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## Analysis and management of cochlear implant explantation in adults

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## **Abstract**

**Objectives:** Cochlear implants have a 10-year manufacturer's warranty and may remain functional for more than 25 years after implantation. With the increasing number of users, the number of explantations is set to increase in the future. The main objective of the present study was to determine reasons for cochlear explantation in adults and the proportion carried out during the warranty period. **Material and methods:** A single-center retrospective multidisciplinary study of cochlear explantation in adults was performed over a 33-month period. Explantation reasons, interval since implantation and warranty application were analyzed. **Results:** 54% of the 71 explantations were for medical reasons, 45% due to failure (35% "hard failure", 10% "soft failure") and 1% could not be classified; 69% were followed by reimplantation. Failure was confirmed before explantation in 66% of cases. Manufacturer warranties were applicable in 70% of explantations for breakdown, for a total €335,500. **Conclusions:** This analysis provides decision support for reimplantation and allows better patient information. Follow-up is essential to optimize warranty application and to promote the proper implant use.

**Keywords:** Cochlear implant, device failure, reimplantation, materials vigilance

## **Introduction**

Until the early 2000s, the number of cochlear implantations was low in France, but has increased sharply since cochlear implants were listed for national health insurance cover in 2009. They count as implantable medical devices, subject to traceability criteria for safety monitoring and for reimbursement on top of the reimbursement of the implantation procedure itself. Any incident or risk of incidence is to be reported to the ANSM Drug and Health Product Safety Agency in the framework of materials vigilance.

Explantation rates range between 4% and 8% [1- 9]. The January 2019 report from the French national registry, EPIIC (post-registration study of cochlear implants: *Etude Post-Inscription des Implants Cochléaires*), included 8,721 cochlear implantations in the period June 2011 to December 2018, with 184 explantations/reimplantations (2.1%) and 42 explantations without reimplantation. Reasons for explantation are classified in the literature as failure or medical reason. An international expert group drew up a consensus on implant failure, requiring manufacturers to publish reliability reports [10, 11]; these have confirmed the low incidence of failure in internal parts, which tend to be still functional after more than 25 years' use.

In France, the list of products covered by national health insurance specifies that cochlear implants have a 10-year manufacturer's warranty. National health insurance covers reimplantation costs and replacement implants only in case of failure outside the warranty period or for medical reasons.

Progress in surgical techniques, technologies and biocompatibility have helped reduce explantation rates [1]. However, as the number of users is rising, the number of explantations is bound to rise, requiring follow-up protocols in ENT centers in coordination with hospital pharmacies in charge of the management and correct use of medical devices. The present study reports a case of such cooperation. The main aims of the study were to determine reasons for explantation and the proportion of explantations performed under warranty in an adult reference center. The secondary objective was to describe the reimplantations performed.

## **Material and methods**

Cochlear explantation data from a French adult reference center for the period March 1, 2013 to December 31, 2016 were analyzed retrospectively by two pharmacists in charge of medical devices and two physicians in charge of the ENT implantation center.

Included patients were implanted and followed up either in the same center or in another center, notably in case of childhood implantation or change of residence. Implants comprised: Advanced Bionics® (Stäfa, Switzerland), Cochlear (Lane Cove, Australia), Medel® (Innsbruck, Austria) and Oticon Médical® (Vallauris, France). In case of suspected internal part dysfunction, systematic clinical and CT examination excluded spontaneous extrusion of the electrode carrier or other local cause. In the absence of any medical cause, the non-invasive “integrity” test was conducted by the manufacturer in consultation following the manufacturer’s own protocol to confirm failure. After explantation, implants were sent to the manufacturer for testing, whatever the reason for explantation, and a materials vigilance report was sent to the ANSM health products safety agency.

Study data comprised demographic data, and patient- and implant-related data: symptoms leading to explantation, 1-step or delayed reimplantation, implantation-to-explantation interval, and implant make, reference and series number. Integrity test and manufacturer’s explant test reports and time to report reception were analyzed.

Two categories of failure were defined, following the 2005 consensus statement 2005 [10, 11]. When the manufacturer’s explant test or the pre-explantation integrity test found failure, this was categorized as “hard failure”, or else as “soft failure” if the integrity test result was normal, there were no medical reasons for explantation and the patient experienced benefit after reimplantation. No classification was made if no reimplantation was performed and the integrity test was normal. Reimplantation not related to device dysfunction was classified as being for medical reasons.

Implants explanted within 10 years of implantation were considered as under warranty, in line with the health insurance criteria. In case of soft failure, application of the warranty was negotiated with the manufacturer.

## **Results**

Between March 1, 2013 and December 31, 2016, 772 adult implantations were performed in the reference center (Cochlear® 47%, Medel® 21%, Advanced Bionics® 17%, Oticon Médical® 15%) and 71 explantations were reported to the hospital pharmacy, amounting to 4% of the 2,000 implant users for the study period. Figure 1 shows the decision-tree for these 71 explantations.

Explant test reports were received within a mean 219 days. 55% concerned females. Mean age at implantation was  $46 \pm 20$  years [range, 3 - 88 years]; mean interval to explantation was  $8 \pm 7$  years [range, 14 days - 26 years], and was  $\leq 10$  years (warranty period) in 70% of cases. 69% of explantations (49/71) were followed by reimplantation.

#### Explantation for suspected failure

52% of explantations were for suspected failure (37/71).

Twenty-five failures (35%) were confirmed: i.e., classified as “hard”. Confirmation was obtained ahead of explantation, on integrity test, in 21 cases; in the other cases, the integrity test result was normal (n=1) or missing from the patient’s file (n=3) and failure was confirmed on explant testing. 88% (22/25) of hard failures were confirmed on explant testing. Reasons for explantation are shown in Table 1. 92% of patients (23/25) were reimplanted in the same surgical step. Reimplantation brought no benefit in 2 cases: the integrity test was performed due to lack of benefit in 1 of these, and for poor acoustic quality, without impaired performance, following an MRI scan in the other; integrity test results were abnormal in both cases. One other patient was frequently abroad and was lost to follow-up after reimplantation. Two patients were not reimplanted: 1 had severe lung failure contraindicating general anesthesia, and the other refused reimplantation for fear of recurrence of the disabling pain that had led to the explantation.

Twelve implants (17%) were explanted for suspected failure that was not confirmed on integrity test of explant testing. One patient did not wish to be reimplanted, for personal reasons and due to auricle pain caused by wearing the external processor, and no classification could be made for this explantation. The other 11 patients were reimplanted. Four ( $\approx$  one-third) showed no clinical improvement, and these explantations were classified as being for medical reasons. Suspicion was based on impaired performance despite

checking that the processor was functioning (3/4) or on reported pain (1/4). Seven patients ( $\approx$  two-thirds) were successfully reimplanted; explanation was for impaired performance (4/7), onset of crackling and tinnitus (2/7) or intermittent connection issues between external processor and implant (1/7). These explanations were classified as soft failure on differential diagnosis.

92% of patients with initially suspected failure (34/37) were reimplanted, always in the same surgical step. Thirty-two of the 37 suspected failures were confirmed: (25 hard and 7 soft failures): i.e., 45% of explanations (32/71); 1 could not be classified. In case of suspected failure with normal integrity test (n=11), failure was confirmed in 55% of cases (Figure 2). Explanation for failure was performed at a mean  $8 \pm 6$  years [range, <1 - 22 years] after implantation. The manufacturer's warranty was applicable for 22 implants (17 hard and 5 soft failures: i.e., 69% of cases (22/32). Warranty application resulted in claims totaling €335,500, the health insurance price per implant being €15,250 (tax included) in July 2017.

#### Explanation for medical reasons

In 48% of cases (34/71), explanation was for medical reasons, and 44% of these patients (15/34) were reimplanted without difficulty. In 4 other cases, failure was initially suspected and the medical reason was later revealed at reimplantation failure; thus explanation was finally for medical reasons in 54% of cases (38/71). Table 2 shows etiologies.

No factors emerged for infection. Onset was in the first month after implantation in 4 patients, at 1-3 months in 1, at 3-6 months in 3, and after 6 months in 1. Three patients were not reimplanted in the longer term: 2 with bilateral implants and good contralateral performance who declined, and 1 with asymmetric hearing loss in whom skin sequelae of the infection would have complicated the procedure.

Among surgical problems, 1 patient, first explanted for hard failure and reimplanted during the same step but with difficulties in implant insertion, was explanted again at 1 month, due to electrode mispositioning.

Only 1 test report found non-conformity to the manufacturer's specifications (electrode abnormality). The device had been explanted 25 years after implantation for lack of benefit, in a patient with long-standing hearing loss following cytomegalovirus (CMV) infection. The

lack of benefit was difficult to classify but likely related to the pathology, although implant abnormality could not be formally ruled out.

Taking all medical causes together, implantation-explantation interval ranged between less than a year (surgical problem) to more than 26 years (lack of benefit).

Reimplantation rates varied according to the medical reason (Table 3). Reimplantation was late in case of infection or cutaneous extrusion.

## **Discussion**

91.6% (n=772) of the 843 implant-related procedures in our reference center between 2013 and 2016 were implantations and 8.4% (n=71) explantations; 5.8% (n=49) involved explantation-reimplantation and 2.6% (n=22) explantation without reimplantation. Explantation concerned 4% of implant users followed in our center during the study period; this rate is close to those in the most recent reports in adults, which range from 3.3% to 6.8% [1-3, 5, 11, 12]. Most explantations without reimplantations (86%, 19/22) were for medical reasons.

45% of explantations were for failure, accounting for about 4% of implant-related procedures. Most failures (78%) were hard, as reported elsewhere [2, 5]. The present methodology precluded analysis of failure according to manufacturer, as many patients (notably pediatric) were implanted in other centers and referred for follow-up, with data only in case of surgery or entry in the national registry. Moreover, given the number of patients followed in our center, loss to follow-up was likely underestimated. However, the CI512 (Cochlear®) model accounted for 28% of hard failures. A tightness defect was found a few months after this implant came onto the market in 2010, leading to worldwide withdrawal in 2011. In our center, 12% of patients receiving CI512 needed reimplantation at 1.7 to 4 years; the others were monitored for any symptoms suggesting failure. This high failure rate on a recent model accounted for the high rate of explantation within 10 years (69%). Explantation later than 10 years concerned only 1% (10/843) of implant procedures. This rate may increase in future, with the increasing number of implantations per year and of patients being followed since 2009. These data could serve as a gold-standard for assessing the reliability of new models available in certain countries.



The present study showed certain findings for explantation for failure that need to be known in considering reimplantation and for patient information.

- In case of suspected failure, the integrity test allowed confirmation ahead of reimplantation in 66% of cases.
- In 2 cases of hard failure confirmed on integrity test, reimplantation did not provide benefit; such possible outcome needs to be anticipated and explained to the patient.
- In case of suspected failure with normal integrity test and explant examination, reimplantation improved symptoms in 56% of cases; these explantations were thus classified as soft failure. Impaired performance had been found on annual audiometry and speech-therapy assessment in 4 of the 7 cases of soft failure. Regular assessment is the only way to detect soft failure. The other 3 patients showed no loss of performance. This shows that the integrity test and explant examination fail to confirm all failures, and reimplantation should be proposed if the implant is being under-used due to impaired performance or onset of subjective symptoms, while informing the patient of the possible lack of benefit. These recommendations are in line with the 2005 consensus statement [10, 11]. Cohort studies analyzing symptoms revealing failure could help draw up guidelines on indications for reimplantation in case of normal integrity test.

47% of explantations for medical reasons concerned lack of benefit. In some cases, patients had been implanted many years ago for profound congenital hearing loss, at a time when prognostic factors were poorly known. Implantation in such cases is no longer indicated. In 72% of explantations for lack of benefit, the etiology of the hearing loss could account for the failure. The benefit of implantation is variable and unpredictable in these etiologies, and patients were informed of the possibility of mediocre performance.

Casing infection was rare (1% of implant procedures) and usually led to explantation due to biofilm on the casing surface, hindering antibiotic therapy [13]. Early infection usually implicated intraoperative contamination; mechanisms in late infection are less clear: late-onset biofilm, or casing contamination from a scalp lesion or otitis externa.

Reimplantation for spontaneous migration of the electrode carrier (n=2) or cutaneous extrusion (n=1, in an elderly patient) is very rare in adults, despite the thinning of the skin with age. Annual medical follow-up can prevent extrusion, checking contact points such as

the arms of glasses and magnet strength, or preventively shifting the casing if extrusion seems likely.

Explantation for isolated recalcitrant pain was performed in 3 patients, with immediate reimplantation in 1, but with no pain relief. These findings diverge from a recent pediatric study reporting resolution of pain with reimplantation in 10 children in whom medical treatment had failed [14]; pain was attributed to low-grade infection or to implant dysfunction.

In the present study, certain explant reports came back late. Management of materials vigilance files is time-consuming for hospital pharmacies, and early completed reporting should feature among the manufacturer's quality criteria. Testing is performed by the manufacturer, which might lead to bias in classifying reasons for explantation in the report. Moreover, these tests may prove non-contributive in case of soft failure.

Warranties were difficult to apply due to delays in test reporting and because manufacturers introduce strict small print poorly adapted to hospital organization. In most cases, reimbursement under warranty depends on confirmation of failure and on reimplantation using the same model; such conditions may not be met, either because the team chooses a different model or because there was no abnormal integrity test result. Although reimplantation was systematically 1-step in cases of suspected failure, prior integrity test confirmed failure in only 66% of cases (21/32). Securing a cost-free implant ahead of reimplantation involves complex negotiations between reference center, pharmacy and manufacturer, and it is rare to be able to avoid down-payment.

Multidisciplinary analysis of reasons for explantation is backed up by an assessment to enable negotiation with the manufacturer so as to apply the warranty. For a total sum of €335,500 over the study period, one reimbursement of €75,000 was negotiated with one manufacturer; negotiations are ongoing. The quality of manufacturers' materials vigilance monitoring and warranty modalities should be taken into account in selecting the cochlear implant model.

## **Conclusion**

As the number of patients being followed increases, cooperation between the ENT reference center and the hospital pharmacy is essential for analyzing cochlear explantation. Follow-up improves understanding of the reasons or explantation in adults and contributes to reimplantation decision-making. It also improves patient information and warranty implementation, as failure accounts for 45% of explantations and 69% of these failures occur within the 10-year warranty period.

**Disclosure of interest:** The authors have no conflicts of interest to disclose.

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***Figure1: Analysis of reasons for explanation***

\*Abnormal result or integrity test impossible due to non-connection to the internal component or due to excessive pain when connection is attempted

***Figure 2: Reasons for explanation for suspected failure with normal integrity test***

Reason for failure	n(%)	Implantation- explantation interval (years)	Implant models (n)
<b>Tightness defect</b>	9 (36)	6 ± 5 [2 - 13]	Cochlear®: CI512 (5) Advanced Bionics®: Hires 90K (2) Oticon medical®: Digisonic SP (2)
<b>Electrode beam dysfunction</b>	6 (24)	10 ± 9 [<1 - 22]	Cochlear®: CI422 (1), CI24R (1) Medel®: Sonata (2) Oticon medical®: Digisonic SP (2)
<b>Electronic failure</b>	5 (20)	8 ± 7 [2 - 20]	Cochlear®: CI512 (2) Oticon médical®: Digisonic SP (2), Digisonic DX10 (1)
<b>Not specified</b>	2 (8)	10 et 3	Advanced Bionics®: CI-1500-04 (1) Cochlear®: CI24RE (1)
<b>Abnormal integrity test<sup>(1)</sup></b>	3 (12)	7 ± 5 [3 - 12]	Oticon®: Digisonic SP (1), Digisonic DX10 (1) Cochlear®: CI24RS (1)

Intervals reported as mean ± standard deviation [range]. Reasons for failure are those given in the manufacturer's test report.

<sup>(1)</sup> Test report considered device met specifications (n=2) or no classification made (n=1).

**Table 1: Explantation for hard failure (n=25)**

Reason for explantation	n (%)	Implantation-explantation interval (years)	Reimplantation in same step n (%)	Late reimplantation n (%)
<b>Lack of benefit</b>	<b>18 (47)</b>	<b>11 ± 8 [1 - 26]</b>	<b>6 (33)</b>	<b>1<sup>(1)</sup> (6)</b>
Congenital/long-standing hearing loss	5	9 ± 6 [3 - 18]	1	0
Meningitis	4	17 ± 10 [2 - 26]	0	1 <sup>(1)</sup>
Suspected neuropathy	4	4 ± 5 [1 - 11]	1+2 <sup>(2)</sup>	0
Vestibular Schwannoma	2	2 and 12	0	0
Hearing loss after CMV infection <sup>(3)</sup>	1	25	0	0
Trauma sequela	1	15	1	0
Suspected central involvement	1	14	1 <sup>(2)</sup>	0
<b>Casing infection</b>	<b>9 (24)</b>	<b>1 ± 2 [&lt;1 - 6]</b>	<b>1 (11)</b>	<b>5 (56)</b>
<i>Staphylococcus aureus</i>	7	1 ± 2 [<1 - 6]	1	5
<i>Staph. aureus + Pasterella canis</i>	1	1	0	0
<i>Staph. aureus + Streptococcus</i>	1	<1	0	0
<b>Implant malpositioning</b>	<b>4 (11)</b>	<b>4 ± 4 [&lt;1 - 9]</b>	<b>4 (100)</b>	<b>0</b>
Electrode migration	2	<1		
Casing too close to auricle	1	9		
Electrode in hypotympanum	1	7		
<b>Other</b>	<b>6 (16)</b>	<b>9 ± 6 [3 - 17]</b>	<b>1 (17)1<sup>(2)</sup></b>	<b>1 (17)</b>
Pain not relieved by explantation	3	8 ± 8 [3 - 17]	0	0
Cutaneous extrusion	1	15	0	1
Need for MRI <sup>(4)</sup>	1	7	0	0
Cholesteatoma	1	9		0
<b>Psychological reasons</b>	<b>1 (3)</b>	<b>6</b>	<b>0</b>	<b>0</b>

<sup>(1)</sup> Brainstem implant reimplanted. <sup>(2)</sup>Explantation initially for suspected failure; medical cause revealed on failure of reimplantation. <sup>(3)</sup> Cytomegalovirus. <sup>(4)</sup>

Magnetic resonance imaging

1 Intervals reported as mean ± standard deviation [range].

***Table 2: Explantations for medical reasons (n=38)***

Reason for explantation	Explantations		Reimplantation in same step		Late reimplantation		Total reimplantations	
	n	%	n	%	n	%	n.....%	
Hard Failure	<b>25</b>	<b>35</b>	<b>23</b>	<b>92</b>	<b>0</b>	<b>0</b>	<b>23</b>	<b>92</b>
Soft Failure	<b>7</b>	<b>10</b>	<b>7</b>	<b>100</b>	<b>0</b>	<b>0</b>	<b>7</b>	<b>100</b>
Medical reason	<b>38</b>	<b>54</b>	<b>12</b>	<b>32</b>	<b>7</b>	<b>18</b>	<b>19</b>	<b>50</b>
- Detected before explantation	34	48	8	24	7	21	15	44
- Revealed secondarily	4	6	4	100	0	0	4	100
Unclassifiable	<b>1</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Total</b>	<b>71</b>	<b>100</b>	<b>42</b>	<b>60</b>	<b>7</b>	<b>10</b>	<b>49</b>	<b>69</b>

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4 **Table 3: Rate of reimplanted patients according to reason for explantation (n=71)**



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