The French National Cochlear Implant Registry (EPIIC): Bilateral cochlear implantation

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The French National Cochlear Implant Registry (EPIIC): Bilateral Cochlear Implantation

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Abstract

OBJECTIVES: Assessment of the incidence and results of bilateral cochlear implantation in adults and children in France.

MATERIALS AND METHODS: Multicenter retrospective study of data in the French national registry of cochlear implantations from January 1st 2012 to December 31th 2016. Functional results from CAP (Category of Auditory Performance) questionnaires and speech audiometry tests, with mono- and di-syllabic word-lists, were compared before and after implantation. Speech audiometry tests were carried out against a noisy background, except before simultaneous implantations.

RESULTS: 942 bilateral cochlear implantations were performed during this period, that is, 16.4% of all cochlear implantations. 588 bilateral implantations were performed sequentially. 59% of the bilateral implantations were performed in children. Bilateral implants significantly improved CAP scores in all cases ($p<0.001$). Auditory performance, with the two types of word-list, were significantly improved after simultaneous implantation ($p<0.01$). After sequential implantation, the speech discrimination score, already very good with the first implant, reached 63 +/- 26% [0-100] with monosyllabic word lists, and 72+/-28% [0-100] with dissyllabic words. There were more complications due to surgery in bilateral cases than in the entire population of cochlear recipients (9.1% vs 6.4%, $p<0.02$).

CONCLUSION: Hearing is significantly improved by simultaneous cochlear implantation. For sequential implantation, at one year, when auditory results were already excellent from the first implant, in the bimodal condition CAP scores were significantly improved, although there was no further change in speech audiometry in noise.

Keywords: bilateral cochlear implantation / French national cochlear implant registry / hearing performance / complications

Introduction

Cochlear implantation has traditionally been unilateral, i.e. performed on one side only. Implantation requires surgery, with the theoretical risks inherent in any ear surgery. The cost of implantation is not negligible either, at around € 22k in France for all brands. It is very likely that bilateral implantation was thus ruled out from the outset for this very reason. The good performance of unilaterally implanted patients also did not prompt the medical profession to propose bilateralization of cochlear implantation. Finally, at least in the pediatric community, the hope of developing gene therapy for deafness has probably hindered bilateral implantation, the fear being of no longer being able to offer effective treatment to deaf children already implanted on both sides, if there were a major discovery in this domain. It is well known that binaural hearing is very useful in everyday life because it improves speech recognition, especially in a noisy background (1-4). In cases of unilateral deafness, functional restoration requires aural rehabilitation in both ears (5). This is the case even if pseudo -stereophony, i.e. contra-lateral routing of signals (CROS) through air or bone could in part solve this hearing deficit, mainly by solving the problem of the head shadow effect (6.7).

In children, bilateral implantation was initially reserved for children whose hearing loss was due to meningitis, Usher syndrome, or post-traumatic cases (8). However prescription has since been extended to most children, with severe or profound bilateral deafness, when stereophony can only be obtained by this means. However, bilateral implants were not recognized by the French health authority, *HAS*, until 2011 (9). The authority recommends bilateral implantation in adults where there is a risk of significant cochlear fibrosis (meningitis or labyrinth fracture) or when a patient, with a single implant plus a contralateral hearing aid, loses the benefit of the latter and suffers a socio-professional impact, or loses autonomy in the case of the elderly (8). In France, the primary health insurance fund fully supports cochlear implantation. However this undertaking, as for most implantable medical devices, is subject to the maintenance of a national registry. The corresponding registry was thus created in 2011. It is accessible at the following online address, www.popsicube.fr/. Here we report the French bilateral cochlear implantation data, since its official authorization, i.e. since 2012, based on the national registry of cochlear implants.

Patients and Methods

The data were extracted by the statisticians of the company in charge of registry management (Popsicube®). All data concerning bilateral implantations from January 1, 2012 to December 31, 2016 were extracted from the file. Pre- and post-bilateral implantation data were compared. The demographic data of the bilaterally implanted patients are reported here. The results of the CAP (Category of Auditory Performance- Figure 1) questionnaire of cochlear implanted patients were also collected from the registry. CAP comparisons were made considering that this numerical scale from 0 to 9 contains category information. A matched

Stuart - Maxwell test for proportions was thus applied. The differences were considered significant for $p < 0.05$.

Data on speech perception after bilateral implantation are also presented. The main variable was the 60 dB discrimination score using mono- and di-syllabic word-lists. These lists were presented from in-front in silence if the patient had not yet had their implant, with one or two external hearing aids, according to *HAS* recommendations. If the patient already had a cochlear implant on one side, the lists were presented in a noisy environment with localized 60 dB sounds coming from in-front, and the patient took the test with their cochlear implant and if necessary also with their contralateral external hearing aid. The noise and signal sound sources were separated according to the instructions of the registry. Best performances were noted for signal to noise ratios between 0 and 10 dB. For these comparisons, a student t test or Wilcoxon test for paired data series was used, considering the results as significant at $p < 0.05$. Not all results could not be matched in all patients because duly interpretable audiometric tests were sometimes absent. However for many patients we considered it informative to study the data from before and after bilateralization with regard to the sequence of events.

Regarding simultaneous cochlear implantations, 53 patients had speech audiometry tests before receiving the cochlear implants on monosyllabic lists in silence with their external hearing aid optimally adjusted. Thirty-four of these patients had the same test after the implantations, but in a noisy background, as indicated above. Ninety-nine patients underwent the dissyllabic voice audiometry test, without a cochlear implant, but with their external hearing aid adjusted optimally. After receiving their two implants, 55 patients took the disyllabic list audiometry, but this time in a noisy background.

Regarding sequential implants, before sequential cochlear implantation, two different hearing aid conditions were differentiated. In the first (C1), patients had voice audiometry in noise just with their sole cochlear implant. In the second (C2), patients also had voice audiometry in noise with their cochlear implant but also with a contralateral external hearing aid. 148 patients had monosyllabic voice audiometry with their first cochlear implant in noise (C1). 53 patients had the same test with their cochlear implant on one side and with their external hearing aid on the other (C2). 238 had vocal audiometry on a disyllabic list with their first cochlear implant, in noise (C1). 113 patients had the same test with their cochlear implant on one side and external hearing aid on the other (C2). One year after bilateral implantation, after optimizing the adjustment of their cochlear implants, 54 patients had voice audiometry in noise with monosyllabic lists, and 112 had vocal audiometry in noise with disyllabic lists. Since auditory performance was not exhaustive, in each group (before and after implantation), a student t-test for unmatched series was also used. The significance level for the probability distribution was set at 0.05. APHAB and EVIP scores of adults and children respectively were insufficiently provided to be used in this analysis. For the other comparisons of variables between adults and children, between bilaterally implanted patients and the whole implanted population, particularly regarding the occurrence of complications, we used a Chi2 test with the level of significance at $p < 0.05$.

Results

Demographic data

The database under consideration included 942 bilateral cochlear implantations from 2012 to 2016. Of the 942 bilateral implantations 354 were simultaneous and 588 took place sequentially. Prescription was always in accordance with the recommendations of the French Higher Health Authority, except for in just three cases. 560 (59%) of the bilateral cases were in children and 382 (41%) were adults. If we compare to the global population of cochlear implanted patients in the registry, bilateral implants concerned 25% of children, against barely 9% in the adult, which is highly significant (Chi 2 = 5.946 ; df = 1 ; $p < 0.02$).

Bilateral cochlear implantations were performed sequentially in 62.4% of the cases. This preference for sequential implantation is statistically significant for both children and adults (CHI 2 = 4.542, df = 1, $p < 0.05$). The average delay between the two cochlear implantations was 18 +/- 11 months. The median was 15 months, the extremes ranging from 7 days to 4 years and 6 days. Overall there were more women than men implanted on both sides (63.4% women vs. 55.6% men; Chi 2 = 5.950, df = 1, $P < 0.02$). In the adult, the sex ratio demonstrates that women were also more likely to be implanted on both sides with 211 (55.2%) women against 171 (44.8%) men. In children it is the opposite, with 264 (47.1%) girls implanted on both sides against 296 (52.9%) boys. These differences are significant.

For most patients implanted on both sides the etiology of deafness remains unknown. Amongst the known causes, in adults, meningitis and otosclerosis predominate. Of the formally identified causes in children, it is cytomegalovirus infections, then cochlear malformations, that predominate. In children, meningitis was also common (Table 1). Cytomegalovirus was never documented in adults. The second implant was usually of the same brand as the first. However, in 22 cases (2.3%) the second implant was a different brand than the first contralateral implant.

Hearing performance

CAP scores were improved by bilateral implantation in all cases. Category analysis was possible in 197 cases of simultaneous implantation and 165 sequential cases. Figures 1 and 2 show a shift toward better CAP categories for all bilateral implantations, whether they were simultaneous or sequential. In the simultaneous cases the number of patients with a CAP below 3 decreased after one year from 169 (85.8%) to 57 (58.8%) and the number with a CAP$\geq$5 increased from just ten (5.1%) to seventy-four (37.6%). Amongst the sequential group sixteen (9.7%) patients had a CAP <3 before bilateralization of the implantation against only three (1.8%) afterwards, and 102 (61.8%) had a CAP$\geq$5 before bilateralization implantation versus 139 (84.2%) thereafter. The difference in CAP before and after cochlear implantation was significant in both the simultaneous and sequential groups ($p < 0.001$).

For a few patients we were able to collect audiometric data before and after bilateralization. Although limited in number, the matched data obtained were nevertheless informative. Eleven patients had monosyllabic-list tests before and after bilateral implantation. The improvement was undoubtedly significant, going from 0% [0; 0] to 65 % [50; 76], $p = 0.003$. Thirty-eight patients had dissyllabic tests before and after bilateral implantation. The dissyllabic vocal discrimination score was similarly significantly increased from 0 % [0; 0] to 70 % [50; 90], $p < 0.001$.

Simultaneous cochlear implantation

Monosyllabic lists

The average discrimination threshold of 60 dB in noise for monosyllabic lists increased from 0% [0-42] to 65% [0-98] ($t = 2.488$, $p < 0.01$).

Dissyllabic lists

The average discrimination threshold of 60 dB in noise for disyllabic lists increased from 0% [0-60] to 70% [0-100] ($t = 11.051$, $p < 0.001$).

Sequential cochlear implantation

Monosyllabic lists

In C1 conditions, with only one cochlear implant before bilateralization, the 60 dB discrimination average in monosyllabic list was achieved at 56 +/- 27% [0-100]. In C2, i.e. with the contralateral hearing aid included it was 62 +/- 21% [0-100]. These scores for monosyllabic lists, at 63 +/- 26% [0-100], were not significantly improved after bilateralization.

Dissyllabic lists

In C1, with only one cochlear implant before bilateralization, the 60 dB discrimination average for disyllabic lists was 70 +/- 27% [0-100]. In C2 (i.e. with an added hearing aid) the average was 77 +/- 26% [0-100]. These scores after the initial implantation are not significantly different from the disyllabic 60dB scores after the full bilateral implantation, at 72 +/- 28% [0-100].

Complications

Eighty-six peri or post-operative complications (excluding equipment failures) occurred in the registry in the bilateral implant population, i.e. 9.1 %. Compared with the 365 (6.4%) surgical complications (excluding equipment failures) identified in the overall population, this complication rate is significantly higher (Chi 2 = 9.756, df = 1, $p < 0.0025$). We noticed there were significantly more complications in adults (46 cases, 12 %) than in children (40 cases; 7.1%) after bilateral implantation (Chi 2 = 6.570, df = 1, $P < 0.02$). Table 2 summarizes the different complications encountered in the population of patients implanted on both sides, compared with the same complications in the implanted population overall. In this unilateral group, there are also 6 cases of perioperative hemorrhage and 3 cases of neurological complications, neither of which were reported in the bilaterally implanted population. The differences in complications due to bilateral surgery, excluding secondary breakdowns of the implanted material, with the overall population, are significant for: infections ((χ^2 = 6.024, df = 1, $P < 0.02$), skin healing problems (χ^2 = 6.356, df = 1, $P < 0.02$), and the occurrence of ipsilateral peripheral facial paralysis at implantation (χ^2 = 4.321, df = 1, $P < 0.05$) (Table 2). Eight cases of dizziness were reported in total (0.9%), with two cases in children (0.4%). No significant difference in complications was attributable to the implantation sequence chosen, i.e., simultaneous or sequential (χ^2 = 2.922, df = 1, $0.05 < P < 0.10$).

Discussion

Cochlear implantation has long been practiced unilaterally, that is on one side only. It is true that with just a single cochlear implant, the majority of implanted patients communicate orally quite acceptably. Many clinical reports have proved this (10-14). However it has also long been known that central auditory functions can only be effective if the hearing is binaural (15). However for a long time, the recommendation of the *HAS* was to reserve bilateral implantation just for children with Usher syndrome or patients, of any age, with meningitis or bilateral fractured labyrinths (8). In France, bilateral implantation encountered a somewhat prolonged reluctance. An initial reason could be the high cost of implants. In fact, studies of the benefit / cost ratio of bilateral implantation produced contradictory results. One may think that another cause of this recalcitrance was the fear of increased surgical risks of the second implantation to children, in view of the observation that patients already communicated remarkably well with just one side implanted (16). Finally, the French pediatric ear, nose, and throat community have often expressed fear of blocking the road to a novel deafness treatment, by gene therapy, if one should arise.

Since an English study (17), it has been evident that bilateral implantation in children provides a major benefit both medically and economically. In 2011, the *HAS* thus expanded the prescription of bilateral implants in children. In adults, several French publications (18,19), in total agreement with the data published in the USA (20), have been able to show an undoubted benefit of bilateral implantation, especially in elderly patients for whom the contralateral external hearing aid no longer relieved their deafness. Despite this, the bilateral implantation rate remains surprisingly low at around 16%. The most frequently used tests, to highlight the hearing impairment in patients whose hearing is asymmetric, as in the profoundly deaf with just one implant, highlight the difficulties these people have understanding conversations due to: the head shadow effect, lack of binaural summation and the limitation of squelch effect in a noisy background.

To simplify matters for the registry, the aural data were limited to a test of voice discrimination against a spatially separated noise source. However, although these tests are simple, they nevertheless require a stereo-auditorium with at least five loud-speakers to be available. Finally, despite these simplified requirements, not all patients were tested. Nevertheless, the analyzable data are pertinent and informative.

The overall performance, judged by the CAP scale, shows indubitably that bilateral cochlear implantation brings a clear benefit to our patients. The proof is provided by category analysis: many patients pass from a lower category where understanding of speech is very limited (CAP <3) to a higher class where their understanding of speech makes oral communication possible. Thus, the rate of patients with a CAP≥5 score, i.e. with a good understanding of speech, increased more than 7-fold (38% as against 5%) for simultaneous implantation, reaching 84% for sequential implantation, which is very significant. In the latter case, the number of patients with a higher CAP score after first cochlear implantation, improved significantly again, thanks to the second implant.

In terms of speech discrimination in noise, here again, the exploitable matched data, although not abundant, demonstrate a clear improvement. For simultaneous bilateral implantations, the comparative data from the audiometric tests confirm quite clearly the major contribution of the cochlear implants. Patients who had two external hearing aids replaced by two cochlear implants had improved discrimination on all word lists. On the other hand, there was no significant improvement in discrimination when the second sequential implant was added (condition C2 vs. C1). This may be due to two different factors. Probably more refined and specific tests of binaural auditory function would be required to show the contribution of the second cochlear implant. Indeed mean scores with a cochlear implant, before bilateralization, with or without contralateral external hearing aid, are already very high at 56% and 63% in monosyllabic lists and can reach 70% and 77%, respectively in C1 and C2. Another factor to consider is perhaps the somewhat early assessment, at just one year after sequential bilateral implantation, when performance can be improved for up to 3 years by bilateral cochlear implantation, at least in children (21).

Complications

It seemed very interesting to us to dwell on the potential complications of bilateral cochlear implantation. Indeed, there should be a tendency, in view of favorable functional results, to promulgate bilateral implantation, provided that the complications remain at a low and acceptable rate. Registry data demonstrate that, indeed, the complication rate after bilateral implantation remains acceptably low compared to the overall cochlear implanted population (9.1% vs 6.54%, excluding equipment failures). Surprisingly, it is not in simultaneous cochlear implantation that these complications are most often observed, but in the sequential ones. The explanation for complications being significantly more frequent in the sequentially implanted than in the overall population remains uncertain. To explain the greater number of infections or skin problems, we could implicate the length of surgical time, but this was disproved by the lower frequency of complications in the simultaneous implantations.

Regarding the greater frequency of peripheral facial palsy, it is difficult to give an explanation other than the doubling of the number of surgical acts compared to the unilaterally implanted population. No data from the registry can answer this question. In the same way we do not have a convincing explanation concerning the cutaneous scarring problems. It should be noted that the incidence of vestibular disorders reported in the postoperative period is very small and insignificant. Fear of inducing a vestibular dysfunction from bilateral implantation is justified in theory, since vestibular disorders can be generated by unilateral cochlear implants (22, 23). Registry data however shows that the vestibular risk in bilateral cases is not higher than that of the overall implanted population and vestibular problems remain rare. Finally, contrary to what one would have expected, simultaneous cochlear implantations are not at the origin of more peri- or post-operative complications.

It therefore appears clear that bilateral cochlear implantation provides clear improvements in oral communication skills, and that it is associated with a very low rate of complications, even if it is higher than that of unilateral implantation. It is difficult to understand the causal mechanism of the higher incidence of complications after sequential bilateral implantations. However we can recommend the following, based on existing data, for bilateral implantation; we can recommend prolonged antibiotic therapy for at least 7 days. Empirically we also recommend changing surgical instruments and drapes between the two cochlear implantations.

Conclusion

Simultaneous bilateral cochlear implantation has a proven beneficial contribution in oral communication with very low and acceptable surgical risk, even if the risk appears higher than in the overall cochlear implanted population. CAP scores and speech audiometry are significantly improved by bilateral implantation. Because the results of individual implantations are very good the results of a second implantation are harder to discern, but significant. The second implant procures a significant improvement in CAP, although no further improvement of speech audiometry in noise can be ascertained in the bimodal situation.

Conflicts of interest: none

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Children

meningitis	labyrinth malformation	nerve hypoplasia type VIII	CMV	unknown	other
19	25	5	39	209	176

Adults

meningitis	labyrinth malformation	otosclerosis	unknown	other
42	4	19	144	172

Table 1: Etiology of deafness in the bilateral cochlear implanted population

	Bilateral implantation		CI population			Age		Cochlear implantation	
						Children	Adults	simultaneous	sequential
infection	17	1,80%	53	0,93%	S (p< 0,02)	9	8	5	12
healing issues	17	1,80%	52	0,91%	S (p< 0,02)	10	7	4	13
facial palsy	11	1,17%	33	0,58%	S (p< 0,05)	2	9	2	9
electrode migration	9	0,96%	28	0,49%	NS	9	0	3	6
vertigo	8	0,85%	57	1,00%	NS	2	6	2	6
hematoma	5	0,53%	15	0,26%	NS	3	2	3	2
pain	5	0,53%	23	0,40%	NS	3	2	2	3
electrode malposition	4	0,42%	14	0,24%	NS	1	3	2	2
tympanic perforation	2	0,21%	4	0,07%	NS	0	2	0	2
tinnitus	2	0,21%	12	0,21%	NS	0	2	0	2
nausea, vomiting	2	0,21%	9	0,16%	NS	0	2	2	0
inner part displacement	1	0,11%	3	0,05%	NS	0	1	0	1
magnet displacement	1	0,11%	1	0,02%	NS	0	1	0	1
CSF leak	1	0,11%	23	0,40%	NS	1	0	0	1

no detail	1	0,11%	29	0,51%	NS	0	1	0	1
total	86	9,13%	356	6,22%		40	46	25	61

Table 2 : Intra and postoperative complications

Figure 1: CAP evolution one year after simultaneous bilateral implantation

CAP AT ONE YEAR

CAP<3: 57 (58.8%)

CAP≥5: 74 (37.6%)

INITIAL CAP

CAP<3: 169 (85.8%)

CAP≥5: 10 (5.1%)

Cat CAP	0	1	2	3	4	5	6	7	8	9	TOTAL
0	2	7	26	11	14	8	5	11	1	1	**86**
1	2	7	7	8	16	11	3	6	0	2	**62**
2	0	1	4	4	4	5	1	1	1	0	**21**
3	0	0	0	1	5	1	1	3	0	0	**11**
4	0	0	0	0	1	0	2	3	0	1	**7**
5	0	1	0	0	0	0	2	1	0	0	**4**
6	0	0	0	0	1	0	0	2	0	0	**3**
7	0	0	0	0	1	0	0	1	0	1	**3**
8	0	0	0	0	0	0	0	0	0	0	**0**
9	0	0	0	0	0	0	0	0	0	0	**0**
TOTAL	**4**	**16**	**37**	**24**	**42**	**25**	**14**	**28**	**2**	**5**	**197**

Figure 2 : CAP evolution one year after sequential bilateral implantation

CAP AT ONE YEAR

CAP<3: 3 (1.8%)
CAP ≥5: 139 (84.2%)

INITIAL CAP

CAP<3: 16 (9.7%)
CAP≥5: 102 (61.8%)

Cat CAP	0	1	2	3	4	5	6	7	8	9	TOTAL
0	0	1	0	0	0	0	0	0	0	0	**1**
1	0	0	0	0	1	1	1	0	0	0	**3**
2	0	0	1	0	4	4	2	1	0	0	**12**
3	0	0	1	3	6	8	1	0	0	0	**19**
4	0	0	0	1	6	12	2	7	0	0	**28**
5	0	0	0	0	1	20	7	12	0	3	**43**
6	0	0	0	0	1	3	3	13	1	2	**23**
7	0	0	0	0	0	2	0	24	1	8	**35**
8	0	0	0	0	0	0	0	0	0	0	**0**
9	0	0	0	0	0	0	0	1	0	0	**1**
TOTAL	**0**	**1**	**2**	**4**	**19**	**50**	**16**	**58**	**2**	**13**	**165**