Tonotopic and Default Frequency Fitting for Music Perception in Cochlear Implant Recipients

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Comparison of tonotopic and default frequency fitting for music perception in cochlear implantees: a randomized, double-blind, cross-over clinical trial

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KEY POINTS

Question: What is the benefit of a tonotopic map on music perception in new cochlear implant users**?**

Findings: In this prospective, randomized, double blind, cross-over clinical trial that included 26 new cochlear implant users, the tonotopic map appeared relevant to obtain better results in perception of complex sound signals such as music listening experience. Ninety-two percent of the subjects kept the tonotopy-based map after the study period.

Meaning: The tonotopic fitting should be proposed to new cochlear implant users to enhance their pitch and musical perception.

ABSTRACT

Importance: Cochlear implants (CI) are an effective technique for enhancing speech perception abilities in quiet environment of people with severe-to-profound deafness. Nevertheless, complex sound signals perception, such as music perception, remains challenging for CI users.

Objective: To assess the benefit of a tonotopic map on music perception in new CI users.

Design: A prospective, randomized, double-blind, two-period cross-over study in 26 new CI users was performed over a 6-month period.

Setting: An anatomical tonotopic map was created using post-operative flat-panel computed tomography and a reconstruction software based on Greenwood function.

Participants: New CI users older than 18 years with bilateral severe-to-profound sensorineural hearing loss or complete hearing loss for less than 5 years were selected in the University Hospital Centre of Rennes in France.

Intervention: Each participant was randomized to receive a conventional map followed by a tonotopic map or vice versa.

Main outcomes and measures: Participants performed pitch-scaling tasks (multidimensional qualitative assessment, melodic contour identification, melodic recognition test) after 6 weeks of each setting.

Results: Thirteen subjects were randomized to each sequence. Two of the 26 subjects recruited (one in each sequence) had to be excluded due to the COVID-19 pandemic. The multidimensional qualitative assessment (Gabrielsson test), melodic contour identification and melodic recognition scores were significantly higher with the tonotopic setting than the conventional one (Mean Effect (ME)=7.8, CI95%=5;10.5, ME=12.1%, CI95%=5.7;18.4, ME=14.4%, CI95%=8.5;20.2, and ME=2.1, CI95%=1.7;2.5, respectively). Among the different dimensions evaluated by the Gabrielsson test, the mean scores for clarity, spaciousness, fullness, nearness, total impression were significantly higher with tonotopic fitting. Ninety-two percent of the subjects kept the tonotopy-based map after the study period.

Conclusion: For new implanted cochlear patients, a tonotopic-based fitting appears relevant to obtain better results in perception of complex sound signals such as music listening experience.

Trial registration: Clinical Trial number NCT04922619

INTRODUCTION

Hearing loss compromises the perception of speech and other complex sound signals[1,2]. Music is a set of complex sounds and, as such, people with hearing loss experience difficulties in perceiving music[3,4]. While speech perception can be provided by a cochlear implant (CI), music perception remains challenging[5–8].

CI users 'perception of musical rhythms is close to that of people with normal hearing, but there is degraded perception of pitch, partly due to degradation of spectral features[9–13]. One explanation for this difference is that the perception of the temporal features, like rhythm, is related to the sampling rate of the CI, which is generally high, while the spectral representation of the CI is generally low[11,14,15]. Part of the reason for this poorer spectral representation is that, due to the variability of cochlear dimensions[16–18] and of surgical aspects[19], a mismatch can be introduced between the frequency allocation of a CI electrode contact and the tonotopic frequency of the neurons stimulated by that contact[20–22]. This frequency-to-place (f-t-p) mismatch, may affect pitch perception.[23]

F-t-p mismatches can be evaluated using flat-panel Computed Tomography (CT) imaging of the cochlea, combined with 3D curved multiplanar reconstruction to identify the position of each electrode contact within the cochlea relative to the apex[24–26]. Using the Greenwood's function[27], these contact positions can then be related to the tonotopic frequency of the proximal hair cells along the organ of Corti (OC). F-t-p mismatches can then be calculated and compensated by adjusting the contact frequency allocations, yielding a personalized tonotopic frequency map[24].

The impact of the f-t-p mismatches on the speech perception has been assessed in several studies[28–30], e.g., Canfarotta et al.[21] demonstrated that reducing mismatches at 1500Hz improved speech perception at 6 months post-activation when CI users alone with greater than 7 semitones were included. Few studies, however, have focused on the impact of mismatches on music perception[11,31–33]. One study found that mismatches could lead to an overlapping or distortion of the perception of the complex spectral cues, including musical extract[11].

The primary aim of the present study was to compare the effect of tonotopic versus conventional maps on perception of complex sound signals in new CI users.

MATERIALS AND METHODS

Ethical considerations and study design

The study was approved by the independent South Mediterranean V Committee for the Protection of Persons on 16-April-2019 (#2018-A01813-52). The Clinical Trial number was NCT04922619. Participants received oral and written information about the study and gave their free and informed consent.

The study was designed in accordance with the current guidelines of the CONSORT 2010 statement for reports presenting randomized clinical trials[34,35]. The participants were randomized during the CI activation session into study arm A: conventional fitting (CF) followed by tonotopic fitting (TF), or in study arm B: TF followed by CF. A block randomization of size two with a ratio 1:1 using a random number table was applied.[36] Participants used each fitting map for 6 weeks. Assessment was performed at 6 and 12 weeks. Participants then chose the fitting they preferred.

Inclusion criteria

The inclusion criteria were: ≥18 years old, bilateral severe-to-profound sensorineural hearing loss with ≤50% preoperative speech discrimination in quiet using Fournier word lists (or equivalent) at 60 dB with optimized hearing aids (the criteria for cochlear implantation in France[37]). The exclusion criteria were: <18 years old, residual low-frequency hearing with a threshold lower than 60 dB HL on 250 Hz and 80 dB HL on 500 Hz, total hearing loss without wearing conventional hearing aids for more than 5 years, CI array insertion depth of <540°[19] (to attain an apical tonotopic frequency not less than about 350 Hz on the OC map), and not having too many (≤4) electrode contacts positioned at tonotopically high frequencies.

Imaging Procedure and Implant Setting

Flat-planel computed tomographic (CT) imaging was performed pre- and post-implantation with a Toshiba Aquilion Prime 128 (Toshiba Medical Systems, Crawley, UK). CTs were imported into the planning software OTOPLAN v1.2 (MED-EL, Innsbruck, Austria)[38,39]. All participants received a SYNCHRONY CI. Array length was based on cochlear size derived from pre-operative CT measurements: participants with cochlear diameter (measure A) of ≤9.2mm received a FLEX28; those with a diameter of >9.2mm received a FLEX31. Participants received a SONNET or RONDO audioprocessor.

For the conventional setting, the strategy High-Definition Continuous Interleaved Sampling (HDCIS) (eTable1) coding strategy was used.

With OTOPLAN, tonotopic frequency was determined by first using the Alexiades method[40] to estimate the cochlear duct length and using the Greenwod function[27] to calculate the corresponding frequency. The complete procedure for setting the CI bandpass filters was detailed by Creff et al.[41] In short, up to the threshold of 3000 Hz, the upper corner frequency of each bandpass filter was set to the tonotopic frequency of the respective electrode contact. The low frequency of the passband was: for the first electrode contact (E1), equal to the high frequency less 84 Hz as with the HDCIS strategy; and for the other contacts equal to the high frequency of the previous contact. No constraint was put (except limitation of the system to 70 Hz) on the low frequency of E1. The 3000-Hz cutoff was chosen because of the importance of mid-frequency information for speech recognition and to avoid the deactivation of contacts at a tonotopic frequency above 8500 Hz[42]. Beyond the threshold of 3000 Hz, a logarithmic filter distribution was applied was estimated based on the formula $\frac{High\ frequency - Low\ frequency}{Central\ frequency} = k$, with k as a constant value and the high frequency of the 12th electrode (E12) less than or equal to 8500 Hz. Then, the high frequency of E12 was set at 8500 Hz.

Moreover, for each CI recipient, the contact with the AID (angle insertion depth) closest to 267° was identified, corresponding approximately to 1500 Hz on the spiral ganglion (SG) map. The f-to-p mismatch for 267° on the SG map was evaluated by subtracting 5.5 semitones of the f-to-p mismatch on the OC map of each of these contacts[21,42].

Assessment procedure

Testing was performed in free field, in a soundproof cabin. The volume setting was left to the discretion of the participant. The contralateral ear was not fitted or masked.

Multidimensional qualitative assessment (Gabrielsson test)

Participants listened to 2 pieces of music: Bach's Suite N°1 in G major, BVW 1007 from the beginning to 1min30sec, and Mahler's Symphony N°5 in C minor from 1min30sec to 3min. After listening, participants rated the sound quality on the Gabrielsson scale (eFigure1)[43,44], which is a visual analogue scale with 8 items scored from 0-10, in which scores of 10 indicate the best sound quality[45,46].

Melodic contour identification

Melodic contour identification (MCI) was measured using Angel Sound software (Angel Sound® v.5.08.03, Emily Shannon Fu Foundation) [47,48]. This program randomly generates stimuli consisting of 9 melodic lines with 5 notes separated by 3 semitones (A1-C2-D#2-F#2-A2) (eFigure2). This interval of 3 semitones was chosen to consider inter-subject variability in performance[49] and to ensure that the F0s for the Rising and Falling contours fell within the 0–500 Hz bandwidth condition.
To assess the spectral complexity of the music, 2 spectral energy distribution tests were performed[50]. The first (MCI1) used 2 distant harmonics (lowest frequencies: 275 and 440Hz) and the second (MCI2) used 2 close harmonics (lowest frequencies: 275 and 330Hz)[51]. During the preparation phase, the patient listened twice to each melodic contour by clicking on each of the pictograms. Then during the test phase, 18 melodic lines were played at random. Each line could be replayed a maximum of 3 times. After listening to each line, the patient had to click on the pictogram that he thought corresponded to the melodic contour. Scores were percentage correct.

Melodic Recognition Test (MRT)

Each participant choose 2 pieces from a list of 10 familiar pieces. These 2 pieces were then each played twice for 40 seconds. Participant assessed how recognizable the melodies were on a visual analogue scale from 0-10 (0 “not at all”, 10 “fully recognized”) (eFigure3).

Statistical Analysis

Multivariate analysis of cross-over data was performed using a mixed model(MM)[52]. The model fixed effects evaluated were the treatment (TF/CF), the period (evaluation at 6 and 12 weeks), and sequence (CF then TF/TF then CF) effects[52,53]. The participant was set as the random factor in the model. A p-value of <0.05 was considered significant. Mean effect (ME) with 95% confidence interval (CI95%) and standardized effect size (ME on within standard deviation; SES) were calculated. To assess the impact of the setting on the qualitative dimension of Gabrielsson test, a MM (with treatment, period, and sequence effect) was performed for each dimension. Various Spearman's correlation analyses were used to investigate correlation between scores on each musical test and 1) participant factors (angular insertion depth, age, duration of hearing deprivation, f-t-p mismatch for each contact, average f-to-p absolute mismatch with CF and TF [28,54], f-to-p mismatch for 1500 Hz (i.e.267°) on the SG map[28,54]) and 2) fitting factors (lowest frequency of TF, centre frequency (Fcen) of TF filters, bandwidth of TF filters, and the difference between TF and CF for these factors). Effects of various fitting factors (lowest frequency difference between TF and CF, average of the absolute value of the f-to-p mismatch, f-to-p mismatch for 1500 Hz on the SG map, average of difference of filters position and bandwidth between TF and CF) were studied by adding a fixed effect in the MM including treatment, period, sequence for each musical test. Assumptions of the MMs were validated by normal Q-Q plot of studentized residuals, plot of the studentized residuals versus the fitted responses from the MM and Shapiro-Wilk tests (p>.05)[52].

All analyses were performed using R software 3.4.0[55].

18 participants are needed to be able to demonstrate a standardized difference (effect size) of 0.7 between the TF and the CF with a power of 80% at the alpha risk of 5% (two-tailed test). Sample size calculation was performed using SSS Software[56].

RESULTS

Population

24/26 participants received the 2 fittings and the 2 phases of musical tests. Two participants were excluded because they could not keep the appointments as planned in the study protocol (Figure1). The participant demographics and clinical characteristics, cochlear dimensions and CI characteristics are presented in Table1. No significant inter-group differences were found.

Implant settings

For each contact, the frequency shift with CF (tonotopy frequency according to OC map-CF center frequency) and with TF in semitone is presented in Figure 2. Compared to CF, TF reduced f-to-p mismatches (mean difference (CF-TF) =2.3 semitones; CI95%=1.2;3.5), and covered a wider frequency bandwidth (mean difference(CF-TF)=92.3 Hz, CI95%: 57.9;126.7). TF did not always have more filters in low frequencies: below 1087 Hz, CF has 5 filters and for TF it depended on the participant (1 with 3 filters, 5 with 4, 9 with 5 and 9 with 6). From E9 to E1, the mean shift between TF and CF was from -3.6 ± 3.7 (E8) semitones to 8.1 ± 7.1 (E1) semitones. This negative shift between TF and CF means that the basal shift from OC was larger for CF than TF.

Multidimensional qualitative assessment (Gabrielsson test)

The mean total score across both study arms was 44.9 for CF (CI95%=42.1; 47.8) and 52.7 for TF (CI95%=51.2; 54.2)(Figure3A). There was a significant effect of fitting on the total score with no significant effect of period or sequence effect(Table2).

The mean scores for clarity, spaciousness, fullness, nearness, global impression were significantly higher with TF (eTable2).

MCI

MCI1

The MCI1 score was 43.7% for CF (CI95%=32.4%; 49.9%) and 55.8% for TF (CI95%=46.6%; 64.9%)(Figure3B). There was a significant effect of fitting and of period but no sequence effect (Table2). Seventeen participants had a better score with TF, 2 with CF and 5 had the same score (4 of whom were in study arm A).

MCI2

The MCI2 score was 41.2% (CI95%=32.4%; 49.9%) for CF and 55.6% (CI95%=46.9%; 64.2%) for TF (Figure3C). There was a significant effect of fitting with no effect of period or sequence (Table2). Twenty participants had a better score with TF, 3 with CF (all in study arm A) and 1 kept the same score.

MRT

The mean MRT score was 5.8 (CI95%=5.2; 6.4) for CF and 7.9 (CI95%=7.3; 8.5) for TF (Figure3D). There was a significant effect of fitting and of period but no sequence effect (Table2). All participants identified the melody better with TF. Only 1 participant gave a better score for 1 of the 2 tracks; 4 participants gave identical scores with the 2 settings for 1of the 2 tracks but gave a better score for the TF for the other track.

Associated factors

No significant Spearman correlation was observed between musical test results and AID of E1; E1 low frequency with TF; the deviation of this frequency with TF compared to CF; the position or bandwidth of the frequency filters of the contact, for each contact, or the f-t-p mismatch with CF; its absolute value for each contact in semitone or the average frequency-shift with CF; or f-to-p mismatch for 1500 Hz on the SG map (eTable3A/B). No significant effect on the musical test results was observed by adding the following factors as fixed effect in the MM (eTable3C):

- the average of the absolute value of the difference of Fcen between TF and CF, or of the absolute value of the difference of bandwidth calculated on all the contcats for each participant

- the average frequency-shift (with CF or TF)
- the f-to-p mistmatching at 1500Hz on the SG map

At the study end, 22/24 participants chose (in a blind way) to keep the tonotopic setting. The 2 who kept the CF were both from study arm n°2 (TF first): 1 because the results were poor with both settings, and he/she did not want to use a new frequency map; the other because his/her personal circumstances that made new fitting sessions impossible.

DISCUSSION

Respecting the natural tonotopic frequency distribution of the cochlea is advantageous to perceiving complex sounds[57]. Jiam et al.[23] observed a significant improvement in pitch scaling accuracy during acute testing when using image-guided frequency allocations compared to a conventional map. In the present prospective study, we evaluated the association between image-guided frequency mapping and music perception among new CI users. In our study we employed intra-subject comparisons, as such there was no variation of electrode array length, angular separation of electrode contacts, or coding strategy (HDCIS), and the filter frequency settings were fixed over time between two evaluations. We found that on average, compared to CF, TF reduced f-to-p mismatches and covered a wider frequency bandwidth[41]. On average, the TF shifted the center frequency of the most apical contacts slightly toward the low frequencies, but with more variability of the bandwidth and without always having more filters in low frequencies. A great degree of variability was found between the locations of the filters and their distribution on the total frequency band (Figure in Supplemental Digital Content 3, http:// links.lww.com/EANDH/B211).

TF facilitated higher performance in musical tests, whether in multidimensional qualitative assessment, MCI, or MRT.

TF significantly improved multidimensional perception of music. Mean scores were higher with the TF in 5 of the 8 dimensions of the Gabrielsson test[43,44,58].The sound quality improvement observed with TF could be due to the delivery of low frequency information[59]. In the present study, 20/24

participants had a lower E1 low frequency(lowF_E1) with TF than with CF. No significant correlation or effect was observed between music test results and lowF_E1 with TF (or with the deviation of lowF_E1 with TF compared to CF). This means that participants with a frequency bandwidth reduction towards the high frequency and those with a frequency bandwidth expended toward the low frequency had the same gain in Gabrielsson assessment. Expansion toward lower frequencies might have had a positive effect, but this effect cannot explain the results for all the participants.

TF improved MCI results. The improvement in MCI results could be due to a denser frequency allocation in low frequencies[60]. For the TF, high variability was found between the locations of the filters and their distribution on the total frequency band. However, for each contact, no correlation was found between the MCI results and the bandwidth, filter location, or the difference of these 2 parameters between TF and CF. Therefore, looking at each electrode, better results were not observed if TF Fcen (or difference (TF-CF)) increased or decreased, or when TF bandwidth (difference (TF-CF)) increased or decreased. Moreover, no significant effect of the average of the absolute value of the difference of Fcen between TF and CF or of the absolute value of the difference of bandwidth calculated on all the contacts for each CI recipient was observed on the MCI results by adding this factor as fixed effect in the MM (eTable3). There was no clear pattern of bandwidth distribution on the band with TF. Moreover, the TF did not, always have more filters in low frequencies. Thus, it did not seem that gain in MCI with TF was due to a specific modification of the position or bandwidth of the filters that would be similar for all CI recipients.

The mean MRT score was greater with TF. These improvements could be due to a better music pitch perception based on place cues[61]. For each contact, no correlation was found between the MRT results and all the position or bandwidth parameters of the contact. No Spearman correlation was found between MRT (with TF or CF) and MCI results. Thus, the improvement may be due to more than just better melodic contour recognition. The improvement could be based on brightness[61], however no correlation was found between melodic recognition results and Gabrielsson results, including for brightness. Finally, no effect of the E1 lowF was observed on the MRT results. Thus, it seems that gain in MRT with TF compared to CF was due to a better tonotopic adjustment, not a denser frequency allocation in low frequency or an expansion toward lower frequencies.

In addition to a better low frequency range coverage, the individualized tonotopic adjustment with personalized assignment of the positioning and width of the electrode filters improved sound quality, contour of melodic and pitch direction change perception, and gave more faithful representation of a familiar melody and a better intelligibility in noise[41](standardized effect sizes between 0.68 and 1.07 depending on the signal-to-noise ratio and between 0.90 and 2.1 for the musical assessment).

The present study has some limitations. While the software is reliable[38,39] and the cochlea measurements were verified by 2 independent physicians, the tonotopic map creation requires manual identification of the contact, which could be source of inaccuracy. In addition, to ensure that the total bandwidth was not a confounding factor, we used a compression formula to set an upper limit of 8500Hz. The Greenwood function was used for technical reasons (SG initiation is more imprecise than OC initiation[62]).Nevertheless, since this study, tonotopic-based electrocochleography have been proposed and also appeared relevant to improve cochlear implant performance[63]. Like Jiam et al.[23], we used the HDCIS strategy in order not to add temporal fine structure information at low frequencies and therefore introduce a confounding factor. In addition to the music assessments realized, psychoacoustic measurement will be interesting to compare the 2 fittings. Finally, as there is no consensus on the ideal duration of the fitting procedure before the audiometric evaluation, we chose a compromise between the 30-minute acclimation period proposed by Jiam et al.[23] and a duration that is ethical for CI users. The change of setting instantly modifies all sound perceptions, which the participant needs time to become accustomed to. While promising over 6 weeks, this difference may diminish over time. Rouger et al.[64] observed increased auditory performance in the first months post-implantation, plateauing around the seventh month, with no significant improvement thereafter. Mertens et al.[28] found a correlation between frequency-to-place mismatch and speech perception in noise at 6 months, which disappeared after 12 months. Brain plasticity may compensate for the mismatch after months or years of CI use[65–67]. However, adaptation may remain incomplete or extend the acclimatization period even after many rehabilitation sessions[68–71]. Further studies on TF and its impact on music perception in experienced CI users will be relevant.

Conclusion

For newly implanted CI users, a tonotopic-based fitting (TF) appears beneficial for perceiving complex sound signals, e.g., music. At study end, 92% of participants chose to keep the TF setting for their daily use.

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Figure legends

Figure 1: Flow Chart, realized according Consort recommendations[35]

Figure 2: Frequency shift in semitones between the frequency according to OC map and the centre frequency with TF or CF for each electrode contact
In light gray: frequency shift for CF; in dark grey: frequency shift for TF; E(X): electrode number X.

Figure3 : Boxplot for the musical test score study arm A and B. CF: conventional fitting (in grey) and TF: tonotopic fitting (in black).

A) Gabrielsson test total score: in the study arm A, the mean total score (on 80) was 43.0 (SD=7.2) for CF and 51.9 (SD=3.7) for TF. In the study arm B, the scores were 46.8 (SD=5.8) and 53.5 (SD=3.4) respectively.
B) MCI1: in the study arm A, the score was 45.4% (SD=16.0) for CF and 48.2% (SD=16.6) for TF. In the study arm B, the mean scores were 42.1% (SD=24.0) and 63.4% (SD=24.0), respectively
C) MCI2: in the study arm A, the score was 44.4% (SD=17.6) for CS and 55.6% (SD=19.8) for TS. In the study arm B, they were 37.9% (SD=23.8) and 55.6% (SD=22.0), respectively
D) MRT: in the study arm A, the score (on 10) was 5.8 (SD=1.3) for CF and 8.4 (SD=1.3) for TF. In the study arm B, the scores were 5.8 (SD=1.7) and 7.5 (SD=1.4)

Tables

Table1: Subject data, cochlear dimensions and implant characteristics

Characteristics	Study arm A (n=13)	Study arm B (n=13)	p-value
Patients			
Gender, n(%) Male Female	 7 (53.9%) 6 (46.2%)	 7 (53.9%) 6 (46.2%)	1.000
Age at diagnosis of deafness, mean (SD)	39.92 (21.5)	36.08 (22.5)	0.643
Age at first hearing aid, mean (SD)	44.23 (21.8)	40.38 (24.1)	0.719
Age at implantation, mean (SD)	58 .00 (20.3)	61.92 (18.9)	0.700
Etiology of deafness Autoimmune Genetic Iatrogenic Infection Otosclerosis Noise exposure Idiopathic	 1 (7.7%) 4 (30.8%) 1 (7.7%) 1 (7.7%) 1 (7.7%) 0 (0.0%) 5 (38.5%)	 0 (0.00%) 7 (53.9%) 0 (0.0%) 1 (7.7%) 1 (7.7%) 1 (7.7%) 3 (23.1%)	0.684
Cochlear dimension (in mm)			
Cochlea diameter, mean (SD)	9.00 (0.5)	9.07 (0.3)	0.408
Cochlea width mean (SD)	7.61 (0.4)	7.76 (0.5)	0.340
Cochlea height, mean (SD)	3.76 (0.4)	3.68 (0.4)	0.550
Estimated CDL[a], mean (SD)	37.04 (2.9)	38.37 (2.4)	0.259
Angle insertion depth, mean (SD)	597.95 (39.3)	632.74 (63.0)	0.106
Cochlear implant			
Implantation side Right Left	 7 (53.9%) 6 (46.2%)	 7 (53.9%) 6 (46.2%)	1.000
Implant model Pin FLEX 28 Pin FLEX 31	 9 (69.2%) 4 (30.8%)	 7 (53.9%) 6 (46.2%)	0.688
E1 tonotopic frequency (OC[b])	255.96 (69.4)	215.00 (104.9)	0.271

[a] CDL: Cochlear Duct Length (in mm), [b]OC: Organ of Corti
Mann-Whitney test for continuous variables, chi² for dichotomous variables

Table 2: Fitting, period and sequence effect for the 3 musical tests

	Gabrielsson test	MCI1	MCI2	MRT
Fitting effect, ME(TF-CF) (CI95%), standardized effect size (SES)	7.8 (5.2; 10.3), 1.2	12.1% (6.0%; 18.1%), 0.9	14.4% (8.9%; 19.9%), 0.9	2.1 (1.7; 2.5), 2.1
Period effect, ME (P2-P1) (CI95%)	1.13 (-1.45; 3.69)	-9.3% (-15.3%; -3.3%)	-3.3% (-8.8%; 2.3%)	0.47 (0.06; 0.87)
Sequence effect, ME (CI95%)	2.67 (-0.66; 5.99)	6.0% (-9.3%; 21.3%)	-3.3% (-19.1%; 12.5%)	0.40 (-1.47; 0.66)