OTOLOGY



Variability of fitting parameters across cochlear implant centres

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Abstract

Objective As a follow-up to the studies by Vaerenberg et al. (Sci World J 501738:1–12, 2014) and Browning et al. (Cochlear Implant Int 21(3):1–13, 2020), who used questionnaires, we determined whether there are between-centre variations in the fitting of cochlear implants by analysing the methodology, fitting parameters and hearing results of patients from four centres with real data. The purpose of this study is to highlight the lack of streamlined mapping guides and outcome measures with respect to cochlear implant (CI) fittings.

Methods A retrospective study with ninety-seven post-lingual adults with a nucleus cochlear implant placed between 2003 and 2013 was included to ensure at least 5 years of follow-up.

The studied data were as follows: the methodology, including the fitter's professional background, the method of activation, the sequence of fitting sessions, the objectives measures and hearing outcomes; and the fitting parameters, including the speech processors, programming strategy, stimulation mode, T and C levels, T-SPL and C-SPL, maxima, pulse width, loudness growth and hearing results.

Results This investigation highlights some common practices across professionals and CI centres: the activation of a CI is behavioural; impedances are systematically measured at each fitting; and some parameters are rarely modified. However, there are also differences, either between centres, such as the sequences of fitting sessions (p < 0.05) or their approach to spectral bands (p < 0.05), or even within centres, such as the policy regarding T and C levels at high frequencies compared to those at low and mid-frequencies.

Conclusion There are important variations between and within centres that reflect a lack of CI-related policies and outcome measures in the fitting of CI.

Clinical trials registry NCT03700268

Introduction

A cochlear implant (CI) is a device that provides functional hearing to patients, children and adults with severe (70-90 dB) to profound (>90 dB) sensorineural hearing loss who received no benefit from conventional hearing aids. Indications vary between countries and competent authorities [1-3].

All CIs share the same basic functions [4] and design, including an external part (external components: sound processor, cable and coil with magnet) and an internal part (internal components: antenna, receiver/stimulator,

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extracochlear electrodes and intracochlear electrode array), which provide electrical stimulation directly to the cochlear nerve fibres, bypassing absent or nonfunctional cells in the cochlea [2].

The programming of the speech processor, commonly called fitting, is used to obtain the best hearing results in different sound situations and is a real challenge. A precise fitting of the electrical stimulation (map) by setting various available parameters of the CI is essential to restore the intelligibility of speech [5, 6]. CI companies provide proprietary fitting software together with recommendations on CI activation and follow-up, but these recommendations are more general rather than detailed, and they are certainly not binding.

The scientific literature on CIs is extensive, but to our knowledge, only five studies with different objectives and methodologies have provided evidence in CI audiologist practice procedures [7-11]. Two studies surveyed the

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state-of-the-art in CI fitting based on a questionnaire that was distributed to 47 centres, mainly in Europe [8] and in medical centres and universities in the United States [10]. Both studies concluded that there was no consensus on good clinical practice (GCP). Audiologists adopt different fitting methods with patients and depend on the manufacturer of the CI. The fitting primarily consisted of setting global profiles of maximum current levels based on subjective feedback from the recipient, which led to disparate fittings [9, 12].

The most elementary task of CI fitting is setting the threshold (T) and comfortable/most comfortable (C) electrical stimulation levels. There are two major approaches to define these T and C levels: the behavioural approach and the objective approach. However, these two approaches do not come with formal guidelines, and many experts do it their own way [9].

The behavioural approach defines the most appropriate electrical stimulation levels for each electrode by measuring the lowest level that gives a hearing sensation (T level) and the highest level that does not cause an uncomfortable hearing sensation (C level).

T and C levels are typically measured for each electrode by time-consuming methods that are similar to the methods used in pure-tone audiometry. Several approaches have been developed to reduce amount of effort required. One approach is to measure the T and C levels at 5 electrodes spread across the electrode array and interpolate the levels for all of the other electrodes. Other approaches consist of only measuring C levels and setting T levels to 0 (Med-El) or to 10% of the C levels (Advanced Bionics). Other methods have been described, such as (1) the count-the-beep method [13], (2) psychophysical loudness scaling, and (3) threshold estimation with voice perception [5].

The objective approach derives the T and C levels from objective auditory responses. Different CI manufacturers use various names to evaluate the same: neural response telemetry (NRT) for cochlear, neural response imaging (NRI) for advanced bionics and auditory nerve response telemetry (ART) for MedEl. These measures capture the compound action potentials (CAPs) of the auditory nerve caused by stimulation with the CI (electrically evoked compound action potential: ECAP) [14, 15]. There is no standard guidance on how to use these measures. Previous studies showed only a moderate or weak correlation between the T and C levels obtained from behavioural measures and the levels predicted based on NRTs and ECAPs [14, 16]. These studies provide only information about the "threshold profile".

Measurement of the stapedial reflex is shown to provide an objective evaluation of high loudness perception, which may be used for the adjustment of C levels. Moreover, it also allows verification of the functioning of the CI and an evaluation of the auditory pathways at the level of the brainstem [17]. It is noteworthy that no recommendations exist for useful adaptations of parameters other than T and C levels, such as T-SPL (the input dB SPL level where the implant starts to stimulate the T level), C-SPL (the input dB SPL value at which the compression starts and stimulates the C levels), loudness growth (the steepness of the logarithmic function used to map input sounds into the recipient's electrical dynamic range), and maxima (number of channels stimulated during one cycle). The manufacturers provide default values that are not often modified by clinicians. Generally, some of these values change with the arrival of a new speech processor.

To date, there have been no universal evidence-based clinical practice guidelines for the fitting of CI. This absence of standardization in CI programming has led to wide variations in patient outcomes and performances between centres.

The purpose of this paper is to highlight the two current lacks in CI fittings, which are streamlined mapping guides and outcome measures.

Materials and methods

Subjects

Fitting data files of ninety-seven post-lingual adult CI recipients were retrospectively analysed from four major CI centres randomly chosen in Belgium and France: Centre 1 (C1): 22 subjects implanted at an average age of 55 years (\pm 14 years); Centre 2 (C2): 22 subjects implanted at the age of 54 years (\pm 17 years; Centre 3 (C3): 28 subjects implanted at the age of 54 years (\pm 17 years); and Centre 4 (C4): 25 subjects implanted at the age of 58 years (\pm 13 years). The subjects received a nucleus cochlear implant (Cochlear Ltd., Sydney, Australia) between 2003 and 2013, which ensured at least 5 years of follow-up. Patients with post-meningitis deafness were excluded to avoid situations of cochlear ossification, which may lead to poorer CI performance [18].

Procedure

This was a retrospective study on the data collected during the 5 years of follow-up.

The methodology used, the fitting parameters and the hearing outcome measures were collected in the four centres.

To ascertain the *fitting methodology*, the clinicians' type (professional background), fitting session timelines, activation methods, objective measures and hearing outcomes were analysed. *The fitting parameters* retrieved from the files at activation, 3, 6 months, 1, 2, and 5 years post activation were the speech processor type, programming strategy (algorithm used to transform features of the incoming signal into an electrical code), stimulation mode (how

channels are connected to form an electrical circuit), T and C levels (softest and comfortable electrical input level). T-SPL (the input dB SPL level where the implant starts to stimulate the T level) and C-SPL (the input dB SPL value at which the compression starts and stimulates the C levels), maxima (number of channels stimulated during one cycle), pulse width (duration of one single phase) and loudness growth (the steepness of the logarithmic function used to map input sounds into the recipient's electrical dynamic range). For the sake of readability, the T and C levels were averaged for the electrodes activated into three spectral bands: LOW (188-938 Hz), which typically corresponded to electrodes 22 to 17; MID (1063-3563 Hz), which typically corresponded to electrodes 16 to 7; and HIGH (4063–7938 Hz), which typically corresponded to electrodes 6 to 1 [19]. The data collected date from 2003 to 2013. The majority of pulse width (PW) is 25 µs except for some patients. For the patients with a PW of 37 µs, we have increased the T and C levels by 22 units, with a PW of 50 µs, we have increased the T and C levels by 40 units, with a PW of 20 µs, we have decreased the T and C levels by 12 units and, with a PW of 12 µs, we have decreased the T and C levels by 40 units.

The *hearing results*, hearing thresholds at 250, 500, 1000, 2000, 4000 and 6000 Hz with warble tones and speech audiometry using mono- or bisyllabic words played from a CD or presented live in quiet at 40, 55 and 70 dB HL, were recorded in centres 1 and 4 at 1 year post intervention (Cfr. Figure 2). Centres 2 and 3 did not systematically perform tone nor speech audiometry.

The following fitting default values were proposed by Cochlear in 2005: ACE and SPEAK strategies; MP1 + 2 stimulation mode; T-SPL set at 25 dB SPL; C-SPL at 65 dB SPL (for the 9 patients with the Esprit 3G, there was no possibility to modify the T-SPL and C-SPL); rate of 900 pps with ACE and 250 pps with SPEAK; 8 maxima; pulse width of 25 μ s; and a loudness growth of 20.

Statistics

All descriptive (mean, standard deviation) and analytical statistics were performed using SPSS software (IBM Statistical Package for Social Sciences version 25).

The average and 95% confidence intervals of the T and C levels are shown in bar diagrams. Box plots were used to show the pure-tone and speech audiometry results.

ANOVA generalized linear mixed models were used to test variability within and between centres, and post hoc Mann–Whitney pair tests were used to evaluate differences between groups. The level of significance was set to $p \le 0.05$.

Results

Fitting procedures

The *clinicians* were audiologists in 3 centres (C1, C3, C4) and either audiologists or speech therapists in one of the centres (C2).

The *fitting session timeline* was different in the 4 centres. Activation was performed between 2 and 5 weeks after implantation, and the number of fitting sessions was 8 or 12 during the first CI year. The fitting was performed in an audiological setting outside of the hospital in three centres (C1, C2, C4) and in the hospital in 1 centre (C3).

The *activation method* was based on the behavioural determination of T and C levels in all four centres. In the follow-up, these T and C levels were controlled during every session for two centres (C2, C3), only at 3 months for one centre (C4) and whenever deemed necessary for the other centre (C1).

The following objective measures were used to adapt the fittings: electrode impedances at each session for all centres; NRT systematically at 1 month post activation for one centre (C3) and in case of limited functional results in three centres (C1, C2, C4); and stapedial reflex thresholds systematically at each session after 1 month of activation in one centre (C3).

The *hearing outcome measures* used to validate the fitting adaptations were variable between centres. Audiometry thresholds were recorded and used systematically for fitting optimization at each session in one centre (C1), only every now and then in two centres and never in one centre (C2). Speech audiometry in quiet was used systematically at each session in one centre (C1), sometimes in one centre (C4) and never in two centres (C2, C3). Speech tests with live utterances pronounced by a speech therapist at a comfortable intensity were the only hearing tests used in one centre (C2) and were sometimes used in the other three centres (C1, C3, C4).

Fitting parameters

Speech processors

Various speech processors were used. In the first 2 years post activation, the Freedom and CP800 processors were used in all centres, and the Esprit 3G processors were used in C1 (6 of 22 cases) and C3 (3 of 28 cases). At 5 years post activation, the processors were Freedom (C1 = 1/22; C2 = 1/22; C3 = 14/28; C4 = 11/25), CP800 (C1 = 14/22; C2 = 18/22; C3 = 9/28; C4 = 7/25), CP900-950 (C1 = 6/22; C2 = 3/22; C3 = 5/28; C4 = 5/25), and CP1000 (C1 = 1/22).

Programming strategy

The programming strategy used at activation was always the default ACE in all centres (C1 = 20/22; C2 = 22/22; C3 = 28/28; C4 = 24/25) and SPEAK (C1 = 2/22; C4 = 1/25).

Stimulation model

All centres used the default stimulation mode MP1 + 2 at activation, and MP1 was sometimes chosen when there was a technical problem with an electrode (C1 = 1/22; C4 = 1/25) or MP2 (C4 = 2/22).

T and C levels

Figure 1 shows the averages and 95% confidence intervals for the T and C levels (current levels) over time according to the spectral bands at LOW, MID and HIGH frequencies in the 4 centres.

These results demonstrate the variabilities between and within centres.

Within-centre variability

The T levels showed significant within-centre differences between the LOW, MID and HIGH frequencies at all times: C1 χ^2 =172,29(2), p < 0.001; C2 χ^2 =219,8(2), p < 0.001; C3 χ^2 =215,41(2), p < 0.001; and C4 χ^2 =215,41(2), p < 0.001 (Table 1).

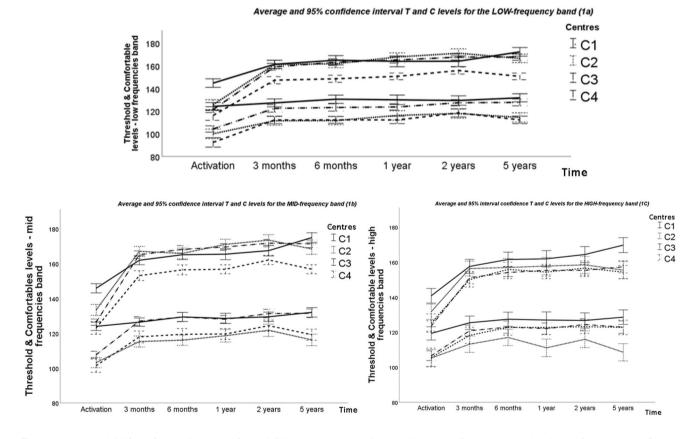


Fig. 1 Average and 95% confidence intervals of T and C levels (current levels) over time according to spectral bands at LOW (a), MID (b) and HIGH (c) frequencies for the 4 centres

Table 1	Means and standard deviation for	T levels by spectral bands	(LOW, MID, HIGH	I) for all centers (C	C1, C2, C3,	C4)
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C1		C2			C3			C4			
LOW	MID	HIGH	LOW	MID	HIGH	LOW	MID	HIGH	LOW	MID	HIGH
135 ± 23	127 ± 19	120 ± 17	120 ± 25	114 ± 24	103 ± 24	129 ± 22	123±21	114 ± 20	126 ± 27	116±25	103 ± 22

LOW had values higher than MID, higher than HIGH. The differences between LOW, MID and HIGH are significant

The C levels showed significant within-centre differences between the LOW, MID and HIGH frequencies at all times: C1 χ^2 =178,24(2), p < 0.001; C2 χ^2 =394,48(2), p < 0.001; C3 χ^2 =467,66(2), p < 0.001; and C4 χ^2 =321,64(2), p < 0.001 (Table 2).

For all the centres, both T and C levels for LOW and MID-frequencies were higher than for HIGH frequencies.

The T and C levels reached more or less steady level after 3 months in one centre, 6 months in one centre, and 1 year in the other two centres.

Between-centre variability

Centres and spectral bands

There was a significant between-centre difference in the three spectral bands for both the T levels (F(6, 12, 183) = 21.09, p < 0.001 and the C levels, F(10, 12, 178) = 5.128, p < 0.001).

Centre C1 applied higher T and C levels at activation than did the other centres. For LOW frequencies, C1 had significantly higher T levels than C2 (U=4959,5; p<0.001), C3 (U=6282; p<0.001) and C4 (U=6136; p<0.001); for MID-frequencies, C1 had significantly higher T levels than C2 (U=10,421; p<0.001), C3 (U=16,359,5; p<0.001) and C4 (U=13,070; p<0.001); and for HIGH frequencies, C1 had significantly higher T levels than C2 (U=2734; p<0.001), C3 (U=4249; p<0.001) and C4 (U=2696; p<0.001).

For LOW frequencies, C1 had significantly higher C levels than C2 (U=6297,5; p<0,001), C3 (U=5389,5; p<0.001) and C4 (U=4209,5; p<0.001); for MID-frequencies, C1 had significantly higher C levels than C2 (U=14,938; p<0.001), C3 (U=12,807; p<0.001) and C4

(U=10,687; p < 0.001); and for HIGH frequencies, C1 had significantly higher C levels than C2 (U=3738,5; p < 0.001), C3 (U=3928,5; p < 0.001) and C4 (U=2817,5; p < 0.001).

Centre C2 applied different C levels than C3 and C4. For LOW frequencies, C2 had significantly lower C levels than C3 (U=8819,5; p=0.002) and C4 (U=6306,5; p<0.001); for MID-frequencies, C2 had significantly lower C levels than C3 (U=24,940; p<0.001) and C4 (U=17,782; p<0.001); and for HIGH frequencies, C2 had significantly lower C levels than C4 (U=6030; p=0.006).

Centre C3 applied different T and C levels than C4. For HIGH frequencies, C3 had significantly lower T levels than C2 (U=8098; p=0.004) and C4 (U=6821; p<0.001). For HIGH frequencies, C3 had significantly higher C levels than C4 (U=7369; p=0.003).

Centres and time evolution

There was a significant difference between the variables centre and time for T levels (F(15, 12, 183) = 8.79, p < 0.001) and for C levels (F(15, 12, 178) = 16.433, p < 0.001).

The observed differences in T and C levels at activation were conserved over time.

Other parameters

For the other parameters, i.e., T-SPL, C-SPL, rate, maxima, pulse width and Q value, Table 3 shows the percentage of subjects with values different from the default setting provided by Cochlear. Some parameters were rarely adjusted, such as the loudness growth (other proposed values = 16, 17, 20), rate (other proposed values = 500, 720, 1200, 1800, 2400 pps) and pulse width (other proposed values = 12, 20, 37, 50 μ s). Some centres changed parameters more

Table 2 Means and standard deviation for C levels by spectral bands (LOW, MID, HIGH) for all centers (C1, C2, C3, C4)

C1			C2			C3			C4		
LOW	MID	HIGH									
169 ± 24	162 ± 23	152 ± 22	171 ± 25	161 ± 25	144 ± 26	168 ± 23	158 ± 23	143 ± 23	159 ± 25	149 ± 24	137 ± 24

LOW had values higher than MID, higher than HIGH. The differences between LOW, MID and HIGH are significant

Table 3	Percentage of subjects					
with val	ues deviant from the					
default setting						

Parameters (default value)	Center 1 $(n=22)$	Center 2 $(n=22)$	Center 3 $(n=28)$	Center 4 $(n=25)$
T-SPL (25 dB SPL)	54%	3%	62%	22.5%
C-SPL (65 dB SPL)	42.5%	0%	49%	9%
Rate (250 and 900 pps)	6%	2.5%	3%	22%
Maxima (8)	5%	24%	80%	36%
Pulse width (25 µs)	6%	10%	7%	7%
Q value (20)	0%	0%	0%	3.5%

frequently (Table 3) than other centres, such as the T-SPL (other proposed values = 30, 33, 34, 35, 40, 45 dB SPL), C-SPL (other proposed values = 70, 71, 75, 80 dB SPL) and the maxima number (other proposed values = 6, 7, 9, 10, 11, 12).

Hearing tests

The tone and speech audiometry results in centres 1 and 4 are shown in Fig. 2.

There was no significant difference between pure-tone audiometries from centre 1 and centre 4 (p > 0.05).

Speech audiometries were not comparable because the lists of words and the modalities of presentation, namely speech or recorded voice, were not the same.

Discussion

Vaerenberg et al. [9] and Browning et al. [11] concluded that there was variability in fittings and different outcome measures based on questionnaires completed by audiologists. Our analysis confirms these findings with numerical data originating from four centres in Belgium and France. We investigated the records of 97 post-lingual deaf adults who received a cochlear implant between 2003 and 2013 at an average age of 50–58 years, and we found important variations with regard to the fitting methodology, the fitting parameters that were modified and the hearing tests used to guide the fitting. Because of the retrospective nature of this analysis, we had to work with relatively old data, but we have no indication that the fitting policies have substantially changed since in any of those centres.

Some practices are common in the four centres:

- 1. The activation of CI is behavioural and based on the measurement of the T and C levels on a number of electrodes along the electrode array, with interpolation of the other electrodes [20].
- 2. Impedances are systematically measured at each fitting. Electrode impedance is the first objective assessment carried out during the surgical procedure and follow-up of cochlear implanted patients [21].
- 3. A number of map parameters rarely change from their default values, such as the programming strategy, stimulation mode, rate, pulse width and loudness growth.

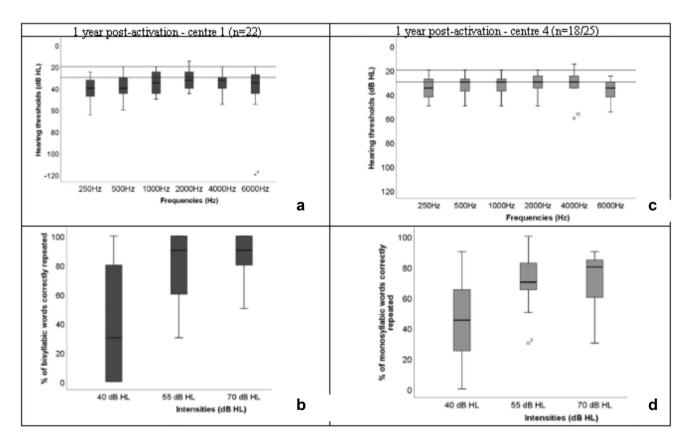


Fig.2 a Pure-tone audiogram (dB HL) (b) speech audiogram % of correct repetition of bisyllabic words presented in quiet at 40, 55 and 70 dB HL for centre 1. c Pure-tone audiogram (dB HL) (d) speech

audiogram % of correct repetition of monosyllabic words presented in quiet at 40, 55 and 70 dB HL for centre 4

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Each CI centre has its own policies in terms of methodology, parameters and hearing tests.

The fittings are mainly done by audiologists, while in one centre (C2), speech therapists were also involved.

The timeline for activation of the CI differs in all four centres. The switch-on of the processor is scheduled between 2 and 5 weeks after surgery. This time frame is relatively late considering that several studies have demonstrated the safety and feasibility of switching on the processor as early as 24 h after surgery [22–25].

The switch-on session is followed by 8 to 12 fitting sessions in the first year. C1 and C3 prefer to start with more sessions during the first month post activation, perhaps for practical reasons or their experience that such intensive schemes lead to fast stable MAPS, unlike C2 and C4, which do not see patients again for 1 month to allow more time for patients to get used to the fittings.

With regard to the content of the follow-up, the NRTs were measured 1 month after activation in C3 as a global indication of T and C levels and in centres 1 and 4 to confirm device functioning and verify questionable behavioural responses. Stapedial reflexes were only measured in C3. The setting of T and C levels per electrode with behavioural assessment was commonly used, systematically for C2 and C3 and whenever deemed necessary for C1 and C4. Every centre appeared to have its own policy on how and when to determine these levels. Behavioural assessment was commonly used to assess the levels on a few electrodes and deduce the values for the remaining electrodes via interpolation. The T and C levels, which were studied at activation, 3 and 6 months, and 1, 2 and 5 years, showed significant differences between and within centres. This result was the same for their absolute values and the profiles across LOW, MID- and HIGH frequencies. It is unlikely that these differences were caused by real physiological differences between the patient populations of the different centres. We believe this can only be explained by different fitting policies at the centres. One could argue that this result indicates that all of these settings may not be extremely important. However, one can then question how to justify all the effort spent at fitting. Evidence exists that optimizing the settings does make a difference. For instance, excessively high T levels are reported to produce the perception of background noise [26], and excessively low T levels produce a decreased detection of quiet sounds [26], which impedes the ability to understand soft voices [27–29]. In fact, there is no global agreement or good clinical practice to set the threshold [30]. The most common way to measure the audibility of electrical signals is the behavioural method [20], which is very similar to audiometry. Alternative methods, such as selftests that allow patients to determine their electrical hearing thresholds themselves without a clinician, may result in better speech perception in noise [30], but it remains unclear whether T levels are optimally set at these measured levels of audibility or rather slightly above or below them. The intrinsic variability of behavioural responses, the influence of NRT measures, and the policy on how this relates to T levels may all contribute to the observed variability between CI centres. It is noteworthy that a novel CI fitting approach based on artificial intelligence (AI), published as "Fitting to Outcome eXpert" [31-34], does not rely on measured T and C levels but on measured audiological outcome rather than solely on comfort. Wathour et al. [35] used AI-assisted fitting with 2 cases and obtained better results on hearing tests with maps without ascertaining the T and C levels as such. A recent study [36] concluded that FOX outcomes, speech audiometry with CNC words and AzBio sentences in noise are comparable to those using manual fitting in 55 CI adults. This target-driven, computer-assisted fitting brings self-testing and self-fitting at home within reach [37].

Map parameters other than T and C are rarely adjusted. All centres systematically overruled some default settings but this again was different for each centre, for instance, T-SPL, which had a value of 30 dB SPL for C3 and 35 dB SPL for C1; C-SPL, which had values of 70 dB SPL and 75 dB SPL for C1 and C3, respectively; and maxima, which had a value of 10 for C2 and 12 for C3 and C4. These results indicate that the default settings do not necessarily give the best results. Whether modifying these map parameters is relevant remains an interesting issue. One of the problems encountered was the difficulty of correctly understanding the underline rational which drove the centres to change the default settings. Even when ask, centres often replied that these were existing policies that had existed for or since a long time without people remembering exactly why.

The audiological tests used also differed between centres. Audiometry and speech audiometry were systematically performed at each fitting in C1, never performed in C2 and performed on demand in C3 and C4. C2 used perceptive tests with live utterances by speech therapists. The centres mostly relied on the recipient's subjective feedback to drive the MAP changes. Comparative evaluations of the preoperative hearing status and the development of speech understanding over time should be documented [38].

Comparisons between the various evaluations were difficult because the speech material used differed, such as the use of monosyllabic or bisyllabic words and use of recordings, as well as test performance, e.g., in a sound booth or office. C1 offered pre-recorded bisyllabic lists, and C4 used monosyllabic words spoken in a direct live voice. There were no specific rules on which tests to use in the follow-up of a CI.

An analysis of the results showed that the within- and between-centre variability depended on a certain policy or way of doing things. This observed difference cannot be explained by the differences in patients. Multiple fitting approaches exist, and it seems impossible to compare all of these differences and judge whether some yield better results or are more efficient than others in the absence of targets or well-defined outcome measures.

Conclusion

Following the studies of Vaerenberg et al. [9] and Browning et al. [11], we analysed the methodology, parameters and hearing tests of patients from four centres to verify whether real differences exist across centres. Our results show that although each CI has the same internal and external components, the way of fitting differs from one centre to another. What justifies this great variability? The actual lack of systematic outcomes measures makes it impossible to determine if one policy results in better hearing results than another policy.

At present, there is no consensus on how to program a CI.

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Compliance with ethical standards

Conflict of interest Authors JW and ND report no conflict of interest relevant to this article. Author PG owns intellectual property rights in FOX® and has royalty benefits related to this product.

Ethics approval This study was approved by the local ethical review board (hospital St-Luc – B403201734403).

Human/Animal rights Retrospective study—this study involves data analysis.

Informed consent Retrospective study.

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