



Trends in Cochlear Implant Complications and Clinical Outcomes from 2016 to 2024

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Hearing Loss and Cochlear Implant Adoption



- Hearing loss: 1.57B people globally, 22% of Americans^{1,2}



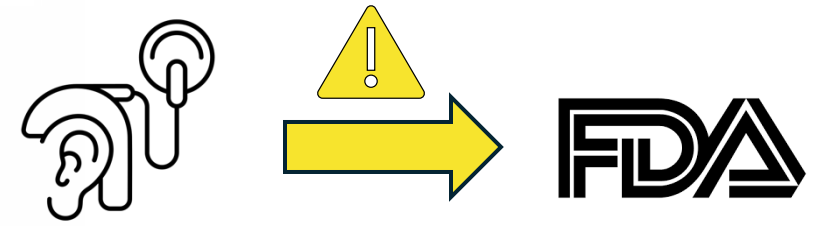
- 180,000+ total cochlear implants (CIs) in U.S.^{3,4}



- Single-center CI complication rates: 9-20%⁵⁻⁸

Manufacturer and User Facility Device Experience (MAUDE) Database

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The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

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CI Adverse Events in MAUDE⁹

- Before 1998 vs in 2002:
↓ device failures, ↑ infection¹⁰
- 2000–2010:
↑ idiopathic adverse events¹¹
- 2010–2020:
Infection, CSF leak, extrusion, facial nerve complication rates differ by manufacturer.¹²

COMPANY ANNOUNCEMENT

Voluntary Field Corrective Action of HiRes Ultra and Ultra 3D

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:	February 20, 2020
FDA Publish Date:	March 10, 2020
Product Type:	Medical Devices
Reason for Announcement:	Reports of hearing performance degradation
Company Name:	Advanced Bionics
Brand Name:	HiRes Ultra and Ultra 3D
Product Description:	Cochlear implants



Hypothesis

Patterns in CI complications and clinical outcomes differed before and after a major VFCA in 2020.





Manufacturer and User Facility Device Experience
(MAUDE) Database

Data

- Patient & device files
[2016–2024]
- Filter by CI product codes
[MCM & PGQ]



Methods



Manufacturer and User Facility Device Experience
(MAUDE) Database

Data

- Patient & device files [2016–2024]
- Filter by CI product codes [MCM & PGQ]

Analysis

- Themes for complications and post-op clinical outcomes
- (quasi-)Poisson regressions for patterns in raw counts [2016–2020 & 2020-2024]
- Cochran-Armitage tests for patterns in relative proportions [2016–2020 & 2020-2024]



Methods



Manufacturer and User Facility Device Experience
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Data

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- Filter by CI product codes [MCM & PGQ]

Analysis

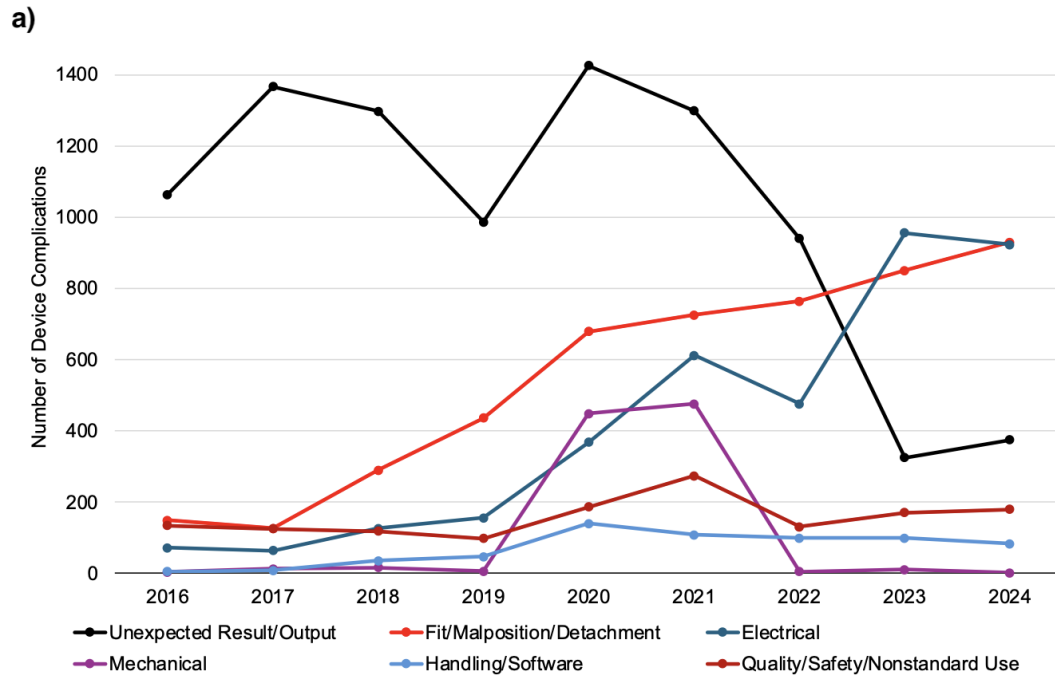
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Outcomes

- 1) Patient Complications
- 2) Device Complications
- 3) Post-Op Clinical Outcomes
 - Required Intervention
 - Hospitalization
 - Life-Threatening Event/Disability/Death
 - Other



Number (a) and Percent (b) of Top Device Complications

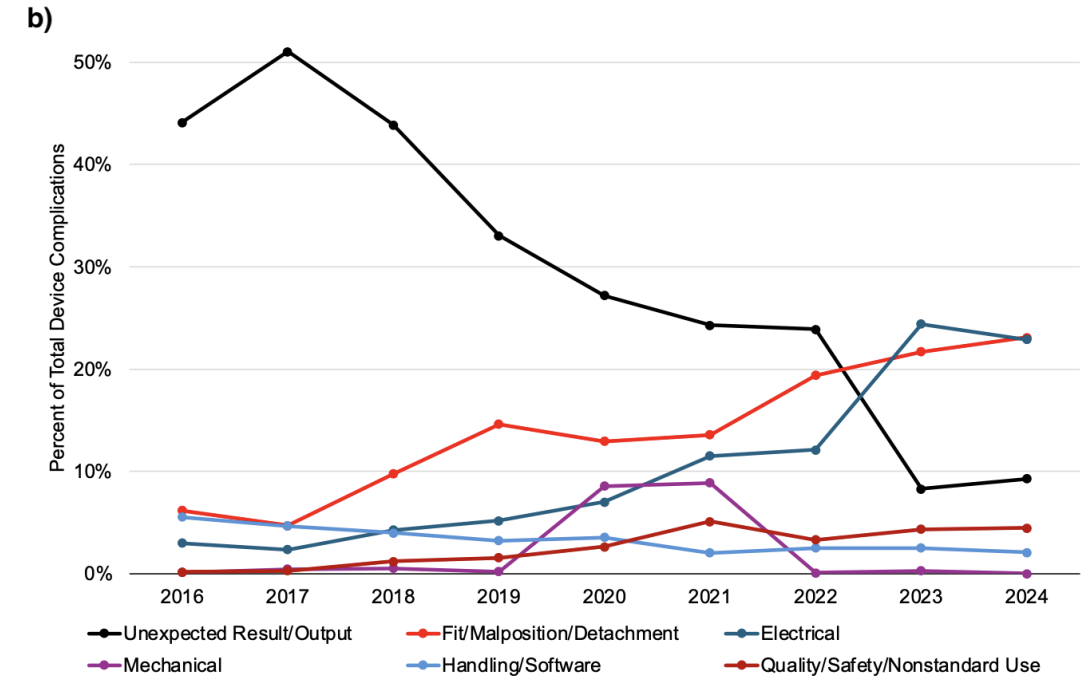
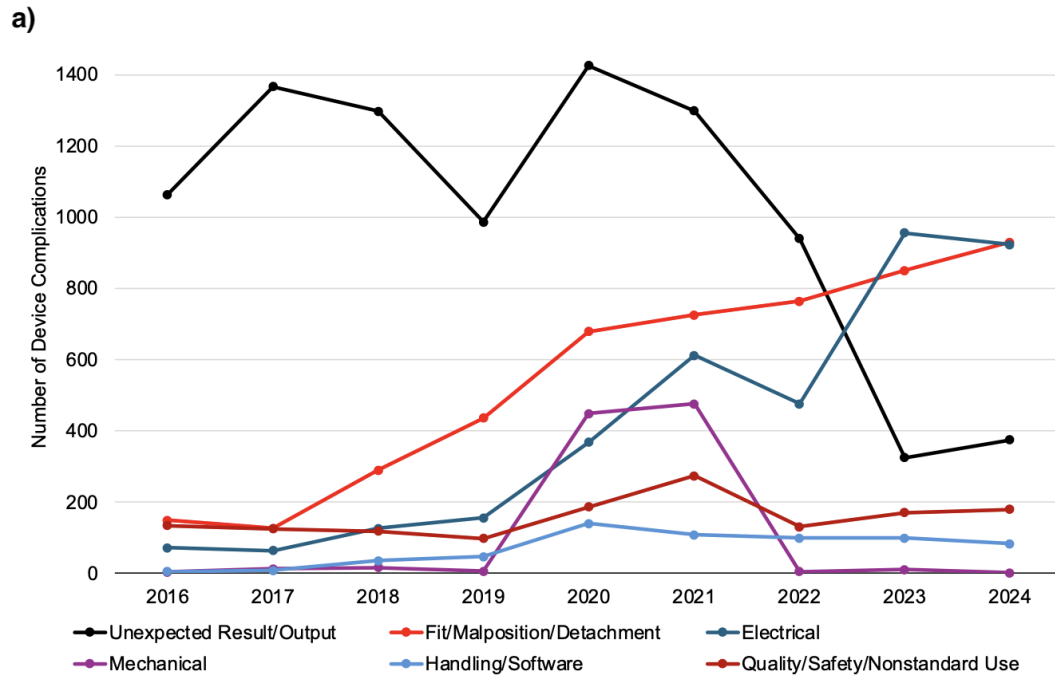


Device Complication	2016-20	2020-24
	IRR (95% CI), P-Value	IRR (95% CI), P-Value
Unexpected Result/Output	1.03 (0.92-1.14), p=.645	0.69 (0.58-0.82), p=.024
Fit/Malposition/Detachment	1.55 (1.39-1.74), p=.005	1.08 (1.06-1.11), p<.001
Electrical	1.61 (1.34-1.93), p=.014	1.25 (1.08-1.44), p=.057
Mechanical	6.63 (1.49-29.38), p=.089	0.37 (0.15-0.89), p=.113
Handling/Software	2.34 (1.91-2.87), p=.004	0.99 (0.79-1.24), p=.918
Quality/Safety/Nonstandard Use	1.06 (0.90-1.24), p=.534	0.83 (0.74-0.93), p=.047

- 33,487 device complications
- 2016–20: ↑ Fit/malposition/detachment, electrical, handling/software
- 2020–24: ↑ Fit/malposition/detachment; ↓ unexpected result/output, quality/safety



Number (a) and Percent (b) of Top Device Complications

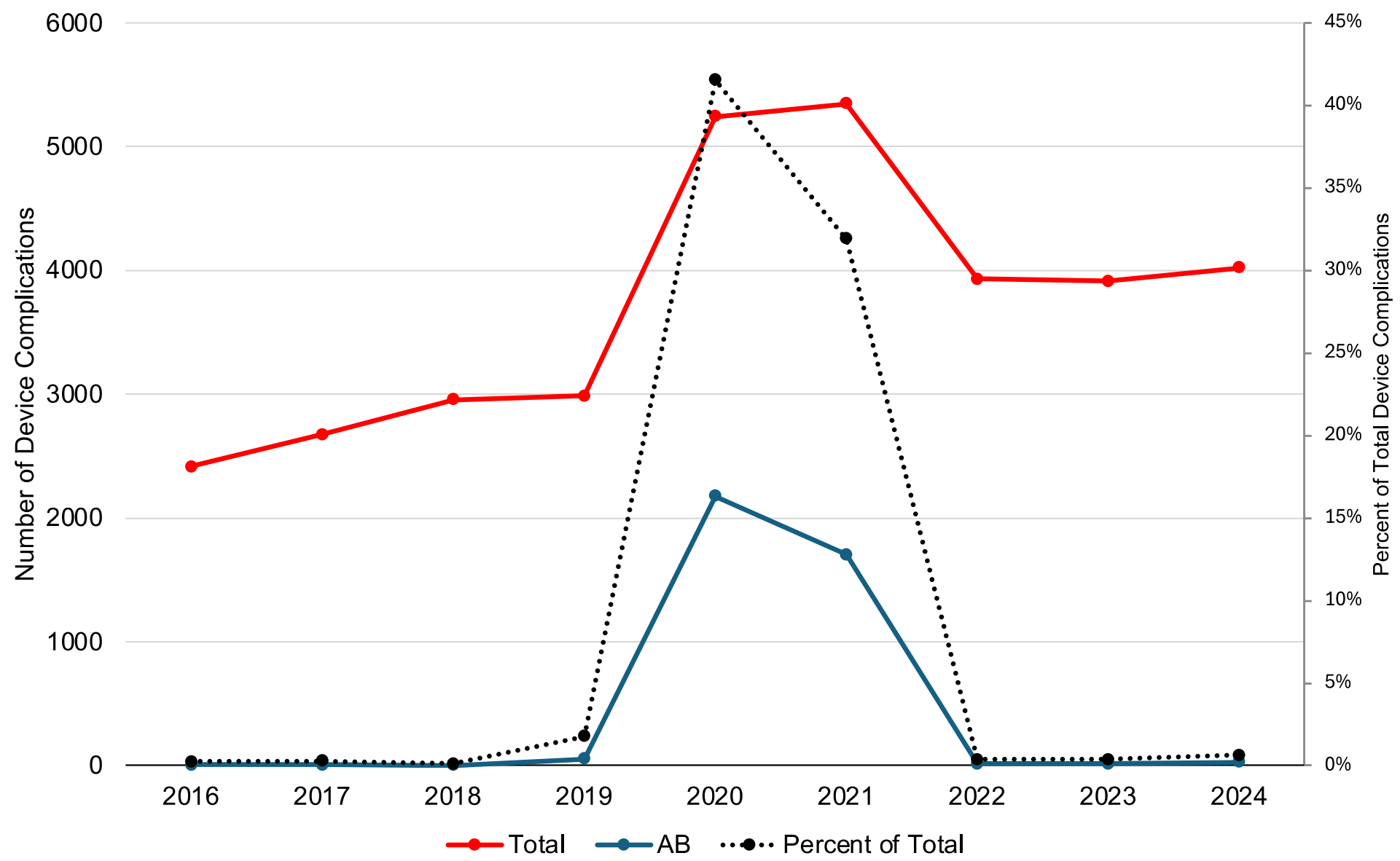


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Device Complication	2016-20		2020-24	
	Z Score, P-Value		Z Score, P-Value	
Unexpected Result/Output	Z=-21.33, p<.001		Z=-27.50, p<.001	
Fit/Malposition/Detachment	Z=13.43, p<.001		Z=16.07, p<.001	
Electrical	Z=10.03, p<.001		Z=26.70, p<.001	
Mechanical	Z=22.49, p<.001		Z=-28.01, p<.001	
Handling/Software	Z=-4.56, p<.001		Z=-3.43, p=.001	
Quality/Safety/Nonstandard Use	Z=10.19, p<.001		Z=3.13, p=.002	

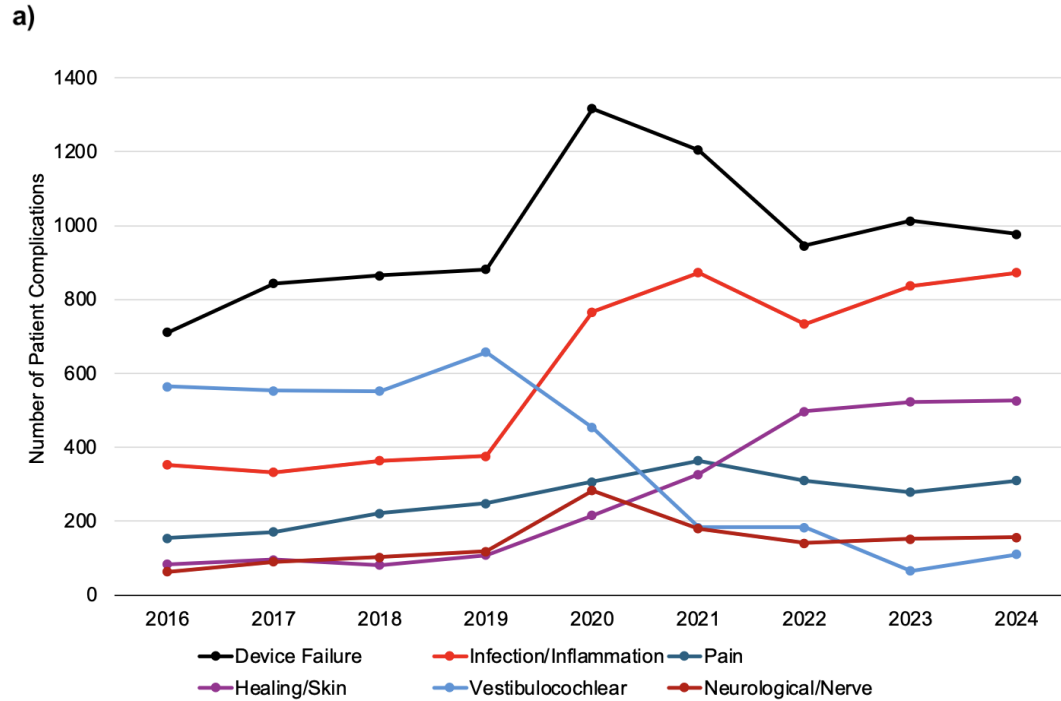
- Mechanical: 2020 spike
- ↓ Handling/Software
- ↑ Quality/Safety/Nonstandard Use

Number and Percent of Advanced Bionics Device Complications





Number (a) and Percent (b) of Top Patient Complications

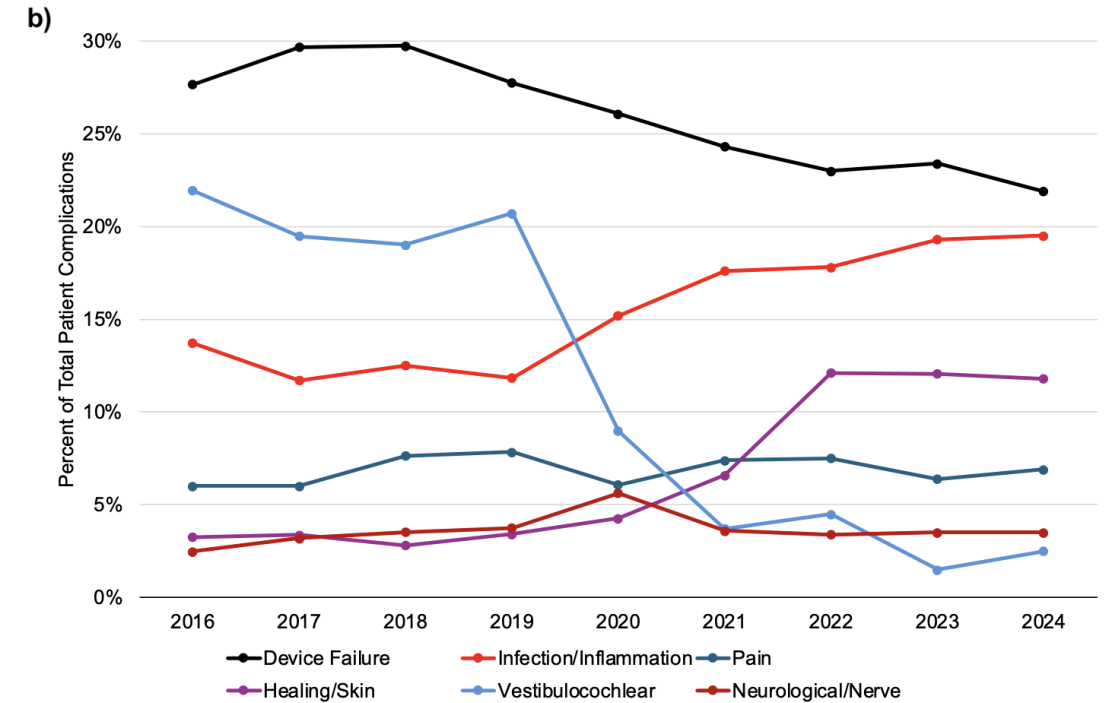
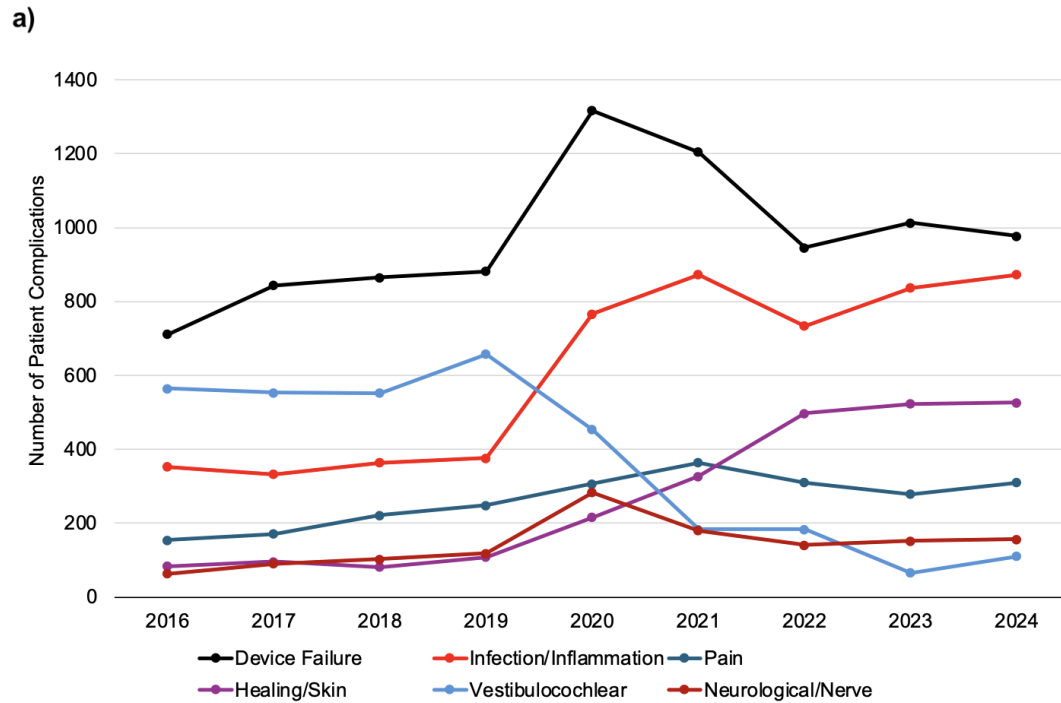


Patient Complication	2016-20	2020-24
	IRR (95% CI), P-Value	IRR (95% CI), P-Value
Device Failure/Unexpected Result	1.15 (1.06-1.24), p=.042	0.92 (0.88-0.97), p=.058
Infection/Inflammation	0.80 (0.46-1.40), p=.492	0.95 (0.61-1.49), p=.841
Pain	3.01 (1.08-8.39), p=.126	1.00 (0.52-1.91), p=.996
Healing/Skin	1.27 (1.07-1.52), p=.075	1.22 (1.08-1.38), p=.047
Vestibulocochlear	1.27 (1.07-1.51), p=.076	0.95 (0.89-1.03), p=.299
Neurological/Nerve	1.22 (1.03-1.45), p=.102	1.02 (0.97-1.07), p=.461

- 34,426 patient complications
- 2016–20: ↑ Device Failure/Unexpected Result
- 2020–24: ↑ Healing/Skin



Number (a) and Percent (b) of Top Patient Complications

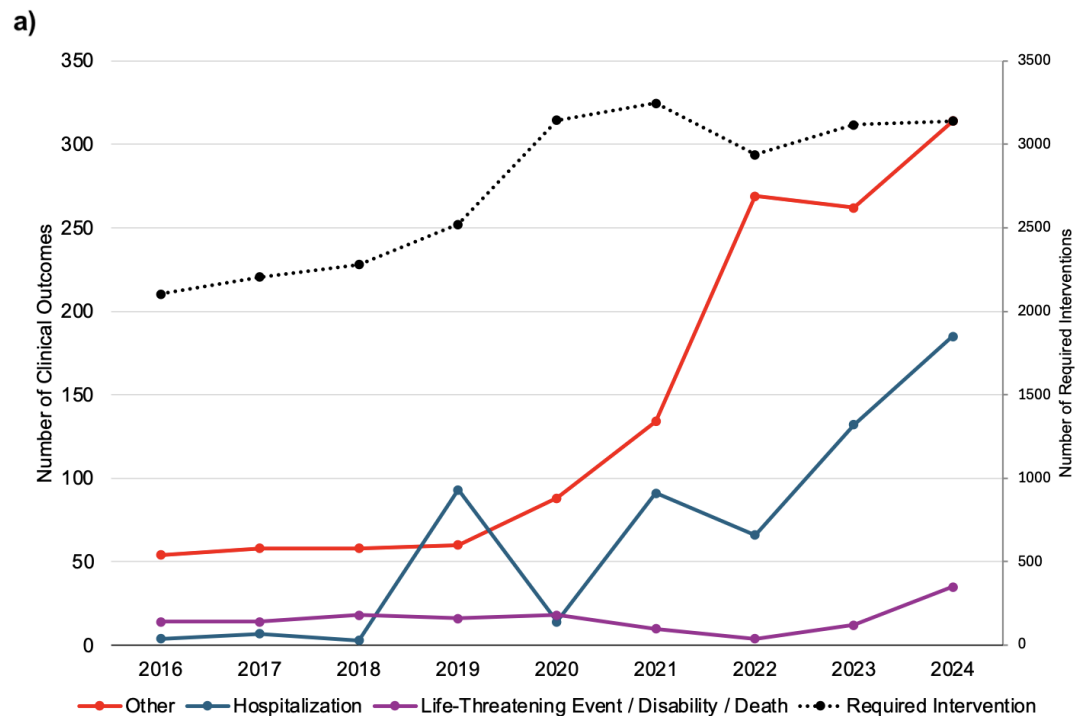


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Device Failure/Unexpected Result	1.15 (1.06-1.24), p=.042	0.92 (0.88-0.97), p=.058	Z=-2.71, p=.007	Z=-4.85, p<.001
Infection/Inflammation	0.80 (0.46-1.40), p=.492	0.95 (0.61-1.49), p=.841	Z=2.70, p=.007	Z=5.92, p<.001
Pain	3.01 (1.08-8.39), p=.126	1.00 (0.52-1.91), p=.996	Z=0.64, p=.525	Z=0.78, p=.438
Healing/Skin	1.27 (1.07-1.52), p=.075	1.22 (1.08-1.38), p=.047	Z=2.60, p=.009	Z=15.66, p<.001
Vestibulocochlear	1.27 (1.07-1.51), p=.076	0.95 (0.89-1.03), p=.299	Z=-14.42, p<.001	Z=-16.38, p<.001
Neurological/Nerve	1.22 (1.03-1.45), p=.102	1.02 (0.97-1.07), p=.461	Z=7.03, p<.001	Z=-4.97, p<.001

- ↓ Device Failure, Vestibulocochlear
- ↑ Infection, Healing
- Neurologic/Nerve: 2020 spike



Number (a) and Percent (b) of Clinical Outcomes

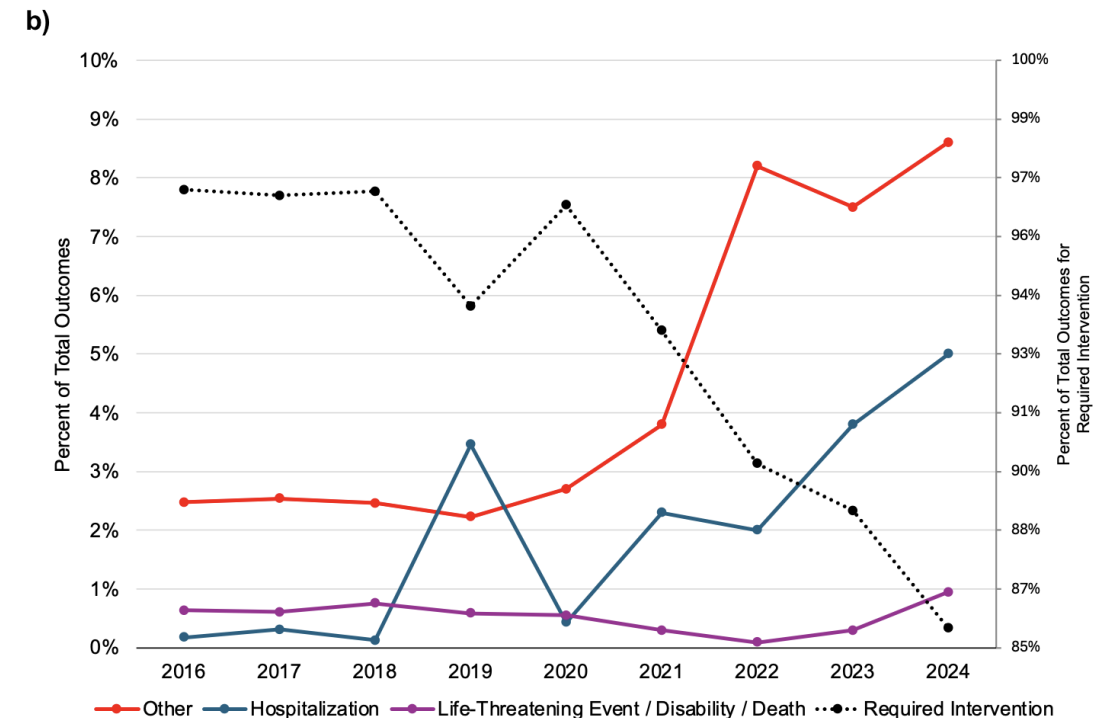
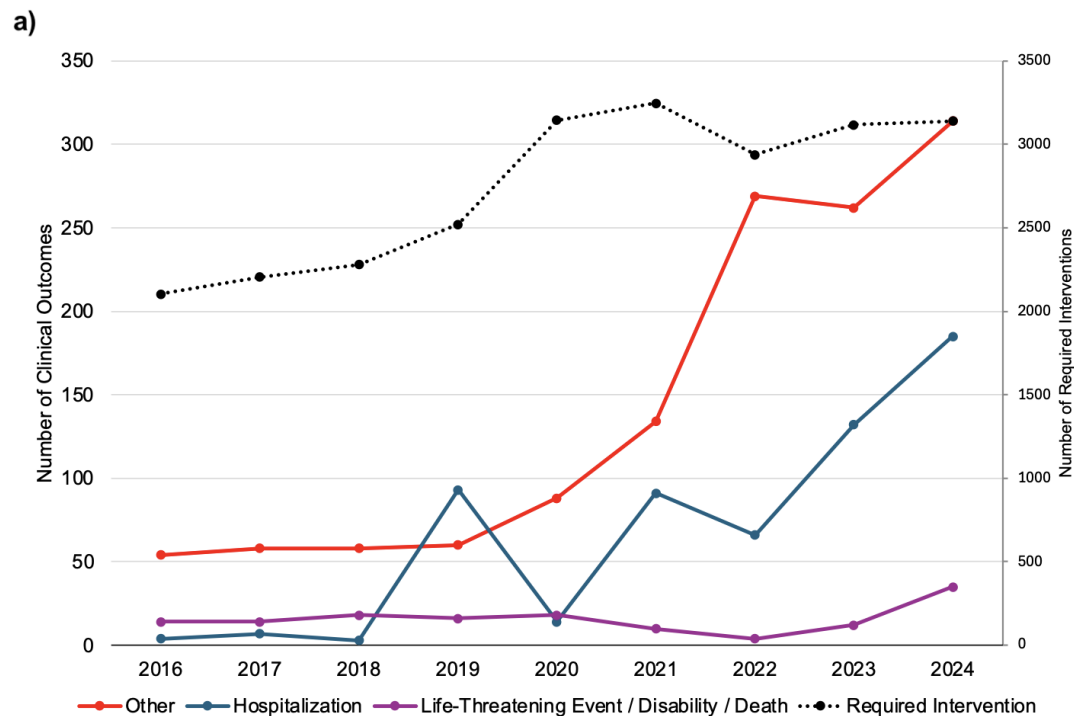


Outcome	2016-20	2020-24
	IRR (95% CI), P-Value	IRR (95% CI), P-Value
Required Intervention	1.10 (1.06-1.15), p=.022	1.00 (0.97-1.02), p=.747
Other	1.12 (1.03-1.21), p=.006	1.32 (1.14-1.55), p=.038
Hospitalization	1.62 (0.55-4.73), p=.445	1.50 (1.14-1.99), p=.064
Life-Threatening Event/Disability/Death	1.06 (0.91-1.24), p=.430	1.26 (0.80-1.99), p=.390

- 26,377 clinical outcomes
- 2016–20: ↑ Required Intervention, Other
- 2020–24: ↑ Other, Hospitalization (non-significant trend)



Number (a) and Percent (b) of Clinical Outcomes



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Outcome	2016-20		2020-24	
	Z Score, P-Value		Z Score, P-Value	
Required Intervention	Z=-2.53, p=.011		Z=-5.55, p<.001	
Other	Z=0.22, p=.823		Z=12.85, p<.001	
Hospitalization	Z=5.20, p<.001		Z=12.12, p<.001	
Life-Threatening Event/Disability/Death	Z=-0.48, p=.628		Z=2.84, p=.005	

- ↓ Required Intervention
- ↑ Hospitalization, Life-Threatening Event



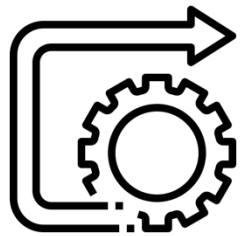
Discussion

Limitations



- Retrospective
- Reporting bias (96.6% mandatory¹³), underreport minor events
- Missing surgical/comorbidity data
- Inconsistent problem classification

Implications



- **Clinical:** Data-driven risk counseling and mitigation
- **Payers:** Value-based models around targeted outcomes
- **Regulators:** Enhanced post-market surveillance mechanisms



Conclusion

Overall



- 2016–2020: Increased total number of patient, device, and clinical outcome complications
- 2020–2024: No significant patterns in total numbers of each

Recent Patterns in Specific Complications/Outcomes



- ↑ Life-Threatening Events and Hospitalizations
- ↑ Healing issues
- ↑ Fit/malposition/detachment issues
- ↓ Unexpected device result/output



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Thank you!

Questions?

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