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Ethical Committee: Informed consent was obtained from each participating subject and ethics approval was given by the French ethical committee: óComité de Protection des Personnes ï Ile-de-France VIô. Subjects obtained no reward or personal gain from taking part in the study. The study was conducted in accordance with the Declaration of Helsinki and followed Good Clinical Practice Guidelines.

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INTRODUCTION

Exchange of the sound processor of cochlear implants (CI) allows existing implant recipients to take advantage of any advances in sound processor technology by exchanging or upgrading their current processor to a newer model [1,2]. Funding of processor upgrade differs from one country to another. Considering the high prices of the processors, the benefit provided by new processors must be demonstrated.

In 2013, Advanced Bionics (AB, Stäfa, Switzerland) introduced the Naída CI Q70 (Naída CI) sound processor. As well as being compatible with the newest AB cochlear implant systems, it was also compatible with the existing HiRes 90KÊ and CIIÊ cochlear implant systems and therefore existing recipients of AB devices, who were using older sound processor types, could be upgraded to the newer technology. In addition to the functions and sound processing technology already available in the previous generation sound processors, the Naída CI introduced an acoustic signal processing beamforming technology called UltraZoom, which was already used in Phonak hearing aids (Nyffeler, Reference Note 1). The intention was to help AB implant recipients to communicate more easily and effectively in noisy environments, which still remains a challenge, even for the best performing recipients [3].

UltraZoom is an adaptive multi-channel dual-microphone beamformer that focuses on input originating from in front of the listener, while attenuating sounds coming from the sides and from the rear (Fig. 1). It works by exploiting timing and phase differences in the signal arriving at two spatially separated front and back omnidirectional microphones, positioned on top of the processor. The inputs from the two microphones are subtracted from each other, after applying an appropriate delay, and a front-facing directionality pattern is created, reducing input from the rear hemisphere and creating a null point where sounds are completely attenuated. The adaptive nature of UltraZoom allows it to constantly change the directionality of the null, based on the loudest noise source in 33 separate channels, thus suppressing moving noise sources as well as static ones [4].

Previous studies evaluating adaptive beamforming technology with ~~Cochlear Ltd.~~ CI devices have shown that it can significantly improve the perception of speech in noise [5-~~9~~8]. Geißler et al. [4] tested UltraZoom as implemented in the Naída CI in 10 subjects, and showed significant improvement in speech perception in noise in a variety of challenging and realistic conditions, when compared to the Harmony sound processor. However, subjects had no take-home experience with the new sound processor and therefore it is not known if they would have been able to transfer these gains shown in the laboratory, into the real world. This is a potential issue for all beamforming technologies, as CI users report smaller subjective benefits than expected from laboratory testing [5]. In part, this may be due to the fact that listeners often find themselves in situations where speech and noise sources are not sufficiently spatially separated, particularly in reverberant environments, which results in cancellation of the speech signal as well as the noise and reduces the signal to noise advantages gained [~~9~~10,~~11~~12]. In the previous studies where subjective measures have been reported, two failed to show a significant improvement in subjective performance with the beamforming technologies using the Speech Spatial Qualities questionnaire, even though the objective results did show a significant benefit [5, ~~9~~10]. Only Mosnier et al. [1] did show a significant improvement in performance in both objective and subjective measures using the Abbreviated Profile of Hearing Aid Benefit (APHAB) [~~12~~13], when subjects using Cochlear Ltd. devices were upgraded to the newer CP810 speech processor with additional directionality.

The objectives of this study were to compare the performance of a group of existing AB cochlear implant users, who were upgraded to the new Naída CI sound processor, in a test of speech perception in noise with and without UltraZoom and to compare their subjective performance with their current sound processor, to their subjective performance after upgrading to the new Naída CI sound processor.

METHODS

Subjects

From February to November 2015, 34 adult subjects aged between 21 and 89 years old (mean 52.8 ± 18.5) were prospectively enrolled in a single tertiary ~~referent~~ referral center. Subjects were required to have at least one CII/HiRes 90K cochlear implant, a postlingual onset of severe-to-profound hearing loss (Ó6 years of age) and French as their first language. The demographic data of these subjects is presented in Table 1. Nine subjects were unilaterally implanted, 11 bilaterally implanted and 14 were bimodal users with a hearing aid on the contralateral ear. All subjects were experienced CI users (5 to 14.7 years, mean 6.9 ± 1.8) who were due to get a processor upgrade to the Naída CI as part of their routine clinical care. A repeated measures design was used, where subjects acted as their own controls.

Fitting

At the baseline visit, subjects were fitted with a loaner sound processor for the purposes of testing, identical to their current processor. This was to ensure that all microphones were new and working optimally. It was programmed with their current clinical program, including the speech enhancement algorithm ClearVoiceÊ [~~13~~14] as well as the T-MicÊ microphone setting (microphone placed within the concha) [6,~~14~~15], if this was used on an everyday basis. They were then upgraded to a new Naída CI sound processor, programmed with the same current clinical program and an identical clinical program plus UltraZoom. The T-Mic microphone and ClearVoice algorithm continued to be used with the Naída CI if they had been used with the original processor. They were given a minimum of a two months take-home trial with the Naída CI sound processor, where they were encouraged to use UltraZoom in appropriate situations, where speech was coming from the front and noise from the back and sides of the recipient. The Advanced Bionics SoundWaveÊ programming software was used and all program parameters remained the same, unless the subject was not happy with the sound quality, in which case alterations to the current clinical program were made accordingly. All bilateral CI users except one were upgraded on both sides.

Speech perception measures

Speech understanding in quiet was evaluated with two lists of seventeen monosyllabic words each (Lafon lists) presented at 60 dB SPL from a source based at one meter in front of the subject. Speech understanding in noise was measured with the Matrix sentence test in French [~~15~~16], which is an adaptive test based on the Oldenburg sentence test (OlSa) [~~16~~17]. The subjects were asked to repeat semantically unpredictable sentences, which always had the same structure: Name, Verb, Number, Common name and Colour. A speech reception threshold (SRT) was automatically measured by adjusting signal to noise ratio until a 50% word understanding score was reached. A lower SRT means a better performance. Prior to testing, at least two practice lists (each containing 20 sentences) were presented to the subject to avoid training effects during the test.

Sentences were presented from a loudspeaker located one meter in front of the subject (0-degree azimuth). Non-correlated stationary speech shaped noise (SSN) was presented at a fixed level of 65 dB SPL simultaneously from all three loudspeakers positioned at +/-90° and 180° to simulate a diffuse noise environment. The level of the speech signal was varied to adjust the signal to noise ratio. A low to moderately reverberant room was used, with a T_{60} of around 0.3 seconds.

Subjects were evaluated while listening with the technology that they utilized in their daily environments; participants with a Naída CI processor on one ear and a contralateral hearing aid were tested with both devices together, bilateral participants (two Naída CI processors or one

Naída CI processor with another processor type contralaterally) were tested with both devices turned on. The contralateral hearing aid was not fitted or changed during the follow-up period.

At the baseline visit, speech perception was measured with words in quiet with the current sound processor and sentences in noise with the current sound processor and the new Naída CI sound processor in the omnidirectional microphone mode, without UltraZoom. At the follow up visit, two months later, speech perception was measured in quiet with the Naída CI processor without UltraZoom and in noise with the Naída CI sound processor with and without UltraZoom (Table 2). The order of the speech test lists and the test conditions were randomized using a randomization table prepared before the start of the study. At the end of the study the subjects returned home with the new Naída CI sound processor.

Subjective Testing

Subjectôs self-assessment of their hearing with the different sound processors and programs was recorded using the APHAB [~~12~~13]. This 24-item self-assessment inventory requires recipients to report the amount of trouble they are having with communication in various everyday situations. Benefit is calculated by comparing the recipient's reported difficulty in listening in the specified scenarios. There are four subscales: Ease of Communication (EC), Reverberation (RV), Background Noise (BN), and Aversiveness (AV). Scores are given on a scale from A to G where A is ñI always experience thisò and G ñI never experience thisò. A percentage score from 1% to 99% is allocated to each category of response to give a mean percentage for each section. The average score for each subsection, recorded at baseline with the previous sound processor, was compared to the average score recorded at the two month follow up visit with the Naída CI sound processor. A global score was also calculated, which is the mean of the scores for all the items in the three EC, RV and BN subscales.

Statistics

The results for each test session were compared independently. Scores for words in quiet and the Matrix sentence test in noise were not normally distributed, so a non-parametric Wilcoxon paired test ~~were~~ was used. Individual scores in quiet were compared using the binomial model described by Thornton and Raffin [18]. The different subsections of the APHAB data were compared using a series of non parametric Wilcoxon tests. A p value of less than 0.05 was considered to be significant, A power calculation showed that in order to detect a difference of 2 dB with sufficient power (80%) and at a significance level of p=0.05, a minimum of 17 subjects was required for the objective testing.

RESULTS

Speech perception testing

When subjects were tested in quiet, there was no difference in group performance between the previous sound processor(s) at baseline and the Naída CI processor(s) in omnidirectional mode after two months use (median score of 53.8% ranging from 5% to 94% and median score of 52.5% ranging from 0% to 97%, respectively) (Wilcoxon paired test, Z=0.37, p>0.05) (Fig. 2~~1~~). Analysis of individual scores using the binomial model, described by Thornton and Raffin (1978), showed that four out of the 34 subjects had a significant improvement in scores between the baseline and second test sessions (18). One subject saw a significant reduction in speech score in quiet in the second test session, but scores in noise between sessions did not reflect this. All other subjects had non significant differences between scores of less than 20% (Table 3).

Twenty-one out of the 34 subjects had sufficiently good performance in quiet with the previous sound processor(s) at the initial session to be able to perform the Matrix test in noise (median scores of 64% for monosyllabic words versus 23% in the group of 13 subjects who were not able to perform test in noise). Matrix test at the follow-up session was only performed in this group of 21 patients. At the initial baseline session, there was no significant difference between the recipientsô previous sound processor(s) (median SRT of -1.1 dB) and the Naída CI sound processor(s) (median SRT of -1.2 dB) for performance in noise when using the omnidirectional microphone (Wilcoxon paired test, Z=1.01, $p>0.05$) (Fig. 3~~2~~A, a lower SRT means a better performance).

At the follow up session, after two months experience with the Naída CI sound processor(s), the median SRT score with Naída CI with UltraZoom was -4 dB (range: +4.8; -10.5 dB) compared to -0.45 dB (range: +6.5; -8.0 dB) with the Naída CI in omnidirectional mode (without Ultrazoom). The use of UltraZoom significantly improved the median SRT by 3.6 dB (range: +0.5; -7.8 dB) (Wilcoxon paired test, Z=3.91, $p<0.0001$) (Fig. 3~~2~~B).

Subjective evaluation

APHAB questionnaires were completed by all 34 subjects. When performance on the APHAB questionnaire was compared across the sessions, significant differences between the scores with the existing sound processor(s) at baseline and the Naída CI sound processor(s) for speech understanding in noisy environments (Wilcoxon paired test, Z=3.57, $p<0.001$), aversive situations (Wilcoxon paired test, Z=2.10, $p<0.05$) and globally (Wilcoxon paired test, Z=2.19, $p<0.05$) were obtained.

When looking at the APHAB outcomes for the group of 21 subjects who were able to perform the Matrix test, a significant improvement when using the Naída CI sound processor(s) compared to the previous processor(s) was found for speech understanding in noisy environments (Wilcoxon paired test, Z= 2.84, $p<0.01$) and in aversive situations (Wilcoxon paired test, Z= 2.10, $p<0.05$) (Fig. 4~~3~~A). For the 13 subjects who were not able to perform the Matrix test at baseline, a significant improvement when using the Naída CI sound processor(s) compared to the previous processor(s) was also shown for speech understanding in noise (Wilcoxon paired test, Z=2.13, $p<0.05$) (Fig. 4~~3~~B).

DISCUSSION

This study showed that for the 21 subjects who were able to complete the testing in difficult noisy conditions, the use of UltraZoom provided a significant improvement in performance of 3.6 dB SRT. The diffuse noise test conditions used in this study were designed to be challenging to represent the most common noise condition that CI users encounter in everyday life. The addition of some reverberation in the testing room also helped to simulate a real world condition and is particularly relevant for beamforming technologies as when the target and interfering noise become more spatially diffuse, beamforming performance can degrade [~~10~~11, ~~11~~12].

Our results were in line with the improvement seen by Geißler et al. [4] in a study evaluating 10 adult Harmony users who had been converted to the Naída CI, but had no take home experience with the new processor. Subjects had been evaluated using the same adaptive test as in our study, but in more challenging conditions with five loudspeakers used to create the noise environment and a higher reverberation time of 0.6s. In our study, twenty-six out of the 34 subjects were using the T-Mic in standard condition which already provides some directionality [6]. Some subjects also used the ClearVoice static noise reduction technology, which in combination with UltraZoom, has been shown to provide the greatest improvement in performance in noise [4, ~~13~~14]. We ~~choose~~ chose to keep the use of ClearVoice and/or the T-Mic constant across all test conditions and for both sound processor types in order to have no impact on the results.

There is considerable variation in the degree of improvements reported for beamforming technology. In previous studies, when compared to the omnidirectional microphone or the T-Mic, UltraZoom improved speech reception thresholds in noise from 4 up to 9.8 dB in optimum conditions [4,~~13~~14] (Advanced Bionics, Reference Note 2). Many factors can explain this variation, such as the speech materials and noise type used, the configuration of the speaker array, the microphone and program configurations compared. In addition, the head alignment of the subject with the speech source can also affect the level of benefits of any adaptive beamformer. Even though instructions about head position were provided to subjects prior to testing, this is something which remained difficult to control over the whole duration of the session. However, these testing conditions reflected óreal lifeô conditions and show the wide range ~~what level~~ of benefit a CI user could expect from using this new technology in ~~their~~ daily life. Unfortunately, one of the limitations of adaptive SRT procedures is that a calculation of individual significant SRT differences cannot be made based on the binomial model. The other limitation is that the Matrix test was only performed in the group of the better performers, meaning that we cannot ruled out that some poorer performers from the baseline session were finally able to do the test at the follow-up session. Therefore, no information can be provided on the percentage of subjects whose performance improved significantly when using the beamformer.

The purpose of providing beamforming to CI users is to improve their ability to communicate in the everyday noisy environments we all encounter. Whilst many studies have shown the benefits of this technology in a laboratory setting [4,5,7,8], a subjective evaluation by subjects is required to show that these benefits can be achieved in real world scenarios. Moreover, the upgrade process was part of the routine clinical practice of the clinic, so both good and poor performers were enrolled. As a result, almost forty percent of the subjects in our study who had poor speech comprehension score in quiet were unable to do the Matrix test in difficult noisy environment before upgrade, but may still have some subjective benefit of the speech processor upgrade. The APHAB results shown here indicate a significant subjective improvement for the listening in background noise, aversiveness and global sections when using the Naída CI sound processor. To check whether the poorer performers benefited from the new sound processor, the APHAB questionnaire was analysed for this particular population and still showed a significant benefit in the background noise section. It is particularly interesting to observe this improvement in poorer performers, for whom the objective improvement could not be shown through the Matrix test. It highlights the importance of evaluating subjective feedback from CI recipients to assess their level of comfort in everyday life. Some previous studies using different subjective measures have been unable to show a subjective benefit along side the laboratory benefits shown [5,8]. Only Mosnier et al. [1] did show a significant benefit on the APHAB when subjects upgraded from the older Cochlear Esprit 3G and Freedom sound processors to the newer CP810. This lack of strong evidence ~~of~~ for any subjective benefits of beamforming is not just an issue for its use in cochlear implants, but is also a criticism for its use with hearing aids [~~17~~19]. The subjective results are limited by the fact that the APHAB in common with most of the subjective measurement tools available, relies on asking subjects about predetermined situations, which may not be relevant or equally important to all subjects. An additional limitation of any study where subjects are upgraded to newer technology and cannot be blinded to the sound processor used is that responses may be biased towards the newer technology.

The results of the speech perception testing at baseline show that group performance with the new Naída CI sound processor in noise was the same as with the subjectsô existing sound processor when using the same programs and omnidirectional microphone settings. This provides clinicians with confidence that subjects can be upgraded to the Naída CI without a change in performance when used with the standard microphone settings and do not require any training period. However, the subjects recruited were all using the Harmony sound processor, so these findings can only be applied to recipients who are currently using this sound processor type.

The improvements in recipientsô use of beamforming in real world environments may result from a better understanding by clinicians of how to use the technology and appropriately counsel recipients and better implementation of the beamforming algorithm, improving its robustness [9]. Indeed, appropriate counselling on the use of UltraZoom is crucial as recipients are required to manually change the program depending on the listening situation encountered. Therefore, it is important to provide recipients with concrete real life examples of situations where this feature helps speech understanding. However, this might be less relevant with the newest generation of sound processors, which offers automatic selection of the microphone settings depending on the incoming signal i.e. UltraZoom is switched on and off automatically depending on the environment.

To conclude, this study showed that all subjects were successfully upgraded to the new Naída CI Q70 sound processor. Once upgraded, subjects who were able to perform the French Matrix test in noise with their previous processor could take advantage of the UltraZoom beamforming technology on the new sound, so that their ability to communicate in noise was improved. S~~s~~ubjective results with the APHAB questionnaire~~,~~ confirmed these objective results, showing improvements in median scores in the whole group, but also in the group of poorer performers, for listening in background noise when using the Naída CI Q70 sound processor. This study highlighted the importance of upgrading CI recipients to new technology and of including adaptive tests in noise and subjective feedback evaluation as part of the process.

Author contribution statements: I.M. is the main researcher, designed experiments, analyzed data and wrote the paper. J.F., D.A., A.L., S.B., E.A.D., M D. performed experiments. N.M. provided writing assistance. D.B. and O.S. provided critical revision. All authors discussed the results and implications and commented on the manuscript at all stages.

Compliance with Ethical Standards

Conflict of Interest: One of the authors (NM) is employee of Advanced Bionics. Other authors declare they have no conflict of interest.

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from all individual participants included in the study.

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FIGURES LEGENDS

Fig. 1: Polar plot showing UltraZoom performance on KEMAR left ear.

Fig. 2~~1~~: Performance score in quiet with the subjectôs original sound processor(s) at baseline and with the Naída CI sound processor(s) in omnidirectional mode at the follow-up visit. Results are expressed as percentage of words correct for the lists of monosyllabic words in quiet for the 34 subjects. The box plots show the first and third quartile values and the central square, the median value. The whiskers indicate the non-outliers values for each group.

Fig. 3~~2~~: Performance in noise for the 21 subjects who were able to perform MATRIX test in noise. A. At baseline with the subjectôs original sound processor(s) and with the Naída CI sound processor(s) in omnidirectional mode (without UltraZoom); B. At the follow-up visit with the Naída CI sound processor(s) in omnidirectional mode and with UltraZoom.

Results are expressed as the speech reception thresholds (SRT, dB) for the Matrix sentence test in noise. A lower SRT means a better performance. The box plots show the first and third quartile values and the central square, the median value. The whiskers indicate the non-outliers values for each group. The asterisks indicate a statistically significant difference in performance (*** p<0.0001)

Fig. 4~~3~~: Median scores for the APHAB self-assessment questionnaire at baseline with the subjectôs original sound processor(s) and at the follow-up visit with the Naída CI sound processor(s). A. **For the 21 subjects who were able to perform MATRIX test in noise**; **B. For the 13 subjects who were not able to perform MATRIX test in noise**

Scores are given for each of the four sub sections and a global value for the average of the Ease of Communication, Reverberation and Background Noise sections. The box plots show the first and third quartile values and the central square, the median value. The whiskers indicate the non-outliers values for each subscale and each group. The asterisks indicate a statistically significant difference in performance (* p<0.05, ** p<0.01)

Table 1 : Demographic details of the population

Number of subjects	34
Age at testing, years	53 ± 18.5 [21-89]
Age at implantation, years	46 ± 18.7 [7-80]
Duration of CI use, years	6.9 ± 1.8 [5.1-14.7]
Male/Female	16/18
Listening modality	
Unilateral CI	9
Bilateral CI (a)	11
Sequentially implanted	6
Simultaneously implanted	5
Bimodal (b)	14
T-Mic microphone	
Yes	26
No	8

Data are presented as mean ± SD [range] or number. CI: cochlear implant. (a) All bilateral CI users except one were upgraded on both sides. (b) CI on one side and hearing aid on the other side.

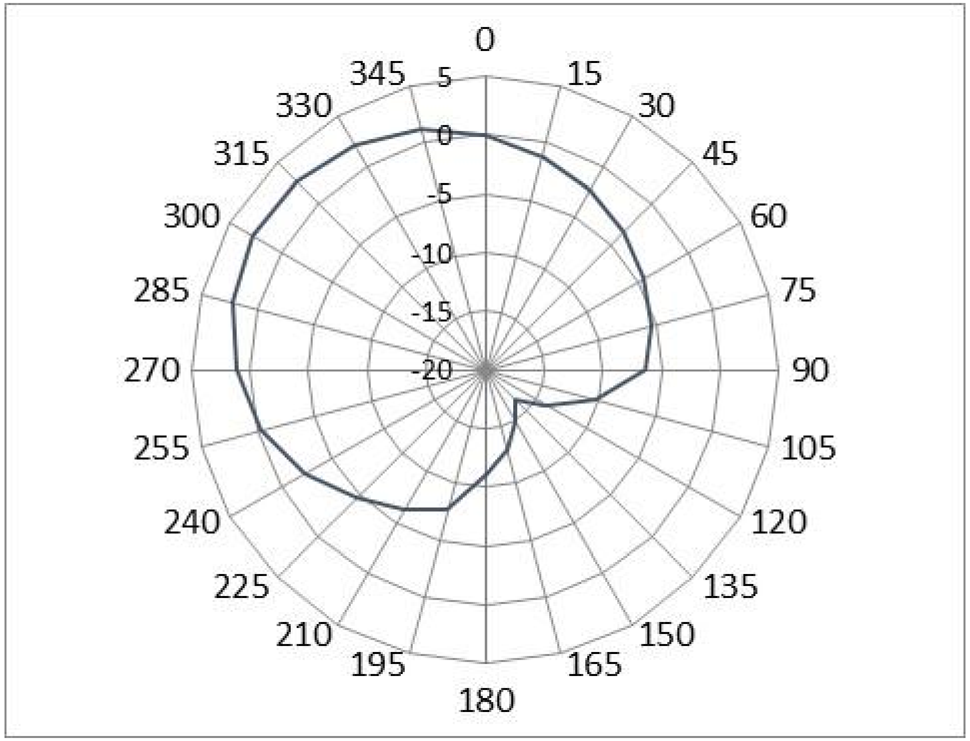
Table 2: Tests conducted at each visit.

Baseline	- Lists of words in quiet with the previous processor (s) - Speech test in noise with signal coming from the front with the previous processor(s) and the Naída CI processor (s) without UltraZoom in a random order - APHAB questionnaire completed with regards to the previous processor(s) use
Follow-up at 2 months after Naída CI upgrade	- Lists of words in quiet with the Naída CI processor(s) without UltraZoom - Speech test in noise with signal coming from the front with the Naída CI processor(s) with and without UltraZoom in a random order - APHAB questionnaire completed with regards to the Naída CI processor(s) use

Table 3. Individual scores for speech perception testing in quiet for Lafon words at baseline with the previous sound processor and at the follow-up visit with the Naída CI processor in omnidirectional microphone mode.

Subject ID	Lafon Words Score (%)		*Subject ID*	Lafon Words Score (%)	
	Previous Processor	Naida Omni		Previous Processor	Naida Omni
1	37.5	58.5	*18*	52	55
2	73	52.5	*19*	17	29
3	67	61	*20*	76	58.5
4	76	67	*21*	55.5	82
5	35	17	*22*	17	41
6	23	20	*23*	85	82
7	26	43.5	*24*	14	23
8	61	49.5	*25*	5	0
9	35	38	*26*	58.5	11
10	79	73	*27*	23	14
11	94	94	*28*	46.5	52.5
12	58	58.5	*29*	11	17
13	64	52	*30*	64	79
14	38	46.5	*31*	61	70
15	29	32	*32*	82	73
16	32	58	*33*	35	35
17	64	67	*34*	94	97

Figure 1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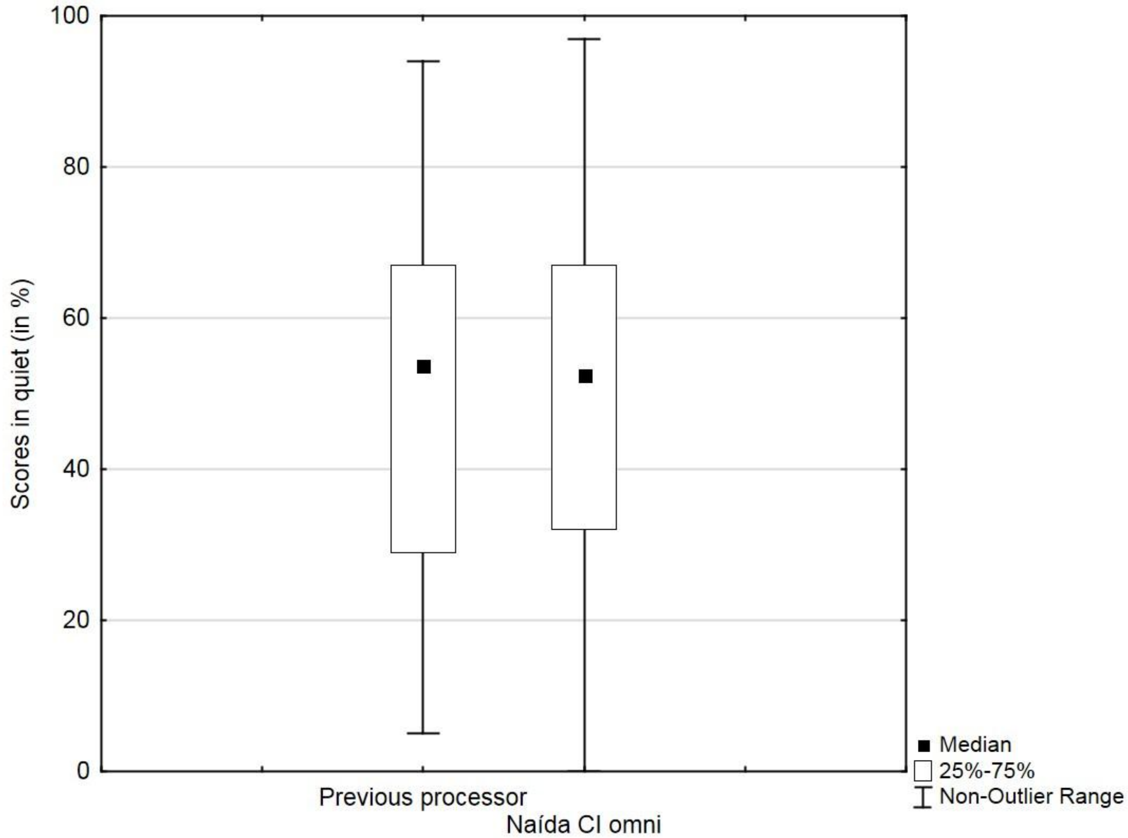
-20

Figure 2



100
80
60
40
20
0
Scores in quiet (in %)
Previous processor
Naída CI omni
Median
25%-75%
Non-Outlier Range

Figure 3A

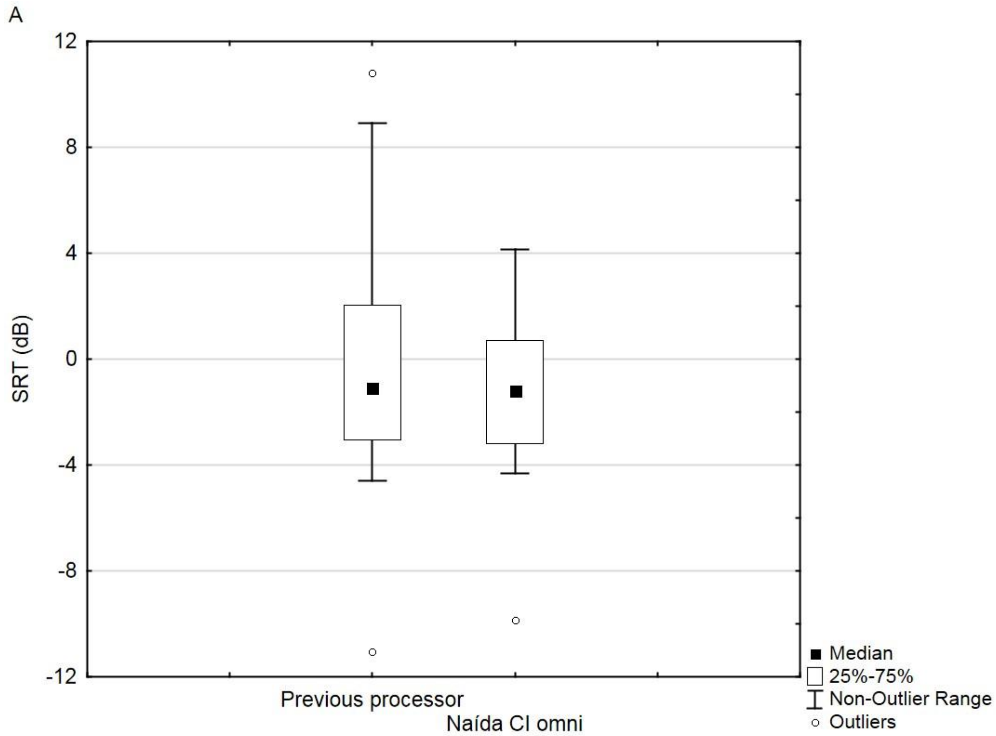

A
12
8
4
0
-4
-8
-12
SRT (dB)
Previous processor
Naída CI omni
Median
25%-75%
Non-Outlier Range
Outliers

Figure 3B

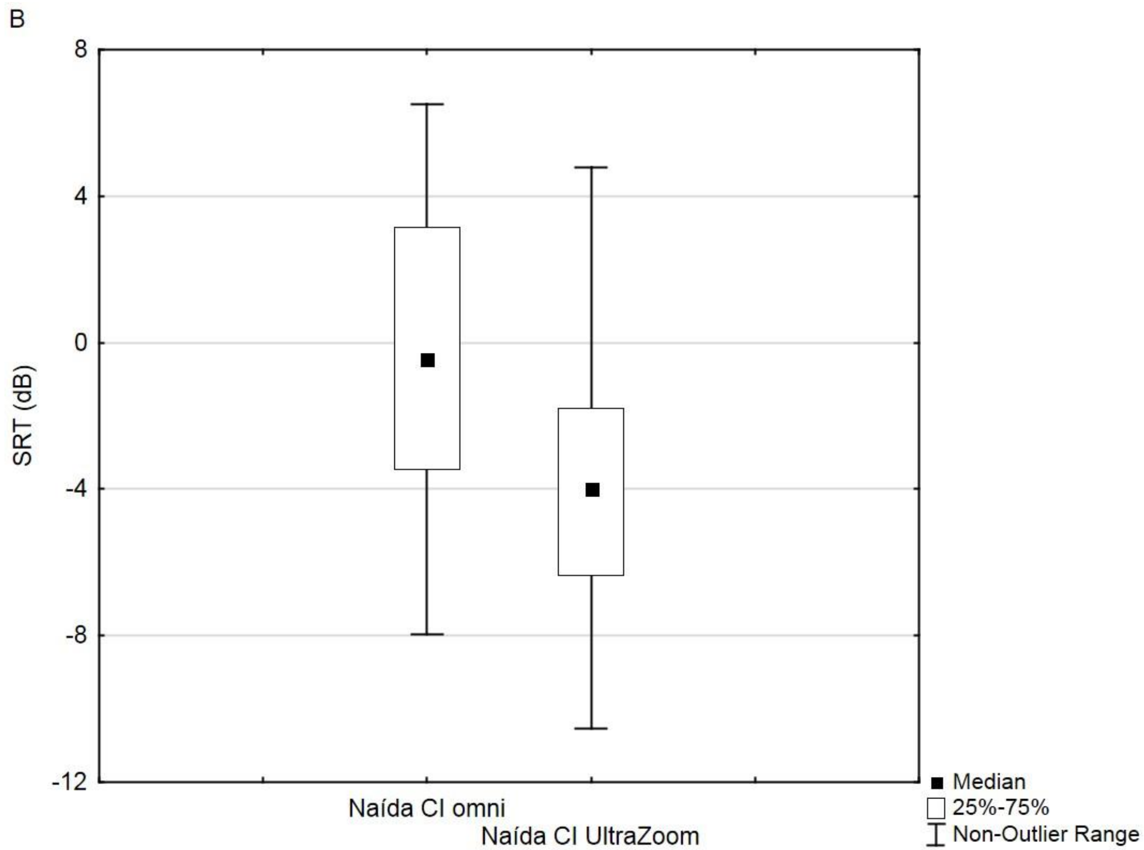
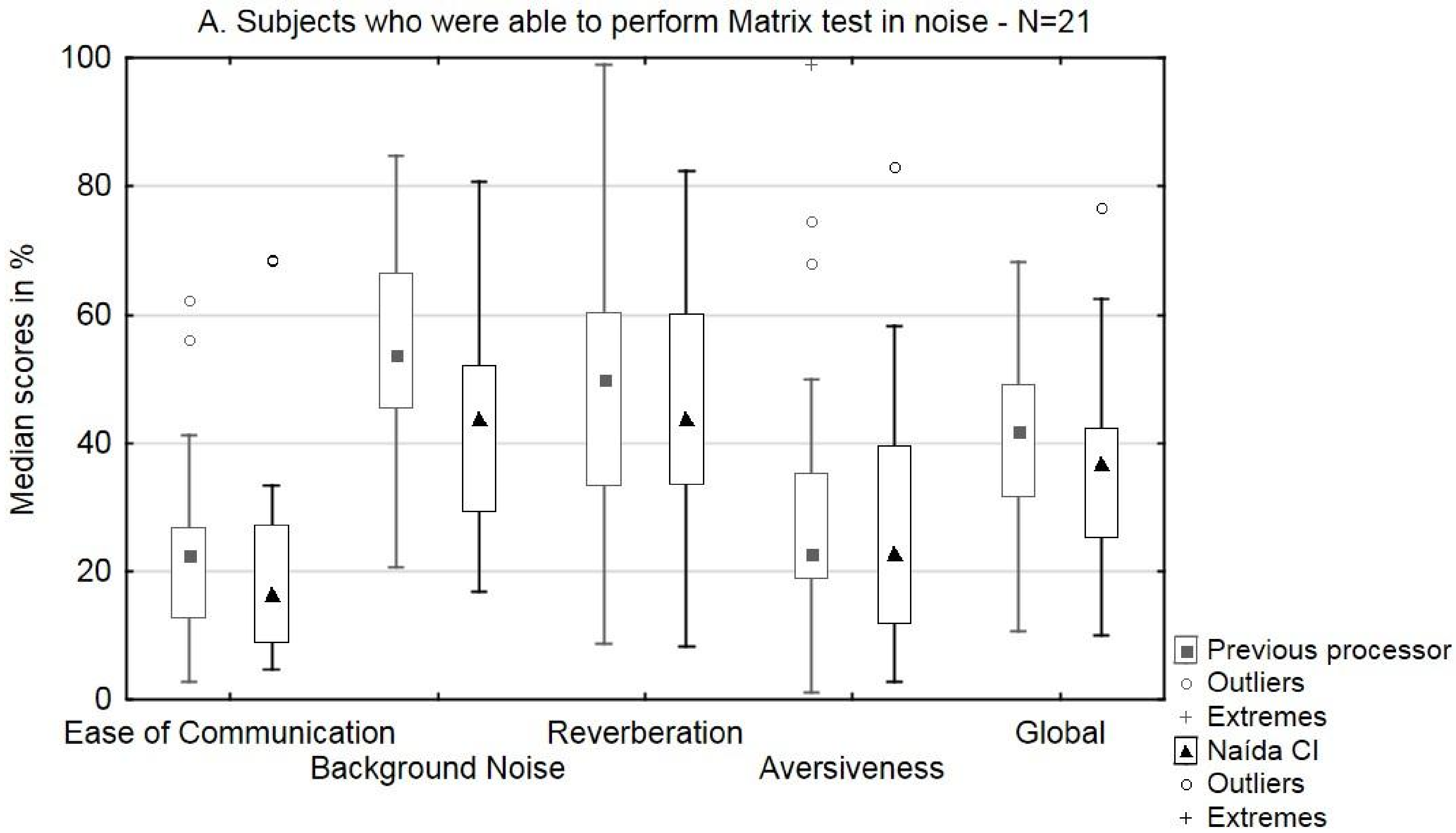

B
8
4
0
-4
-8
-12
SRT (dB)
Naída CI omni
Naída CI UltraZoom
Median
25%-75%
Non-Outlier Range

Figure4A



A. Subjects who were able to perform Matrix test in noise - N=21
Median scores in %
100
80
60
40
20
0
Ease of Communication
Background Noise
Reverberation
Aversiveness
Global
Previous processor
Outliers
Extremes
Naída CI
Outliers
Extremes

Figure 4B

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