



# Flat-based fitting: the evaluation and usefulness of a new strategy-based fitting approach for cochlear implants

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## Abstract

**Purpose** The traditional fitting method for cochlear implants (CI), the single-channel fitting (SCF), is effective but time-consuming. A fitting method that is significantly faster to perform, but provides at least equivalent speech understanding and subjective benefit would be of clinical usefulness. The study explored the ability of flat strategy-based fitting (FSBF) maps to fill this need.

**Methods** Participants were 16 experienced CI users. They were fit with: SCF maps; the maps that the participants used in their everyday lives, called fine-tuned clinical (FTC) maps; and FSBF maps. The fittings were assessed objectively via speech understanding in noise, time needed to create the map, deviation from FTC map, and correlation between auditory response telemetry thresholds and normalized charge levels; and subjectively via spectral balance and hearing quality.

**Results** FSBF maps were significantly faster to generate. FTC maps provided the best subjective hearing quality. In all other assessments, no significant differences were found.

**Discussion** FSBF maps can save time and provide CI users with the same level of speech understanding in noise. Participants may have preferred the FTC maps that they were already acclimated to them. These results suggest that the FSBF method could be used in first-fittings or in challenging fitting situations, but subsequent fine-tuning is required in follow-up appointments to improve sound quality.

**Conclusion** The FSBF method can be a useful and time-saving alternative fitting method in first-fittings or in challenging fitting situations.

**Keywords** Cochlear implant · Programming · Fitting · Flat-based map · Fine tuning · Speech understanding in noise

## Introduction

Adults and children with severe to profound sensorineural hearing loss can derive significant benefit from cochlear implant (CI) use, namely, speech understanding and an enhanced quality of life [1–4]. To provide the best possible clinical benefit, a CI must be appropriately adapted for each

individual user [5]. This process of adjusting the parameters of a CI to user-specific values is termed “fitting” and is performed by appropriately-trained clinical staff. Fitting is usually first performed approximately 4 weeks after implantation when the implantation wound has healed sufficiently, and then at regular intervals thereafter for as long as the CI is used. The traditional fitting method, sometimes called the single-channel fitting (SCF) method, is used by the audiologist to fit each channel individually. From a results/benefits perspective, the SCF method is effective. However, the SCF method is time-consuming: taking approximately 1 h or longer to perform [6]. If only a few people used a CI, then the time needed for every follow-up fitting with the SCF method might not be considered problematic; however, the number of CI users is constantly increasing, partly due to expanding indications [7, 8], and all CI users need to be periodically re-fit. Thus, the time required to refit every CI user

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is increasing and putting extra demands on clinics, which are likely already working at full capacity.

Therefore, there exists a clinical need to have a fitting method that is significantly faster to perform and that can create maps that provide users with at least the same levels of speech understanding and subjective benefit. A possible solution would be using “flat maps”, i.e., the maximum comfortable levels (MCLs) are set to identical charge levels in all channels and the pulsewidth is automatically adapted, as available in MAESTRO, MED-EL’s fitting software (Innsbruck, Austria). Thus, the primary objective of this prospective, acute, randomized, open-label, multicenter study was to evaluate if CI users have a similar or better objective and subjective hearing performance using maps created with such a method or with the traditionally created maps.

## Materials and methods

### Participants

To be included, all participants had to: be at least 18 years at study start; have post-lingual bilateral deafness; be unilateral CI users with at least 12-month experience with the OPUS1 (MED-EL, Innsbruck, Austria) or newer audio processor; have at least ten active electrode contacts; use the FSP, FS4, or FS4-p stimulation strategy; have a best-aided speech understanding with their implanted ear of  $\geq 45\%$  on a monosyllables test at  $65 \pm 5$  dB SPL or an speech reception threshold (SRT) of  $\leq 20$  dB SNR on a sentence-in-noise test; be willing and able to give feedback on the fitting process and map; and give their signed and dated informed consent before participating in any study-related procedures. Potential participants were excluded if they already used or were using a flat map (defined as:  $Q_{MCLmin}/Q_{MCLmax} \leq 1.03$ ).

All participants were recruited by and tested at the Klinik and Poliklinik für Hals-, Nasen- und Ohrenkrankheiten, plastische und ästhetische Operationen (Würzburg, Germany) or the Antwerp University Hospital (Antwerp, Belgium) between March 2016 and April 2017. The ethics committees in Würzburg (Julius-Maximilians Universität Würzburg-Ethik-Kommission bei der Medizinischen Fakultät, Versbacher Straße 9-97078 Würzburg) and in Antwerp (Comite voor medische Ethiek- Universiteit Antwerpen, UZA, Wilrijkstraat 10, 2650 Edegem) approved the study under the approval n. 88/16\_mp-ge and n. 5/48/520, respectively.

### Fitting strategies

Participants were tested while using three different maps: single-channel fitting (SCF) maps, fine-tuned clinical (FTC) maps, and flat strategy-based fitting (FSBF) maps.

SCF maps are created by fitting one channel after the other. This is the clinical routine in fitting CIs. The map from a first-fitting would be an SCF map.

FTC maps are the maps the participants had been using in their everyday lives at study start. While FTC maps are created in the same way as SCF maps, FTC maps are the result of months or years of refitting and adjusting participants’ maps at each routine fitting session. As such, they have evolved to suit each participant’s individual hearing profile.

FSBF maps are created via the new flat strategy-based fitting method, a simplified mapping approach. The FSBF method is based on the automatic adaptation of pulsewidth implemented in the MED-EL fitting software MAESTRO. Specifically, using International Speech Test Signal (ISTS) as a signal for the FSBF map generation and MAESTRO “Keep Live” mode, participants are offered all the properties of natural speech to allow the fitting in “real-life” settings. During the FSBF procedure, MCLs were increased for all channels simultaneously while presenting ISTS until the participants reported that the overall volume was optimal. The threshold was locked to 5% of the MCL for the SCF and FSBF maps.

### Assessment

Fitting and speech testing were conducted on a single day for each participant. All participants were tested with all three maps (SCF, FSBF, and FTC). The SCF and FSBF maps were newly generated during the study visit. Each map was downloaded onto the participants’ processors in a randomized order; therefore, participants did not know which map they were using while performing the speech reception testing or completing the subjective assessments.

### Hearing performance: SRTs

SRTs were determined for each map via the Oldenburg matrix sentence test (OLSA: the acronym is from the test’s original German name: *Oldenburger Satztest*). The OLSA is a sentence recognition test, which can be used to rapidly assess the SRT in dB SNR, i.e., 50% word understanding in noise, in dB. Lower numbers indicate a better score [9].

For the assessment of each participant, one 30-sentence test list was used for training purposes and to verify the inclusion criterion on speech understanding with the current clinical map of the participant. The speech level was fixed to 65 dB SPL and noise was adaptive. Speech and noise were presented simultaneously via the  $S_0N_0$  speaker setup, 1 m in front of the subject.

## Subjective assessments

The spectral balance of all three maps was assessed via study-specific visual analogue scales (VAS). Participants rated low frequencies (“bass”) and high frequencies (“treble”). These two frequency ranges were judged on a scale from “too soft” (with a value of 0) to “too prominent” (with a value of 100). The middle of the scale (a value of 50) corresponded to a pleasant perception of that frequency range. Participants were asked to rate sound perception after listening for a minimum of 10 s to ISTS at comfortable loudness level. Then, the results of the VAS scale were normalized to show spectral balance via the following equation:  $SB_{norm} = \frac{abs(VAS_{bass}-50)+abs(VAS_{treble}-50)}{100}$ . The range of this normalised parameter is from 0 to 1, wherein 0 indicates an optimal spectral balance and 1 the worst possible spectral balance.

After rating spectral balance of each map, participants’ self-assessed the sound quality of each map via VAS scales. For this, the same sound sample as for the spectral balance test was used. Subjective perceived sound quality was judged on a scale from “worst (unwearable)” with a value of 0 to “best” with a value of 100.

## Fitting duration (FSBF vs. SCF)

Start time was recorded upon loading the map template and stopped when comfortable loudness of map was reached.

## Deviation from the FTC map

To evaluate whether an SCF or an FSBF map is a better starting point for subsequent fine-tuning fitting, an overall deviation parameter (SdB) relative to FTC maps was calculated on normalized MCL charge values in dB by  $S_{dB} = \frac{\sum abs(Q_{normA,n,dB} - Q_{normB,n,dB})}{N}$ . Where *A* is SCF or FSBF map and *B* is the reference map FTC. The normalisation is done by  $Q_{norm,n,dB} = Q_{n,dB} - Q_{dB}$  where  $Q_{n,dB} = 20 * \log_{10}(Q_n)$ ,  $Q_{dB} = \frac{\sum Q_{n,dB}}{N}$  and  $n = \{1, 2, 3, \dots, N\}$  represents the index of all available channels/electrodes. This deviation parameter is indicative on how much modification during a fine-tuning is required to reach the final FTC map.

## Correlation between auditory response telemetry thresholds and normalized charge levels as generated by FSBF, SCF, and FTC approaches

Correlational analyses were performed to test the relationship between normalised auditory response telemetry (ART) thresholds across electrode contacts and the SCF and FTC normalised charge levels.

## Safety

As a safety endpoint, the occurrence of adverse events and device deficiencies was recorded.

## Statistical analysis methods

The mean with standard deviation (SD) or the median with the range (minimum and maximum) was used to report participants’ characteristics (e.g., age, sex, type of hearing loss, etc.) and to describe location parameter of the study outcomes. Qualitative data were presented as absolute and relative frequencies. The Wilcoxon signed-rank test was applied for all pairwise comparison.

Correlational analyses were performed to test the relationship between ART thresholds across electrode contacts to the single maps (SCF, FTC, and FSBF).

IBM SPSS Statistics (IBM, Armonk, New York, USA) was used for all analyses. A *p* value of  $\leq 0.05$  was considered statistically significant. For multiple comparisons, the Bonferroni correction method was used to adjust for multiplicity. Hence, for two pairwise, a *p* value of  $\leq 0.025$  was considered significant, for three pairwise comparisons, a *p* value of  $\leq 0.017$  was considered significant. The Kolmogorov–Smirnov test, the Shapiro–Wilk test, and a graphical examination were performed to check the data distribution.

## Results

### Participants

16 participants were included in the study. No subjects withdrew or dropped out. Participants were a mean 31.4 years at time of hearing loss (range 3–65 years), 57.3 years at implantation (range 27–80 years); and 62.8 years at testing (range 29.2–84.9). 15 participants had post-lingual hearing loss. 13 participants had progressive hearing loss; 2 had sudden hearing loss, and data are missing for 1 participant (Table 1).

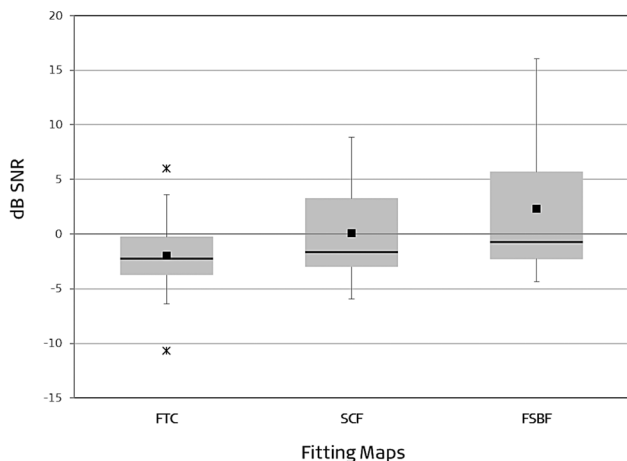
### Hearing performance: speech understanding in noise

Median SRTs with the range were as follows:  $-0.7$  (20.4) dB SNR with the FSBF map,  $-1.6$  (14.8) dB SNR with the SCF map, and  $-2.2$  (16.7) dB SNR with the FTC map. The difference between the score with the FSBF map and the SCF map was not significant (Wilcoxon signed-rank test:  $z = 1.268$ ,  $p = 0.205$ ). In addition, the difference between the score with the FTC map and the score with the FSBF map (Wilcoxon signed-rank test:  $z = 1.500$ ,  $p = 0.134$ ) or the SCF

**Table 1** Demographic data for all participants

Participant	Years old at			Implant type	Processor	Array	Fitting strategy	Side implanted
	HL	Implantation	Testing					
1	65	80	84.9	SONATAti100	OPUS 2	FLEXSOFT	FS4	Left
2	43	60	68.8	PULSARci100	OPUS 2	FLEXSOFT	FS4	Left
3	28	56	63.8	SONATAti100	OPUS 2	FLEXSOFT	FSP	Right
4	26	29	36.9	SONATAti100	OPUS 2	FLEXSOFT	FS4	Right
5	35	63	67.7	SONATAti100	OPUS 2	FLEXSOFT	FS4	Right
6	52	53	58.2	SONATAti100	OPUS 2	FLEXSOFT	FS4	Right
7	58	62	64.4	SYNCHRONY	SONNET	FLEX28	FS4	Left
8	20	48	56.5	PULSARci100	SONNET	FLEXSOFT	FS4	Left
9	40	65	71.4	SONATAti100	OPUS 2	STANDARD	FSP	Right
10	14	65	66.5	SYNCHRONY	SONNET	FLEX28	FS4	Left
11	34	46	50.3	SONATAti100	OPUS 2	FLEX28	FSP	Left
12	13	76	79.7	SONATAti100	OPUS 2	FLEXSOFT	FS4	Left
13	4	70	71.0	SYNCHRONY	SONNET	FLEXeas	FS4	Right
14	3	27	29.2	SONATAti100	SONNET	FLEX28	FS4	Left
15	32	65	69.1	SONATAti100	OPUS 2	FLEXSOFT	FS4	Right
16	36	51	66.4	C40+	OPUS 2	STANDARD	FSP	Right

HL hearing loss



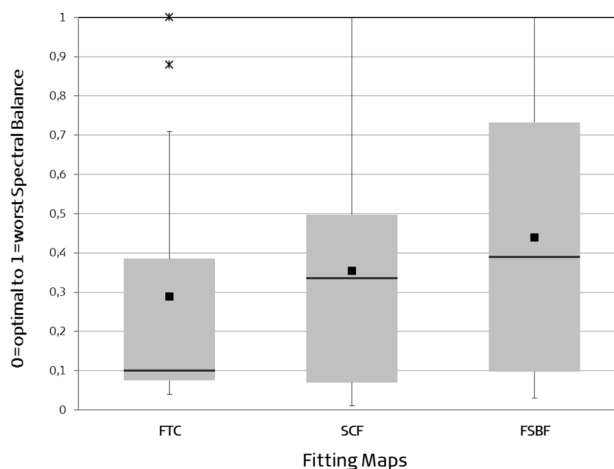
**Fig. 1** Results of speech reception thresholds (OLSA SRT) in dB SNR for each fitting map ( $n=16$ ). Black squares represent the mean, the horizontal lines the median. The black asterisks depict outliers. *FTC* fine-tuned clinical, *SCF* single-channel fitting, *FSBF* flat strategy-based fitting

map (Wilcoxon signed-rank test:  $z=1.501, p=0.133$ ) were not significant (Fig. 1).

**Subjective assessments**

**Spectral balance**

The median with range spectral balance scores was FTC: 0.1 (0.96), SCF 0.33 (0.99), and FSBF 0.39 (0.97). The spectral



**Fig. 2** Results on spectral balance for the three fitting maps, where 0 indicates an optimal spectral balance and 1 the worst possible spectral balance. Mean values are depicted as black squares, median values as horizontal lines. The black asterisks depict outliers. *FTC* fine-tuned clinical, *SCF* single-channel fitting, *FSBF* flat strategy-based fitting

balance with the FSBF map was not significantly different to the spectral balance with the FTC map (Wilcoxon signed-rank test:  $z=1.363, p=0.173$ ). Similarly, the spectral balance with the SCF map was not significantly different from the spectral balance with the FTC map (Wilcoxon signed-rank test:  $z=0.595, p=0.552$ ) (Fig. 2).

**Table 2** Participants' ranking (*n*; %) for sound quality according to map

	Quality		
	Best (%)	Intermediate (%)	Poorest (%)
FTC	14 (87.5)	0 (0.0)	2 (12.5)
SCF	1 (6.3)	13 (81.3)	2 (12.5)
FSBF	1 (6.3)	3 (18.8)	12 (75.0)

FTC Fine-tuned clinical (map), SCF single-channel fitting (map), FSBF flat strategy-based fitting (map)

### Self-perceived hearing quality

The FTC map provided significantly better self-perceived hearing quality than the SCF map (Wilcoxon signed-rank test:  $z = -2.540$ ,  $p = 0.011$ ) and the FSBF map (Wilcoxon signed-rank test:  $z = -3.092$ ,  $p = 0.002$ ), see Table 2 for the scores.

### Time needed to create fitting map

The mean time needed to complete SCF maps was 9.5 min ( $\pm 2.37$ , range 6.1–16.0). The mean time needed to complete FSBF maps was 1.82 min ( $\pm 0.64$ , range 0.57–3.0). This difference was significant (Wilcoxon signed-rank test:  $z = -3.517$ ,  $p < 0.001$ ). This result was consistent through all participants. The 95% confidence interval for the mean was 8.27–10.79 min for the SCF map and 1.48–2.16 min for the FSBF map.

### Deviation from the FTC map

The deviation of the FSBF map from the FTC map was  $-17.09$  dB and corresponds to 13.97%. The deviation of the SCF map from the FTC map was  $-18.38$  dB and corresponds to 12.04%. The difference between the two deviations was not significant (Wilcoxon signed-rank test  $z = -0.982$ ,  $p = 0.326$ ).

### Correlation between ART thresholds and normalized charge levels as generated by FSBF, SCF, and FTC approaches

No significant correlation between normalized ART thresholds across electrode contacts to the SCF and FTC normalised charge levels was found (FTC:  $r = -0.070$ ;  $p = 0.583$ ; SCF:  $r = -0.086$ ;  $p = 0.500$ ).

## Discussion

The aim of this study was to evaluate if using the FSBF method to fit CI users is an effective and time-saving alternative to using the traditional SCF approach. The clinical need exists for such a fitting method, because while more candidates receive a CI and, therefore, require follow-up care and fitting, clinical structures and resources have not grown to meet this increased need. Finding a fitting approach that is quick and easy to perform yet can provide CI users with the same hearing accuracy as the slower traditional fitting approach would greatly speed up the fitting sessions and, therefore, facilitate daily clinical routine in busy departments.

The speech understanding in noise results in the present study demonstrating that performance with an FSBF map is not significantly different than with an SCF or an FTC map. As this study had an acute, prospective design, participants' habituation time with the newly created FSBF maps was not equal to that with the FTC maps, which they had already been using and become habituated to. FTC maps are usually created over months or even years to provide optimal hearing performance for each user's individual hearing profile and preferences. In our acute setting, using a newly created FSBF map did not worsen speech understanding, despite the short acclimatization time.

To prevent loudness imbalance in our study, the International Speech Test Signal was presented at 65 dB SPL, while charge levels were increased equally over all channels in "live mode". The perception of spectral balance was judged for each of the three maps and showed that the most optimal spectral balance was rated with the FTC map, whereas the FSBF map showed a trend towards poorer spectral balance. On a personal ranking, the FTC map provided the best sound quality and the FSBF map the worst sound quality. This subjective finding may be explained by the fact that the FTC map was the map that the participants were familiar with and had been customized for their individual hearing profiles over several clinical visits. It is possible that if users had been acclimated to the FSBF like they were to the FTC map, the subjective hearing quality result may not have been significantly different. Technological development may also explain the differing results between the present study and Boyd [10] who, in his study on 12 adults who had 7–46 months of CI experienced CI, found that speech discrimination was significantly poorer with the flat-based map compared to the fine-tuned map. Whereas the participants in Boyd [10] used the then-current TEMPO + audio processor and an older coding strategy, the participants in the present study used newer audio processors (such as OPUS 2 or SONNET) and the newer coding strategies. The advantages

of fine-structure sound-coding strategies have been reported in several studies [11, 12].

The calculation of deviation parameters from the participants' FTC map revealed that there was no significant difference. This parameter supports the idea that using a flat-based fitting approach may cause sound quality to be subjectively appraised differently than with an FTC or SCF map, but does not deteriorate speech understanding. In addition, the time needed to create an FSBF map was significantly shorter than the SCF map. CI manufacturers aim to find alternatives to the time-consuming psychophysical process provided by single-channel stimulation.

Several “quick-fit” and time-consuming ideas exist, e.g., “streamlined fitting” (Custom Sound Fitting SW, Cochlear Ltd., Sydney, Australia). Here, the MCL of 3–5 electrodes spread widely across the array are determined and MCL for all other electrodes are interpolated. The audio processor is then set to “live” and the clinician talks with the CI recipient until a satisfactory perceived loudness level is established. Another approach using “speech bursts” is implemented in the fitting software “Soundwave” (Advanced Bionics, Stäfa, Switzerland). Here, 4 channels are activated simultaneously using speech bursts that are elevated until the most comfortable level is found (AB refers to this as the “M level”).

The FOX algorithm, which is an outcome-based fitting approach (FOX- Fitting to Outcome eXpert) [13], is an alternative approach that can be used for first-fitting sessions and in follow-up fittings with experienced CI users [14]. This algorithm establishes the fitting parameters based on hearing performance, not on loudness and threshold perception. A number of measurements, e.g., soundfield-aided thresholds using warble tones at determined frequencies, phoneme discrimination, loudness scaling, and speech audiometry results, are considered for the FOX-fitting [13]. Overall, it seems that the choice of fitting approach is also dependent on the clinician's preference and training provided by CI manufacturers.

Although all the participants in the present study were experienced CI users, the objective results suggest that the FSBF approach would be useful for first-fittings. In subsequent fitting sessions; however, fine-tuning should be used to optimize sound quality and support the adaptation process. In addition, the FSBF approach could be especially helpful to use with CI users/recipients who have difficulty expressing their needs and are, therefore, challenging to fit via the traditional methods.

In conclusion, a flat-based fitting approach is a straightforward and easy-to-implement procedure that can be a useful alternative to single-channel fitting in challenging situations or in situations, where CI recipients cannot express their hearing sensations. Speech understanding with a flat

map is not significantly different than with maps created with single-channel stimulation and may, therefore, serve as a good starting point for fittings. Subsequent fine-tuning is required in follow-up appointments to raise spectral balance and sound quality. Further testing is necessary to assess the effect of a longer habitation period with an FSBF map on users' subjective feedback.

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## Compliance with ethical standards

**Conflict of interest** The Antwerp University Hospital is currently receiving a grant from MED-EL Medical Electronics. This study was sponsored by MED-EL and supported by HEARRING.

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