Impedance Change as an Indicator of Cochlear Implant Failure

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Objective: In February 2020, Advanced Bionics initiated a field action notice to remove the MS Ultra (V1) implant from circulation. In this study, we quantify a single site's incidence with device failure and examine the relationship between impedance change and declining speech perception.
Study Design: Retrospective/cohort study.
Setting: Tertiary healthcare center.
Patients: Forty-nine adult patients (52 devices) were implanted between October 2017 and December 2019, with the following exclusion criteria: <18 years of age, medical/surgical failures, and lack of English-language proficiency.
Interventions: Diagnostic.
Main Outcome Measures: Postoperative speech perception (AzBio sentence test) scores at 12 months postactivation were compared with repeat testing at 6- to 12-month intervals. Degree of change in impedances from 1 month postactivation was analyzed at similar intervals. Device failures were suspected when impedance levels on three or more electrodes dropped to <3.5 kΩ and AzBio scores declined >15%. Device failures were confirmed through analyses completed by the manufacturer.
Results: To date, 21% (11/52) of devices have met all three criteria for a confirmed failure with an average decline in speech perception of 27.7 ± 22%. The average length of time for detection of device failure was 21.9 ± 5 months postimplantation. An additional 7 devices (13%) are currently being monitored for failure but have not yet met full criteria. There was no predictive relationship between degree of impedance change and speech perception scores. Electrodes along the entire array (channels 1–16) can be affected.
Conclusions: Impedance values can be used as a reliable indicator of device malfunction, thus facilitating patient counseling and early intervention. No correlation was identified between impedance changes and speech perception scores.
Key Words: Cochlear implant—Electrode—Hardware failure—Impedance—Recall—Speech perception.

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INTRODUCTION

Cochlear implants (CIs) are a well-documented treatment option for patients with severe-to-profound sensorineural hearing loss. Current era CIs typically show a cumulative survival percentage above 99% within the first 5 years (1–4). Internal device failures have been well documented and can be classified into three main categories: hardware failure, medical/surgical failure, and soft failures (5–8).

In February 2020, Advanced Bionics initiated a field action notice for the removal of the HiRes Ultra/HiRes Ultra 3D V1 CI from circulation. A defect was identified whereby fluid could seep into the silastic casing around the receiver–stimulator and alter the stimulation of the electrode array. The issue primarily affected electrodes at the basal end of the array, although there were some instances in which the apical electrode contacts were affected as well. The issue typically caused electrical impedance levels to decline below 3.5 kΩ, which affected audibility, loudness growth, and ultimately speech understanding in most instances.

Impedance levels are a measure of the resistance to electrical current flow. Impedances are measured at each electrode contact along the array, and values may vary from one electrode to another. Factors affecting this variability include the constituent materials, shape, and size of the electrode contacts (9). After the initial activation of the CI, impedance values typically decrease over several weeks before stabilizing (10–13). Further changes in impedances have been well described and can represent underlying inflammatory processes as well as fibrosis (14,15).

In this study, we examine impedance changes as an indicator of device failure and the relationship between impedance changes and AzBio sentence test scores. Secondary considerations included assessment of the extent of impedance changes along the entire electrode array and to determine whether impedance decline could be used as a predictor for reduced speech perception scores in HiRes Ultra/HiRes Ultra 3D V1 CI users.

METHODS

This research study was approved by the Research Ethics Board at the University of Manitoba (HS18623/H2015:209).

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TABLE 1. *Participant demographics, including age at implantation, duration of preoperative hearing loss, duration of preoperative hearing aid use, and time course for device failure detection*

	Female	Male
Sex	n = 26 (52%)	n = 24 (48%)
Ear implanted	Left = 16 (61%)	Left = 12 (50%)
	Right = 10 (39%)	Right = 12 (50%)
	Range (years)	Mean (years)
Age at implantation	19–80	58.2 (+15.2)
Duration of deafness	1–56	21.4 (+14.9)
Duration of hearing aid use	0–40	15.9 (+10.1)
	Range (months)	Mean (months)
Device failure detected	11–40	21.9

A retrospective/cohort study was completed on 49 adult patients (52 devices) who were implanted with the HiRes Ultra V1 CI, at a single tertiary referral institute by a single surgeon between October 4, 2017, and December 11, 2019. Review included patient demographics, operative notes, device model, AzBio sentence test scores, and impedance levels from each clinical visit.

Exclusion criteria included patients less than 18 years of age, medical/surgical/soft failures, and lack of English-language proficiency.

AzBio sentence test scores measured using the patient's CI at 12 months postactivation were used as a baseline to compare against scores taken at 6-month intervals after the field action notice to monitor device performance. The reference point for establishing a baseline measurement of 12 months is in line with previous literature, such as Caswell-Midwinter et al. (2022), who reported that the greatest improvement in scores was attained within a year postactivation with most patients plateauing at 6 months postactivation (16–19).

Impedances were measured with the use of the manufacturer's programming software at each clinical visit. The impedance values were noted and logged during each visit. In this study, a "confirmed failure" was defined as at least three individual electrode impedance values dropping below 3.5 kΩ in addition to a decreased AzBio score of at least 15% along with manufacturer verification through internal proprietary analysis. For the purpose of this study, a "functional failure" was defined as a device that had not yet met all three criteria for failure. Statistical analysis included an analysis of variance to compare average impedances and speech perception scores between groups as well as Pearson product–moment correlation to measure the relationship between impedance levels and speech perception scores.

RESULTS

Patients implanted with the affected device had similar demographics as the general cohort of CI recipients implanted at the same center (Table 1). Two patients with V1 devices were excluded because of the lack of English-language proficiency and an inability to complete standardized speech perception testing. There were no medical or surgical failures noted.

The average length of time from implantation to failure detection (meeting at least one of the three failure criteria) was 21.9 months with a range of 11 to 40 months (Fig. 1). After approximately 24 months since the initiation of the field action notice, 11 (21%) out of 52 devices exhibited a confirmed failure and 7 (13%) out of 52 devices exhibited a functional failure where declines in impedance values were present but the user had not yet demonstrated a significant drop in speech perception or internal manufacturer verification.

Confirmed device failures demonstrated average measured impedances below 3.5 kΩ on basal electrodes 13–16, representing a statistically significant difference in impedance values ($p < 0.01$) compared with the general cohort (Fig. 2). Functional device failures were initially detected through the manufacturer's proprietary algorithm and are characterized by a statistically significant difference ($p < 0.01$) in impedances that were not, on average, below 3.5 kΩ on electrodes 13–16, compared with the general cohort (Fig. 2).

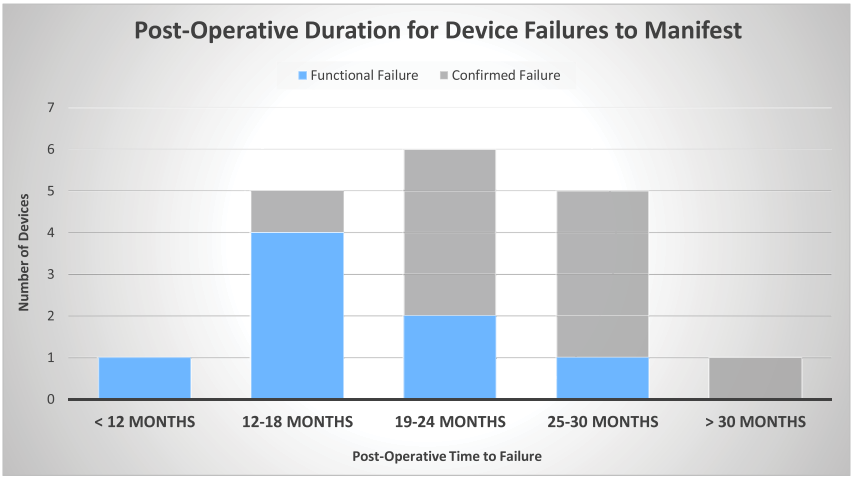

FIG. 1. Detection of postoperative device failure within the functional failure cohort (*light blue*) and confirmed failure cohort (*gray*), based on manufacturer's propriety detection algorithm.

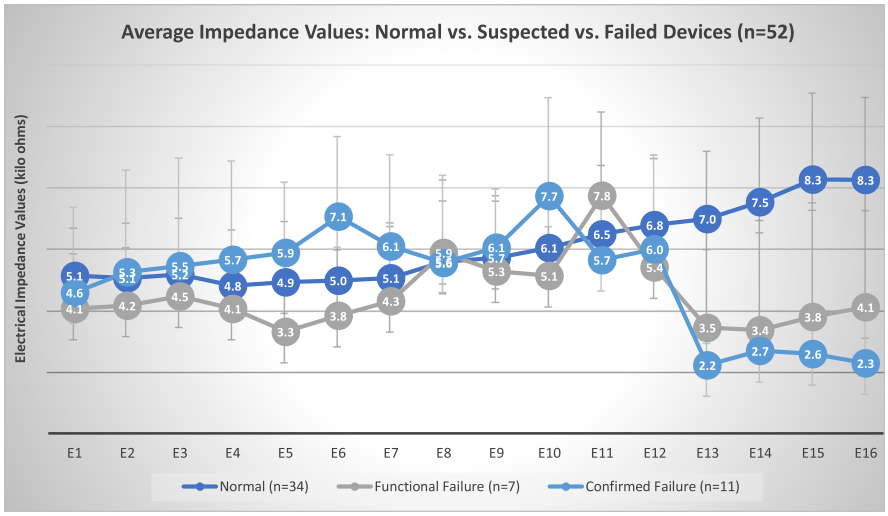

FIG. 2. Average impedance values across the entire electrode array from the normal functioning cohort (*dark blue*), functional failure cohort (*gray*), and the confirmed failure cohort (*light blue*).

Speech perception scores for the confirmed failure group exhibited a significant decline in speech understanding of 27.7% ($p < 0.001$) after the V1 field action notice when compared with baseline scores and normally functioning V1 devices in the general cohort (Fig. 3). Speech perception scores for the functional failure cohort decreased an average of 3.0% from baseline, which did not represent a significant shift in overall performance (Fig. 3).

No predictive relationship was identified in our study to quantify reduction in impedance levels in electrodes 13 through 16 with AzBio scores (Fig. 4). Although the V1 manufacturing issue primarily affected basal electrodes 13 through 16, additional electrode failures were present along the entire array for the confirmed and functional failure cohorts (Fig. 5).

DISCUSSION

Within the CI industry, internal device failures are rare but present. Previous CI device failures have been well described in the literature (5,7). Hildrew et al. (2013) classified the factors that contribute to CI failure into four categories: surgical technique, medical complications, patient related factors, and manufacturing/engineering (5). A manufacturing/engineering-related failure, specific to Advanced Bionics, is the basis of this study and should not be generalized to other manufacturers. In this patient population, 11 devices (21%) have been identified with a confirmed failure. A further 7 devices (13%) have a functional device failure that has yet to significantly affect speech understanding. The current revision rate for the adult recipient cohort at this

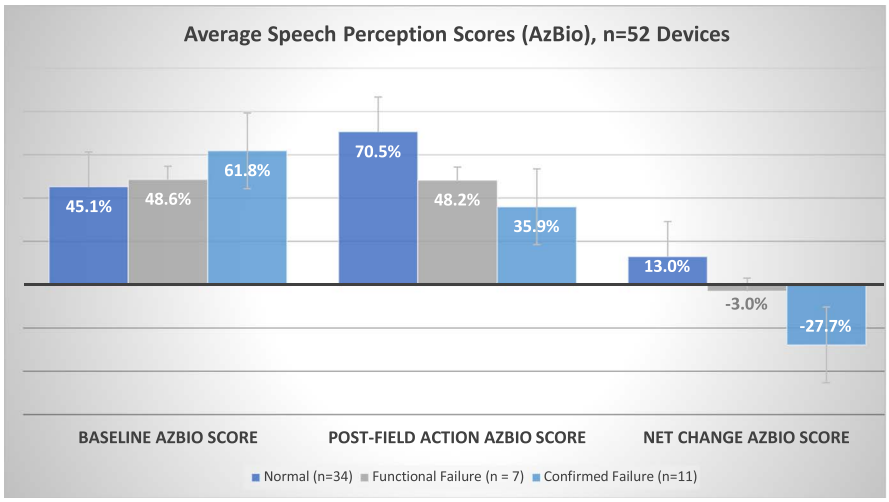

FIG. 3. Average speech perception scores (AzBio sentence test) 12-month postimplantation compared with 24-months postfield action notice from the normal cohort (*dark blue*), functional failure cohort (*gray*), and the confirmed failure cohort (*light blue*).

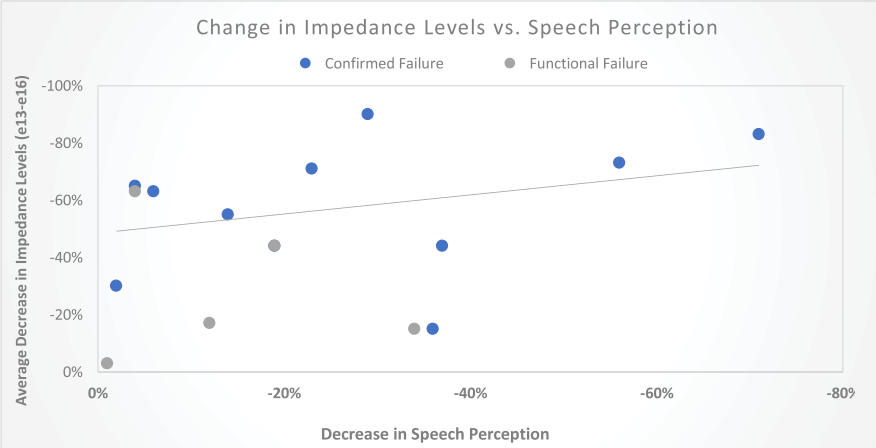

FIG. 4. Correlation data between average decrease in impedance values (electrodes 13–16) and decline in speech perception score (AzBio sentence test) from the confirmed failure cohort (*blue*) and the functional failure cohort (*gray*).

implant center is 9% as of January 2022. This is in line with the published explantation rate for HiRes Ultra V1 devices (3). A recently published retrospective case series by Lindquist et al. (20) showed a near identical failure rate of 21.1% with 65 confirmed failures out of 308 implants. The mean time to failure in this series was 2.2 years compared with our cohort that showed time to failure mean of 21.9 months.

Our results indicate that basal electrodes 13–16 were affected in keeping with the manufacturer's preliminary information. In the confirmed device failure group, elevated average impedances in electrodes 6, 7, 9, and 11 were also noted. This was not significant and were not included as criteria for device failure but have been indicative of the need for additional programming changes to overcome early device malfunction. This has been described by Carlson et al. (19), where high impedance levels were associated with poor CI outcomes.

No clear relationship was identified between absolute impedance level change with speech perception scores. This is in keeping with the research carried out by Prenzler et al. (10), which showed no correlation between impedances and performance in speech discrimination tests. However, there is strong suggestion that impedance levels can guide implant teams in counseling patients on appropriate expectations within the confines of this device recall.

Limitations identified include patient assessments that were based on clinical standards, not an *a priori* research schedule and further complicated owing to public health measures enacted a corollary to Sars CoV-2. This study is being conducted in real time, where this entire cohort of patients may all be affected over a greater period of surveillance. Further, the sample size is limited to only 52 devices.

This study may assist clinical practice to help guide patient counseling, specifically the import of changes in impedance as an indicator of possible future decline for V1

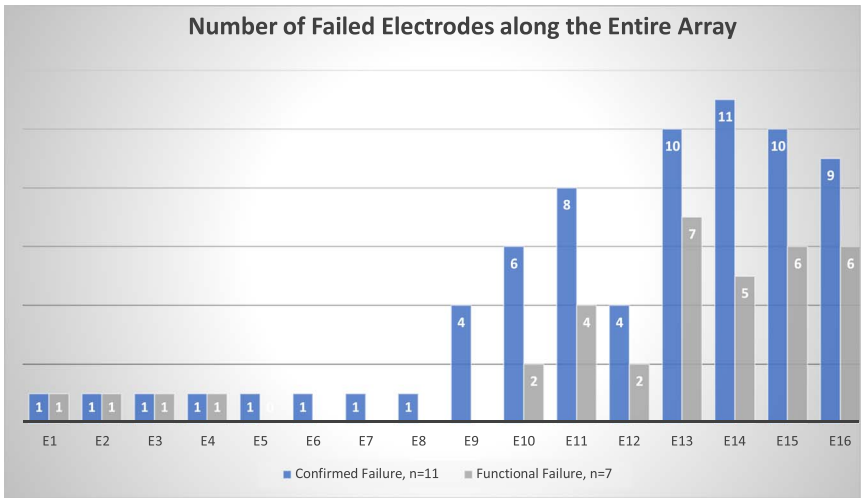

FIG. 5. Total number of failed electrodes along the entire electrode array in the confirmed failure cohort (*blue*) and the functional failure cohort (*gray*).

recipients. Regular monitoring of electrode impedances and speech perception testing should be a priority in individuals implanted with the HiRes Ultra/Ultra 3D V1 CI.

CONCLUSION

This study quantified CI failure rates at a single center and examined the relationship of impedance change as a precursor to and declining speech perception for V1 recipients. Although lowered impedances were indicative of declines in audibility and speech understanding, no predictive relationship was found between degree of impedance change and speech perception scores.

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