A§E COALA VS FREE FIELD CLINICAL VALIDATION:
SPEECH AUDIOMETRY WITH NUCLEUS® 6

Introduction

Coala Link offers a way of performing psychoacoustic tests in Audiqueen with Nucleus® CI recipients without the need of having a sound proof test booth and calibrated audiometer. Coala Link is compatible with the Cochlear™ Nucleus® 6 (CP910) and 7 (CP1000) sound processors. For Nucleus 6, sounds are delivered through an AUX cable that is connected to the processor of the recipient and the computer's sound card. For the Nucleus 7 processor this is done through a Bluetooth connection with a Cochlear Mini Microphone which in turn is connected to the PC. The audio chain is automatically calibrated for an individual sound processor before each test. The goal of this study is to investigate the clinical efficacy of speech audiometry delivered with Coala Link (Nucleus 6, with AUX entry) compared to testing in free field conditions.

Coala Link characteristics and calibration

Background noise measurements were performed with the AUX input and showed that the average background is around 12 dBA, which is substantially lower than in typical sound proof audiometric test rooms (around 35-40 dB A). The volume characteristics of the AUX entry were compared against typical free field characteristics, and calibration was established according to these findings[1]. Before starting a test, A processor-specific calibration is performed by means of a feedback system that records the intensity of incoming stimuli.

Materials & Methods

Subjects entry criteria

The speech audiometry validation of Coala Link (Nucleus 6) compared to free field conditions was performed on 30 CI recipients with a CP910 as their home processor. The inclusion criteria were the following:

- Subjects have at least an average speech understanding (phoneme score) across the four intensities of 40% and at least 30% at 40 dB SPL to avoid any floor effect.
- All subjects were at least 16 years of age and willing and able to perform a psychoacoustic test twice.

Test procedure

All subjects were assessed by means of two speech audiometry tests with adult open set monosyllables (CVC) at 40, 55, 70, and 85 dB SPL in quiet. Two lists of twelve words were presented

[1] Details of the calibration procedure are confidential.

at each intensity. The speech tests were performed in free field and with Coala Link in a random sequence. An audiologist recorded the phoneme score of the subject.

Statistics

Nonparametric statistics were used for the analysis of data, with Tukey's five parameters (median, lower and upper quartiles and extremes) and box and whisker plots for descriptive statistics (Tukey JW 1977, Hollander M 1999).

The Wilcoxon test statistic was used to detect significant within-subject differences between the data groups. Furthermore, to investigate clinical equivalence between free field conditions and Coala Link, the TOST[2] procedure was used. With this test, equivalence is established at the α significance level if a (1–2α) × 100% confidence interval for the within-subject difference distribution is contained within an interval (-δ, δ) (Walker E 2011). The value δ is defined as the clinical equivalency margin. This is the difference in measurement that would not be considered as clinically significant. The equivalency margin for speech audiometry phoneme score will be set to 5%, based on both internal data and clinical experience.

Tests for normality are performed with the Shapiro-Wilk test statistic. Since it will turn out that not all data sets are normally distributed on a 5% significance level, and thus there is no reliable indicator that the within-subject differences are normally distributed, confidence intervals are consistently created with the empirical bootstrap method (Chernick MR 2007). The statistical significance level used is 5%.

Results

Phoneme scores for all subjects at 40, 50, 70 and 85 dB SPL, as well as the average phoneme score, are depicted in table 1 for both test conditions. The statistics of the within-subject distribution for all intensity groups are depicted in table 2.

The Shapiro-Wilk test statistic shows that the within-subject differences between free field and Coala Link cannot be considered normally distributed, so it is chosen to calculate confidence intervals with the bootstrap method. The Wilcoxon test indicated that there is a significant difference ($p < 0.05$) between free field conditions and Coala Link at 40 dB and 85 dB SPL.

In figure 2, a box-and-whisker plot shows the Tukey parameters of the within-subject difference distribution at all intensities.

Table 1: Phoneme scores (%) of the 30 subjects at all intensities as well as the average phoneme score (AVG) for the two test conditions, free field and Coala Link.

	Free Field					Coala Link				
Intensity [dB[	**40**	**55**	**70**	**85**	**AVG**	**40**	**55**	**70**	**85**	**AVG**
S01	63.9	69.4	76.4	73.6	70.8	66.7	76.4	68.1	66.7	69.5
S02	86.1	90.3	94.4	95.8	91.7	83.3	90.3	90.3	91.7	88.9
S03	62.5	79.2	87.5	87.5	79.2	69.4	84.7	87.5	88.9	82.6
S04	93.1	97.2	97.2	97.2	96.2	93.1	94.4	97.2	97.2	95.5
S05	63.9	83.3	91.7	88.9	82.0	76.4	91.7	87.5	88.9	86.1
S06	52.8	88.9	90.3	87.5	79.9	73.6	83.3	91.7	81.9	82.6

[2] TOST: Two one-sided tests

S07	84.7	93.1	98.6	97.2	93.4	87.5	98.6	95.8	93.1	93.8
S08	52.8	73.6	75.0	79.2	70.2	59.7	76.4	84.7	61.1	70.5
S09	51.4	81.9	86.1	93.1	78.1	47.2	80.6	84.7	94.4	76.7
S10	88.9	93.1	91.7	93.1	91.7	93.1	95.8	88.9	90.3	92.0
S11	80.6	86.1	94.4	94.4	88.9	79.2	86.1	88.9	98.6	88.2
S12	72.2	90.3	86.1	86.1	83.7	63.9	86.1	84.7	86.1	80.2
S13	87.5	97.2	97.2	91.7	93.4	92.6	95.8	93.8	84.7	91.7
S14	95.8	95.8	100.0	95.8	96.9	100	95.8	97.2	98.6	97.9
S15	83.3	94.4	90.3	88.9	89.2	90.3	90.3	88.9	86.1	88.9
S16	53.9	72.5	73.5	70.6	67.6	68.6	71.6	75.5	66.7	70.6
S17	73.6	83.3	88.9	83.0	82.3	70.8	75	84.7	84.7	78.8
S18	51.4	68.1	69.4	63.9	63.2	68.1	72.2	65.7	66.7	68.2
S19	55.6	77.8	86.1	80.6	75.0	77.8	90.3	72.2	68.1	77.1
S20	98.6	100.0	97.2	98.6	98.6	97.2	100	98.6	98.6	98.6
S21	59.7	77.8	77.8	72.2	71.9	66.7	83.3	77.8	68.1	74.0
S22	63.9	88.9	88.9	87.5	82.3	83.3	87.5	87.5	87.5	86.5
S23	44.4	69.4	68.1	72.2	63.5	61.1	68.1	63.9	59.7	63.2
S24	87.0	83.3	72.2	75.0	79.4	51.5	80.5	80.5	69.5	70.5
S25	38.9	43.1	47.2	51.4	45.2	38.9	51.4	48.6	37.5	44.1
S26	31.9	59.7	68.1	59.3	54.8	54.2	70.8	70.8	56.9	63.2
S27	52.8	62.5	86.1	58.3	64.9	67.6	70.8	70.8	63.9	68.3
S28	72.2	86.1	86.1	84.7	82.3	80.6	87.5	91.7	81.9	85.4
S29	51.4	86.1	75.9	75	72.1	75	79.2	80.6	70.8	76.4
S30	63.9	81.9	75	75	74.0	69.4	72.2	81.9	79.2	75.7

Table 2: Tukey parameters, Wilcoxon and Shapiro-Wilk p-values and bootstrap confidence intervals of the within-subject differences (free field – Coala) at all four intensity groups.

Intensity [dB SPL]	40	55	70	85
# cases	30	30	30	30
P25	-15.3	-5.5	-2.0	-1.3
P50	-6.2	0.0	1.4	2.8
P75	0.4	2.8	4.1	5.6
Mean	-6.3	-1.1	0.8	3.2
St dev	11.8	5.7	5.9	5.7
Wilcoxon p-value	0.001**	0.3	0.3	0.1
Shapiro-Wilk p-value	0.005**	0.8	0.2	0.05*
90% conf on mean	[-10.0,-2.9]	[-2.8,0.7]	[-0.4,2.9]	[1.3, 4.6]
90% conf on median	[-8.9,-4]	[-1.3,2.8]	[0.0,2.8]	[1.5,5.6]

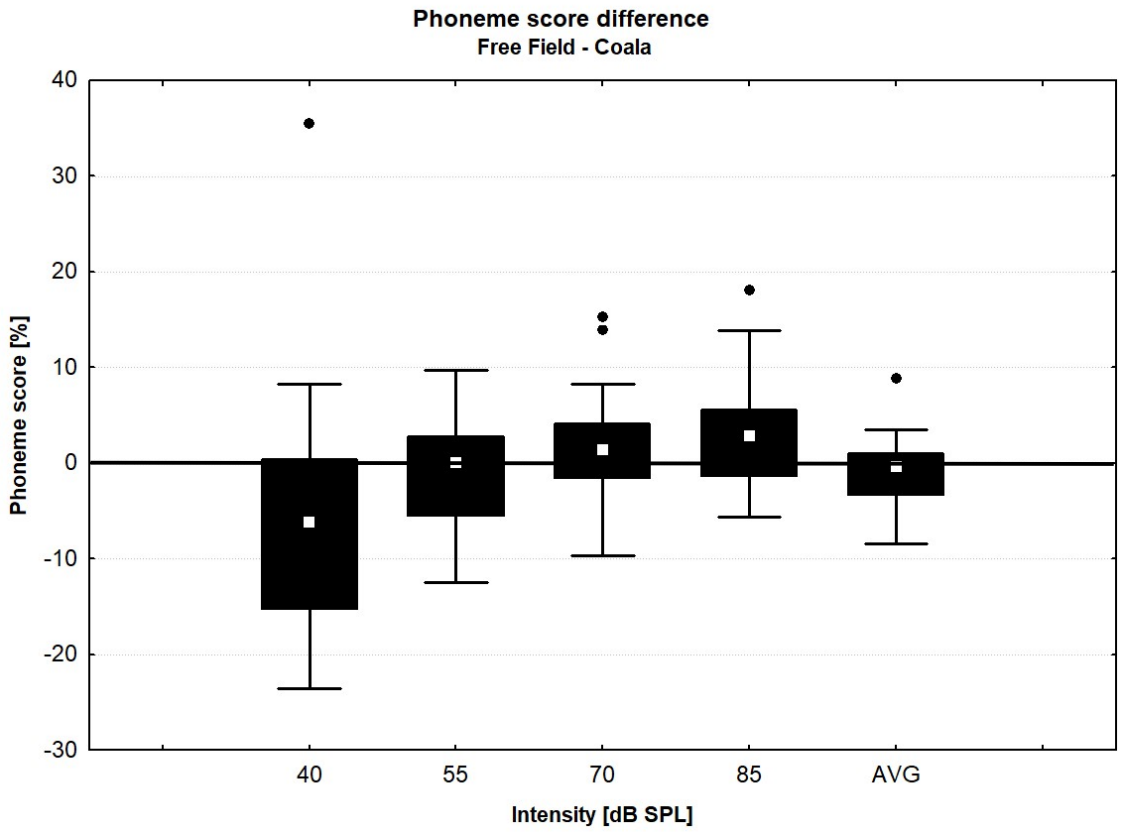

Figure 2: Box and whisker plot of within-subject phoneme score difference between free field and Coala Link. If the difference is positive, this means that the recipients scored better in free field conditions than with Coala stimulation. Box and whiskers represent the median (square), interquartile range (box), non-outlier range (whiskers) and outliers (dots). An outlier is defined as any value that lies more than one and a half times the length of the box from either end of the box.

Discussion

From table 2, it can be seen that all median within-subject differences are fairly close to zero (less than 5%), except at 40 dB SPL. A Wilcoxon test revealed that there is a significant difference between free field and Coala Link at this intensity. At 85 dB, the median difference of 2.8 % is statistically significant as well. At the other two intensities, it could not be shown that there exists a statically significant difference between Coala and free field conditions. Moreover, the 90% confidence intervals on the median and mean within-subject differences are contained between [-5%, 5%] at 55 and 70 dB, meaning that there is a clinical equivalence at the 0.05 confidence level. This is not the case at 40 dB, where the confidence intervals clearly fall outside the clinical equivalence limit. It can thus be stated that there is a statistical as well as clinical difference between free field and Coala at low intensities. The better performance at low intensities with Coala Link can be attributed by the almost total lack of background noise with the Coala AUX cable. This can be considered an exceptional feature that does not occur in normal free field conditions.
At 85 dB, there is a small yet statistically significant difference, indicating that there can be a small deterioration of performance with Coala at high intensities, possibly due to the higher amount of energy that is delivered through the AUX cable. Indeed, the 90% confidence interval on the mean lies just outside the clinical equivalence limit of 5%.

Conclusion

At 55 and 70 dB SPL, there is no clinical and statistical difference between Coala testing and free field testing and therefore the two transducers can be considered equivalent. At 40 dB SPL, Coala has higher performance due to a lack of background noise. Possibly due to higher amounts of energy delivered through the AUX cable a small deterioration of performance with Coala is seen at 85 dB SPL. This small difference can however, from a clinical point of view, be neglected.

References

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