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Cochlear implant revisions over three decades of experience

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Abstract

Importance—The indications, technology, and surgical technique for cochlear implantation have evolved over the last three decades. Understanding the risk of cochlear implant revision (CIR) is important for patient counseling.

Objective—The objective of this study was to analyze the rates, indications, and audiologic outcomes for cochlear implant revision (CIR) over three decades of experience at a single academic medical center.

Design—A retrospective chart review was performed at a single academic medical center for individuals who underwent cochlear implantation between 1985–2022.

Setting—Single academic medical center.

Participants—Three-thousand twenty-five individuals who underwent 3,934 cochlear implant surgeries from 1985–2022.

Exposure—Cochlear implantation.

Main Outcomes and Measures—Rates, indications, risk factors and audiologic outcomes for CIR.

Results—There were 276 cases of CIR following primary implantation and an overall revision rate of 7.6% (95% CI 6.8–8.5%) over 37 years of follow-up with many cases of CIR secondary to Advanced Bionics Vendor B and Field action failure groups. CIR rates increased sharply through the early and mid-2000s and have since remained stable. Hard or soft device failure was the most common indication for CIR, accounting for 73% of cases. Pediatric patient status and prior CIR

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were associated with an increased risk of CIR. Audiologic outcomes following CIR were similar to those before device failure.

Conclusions and Relevance—CIR remains a common procedure most often performed for device failure. Pediatric patients and those who have undergone prior CIR are at the highest risk for future CIR. Audiologic outcomes remain stable following CIR and these data will help providers counsel patients on the risk of future CIR and understand the risk factors associated with CIR.

Keywords

cochlear implantation; cochlear implant revision; audiologic outcomes

Introduction

Since the first cochlear implant (CI) was performed in 1961[1] CIs have offered a means to restore hearing to individuals with sensorineural hearing loss (SNHL) too severe to treat adequately with traditional amplification.[2] After further innovation by multiple international research groups and the invention of the multichannel implant, CIs became the predominant treatment for profound SNHL by the 1980s.[1] Since then CI technology has continued to improve, and the United States Food and Drug Administration (FDA) approved indications for CIs have expanded to include children as young as nine months, second-side CI, adults with moderate SNHL, and reduced speech understanding, and adults with single-sided deafness.[2] As of 2015 it was estimated that over 170,000 individuals have undergone CI surgery in the United States[3] and over 700,000 worldwide.[4]

As with any implanted medical device, CI surgery carries an inherent risk of future revision surgery due to device malfunction, exposure, infection, or other causes. Understanding the likelihood of cochlear implant revision (CIR) is increasingly important as the number of CIs performed per year continues to increase, younger individuals undergo implantation, and the population of existing CI recipients continues to age. The existing literature describes highly variable CIR rates that range from 1% to 15%.[5–12] Further, the variables that may affect the risk of future revisions remain poorly understood. CIR places significant burdens on both patients and CI centers and a better understanding of revision surgery would provide some insights into the nature of these burdens and the risk of revision.

Due to the variability in CIR rates and outcomes across studies, characterizing a largescale CIR cohort may improve our understanding of the indications and outcomes, therefore improving clinical decision-making and patient counseling. In this study, we present 3,934 surgeries performed at a high-volume CI clinic over 37 years. The goals of this study were to describe the rates of CIR in both pediatric and adult patients, reasons for CIR, risk factors of CIR, and audiologic outcomes following CIR.

Methods

Institutional review board approval (IRB00188251) was obtained for this study. A retrospective analysis was performed of all CI surgeries that occurred at a single academic medical center (Johns Hopkins) between 1985 and April 2022.

Individual patient data were extracted from an institutional CI patient database and included age, sex, date of initial surgery, date of revision surgery, type of CI device implanted, and preoperative and postoperative speech perception scores. Individuals who required revision surgery were assumed to have returned to the same CI center as there was no way to account for individuals who may have gone elsewhere. The distances traveled by patients from home to our institution were calculated using the National Bureau of Economic Research Zip Code Distance Database[13] and Stata statistical software version 17 (College Station, TX). Cases of scalp flap revision and device repositioning without device removal/replacement were counted as revision surgeries. Based on the age at primary implantation, patients were stratified into adult (≥18 years of age) or pediatric (<18 years of age) cohorts. Device failure was determined from chart review and classified into eight categories: hard failure, soft failure, infection, desired upgrade, exposed hardware, device migration, facial nerve stimulation, or other. Hard versus soft failures were differentiated based on the clinical records using standardized criteria described in the 2005 Cochlear Implant Soft Failures Consensus Development Conference Statement.[14] Cases of a complete loss of sound perception without a functioning internal device were interpreted as hard failure while cases of gradual sound degradation over time were interpreted as soft failure.

Pre- and post-CIR speech performance scores in a sound field under quiet conditions for the Arizona Biomedical (AzBio) sentences, Consonant-Nucleus-Consonant words (CNCw), and Hearing in Noise Test (HINT) sentences were collected for the implanted ear. Post-CIR speech perception data were taken from the time-point closest to 12 months post-CIR. For patients who experienced hard or soft device failure, pre-CIR audiologic data was obtained from the most recent audiologic test *prior* to the clinical detection of device malfunction. For individuals who did not experience device failure, pre-CIR audiologic data was taken from the most recent test before CIR.

Stata statistical software was used for data analysis. The proportion of yearly CI surgeries for revision was calculated using the total number of CIR cases per year divided by the total number of CI cases per year for each year of the analysis. Kaplan-Meier curves to estimate the risk of CIR were calculated in a separate manner by specifically analyzing which CIs later underwent CIR. Kaplan-Meier curves were created for the outcomes of interest and illustrated graphically as cumulative revision rates over the number of years following initial CI surgery for different subgroups. Pre- and post-CIR speech performance scores (AzBio, CNCw, HINT) were compared using paired Student’s t-tests.

Results

Between 1985 and April 1, 2022, 3934 CI surgeries (including primary and revision) were performed on 3025 patients at the Johns Hopkins Cochlear Implant Center. Two thousand

six hundred fifty-five of these surgeries were performed on 2185 adult patients and 1279 CI surgeries were performed on 840 pediatric patients. The mean age at surgery for all study participants at the time of primary implantation was 40.3(±28.4) years and the mean time interval to CIR was 4.6(±5.2) years (Table 1). Three hundred and twenty-seven (9.0%) primary CI surgeries were performed between the years 1985–1999, 1906 (52.6%) between 2000–2009, and 1396 (38.5%) between 2010–2022 (Table 1). Further demographic characteristics are described in Table 1. The distances traveled by patients for surgery did not vary by primary or revision cases or time period of implantation (Supplemental Table 1).

Among the 3934 CI surgeries performed, 3623 were cases of primary implantation and 276 were first revised CIs, making an overall revision rate of 7.6% (95% CI 6.8–8.5%) over 37 years of follow-up. Overall CIR rates over 2, 5, and 10-year intervals were 2.6% (95% CI 2.1–3.2%), 4.8% (95% CI 4.2–5.6%), and 6.4% (95% CI 5.6–7.2%), respectively. There were an additional 29 (17 adult and 12 pediatric) cases of CIR from already revised implants, making for 305 total cases of CIR. For adult patients the post-primary revision rate was 6.1% (151 revisions/2487 CI surgeries) over a 37-year period with 2, 5, and 10-year rates of 2.1% (95% CI 1.6–2.8%), 3.7% (95% CI 3.0–4.5%), and 4.8% (95% CI 4.0–5.7%). For pediatric patients the post-primary revision rate was 10.9% (125 revisions/1142 primary CI surgeries) over a 37-year period with 2, 5, and 10-year rates of 3.6% (95% CI 2.6–4.8%), 7.4% (95% CI 5.9–9.0%), and 10.0% (95% CI 8.3–11.9%). One thousand three hundred seventy (37.8%) primary implants were Advanced Bionics implants, which have had historically higher revision rates.[15–17]

CIR was very uncommon until the mid-2000s and increased through the mid-2000s and has since remained relatively stable (Figure 1). Amongst all revisions, 164 (53.8%) were due to hard device failure, 58 (19.0%) for soft failure, 13 (4.4%) for infection, 14 (4.6%) for desired technology upgrade, 5 (1.6%) for exposed hardware, 20 (6.6%) for device migration, 5 (1.6%) for facial nerve stimulation, and 26 (8.5%) for other reasons. Amongst pediatric revisions, 83 (60.6%) were due to hard device failure, 25 (18.2%) for soft failure, 6 (4.4%) for infection, 1 (0.7%) for desired technology upgrade, 7 (5.1%) for device migration, 1 (0.7%) for facial nerve stimulation, and 14 (10.2%) for other reasons. Amongst adult revisions, 81 (48.2%) were due to hard device failure, 33 (19.6%) for soft failure, 7 (4.2%) for infection, 13 (7.7%) for desired technology upgrade, 5 (3.0%) for exposed hardware, 13 (7.7%) for device migration, 4 (2.4%) for facial nerve stimulation, and 12 (7.1%) for other reasons including cholesteatoma and failed electrode deployment. The overall device failure rate including hard and soft failure was 5.5% over 37 years.

The Kaplan-Meier estimate of the cumulative incidence of CIR over time for primary implantation for the entire cohort is displayed in Figure 2A. When separated according to pediatric or adults CIs, the Kaplan-Meier analysis showed a higher risk of revision for pediatric patients (X^2=42.3, p<0.0001)(Figure 2B). Stratification according to the era of initial CI did not show a higher risk of CIR according to the era of implantation (Figure 2C). When compared to the risk of CIR after primary implants, CIs implanted during revision surgery had a higher rate of revision but this relationship did not reach statistical significance (Figure 2D).

Following CIR, speech understanding scores for AzBio (p=0.82, mean change=1.4%, 95% CI=−11.4–14.2%), CNCw (p=0.19, mean change=6.05%, 95% CI=−3.2–15.3%), and HINT (p=0.41, mean change=5.5%, 95% CI=−7.9%−19.1%) were similar relative to scores before device failure (Figure 3). For pediatric patients AzBio (p=0.61, mean change=4.6%, 95% CI=−13.7–22.9%), CNCw (p=0.63, mean change=3.4%, 95% CI=−10.7–17.6%), and HINT (p=0.32, mean change=9.2%, 95% CI=−9.2–27.5%) scores were also similar. For adult patients AzBio (p=0.94, mean change=0.7%, 95% CI=−19.7–21.1%), CNCw (p=0.78, mean change=2.1%, 95% CI=−12.9–17.2%), and HINT (p=0.43, mean change=10.8%, 95% CI=−16.1–37.6%) scores did not change.

Discussion

This study provides a comprehensive description of CIR at a busy cochlear implant center over 37 years with >3900 CI surgeries. To date, this is the largest patient cohort and the longest time period over which CIR has been described. In this case series, the overall revision rate was 7.6% with 2, 5, and 10-year rates of 2.1% (95% CI 1.6–2.8%), 3.7% (95% CI 3.0–4.5%), and 4.8% (95% CI 4.0–5.7%). Consistent with other case series, device failure was the most common reason for CIR in both adult and pediatric patient populations. We found that pediatric patients and those who had undergone prior CIR were at higher risk for future CIR. Overall audiologic outcomes following CIR were similar to those before device failure.

Rates of Revision

Understanding the risk of future CIR is important for both patient counseling and for CI centers to understand the resources and follow-up needed to provide long-term CI care. There are over 30 reports describing the proportion of CI revisions. Wang et al. summarized the proportion of CI surgeries that were revisions for 29 studies published in 2012 or earlier and found widely ranging revision rates from 1.2–15.1% with a mean of 7.6%.[8] In an updated literature review of published CIR rates for 2013–2022 we found CIR rates of 1.7–19.9% with a mean of 7.1%(Table 2). The overall CIR rate of 7.6% over 37 years of follow-up reported in this study is consistent with these reports, and it is possible that the long period of follow-up in this study resulted in higher CIR rates than would have been observed over a shorter time period. A large portion of implants (37.8%) in this series were Advanced Bionics implants that have historically higher failure rates[15–17] with revision rates approaching 40% for the HiRes 90K (vendor B) device.

The 0.5% decrease in mean CIR rate for studies published after 2012 compared to earlier reports may reflect a decrease in CIR rate over time. This study did not show a decrease in the CIR rate for CIs implanted within the 2010–2022 era. However, the length of follow-up for the more recently implanted CIs in our cohort is limited and a longer period of follow-up may have shown a lower CIR rate for more recently implanted CIs based upon surgical and technological improvements over the previous three decades.

Overall CIR rate is the most commonly reported parameter in CI studies,[6,18–24] followed by overall device failure rate.[25] The overall device failure rate in this study was 5.5%. Device failure rates are similarly highly variable within the literature with rates ranging from 0.5–

14.7% and a mean of 5.1% in reports published before 2012.[8] In our review of the literature we found an average device failure rate of 3.4% (Table 2).[26] The lower device failure rates seen in more recently published studies may reflect improvements in device design and reliability over the last 10–15 years. Further, the device failure rate in this study is subject to additional considerations that may result in higher device failure rates. Tertiary care centers may be more likely to care for patients with comorbid conditions that place them at a higher risk of CIR. Further, tertiary care centers are more likely to care for pediatric CI recipients who tend to have higher CIR rates[8] as seen in our report and to have performed CI surgeries in the earlier era of CI surgery, which may increase rates of CIR due to device failure in addition to other causes.

The overall rates of cochlear implant revision increased sharply during the early 2000s and have since remained relatively stable. Wang et al. showed that individuals implanted in the late 2000s had a lower risk of revision compared to individuals implanted in the 1990s or even early 2000s.[8] Similar observations were made in this study. This is consistent with further improvements in both device design and function, which is common to all device manufacturers.[7,21,26–29] These improvements in device design have likely resulted in a decreased number of recalled devices, which have accounted for a large proportion of cases of CIR. CIR rates may have decreased as surgeons have become more experienced with cochlear implantation. However, it is difficult to interpret the impact of surgical technique and experience, since the indications and types of patients undergoing cochlear implantation have changed dramatically over the last three decades.

Indications for Revision

The most common indication for CIR in this study was device failure (73%), in which 54% and 19% were for hard and soft failure, respectively. This is consistent with the literature on CIR in which other large case series have consistently found that device failure accounts for the majority of CIR cases.[8,30,31] In this study pediatric patients were found to have a higher device failure rate. It is unclear what is responsible for the higher device failure rate in children but children may be more prone to head trauma which may result in device damage and failure. Device migration and infection were relatively rare in this review but remain important considerations for the surgeon. Five individuals in this series underwent CIR for facial nerve stimulation that was refractory to device reprogramming and resolved with reimplantation of a perimodiolar electrode.[32] There were several cases of CIR for an elective technology upgrade, which may become more common in the future[33] given that some older processors are no longer compatible with newer external devices.

Risk Factors for Revision

This study found that pediatric patients and prior revision were associated with a higher risk of CIR. The increased risk of CIR in pediatric patients relative to adults is well known[8] and may suggest that pediatric patients are at increased risk of device failure potentially due to mechanisms such as head trauma. Interestingly the increased rates of CIR did not appear to be associated with higher rates of infection or device migration. The increased rate of CIR for individuals already undergoing CIR has been less frequently described in the literature, and we speculate that this is explained by patient-specific factors. Earlier era of implantation

has been described elsewhere as a risk factor for CIR.[8] In this study there was no association between the era of implantation and CIR, but it is possible that with a longer period of follow-up differences would emerge.

Audiologic Outcomes

Overall audiologic outcomes were similar following CIR. This is consistent with reports from other case series in which speech perception following CIR remains stable.[18,24,34,35] In the coming decades CIR may become more common as the number of CI recipients continues to grow and this population continues to age. Further, in the future there may be an increasing demand for elective CIR for technology upgrade for older CI devices, such as the Advanced Bionics Clarion 1.2, that lack connectivity with newer external processors.[33] Device selection in CIR is also an important consideration but beyond the scope of this report.

Limitations

The primary limitation of this study is that it relies upon an institutional database of CI surgeries to define individuals who underwent implantation/CIR, and any surgeries not included within this database, would be missed and potentially result in an underestimation of the revision rate. Given the mobility of the United States population it is possible that an individual may undergo primary implantation at one center and revision surgery at another. Further, it is possible that patients may have been more likely to travel further distances for surgery when CIs were a new technology and underwent a later revision at a center closer to their home. It is not possible to precisely estimate the influence of these factors, but there are two observations from this study that are relevant. First, in the last 37 years the number of revision surgeries at our institution for individuals who underwent primary implantation elsewhere has been limited (16 cases). A similar trend in the reverse direction (ie individuals going elsewhere for revision) would result in an under-estimation of revision rates by ~0.4% if one assumes the same number of patients. Second, the distances traveled by patients for surgery were similar for both primary and revision surgeries and across different time periods (Supplemental Table 1), suggesting that there may not have been a large number of patients who sought later revisions closer to home.

This study is also subject to several additional limitations. Clinical histories were used to define hard and soft failure were based on clinical presentation rather than device testing as this data was more readily available. The institutional database used in this study did not contain detailed patient information that may have aided our analysis such as demographic features and medical comorbidities. Last, audiologic data was extracted from our institutional database and was not available for a substantial proportion of patients, and for those whom it was available, the same speech understanding testing was often not available pre- and post-operatively thereby limiting our assessment of the effects of cochlear implantation on speech understanding.

Conclusions

CIR remains a common procedure most often performed for device failure. Pediatric patients and those who have undergone prior CIR are at the highest risk for future CIR.

Audiologic outcomes remain stable following CIR and these data will help providers counsel patients on the risk of future CIR and understand the risk factors associated with CIR.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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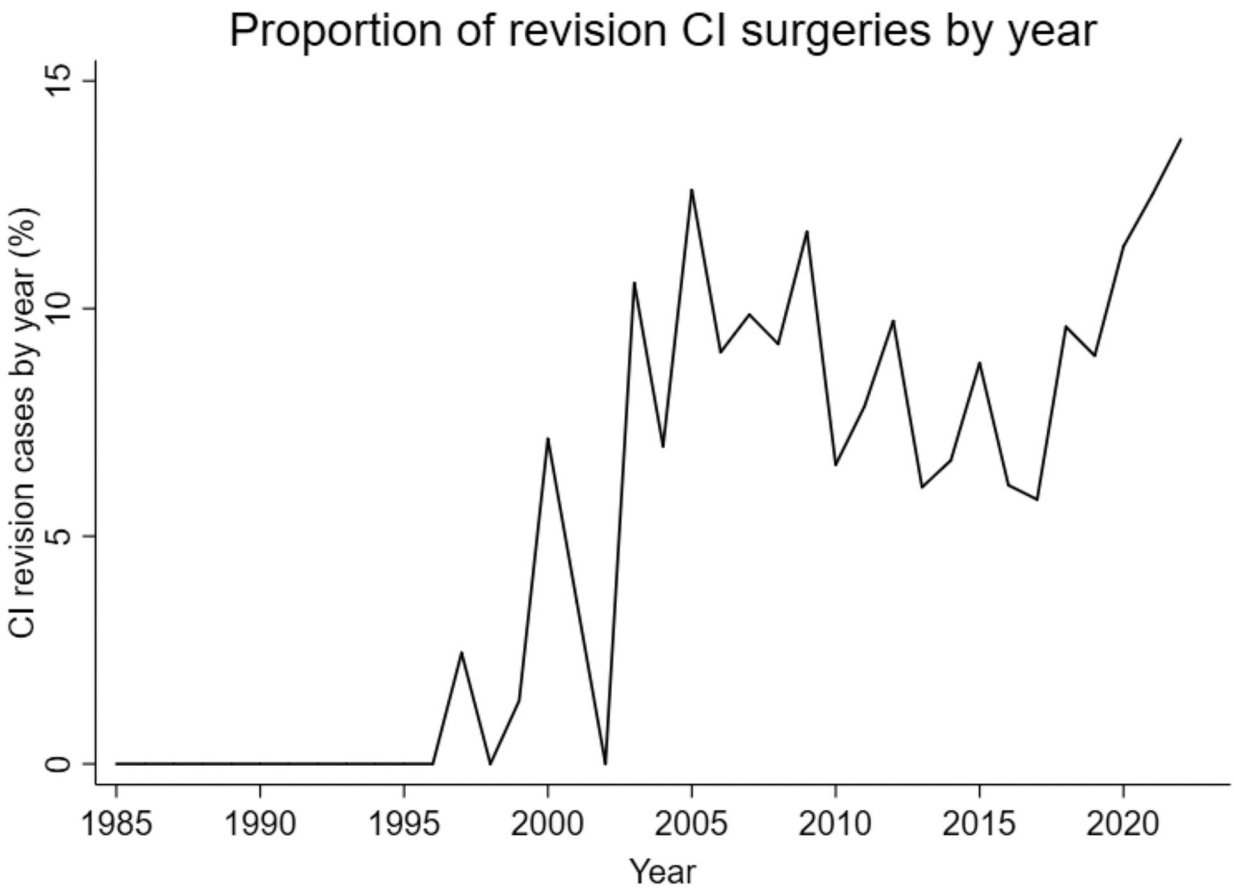

Figure 1.
Proportion of revision cochlear implant cases by year for the years 1985–2022 (revision cases per year divided by total CI surgeries per year).

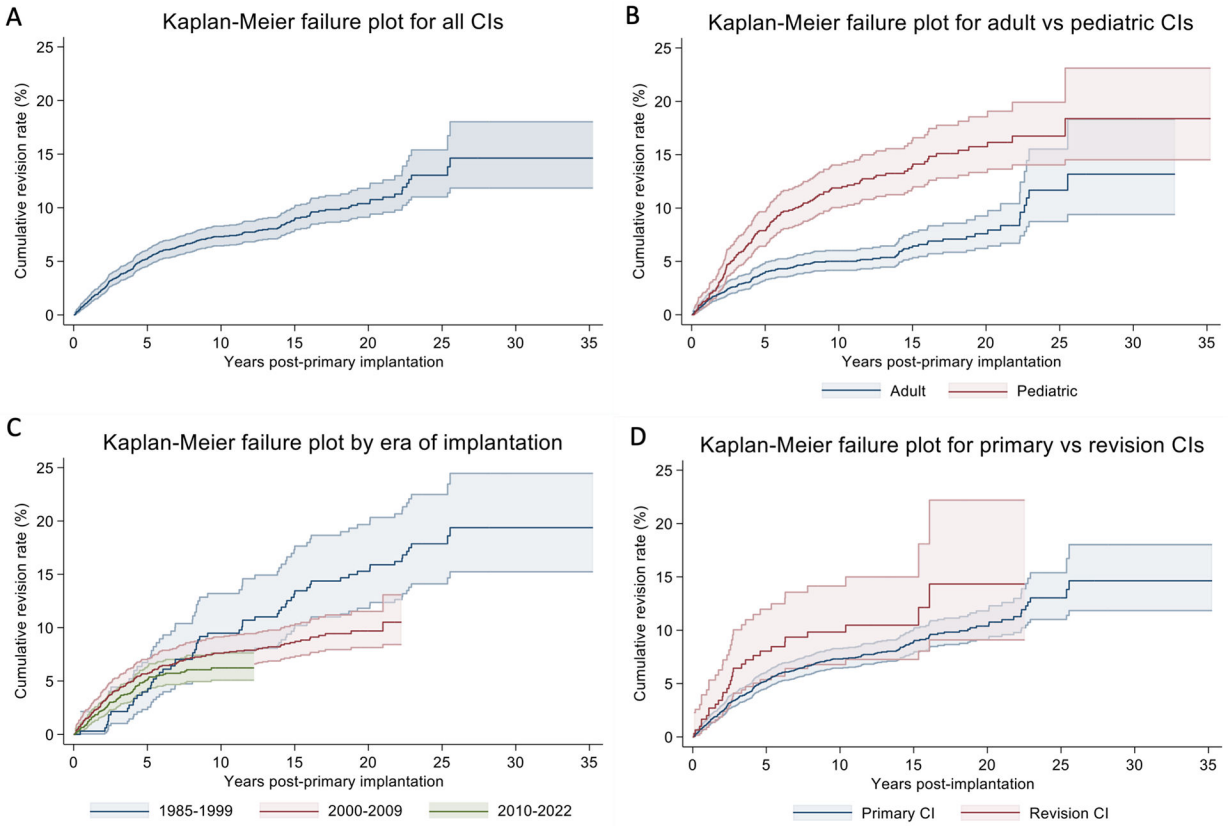

Figure 2A-D.

Kaplan-Meier estimates of cumulative incidence of CIR over time for the entire patient cohort (Panel A), by pediatric vs adults CIs (Panel B), according to the era of primary implantation (Panel C), and by primary vs revised implants (Panel D).

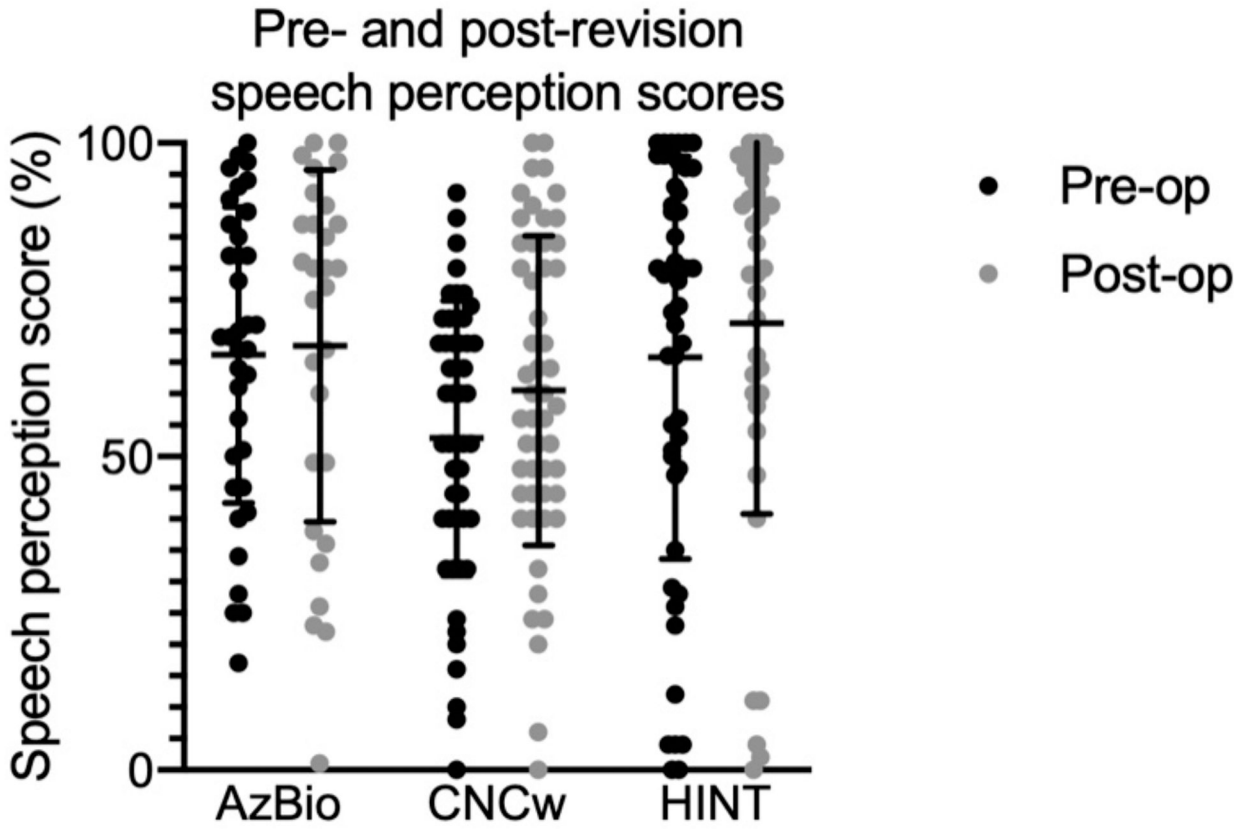

Figure 3.
Pre- and post-revision speech understanding scores for the entire cohort.

Table 1.

Demographic characteristics of the patient cohort.

	Children (n=1,279)(%)	Adults (n=2,655)(%)	All (n=3934)(%)
No. of primary implants	1142 (89.3)	2487 (93.4)	3,629 (92.2)
Number of initial revision surgeries	15 (9.8)	151 (5.7)	276 (7.0)
Total no. of revision surgeries (including repeat revisions)	137 (10.7)	168 (6.6)	305 (7.8)
Age at primary CI in years, mean (SD)	5.5±4.5	56.4±18.6	40.3±28.7
Age at primary CI in years for those undergoing revision, mean (SD)	4.5±3.7	53.6±17.6	29.0±27.7
Age at revision in years, mean (SD)	8.0±4.1	54.5±19.4	33.6±27.4
Interval between primary surgery and revision in years, mean (SD)	4.7±4.4	4.6±5.8	4.6±5.2
Year of primary CI surgery			
1985–1999	156 (13.7)	171 (6.9)	327 (9.0)
2000–2009	509 (44.6)	1397 (56.2)	1906 (52.6)
2010–2022	477 (41.8)	919 (37.0)	1396 (38.5)
Year of revision CI surgery			
1985–1999	1 (0.7)	1 (0.6)	2 (0.6)
2000–2009	65 (47.4)	64 (38.1)	129 (42.3)
2010–2022	71(51.8)	103 (61.3)	174 (57.0)

Table 2.

Literature review of CI revision rates for papers published from 2013–2022. Studies are listed in order of sample size (revision number). Device failure rates included hard and soft failures.

Study	Location	No. of Revision Surgeries	No. of Primary Implants	Overall Revision Rate (%)	Overall Device Failure Rate (%)
Present Study	Baltimore, MD	276	3623	7.6	5.5
Parent et el (2020)[36]	France	392	5278	6.8	0.5
Wang et al. (2014)[8]	Sydney, Australia	234	2827	8.3	4.8
Sagiv et al. (2021)[12]	Israel	172	1465	11.7	8.1
Ozdemir et al. (2022)[37]	Istanbul, Turkey	157	1148	13.7	1.0
Batuk et al. (2019)[38]	Ankara, Turkey	127	2181	4.7	-
Karamert et al. (2019)[31]	Ankara, Turkey	102	924	11.0	3.0
Rayamajhi et al. (2021)[39]	Chennai, India	94	1636	5.7	4.1
Reis et al. (2017)[40]	Australia	87	2055	4.2	1.4
Kimura et al. (2020)[34]	Nashville, Tennessee	172	1469	5.5	4.6
Farinetti et al. (2014)[41]	Marseille, France	80	403	19.9	2.2
Blanchard et al. (2015)[35]	Paris, France	62	877	7.0	5.7
Olgun et al. (2014)[42]	Izmir, Turkey	62	957	6.5	3.8
Wijaya et al. (2019)[43]	Dublin, Ireland	60	1207	5.0	3.1
Yeung et al. (2018)[44]	Boston, Massachusetts	53	868	5.9	6.1
Kim et al. (2020)[45]	Seoul, South Korea	43	925	4.6	3.0
Kou et al. (2020)[46]	Dallas, Texas	40	834	4.8	3.0
Stevens, et al. (2019)[47]	Cincinnati, Ohio	38	512	7.4	5.1
Aldhafeeri et al. (2021)[48]	Saudi Arabia	37	922	4.0	3.0
Layfield et al. (2021)[49]	Philadelphia, Pennsylvania	32	498	5.9	3.4
Amaral et al. (2019)[50]	São Paulo, Brazil	32	165	12.1	0.8
Gardner et al. (2018)[51]	San Antonio, Texas	31	579	5.4	4.7
Gumus et al. (2021)[52]	Eskesehir, Turkey	27	490	6.3	3.6
Lane et al. (2020)[45]	Ontario, Canada	23	804	2.9	1.7
Hwang et al. (2016)[53]	Taiwan	22	589	3.7	1.4
Petersen et al. (2018)[54]	Dublin, Ireland	21	1266	1.7	-
Sunde et al. (2013)[55]	Little Rock, Arkansas	18	439	4.1	1.8
Bhadania et al. (2018)[56]	India	10	250	4.0	2.4
Ozer et al. (2021)[57]	Ankara, Turkey	10	121	6.7	5.0
Cumulative		2514	35312	7.1	