Prospective Comparison Between Manual and Computer-Assisted (FOX) Cochlear Implant Fitting in Newly Implanted Patients

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Objective: A prospective, longitudinal, randomized controlled trial with an original crossover design for 1 year was conducted to compare manual fitting to artificial intelligence-based fitting in newly implanted patients.

Design: Twenty-four patients who received their first cochlear implant (CI) were randomly assigned to the manual or Fitting to Outcome eXpert (FOX) arm; they followed the corresponding fitting procedures for 1 year. After 1 year, each patient was switched to another arm. The number of fittings, auditory outcomes (pure-tone thresholds, loudness scaling curves, spectral discrimination scores, bisyllabic word recognition in quiet and noise, and speech tracking), fitting session questionnaire, and CI parameters (T level, C level, Threshold Sound Pressure Level (T-SPL), Comfortable Sound Pressure Level (C-SPL), and loudness growth value) were compared between the two groups. Differences between the two groups were analyzed using the Mann-Whitney test, and Holm corrections were applied for multiple statistical tests. At the end of the crossover session, patients were offered the choice to continue with their old or new map.

Results: As early as 3 mo postactivation, the FOX group showed less variability and significantly better speech intelligibility in quiet conditions at 40 and 55 dB SPL and noise ($p < 0.05$) with median phoneme scores of 50%, 70%, and 50% at 55, 70, and 85 dB SPL compared with 45%, 50%, and 40%, respectively. This group showed better results at 12 mo postactivation ($p < 0.05$). In the manual group, 100% of the patients decided to keep the new FOX map, and 82% performed better with the FOX map. In the FOX group, 63% of the patients decided to keep the manual map, although the measurable outcome had not improved. In this group, participants reported to prefer the manual map because it felt more comfortable, even if the FOX map gave better measured outcome.

Conclusion: Although the study size remains relatively small, the AI-FOX approach was equivalent to or even outperformed the manual approach in hearing performance, comfort, and resources. Furthermore, FOX is a tool capable of continuous improvement by comparing its predictions with observed results and is continuously learning from clinicians' practice, which is why this technology promises major advances in the future.

Key words: Artificial intelligence, Cochlear implant, Newly users, Programming.

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INTRODUCTION

A cochlear implant (CI) is an advanced implantable medical device capable of restoring hearing functionality. Its main indication is severe to profound sensorineural HL, but its use is expanding as candidacy criteria evolve (Varadarajan et al. 2021).

The current practice of CI fitting is manual fitting. The essence of manual fitting (MF) is to find and establish threshold levels (T) and comfortable electrical stimulation levels (C). Before looking for these, most clinicians start by measuring impedances (Vaerenberg et al. 2014). There are two approaches to determining these T and C levels: the behavioral approach and the objective approach. However, both approaches lack a formal procedure, and many clinicians have their own way of doing things (Vaerenberg et al. 2014). Once the T and C levels are determined, the following programming sessions serve to optimize the CI patient's auditory abilities. Optimization is primarily (or exclusively) based on subjective auditory feedback from the patient to the clinician. Conventional auditory tests, namely tone and speech audiometry, are often, but not always, used for programming (Zwolan et al. 2020). There are guidelines (Has 2007), recommendations in text books (Wolfe 2018; Gifford 2019) and Cochlear company have recommended "best practice" programming that they teach to new programming audiologists, but at the clinical level, the guidelines are often not or not strictly followed by clinicians (Vaerenberg et al. 2014). This has resulted in diverse programming techniques among centers and even within centers, as well as varying patient management protocols and outcomes (Vaerenberg et al. 2014; Browning et al. 2020; Wathour et al. 2021). The lack of standardized protocols among CI centers is concerning, as postoperative audiological care received by patients can have a great impact on their outcomes (Zwolan et al. 2020).

To overcome this lack of standardization, Eargroup (Antwerp, Belgium) developed a computer-assisted fitting strategy, referred to as the "Fitting to Outcome eXpert" (FOX, Otoconsult NV, Antwerp, Belgium, CE certified class I medical device, not yet certified by FDA). Its objectives were to optimize the programming, reduce intercenter and intracenter variability in fittings, base the fitting on hearing test results and targets, and limit the number of fitting sessions (Vaerenberg et al. 2014). The first version, FOX1G, used algorithms in a deterministic way to analyze and optimize the patient's map (Govaerts et al. 2010; Meeuws et al. 2017). FOX1G processed the results of the hearing tests using the patient's map. If certain targets were not reached, the performance was judged to be suboptimal and FOX proposed a new map with modified parameters. The current generation, FOX2G, is based on a hybrid model

with deterministic and probabilistic logic and learning capabilities. Based on the active map and audiological outcomes, a new map is proposed with predicted outcomes that outperform the measured outcomes with the active map. The selection of this new map is based on a utility function that calculates a weighted combination of outcome measures. The tests (puretone audiometry, phonemic discrimination, loudness scaling, and speech audiometry) are administered by the software application Audiqueen (Otoconsult NV, Antwerp, Belgium). The utility function, which maps the predicted outcomes onto a real number, is always updated as the system learns from previous outcomes (Meeuws et al. 2017; Wasmann et al. 2021). The clinician is free to accept or overrule the new map.

Parallel to the development of FOX, the Eargroup introduced a fitting protocol consisting of three postoperative fitting sessions, including the CI activation within the first 3 mo postactivation, one fitting session at 9 mo postactivation, followed by annual control sessions. During a typical CI activation with FOX, a list of 10 "automaps" (computer-generated maps) is generated with incremental T and C levels. The CI recipient starts with the lowest automap and is instructed to change progressively to the next automap, and hence to higher T and C levels, allowing for a progressive experience and tolerance. The highest automap reached, without causing lasting discomfort, serves as the starting point for the next fine-tuning based on the measured outcomes. This is often the fifth or sixth map of the incremental series (Govaerts, unpublished data). During the three following sessions, typically at intervals of 15 days, 3 mo, and 9 mo, audiological test results (pure-tone audiometry, spectral discrimination, loudness scaling, and speech audiometry) are performed using FOX to optimize the MAP. This is a substantial reduction in fitting time and resources compared with manual fitting, which typically takes between 5 and 10 scheduled programming sessions in children (Goehring & Hughes 2016) and adults (Vaerenberg et al. 2014; Wathour et al. 2021). Vaerenberg's survey is more than 10 years old and practice has undoubtedly changed since then in most CI centers. But the essence of manual fitting has still remained largely the same. It must be said that in addition to changing T and C levels, FOX also adjusts all other parameters that can be changed with Cochlear's fitting software, such as LG, T-SPL, C-SPL and the number of active electrodes (Meeuws et al. 2017). These parameters are adjusted much less by audiologists performing MF.

The reliability of FOX has been previously demonstrated in a prospective multicenter randomized controlled trial for initial CI activation by providing a standard fitting protocol and reducing variability between centers (Battmer et al. 2015). Waltzman and Kelsall (2020) reported that speech performance outcomes in 55 experienced CI users after 1 mo of use of the FOX2G map were equivalent compared with their clinician-created maps, and the majority of patients (82%) preferred the new FOX map. Complementary, improved hearing outcomes with FOX2G maps were found in two cases (Wathour et al. 2019) and in a larger group of experienced CI recipients with poor to moderate performance (Wathour et al. 2021). Furthermore, another recent study showed equivalent hearing scores in quiet and noise in 31 newly fitted patients with FOX compared with their former patients with CI532 (Zwolan et al. 2020). These studies demonstrate the feasibility and usefulness of FOX but have limitations, such as a small number of subjects or the absence of a randomized control group.

This study aimed to extend our previous research on FOX and address the limitations of previous studies on fitting in newly CI patients. To compare manual fitting with FOX-based fitting, we conducted a prospective, longitudinal, randomized controlled trial with a crossover design over 1 year. The primary study outcome consisted of auditory results. The secondary outcome consisted of the number of fitting sessions and the map parameters.

MATERIALS AND METHODS

Participants and Study Design

Twenty-four patients who received their first CI between September 2017 and August 2020 were included in this study. Two patients left the study just before the crossover session for personal reasons. All patients were ≥18 years old, had post-lingual deafness, and spoke French as their mother tongue. Written informed consent was obtained from all patients before inclusion. Patients with deafness due to meningitis were excluded. There was no monetary incentive to participate in the study.

We performed a prospective longitudinal randomized crossover study with two study arms (Table 1) that were randomly

TABLE 1. Demographic data of study participants by group manual fitting (MF) and FOX

	MF (n = 12)	FOX (n = 12)
Age at enrollment = Age of CI (years)		
Mean (standard deviation)	62 ± 8	57 ± 14
Median (range)	63 (43–71)	59 (32–79)
Age of onset of hearing loss (years)		
Mean (SD)	46 ± 17	31 ± 19
Median (range)	50 (6–70)	33 (5–57)
Speech audiometry preop (%) (phon monosyll)		
• Auditory condition (Median (range))	40 (13–73)	45 (20–75)
• Audiovisual condition (Median (range))	70 (60–85)	76 (62,5–92)
Sex	Number and % of subjects	Number and % of subjects
• Female	11 (92%)	8 (66%)
• Male	1 (8%)	4 (34%)
Speech intelligibility rating (SIR) 5	12 (100%)	12 (100%)
Etiology of hearing loss		
• Unknown	6 (50%)	3 (25%)
• Genetic	3 (25%)	7 (58%)
• Post-trauma	1 (8%)	
• Auditory neuropathy	1 (8%)	
• Otosclerosis	1 (8%)	
• Meniere's disease		2 (17%)
Implanted ear		
• Right	5 (42%)	8 (66%)
• Left	7 (58%)	4 (34%)
Contralateral ear		
• No hearing aid	2 (17%)	
• Hearing aids	10 (83%)	12 (100%)
Sound processor		
• CP900	9 (75%)	4 (34%)
• CP1000	3 (25%)	8 (66%)
Cochlear implant		
• CI5	5 (42%)	10 (83%)
• CI6	7 (58%)	2 (17%)

assigned to the manual (MF) or FOX (FOX) arm. They followed the corresponding fitting procedures, MF or FOX, for 1 year. After 1 year, each patient was switched to another arm. Each patient had been implanted with a Cochlear device (Cochlear Ltd., Sydney, Australia) in our academic hospital and performed all fitting sessions in our hearing rehabilitation center.

Only two clinical audiologists participated to the fittings and the outcomes assessment. Manual programming was performed by always the same clinician audiologist with over 20 years and more than 700 CI fittings experience. Programming with FOX software was done by always the same young clinician audiologist who received extensive training in the use of FOX.

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

Fitting Procedures

Manual Fitting • Before starting manual fitting, the audiologist must wait 2 to 4 weeks after CI implantation to give the patient time to heal. In our center, manual programming takes place over ten sessions in the first year: At the first programming session, the audiologist performs a postoperative pure-tone audiometry to verify residual hearing and performs the impedance measurement. At each session, the manual fitting starts with the evaluation of the impedances. The recommended default strategy recommended by the company for starting a program is ACE with a stimulation speed of 900 pps, a T-SPL of 25 dB SPL, a C-SPL of 65 dB SPL, a pulse width of 25 μs, 8 maxima, a volume of 6 and a sensitivity of 12. When an audiologist creates a new program on the Custom Sound (Cochlear's programming software), channels 22, 16, 11, 6, and 1 are highlighted to measure the T and C levels, and then extrapolate the intermediate values. Once these levels are obtained, the audiologist decreases the T and C levels by 10 to 20 steps, and activate the speech processor to adapt the T and C levels according to the patient's reactions, looking for comfort. The audiologist creates 4 progressive MAPs so that the patient gets used to it step by step.

The second session usually takes place 1 week after the first session. The audiologist performs a pure tone and speech audiometry with the cochlear implant to see how the patient is progressing, and checks the impedances. The audiologist will modify the T and C levels according to the pure-tone audiometry.

The third fitting takes place 1 week after the second fitting. The fitting sessions follow the same pattern: pure tone and speech audiometry with the implant, impedance measurement, and modification of the T and C levels according to the tests performed. The audiologist continues to implement progressive MAPs into the patient's processor until the pure-tone audiometry is within range (20 to 30 dB HL).

The fourth fitting takes place 2 weeks after the third fitting. As in the previous sessions, the audiologist performs audiometric testing, impedance measurement, and MAP optimization. The audiologist may perform the NRTs if they were not measured during the CI surgery, to verify that they are within ¾ of the patient's dynamic range. The results obtained in speech therapy are taken into account to adapt the implant. For example: if low-pitched words are less well perceived, the audiologist increases the T & C levels of the low-pitched electrodes. If there is background noise in the processor, the T-SPL can be increased.

The fifth, sixth, seventh, eighth, ninth, and tenth sessions always follow the same principle with the aim of achieving an ideal MAP giving to the patient's his or her hearing best test results.

FOX • The FOX protocol established by the Eargroup was followed (see Introduction). Briefly, it consists of three switch-on sessions. During the first session, the clinician uses the set of 10 pre-constructed automaps (Govaerts et al., 2010; Buëchner et al., 2014). Activation begins with the first map in live mode. The first map is the map with the lower T- and C-values, also called the "Switch-on" map. With this map in live mode, the audiologist explains how to manipulate the processor and other basic information is given. This gives the CI receiver some time to adjust to the new stimulation of his auditory system. Then the next 4 maps are written into the processor and the patient goes home with the first map active. He or she is encouraged to move to a higher map every few days to build up loudness tolerance in particular. The patient then comes to the second session with the fourth map. During the second session, even higher automaps are tried and the highest automap tolerated by the patient serves as the starting point for further adjustments. These adjustments are based on the patient's audiological test results. In the second session, audiometry and spectral discrimination tests are performed, in the third session loudness scaling and speech audiometry. The results, together with the map data, are analyzed by FOX and a new map is proposed. The audiologist is then free to accept or reject this map, but in the present study all proposed maps were accepted by the audiologist without any manual modification. These maps were then written to the processor for home use.

Outcome Assessment

Protocol • The number of sessions for each fitting procedure type was recorded; with manual programming, eight to ten sessions were scheduled, meanwhile with FOX, four sessions were scheduled. The subjects were free to ask for more sessions if needed.

Hearing Performance Measurement • The audiological assessment consisted of four tests required by the FOX protocol (audiometry, spectral discrimination, loudness scaling, and speech audiometry in quiet). In addition to these tests, clinicians were free to use other tests (e.g., speech tracking), as they are sometimes considered useful to document patient's performance.

The time schedules are shown in Table 2. For each test, the contralateral ear was plugged to ensure that only the studied CI ear responded.

The acoustic hearing tests are performed in free-field conditions in a soundproof booth.

Pure-tone Audiometry

Audiometric-aided thresholds for warble tones were obtained in free-field conditions at 250, 500, 1000, 2000, 4000, and 6000 Hz (the 8000 Hz frequency warble tone was not used in FOX).

Spectral Discrimination

Phoneme discrimination was performed using up to 20 speech sound contrasts (a-r, u-ʃ, u-a, u-i, i-a, o-a, i-ɛ, m-z, s-ʃ, ɛ-a, u-o, ə-a, ə-o, ə-ɛ, ə-i, z-s, v-z, ə-u, u-y, y-i), presented at 70 dB hearing loss (HL) in an oddity paradigm (see Govaerts 2006 or https://support.otoconsult.com/support/solutions/articles/3000089579-how-to-perform-the-a-e-discrimination-test- for test details).

TABLE 2. Timetable for hearing performance measurement post-CI activation and during the crossover session.

	Pure-tone Audio	Spectral discrimination	Loudness scaling	Speech audio quiet	Speech audio noise	Speech tracking
+2 weeks	X	X				
+1 mo						X
+3 mo	X		X	X	X	X
+6 mo						X
+9 mo	X			X	X	
+12 mo	X		X	X	X	X
Crossover						
session 1 (home map)				X	X	
session 2 (alternative map)				X	X	

The odd phoneme is presented no more than eight times. Based on the patient's responses, the audiologist determines whether the patient discriminates the odd phoneme from the background phoneme. As a general rule, a positive score is given after three consecutive correct answers. A result of yes or no was recorded for the discrimination of each contrast.

Loudness Scaling Curves

The A§E loudness scaling test (Otoconsult NV, Antwerp, Belgium) was performed using one-third octave narrow-band noise centered at 250, 1000, and 4000 Hz. The 1876 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 in 5 dB increments between 30 and 80 dB HL (Vaerenberg et al. 2014). The root means square (RMS) value was calculated as a measure of error compared with the normal line. The normal line is the average of the data obtained from 30 volunteers with normal hearing (unpublished data). The RMS is the root of the sum of the median response (normal response) of all intensities (presentation levels) (for more details, https://audiqueen.support. otoconsult.com/support/solutions/articles/3000089582-how-to-perform-the-a-e-loudness-scaling-test).

Speech Audiometry in Quiet

Speech comprehension of words was performed with monosyllabic French words (Tixier et al. 2012) presented at 40, 55, 70, and 85 dB SPL in the free field. A list of 15 words was presented, and the percentage of correctly repeated phonemes was recorded. A weighted score, the Eargroup Speech Intelligibility Index (EaSI), was calculated as the average of the scores at 40, 55, 70 (×2), and 85 dB SPL.

Speech Audiometry in Noise

Speech audiometry was performed using Marginal Benefit Acoustic Amplification (MBAA, 36 French lists of 15 sentences), presented with two signal-to-noise ratios (SNR), 0 and +10 dB SPL (Richard et al. 2012; Mosnier et al. 2014; Leclercq et al. 2018). The length of the sentences ranged from 3 to 15 words and all types of sentences were presented. The percentage of correctly repeated words was then recorded. The speaker was a female speech-language pathologist with a normal speech rate in babbling noise (2 female and 2 male voices) presented at a fixed level of 60 dB SPL (James 2015).

Speech Tracking

An experienced speech therapist read a phonetically balanced text through a live voice to obtain the patient's tracking rate (Filippo and Scott 1978). Patients were asked to repeat word by word and sentence by sentence. The number of correct words repeated in 3 minutes was calculated and divided by 3 to measure the number of correct words per minute (wpm). A score of ≥60 can be considered a good performance for patients with CI (Plant 2001).

Questionnaire

Fitting Session Questionnaire

At the end of each fitting session, all patients were asked to complete a five-step worst-best Likert scale questionnaire about the duration of the session and the tests (1 = very long; 5 = very short), the general feeling of the session (1 = unpleasant; 5 = pleasant), pain during fitting (1 = intolerable; 5 = no pain), the clinician's explanations (1 = not clear; 5 = very clear), and general appreciation (1 = I do not like to come for my CI fitting; 5 = It is a pleasure to come for my CI fitting).

CI Fitting Parameters

The CI fitting parameters collected for analysis in this study where those fitted at activation and at 12 mo postactivation were: T level (corresponding to electrical thresholds expressed in current units that are determined by the electric charge delivered per phase [Incerti et al. 2018]), C level (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 (LG) value (a logarithmic function that compresses the acoustic input range into the electrical output range).

Audiological tests were performed using the software application Audiqueen (Otoconsult NV, Antwerp, Belgium). The fitting software Custom Sound 5.0 (Cochlear Ltd, Sydney, Australia) for Cochlear processors and the FOX2G version of the artificial intelligence (AI) application (Otoconsult NV, Antwerp, Belgium) were used for the fittings.

Crossover Session

The "FOX group" is the group that started with FOX for 1 year and then switched to MF, meanwhile the "MF group" started with MF for 1 year and then switched to FOX.

They followed the corresponding fitting procedures, MF or FOX, for 1 year. After 1 year, each patient was switched to the alternative study arm. This means that patients with the manual arm were attended by the FOX audiologist who used FOX in an attempt to optimize the manual map, and patients with the FOX arm were attended by the manual fitter who attempted to

optimize manually the FOX map. All this was done in two sessions. In the first crossover session, hearing performance (speech audiometry in quiet and in noise) was assessed with the original (= "current active") map by the "other" audiologist before the map optimization by FOX or manually. The audiologist considers these outcome measures to propose an alternative map. In the second session, 15 days later, the participants were assessed with the alternative map. The map parameters (T and C levels, volume, number of electrodes, T-SPL, C-SPL, and LG) were compared, as well as the patient's preference for either map. We then compared the map used before the cross to the alternative map in terms of speech audiometric results in quiet and noise (<15%, >15% and +/- 15%) and subjective opinion on comfort.

Statistical Analysis

All descriptive (mean, median, and standard deviation) and analytical statistics were performed using SPSS software (IBM Statistical Package for Social Sciences version 27 for Windows). Box plots were used to show the results of speech audiometry in noise and speech tracking, and error bars indicating 95% confidence interval were used to show the results for the T and C levels and speech audiometry in quiet conditions. These graphs were run after the CI activation and during the crossover session.

The Shapiro-Wilk test was used to evaluate the normality of the data distribution. As the data were not normally distributed, comparisons between the MF and FOX groups were performed using the nonparametric Mann-Whitney U test. The Levene's test was used to determine homogeneity in variance between the two groups. The p values were adjusted with the Holm correction, a sequentially rejective Bonferroni test that progressively adjusts the threshold for multiple comparisons (Pfister et al. 2020). A p value < 0.05 was considered significant.

RESULTS

Outcome Assessment
Protocol • As expected, the number of sessions over the year was significantly lower (U = 0; p < 0.001) in the FOX group (median, 4; range, 4 to 7) than in the MF group (median, 9; range, 8 to 13).

Hearing Performance Measurement
Pure-tone Audiometry
The group comparison at 12 mo postactivation showed only one significant difference for the audiometric thresholds at 6000 Hz, which were significantly better (U = 22; p = 0.007) with the FOX maps, ranging from 10 to 35 dB HL (median, 20 dB HL) compared with those obtained with the manual map ranging from 20 to 80 dB HL (median, 25 dB HL).

Loudness Scaling Curves
There were no significant differences at 3 and 12 mo postactivation between the two groups (p > 0.05)

Phonemic Discrimination
The group comparison, 2 weeks postactivation, did not show significant differences in phonemic discrimination scores between manual (median, 87.5%; range, 54% to 100%) and FOX (median, 95%; range, 95% to 100%) maps. The Levene's test did not show homogeneity in variances, $F(1,22) = 6.35$; $p = 0.019$, between the MF ($\sigma = 16.17$) and FOX ($\sigma = 2,57$) groups.

Speech Audiometry in Quiet
As shown in Figure 1, group comparison showed that the FOX maps had higher scores than the manual map at 40 dB SPL (Fig. 1A) at 12 mo postactivation with a median of 35% and a range of 20% to 55% versus a median of 15% and a range of 0% to 30% (U = 7; p = 0.016); at 55 dB SPL (Fig. 1B) at 3 mo postactivation with a median of 65% and a range of 40% to 85% versus a median of 30% with a range of 0% to 80% (U = 26; p = 0.025), 9 mo postactivation with a median of 70% and a
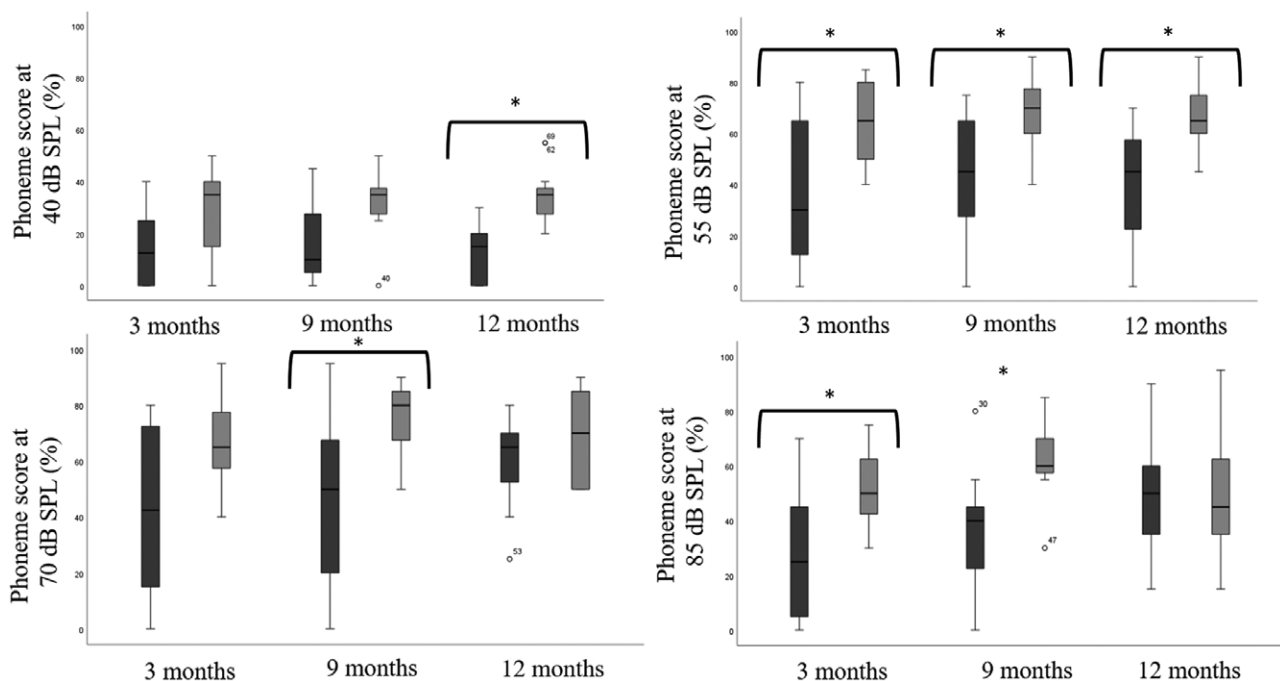

Fig. 1. Box plots displaying the scores of speech audiometry phoneme at (A) 40 dB SPL; (B) 55 dB SPL; (C) 70 dB SPL; and (D) 85 dB SPL at 3, 9, and 12 mo postactivation, with the manual map (Black) and the FOX map (gray). Boxes range between the 25th and 75th percentile, whiskers show the top and bottom 25% of the scores (approximately), and central point: median (*p < 0.05).

range of 40% to 90% versus a median of 45% with a range of 0 to 75% (U = 27; p = 0.05), at 12 mo with a median of 65% and a range of 45% to 90% versus a median of 45% with a range of 0% to 70% (U = 19; p = 0.016); at 70 dB SPL (Fig. 1C) at 9 mo postactivation with a median of 80% and a range of 50% to 90% versus a median of 50% and a range of 0% to 95% (U = 25; p = 0.016); at 85 dB SPL (Fig. 1D) at 3 mo postactivation with a median of 50% and a range of 30% to 75% versus a median of 25% and a range of 0% to 70% (U = 28.5; p = 0.025), at 9 mo postactivation with a median of 60% and a range of 30% to 85% versus a median of 40% and a range of 0% to 80% (U = 16.5; p = 0.016). In summary, at 12 mo postactivation, the FOX group maintained better results at low intensities (40 and 55 dB SPL).

Speech Audiometry in Noise

As shown in Figure 2, group comparison showed that the FOX maps had higher scores than the manual map at SNR0 at 3 mo postactivation with a median of 40% and a range of 0% to 70% versus a median of 5% and a range of 0% to 40% (U = 22.5; p = 0.001), at 9 mo postactivation with a median of 55% and a range of 20% to 95% versus a median of 10% and a range of 0% to 75% (U = 19.5; p = 0.008), at 12 mo postactivation with a median of 40% and a range of 15% to 80% versus a median of 10% and a range of 0% to 30% (U = 10; p = 0.01); at SNR10 at 3 mo postactivation with a median of 95% and a range of 70% to 100% versus a median of 65% and a range of 0% to 95% (U = 26; p = 0.05), at 9 mo postactivation with a median of 95% and a range of 90 to 100% versus a median of 70% and a range of 0% to 70% (U = 16.5; p = 0.0125), at 12 mo postactivation with a median of 100% and a range of 80% to 100% versus a median of 80% and a range of 10% to 95% (U = 10; p = 0.025). So in summary, at 12 mo postactivation, the FOX group maintained better results in noise for both SNRs.

Speech Tracking

Figure 3 shows the speech tracking results obtained using the manual and FOX maps. The group comparison analysis did not show a significant difference (p > 0.05) over time. The Levene's test did not show homogeneity in variances 3 mo postactivation, $F(1,22)$ = 9.53; p = 0.016, MF (σ = 33.28) and FOX (σ = 15.3) and 6 mo postactivation, $F(1,22)$ = 8.09; p = 0.0125, MF (σ = 29.58) and FOX (σ = 14.9) between both groups.

Questionnaire
Fitting Session Questionnaire

There was no significant difference between the two groups for any of the items evaluated. Concerning pain during fitting, three patients in the FOX group reported a score of 2 only during the first activation session.

CI Fitting Parameters

At activation, the C and T levels from the 21 to the 16 electrodes of the FOX group were significantly higher than those of the MF group (p < 0.05). At 12 mo postactivation, the T and C levels from electrodes 21 to 8 remained significantly (p < 0.05) higher in the FOX group (Fig. 4).

The T-SPL values can range from 9 to 50 dB SPL in Cochlear's fitting software. At the activation, the default value is 25 dB SPL for the MF group and 20 dB SPL for the FOX group. At 12 mo postactivation, the median value of the T-SPL was significantly higher in the MF group than in the FOX group (U = 4; p < 0.001 (Table 3). Levene's test did not show homogeneity in variances at 12 mo postactivation, $F(1,20)$ = 6.3; p = 0.021, MF (σ = 4.1) and FOX (σ = 1.8).

The C-SPL values can range from 65 to 84 dB SPL in Cochlear's fitting software, with a default value of 65 dB SPL. In Cochlear's fitting software, this value is coupled to the LG
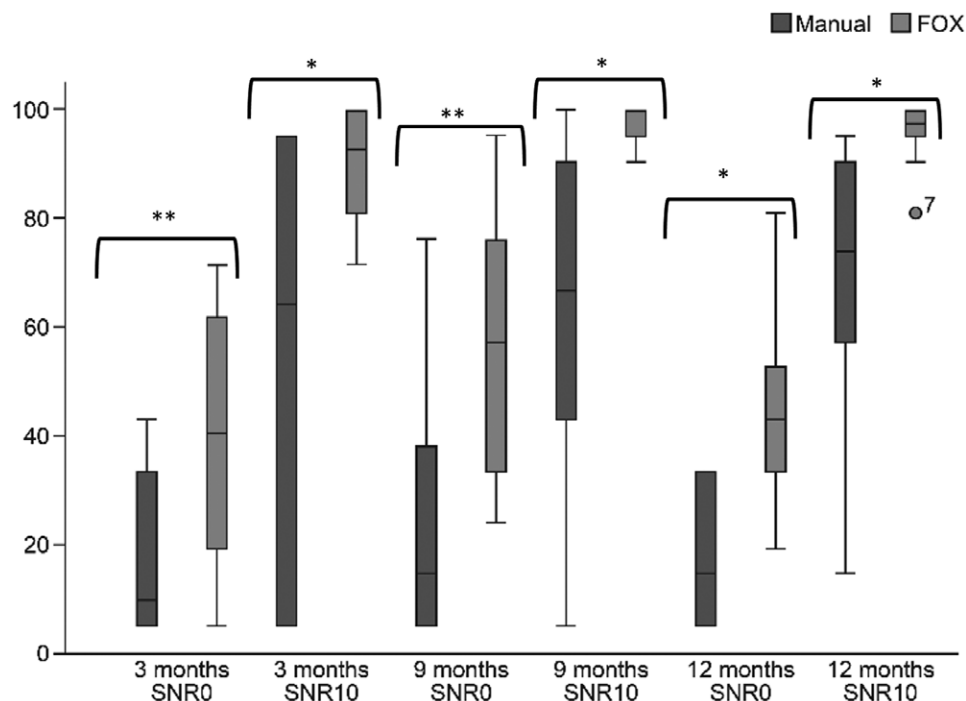

Fig. 2. Box plots displaying the scores of speech audiometry in noise at 3, 9, and 12 mo postactivation at SNR0 and SNR10 with the use of the manual map (Black) and FOX map (gray). Boxes range between the 25th and 75th percentile, whiskers show the top and bottom 25% of the scores (approximately), and central point: median (*p < 0.05; **p < 0.001).
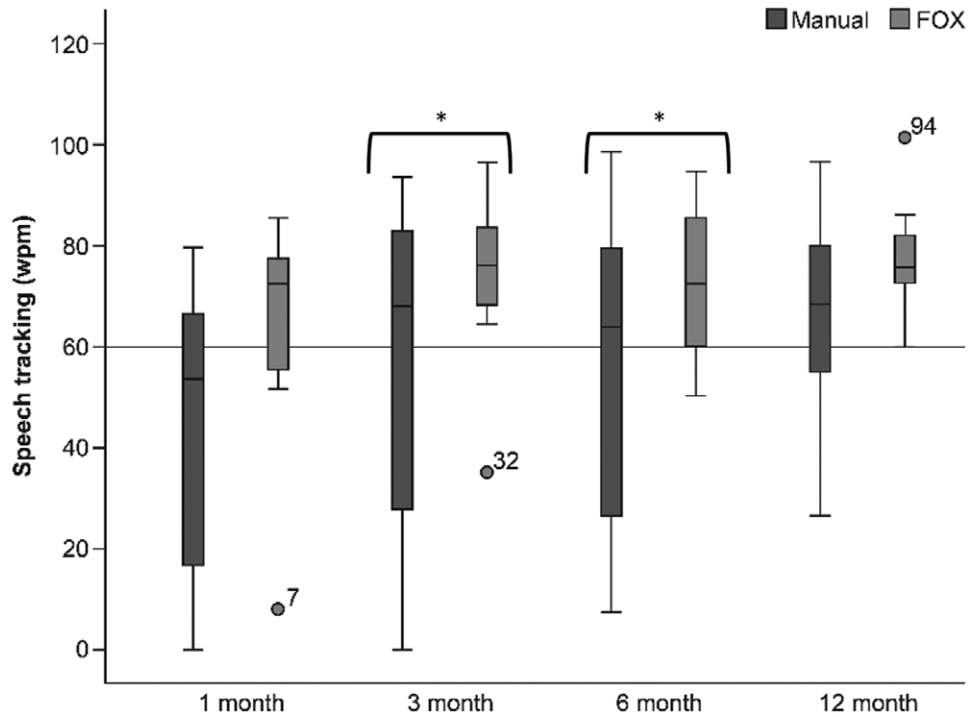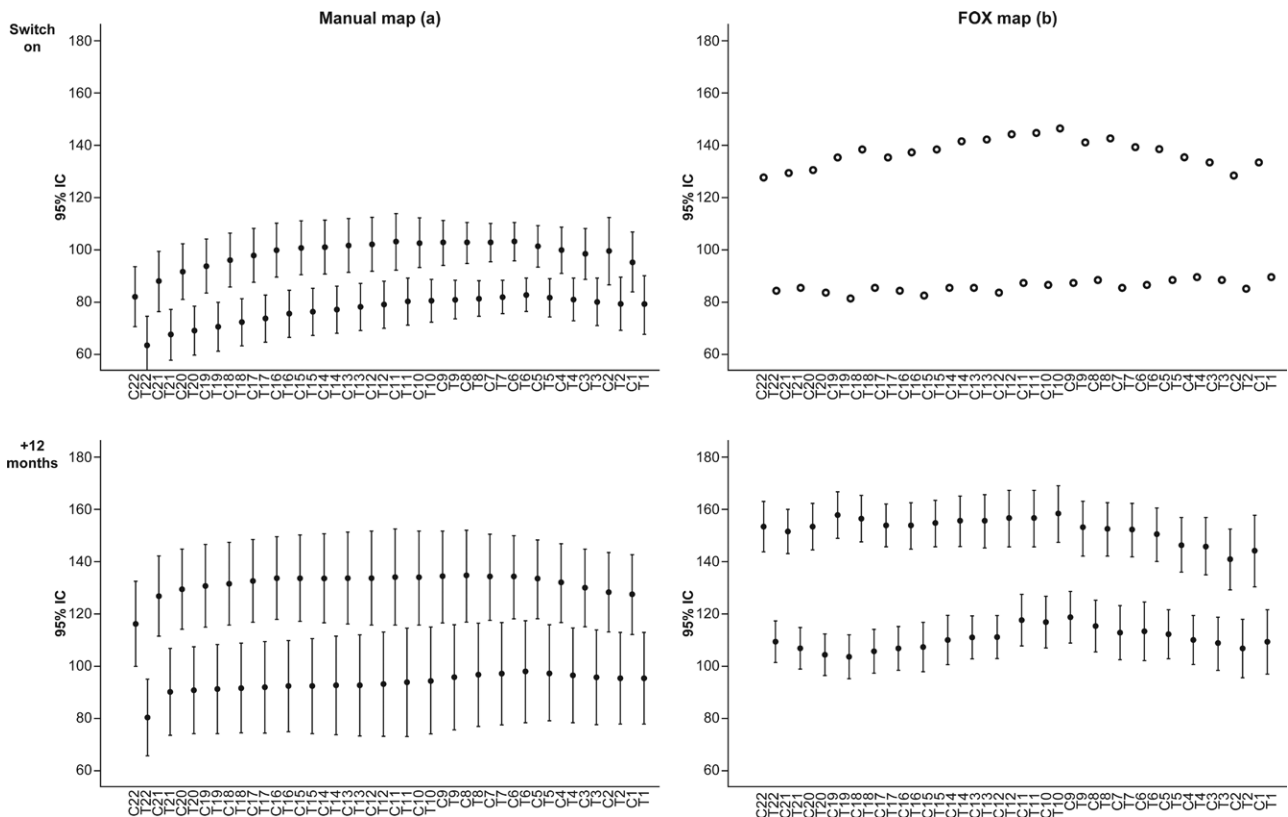
Fig. 3. Box plots displaying the scores of speech tracking at 1, 3, 6, and 12 mo postactivation with the use of the manual map (Black) and FOX map (gray). Boxes range between the 25th and 75th percentile, whiskers show the top and bottom 25% of the scores (approximately), and central point: median. (*$p < 0.05$).

Fig. 4. Error bar chart displaying the value of T and C levels at switch-on and 12 mo by electrode (X axis). Electrodes (E) 22 to 17 correspond to spectral bands of low frequency (188–938 Hz), E 16 to 7 correspond to mid frequency (1063–3563 Hz), and E 6 to 1 correspond to high frequency (4063–7938 Hz). Error bars: 95% CI.

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 is automatically set to 20, 18, 16, and 15 respectively. FOX does not apply this automatic coupling.

TABLE 3. Values of T-SPL, C-SPL, and LG for the Manual (MF) and FOX groups at switch-on and 12 mo postactivation.

	MF group		FOX group	
	Switch-on Default values	12 mo post activation median (range)	Switch-on Default values	12 mo post activation median (range)
T-SPL (dB SPL)	25	25 (25–35)	20	20 (20–25)
C-SPL (dB SPL)	65	70 (65–75)	70	65 (65–70)
LG	20	18 (16–20)	20	22 (20–24)

The default value for the FOX maps was 70 dB SPL. At 12 mo postactivation, the median value of the C-SPL was significantly higher in the MF group than in the FOX group (U = 12.5; $p <$ 0.001 (Table 3).

The LG values range from 10 to 50 in Cochlear's fitting software. The default value of 20 was the same for both groups. At 12 mo postactivation, LG was significantly higher in the FOX group than in the MF group (U = 2.5; $p <$ 0.001 (Table 3).

Crossover Session
Hearing Performance Measurement
Speech Audiometry in Quiet

As observed in Figure 5, the comparison between groups showed that the MF group showed an improvement with the use of the new FOX maps in 55 dB SPL with a median of 50% and a range of 15% to 85% versus a median of 45% and a range of 0% to 75% (U = 2.39; $p =$ 0.0125), in 70 dB SPL with a median of 70% and a range of 20% to 90% versus a median of 50% with a range of 0% to 95% (U = 2.5; $p =$ 0.016), in 85 dB SPL with a median of 50% and a range of 20% to 85% versus a median of 40% with a range of 0% to 80% (U = 2.5; $p =$ 0.025); and for the EaSI score with a median of 53% and a range of 20% to 72% versus a median of 47% with a range of 0% to 71% (U = 2.58; $p =$ 0.05). For the FOX group, there were no significant differences between the results of the manual map and the FOX map.

Figure 6 shows the gains from speech audiometry, value before minus value, after the FOX intervention.

Speech Audiometry in Noise

The within-patient analysis showed that the MF group improved with the use of the new FOX maps at SNR10 with a median of 95% and a range of 0% to 100% versus a median of 70% and a range of 0% to 100% (U = 2.37; $p =$ 0.018). For the FOX group, there were no significant differences between the results of the manual map and the FOX map.

Figure 7 shows the gains from speech audiometry, value before minus value, after the FOX intervention.

There was no significant improvement in speech comprehension with RSB0 in any of the two groups.

Map Parameters
T and C Levels

Figure 8A,B show the mean differences in T and C levels per electrode (n = 22) between the manual and FOX maps for the MF group (Figure 8A) and the FOX group (Figure 8B). The FOX changes in T and C levels were qualitatively larger and non-linear (Figure 8A) compared with those proposed by the MF clinician (Figure 8B).

Map Parameters

For the MF group, the T-SPL, C-SPL, and LG values were significantly modified in the switch-over session, meanwhile for the FOX group, the volume and C-SPL were significantly modified (Table 4).

Patient Choice • In the MF group, 100% (11/11) of the patients decided to keep the new map (FOX map); 82% (9/11)
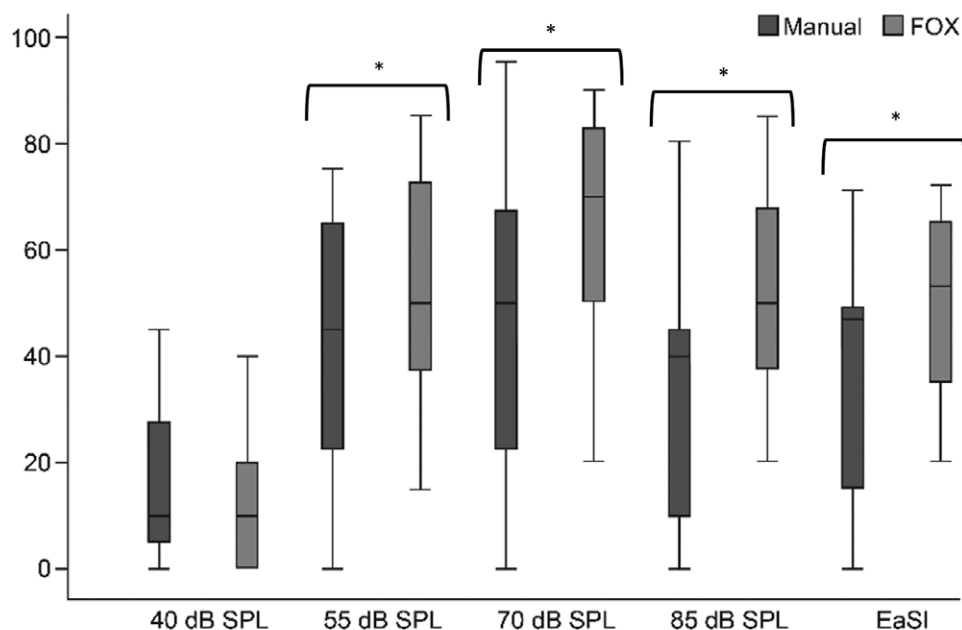

Fig. 5. Box plots displaying the scores of speech audiometry in quiet during the crossover session for the FOX group at 40, 55, 70, 85 dB SPL and the EaSI score with the use of the manual map (Black) and FOX map (gray). Boxes range between the 25th and 75th percentile, whiskers show the top and bottom 25% of the scores (approximately), and central point: median. (*$p <$ 0.05).
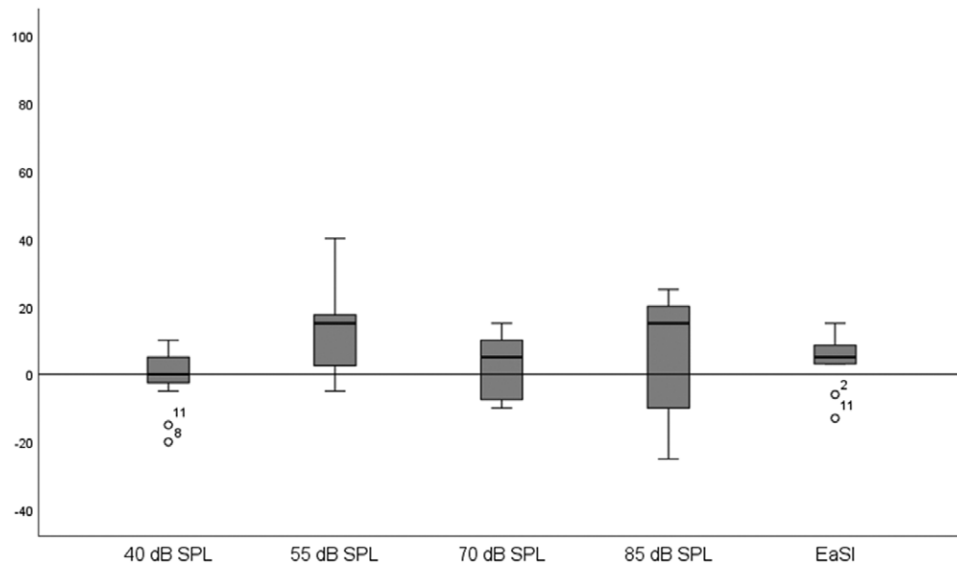
Fig. 6. Box plots displaying the gains (value before minus value after the FOX intervention) at 40, 55, 70, 85 dB SPL and the EaSI score for the MF group. Boxes range between the 25th and 75th percentile, whiskers show the top and bottom 25% of the scores (approximately), and central point: median. The open circles and numbers are patients-outliers.
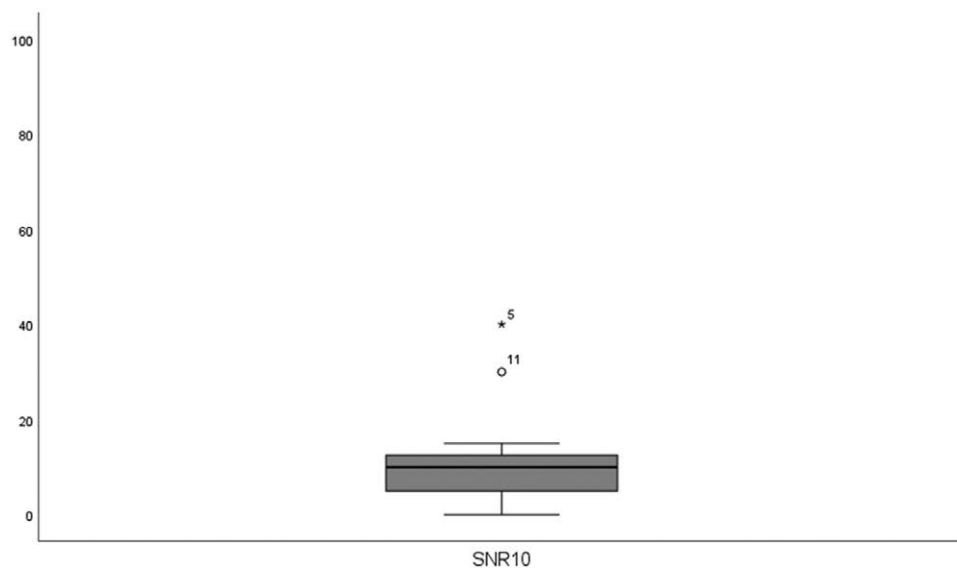

Fig. 7. Box plots displaying the gain (value before minus value after the FOX intervention) at SNR10 for the MF group. Box ranges between the 25th and 75th percentile, whiskers show the top and bottom 25% of the scores (approximately), and central point: median. Open circle et asterisk are 2 patients-outliers.

of the patients performed better at speech audiometry in quiet or in noise, with the use of the FOX map (Table 5).

In the FOX group, 63% (7/11) of the patients decided to keep the new map, the manual map. Thirty-seven percent (4/11) kept the FOX map (old), half of this 4 patients had better outcomes but were less comfortable with the new map, while the opposite for the other half (Table 5). For the FOX group, comfort seems to take priority over hearing performance in their choice.

DISCUSSION

Our main objective was to evaluate whether patients who received initial programming with FOX, a target-driven, AI-based fitting approach, had comparable results to those who received initial manual programming. It was not our intention to evaluate manual fitting as such. As explained in the introduction,

there are many policies and the reader who has a different fitting policy to ours may judge ours as not good and reject it. But the reader must realize that so many approaches exist because there is no universally recognized GCP (Good Clinical Practice) with rules that appear to be valid in everyone's hands. This fact alone justifies the search for more systematic approaches, and AI can provide tools for this.

FOX is one such new A.I. based technology, and it is gradually proving its worth. Indeed, results comparable to those obtained with manual programming have been found in patients initially programmed with FOX (Battmer et al. 2015; Wathour et al. 2016; Meeuws et al. 2017; Zwolan et al. 2020) as well as in experienced patients with CI (Buechner et al. 2015; Waltzman and Kelsall 2020; Wathour et al. 2019). Zwolan et al. (2020) reported equivalent results for speech comprehension in quiet and noisy conditions between their new patients initially programmed with
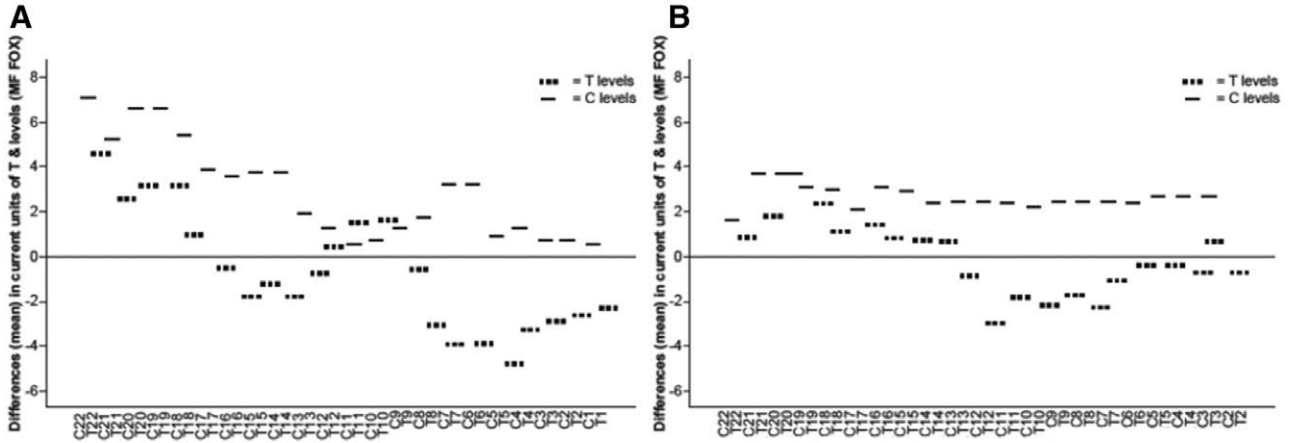
Fig. 8. Differences in T and C levels for (a) the MF group (FOX–Manual) and (b) the FOX group (Manual–FOX) by electrodes (X axis). Electrodes (E) 22 to 17 correspond to spectral bands of low frequency (188–938 Hz), E 16 to 7 correspond to midfrequency (1063–3563 Hz), and E 6 to 1 correspond to high frequency (4063–7938 Hz).

TABLE 4. Changes in the map parameters for the MF and FOX groups during the crossover session.

	MF group MF map → FOX map	FOX group FOX map → MF map
Volume	6 (6–6) → 6 (6–6) $p > 0.05$	10 (10–10) → 6 (6–10) $Z = -2.636; p = 0.008$
Number of electrodes	22 (19–22) → 22 (19–22) $p > 0.05$	21 (21–21) → 21 (21–21) $p > 0.05$
T-SPL	25 (25–35) → 25 (21–31) $Z = -3.127; p = 0.002$	20 (20–25) → 20 (20–30) $p > 0.05$
C-SPL	70 (65–75) → 65 (65–70) $Z = -3.162; p = 0.002$	65 (65–70) → 70 (65–70) $Z = -2.828; p = 0.05$
LG	18 (16–20) → 18 (18–22) $Z=-2,428; p = 0.015$	22 (20–24) → 18 (18–20) $Z = -2.549; p = 0.011$

The fields show the median values, the range in parenthesis of the original map (before crossover), and the alternative map (after crossover).
FOX, Fitting to Outcome eXpert; MF, manual fitting.

TABLE 5. Number of patients (n) who keep the new map for the MF and FOX (new–old) groups according to outcomes and comfort.

Speech tests	Outcomes + 15% and more		Outcomes - 15% and more		Outcomes are equal (within ±15%)	
	MF	**FOX**	**MF**	**FOX**	**MF**	**FOX**
	new old	new old	new old	new old	new old	new old
Comfort +		3		3 2		1
Comfort −	2	2 1				
Comfort =	7		1			

Outcomes with the new map are better (+15%), worse (−15%), and equal (within ± 15%) to speech audiometry in quiet or noisy conditions.
Patient subjectively evaluates the comfort with the new map as better (+), worse (−), and similar (=).
FOX, Fitting to Outcome eXpert; MF, manual fitting.

FOX and their historical data of manually programmed patients with CI, as also stated by Buchman et al. (2020).

The analysis of the results of our study not only shows comparable results but as early as 3 mo postactivation, the FOX group showed better speech intelligibility in quiet conditions at 40 and 55 dB SPL and noise. At 12 mo postactivation, the FOX group confirmed and maintained its significantly better performance for speech intelligibility under quiet and noise conditions, showing a better auditory perception of high frequencies. We also observed significantly less intragroup variability in the FOX group, especially for speech tracking and phonemic discrimination.

These results may be influenced by FOX initial defaults differing from those in Cochlear's CustomSound™ software, such as 11 maxima (vs. 8), 37 μs pulse width (vs. 25 μs), T-SPL of 20 (vs. 25), C-SPL of 70 (vs. 65), the volume of 10 with 0% volume control (vs. volume of 6 with 20% volume control), and 21 active electrodes (vs. 22). We cannot determine to what extent these differences in the default parameters are involved in explaining the better results of the FOX group. However, most of the parameters selected by FOX are supported by the existing scientific literature. For example, Wolfe (2018) recommends using 10 maxima (vs. 8) in combination with a pulse width of 37μs to improve the comprehension in noise. A pulse width of 37 μs with a stimulation rate of 900 Hz and deactivation of the most acute electrode (this refers to electrode 1, which codes for the highest frequencies) have been reported to decrease the risk of nonauditory stimulation that can be elicited by the most basal electrodes (Schvartz-Leyzac et al. 2017).

At 12 mo postactivation, the better hearing performance of the patients in the FOX group was associated with significantly lower T and C-SPL, higher T and C levels in the low and mid frequencies, and a higher LG value. However, while FOX provides better hearing performance with higher defaults, it comes at the expense of higher battery consumption (Lee & Mendel 2016). This opens the debate on the trade-off between hearing quality and battery consumption. We believe that hearing quality should not be sacrificed to battery consumption because hearing with CI is still not equivalent to normal hearing and because we still consider it worth fighting for every percentage point of better speech understanding. Furthermore, technological advances are expected to increase the battery capacity; therefore, the dilemma is temporary in nature.

The use of automaps (Govaerts 2010) may raise questions. Automaps consist of an incremental set of maps based on the statistical analysis of maps from previous patients with CI with

good hearing performance. At first glance, this seems to be a "one-fits-all approach," however, this is not the case. The concept is based on the assumption that it does not make sense to spend a lot of time fine-tuning immediately at first activation, especially since the patient still has to get used to the new sound of a CI. Therefore, the initial period is only used to build the loudness tolerance through the progressive buildup of maps. It is only in the second and subsequent fitting sessions that fine-tuning comes into play. This is done by measuring auditory performance, where the intelligent agent FOX adjusts the maps in an attempt to improve the results. It is a notable and intrinsic part of the concept to fix the volume at 10 without the patient being able to change it. Our patients in the FOX group tolerated this approach without difficulty and developed a good understanding of speech. This is a demonstration of the cerebral adaptation that humans are capable of and calls into question the need to search for individual T and C levels for each electrode, especially since this practice, although widely used in CI centers, is time-consuming (Vaerenberg et al. 2014), varies (Vaerenberg et al. 2014; Browning et al. 2020; Wathour et al. 2021), and is difficult for some patients to perform (Caner et al. 2007; De Vos et al. 2018).

The use of FOX leads to reflections on the way CIs have been programmed for years. Clinicians work according to the expertise they have acquired at their CI center, guidelines in the Cochlear software with some information but no justification, and their personal experience. They may also question their way of doing things.

This study also confirmed that FOX programming requires fewer fitting sessions than what is usually done. Zwolan et al. (2020) showed that FOX programming reduced the number of fittings by 43% during the 6 mo postactivation. In our study, FOX reduced the total number of fitting sessions by 55% during the period up to 1-year postactivation. This reduction is likely to increase further as the Eargroup has reduced its protocol to three sessions during the 1-year postactivation (Govaerts, personal information). Fewer programming sessions mean less cost to both the clinician and patient.

In addition to comparing the settings and hearing results of our two groups for 1 year, we conducted a crossover study with the same patients (see Table 1). Such experiments have never been performed or published. This design allows each patient to be his/her own control, which avoids variability due to individual differences. Each patient has the option to continue with his/her old program or continue with a new one. Remarkably, all patients initially programmed with the manual method preferred the FOX map (see Table 5).

When analyzing the map modifications by FOX, they appear to be less "conservative" than manual modifications, with more substantial and less homogenous changes in T and C levels and lower absolute values of the T-SPL and LG value (see Table 4). The impact of these changes can be seen 2 weeks later in improved speech audiometry performance in quiet conditions at 55, 70, and 85 dB SPL and in noise (see Figure 8). In contrast, the manual intervention resulted in changes mainly in volume and C-SPL compared with FOX programming (see Table 4). However, these manual changes do not seem to have direct implications for the patient's hearing performance but rather for hearing comfort.

Comfort in FOX programming remains an important issue. It could be hypothesized that comfort is not considered because FOX is a standardized approach based on hearing performance and not on patient subjectivity. However, according to various studies, a large majority of patients with long-term CI experience (Wathour et al. 2021: 90%; Waltzman and Kelsall 2020: 82%) prefer FOX to manual map because it provides better acoustic quality in addition to improved hearing performance. In a study by Zwolan et al. (2020), only two out of 31 patients requested an additional fitting to decrease the volume of their map following their first FOX programming session. Our current results regarding comfort appear to confirm this: only three patients in the FOX group gave a score of 2 out of 5 (1 = intolerable; 5 = no pain) to the item "pain in adjustments." In addition, during the crossover session, 100% of the manual programming group preferred the FOX map mainly for better hearing performance and no complaints regarding comfort. Meanwhile, in the crossover session of the FOX group, 63% of the FOX patients preferred the manual map, which could not be attributed to better performance. Hence, we speculate that this could only be for comfort reasons (see Table 5). Therefore, it appears that FOX adds performance and comfort to the manual map, while the manual fitter adds comfort to the FOX map. Once again, this shows the difficulty of "comfort." The patient's preference probably reflects not only the real comfort and performance but also other issues that are difficult to quantify, such as the hope placed in the prospects offered by AI, the will to comply with the clinician's expectations, or, on the contrary, the desire to remain in the known. These subjective parameters cannot currently be evaluated by FOX but are part of the discussion between the patient and the clinician. In our study, we strictly applied the recommendations proposed by FOX and provided informative and encouraging counseling. However, it is obvious that discussions with the patient and the integration of his/her feelings remain fundamental in these settings. This is why we believe that FOX will always remain no more than an assistive tool in the hands of an expert audiologist, even when integrating more subjective measures, such as a questionnaire.

Our study addressed several of the limitations found in previous studies, namely, the small number of subjects (Wathour et al. 2019), a control group consisting of former patients with CI accustomed to wearing their manual map (Waltzman & Kelsall 2020), or the lack of a control group (Zwolan et al. 2020). A weakness of our study is that it was not double-blind or even blind. Ideally, both the patient and clinician would have been blinded, but this is not feasible in a realistic study design where patients are well informed and knowledgeable, and audiologists clearly know the method they use.

In conclusion, we wanted to evaluate whether an activation procedure with the intelligent agent FOX would be equivalent to classical manual programming. This point is convincingly made. We believe that the FOX approach is equivalent or even outperforms the manual approach in terms of hearing performance and comfort, as well as in terms of resources. Furthermore, FOX is a tool that is capable of continuous improvement by comparing its predictions with observed results and continuously learning from clinicians' practice, which is why this technology promises major advances in the future.

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