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EVALUATION OF KONAN MEDICAL CCT HD

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14. ABSTRACT This report describes the evaluation of a new color vision test, the Konan Medical CCT HD, that was developed through a Cooperative Research and Development Agreement between the 711 th Human Performance Wing, Operational Based Vision Assessment (OBVA) Laboratory and Konan Medical. The results of this evaluation show that the Konan Medical CCT HD is precisely calibrated and replicates the scores of a similar computer-based color vision test developed for laboratory use by the OBVA Lab. The CCT HD is a substantial improvement over other commercially available cone contrast tests (CCTs).					
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1.0 INTRODUCTION

The Rabin Cone Contrast Test (RCCT) was developed by the U.S. Air Force (USAF) to replace pseudoisochromatic plate tests (PIP tests), which had been in use for many years to screen for color vision deficiency (CVD) (Rabin, 1996; Rabin, 2004; Rabin, Gooch, & Ivan, 2011). However, the PIP tests do not quantify type or severity of CVD (Rabin et al, 2011; Barbur & Rodriguez-Carmona, 2017), which is critical in order to quantify the potential effects of CVD on performance and safety. Additionally, the PIP tests can be memorized, which clearly diminishes their effectiveness for screening purposes for career fields where CVD could be a serious safety concern. The USAF adopted the RCCT in 2011 for aircrew vision screening and it has been shown to very reliably screen for CVD (Rabin et al, 2011; Hovis, 2017). However, technology improvements, hardware improvements, and understanding of color deficiency has evolved in the years since the RCCT was introduced. The next generation Operational Based Visual Assessment (OBVA) CCT, or OCCT, was therefore developed with improved and precise color calibration, adoption of a validated and peer-reviewed threshold estimation procedure (Psi method, Prins, 2018), improved test-retest reliability (specificity), and a simplified four alternative forced choice response using a Landolt C optotype. The very precise color calibration of the OCCT eliminates the large ceiling effect that is evident with the RCCT. The development of the OCCT is described in more detail in a previous report (Gaska, Winterbottom, & Van Atta, 2016). Figure 1 shows the distribution of OCCT scores vs. the distribution of RCCT scores (Winterbottom, Gaska, Wright, & Hadley, 2017). As shown, approximately 60% of the participants simply score at the maximum value of 100 on the RCCT. However, the OCCT, with precise color calibration, can achieve the very low cone contrast values needed to accurately quantify cone contrast thresholds even for CVN individuals. The OCCT data reveals that the USAF pass/fail threshold of 75, used until 2018, is 3.7 standard deviations below the mean cone contrast for CVN individuals. The capability to test CVN individuals is essential in order to research the relationship between color vision and operationally relevant performance, and enables early detection of disease, improved ability to quantify the effect of hypoxia and other environmental stressors on vision, and to investigate the potential effects of chemicals/pharmaceuticals. The precise calibration also enables binocular testing, which is not possible with the RCCT due to the ceiling effect.

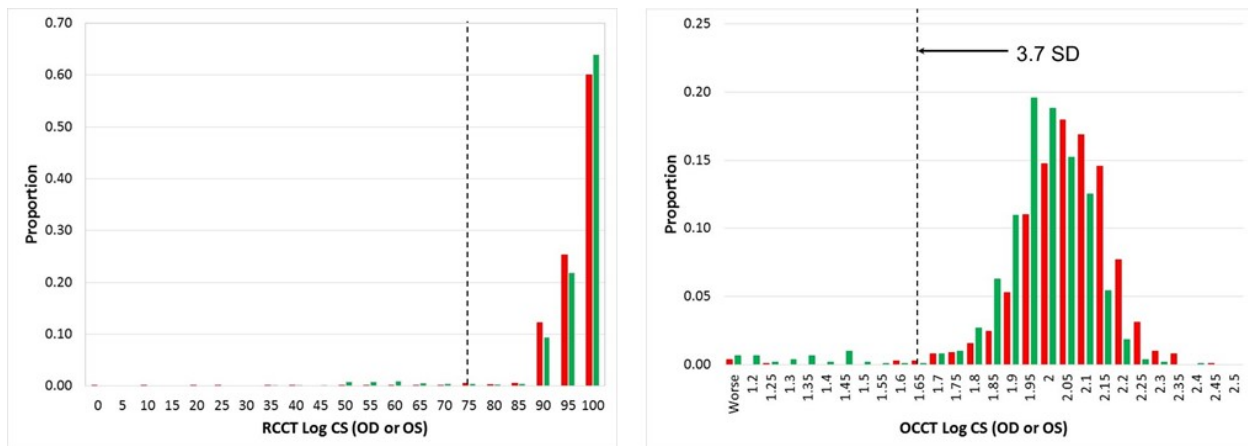


Figure 1. Left: Distribution of RCCT scores (L-cone – 2,182 eyes tested; M-cone – 2,168 eyes tested). Right: Distribution of OCCT scores (L-cone – 1,091 eyes tested, M – cone – 1,084 eyes tested). Dashed line shows the USAF pass/fail criterion used until 2018.

In 2016, the OBVA Laboratory partnered with Konan Medical through a cooperative research and development agreement (CRADA) to develop a commercial version of the OCCT – named the CCT HD. This report describes the evaluation of the pre-production version of the CCT HD.

2.0 METHODS

2.1 Calibration

An ideal Cone Contrast Test (CCT) will generate a stimulus that provides precise contrast to a given cone while maintaining zero contrast to the other two cones. This ideal is practically impossible because of individual differences in cone mechanism spectral sensitivity even within the CVN population. The individual variability limitation of normal observers is well understood and does not invalidate the CCT because the magnitude of individual differences in the normal population is much less than the differences between CVN and CVD observers. The CCT starts with the spectral sensitivity of the cones of an average normal observer, in this case the Stockman and Sharpe (2000) 2° cone fundamentals. Given the cone spectral sensitivity and the spectral power of the monitor primaries, one can use matrix algebra to compute the intensities of monitor primaries (r, g, b) needed to isolate the contrast provided to one of the cone types (L, M, S) of the average normal observer, where L indicates the cone most sensitive to

long wavelengths (red), M indicates the cone most sensitive to medium wavelengths (green), and S indicates the cone most sensitive to short wavelengths (blue). Figure 2 shows the appearance of the Landolt C stimulus for each of the three cone types.

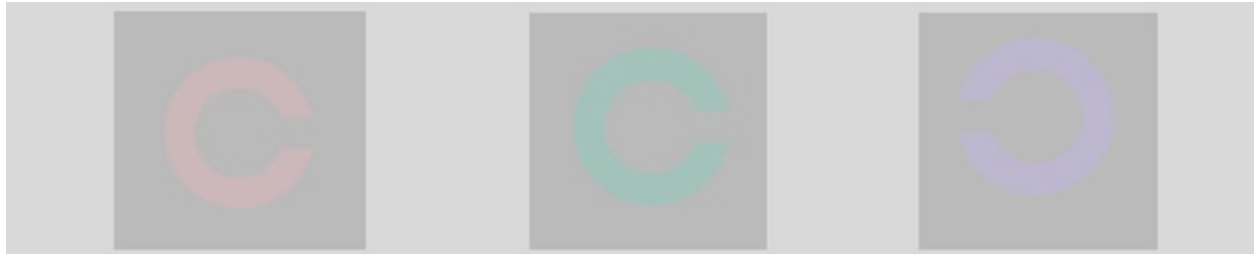


Figure 2. L, M, and S Landolt C optotypes used in both the CCT HD and OCCT.

While one can compute the primary intensities required with double precision floating-point accuracy it is not certain that these intensities can be accurately and reliably generated on a monitor. The methods used to maximize the accuracy and reliability of a device use colorimetric or radiometric instruments to characterize the device, and then calibrating the device (i.e. putting the device in a known state) that maximizes the accuracy, and reliability. A more detailed description of this calibration procedure is provided in a previous report (Gaska et al, 2016). However, the OBVA lab is responsible for validating their device. Here, we describe the colorimetric measurements used to evaluate how well the Konan CCT met the goal of stimulus accuracy and intended cone isolation.

2.1.1. Measurement Method

An Ocean Optics Maya 2000 Pro spectrometer was used to measure the spectral irradiance of light generated by each color patch. The dot product between the spectral irradiance and the three (L, M, S) Stockman and Sharpe (2000) 2° cone fundamentals was used to compute L, M, and S cone excitation levels for both background and stimulus. Cone contrast $c(l,m,s)$ is computed by taking the difference between the cone excitation levels of a stimulus $e(l,m,s)$ and the cone excitation levels of a uniform background $b(l,m,s)$ and dividing the difference by the cone excitation levels of the background as shown in Equation 1. A more detailed description of the display characterization procedure can be found in Gaska et al, 2016.

$$c(l, m, s) = \frac{e(l, m, s) - b(l, m, s)}{b(l, m, s)}$$

Equation 1.

Cone contrast values were computed by the difference between the cone excitation of the stimulus and background (Δ) by the background excitation ($\Delta L/L$, $\Delta M/M$, $\Delta S/S$). The desired contrast condition was varied over the range of 0.001 to 1.0 in 0.1 log unit steps in low to high order. The cone isolation conditions were ordered as L, M and S and the colorimetric data array was captured using 2 nested loops with the outer loop = desired contrast and the inner loop = cone isolation type. This block of measurements was repeated 21 times and averaged over time. The total measurement time was approximately 8 hours.

2.1.2. Calibration Measurement Results

Figure 3 shows the calibration test results. The left column of the figure plots the desired cone contrast on the horizontal axis and the measured cone contrast on the vertical axis. L, M and S results are plotted using red, green and blue symbols, respectively. The right column of the figure plots an error metric as a function of desired cone contrast. The error metric, E , was computed by taking the Euclidian distance, D , between the desired cone contrast and the measured cone contrast in 3-dimensional cone contrast space and normalizing the distance by the desired cone contrast of the isolated cone type, C_{iso} .

$$E = 100 \cdot D / C_{iso}$$

Equation 2.

Where

$$D = \sqrt{(L_{measured} - M_{desired})^2 + (M_{measured} - M_{desired})^2 + (S_{measured} - S_{desired})^2}$$

Equation 3.

Multiplying by 100 converts the proportional error to percent error. The average percent error for the L, M and S cones was 7.0, 8.7 and 4.4, respectively. The largest average percent error was obtained from the M-cone data set with the maximum (26.9) at the desired cone contrast of 10-1 or 0.1 percent. These results demonstrate that the Konan CCT provides highly accurate cone contrast stimuli. Descriptive statistics for all cone types are shown in Table 1.

Table 1. Mean and maximum error for each cone type.

Mean Percent Error			Max Percent Error		
L	M	S	L	M	S
6.98	8.65	6.02	14.51	26.96	6.02

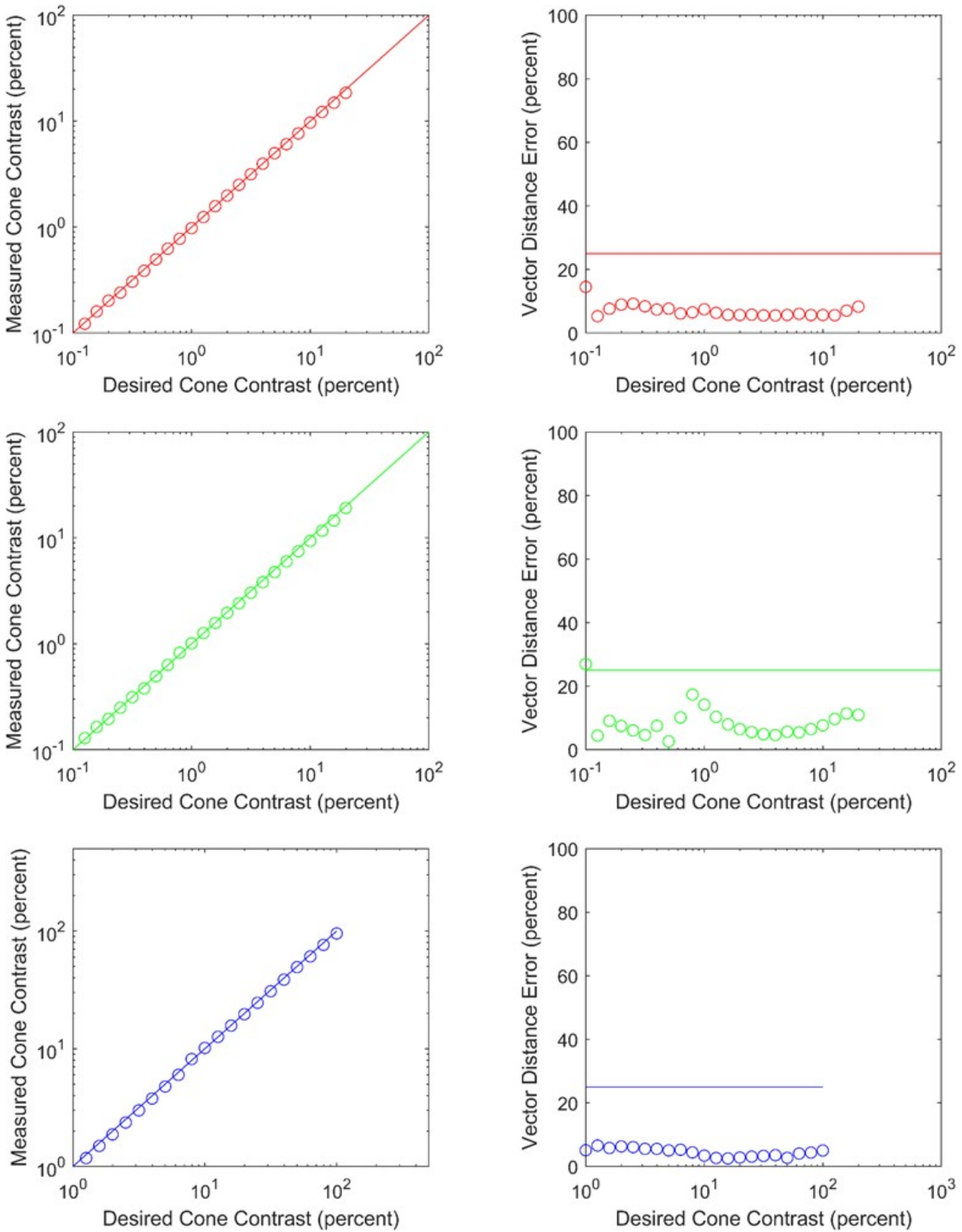


Figure 3. Left: desired vs. measured cone contrast for each cone type. Right: Error metric (E) for each cone type.

3.0 COMPARISON OF TEST SCORES FOR OCCT AND KONAN CCT HD

The OBVA and Konan CCTs should provide the same scores for an individual observer. Therefore, a regression plot of all observers' OBVA CCT and Konan CCT HD scores should result in a slope of 1 and an intercept of 0.

3.1 Method

Twenty-seven observers with a wide range of color discrimination capabilities were tested using the Konan CCT HD and OCCT. Each test was administered twice and the test scores were averaged.

3.2 Results

Figures 4, 5, and 6 show the relationship between the OCCT and CCT HD for the L, M, and S cone test results, respectively. Tables 2, 3, and 4 summarize the results of the regression analysis for each cone test.

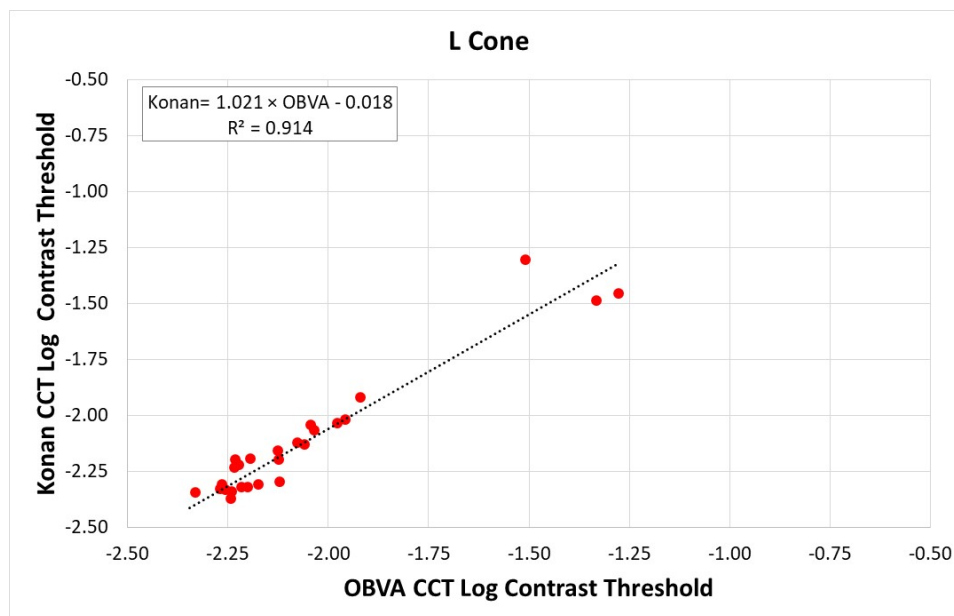


Figure 4. Correlation between L-cone OCCT and CCT HD test results.

Table 2. OCCT vs. CCT HD L-cone regression analysis results.

	<i>Coefficients</i>	<i>Standard Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>Lower 95%</i>	<i>Upper 95%</i>
Intercept	-0.018	0.131	-0.139	0.891	-0.287	0.251
Slope	1.021	0.062	16.343	7.45E-15	0.892	1.150

As shown in Table 2, the estimate of the L-cone intercept (-0.018) is within the 95% confidence interval and the estimate for slope (1.021) is within the 95% confidence interval. Note the highly significant P-value for the slope estimate reflects the probability that the slope is zero.

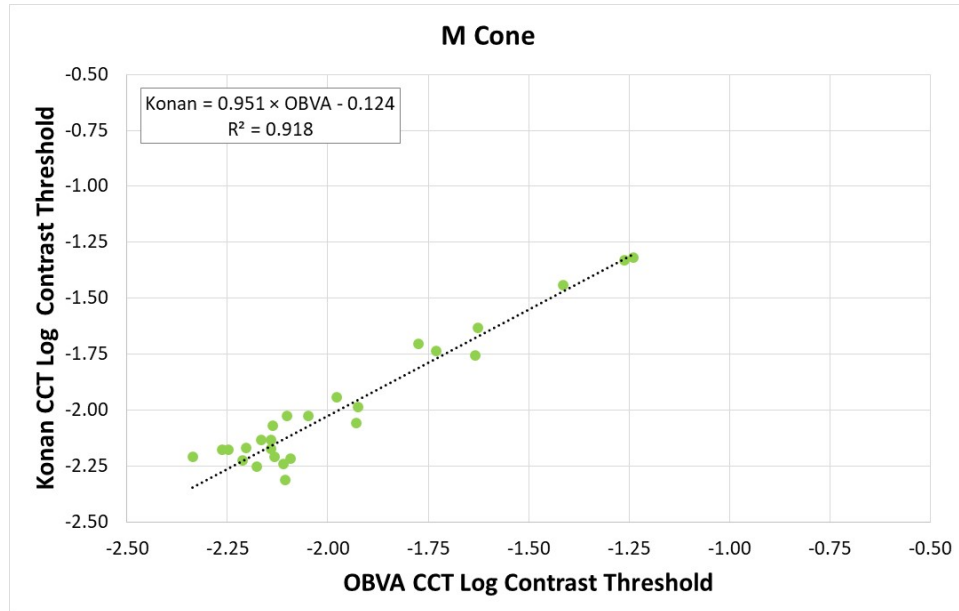


Figure 5. Correlation between M-cone OCCT and CCT HD test results.

Table 3. OCCT vs. CCT HD M-cone regression analysis results.

	<i>Coefficients</i>	<i>Standard Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>Lower 95%</i>	<i>Upper 95%</i>
Intercept	-0.043	0.117	-0.365	0.718	-0.284	0.199
Slope	0.965	0.058	16.703	4.51E-15	0.846	1.084

As shown in Table 3, the estimate of the M-cone intercept (-0.043) is within the 95% confidence interval and the estimate for slope (0.965) is within the 95% confidence interval.

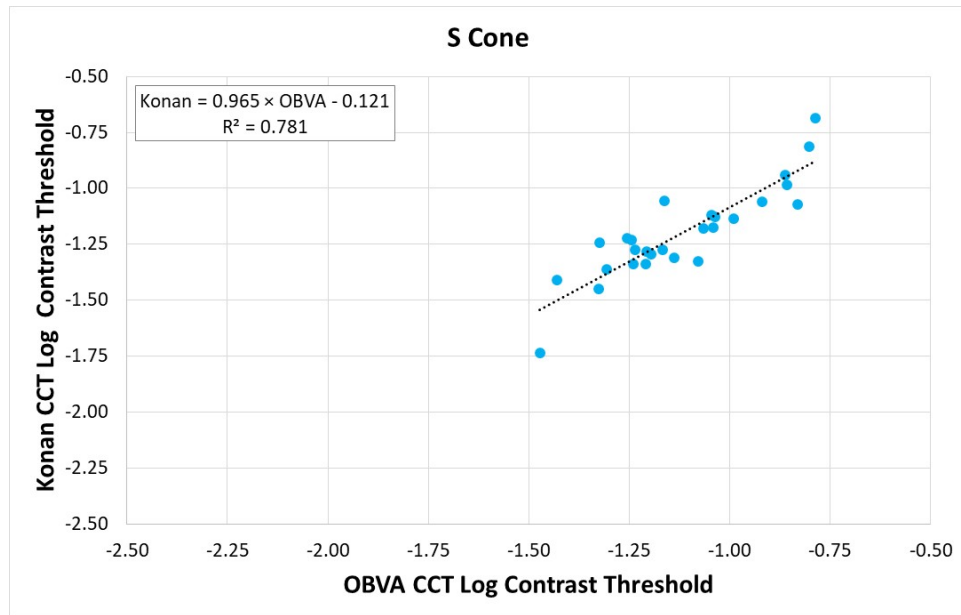


Figure 6. Correlation between S-cone OCCT and CCT HD test results.

Table 4. OCCT vs. CCT HD S-cone regression analysis results.

	<i>Coefficients</i>	<i>Standard Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>Lower 95%</i>	<i>Upper 95%</i>
Intercept	-0.121	0.116	-1.041	0.308	-0.360	0.118
Slope	0.965	0.102	9.434	1.03E-09	0.755	1.176

As shown in Table 4, the estimate of the S-cone intercept (-0.121) is within the 95% confidence interval and the estimate for slope (0.965) is within the 95% confidence interval.

4.0 CONCLUSION

The results of this evaluation show that the Konan Medical CCT HD is precisely calibrated and replicates the scores of the OCCT. In fact, the correlation between the CCT HD and OCCT is nearly indistinguishable from that of the correlation of the OCCT with itself. Figure 7 shows the correlation between the CCT HD and OCCT (left, M-cone) in comparison to a similar correlation for the OCCT administered on one day, and then repeated on a second day (right, M-cone).

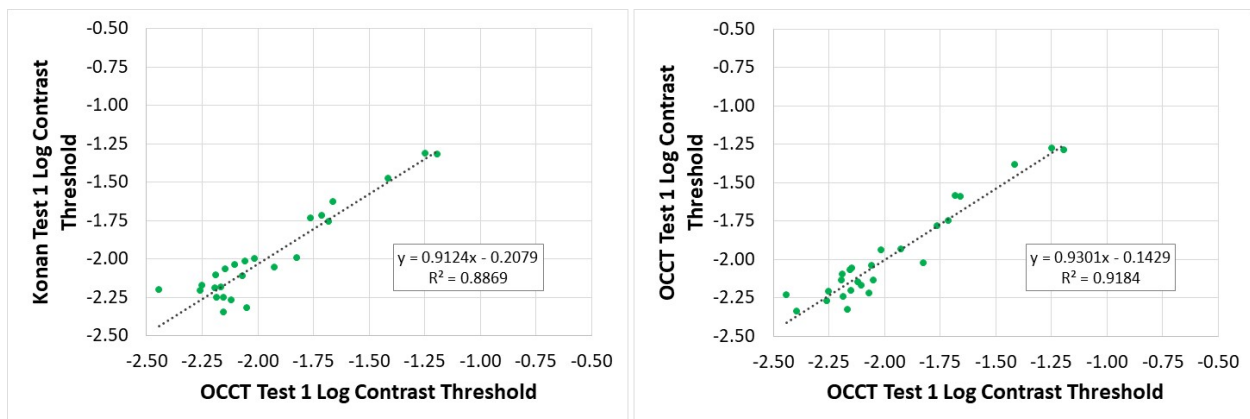


Figure 7. Correlation between the CCT HD and OCCT (left, M-cone) in comparison to the correlation between the OCCT Test 1 and Test 2 (right, M-cone).

The CCT HD, with very precise color calibration, can achieve the very low cone contrast values needed to accurately quantify cone contrast thresholds even for CVN individuals. The capability to test CVN individuals is essential in order to research the relationship between color vision and operationally relevant performance. Additionally, the CCT HD, with precise calibration and excellent test-retest reliability can also enable early detection of disease, improved ability to quantify the effect of hypoxia and other environmental stressors on vision, and improved ability to investigate the potential effects of chemicals/pharmaceuticals. The precise calibration also enables binocular testing, which is not possible with the RCCT due to the ceiling effect. The RCCT was a substantial improvement over PIP tests when it was introduced, and the CCT HD is a substantial improvement over other commercially available CCTs.

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LIST OF ACRONYMS

CCT	Cone contrast test
CRADA	Cooperative research and development agreement
CVD	Color vision deficient
CVN	Color vision normal
L-cone	Long wavelength sensitive cone
M-cone	Medium wavelength sensitive cone
OBVA	Operational Based Vision Assessment
OCCT	OBVA cone contrast test
PIP	Pseudoisochromatic plate
RCCT	Rabin cone contrast test
S-cone	Short wavelength sensitive cone
USAF	United States Air Force