Original research paper

Assessment of 'Fitting to Outcomes Expert' $FOX^{\mathbb{R}}$ with new cochlear implant users in a multi-centre study

Rolf-Dieter Battmer¹, Stephanie Borel², Martina Brendel³, Andreas Buchner⁴, Huw Cooper⁵, Claire Fielden⁵, Dzemal Gazibegovic³, Romy Goetze⁶, Paul Govaerts⁷, Katherine Kelleher⁸, Thomas Lenartz⁴, Isabelle Mosnier², Joanne Muff⁹, Terry Nunn⁸, Bart Vaerenberg^{7,10}, Zebunissa Vanat⁹

¹UKB, Berlin, Germany, ²Beaujon, Paris, France, ³Advanced Bionics, Clinical Research International, ⁴MHH, Hannover, Germany, ⁵University hospital, Birmingham, UK, ⁶HTZ, Potsdam, Germany, ⁷The Eargroup, Antwerp-Deurne, Belgium, ⁸Guy's and St. Thomas', London, UK, ⁹Adenbrookes, Cambridge, UK, ¹⁰Laboratory of Biomedical Physics, University of Antwerp, Belgium

Objective: To compare the fitting time requirements and the efficiency in achieving improvements in speech perception during the first 6 months after initial stimulation of computer-assisted fitting with the Fitting to Outcome eXpert' (FOX[™]) and a standard clinical fitting procedure.

Method: Twenty-seven post-lingually deafened adults, newly implanted recipients of the Advanced Bionics HiRes 90K[™] cochlear implant from Germany, the UK, and France took part in a controlled, randomized, clinical study. Speech perception was measured for all participants and fitting times were compared across groups programmed using FOX and conventional programming methods.

Results: The fitting time for FOX was significantly reduced at 14 days (P < 0.001) but equivalent over the 6-month period. The groups were not well matched for duration of deafness; therefore, speech perception could not be compared across groups.

Discussion: Despite including more objective measures of performance than a standard fitting approach and the adjustment of a greater range of parameters during initial fitting, FOX did not add to the overall fitting time when compared to the conventional approach. FOX significantly reduced the fitting time in the first 2 weeks and by providing a standard fitting protocol, reduced variability across centres.

Conclusions: FOX computer-assisted fitting can be successfully used at switch on, in different clinical environments, reducing fitting time in the first 2 weeks and is efficient at providing a usable program.

Keywords: Cochlear implant, FOX, Computer-assisted fitting, Programming, MAP, T-levels, M-levels, Initial stimulation

Introduction

A cochlear implant is activated a few weeks following surgery and an individual program created. The levels of current required to produce auditory sensations are set for each individual and these may vary considerably among individuals and between different electrodes along the array. Two levels are required: the lowest amount of current needed to elicit a response and the amount of current tolerated before the stimulus is deemed to be too loud and once these are set, an individual program is created. These two key parameters are still considered to be the most essential components in an effective program (Baudhuin *et al.*, 2012; Dawson *et al.*, 1997; Holden *et al.*, 2011; Plant *et al.*, 2005; Sainz *et al.*, 2003). However, today's cochlear implant programming software is becoming more complex, allowing the adjustment of many other parameters, such as processing strategy options, channel gains, audio input control, and many more. Many of these parameters are interdependent and setting them individually can be a time-consuming task. The role of the cochlear implant audiologist is to know when and how to adjust these parameters in order to optimize the hearing performance of the cochlear implant user.

Following the first fitting and the user's acclimatization to the electrical sensation, several follow-up

Correspondence to: Dzemal Gazibegovic, Advanced Bionics, CB225LD Cambrdige, UK. Email: dzemal.gazibegovic@advancedbionics.com

fitting sessions are needed to adjust and optimize the most comfortable levels and thresholds. In adults, the levels typically stabilize at around 1 month postactivation (Walravens et al., 2006). Once this point has been reached, further adjustment very much depends on the routine clinical practice of the centre. Published evidence has shown that the adjustment of other parameters, such as stimulation strategy and input dynamic range, can produce performance gains for some individuals (Holden et al., 2011; Plant et al., 2007; Skinner et al., 2002). However, the other parameters are rarely changed and often remain on the manufacturer's defaults. This point is illustrated when you consider that 90% of the variance between different processor programs comes from the difference in the overall levels of stimulation between them (Smoorenburg et al., 2002).

The fitting of cochlear implant processors is often based on user's comfort rather than outcomes. Many clinicians use measures of performance to assess any changes made to a program, but there is no standardized approach to assure follow-up quality and performance across cochlear implant centres. Fitting approaches based on measures of speech perception go some way towards addressing this; however, a subjective evaluation of user's comfort must still be considered in both conventional and standardized fitting procedures.

The 'Fitting to Outcome eXpert' (FOXTM) was developed at the Eargroup in Antwerp, Belgium, to provide a structured method for adjusting sound processor parameters (Govaerts et al., 2010). FOX is a software tool that uses a set of programmed rules to recommend changes to a program to improve outcomes. A set of outcomes are used which were chosen because they assess the auditory system at a psychoacoustic level and can be compared to data collected from normally hearing individuals. A target for each measure is set, FOX then uses a systematic methodology to make adjustments to the program, based on the outcomes, to achieve the target (Govaerts et al., 2010). The same measures are repeated to determine if a parameter change has been effective (Govaerts et al., 2010; Vaerenberg et al., 2011). The adjustments to the program recommended to improve a particular outcome were derived from the programming experience at the Eargroup clinic. The audiologist is given an option to either accept or reject this advice, based on their own fitting experience. Once a new subject has been created in FOX, a set of 10 auto-programs are generated where upper stimulation levels (M-levels) and threshold levels (T-levels) for the Advanced bionics device are based on statistical analysis of the initial fitting parameters collected from several hundreds of conventionally fitted cochlear implants. These initial values are then progressively increased globally, rather than individually measured.

Other speech-based optimization procedures using objective assessment of performance have been described in the literature; in Holmes et al. (2012), a phoneme error matrix was used to produce a model of each listener's performance, as a function of device parameter, with different combinations of frequency allocation table, rate of stimulation, and loudness growth. However, no prior assumptions were made about how different parameter combinations might affect performance. The use of this systematic optimization produced significantly better results for speech testing in quiet and noise, when compared to the baseline programs for the 20 adult cochlear implant users. Participants also commented that the programming session was more meaningful and less stressful than traditional programming.

The application of electrically evoked potentials (ECAP) has also allowed successful programs to be created with minimal subjective input from the recipient, especially in children (Ramos et al., 2004; Seyle and Brown, 2002; Willeboer and Smoorenburg, 2006). However, while the use of such measures can provide a guide to the current level required to elicit an acoustic response, there is limited evidence to show they correlate well with threshold, maximum stimulation levels, or outcomes (Cosetti et al., 2010; Holstad et al., 2009). Enhanced ECAP fitting methods have used scaling profiles to flatten the ECAP profile with increasing mean T or maximum stimulation levels to improve the correlation between ECAP and behaviourally measured profiles (Botros and Psarros, 2010). Other fitting methods have been designed to enable recipients to make program adjustments themselves (Botros et al., 2013). These use profiles based on the automatic measurement of ECAP levels on each electrode. Fixed average T and maximum stimulation levels are then applied, based on population means, and the clinician then adjusts the overall level by increasing both profiles together. When the required loudness is reached, a base and treble tilt to the profile can then be applied, based on user preference. Equivalent speech perception was shown with this automated fitting procedure compared to a conventional fitting method. However, it differs from FOX substantially as it remains entirely based on comfort, with the only performance measure being an optional sound detection task. It also relies on either manufacturer's or clinic defaults for all other parameters, only adjusting the threshold or maximum stimulation levels of individual recipients.

Previous studies using FOX have looked at programming changes in eight subjects from switch on to 3 months (Vaerenberg *et al.*, 2011). At the final session, 3 months post-switch on, 50% of programs were defined as being optimal by FOX and FOX had suggested and implemented 10 parameter changes across the eight subjects. By using its algorithms to assist the audiologist in changing the program settings, FOX allowed a large number of parameter combinations to be adjusted in a short time. However, no study has yet compared the FOX system to a conventional programming approach, either in terms of time taken or the outcomes achieved. The primary aim of this study is to compare computerassisted fitting with FOX to standard clinical fitting procedures. We compared the overall fitting time and speech perception during the first 6 months after initial stimulation.

Methods

Subjects

The study was conducted as a multi-centre trial and involved six clinics, two from Germany, one from France, and three from the UK. Subjects were required to be post-lingually deafened adults, aged 18 years or older, and have the language of the test materials as their primary spoken language. They were all unilaterally implanted with the Advanced Bionics HiRes 90KTM implant, with a duration of profound deafness <20 years (defined as a point in time where no reasonable speech understanding in the best fitted condition was possible), a full insertion of the electrode array, with a minimum of 14 contiguous electrodes with normal impedances and normal cochlear structure and nerve function. Each subject was followed up over a period of 6 months following device activation. The relevant ethics approvals were obtained by each participating clinic, each subject signed an informed consent form, and Advanced Bionics acted as the study sponsor.

Twenty-seven subjects were recruited and randomly allocated to either the FOX or control group, based on a randomization table. The first subject in each centre was allocated a random number, generated in Excel, between 0 and 1. If the number was <0.5 then the subject was assigned to the FOX group and if the number was >0.5 then the subject became a control. This assured a 50% chance of randomly being assigned to each group. To ensure that both groups were balanced between centres and languages, once the initial subject had been allocated the second subject from each centre was then automatically assigned to the alternate group. This process was then repeated for each pair of subjects until every subject was allocated. There were 13 subjects in the FOX group with a median age of 73 years (interquartile range 56-76 years) and duration of deafness of 4.8 years (interquartile range 1.9-6.5 years). There were 14 subjects in the control group with an average age of 65 years (interquartile range 51-78 years) and duration of deafness 13.1 years (interguartile range 1–20 years). Table 1

Table 1 Descriptive data for all 27 subjects showing: the allocated study group, the age and duration of deafness at the first study appointment, if a contralateral hearing aid is used, the type of Advanced Bionics electrode inserted, and the word and sentence tests used for assessment (Freiburger monosyllables and HSM sentences in German, Arthur Boothroyd words (AB) and Bamford–Kowal–Bench sentences in English (BKB), and Lafon words and Marginal Benefit from Acoustic Amplification (MBAA) sentences in French)

Subject	Study group	Age (years)	Duration of deafness (years)	Using HA	Electrode	Words in quiet	Sentences in noise
S01	FOX	32	0	Yes	Helix	Freiburger	HSM
S02	FOX	74	3	Yes	Helix	Freiburger	HSM
S03	FOX	73	0	NA	Helix	Freiburger	HSM
S04	FOX	58	0	Yes	Helix	Freiburger	HSM
S05	FOX	76	4	Yes	Helix	Freiburger	HSM
S06	FOX	26	4	Yes	Helix	Freiburger	HSM
S07	FOX	54	3	Yes	Helix	Freiburger	HSM
S08	FOX	67	6	Yes	1j	Lafon	MBAA
S09	FOX	76	11	Yes	1j	Lafon	MBAA
S10	FOX	51	3	No	1j	Lafon	MBAA
S11	FOX	74	3	Yes	1j	AB words	BKB
S12	FOX	77	12	Yes	1j	AB words	BKB
S13	FOX	72	0	Yes	1j	AB words	BKB
S14	Control	76	0	Yes	Helix	Freiburger	HSM
S15	Control	41	18	Yes	Helix	Freiburger	HSM
S16	Control	74	0	Yes	Helix	Freiburger	HSM
S17	Control	40	11	Yes	Helix	Freiburger	HSM
S18	Control	61	0	Yes	Helix	Freiburger	HSM
S19	Control	81	20	NA	Helix	Freiburger	HSM
S20	Control	49	0	No	Helix	Freiburger	HSM
S21	Control	50	20	Yes	Helix	Freiburger	HSM
S22	Control	77	13	Yes	Helix	Freiburger	HSM
S23	Control	78	19	Yes	1j	Lafon	MBAA
S24	Control	60	18	Yes	1j	Lafon	MBAA
S25	Control	67	15	Yes	1j	Lafon	MBAA
S26	Control	37	0	Yes	1j	AB words	BKB
S27	Control	77	12	No	1j	AB words	BKB

outlines subject demographics as well as device characteristics, speech assessments used, and the allocated group.

Procedures

The speech processor fitting was performed through the Advanced Bionics[®] SoundWave[™] clinical fitting software.

Subjects in the control group received centrespecific, routine follow-up based on the manufacturer's guidelines for device programming. At initial stimulation, M-levels are measured using speech bursts and a visual scale (1-10) to determine the subjective most comfortable loudness. Four channels are stimulated at the same time, with the next set of 4 channels overlapping the previous set by 2 channels, until all 16 channels have been measured. The T-levels are automatically set to 10% of the dynamic range by the SoundWave[™] fitting software. This makes an overall total of seven measuring points at the first session. At follow-up sessions, M-levels for each of the 16 channels are individually measured using tone bursts but T-levels still remain at 10%. One centre measured all 16 M-levels individually at initial stimulation. Subjects participating in the FOX group underwent a structured fitting protocol that was identical in all centres. All subjects were activated with the same 'switch on' program and went through a series of auto-programs in the first 2 weeks. The autoprograms were implemented with a gradual increase of M- and T-levels and gains, following a dedicated pattern as described in Vaerenberg et al. (2011). The purpose of the auto-programs was to familiarize subjects with a tolerable loudness level before the individual fine tuning sessions began. At the 2-week session, the program with the most comfortable loudness was selected as the subject's individual baseline program. This baseline program was then optimized by FOX over the following weeks and months, based on the set of predefined speech perception and psychophysical measures outlined below. Speech audiometry, phoneme discrimination, and loudness scaling tests were performed within the $A \& E^{\mathbb{R}}$ test suite (Govaerts et al., 2006) implemented through FOX and if the outcome was within the target range defined, the audiologist did not undertake any modifications. If the outcome was not within the target, FOX made recommendations for modifying the program in an attempt to bring it closer to the target. In all cases, the audiologist accepted the recommendations made, although he/she had the option to overrule them if they did not agree with the modification suggested. The same outcome was then measured again and if still out of the target, FOX made further suggestions, possibly changing the program several times before finalizing the parameters.

Table 2Speech perception and psychophysical outcomemeasures, conducted as part of the FOX test battery, pairedwith their target values as defined in FOX

Outcome	Target			
Sound field audiometry: Warble tones presented at 250, 500, 1000, 2000, 4000, and 8000 Hz Spectral discrimination: Phoneme discrimination performed within A§E [®] psychoacoustical test battery using 20 speech sound contrasts presented at 70 dB(SPL)	Thresholds equal to or better than 30 dB(HL) for 500–8000 Hz and 35 dB(HL) at 250 Hz At least 18/20 pairs identified correctly			
Loudness growth function: Loudness scaling test, performed within the A§E [®] test suite, using one-third octave narrow band noises, centred at 250, 1000, and 4000 Hz	Values correspond to the 95% confidence interval in normally hearing subjects			
Speech audiometry: Freiburger monosyllables (Germany), AB words (UK), and Lafon bisyllables (France) presented at 40, 55, 70, and 85 dB(SPL)	Recipients to achieve equivalent performance at the four intensities			

FOX speech perception and psychophysical outcomes

The outcomes and their targets, which were entered into FOX for verification and optimization of processor programs, are shown in Table 2.

FOX speech perception and psychoacoustic measures were performed through the auditory speech sounds evaluation software ($A\S E^{\mathbb{R}}$). Specific details of this test setup are provided in Govaerts et al. (2006). Sounds were delivered via the internal sound card of the laptop, connected to a loudspeaker. Loudness scaling was also performed through the auditory speech sounds evaluation software using 1.8 seconds, one-third octave narrow band noises, centred at 250, 1000, and 4000 Hz. Each stimulus was presented twice at each level and scored on a visual analogue scale ranging from 0 (inaudible) to 6 (too loud). Levels were randomly presented at 5 dB increments between 30 and 80 dB(HL), while the subject was required to indicate the perceived loudness on the scale. A loudness index was calculated based on the average root mean square of scores compared to the average score at the same intensity for a normally hearing listener.

Additional speech perception measures

Both study groups underwent an additional speech assessment using language-specific materials; Freiburger monosyllables (Hahlbrock, 1953) and Hochmair–Schulz–Moser (HSM) sentences in German (Hochmair et al., 1997), Arthur Boothroyd words and (Boothroyd, 1968) Bamford-Kowal-Bench sentences in English (Bench et al.,

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1979), and Lafon words (Courtade, 1966) and Marginal Benefit from Acoustic Amplification sentences in French (Centre Hospitalier Universitaire, Toulouse). Words in quiet were presented at 65 dB(A) at 2 weeks, 1, 3, and 6 months following device activation and were administered through the $A\S E^{\mathbb{R}}$ test suite as before and scored by phoneme. At 6 months post-activation, an additional sentence test in noise was performed in fixed noise at +10 dB signal-to-noise ratio (SNR). Clinics either played the test material via an amplifier (Denon PMA-250E, Tangent Ampster AMP 30, HVA-8030 Concert 300W) connected to a loudspeaker (Tangent EVOE5, Samson Media One 4a, Eltax millennium mini, Mordaunt-Short MS10i, Truth B2030A) or an audiometer (Homoth Audio4000, Affinity 2.0) connected to a loudspeaker. Competing noise with the same long-term spectrum as that of the test material was presented coincidentally from the front speaker with the speech material. Following a practice list, two test lists were presented and the scores achieved for each test list averaged to produce a single test score.

All testing, including the FOX measures, was carried out in a sound-treated room with a noise floor of 30 dB(A) or less and a speaker positioned at 1 m directly in front of the subject. Hearing aids, if worn, were not used during any testing.

The time required to complete a fitting was also measured at each session for both groups. Fitting time typically covered all procedures relevant for performing a fitting, including connecting processor to the fitting system, measuring psychophysics, and downloading final programs into the processor. It did not include the time spent on counselling subjects or performing the additional sentence testing in noise. For the FOX group only, the time for completing the FOX outcomes was added to the actual fitting time, as these form an integral part of the fitting process within FOX.

Statistical analysis

A series of non-parametric pairwise comparisons with a Mann–Whitney U test for comparing ranks of independent samples were conducted to assess differences between the two study groups. A significant difference was recorded if the P value was ≤ 0.01 .

Results

Twenty-five out of the 27 subjects completed the 6month study. The two remaining subjects, both from the control group, were lost to follow-up before attending the 6-month session. For sentences in noise, data were missing for three further subjects, two in the control group and one in the FOX group, either due to technical issues with test set-up or for subject 27, poor performance during word testing. In order to make the statistical model more robust, the fitting times for the missing subjects were replaced by the control group's median fitting time for the 6-month session for the relevant centre. Conducting a complete case analysis was not considered viable due to the cumulative nature of the data, this means that leaving out the fitting time for a single session would result in a lower cumulative fitting time at the 6-month period. Where word and sentence scores were missing, the statistics were done without the figures for those subjects.

Although there was no statistically significant difference between them (U(27) = 51, Z = -0.89, P = 0.37), the groups were not well matched for duration of deafness. The FOX group had a much smaller range of duration of profound deafness (Fig. 1). Therefore, a direct comparison of speech perception measures between the groups should be interpreted with caution. Due to the small numbers, line graphs for individual word scores over time are shown for the French and English language groups in Figs. 2 and 3 and statistical comparisons could not be made. The German group was the largest, with 16 subjects in total and box plots of the data are presented in Fig. 4. Statistical analysis showed no difference in



Figure 1 Duration of deafness for each subject in years as measured at entry to the study. Subjects are ordered by the length of severe-to-profound deafness and colour coded with dark grey indicating the control group and light grey indicating the FOX group.



Figure 2 Individual per cent correct scores for Lafon words presented at 65 dB(A) for the six French-speaking subjects. Scores are shown for each test interval. One subject in the control group was not tested at the 2-week test interval. Closed light grey circles indicate the subject was part of the FOX group and open dark grey circles indicate the subject was part of the control group.



Figure 3 Individual per cent correct scores for the Arthur Boothroyd words presented at 65 dB(A) for the five English-speaking subjects. Scores are shown at each test interval. Closed light grey circles indicate the subject was part of the FOX group and open dark grey circles indicate the subject was part of the control group.

scores between the groups at any test interval. However, using a Wilcoxon matched pairs test for dependent samples, scores significantly improved from 2 weeks to 6 months (P = 0.03) for the control group and from 3 to 6 months for the FOX group (P = 0.04). Fig. 5 shows box plots for each language group for the 22 subjects who participated in speech testing in +10 dB of noise at 6 months. Again, due to the small numbers in each group, meaningful statistical analysis could not be performed.

The median cumulative fitting time over the first 2 weeks was 33 minutes for the FOX group and was significantly lower than the median cumulative fitting time for the control group of 54 minutes (U(27) =



Figure 4 Box plots showing the percentage correct scores for Freiburger monosyllables presented at 65 dB(A) for the Germanspeaking subjects. N = 7 for the FOX group indicated by closed circles and n = 9 for the control group indicated by the open circles, except at 6 months where n = 7. Boxes indicate first and third quartile range with light grey for FOX and dark grey for the control group with the middle line indicating the median value. Error bars indicate the maximum and minimum values. Based on Mann–Whitney U test, there was no significant difference in scores between groups.



Figure 5 Box plots showing the speech perception scores for sentences in a +10 dB SNR ratio split by languages and study groups. The German subjects were tested with the HSM, French with the MBAA, and the English with the BKB sentence tests. For each language group, the dark grey indicates the control group with light grey indicating the FOX group.

19.5, Z = -3.4, P < 0.001). From the 1-month session onwards, the time spent on fitting becomes comparable between the two study groups (Fig. 6).

The median cumulative fitting time across the 6month period was 2 hours and 12 minutes for the FOX group (interquartile range 114–158 minutes) and 1 hour and 57 minutes for the control group interquartile range (95–156 minutes). There was no significant difference between them (U(27) = 76, Z = 0.70, P = 0.48).

Discussion

The ability to compare the speech test results was severely compromised by the mismatch in duration



Figure 6 Box plots showing the cumulative fitting time at each test interval. Boxes indicate first and third quartile range in light grey for the FOX and dark grey for the control group with the middle line indicating the median value. Error bars indicate the maximum and minimum values. One outlier was identified in the FOX group at 14 days. Starred brackets indicate a statistically significant difference. N = 27 at 14 days, 1 month, 3 months, and n = 25 at 6 months.

of deafness between the groups; duration of profound deafness is a key factor in predicting outcomes (Holden *et al.*, 2013) and was lower in the FOX group. This prevented any meaningful comparisons of speech perception outcomes being made across groups. The small numbers for the English and French language groups also meant that only individual scores could be reported for these speech tests. However, the fitting times across groups could be compared, as these are unaffected by duration of deafness or language.

The overall fitting time results indicate that, despite including more testing of outcomes during fitting and the adjustment of a greater range of parameters, FOX does not add to the overall fitting time. Initially, during the first 14 days, the fitting time for the FOX group was significantly lower than for the control group. However, by the end of the 6-month trial, the overall fitting times were equivalent.

In the first 2 weeks, the FOX group had three fitting sessions and the control group, depending on the centre, between two and five sessions. The control group underwent several fitting sessions where typically T- and M-level adjustments were performed, while the FOX group was fitted using the predefined auto-programs. In the first 2 weeks in the FOX standardized fitting procedure, the main focus of the fitter was to choose and download the auto-programs and instruct the subject on how to use them (Vaerenberg *et al.*, 2010). This resulted in a significant time advantage for the FOX group at the 2-week

assessment point. With the introduction of the additional speech perception and psychophysical testing required for the fitting of the FOX group after the 2-week session, this initial fitting time advantage was no longer present for the 1-, 3-, and 6-month sessions. However, the interquartile ranges for the control group were larger than for the FOX group, reflecting the variability in fitting times between subjects, centres, or individual clinicians. For the entire study duration, the median cumulative fitting time per subject for the FOX group was 2 hours and 12 minutes and for the control group was 1 hour and 57 minutes. The differences were not significant.

Conventional fitting procedures require each T and maximum comfort level to be individually measured; this can be done in a number of ways, therefore, there is not only variability in the absolute levels, but also in the way they are measured (Skinner et al., 1995). It is possible, however, to reduce the number of measurements to be made at switch on, without reducing speech perception performance, by interpolating values between electrodes, thus reducing the fitting time (Plant et al., 2005). Once the initial program is created, individual adjustments may then be made to any of the parameters depending on the feedback of the recipients. Cochlear implant clinicians may respond to user complaints differently and all these factors contribute to the variability in fitting times observed in the control group. The use of Tand M-level profiles for Advanced Bionics devices within FOX, which are then adjusted for audibility, eliminate the need to measure individual electrodes. Instead, adjustments to these generalized profiles are made on the basis of the FOX outcome measures. Therefore, the reduced variability observed in the FOX group is not an unexpected finding as it inherently reduces variability by introducing a standard fitting protocol, which was followed by all participants in the study group. No defined fitting protocol was followed in the control groups and if this had been done, then the variance in this group might also have been reduced.

A range of differing clinics participated in the study, all with many years of experience and implanting from 50 to a few hundred patients per year. They all based their fitting protocols on the manufacturer's guidelines but the participating clinics may still not be completely representative of all centres. If a more rigid conventional fitting protocol had been applied to the control group, there would have been less variability in the fitting times. However, the aim of the study was to compare FOX to the current norms of clinical practice, which are known to vary widely across centres and countries (Vaerenberg *et al.*, 2014).

Conclusion

Despite including more objective measures of performance than a standard fitting approach and the adjustment of a greater range of parameters during initial fitting, FOX did not add to the overall fitting time when compared to the conventional approach and significantly reduced the fitting time in the first 2 weeks. Based on these results, computer-assisted fitting can be successfully used at switch on, in different clinical environments and is efficient in providing a usable program.

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Disclaimer statements

Contributors

All authors contributed to this study.

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Conflicts of interest

FOX has been developed by the members of the Eargroup who have commercial rights to this product. No other author has any financial interest in FOX or any other conflict of interest to declare. An external consultant has been used to help with writing of this paper funded by Advanced Bionics.

Ethics approval

Country specific ethics approvals were obtained by each participating clinic.

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