Early Post-Market Adverse Events Associated with the SENTIO Bone-Anchored Device - A MAUDE Database Analysis

WAYNE STATE
School of Medicine

Anagha Srivatsa BS[1], Tyler J. Gathman MD MS[1], Bora Agabigum MD[2], Eleanor Chan MD[1]
[1]Department of Otolaryngology, Wayne State University, Detroit, MI, USA.
[2]Michigan Ear Institute, Farmington Hills, MI, USA.

Introduction

- The SENTIO device is a transcutaneous active bone conduction hearing device used to treat conductive and mixed hearing loss.[1]
- It received Food and Drug Administration (FDA) approval in 2024.[2]
- Few studies have critically examined the post-market safety profile of the device.
- Preliminary post-market surveillance is crucial for identifying preventable safety concerns during the adoption of new implantable hearing devices.
- This study aims to characterize adverse events associated with the SENTIO device reported through the Manufacturer and User Facility Device Experience (MAUDE) database curated by the FDA.

Methods

- This retrospective review analyzed all reports submitted to the MAUDE database for the SENTIO device from the date of FDA approval.
- Event characteristics and secondary interventions were examined for initial trends.
- The MAUDE database compiles both voluntary and mandatory reports of adverse events but lacks a reliable denominator.[3]

Results

- Nine reports related to the SENTIO device were extracted from the MAUDE database for review.
- All reports were categorized as “serious injury.”
- Eight reports required surgical intervention for complication management.

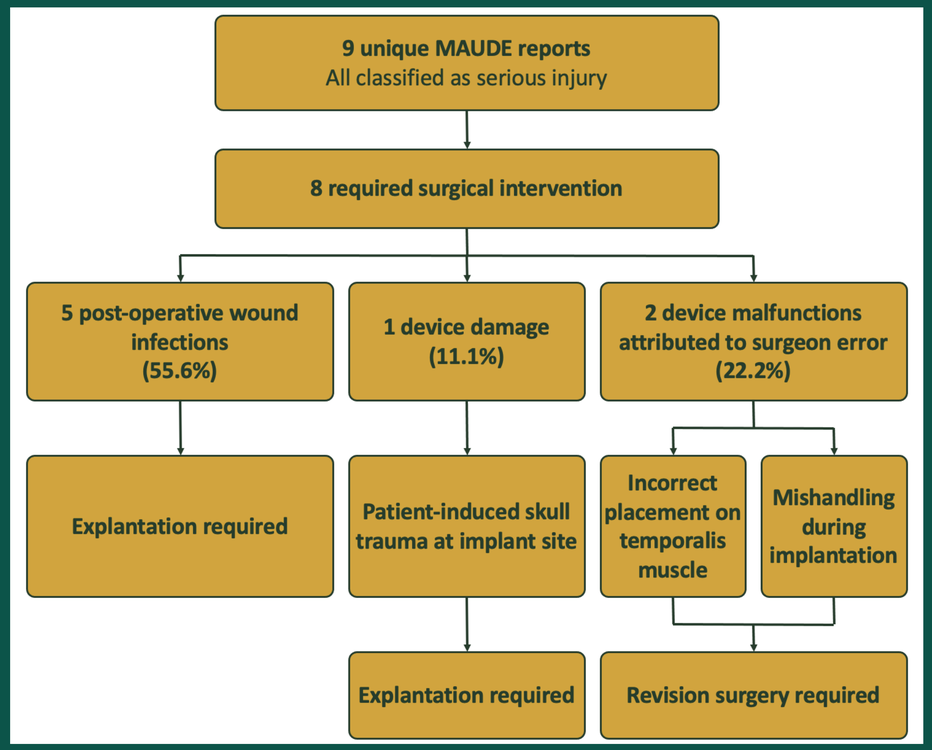


Figure 1: Overview of SENTIO Device MAUDE Reports

- Five reports involved post-operative wound infections, all requiring device explantation. Among these, two required emergent explantation for infection control.
- Two cases of device malfunction were attributed to surgeon error, including incorrect placement on the temporalis muscle and mishandling during implantation, resulting in component failure.
- No reports identified any intrinsic device malfunctions during the manufacturer’s examination after the incident.

Discussion

- No intrinsic device malfunction was confirmed in early MAUDE reporting, which suggests, but does not establish, that surgical technique and postoperative management contributed to the reported adverse events.
- The preliminary MAUDE profile for SENTIO is distinct from that of Bonebridge for which malfunction was the leading category of MAUDE reports (73.7%).[3]
- SENTIO’s distribution of injury/malfunction events (100%/0%) more closely mirrors that of Osia (91.2%/8.8%) in MAUDE reports.[3]
- There was a greater share of MAUDE reports for infection with SENTIO (55.6%) compared to Bonebridge/Osia (15.4%) and Baha/Ponto/Sophono (14.7%).[3,4] It is important to remember that these do not reflect infection incidence rates of each device.

Conclusion

- This early post-market analysis underscores the importance of preoperative patient counseling on infection risk and the potential need for revision surgery or device explantation.
- Limitations of MAUDE include underreporting, reporting bias, inaccurate classification, duplicate reports, and inability to determine true incidence rates of adverse events.
- These results may inform surgical education and future patient selection.

References

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