# The French National Cochlear Implant Registry (EPIIC): Cochlear explantation and reimplantation

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**Summary**

This study aims to determine the frequency and causes of cochlear explants with re-implantation (ERI) after 5 years' follow up of the patients included in the French national EPIIC (*Etude Post-Inscription des Implants Cochléaires*) registry tracking patients with cochlear implantation. This multicenter, descriptive prospective study was conducted on 5051 patients enrolled in the EPIIC database between January 2012 and December 2016.Ninety-five patients (1.9%) received a primary implant and an ERI during the study. Of these, four benefitted from two ERIs. The number of ERIs was significantly higher in the pediatric population than among adults. The explantation and reimplantation were performed simultaneously in 86% of cases. The reasons for explantation were: in 46.4% of cases linked to a malfunction of the implant, and in 39.3% of cases for medical or surgical reasons. The number of electrodes inserted was significantly higher after the ERI than after the first implantation. There was just one post-ERI infection for these 95 explanted and re-implanted patients. As well as explantation with reimplantation rarely being necessary, it generally presents no major surgical difficulty and in most cases it allows a better integration than in the first implantation.

Key words: cochlear implant, explantation, reimplantation, registry

## Introduction

For decades now, cochlear implants (CIs) have been a common treatment for child and adult severe-to-profound deafness. Technical and material advances have made cochlear implantation a safe and effective technique. Nevertheless, like any medical device, CIs are prone to malfunction and like any biotechnology, cochlear implants can experience surgical and or medical complications. These dysfunctions and these complications, whatever their nature, can necessitate simultaneous or sequential explantation and reimplantation (ERI). The frequency of these ERIs is 8.2%, on average and the frequency varies between 4.2 and 13% in the literature [1][2,3]. In more than two thirds of cases, the ERI is linked to a failure of the implanted device [1]. When it is possible to implicate this kind of fault it is referred to as "hard failure". However a drop in performance can also occur without obvious hardware failure. This is called "soft failure"[4]. Finally, medical or surgical reasons can be the cause of the ERI, most notably through an infection of the implanted material or poor positioning of the electrode holder during the operation. From a functional point of view, the ERI process does not appear to reduce implant performance. Indeed, most studies interested in hearing performance after ERI found results in speech audiometry at least equivalent to those before implantation, whether in children or adults [2,5,6]. In general the literature does not describe any major surgical difficulty in reimplantation, apart from a risk of labyrinthitis ossificans [1,3,7].

The EPIIC registry and study for Post-Registration of Cochlear Implants was instigated in France under the auspices of the French Health Authority (*Haute Autorité de Santé* - HAS). The purpose of this registry is to have information on: the demographics of implanted patients, the implanted population, causes leading to implantation, the implanted side (left/right), the etiology, monitoring of complications, simple indicators of evolution of performance in adults and children, differences between implant brands, complications and potential need for reimplantation, explant and reimplantation occurrence, and finally the number of patients implanted bilaterally either simultaneously or sequentially. The registry also covers the level of financial support for cochlear implantation programs and obtaining certification for the implanting centers. Five years after the establishment of the registry this study aims to determine the frequency of and reasons for ERI in the cochlear-implanted adult and child patients included in the EPIIC registry and compare them with the literature data.

## Materials and methods

This is a descriptive prospective multi-center study based on the (EPIIC) Post-Registration Cochlear Implant database over a 5 year period between 01/01/2012 and 31/12/2016. The 5051 patients who received CI included in the EPIIC registry during this period were all systematically analyzed; among them were 95 patients who underwent a primary implantation and then were explanted and re-implanted (ERI) during the study. Our study was made possible thanks to the EPIIC Registry documenting the follow up of Cochlear Implants, as required by the French Higher Health Authority (*Haute Autorité en Santé* – HAS). No data concerning the implant center or the implant make can be extracted from the registry, according to the operating rules established between the HAS, the makers and the implantation centers. Data

collected included patient age at implantation, and the ages at explantation and at reimplantation, plus the etiology of hearing loss including the age that hearing loss commenced. The percentage of electrodes inserted during the first implantation and during the ERI is indicated in the registry. This percentage indication makes it possible to omit the actual number of electrodes, which is dependent on the brand used, which itself is not included in this data.

The causes of explantation indicated in the EPIIC database were given as a restricted set of choices from among the following propositions: "Apparent damage on the packaging or on the implant", "Device that did not function during the intraoperative tests", " Failure of insertion of the electrode array"," Inappropriate electrode placement or electrode array migration", "Complication or surgical problem", "Implant failure or nonfunctional electrodes", "Performance decrease", "Pain felt by patient with implant", "Implant not used", "Unknown problem/Other reason for explantation". We used the classification according to the European Consensus Statement on Cochlear Implant Failure and Explantation, 2005 (ECSCIFE) [8]. The purpose of this classification is to homogenize and compare published data. The different parameters and hence categories of cause of explantation according to ECSCIFE are detailed in Figure 1. Patients who received a primary implantation before the age of 18 years were considered part of the pediatric population. Statistical analysis was performed using the R software (Foundation for Statistical Computing, Vienna, Austria) through Chi2 and Student tests. All tests were two-sided and a P value $<0.05$ was considered statistically significant.

**Results**

Between January 2012 and December 2016, ninety-five patients included in EPIIC underwent explantation and reimplantation (ERI), which corresponds to 1.9% of the general population of primarily implanted patients included in the EPIIC. Of these patients, four required a second ERI. Ninety-nine ERI interventions were thus completed. Of these 99 interventions, reimplantation was performed simultaneously in 85 cases (53 children and 32 adults) and sequentially in 14 cases (7 children and 7 adults). For sequential surgery, the mean time between explantation and reimplantation was 9 months ($\sigma$: 0.35, min: 0.29 years, max: 1.80 years). **Table 1** shows the mean age at first implantation, age at explantation and also at reimplantation in the general population and in the pediatric and adult populations. A higher proportion of children had ERIs versus adults (31.0% vs 11.6%, $p < 0.00001$).**Table 2** indicates the etiology of deafness focusing on ERI patients. The number of electrodes inserted during the first implantation and during the ERI was reported in 83/95 cases (87%). In these 83 cases the mean percentage of electrodes inserted during primary implantation was significantly lower (97.6%) than in the reimplantation (99.8%, $p < 0.05$). In eight cases, the reimplantation allowed the insertion of a greater number of electrodes than the first implantation (100% in each case vs 73.6% on average). In a single case, the percentage of electrodes inserted after reimplantation was lower than in the first implantation (100% vs. 90%). In 74 cases, all the electrodes were implanted during both surgeries. The causes of explantation for the 99 interventions are detailed in **Table 3**. Failure of the cochlear implant was more common in

children (53%) than in adults (18%, p <0.01). Four patients required a double ERI, i.e. 0.08% of the general population. The four patients were children and their mean age at first implantation was 4.23 years. Their data are detailed in **Table 4**. Of the 95 patients who received ERIs, only one had postoperative infection after the second implantation. The management of this infection was medical without the need for surgical revision.

## Discussion

The purpose of this study was to determine the frequency and cause of ERIs in the patients entered in the EPIIC database since the establishment of this registry 5 years ago. To our knowledge, with 5051 implanted patients, including 95 requiring explantation and reimplantation (ERI), this study is based on the largest cohort of ERIs published to date. The overall rate of ERI in our study was 1.9%. In the literature the rate varies between 4.2% and 13% [2, 3]. Although this result is encouraging in terms of practices in cochlear implant centers in France, the rate of ERI is probably underestimated compared to other studies published to date. In fact, despite a relatively large cohort, the follow-up duration of our study is lower than those in the literature. Indeed, in most articles the study duration varies between 10 and 30 years [1–3,5,6]. However, the increase in the cumulative rate of ERI is globally estimated at only 1% per year following the year of implementation [9]. In addition, in case of follow-up over several decades, some patients benefitted from the explantation of a functional cochlear implant to be replaced by a more efficient new-generation implant, which is not the case in the patients of our study. A new evaluation of the causes of ERI in the EPIIC registry in 5 to 10 years' time could therefore be proposed to allow greater comparability. Another explanation for this low rate of ERI could be that all patients were included after January 2012; they thus benefitted from the technical and surgical advances that have likely improved cochlear implants over the decades, in new implant generations, including in terms of reliability. Moreover these patients were all implanted since a certain period during which an abnormal number of failures was highlighted for certain models, that have since been withdrawn from the market. Analysis of the literature could show an abnormal number of failures of a given model of a given firm at a given point in the historical development of the cochlear implant; however it does not seem appropriate to us to revisit this historical analysis because our study focuses on a more recent period.

In our study, cochlear implant failures were significantly more frequent in children, for whom failures caused more than half of the ERIs, than in adults where less than one in five ERIs came from implant failure. This peculiarity has already been noted previously [10]. This could be linked to a greater risk of falls in this age group that could damage the cochlear implant [11]; falls are common in children when they start walking. Also, concomitant vestibular lesions are frequent in children with severe to profound deafness and these lesions can lead to delays in the acquisition of walking, increasing the risk of device failure all the more [12].

Neither the implantation center nor the brand and model of the implants used in ERI were visible in the database. As this study is financed jointly by the different implant companies, no data relating to the type or brand of the implant is possible to extract from this registry,

according to the operating rules established between the HAS, the manufacturers and implantation centers.

The cause of explantation was related to implant malfunction in 46.4% of cases and in 39.3% of cases the reason was medical or surgical. Implant malfunction categories in the registry were "failure of the implant / non-functional electrodes" or "Performance Decreases". The medical/surgical categories were "inappropriate placement of electrodes or electrode array migration" or "complication / surgical problem" with no other choice. In 14.1% of cases the cause could not be determined. These unknown causes were entered in the registry in the categories "Painful sensations", "cause not found", "problem unknown / other reason for explantation". In the literature, the causes of explantation seem to be related to the device in 69.2% of cases on average (50.1% of "hard failure" and 19.1% of "soft failure") and for surgical/medical reasons in 30.8% of cases (medical reason 20.9% [local infection, meningitis extrusion of the receiver or electrode holder, cholesteatoma, exposure of the electrode holder through the tympanic membrane, disabling pain, migration of the implant body ] and inappropriate electrode placement in 9.9% of cases) [1]. A classification between "Hard" and "Soft" failure could not be realized in this study because of a lack of information, this distinction not being entered in this registry. The proposal of a limited specific set of choices, as is the case for the explantation causes in the EPIIC registry, saved significant and crucial time to allow the registry to reach completeness. Nevertheless, this restriction also results in a certain lack of precision in the collected information. Similarly for documenting "Soft Failure", the number of ERIs due to infection could not be identified. Considering that these infections were classified in the categories "Complication / Surgical problem" (17 cases) and / or "Unknown problem / Other reason for explantation" (8 cases) their rate should not exceed 0.5%. Furthermore post-operative infections do not always require surgical revision [13]. Moreover, if a surgical revision is necessary, this is not always synonymous with explantation because draining or simply dealing with the infection can suffice [14]. Nevertheless, an ERI seems necessary in 0.3-1% of cases [13,14]. Re-implantation in these cases may be ipsilateral to primary implantation or contralateral (in case of local infection requiring prolonged treatment, for example). In addition, with respect to postoperative infections, only one patient (1%) had a post-operative infection after reimplantation. This percentage corresponds to the rate of postoperative infection found in the literature for primary implantation [15]. From a surgical point of view, ERIs allow a significant increase in the number of inserted electrodes. This testifies, on the one hand to the feasibility of this kind of surgery but also, to its usefulness.

Functional evolution (speech perception, oral language in children) could not be studied in this cohort due to a lack of comprehensiveness with regard to audiometric data; indeed these data could only be interpreted in 16 out of the 95 cases. Moreover, the type of audiometric data entered in this registry does not allow such a fine analysis. The purpose of the registry, however, is not only the functional analysis of results, failures and re-implantations, but also that of epidemiological surveillance in terms of complications. Building any registry implies a compromise between the time that each investigator is willing to devote to complete it and the maximum amount of information that could possibly be entered. This compromise can be particularly difficult to reach in a multicenter study involving a potentially large number of variables, as is the case for EPIIC. Moreover, the multiplicity of stakeholders is undoubtedly an important factor in the quality of data collection of any registry, including this one. To

remedy the lack of comprehensiveness, it would be necessary to increase the staffing time dedicated to data entry, or to work on computer systems for exporting raw data from the computerized files of the implanting centers to the EPIIC database. Nevertheless, the creation and maintenance of national registries, such as the EPIIC, is essential for the evaluation, improvement and standardization of current practices and of the Implantable Medical Devices (IMDs).

## Conclusion

Explantation and reimplantation of cochlear implants is rarely necessary. It does not present major surgical difficulty and in most cases allows a better insertion than the initial manipulation. In almost half of the cases, the ERI is necessitated by a dysfunction of the original implanted device and this is particularly common in the pediatric population. The EPIIC registry is an important tool for patient follow-up regarding the surgical, medical and reliability aspects of IMDs.

## Conflicts of interest

None

**Figure 1:** The different categories relating to the operation of the cochlear implant. A, implant functioning normally; B1, deteriorating characteristics: no replacement necessary if clinical benefit; B2, Decline in performance: Explantation and relocation recommended; C, device failure: explantation and relocation recommended; D, medical reason: explantation for medical reasons. Adapted from European Consensus Statement on Cochlear Implant Failure and Explantation, 2005 [8].

| | **Age in years at the time of the first implantation in the EPIIC population** | **Age at the time of the first implantation in the ERI population** | **Age at the time of explanation in the ERI population** | **Age at the time of re-implantation in the ERI population** |
|---|---|---|---|---|
| **General population** | *n = 5051*<br>37.8<br>(σ 28.9) | *n = 95*<br>25.0<br>(σ 29.0, min 0.8, max 87.8) | *n = 95*<br>27.0<br>(σ 29.0, min 0.8, max 89.3) | *n = 95*<br>27.1<br>(σ 29.0, min 0.8, max 89.3) |
| **Pediatric population** | *n = 1873*<br>4.5 (σ 4.1) | *n = 58*<br>3.5 (σ 3.5) | *n = 58*<br>4.6 (σ 3.6) | *n = 58*<br>4.7 (σ 3.6) |
| **Adult population** | *n = 3178*<br>57.4 (σ 16.7) | *n=37*<br>58.9 (σ 15.7) | *n=37*<br>61.2 (σ 15.7) | *n=37*<br>61.3 (σ 15.8) |

**Table 1:** Mean age in years at primary implantation, at explantation and at reimplantation in the general population and in the pediatric and adult populations. σ: standard deviation; min: minimum age; max: maximum age.

| | Etiology of deafness | Pediatric Population | Adult population | Total |
|---|---|---|---|---|
| **Congenital** | | | | |
| | Genetic without malformation | 11 | 4 | 15 |
| | Genetic with malformation | 5 | | 5 |
| | Malformation without genetic character | 1 | | 1 |
| | Chronic fetal suffering | 8 | | 8 |
| **Acquired** | | | | |
| | Auto-immune | | 1 | 1 |
| | Cholesteatoma | | 2 | 2 |
| | Menière's disease | | 3 | 3 |
| | Meningitis | 1 | 2 | 3 |
| | Neurofibromatosis type 2 | | 2 | 2 |
| | Cholesteatomatous chronic otitis | | 2 | 2 |
| | Otosclerosis | | 1 | 1 |
| | Ototoxicity | | 1 | 1 |
| | Progressive deafness of unknown nature * | | 4 | 4 |
| | Trauma | | 2 | 2 |
| **Unknown** | | 22 | 12 | 34 |
| **Unspecified** | | 10 | 1 | 11 |
| **Total** | | 58 | 37 | 95 |

**Table 2:** Etiology of deafness in the pediatric and adult population of explantation and reimplantation patients. * In the 4 cases of progressive deafness of unknown nature, one patient had a Minor syndrome association.

| Cause | ESCIFE Classification | Pediatric Population | Adult Population | Total |
|---|---|---|---|---|
| **Painful sensations** | A | 1 | 2 | 3 |
| **Implant failure / non-functional electrodes** | C | 31 | 7 | 38 |
| **performance reduction** | B2 | 3 | 5 | 8 |
| **Inappropriate placement of electrodes / electrode array migration** | D | 12 | 10 | 22 |
| **Complication / surgical problem** | D | 10 | 7 | 17 |
| **Unknown problem / Other reason for explantation** | B2, C or D | 3 | 5 | 8 |
| **Unspecified** | | 2 | 1 | 3 |
| | | 62 | 37 | **99** |

**Table 3:** Causes of Explantation in the Pediatric and Adult Population of Explanted and Re-implanted Patients. The first column describes these causes in relation to the fixed categories of the EPIIC registry. The second column describes these causes in relation to the detailed categories in ECSCIFE.

| Case | Etiology of deafness | Age at first impl. | First ERI | | | Second ERI | | |
|---|---|---|---|---|---|---|---|---|
| | | | Age at Expl. | Age at Impl. | Cause | Age at Expl. | Age at Impl. | Cause |
| **1** | Cochlear malformation | 1,13 | 1,14 | 1,14 | Surgical problem | 1,30 | 1,59 | Surgical problem |
| **2** | Genetic | 1,37 | 1,85 | 1,85 | Unknown | 3,76 | 3,76 | Implant breakdown |
| **3** | Unknown | 5,18 | 5,33 | 5,33 | Implant breakdown | 7,00 | 7,00 | Implant breakdown |
| **4** | Meningitis | 9,25 | 10,87 | 10,87 | Misplaced electrodes | 11,41 | 12,18 | Unspecified |

**Table 4:** Etiology of deafness, age at different surgeries and cause of explantation and reimplantation (ERI), in patients requiring two ERIs. Impl. : Implantation; Expl. : Explantation.

**References**

1. Masterson L, Kumar S, Kong JHK, Briggs J, Donnelly N, Axon PR, et al. Cochlear implant failures: lessons learned from a UK centre. J Laryngol Otol. 2012 Jan;126(1):15–21.

2. Reis M, Boisvert I, Looi V, da Cruz M. Speech Recognition Outcomes After Cochlear Reimplantation Surgery. Trends Hear. 2017 Dec;21:2331216517706398.

3. Sorrentino T, Coté M, Eter E, Laborde M-L, Cochard N, Deguine O, et al. Cochlear reimplantations: technical and surgical failures. Acta Otolaryngol (Stockh). 2009 Apr;129(4):380–4.

4. Balkany TJ, Hodges AV, Buchman CA, Luxford WM, Pillsbury CH, Roland PS, et al. Cochlear implant soft failures consensus development conference statement. Cochlear Implants Int. 2005 Sep;6(3):105–22.

5. Rivas A, Marlowe AL, Chinnici JE, Niparko JK, Francis HW. Revision cochlear implantation surgery in adults: indications and results. Otol Neurotol Off Publ Am Otol Soc Am Neurotol Soc Eur Acad Otol Neurotol. 2008 Aug;29(5):639–48.

6. Sterkers F, Merklen F, Piron JP, Vieu A, Venail F, Uziel A, et al. Outcomes after cochlear reimplantation in children. Int J Pediatr Otorhinolaryngol. 2015 Jun;79(6):840–3.

7. Gardner PA, Shanley R, Perry BP. Failure rate in pediatric cochlear implantation and hearing results following revision surgery. Int J Pediatr Otorhinolaryngol. 2018 Aug 1;111:13–5.

8. European consensus statement on cochlear implant failures and explantations. Otol Neurotol Off Publ Am Otol Soc Am Neurotol Soc Eur Acad Otol Neurotol. 2005 Nov;26(6):1097–9.

9. Wang JT, Wang AY, Psarros C, Cruz MD. Rates of revision and device failure in cochlear implant surgery: A 30-year experience. The Laryngoscope. 124(10):2393–9.

10. Brown KD, Connell SS, Balkany TJ, Eshraghi AE, Telischi FF, Angeli SA. Incidence and indications for revision cochlear implant surgery in adults and children. The Laryngoscope. 2009 Jan;119(1):152–7.

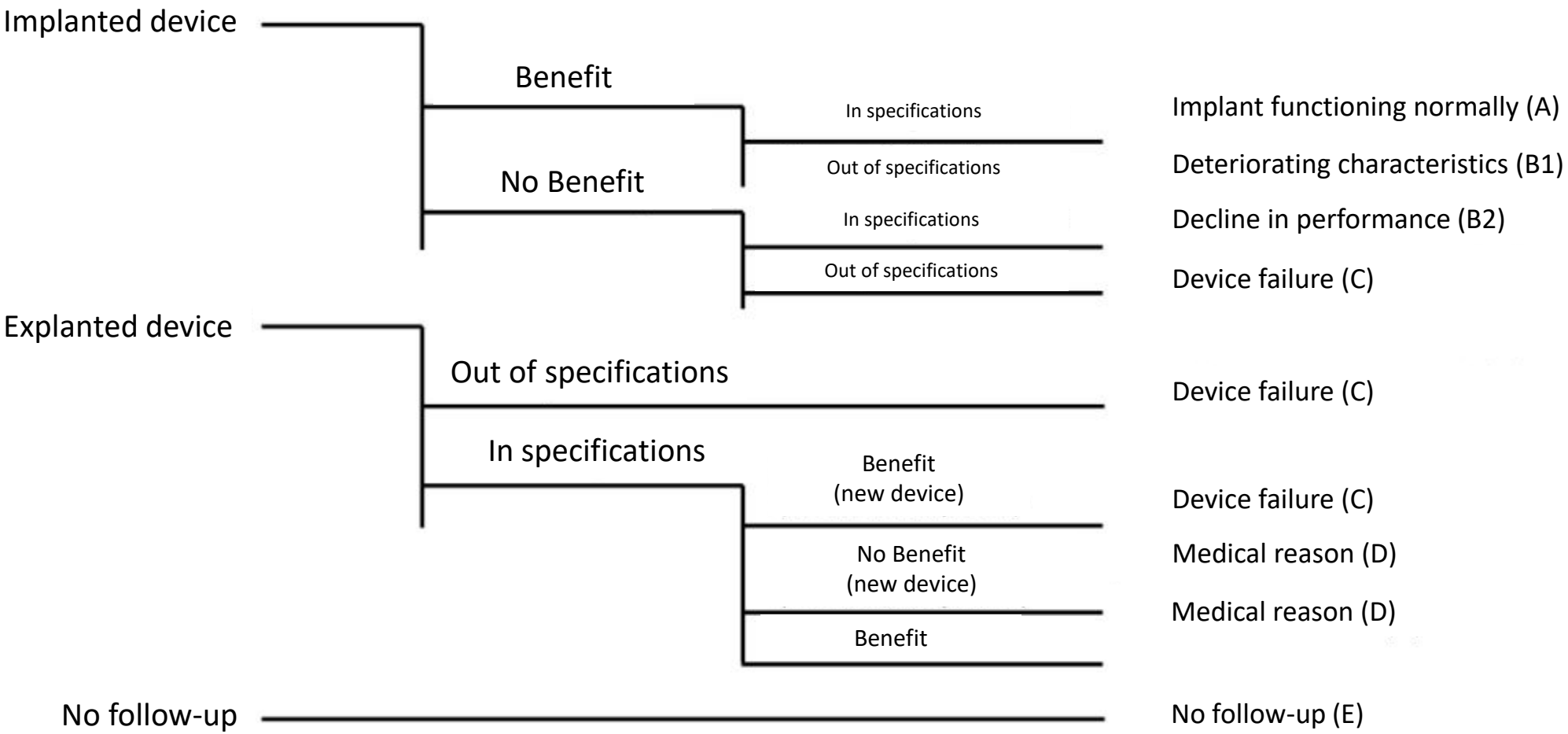
11. Weise JB, Muller-Deile J, Brademann G, Meyer JE, Ambrosch P, Maune S. Impact to the head increases cochlear implant reimplantation rate in children. Auris Nasus Larynx. 2005 Dec;32(4):339–43.

12. Inoue A, Iwasaki S, Ushio M, Chihara Y, Fujimoto C, Egami N, et al. Effect of vestibular dysfunction on the development of gross motor function in children with profound hearing loss. Audiol Neurootol. 2013;18(3):143–51.

13. Olsen LB, Larsen S, Wanscher JH, Faber CE, Jeppesen J. Postoperative infections following cochlear implant surgery. Acta Otolaryngol (Stockh). 2018 Jul 17;1–5.

14. McAllister K, Linkhorn H, Gruber M, Giles E, Neeff M. The Effect of Soft Tissue Infections on Device Performance in Adult Cochlear Implant Recipients. Otol Neurotol Off Publ Am Otol Soc Am Neurotol Soc Eur Acad Otol Neurotol. 2017;38(5):694–700.

15. Almosnino G, Zeitler DM, Schwartz SR. Postoperative Antibiotics Following Cochlear Implantation: Are They Necessary? Ann Otol Rhinol Laryngol. 2018 Apr;127(4):266–9.


Implanted device
Benefit
In specifications
Out of specifications
No Benefit
In specifications
Out of specifications
Explanted device
Out of specifications
In specifications
Benefit
(new device)
No Benefit
(new device)
Benefit
No follow-up
Implant functioning normally (A)
Deteriorating characteristics (B1)
Decline in performance (B2)
Device failure (C)
Device failure (C)
Device failure (C)
Medical reason (D)
Medical reason (D)
No follow-up (E)