

Effect of a CI Programming Fitting Tool with Artificial Intelligence in Experienced Cochlear Implant Patients

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Objective: Cochlear implants (CIs) are the treatment of choice for patients with severe to profound hearing loss. The hearing results, however, considerably vary across patients. This may partly be due to variability in the CI fitting. We investigated the effect of FOX, a software tool to program CIs using artificial intelligence (AI), on hearing outcomes.

Methods: Forty-seven experienced CI patients who came to our tertiary CI center for their annual follow-up between 2017 and 2020 were recruited for this study. They received a new CI map created by the AI software tool. CI parameters and auditory outcomes obtained with this new map were compared with those of the initial manual map after 15 days of take-home experience. Within-patient differences were assessed. At the end of the study, the patients were offered a choice to continue using the AI map or to revert to their old manual map.

Results: Several auditory outcomes improved with the AI map, namely, pure tone audiometric threshold at 6,000 Hz (median

improvement 10 dB, range = -20 to 50 dB, $Z = -2.608$, $p = 0.008$), phonemic discrimination scores (median improvement 10%, range = 0% to 30%, $Z = -4.061$, $p = 0.001$), and soft-intensity (median improvement of 10%, range = -20% to 90%, $Z = -4.412$, $p < 0.001$) to normal-intensity (median improvement of 10%, range = -30% to 60%, $Z = -3.35$, $p < 0.001$) speech audiometric scores.

Conclusion: The AI-assisted CI mapping model as a potential assistive tool may improve audiological outcomes for experienced CI patients, including high-frequency pure tone audiometry and audiometric speech scores at low and normal presentation levels. Clinical trial registration: NCT03700268

Key Words: Artificial intelligence—Cochlear implant—Fitting—Hearing tests—Parameters.

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INTRODUCTION

Cochlear implantation is an effective technique for restoring hearing in patients with severe to profound hearing loss. Although it currently provides good to excellent outcomes, substantial variability in speech recognition exists among cochlear implant (CI) patients (1–4).

The reasons behind the variable and lower auditory performances are still poorly understood (2,5,6). Factors that play a role include the extent and duration of auditory deprivation, differences in auditory sensitivity, language, and neurocognitive skills (2). Another factor observed is the significant

variability that exists in CI programming by centers and experts, which has an effect on the outcome of cochlear implantation (7–10).

The interactions between the different programmable parameters are not always clear, and most of them are rarely modified (7). Some CI patients may continue to experience poor to moderate hearing outcomes, despite many manual programming sessions by experienced clinicians. Although hearing outcomes vary greatly from patient to patient (4), reports show that stable fitting parameters can be reached after 3 months of activation (11,12). Different factors, such as age at cochlear implantation, age at onset of hearing loss, etiology of hearing loss, among others, contribute to the variability in outcome (13).

Recently, the Fitting to Outcome eXpert (FOX; Otoconsult NV, Antwerp, Belgium) software was developed to standardize and optimize the fitting of CI. The first generation of FOX (FOX1G) implemented a computer-assisted fitting strategy using deterministic logic (that is rule set), which was driven by measurable audiological targets. The second generation of FOX (FOX2G) has been developed using artificial intelligence (AI) with probabilistic logic and self-learning

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capabilities (14). Briefly, FOX2G is an intelligent and evolutive tool to assist the audiologist in the programming of CIs. It is based on an underlying model that simulates what happens in the electric field after acoustic stimulation of the system in function of the map (15). After measuring results with the current map, FOX2G generates millions of new maps and predicts the effect of each on the outcome. The outcomes used by FOX for map optimization are thresholds at 250, 500, 1,000, 2,000, 4,000, and 6,000 Hz (warble tones); speech audiometry in quiet (mono- or bisyllabic recorded words) at 40, 55, 70, and 85 dB SPL; spectral discrimination scores using an odd ball test in which 20 spectral contrasts are presented and the listener is expected to discriminate them (16); and loudness growth curves with narrow-band noises centered at 250, 1,000, and 4,000 Hz and a six-point visual analog scale for loudness scoring (14). The map with the better predicted effect is then suggested to the audiologist who can program it into the processor. For safety reasons, FOX2G is restricted in the magnitude of the map changes per step (17). For patients newly fitted with CIs, FOX offers the use of a set of predefined maps, called Automaps, as starting points for the activation (18). For experienced (manually fitted) CI patients, FOX provides two optimization approaches. The first one is called “FOX advice,” where the home map of the CI patient is the starting point. The CI patient undergoes extensive audiological testing with this map, which is then optimized by FOX (14). The second approach is called “Automap,” which is similar to the activation for a CI patient with a newly fitted CI. The manual map is replaced by a series of Automaps, with incremental T and C levels that are automatically generated by FOX and based on a statistical analysis of population data (19).

FOX has been demonstrated to be a valid assistive tool for CI fitting in the hands of audiologists (20). A prospective multicenter randomized controlled trial showed that FOX1G was reliable for initial CI activation. It provided a standard fitting protocol and reduced variability between centers (21). Among experienced CI patients with manual fitting, the “FOX1G advice” (18) and the “Automap” approach with FOX2G (20) were evaluated and showed equivalent performance to the manual map. However, the effect was not consistent across patients (18,20). Recently, we demonstrated improved hearing outcomes in two single cases that were experienced CI users with lower than average speech performance before FOX2G intervention (22). However, it is not yet known if the FOX2G “advice” approach produces the same results as the Automap approach (20).

Therefore, the purpose of this pilot study was to extend our previous research on a larger group of experienced CI patients and to see if their results could be optimized by means of “FOX advice.”

MATERIALS AND METHODS

Subjects

Forty-seven experienced CI patients between 10 and 87 years old, with an average CI experience of 10 years (Table 1), who came to our tertiary CI center for their annual follow-up be-

TABLE 1. Demographic data of the study patients

	Mean ± Standard Deviation or Median (Min–Max)
Age at enrollment (yr)	44 ± 25 55 (10–87)
Age of onset of hearing loss (yr)	13 ± 18 4.5 (0–69)
Age of CI (yr)	34.94 ± 25.42 38 (0.6–76)
Duration of CI use (yr)	9.8 ± 6 9 (1–23)
Number (% of patients)	
Sex	
• Women	26 (55%)
• Men	21 (45%)
Oral language users	47 (100%)
Hearing loss	
• Prelingual	19 (41%)
• Post lingual	28 (59%)
Etiology of hearing loss	
• Unknown	20 (43%)
• Genetic	10 (22%)
• Congenital infection	6 (13%)
• Auditory neuropathy spectrum disorder	2 (4%)
• Otosclerosis	3 (6%)
• Acquired infection	3 (6%)
• Others	3 (6%)
Implanted ear	
• Right	24 (51%)
• Left	23 (49%)
Contralateral ear	
• No hearing aid	18 (38%)
• Conventional hearing aid	13 (28%)
• CI	16 (34%)
Sound processor	
• CP800	6 (13%)
• CP900	29 (61%)
• CP1000	12 (26%)
Cochlear implant	
• CI24	28 (60%)
• CI4	9 (19%)
• CI5	9 (19%)
• CI6	1 (2%)
Speech processing strategy	
• ACE	39 (83%)
• SPEAK	8 (17%)

tween 2017 and 2020 were recruited. Subjects were excluded from the study if they demonstrated cognitive, medical, or social handicaps that would prevent completion of the study. An additional inclusion criterion was to have an Eargroup Speech Intelligibility Index (EaSI) score, i.e., a weighted score calculated as the average of the scores at 40, 55, 70 (×2), and 85 dB SPL) below 70%. This excluded patients with excellent results to avoid a ceiling effect.

Each patient had been implanted with a Cochlear device (Cochlear Ltd., Sydney, Australia), and except for two patients, all had undergone their switch-on session at our center. In case of bilaterally implanted patients, the side with the worst postoperative results was chosen.

Manual programming was performed by two experienced clinicians with over 20 years of experience. Programming with FOX software was done by a single clinician who received extensive training in the use of FOX.

The study was approved by the local ethical review board (Hospital St-Luc B403201734403), and all eligible patients agreed to participate in the study. There was no monetary incentive for participation in this study.

Procedure

The study was conducted in two sessions, with a 15-day interval. During the first session, CI patients underwent extensive audiological testing (see below for detailed outcome measures) with their manually fitted map. These auditory outcomes and map parameters were used by FOX to propose modifications to the manual map. Both the old and the new maps were written to the processor. Patients were encouraged to use the “FOX advice” map, but they were allowed to switch back to their old manual map if needed. The data logging of each map was recorded to control the daily duration of map use. During the second session, all audiological tests were performed with the “FOX advice” map, even if they did not use it, and subjects were asked to select their preferred map for future use.

CI Fitting Parameters

The studied CI fitting parameters were the T levels (corresponding to electrical thresholds expressed in current units), C levels (comfortable electrical levels in current units), T-SPL (the acoustical sound threshold sent at the electrical T levels), C-SPL (the acoustical sound comfort level sent at the electrical C levels), and electrical loudness growth value (a logarithmic function that compresses the acoustic input range onto the electrical output range).

The tests were administered using the software application Audiqueen (Otoconsult NV). The fitting software, Custom Sound 5.0 (Cochlear Ltd.), for cochlear processors and the FOX2G version of the AI application (Otoconsult NV) were used for the fittings.

Auditory Outcomes

The outcomes used by FOX for map optimization were pure tone audiometry, phonemic discrimination, loudness scaling, and speech audiometry. During the evaluation, the contralateral ear was plugged to ensure that only the CI ear responded.

Pure Tone Audiometry

Thresholds for warble tones were obtained in free-field conditions at 250, 500, 1,000, 2,000, 4,000, and 6,000 Hz. The 8,000-Hz frequency warble tone is not used by FOX. A pure tone average was calculated using thresholds of 500, 1,000, 2,000, and 4,000 Hz.

Loudness Scaling Curves

The A δ E loudness scaling test was performed using one-third octave narrow-band noises centered at 250, 1,000, and 4,000 Hz. The 1,876-ms stimulus was presented twice at each level, and the loudness was scored on a visual analog scale ranging from 0 (inaudible) to 6 (too loud). Levels were randomly presented at 5-dB increments between 30 and 80 dB HL (22). The root-mean-square (RMS) value was calculated as a measure of error compared with the normal

line. The normal line is the average of data obtained from 30 normally hearing volunteers. The RMS is the root of the sum of the (median response – the normal response) of all intensities (presentation levels).

Phonemic Discrimination

A δ E phoneme discrimination was performed using up to 20 speech sound contrasts (a-r, u-f, u-a, u-i, i-a, o-a, i- ϵ , m-z, s-f, ϵ -a, u-o, ∂ -a, ∂ -o, ∂ - ϵ , ∂ -i, z-s, v-z, ∂ -u, u-y, y-i), presented at 70 dB HL in an oddity paradigm (16). Briefly, the odd phoneme is presented no more than eight times. Based on the patient’s responses, the audiologist judges whether the patient discriminates the odd phoneme from the background phoneme. A positive score is given after three consecutive correct answers. A result of yes or no was recorded for the discrimination of each contrast. The percentage of well-discriminated contrasts was calculated.

Speech Audiometry

Speech audiometry was performed with bisyllabic French words (23) presented at 40, 55, 70, and 85 dB SPL in free field. Lists of 10 words were presented, and the percentage of correctly repeated words was recorded. A weighted EaSI score was calculated as the average of the scores at 40, 55, 70 ($\times 2$), and 85 dB SPL.

Statistical Analyses

All descriptive (mean, median, and standard deviation) and analytical statistics were performed using the SPSS software (IBM Statistical Package for Social Sciences version 26).

Box plots were used to show the results of the hearing tests (pure tone audiometry, phonemic discrimination, loudness scale curves, and speech audiometry).

The Wilcoxon signed rank test with Holm correction was used to assess whether the mean ranks of our samples differed. The Holm correction is a sequentially rejective Bonferroni test that progressively adjusts the threshold for multiple comparisons (24).

RESULTS

CI’s Parameters

Forty-seven patients, 10–87 years old, with an average implant use of 10 years were enrolled in this study between 2017 and 2020 (Table 1).

Figure 1 shows the mean differences in T and C levels per electrode ($n = 22$) between the manual and the FOX advice maps. It shows that FOX made different and subtle changes per electrode. Overall, FOX showed a tendency of lowering the electrical T and C levels at low frequencies and increasing them at high frequencies. The changes were larger for C levels than for T levels, resulting in a decrease in the electrical dynamic range for low frequencies and an increase for high frequencies.

The parameters T-SPL and C-SPL determine the acoustic input dynamic range. Overall, FOX tends to decrease this input dynamic range by increasing T-SPL and decreasing C-SPL. The T-SPL values can range from 9 to 50 dB SPL in the cochlear fitting software, with a default value of 25 dB SPL.

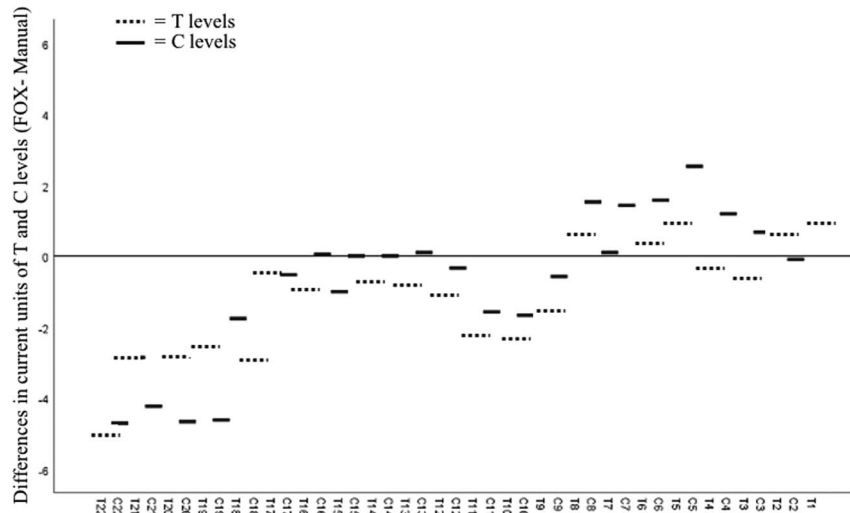


FIG. 1. T and C level differences (FOX – manual) by electrodes (x-axis). Electrodes (E) 22 to 17 correspond to spectral bands of low (188–938 Hz), E 16 to 7 correspond of mid (1,063–3,563 Hz), and E 6 to 1 correspond of high frequencies (4,063–7,938 Hz).

In the majority of manual maps, the default value of 25 dB SPL was not modified (Table 2A). FOX tended to increase the manual fitting values ($Z = -2.899$, $p = 0.004$). The highest T-SPL in FOX maps never exceeded 36 dB SPL, and FOX itself never modified manual values to above 27 dB SPL. The C-SPL values can range from 65 to 84 dB SPL in the cochlear fitting software, with a default value of 65 dB SPL. This value is coupled to the LG value, which means that changing one value automatically changes the other. For instance, for C-SPL values of 65, 70, 75, or 80 dB SPL, the LG was automatically set to 20, 18, 16, and 15, respectively. Although the majority of manual maps had values higher than the default 65 dB SPL, FOX tended to reduce them to 65 in most of the cases (Table 2B). The values proposed by FOX were significantly smaller than those previously reported ($Z = -3.78$, $p < 0.001$).

The LG values were between 10 and 50 for the cochlear fitting software. FOX significantly reduced LG ($Z = -2.746$, $p = 0.006$) (Table 2C). Cochlear's fitting software locks combinations of C-SPL and LG, meaning that changing one automatically changes the other parameter. In consequence, the manual maps respected this combination in 100% of cases. In FOX maps, this was only so in 34% of the cases.

In summary, the manual fitting was often within the cochlear default parameters, T-SPL = 25, C-SPL = 65 or 70, and LG = 20. FOX advice maps often deviated from these values and were most often as follows: T-SPL = 23, 25, or 27; C-SPL = 65; and LG = 18. As a result, the FOX fittings allow the auditory perception of low-intensity sounds (25).

Supplemental Content, <http://links.lww.com/MAO/B570>, including raw data of T and C levels, T-SPL, C-SPL, and loudness growth with manual map and FOX map is available.

Auditory Outcomes

Within-patient analysis showed that at 6,000 Hz, the audiometric thresholds were significantly better (median improvement 10 dB, range = -20 to 50 dB) with the FOX advice maps ($Z = -2.608$, $p = 0.008$). Group results showed more

consistent thresholds with smaller ranges (15–55 dB HL) and fewer outliers compared with those obtained with the manual map ranging (range = 15–85 dB HL).

The loudness scaling results for the tested frequencies were not significantly different between the manual and the FOX advice maps ($p > 0.05$).

The phonemic discrimination scores were significantly better (median improvement 10%, range = 0% to 30%) with the FOX advice maps in the within-patient analysis ($Z = -4.061$, $p = 0.001$) (Fig. 2). The FOX maps were also more consistent with a distribution ranging from 80% to 100% as compared with 60% to 100% with the manual map.

FOX maps also showed better speech audiometric scores more frequently (Figs. 3 and 4). Within-patient analysis showed that the FOX advice maps had higher scores than the manual map at 40 dB SPL with a median improvement of 10% (range = -20% to 90%) ($Z = -4.412$, $p < 0.001$) and at 55 dB SPL with a median improvement of 10% (range = -30%

TABLE 2. Number of subjects with a T-SPL value range of 15–20, 21–25, 26–30, and >30 dB SPL and the maximum value (max) with MF and FOX (A); with a C-SPL value of 65, 70, 75, or 80 with MF and FOX (B); and with LG values ranging from 15 to 24 with MF and FOX (C)

		A						
		15–20	21–25	26–30	>30 (Max)			
MF		3	30	7	7 (40)			
FOX		3	22	18	4 (36)			
		B						
		65	70	75	80			
MF		22	16	8	1			
FOX		33	13	1				
		C						
		15	16	18	19	20	22	24
MF		1	8	16		22		
FOX				24	1	14	4	4

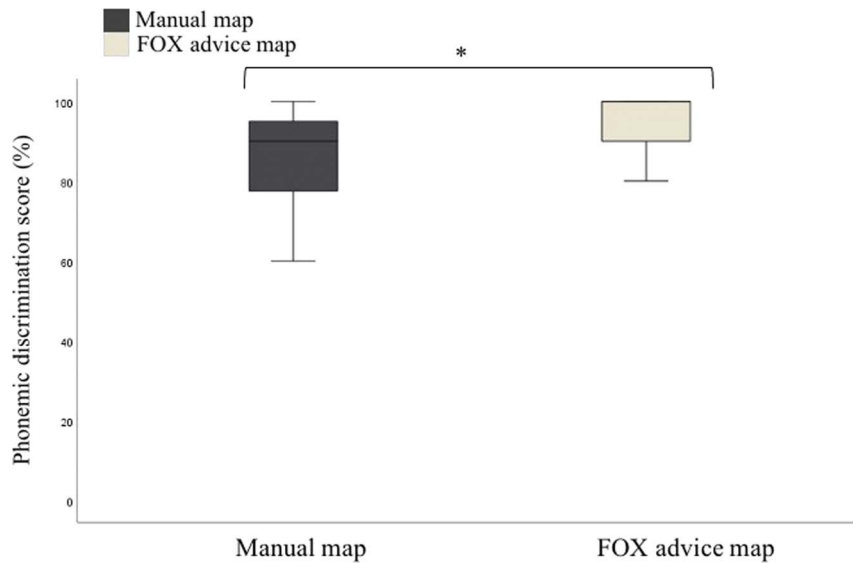


FIG. 2. Box plots displaying the phonemic discrimination score with the manual map (*black*) and the FOX advice map (*gray*). Boxes: range between 25th and 75th percentile; whiskers: 1.5*interquartile (IQR); and central point: median (* $p = 0.001$).

to 60%) ($Z = -3.35, p < 0.001$), and also for the EaSI score with a median improvement of 10% (range = -21% to 35%) ($Z = -4.405, p < 0.001$).

The analysis of the EaSI scores showed an improvement for 89% (42/47) of the patients, no change for 4% (2/47), and a slight decrease for 6% (3/47), with the FOX advice map (Fig. 4). In case of improvement, almost all patients (91%) appreciated this new map and chose the FOX map as the preferential map for the future. The few patients who did not select the FOX map (9%) were interviewed for their reasons for the other choice. These patients stated that the sound from FOX map was uncomfortable due to the presence of high frequencies (6,000 Hz).

Data logging was recorded in 38/47 CI patients (nine were not available for technical reasons). Actual daily duration

(in hours) of CI use with AI map was significantly longer than with the manual map, with a median of 9.75 h and a range from 0.7 to 15.8 versus a median of 1.2 h with a range from 0 to 10 ($Z = -4.982, p < 0.001$).

DISCUSSION

In this pilot study, we investigate whether FOX can improve the performance of experienced CI patients with poor performance. For this, we used the second generation of FOX (FOX2G), which uses full AI to optimize the map (14,17,19,20). Instead of starting from scratch with Automaps, we asked FOX to start from the existing home maps that had been programmed by expert CI clinicians and that the CI patients had been wearing for a long time.

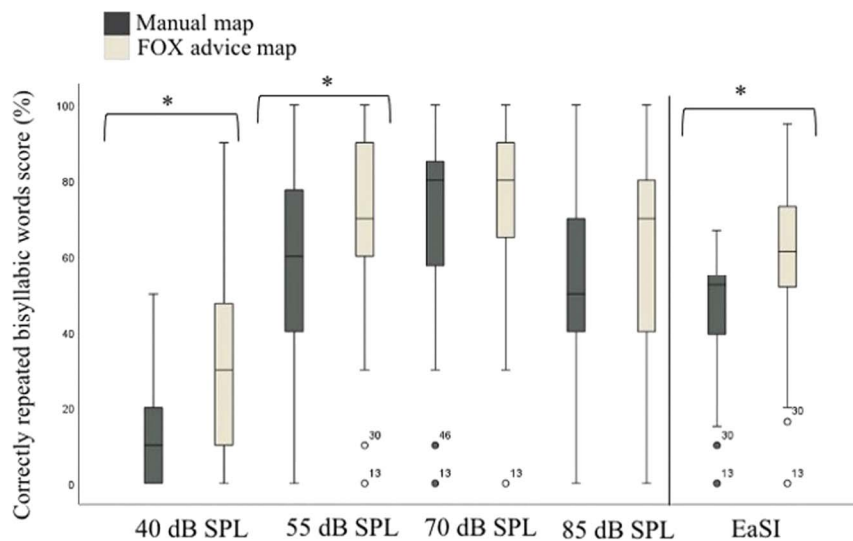


FIG. 3. Box plots displaying the speech audiometry scores at 40, 55, 70, and 85 dB SPL and the EaSI score, with the manual map (*black*) and the FOX advice map (*gray*). Boxes: range between 25th and 75th percentile; whiskers: 1.5*interquartile (IQR); and central point: median (* $p < 0.001$).

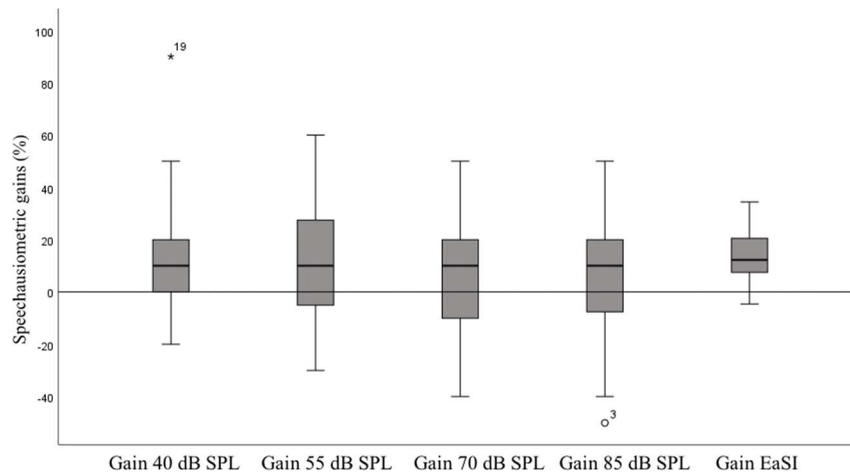


FIG. 4. Box plots displaying the distributions of within-subject speech audiometric gains (scores with FOX map – scores with manual map) at 40, 55, 70, and 85 dB SPL and the EaSI score. Boxes: range between 25th and 75th percentile; whiskers: $1.5 \times \text{IQR}$; and central point: median ($*p < 0.001$).

Compared with manual maps, FOX seems to modify more electrical parameters. It seems that clinicians program with their habits, which are defined by center policy and personal experience. Therefore, when fitting parameters stabilize after a few months, it does not necessarily mean that optimal performance has been reached. It could be that the clinician believes that they have reached their best fit. The changes in FOX were often subtle, and there seems to be an overall tendency to tilt the manual maps by decreasing the energy at low frequencies and increasing it at high frequencies. For T-SPL, C-SPL, and LG, FOX often modifies the default values. It tends to decrease the acoustic dynamic range by increasing the T-SPL and decreasing the C-SPL. In our data set, the effect of all these subtle modifications was mainly shown by better hearing thresholds at 6,000 Hz, better spectral discrimination scores, and better speech recognition at 40 and 55 dB SPL and better EaSI scores. One can argue whether a slight increase in speech recognition score is clinically significant or whether a threshold needs to be set to define clinical significance. However, such threshold would be arbitrary, and it would depend on many other factors for which we do not control, such as acoustical environment, linguistic knowledge, linguistic complexity, etc. For that reason, we have chosen to report all positive values as “improvement” and all negative values as “deterioration.” It is up to the reader to interpret the medians and ranges given in view of clinical significance. Taking into consideration that EaSI score is the average of 5 scores, an average within-patient improvement of 9% is not only statistically significant but also seems clinically significant as most patients prefer the FOX mapping in this study.

It should be noted that 11% of our CI patients did not improve with the new AI map. There are two potential reasons for this lack of acute improvement. First, it is possible that these patients need more time to adapt to their new map, especially for older patients who have become accustomed to their usual map for years (29). A second reason is that FOX itself has some limitations in the map changes it is authorized to make. For some patients, the first map proposed

by FOX may not be ideal, and it is possible that several steps are required for FOX to achieve the optimal map. However, our study protocol did not include multiple sessions. Additional sessions may allow FOX to implement incremental map changes. In these cases, the alternative approach of “start again with Automaps” may be a more appropriate methodology as FOX will then be operating within the area of expertise.

In this study, we chose to use FOX in experienced CI patients with an EaSI score below 70%. One might argue that it would have been more complex to demonstrate better hearing performance in more patients who are willing to participate (2) because of “the ceiling effect” (26). On the other hand, our selected patients constitute cases whose performance could not be improved despite numerous manual fitting sessions. In our group of 47 experienced CI patients, FOX managed to improve the speech audiometric outcome in 89% of cases. Our results suggest that the performance may still be improved among the experienced CI patients with AI-assisted programming such as FOX despite previous thoughts that they had reached maximal performance after multiple manual fitting sessions.

It seems relevant that FOX2G can improve both the hearing outcome and the acceptability of the map in experienced CI patients, with a large majority (89%) preferring FOX’s map over the manual map in our study. This is in line with the findings of Waltzman and Kelsall (20), who reported 82% of their study group preferring the FOX map. These results indicate that FOX’s strategy of fitting “for performance” is compatible with a comfortable outcome for the patient.

Finally, we want to point out that external factors may also have an effect on the results, such as the type of counseling given. Expectations regarding new fitting methods and confidence in AI technology may influence the patient’s attitude toward the FOX map. Ideally, to avoid any bias, both the patient and the clinician should be “blinded,” which means that the patient should not know which map is the new one, and the clinician testing the patient should not be the one programming the processor (27). However, blinding the patient

is not possible. Even without being informed, our patients could easily identify the new map. For practical reasons, we could not organize the testing performed by a different audiologist than the one programming the processor. Other limitations of the study include relatively low sample size and statistical power along with the heterogeneity of the participant characteristics (i.e., age, duration of deafness, etc.) given the pilot nature of the study. Despite these limitations, our results add to the growing evidence on the value of AI-assisted CI fitting.

Most audiological tests we used are beginning to become available as self-tests, namely, pure tone audiometry, spectral discrimination, and loudness scales, whereas speech audiometry self-tests are still under development. Self-tests will not only save time but also eliminate possible tester bias by leaving the interpretation of the patient's responses to the systematics of the computer algorithms (28).

CONCLUSION

This pilot study with 47 experienced CI users shows that FOX is a useful tool in the hands of experienced audiologists to modify the maps using AI-driven algorithms to possibly achieve better audiological results. Moreover, it shows that FOX fitting changes parameters that are rarely changed in manual programming. Although FOX does not currently aim to replace manual expertise, it does seem suitable as an additional tool in combination with manual procedures.

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