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Cochlear Reimplantation and Its Etiology at the Antwerp University Hospital: A 29-Year, Single-Center Experience in Children and Adults

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ABSTRACT

Background: As the number of cochlear implantations is increasing and devices are aging, the amount of revision cochlear implant surgery is becoming more frequent. The aim of this study is to present an institutional experience of cochlear reimplantation rate and its etiologies.

Methods: Patients who underwent revision cochlear implant surgery at the Antwerp University Hospital between August 1993 and August 2022 were retrospectively reviewed.

Results: A total of 1313 cochlear implantations were performed at the Antwerp University Hospital (UZA) over a period of 29 years. There have been 60 cochlear reimplantations in the center, 6 of which received their first implant in another medical center than UZA. Therefore, the institutional failure rate is 4.3% (54/1253). Reimplantation in children (<10 years old) accounted for 28% (17/60) of the cohort. Device-related failure was the most prevalent etiology and amounted to 70% (42/60) of the reimplantations; 26.7% (16/60) were medically related failures. One case was registered as an inconclusive failure (1.7%) and 1 case was an elective upgrade (1.7%). The mean duration to failure was 11.0 years (ranging 0.8-22.7 years). Revision cochlear implantation is challenging with respect to indication (in cases without device failure), preoperative workup (incl. imaging), electrode array choice (matching the dimensions of the original electrode type), as well as the surgical procedure itself.

Conclusion: The number of reimplantations is expected to grow in the coming years due to the increasing number of patients that have been implanted in the last decades. Device-related failure was the most prevalent reason for reimplantation in the present study.

Keywords: Cochlear implant, cochlear reimplantation, failure analysis

Introduction

Cochlear implantation is a recognized treatment for pediatric and adult patients with severe-to-profound sensorineural hearing loss. The implantation rates have increased significantly in the past few decades, and so have revision cochlear implant surgeries because of anticipated device failures in aging cochlear implants.

Unfortunately, there is no uniform reporting of causes for cochlear implant failures and indications for revision cochlear implant surgery in the literature. Therefore, the Association for the Advancement of Medical Instrumentation (AAMI) developed a standard for cochlear implant reliability reporting in 2017.[1] The causes of implant failure are divided into 6 categories, the 3 most frequent causes being medical-related, device failure, and inconclusive. This categorization allows manufacturers and healthcare professionals to report implant failure more uniformly, which gives more opportunities for future research and should improve informed decision-making. Two other classifications that have been used in the literature are the European Consensus Statement on Cochlear Implant Failures and Explantations (2005) and the International Classification of Reliability for Implanted Cochlear Implant

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Receiver Stimulator (2010).[2,3] Both classifications are based on the ISO (International Organization for Standardization) standard 5841-2/2000. This classification was originally designed for reporting the reliability of leads for cardiac pacemakers or pulse generators and has been adapted by cochlear implant manufacturers for reporting the reliability of cochlear implants. The reasons leading to revision surgeries are medical reasons, device failure, performance decrement, and characteristics decrement. Performance decrement is comparable to inconclusive failure. Characteristics decrement implies that the device is out of specification while there is still some clinical benefit for the patient. Terms that are also widely used in cochlear implant failure reporting are hard and soft failure. In hard failure, there is an evident broken device, and the integrity tests identify device failure. Soft failure is comparable to inconclusive failure, where a device malfunction is suspected due to declined implant performance or aversive auditory or nonauditory stimuli, but integrity tests do not show an abnormal function.[4]

This study aimed to present a 29-year institutional experience of cochlear reimplantation in both pediatric and adult patients, the causes of revisions as well as diagnostic and surgical challenges.

Methods

A retrospective analysis was performed on patients who underwent revision cochlear implant surgery in the Antwerp University Hospital (UZA) between August 1993 and August 2022. Patients were included in this study if they met the following inclusion criteria: implanted with a multi-channel cochlear implant (at UZA or elsewhere) and reimplantation was performed at UZA. There were no age restrictions for inclusion.

Main Points

- This study presents an institutional experience of cochlear reimplantation and its etiologies.
- Increasing need for reimplantation is to be expected due to the increasing number of patients that have been implanted in the last decades and are using their cochlear implants up to 25 years.
- Device failure is the most prevalent cause of implant failure in this study.

In total, 1313 implantations were registered in the cochlear implant (CI) database of UZA.

The study reported on retrospective demographic data. Therefore, the study was conducted in accordance with the recommendations of the ethics committee of UZA that waived the need to obtain informed consent for this study.

The clinical charts of all patients were reviewed and the age at first implantation, the time to failure, and the type of failure were obtained. Children and adults were separated with the cutoff being 10 years at the time of first implantation. Cochlear implant failures were categorized according to the AAMI categorization for cochlear implant reliability reporting (Table 1).[1]

Statistical analysis was performed using SPSS (SPSS Statistics 28.0 for Windows; SPSS, Chicago, Illinois, USA). Data concerning the number of failures, type of failures, demographics, implant center, and side of reimplantation were summarized using descriptive statistics. Normality was tested using the Shapiro–Wilk test. Given the small sample size and the non-normal distribution, quantitative data were reported as median (range minimum and maximum). Mann–Whitney *U*-test was used to compare time to failure in both children and adult groups. χ^2 test was used to compare categorical variables. All *P*-values were two-sided and a *P*-value of <.05 was considered statistically significant.

Results

A total of 1313 cases, including 386 in children and 927 in adults, underwent cochlear implant surgery at UZA over a period of 29 years. There have been 60 cochlear reimplantations in the center, 6 of which had received their initial cochlear implant in another hospital (Table 2). Therefore, a device failure rate of 4.3% was observed at the institution (54/1253). Among the 60 subjects with revision cochlear implant surgery, 21 (35%) were male and 39 (65%) were female. The mean age at implantation was 37.0 (0-74) years. The mean duration between the time of the first implant and revision surgery, more specifically time to failure, was 11.0 (0.8-22.7) years. There was an equal distribution between left and right sided cochlear reimplantations (Table 3).

The causes of cochlear implant failure are presented in Table 4. Data analysis revealed that device failure occurred in 42 of 60 (70.0%) revision cases. The revision surgeries in 16 out of 60

Table 1. Failure Categorization According to the Association for the Advancement of Medical Instrumentation

Medical-related explant	A device that was normally functioning but had to be removed for medical reasons (infection, cerebrospinal fluid (CSF) leakage, implant migration, pain).
Device failure explant	A malfunctioning implant where integrity testing can be used to identify the failing element of the device (failure of the electrode lead, receiver coil).
Inconclusive failure	An implant where a device malfunction is suspected due to declined implant performance or aversive auditory or nonauditory stimuli, but integrity tests do not show an abnormal function. This is a diagnosis of exclusion.
Unrelated medical explant	An explantation for medical reasons that is not related to the functioning of the device.
Depleted battery explant	An explantation due to depletion of the implanted battery.
Elective upgrade explant	An explantation that is planned because the patient wants to upgrade the device.

Table 2. Institutional Overview of Cochlear Reimplantations

	Children (<10 yo)	Adults (>10 yo)	Total
Implantations	369	884	1253
Reimplantations	17	43	60
Primary implant in UZA	15	39	54
Primary implant elswhere	2	4	6
Total	386	927	1313

UZA, University Hospital of Antwerp.

Table 3. Patient Demographics

	Reimplantations (n = 60)
Sex	
Male	21
Female	39
Side of reimplantation	
Right	30
Left	30
Implant center of first implant	
UZA	54
Elsewhere	6
Mean age at implantation (years)	37 (0-74)
Mean time to failure (years)	11 (0.8-22.7)

UZA, University Hospital of Antwerp.

patients (26.7%) were due to medical-related factors including infection with or without fistulization (n = 5), neuralgia (n = 5), anomalous percepts (n = 2), facial nerve stimulation (n = 2), dysfunction due to polyneuropathy (n = 1) and surgical error (n = 1). Finally, there was also 1 case of inconclusive failure and 1 elective device upgrade (explant of an Antwerp Bionics Systems Laura).

No statistically significant difference was found in the failure rate between children and adults ($P = .853$). Comparison between children and adults by cause of failure did not yield a statistically significant difference ($P = .406$), nor was there a statistically significant difference between time to failure ($P = .740$) in these 2 patient groups.

Discussion

As the number of cochlear implantations is increasing and devices are aging, the number of cochlear implant failures and associated revision cochlear implant surgery is becoming more frequent. The institutional failure rate of 4.3% is consistent with the range reported in the literature: 0.5%-14.7%, mean 5.1%.[5] In this study, as well as in the literature,[5-7] device-related failure is the most frequent failure type and occurred in 70.0% of the cases (70.6% children group, 69.8% adult group). It is difficult to compare exact rates as studies use different classifications and varying definitions for types of cochlear implant failure. Lane et al[6] used the same failure classification (AAMI) and reported a device failure rate of 60.8%, which is in line with the current study's results. Some studies found a significantly higher percentage of device-related failure in children,[8-10] which has been suggested to correlate with head trauma. However, a higher device-related failure rate was not found in children in this series. This might be explained by the surgical technique, where the electrode is placed in a bony canal. So if a blow hits the head, it is difficult to hit the electrode as it is buried in the bone. The second most common failure type, both in the current study and in the literature,[7] is medical-related failure. This is followed by inconclusive failure, which was rare in the current study population (1/60 patients).

It is expected to have more elective upgrades in the coming decades, as some implants are aging and cochlear implant technology is improving. Some reasons for elective upgrades are incompatibility of the most current external processor, longer battery life, newest devices are waterproof, the possibility to stream to electronic devices, and potential improvements in audiologic performance. In the study of Holcomb et al,[11] word and sentence recognition scores after cochlear reimplantation met or exceeded the best scores 3 months after activation of the primary cochlear implant in patients with elective device upgrade.

According to the data, the mean time to failure was 11.0 (0.8-22.7) years. Literature reports a range of 2.1-6.2 years.[6] This value can vary depending on factors such as follow-up duration, cochlear implant type (e.g. cochlear implant devices that have been recalled), and patient population (children versus adults).[12] However, concerning the latter, no significant difference was found when comparing time to failure between children and adults. The reason that the institutional mean time to failure is favorable compared to the literature can be partially explained by the fact that there was no significant impact of device recall. It is expected that advances in technology and improvements in device reliability will contribute to an increase in the mean time to failure in the future.

Table 4. Causes of Cochlear Implant Failures

	Children (<10 yo)		Adults (>10 yo)		Total	
	Cases (n = 17)	Failure Rate (%)	Cases (n = 43)	Failure Rate (%)	Cases (n = 60)	Failure Rate (%)
Medical-related explant	4	23.5	12	27.9	16	26.7
Device failure explant	12	70.6	30	69.8	42	70.0
Inconclusive failure	1	5.9	0	0.0	1	1.7
Elective upgrade	0	0.0	1	2.3	1	1.7

Revision cochlear implant surgery should be performed by experienced cochlear implant surgeons considering the challenging aspects of explanting older generation electrode arrays, fibrosis in the scala tympani, and the challenges in inserting the new electrode array as well as the intraoperative telemetry. Because of evolution in electrode properties, careful preoperative matching of currently available electrode types to the dimensions of the original electrode type is essential. Lassig et al[13] studied the depth of electrode insertion between the first and second implant and found that it was equal to or higher in most reimplantation cases. Revision cochlear implant surgery has a high success rate, with audiological findings that remain stable or even improve after reimplantation. Success rates in current literature vary between 81% and 94%.[7,14-17]

Determining the specific cause of cochlear implant failure can be challenging. Differentiating between device failure, medical-related reasons, and inconclusive failure requires a multidisciplinary approach with evaluation of the patient's symptomatology (such as pain or seizures), audiological performance, computed tomography imaging, and integrity testing. Inconclusive failure—also categorized as soft failure or performance decrement in the literature—is a diagnosis of exclusion. Since the diagnosis of inconclusive failure is based on subjective complaints and lack of speech and language development, diagnosis and treatment are challenging and frequently delayed. However, it is still of great interest to diagnose this type of failure, as these patients may also benefit from revision cochlear implant surgery.

Reviewing patients with cochlear implant failure followed by reimplantation gives the possibility to draw conclusions regarding failure etiology and to improve management in these situations. Failure rates seem to decrease over time. This is mostly observed for device failures; however, there is also a trend in decreasing medically related failures.[5]

The limitations of this study include difficulty comparing the frequency of failure types due to the use of different failure classifications and definitions. As well, literature uses different age cutoffs for children and adult groups.

This study retrospectively reviewed the rate and causes of cochlear implant failure at the Antwerp University Hospital. The most common reason for reimplantation was device failure, followed by medically related failure. Increasing need for reimplantation is to be expected due to the increasing number of patients that have been implanted in the last decades and are using their cochlear implants up to 25 years.

Data Availability Statement: The data that support the findings of this study are available on request from the corresponding author.

Ethics Committee Approval: Ethical committee approval was received from the Ethics Committee of University of Antwerp (Approval No.: 2021.041; 10/05/2021).

Informed Consent: The ethics committee approved a waiver of consent.

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Declaration of Interests: The authors have no conflicts of interest to declare.

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