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## **The French Cochlear Implant Registry (EPIIC): cochlear implantation complications**

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## **Abstract**

**Objectives:** The aim of this study was to evaluate peri- and post-operative complications related to cochlear implantations. We searched for risk factors predicting these complications and analyzed the complications in the youngest and most elderly.

**Study design:** Retrospective analysis of cochlear implant patients.

**Materials and Methods:** All patients who underwent cochlear implantation in France between January 2012 and December 2016 were anonymized and registered in the EPIIC database. This population included 3483 adults and 2245 children. Their demographic and surgical data and their incidence of peri- or post-operative complications, including their severity, whether major or minor, were all indicated.

**Results:** The global complication rate was 6.84%. The risk of complication was higher in initial implantation versus reimplantation ( $p < 0.0001$ ). The risk was also higher for bilateral implantation versus unilateral ( $p < 0.0001$ ). Complications were more frequent for patients with cochlear malformation ( $p = 0.002$ ). There was no difference in complication rates across age groups; babies under 1 year old, and the elderly over 80 and even over 90, did not have more complications than the rest of the population. Patients treated in the daily care unit had no more complications than those who were hospitalized for one night or more ( $p = 0.64$ ).

**Conclusion:** Cochlear implantation is a safe technique with a low incidence of complications. The absence of increased risk in patients at the extremes of the age spectrum justifies offering this solution to all, without age limitation.

**Key words:** complications, cochlear implant, registry

## Introduction

Cochlear implantation (CI) is a technique for the auditory rehabilitation of children and adults with severe or profound sensorineural hearing loss, for when the benefit of hearing aids is insufficient. This procedure can be performed as early as a few months of life for children with congenital deafness, and in adults throughout old age. Implantation can occasionally lead to complications that may be related to the surgical technique, patient anatomy, foreign body placement, or to dysfunction of the implanted device. Some authors classify complications simply as major or minor. Major complications are those requiring reoperation or hospitalization to initiate medical treatment, and minor complications are treated in outpatients who do not necessarily require a further operation (1, 2). Other authors classify complications according to the delay of occurrence, defining them as ‘perioperative’ if they occur within 24 hours, ‘early postoperative’ if under a 7 days or ‘late postoperative’ thereafter (3).

In 2009, the French higher health authority, the *Haute Autorité de Santé* (4), recommended drafting of article 165-1 of the Social Security Code. This asked the French CI centers to keep a national registry providing information on all implantations on: prior hearing loss, implantation, the operation itself, arising complications, and patient follow-up. The registry began in 2011. The number of implantations has increased significantly in recent years thanks to an improved information environment for deaf patients and greatly improved financial support for implantation.

Regular evaluation of the safety of devices and surgical procedures is important. The main objective of this study was to evaluate the rate of complications in the population of cochlear implanted patients in France between January 2012 and December 2016. The secondary objectives were, on the one hand to look for possible complication-risk factors, and, on the other to analyze complications in the first and last windows of life.

## Materials and Methods

We report here a retrospective, multicenter study of the 5728 cochlear implantations performed between January 2012 and December 2016, in the 33 hospitals performing cochlear implantations in France and French overseas territories. The referring physicians from each center anonymized the patient data and digitized it into the Clinical Database of the EPIIC (*Etude Post-Inscription à la Liste des Produits et Prestations Remboursables des systèmes d’Implants Cochléaires et du tronc cerebral*).

All patients or legal representatives were informed of the registry and permitted use of their data. The data collected in 5728 patients were demographic (etiology of deafness, age at implantation), and also concerned the type of implantation (primary implantation or reimplantation, the uni or bilateral character, the implanted side), the number of nights of hospitalization, and finally, the timing of any complications. The noted complications were categorized as either (i) intraoperative or (ii) postoperative complications. (i) Complications

during surgery included cerebrospinal fluid leakage, autonomic disorders, major bleeding, and the occurrence of neurological complications. (ii) Postoperative complications included: facial paralysis, disabling tinnitus or vertigo, debilitating pain, skin problems, electrode displacement, infections, hematomas, processor failures, and tympanic perforations. The intra- and post-operative complications were also grouped into 4 subgroups: device-related (malfunctions, poor electrode placements, movements of part of the implant), local (pain, infections, scar problems, hematomas), cochleo- vestibular (tinnitus, vertigo), or related to lesions of adjacent structures (leakage of cerebrospinal fluid, facial paralysis, tympanic perforations). The indicated postoperative complications were also classified as major or minor. Major complications were defined as adverse events that caused one or more of the following undesirable events: need for surgery, hospitalization, permanent disability, or severe symptoms. Minor complications were those treated medically or by minor surgical intervention.

Quantitative variables were expressed as averages with a 95% confidence interval; qualitative variables were expressed as percentages in various groups also with a 95% confidence interval. The adult and pediatric populations were compared using a Mann-Whitney test for quantitative variables, and a Chi2 for ordinal variables. A p-value under 0.05 was considered statistically significant. Univariate analyzes were performed using the SAS© version 9.1 software. When the univariate analysis showed a difference, a multifactorial analysis was performed by logistic regression using the Marschner algorithm (5) (R software version 3.1). For each factor studied, the probability was calculated based on the estimated coefficient of each explanatory factor and on the ratio between the estimate and the standard error. The explanatory factor was considered significant when the p of the logistic regression was < 0.05.

## Results

Between January 2012 and December 2016, 5728 patients underwent cochlear implantation, and their characteristics are listed in Table 1. Sixty-one percent of the cochlear-implanted patients were adult and 39% were children. The average age of cochlear implantation was 56.8 years in adults and 4.3 years' old for the children. The age of implantation ranged from 11 months to 94 years. These were first-time implantations in 92% of the adult operations and in 84% of cases in children.

In this study, 392 complications were identified in 319 of the 5728 patients. The complication rate was thus 6.84% (392/5728). The percentage of patients who had one or more complications was 5.57% (319/5728) overall: 5.63% (196/3483) of the adults and 5.50% (123/2245) of children. The rate of complications was much lower in re-implantations than in the initial implantations. In adults and children the respective rate of complications was 6.2 and 6.4 % for initial implantations and 0.4 and 0.6 % only for the re-implantations (p <0.0001; the significance was even greater p <0.00001 by multivariate analysis p <0.0001).

Over 50% of complications occurred late (over a week after the operation), with a significantly longer average delay in the pediatric population (141 days) than in the adult population (68 days,  $p = 0.0038$ ).

Ninety-three percent of the cochlear implantations in the database were unilateral. These unilateral implantations involved 96% of the adult population and 89% of the pediatric population. Implantations were bilateral in 7% of cases overall and were significantly more common in the pediatric population (11%) than in the adult population (4%,  $p < 0.001$ ). Complications were significantly higher in bilateral implanted patients (14.1% for adults and 14.7% for children) than for unilateral implanted patients (5.3% for adults and 4.4% for children,  $p < 0.0001$ ).

A total of 664 cochlear implantations were performed on an outpatient basis (455 adults and 209 children), representing a rate of 11.6%. For hospitalized patients, the average duration of hospitalization was 2.54 days. Among adults, the complication rate among outpatients (5.7%) was similar to the complication rate among patients who remained in hospital (5.7%). Among children, the number of complications in ambulatory patients (4.8%) was not significantly different from those who remained in hospital (5.6%) either ( $p = 0.6433$ ). In adults, the average duration of hospitalization was significantly longer for those who had a complication (3.4 nights) than for those who did not have a complication (2.9 nights) ( $p < 0.0001$ ). In children, mean hospital stay was not different between those who had a complication (2.9 nights) and those who did not have a complication (2.8 nights) ( $p = 0.49$ ).

The etiology of deafness was unknown for 86.8% of implanted patients. The etiologies reported for the remainder of cases, in decreasing order of frequency, were otosclerosis, meningitis, cochlear malformation, CMV infection, and auditory nerve hypoplasia. Table 2 reports the rate of complications by etiology. Complications were not significantly more common when the etiology was unknown ( $p = 0.36$ ); the only situation associated with more complications were cochlear malformations ( $p = 0.02$ ). In multivariate analysis, in case of cochlear malformation, the complication rate in cochlear malformation was higher in adult than in pediatric patients ( $p = 0.047$ ). The highest complication rate (13.04%) was found for auditory nerve hypoplasia. However the number of cases ( $n = 3$ ) was insufficient for statistical significance ( $p = 0.15$ ).

### **Complications encountered during and after surgery.**

Table 3 describes the types of complications experienced by our patients. 58 peri-implantation complications were reported in 58 of the 5728 patients (1.01%). The rate of intraoperative complications was not significantly different between the adult and pediatric populations, at 1.15 and 0.8 % respectively ( $p = 0.20$ ). The average duration of hospitalization was 3.07 nights; it was higher in patients who had an intraoperative complication ( $p = 0.015$ ). Complications during surgery were of 4 types: cerebrospinal fluid leakage, neuro-vegetative disorders, major bleeding, and neurological complications. The risk of cerebrospinal fluid leaks was the highest risk intraoperative complication at 0.40%



incidence of all patients. Only the risk of neuro-vegetative disorders was significantly higher in the adult population (0.26%) than in pediatric patients (0.00%) ( $p = 0.016$ ).

Regarding postoperative complications, a total of 334 complications were identified in 265 patients. They were grouped into four main types: (i) local complications, (ii) device-related complications, (iii) cochleo- vestibular complications, and (iv) complications related to lesions of adjacent structures. (i) Local complications accounted for 43% of the detected post-operative complications. Their risk of occurrence was not significantly higher in the pediatric population (2.67%) than in the adult population (2.38%,  $p = 0.49$ ). Among these local complications infection, scarring, pain and hematomas accounted for, 0.93% 0.91%, 0.40% and 0.26% of the total patients respectively and none were significantly different between the adult and pediatric population ( $p > 0.05$ ).

(ii) The risk of device-related complications (breakdowns, electrode displacements, magnet displacements, implant body displacement, and poor electrode positioning) overall was significantly higher in the pediatric population (2.00%) than in the adult population (0.80%,  $p < 0.0001$ ). This difference was due to a significantly higher risk of breakdowns in the pediatric population (1.16%) than in the adult population (0.03%,  $p < 0.0001$ ). There was no difference in the occurrence of the four other device related local complications between the adult and pediatric population,  $p = 0.078$ , 0.644, 0.085 and 0.949 respectively for electrode displacements, magnet displacements, implant body displacement, and poor electrode positioning (with 0.49, 0.02, 0.05 and 0.24% overall incidences, respectively).

(iii) Cochleovestibular complications included dizziness and tinnitus. Their rate was significantly higher in the adult population (1.72%) than in the pediatric population (0.40%,  $p < 0.0001$ ). Among these complications, the risk of vertigo was significantly higher in the adult population (1.38%) than pediatric (0.40%,  $p = 0.0003$ ); the risk of developing tinnitus was also higher in the adult population (0.34%) than pediatric (0.00%,  $p = 0.005$ ). (iv) Complications of adjacent structure lesions included facial paralysis, tympanic perforation, and cerebrospinal fluid leaks. The risk of these complications was significantly higher in the adult (0.83%) than the pediatric (0.36%) population ( $p = 0.028$ ), and this difference was mostly due to facial paralysis (adult and child, 0.75% and 0.31% respectively,  $p < 0.04$ ).

### **Major and minor complications**

The rate of major postoperative complications was 2.51%, and that of minor complications was 2.88%. The nature of 23 of the 322 postoperative complications was not characterized. Major complications were significantly more common in the pediatric population (3.25%) than in the adult population (2.00%,  $p = 0.004$ , Table 4). These major complications were dominated by local complications (52%) and by complications associated with the device (42%). Among the major complications, only the device-related complications were significantly more frequent in the pediatric population (1.74%) than in the adult population (0.60%,  $p < 0.0001$ ). Minor complications, on the other hand, were significantly more common in adults than children (3.47% vs. 1.96%,  $p = 0.0008$ ). Of the minor complications encountered, 39% were local and 35% were cochleo- vestibular. Only the cochleo - vestibular

minor complications were significantly more common in the adult population (1.49%) than in the pediatric population (0.27%,  $p < 0.0001$ ).

### **Postoperative complications by age**

The overall complication rate was not significantly different between the adult (6.9%) and pediatric populations (6.7%,  $p = 0.78$ ). Table 5 provides information on implantation rates and complications by age group. 35% percent of cochlear implantations were performed before the age of 10, and 29% after 60 years. Complication rates in these age groups were not significantly different from those in the overall population ( $p = 0.51$ ). In multivariate analysis, there was no effect of age groups on the occurrence of complications. Regarding extremes on the age spectrum, 13.7% of cochlear patients were under the age of two. Complication rates before the age of 1 (7.32%) or between 1 and 2 years (7.52%) were not significantly higher than the complication rates in the overall population (6.84%). Implantations after 80 years accounted for 3.7% of global cochlear implantations, with a complication rate of 5.69% between 80 and 90 years, and 0% after 90 years; these rates were not significantly different from the complication rates in the overall population (6.84%). The major postoperative complications reported in adults were dizziness and scarring, accounting for 32% of the postoperative complications; in children, it was mainly infections (18%) and device breakdowns (17%).

### **Discussion**

Cochlear implantation has been a common practice for over 20 years. It is given to children aged from a few months to adults over 90 years old. The techniques, the surgical tools and the implants themselves have evolved. Cohen and Hoffman were the first authors to report surgical complications at a rate of 12% (1, 6, 7). Since then numerous studies of have been conducted in adult and pediatric populations, where complications were found at rates ranging from 7% to 19.9% (2, 3, 8-11). Different classifications have been described, based on the minor or major nature of the complication (1, 2, 12, 13), the time to onset (3) or the need for re-hospitalization, re-intervention or reimplantation (10, 14).

The main objective of the study was to carry out an exhaustive analysis of complications related to cochlear implantations performed in France between January 2012 and December 2016, in adults and children, and to compare these data with the existing literature. The study compiled 392 complications in 5728 patients and is the largest cohort published in the literature. The overall complication rate of 6.84% was lower than those up to 20% described in the literature (11, 13, 15, 16); these other reported rates are clearly outside the confidence interval of our study (6.2%, 7.5%). It is unlikely that complications in France are really less frequent than in the rest of the world. The difference may reflect methodological differences, as our data are always systematically taken at specified times with respect to surgery and the adjustments made. Our data also has a minimum of 'random' events such as minor

complications at distance from the implantation. As with the low major complication rate in our study, the rate of minor complications was also lower than in the literature (2). Compared to other studies, the 5-year inclusion period was short, which also limited the biases due to changing practices and devices. The mean age of cochlear implantation was comparable to recent data from the literature (11).

Multivariate analysis showed that three factors appeared to be significant for the occurrence of complications: (i) bilateral implantation, (ii) primary (vs. re-)implantation, and (iii) prior cochlear malformation. (i) In this study, we find a significantly lower complication rate in re-implantations compared to first implantation. This can be explained by several elements: reimplantation surgery is usually completed more rapidly than the initial act, which helps to reduce the risk of infection; moreover, mastoidectomy and cochleostomy have already been performed, which reduces the risk of adjacent structure damage and cochleo- vestibular complications. (ii) The rate of postoperative complications was significantly higher in bilateral implantations in both children and adults. The higher risk may be partly explained by the longer duration of surgery, increasing the risk of infection. Clearly the risk, of local device-related and cochleo- vestibular complications and lesions of adjacent structures, is twice as high. (iii) Among the etiologies of deafness, only cochlear malformation was associated with an increased risk of complications. In malformations, the facial nerve may have an aberrant localization. The risk of balance disorders is also increased if the malformation concerns the vestibules. The small size of the malformed cochlea also increases the risk of malposition of the electrode.

Of the 11.6% of patients treated on an outpatient basis, postoperative complication rates were not higher than inpatient rates in the adult or the pediatric populations. There are very few articles in the literature about cochlear implantation that focus solely on outpatient hospitalization (17-21).

In our study, the rate of intraoperative complications was 1.01%, and the post-operative rate was 5.83%. Complications during surgery were mainly due to the device implantation process whereas postoperative complications were related to the function or tolerance of the device. Our study is the only one analyzing these factors separately. The rate of intraoperative complications was not significantly different between the adult and pediatric populations ( $p = 0.20$ ). Postoperative complications were grouped into four subtypes: cochleo- vestibular, local cutaneous, device-related, and related to lesions of adjacent structures. This categorization is original and has not been previously used in the literature. Local complications included scar disorders, hematomas, infections and pain. The scar disorders are a frequent complication, in our study and in the literature, which can generate infections and re-interventions. Many authors emphasize the importance of small incisions preserving vascularization of the flap, and away from the implant bed (9, 22-24). In our study, post-operative infections occurred in 0.8% of the implanted population, accounted for 17.4% of postoperative complications and involved children in 52% of cases; no case of meningitis was reported. The possible treatments for infections described in the literature range from oral or intravenous antibiotic treatment, to surgical re-intervention and even to explantation (25). Our database did not allow for more clinical information regarding the risk factors of

patients who had post-operative infections, nor to know the bacteria involved in these infections. Many authors have also studied these postoperative complications, reporting rates ranging from 1.7 to 6.8% (25-27). Some authors consider that there are no predisposing conditions for infection (25), unlike others for whom children with associated chronic conditions are at higher risk of infection (27). The American Academy of Pediatrics Committee on Infectious Diseases listed many potential risk factors including being aged under two or over 65, immunosuppression, otorrhoea, cerebrospinal rhinorrhea, the presence of neurosurgical prostheses and a history of meningitis (28). Since 2002, following several cases of meningitis occurring after cochlear implantation in the pediatric population (29), the Food and Drug Administration has recommended routine pneumococcal vaccination before cochlear implantation. However there is no consensus on the value and duration of routine antibiotic prophylaxis (25).

Concerning the complications related to the device, the two main ones were implant failures and the movements of the implant (magnet, electrode holder). The risk of failure was 0.47% overall but more common in the pediatric (1.16%) than in the adult population (0.03%). In the literature, spontaneous breakdowns occur mainly in adults, whereas traumatic failures occur mainly in children (30, 31). Serial re-implantations exposes can lead to cochlear fibrosis and impeded insertion of the electrode array that is sometimes incomplete as a consequence. Insertion of the electrode array can be impossible with ossified cochleas (32-34). Results after reimplantation can be stable, sometimes they are degraded and sometimes improved (31, 33, 35). We found that the incidence of cochleo- vestibular complications was lower in children, as reported by several authors (2, 36, 37). However these complications are likely underestimated in children because the symptoms are difficult to detect, and only 3% are symptomatic (38). These studies reinforce the interest of evaluating vestibular function pre- and post-implantation, especially when bi-lateralization is envisaged.

Complications related to lesions of adjacent structures include tympanic perforations, cerebrospinal fluid leaks. The leakage of cerebrospinal fluid produces a risk of postoperative meningitis, although no cases were reported in our study. Tympanic perforations confer a risk of iatrogenic cholesteatoma, a complication not described in the study. The risk of peripheral facial palsy was 0.58% in our study, which is comparable to the literature (7, 11, 39, 40 ). These problems may be related to nerve heating during mastoidectomy, neural edema, or sometimes to a reactivation of Herpes Simplex Virus related to surgery (39).

Our study analyzed the rates of complications by age groups; we did not find an age range during which implantation would be more unfavorable. Complication rates in the adult and pediatric population were not different, which is consistent with the literature (15, 35). The delay in onset of complications was longer in the pediatric population, and mainly involved breakdowns and infections (11). Complications were not more frequent in children implanted before the age of 1 year, which confirms the value of early implantations. The most common complications in adults were dizziness, scarring, infections and facial paralysis. These complications were not more frequent after 80 years, and none were noted in the 8 patients over 90 years old. The benefit of implantation in the elderly is known, in terms of improved

quality of life and delayed cognitive decline (41, 42). Overall the data therefore support proposing an implantation, whatever the age, if the patient wishes it.

### **Conclusion**

The overall complication rate of cochlear implantations was 6.84% in the study. This rate was higher in the case of bilateral implantation than unilateral, and less in case of reimplantation compared to the first implantation, whether in the adult or pediatric population. There was no age effect on the risk of complications, whether patients were under 1, over 80, or over 90, confirming that this kind of surgery may be achieved safely at the extreme ends of life. The complications were distributed differently according to age: vertigo was predominant in adults, and failures in children. The risk of complications was not greater in outpatients ( $p = 0.64$ ), which is currently a medico-economic issue.

**Conflicts of interest** - The authors declare that they have no conflicts of interest

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Table 1. Complications according to age, type of implantation, length of hospital stay

	ADULTS (n = 3483)					p	CHILDREN (n = 2245)					p	
	no complications (n = 3287)		complications (n = 196)		95% CI		no complications (n = 2122)		complications (n = 123)		95% CI		
	n	%	n	%			n	%	n	%			
<b>Complication rate</b>				5.6	5.0 to 6.5				5.48	4.7 to 6.5			
<b>Age at implantation</b>	56.93		55.27				4.36		4.02				
<b>Type of implantation</b>													
Initial implant	3018	93.9	195	6.1	5.4 to 7.0		1773	93.6	121	6.4	5.4 to 7.6		
Reimplantation	269	99.6	1	0.4	0.1 to 2.1	<0.0001	349	99.4	2	0.6	0.2 to 2.1	<0.0001	0.7404
Unilateral	3165	94.7	176	5.3	4.6 to 6.2	<0.0001	1907	95.7	86	4.4	3.6 to 5.4		
Bilateral	122	85.9	20	14.1	9.3 to 20.8		215	85.3	37	14.7	10.8 to 19.6	<0.0001	
<b>Time to complication</b>													
Average (days)			68.45						140.98			0.0038	
<24H			47	24.0					21	16.94			
<7d			39	19.90					12	9.68			
> 7d			110	56.1					90	73.38			
<b>Duration of hospitalization</b>													
Ambulatory	431		24	5.7	3.9 to 8.2		199		10	4.8	2.6 to 8.6		
Non ambulatory	2856		172	5.7	4.9 to 6.6		1923		113	5.6	4.7 to 6.7		
Number of hospitalized nights	2.9		3.4			<0.0001	2.8		2.9			0.49	

Table 2. Etiology of deafness

Etiologies (n = 5728)	no complication		complication		95% CI	p
	n	%	n	%		
Unknown (n = 4194)	3949	94.16	245	5.84	5.2% - 6.6%	0.36
Otospongiosis (n = 236)	219	92.80	17	7.20	4.5% - 11.2%	0.41
Meningitis (n = 180)	171	95.00	9	5.00	2.7% - 9.2%	0.58
CMV (n = 151)	146	96.69	5	3.31	1.4% - 7.5%	0.17
Cochlear malformation (n = 168)	151	89.88	17	10.12	6.4% - 15.6%	0.02
Type VIII hypoplasia (n = 23)	20	86.96	3	13.04	4.5% - 32.1%	0.15
Genetic (n = 5)	5	100 %	0	0.00	0% - 43.4%	0.57
Not specified (n = 771)						

Table 3. Rates of postoperative complications grouped by subtypes.

Complications	Adults (n = 3483 )			Children (n = 2245 )			Total (n = 5728 )		p
	n	%	95% CI	n	%	95% CI	n	%	
<b>Intraoperative</b>	<b>40</b>	<b>1.15</b>	<b>0.8-1.6%</b>	<b>18</b>	<b>0.80</b>	<b>0.5-1.3%</b>	<b>58</b>	<b>1.01</b>	0.2008
CSF leaks	11	0.32	0.2-0.6%	12	0.53	0.3-0.9%	23	0.40	0.2013
Neurovegetative disorders	9	0.26	0.1-0.5%	0	0	0-0.2%	9	0.16	<b>0.0159</b>
Major bleeding	4	0.11	0-0.3%	2	0.09	0-0.3%	6	0.10	0.7686
Neurological complications	2	0.06	0-0.2%	1	0.04	0-0.3%	3	0.05	0.8353
ND	14			3			17		
<b>Postoperative</b>	<b>201</b>	<b>5.79</b>	<b>5.1 to 6.6%</b>	<b>13</b>	<b>5.88</b>	<b>5.0 to 6.9%</b>	<b>33</b>	<b>5.82</b>	0.6214
				<b>3</b>			<b>4</b>		
<b>Local</b>	<b>83</b>	<b>2.38</b>	<b>1.9 to 2.9%</b>	<b>60</b>	<b>2.67</b>	<b>2.1 to 3.4%</b>	<b>143</b>	<b>2.50</b>	0.4928
Infections	26	0.75		27	1.20		53	0.93	0.0783
Scar disorders	30	0.86		22	0.98		52	0.91	0.644
Pain	18	0.52		5	0.22		23	0.40	0.0858
Hematoma	9	0.26		6	0.27		15	0.26	.9489
<b>Device-linked</b>	<b>28</b>	<b>0.80</b>	<b>0.6-1.2%</b>	<b>45</b>	<b>2.00</b>	<b>1.5 to 2.7%</b>	<b>73</b>	<b>1.27</b>	<b>&lt;0.0001</b>
Breakdowns	1	0.03		26	1.16		27	0.47	<b>&lt;0.0001</b>
Electrode displacements	14	0.40		14	0.62		28	0.49	0.2403
Magnet displacement	1	0.03		0	0.00		1	0.02	0.442
Implant body displacement	2	0.06		1	0.04		3	0.05	0.8353
Poor electrode positioning	10	0.29		4	0.18		14	0.24	0.415
<b>Cochleovestibular</b>	<b>59</b>	<b>1.72</b>	<b>1.3-2.2%</b>	<b>9</b>	<b>0.40</b>	<b>0.2-0.8%</b>	<b>68</b>	<b>1.20</b>	<b>&lt;0.0001</b>
Dizziness	47	1.38		9	0.40		57	1.00	<b>0.0003</b>
Tinnitus	12	0.34		0	0.00		12	0.21	<b>0.0051</b>
<b>Linked to lesions of adjacent structures</b>	<b>29</b>	<b>0.83</b>	<b>0.6-1.2%</b>	<b>9</b>	<b>0.40</b>	<b>0.2-0.8%</b>	<b>38</b>	<b>0.66</b>	<b>.0281</b>
Facial paralysis	26	0.75		7	0.31		33	0.58	<b>0.0338</b>
Tympanic perforations	3	0.09		1	0.04		4	0.07	0.5608
CSF leak	0	0		1	0.04		1	0.018	0.442
ND	2	0.06		10	0.45		12	0.21	0.5332

Table 4. Complication rate by gravity: major or minor

Postoperative complications	Adults (n = 201)			Children (n = 133)			Total (n = 334)	p	
	n	%	95% CI	n	%	95% CI	n	%	
<b>major</b>	<b>70</b>	<b>2.04</b>	<b>1.6 to 2.6%</b>	<b>73</b>	<b>3.25</b>	2.6 to 4.1%	<b>143</b>	<b>2.51</b>	<b>0.0042</b>
Local	42	1.21		33	1.47		75	1.31	0.3907
Device-linked	21	0.60		39	1.74		60	1.05	<b>&lt;0.0001</b>
Cochleovestibular	3	0.09		0	0.00		3	0.05	0.1642
Lesions of adjacent structures	5	0.14		1	0.04		6	0.10	0.2581
<b>minor</b>	<b>121</b>	<b>3.47</b>	<b>2.9 to 4.1%</b>	<b>44</b>	<b>1.96</b>	1.5 to 2.6%	<b>165</b>	<b>2.88</b>	<b>0.0008</b>
Local	39	1.12		26	1.16		65	1.13	0.8934
Device-linked	6	0.17		4	0.18		10	0.17	0.9583
Cochleovestibular	52	1.49		6	0.27		58	1.01	<b>&lt;0.0001</b>
Lesions of adjacent structures	24	0.69		8	0.36		32	0.56	0.0991
Not indicated	10			16			26		

Table 5. Complication rate by age

Years	%	Intraoperative complications (n = 58)			Postoperative complications (n = 334)			Total complications (n = 392)		p
		n	%	95% CI	n	%	95% CI	n	%	
<1 (n = 123)	2.14	0	0.00	0-3%	9	7.32	3.9 to 13.3%	9	7.32	0.939
1 - 2 (n = 665)	11.61	5	0.75	0.3-1.7%	45	6.77	5.1 to 8.9%	50	7.52	0.956
2 - 10 (n = 1204)	21.00	10	0.83	0.5-1.5%	67	5.56	4.4 to 7.0%	77	6.39	0.940
10 - 20 (n = 294)	5.13	3	1.02	0.3-3.0%	17	5.78	3.6 to 9.1%	20	6.80	0.762
20 - 30 (n = 251)	4.38	4	1.59	0.6 to 4.0%	8	3.19	1.6 to 6.2%	12	4.78	0.336
30 - 40 (n = 338 )	5.93	6	1.76	0.8 to 3.8%	27	7.94	5.5 to 11.3%	33	9.70	0.337
40 - 50 (n = 498)	8.69	5	1.00	0.4 to 2.3%	46	9.24	7.0 to 12.1%	51	10.24	0.199
50 - 60 (n = 681 )	11.91	5	0.73	0.3-1.7%	38	5.56	4.1 to 7.5%	43	6.29	0.822
60 - 70 (n = 842)	14.69	8	0.95	0.5-1.9%	42	4.99	3.7 to 6.7%	50	5.94	0.852
70 - 80 (n = 619)	10.80	10	1.61	0.9 to 2.9%	25	4.04	2.8 to 5.9%	35	5.65	0.564
80 - 90 (n = 205)	3.58	2	0.97	0.3 to 3.5%	10	4.88	2.7 to 8.7%	12	5.85	0.704
> 90 (n = 8)	0.14	0	0	0 to 32.4%	0	0.00	0 to 32.4%	0	0.00	0.970
<b>Total</b> (n = 578 )		58	1.01	0.8-1.3%	334	5.83	5.2 to 6.5%	392	6.84	