vulnerabilities in device design and highlight clinical symptoms patients face.

Company	Top Associated Device Problems		Top Associated Patient Problems	
	Problem	Count (%)	Problem	Count (%)
Advanced Bionics	Impedance Problem	1889 (19%)	Asymptomatic	775 (8%)
	Mechanical Problem	1646 (17%)	Infection	475 (5%)
	Output Problem	961 (10%)	Hearing Loss	335 (3%)
	Migration or Expulsion	336 (3%)	Pain	308 (3%)
	Extrusion	124 (1%)	Swelling	25 (1%)
Cochlear Limited	Output Problem	1682 (12%)	Hearing Loss	4079 (29%)
	Migration or Expulsion	1178 (8%)	Infection	2201 (16%)
	Extrusion	343 (2%)	Pain	938 (7%)
	Intermittent Failure	325 (2%)	Asymptomatic	579 (5%)
	Impedance Problem	114 (1%)	Injury	299 (2%)
MED-EL	Output Problem	3738 (40%)	Asymptomatic	840 (9%)
	Migration	404 (4%)	Hearing Loss	522 (6%)
	Fluid / Blood Leak	216 (2%)	Injury	306 (3%)
	Impedance Problem	164 (2%)	Infection	152 (2%)
	Triggers Rejection	129 (1%)	Pain	81 (1%)

Table 3: A summary of recent cochlear implant recalls from the FDA reveals that a predominant number of recalls stem from device design or functionality flaws. In comparison, concerns over biocompatibility or expiration issues are less frequent. This underscores the importance of rigorous design and functionality testing in ensuring patient safety. The recalls highlight potential areas for device improvement and serve as a call to manufacturers for greater vigilance in these aspects.

Manufacturer	Recall Class	Date Posted	Reason	Units
Advanced Bionics	III	11/25/2020	Battery life issue	81
Advanced Bionics	**II**	**5/15/2020**	**Body fluid entrance/leakage**	**22227**
Advanced Bionics	III	3/4/2020	Software issue	364
Advanced Bionics	III	2/18/2020	Biocompatibility	4
Advanced Bionics	II	4/3/2019	Software issue	8
Cochlear Americas	II	7/20/2015	Expired product	26
Advanced Bionics	II	10/22/2012	Loose-fitting insertion tool assemblies	17
Cochlear Americas	**II**	**10/3/2011**	**Functionality issues leading to shutdown**	**33645**
Advanced Bionics	II	12/21/2010	Malfunctions requiring explantation	414
Cochlear Americas	II	11/3/2009	Mislabeling	10
Advanced Bionics	II	9/11/2009	Improperly welded internal magnet	18
Advanced Bionics	II	2/3/2009	Mistuned headpiece	4380

Table 4: This figure highlights the three leading Cochlear implant device problems, ranked by frequency. For each, the top three associated patient issues are detailed, offering a focused view of the most pressing device challenges and their patient impacts.

Device Problem	Patient Problem #1	% of MDRs	Patient Problem #2	% of MDRs	Patient Problem #3	% of MDRs
Output Problem	Hearing Loss	84%	Head Injury	6%	Asymptomatic	3%
Mechanical Problem	Hearing Loss	36%	Asymptomatic	3%	Headache	1%
Migration or Expulsion	Hearing Loss	10%	Pain	8%	Infection	7%

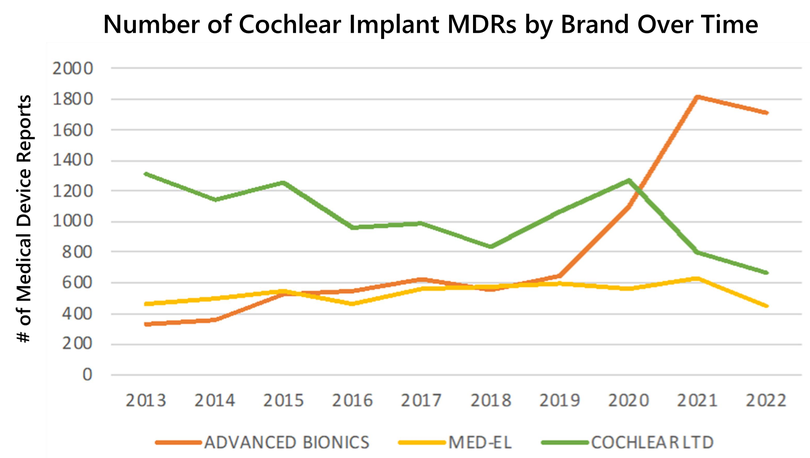

Figure 1. Number of MDRs over Time: Trends may reflect the rising popularity or larger market share of Advanced Bionics but should be contextualized alongside a 2020 recall. Cyclical fluctuations of MDRs appear to be related with learning curve evolution and decreased risk of adverse events after a new product launch.

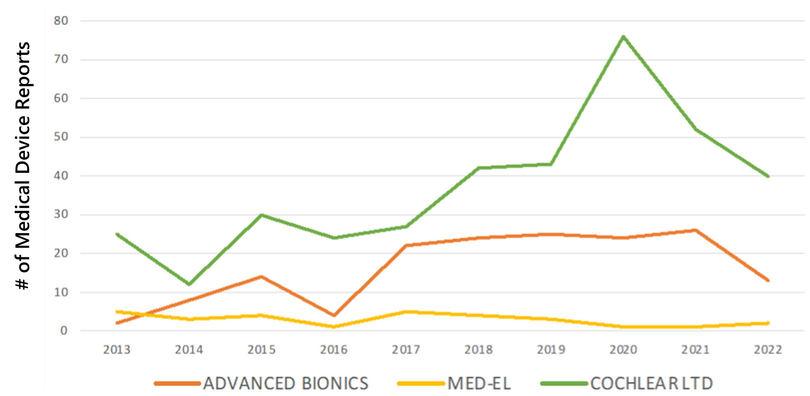

Figure 2. Number of MRI-Related MDRs over Time: Trends reflect a pronounced number of MRI-related adverse events from 2019-2021. A drastic decline in recent years likely corresponds to the FDA approval and introduction of diametric magnet cochlear implants in 2015, with legacy implants being phased out of clinical use.

Conclusions

While subject to reporting and learning curve biases (complicating direct manufacturer comparisons), the MAUDE database exemplifies information not ubiquitously captured in literature surrounding device malfunctions in their entirety. Moreover, the collected outcomes provide a unique clinical perspective for prioritizing risk, ensuring safe technology use, and improving patient counseling – in addition to fostering further research to address these complications. Ultimately, this retrospective study characterizes high-level insight surrounding the most common and consequential adverse events for cochlear implant medical devices in Otolaryngology.

[1]MAUDE - Manufacturer and user facility device experience. (n.d.). Retrieved October 31, 2022, from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

[2]The truth about Cochlear's market share. (n.d.). Intelligent Investor. Retrieved September 23, 2023, from https://www.intelligentinvestor.com.au/recommendations/the-truth-about-cochlears-market-share/142882