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

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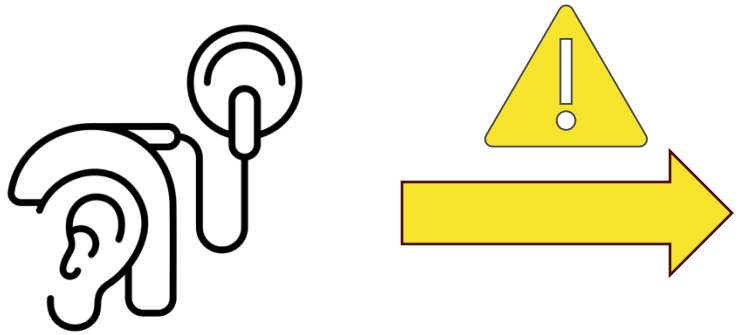
Cochlear Implantation Prevalence and Complications

- 180,000+ total cochlear implants (CIs) in U.S.[1,2]

- Single-center CI complication rates: 9-20%[3-6]

Cochlear Implant Adverse Events in MAUDE



FDA

Manufacturer and User Facility Device Experience (MAUDE) Database[7]

- Before 1998 vs in 2002: ↓ device failures, ↑ infection[8]
- 2000–2010: ↑ idiopathic adverse events[9]
- 2010–2020: Infection, extrusion, and neurologic complications differed by manufacturer.[10]

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.

Read Announcement

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

Research Question

How did U.S. CI complications and clinical outcomes differ before and after a major VFCA in 2020?

Hypothesis

After a major VFCA in 2020, there will be decreases in U.S. CI failures and required interventions.

Methods

Manufacturer and User Facility Device Experience (MAUDE) Database

Data

- Filter by CI product codes [MCM & PGQ] from 2016–2024

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- Quasi-Poisson regressions for patterns in raw counts [2016–2020 & 2020-2024]

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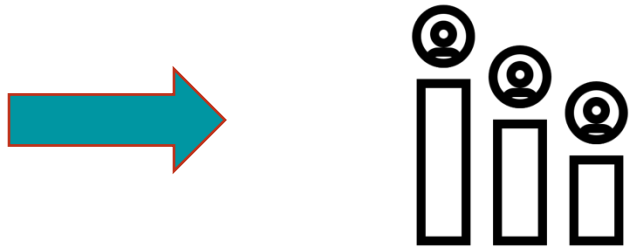


Data

- Filter by CI product codes [MCM & PGQ] from 2016–2024

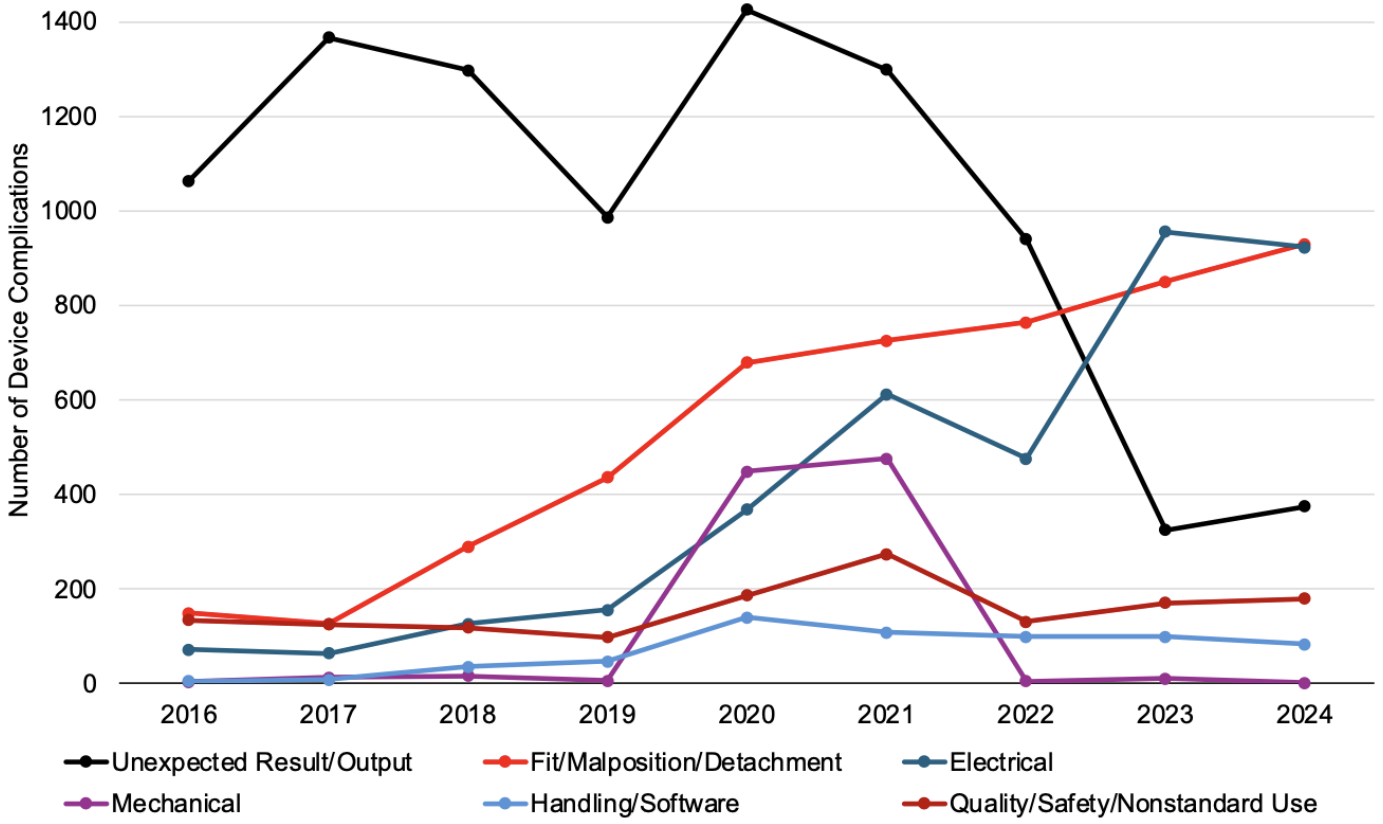
Analysis

- Quasi-Poisson regressions for patterns in raw counts [2016–2020 & 2020-2024]

Outcomes

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

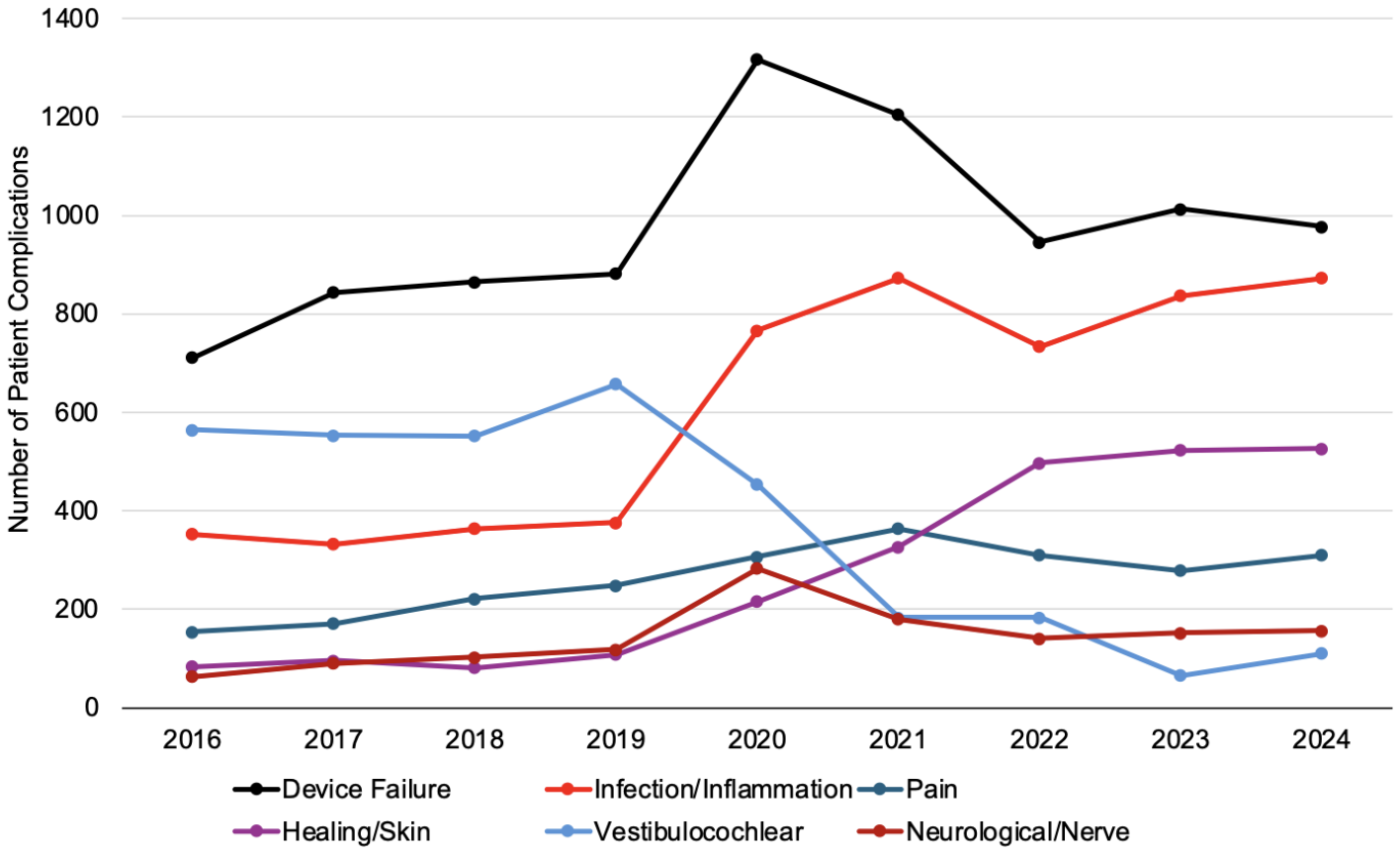
Number of Top Device Complications



- 33,487 device complications
- 2016–20: ↑ Fit/malposition/detachment, Electrical, Handling/software issues
- 2020–24: ↑ Fit/malposition/detachment; ↓ Unexpected result, Quality/safety issues

Device Complication	2016-20 IRR (95% CI), P-Value	2020-24 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
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**

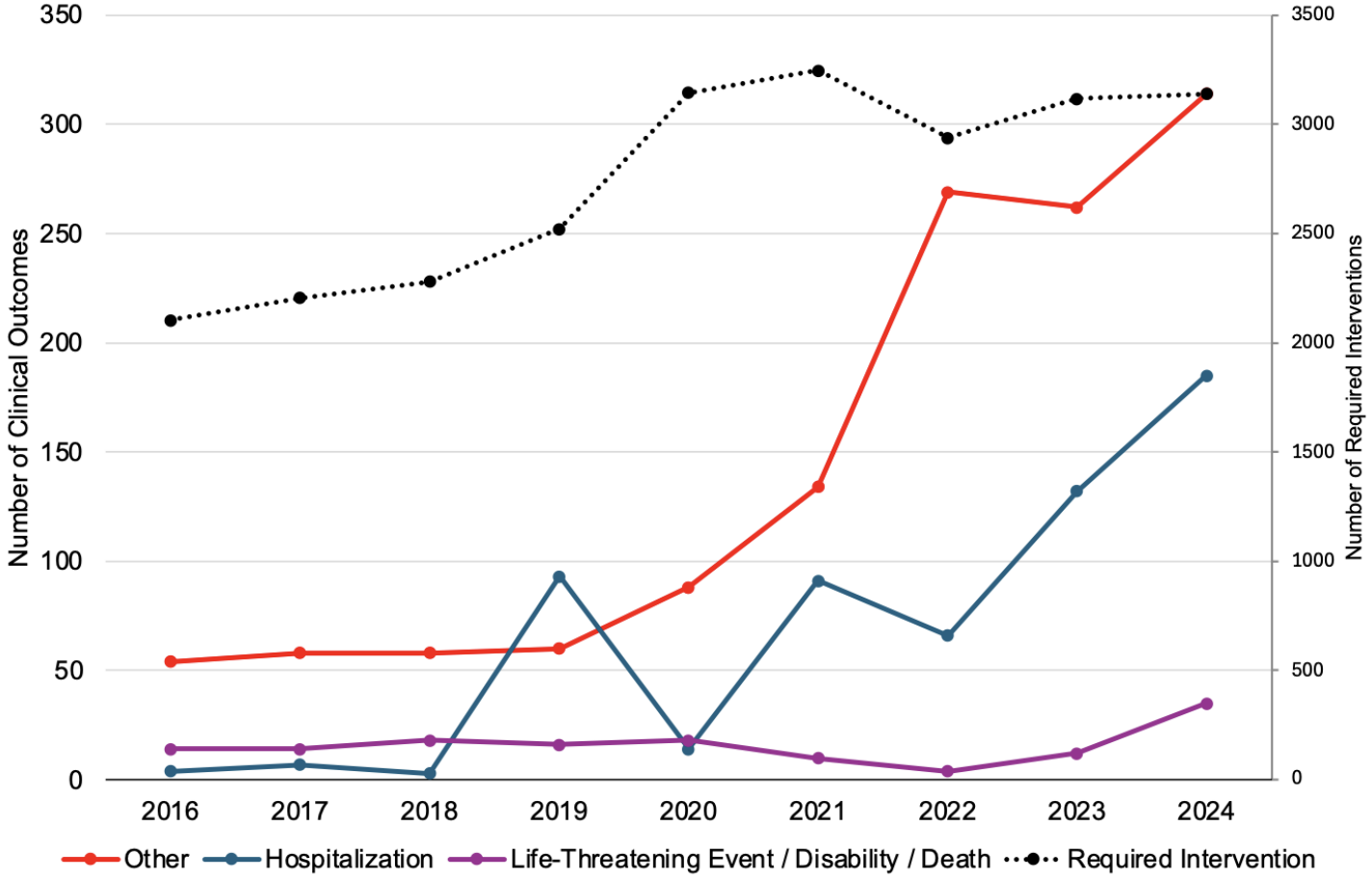
Number of Top Patient Complications



- 34,426 patient complications
- 2016–20: ↑ Device failure/unexpected result
- 2020–24: ↑ Healing/skin issues

Patient Complication	2016-20 IRR (95% CI), P-Value	2020-24 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
Healing/Skin	1.27 (1.07-1.52), p=.075	**1.22 (1.08-1.38), p=.047**

Number of Clinical Outcomes



- 26,377 clinical outcomes
- 2016–20: ↑ Required intervention, Other
- 2020–24: ↑ Hospitalizations, Other

Outcome	2016-20 IRR (95% CI), P-Value	2020-24 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

Limitations

- Retrospective
- Reporting bias (96.6% mandatory[11])
- Missing surgical/comorbidity data

Conclusion

- Stable total number of complications and required interventions

- ↑ Fit/malposition/detachment, Healing/skin issues, Hospitalizations

- ↓ Unexpected device result/output

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Thank you!

Questions?

Slides

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Advanced Bionics Complications