
AŞE COALA VS FREE FIELD CLINICAL VALIDATION: TONAL 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 audiometry delivered with Coala Link (Nucleus 6, with AUX entry) compared to Free field testing.



Calibration

Reference equivalent threshold sound pressure levels (RETSPL) were carefully constructed by means of a biological calibration procedure. Before starting a test, A processor-specific calibration is performed by means of a feedback system that records the intensity of incoming stimuli.

Material and methods

Test procedure

Constructing the RETSPL tables (e.g. the biological calibration) was done in five rounds of 10 CI recipients, and the RETSPL were fine tuned after each iteration. Then, a final verification was performed on at least 20 CI recipients.

Subject entry criteria

The biological calibration and final validation were performed on Nucleus CI recipients who:

- were at least 16 years of age at the time of the validation.
- had their switch-on session at least two weeks prior to the validation.

Statistical analysis

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).

To investigate clinical equivalence between tonal audiometry with Coala and in Free Field the TOST (Two one-sided tests) procedure was used. With this test, equivalence is established at the α significance level if a $(1-2\alpha) \times 100\%$ confidence interval for the within-subject difference distribution is contained within an interval $(-\delta, \delta)$ (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 (Whitton JP 2016). We can use the test resolution of 5 dB as the clinical equivalence margin.

Confidence intervals are created with the empirical bootstrap method (Chernick MR 2007). The statistical significance level used is 5%.

Results

Only the data of final verification will be discussed here, not the initial rounds for biological calibration. For the final verification, the audiometry threshold differences between free field and with Coala Link for each subject are listed in table 1. The Tukey parameters of these within-subject differences are listed in table 2

Table 1: Audiometry threshold differences [dB] between Free Field and with Coala Link (FF – Coala) for all subjects.

Frequency [Hz]	250	500	1000	2000	4000	6000
S01	5	0	5	0	5	5
S02	5	0	0	-5	0	-5
S03	-5	0	-5	0	0	-5
S04	-10	-10	-10	-5	-5	0
S05	-15	0	0	10	0	5
S06	5	5	0	0	5	-10
S07	10	5	-5	5	5	5
S08	5	-5	-5	-5	-5	-5
S09	-5	-10	-5	-5	0	-5
S10	-5	-5	0	0	5	15
S11	5	-5	-5	0	-5	0
S12	5	-5	-5	0	15	5
S13	-5	-5	-5	0	10	-5
S14	-5	5	5	0	5	-5
S15	-5	-10	5	0	-10	5
S16	0	-10	-10	-10	-10	5
S17	-5	0	5	0	10	10
S18	10	-10	0	-5	0	0
S19	-10	-10	-5	-5	0	-5
S20	-10	5	-5	-5	5	5
S21	0	-5	5	0	-10	5
S22	5		-5	-5	-5	5
S23	-10		-10	0	-5	10
S24	5		-5	-10	-5	10
S25	-5		5	0	0	5
S26	5		-10	-5	-10	-5
S27	0		0	-5	-15	-15
S28	5		0	-5	-10	-10
S29	0		5	-5	-5	5

S30	0		-10	-10	-5	-15
S31	-5		0	-5	-5	-10
S32	-5		5	-10	-5	-5
S33	5		0	0	10	0
S34	5		5	-5	-5	0
S35	5		-5	0	0	5

Table 2: Tukey parameters of the within-subject differences [dB] (FF -Coala) for each frequency.

Frequency	250	500	1000	2000	4000	6000
# cases	35	21	35	35	35	35
P0	-15	-10	-10	-10	-15	-15
P25	-5	-10	-5	-5	-5	-5
P50	0	-5	0	-5	0	0
P75	5	0	1.25	0	5	5
P100	10	5	5	10	15	15
90% confidence interval on median	[-5, 5]	[-10, -5]	[0, 5]	[-10, -5]	[0,5]	[-5,5]
Interquartile range	10	10	6,25	5	10	10

At the frequencies 250, 1000, 4000 and 6000 Hz, all median within-subject differences are zero and 90% confidence intervals around the median lie inside -5 and 5 dB. At 500 Hz, it was prematurely decided (after N =21) to adjust the calibration and raise the RETSPL value at this frequency with 5 dB. For 2000 Hz, it was decided not to make such an adjustment because the first quartile (P25) was located at -5 (both at the stage of N=21 and the end stage).

18 additional measurements were then performed against Otocube¹ as a Free Field condition. This was done because of the immediate control we have on the calibration of the Otocube, with daily checks, and a measurement resolution of 0.1 dB. In table 3, the Tukey parameters of these measurements are depicted for 500 & 2000 Hz.

Table 3: Tukey parameters of the within-subject differences (Otocube -Coala) for the frequencies 500 and 2000 Hz.

Frequency	500	2000
# cases	18	18
P0	-10	-5
P25	-5	-5
P50	0	0
P75	1.25	0
P100	10	5
90% confidence interval on median	[0, 5]	[0, 2.5]
IQR	6,25	5

¹ Otocube™ is a portable desktop box which replaces a fully equipped audiological room for CI recipients.

Discussion

After 35 measurements, it can be concluded that for the frequencies 250, 1000, 4000, 6000 Hz, the Coala audiometry testing is clinically equivalent against free Field. For 500 Hz, an additional fine-tuning was needed during the verification. Eighteen measurements were then performed in Otocube as Free Field condition. It was concluded not to change the calibration at 2000 Hz, and measurements in Otocube confirmed the clinical equivalence at this frequency.

Variation

Based on literature (Landry 1999) the standard deviation² of the within-subject test-retest examination for tonal audiometry in normal hearing persons is around 6 dB. This corresponds to an interquartile range of (roughly) 8 dB. When looking at table 2 and 3, the IQR of the within-subject difference distribution is not more than 10 dB at each frequency, indicating that Coala vs Free field testing does not introduce significantly more variability than the ordinary test-retest variability.

Conclusion

It can be concluded that at the standard audiometry frequencies (250 Hz - 6000 Hz), testing tonal audiometry with Coala is clinically equivalent with testing in Free Field conditions.

References

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² In the literature, the within-subject test-retest distribution is considered normally distributed.