RightEye Vision System

Clinical Performance Testing

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TABLE OF CONTENTS

Section 1: Reliability Testing of the RightEye Vision Tests

Purpose: to establish the reliability of the RightEye Horizontal Random Saccades (HRS) and metrics.

Methods

Participants

Participants were selected for this study through advertisements placed on the internet, social media, bulletin boards, and via word of mouth. To establish test-retest reliability, a separate set of participants (n = 241) completed RightEye Vision Tests (HRS) twice (i.e., Trial1 and Trial2). These participants were between the ages of 5-62 years (M = 25, SD =17.47); 128 were males (53.11%), 113 were females (46.88%). Of the 241 participants, 67% were white, 11% black, 13% Hispanic, and 9% opted not to report ethnicity. Participants had not been part of any other testing protocol on the RightEye Vision System and all participants had no prior experience with eye tracking technology.

A sample size of 241 participants with varied demographic backgrounds and both genders is reflective of the intended use of the RightEye Vision System. It is deemed that 241 participants are more than suffice for determination of reliability as past research has used considerably fewer participants (n = 15, Farzin, Scaggs, Hervey, Berry-Karvis, Hessl, 2011; n = 36; Marks, Pike, Stroop, Rush, 2014; n = 130, Pal, Manders, van der Steen, 2010) to measure eye tracking reliability.

All participants passed pre-screening requirements. Participants were excluded from participation in the study if they met any of the following pre-screening conditions: neurological disorders (such as concussion, traumatic brain injury, Parkinson's Disease, cerebral palsy); vision related issues that prevented successful calibration (Niehorster et al., 2017; Renard et al., 2015) of all 9-points (such as extreme tropias (Han, Guo, Granger-Donetti, Vicci, Alvarez, 2010) phorias (Han, Guo, Granger-Donetti, Vicci, Alvarez, 2010; Kooiker, Pel, Verbunt et al., 2016) static visual acuity of greater than 20/400 (Niehorster et al., 2017), nystagmus (Niehorster et al., 2017; Kooiker, Pel, Verbunt et al., 2016) cataracts or eye lash impediments (Holmqvist & Nystrom, 2011); or if they had consumed drugs or alcohol within 24 hours of testing. All participants provided informed consent to participate in this study in accordance with IRB procedure (IRB: UMCIRB 13-002660).

Dr. Nicholas Murray an Associate Professor at East Carolina University and Director of the Visual Motor Laboratory conducted testing. Dr. Murray is a vision scientist, and had received and passed the RightEye training, education, and protocol procedures prior to testing.

Materials and Equipment

Materials and Equipment

The participants were seated in a stationary (non-wheeled) chair that could not be adjusted in height at a desk within the Visual Motor Laboratory (see Figure 3). The participants were asked to look at a Tobii Dynavox, i15 all-in-one system. The screen size was 12” wide and 9” high, with a 15-inch diagonal. The system was fitted with an Tobii 90 Hz remote eye tracker connected to Tobii i15, and a Logitech (model Y-R0017) wired keyboard and mouse.

Figure 3: RightEye Vision Testing System: Tobii Dynovox i15 all-in-one device.

Testing Procedure

Following informed consent, participants were asked to complete a pre-screen questionnaire and an acuity vision screen where they were required to identify four shapes at 4mm in diameter. If any of the pre-screen questions were answered positively or any of the vision screening shapes were not correctly identified, then the participant was excluded from the study.

For standardization of testing, participants were asked to sit in front of the eye tracking system at an exact measured distance of 60cm (ideal positioning within the head box range of the eye tracker) from the eye tracker. A nine-point calibration was conducted with points spanning the computer screen (see Figure 4). Upon completion of calibration, the data was saved. Written instructions and animations were provided before calibration to model appropriate behavior. Once complete the testing process was repeated for reliability.

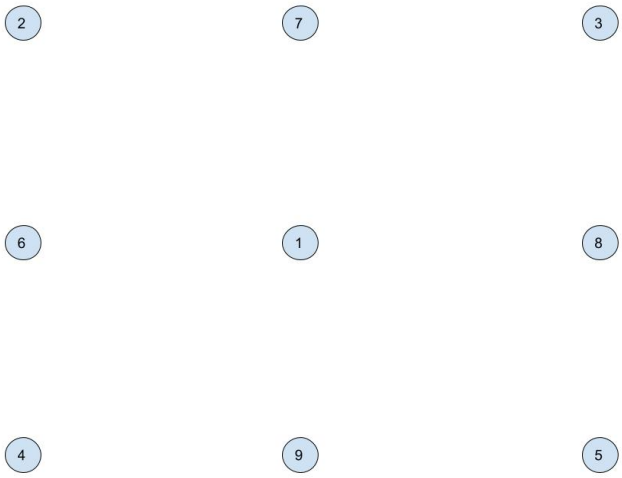

Figure 4: 9-Points of calibration in sequence of appearance.

Horizontal Random Saccade (HRS) Test for Nystagmus. The HRS test presents a target stimulus, a white circular dot on a black background, of 0.2 degrees' diameter on a horizontal plane. The dot begins in the center of the screen and moves randomly on the horizontal axis, every 400-1500ms, and is always visible. Three 'guaranteed points' are initiated as the first dot located in the center of the screen, then at 1/5, 2/5, 3/5 of the test duration of 60 seconds. Guaranteed points will appear for a duration of two seconds. Guaranteed points are at visual degrees from central are right +20, left -20, left –23 and central gaze at zero degrees. The eccentric points of gaze are used to calculate a nystagmus metric.

Testing Procedure

Qualified participants who successfully passed the 9-point calibration procedure completed the test. The participant was asked to follow the stimuli as "accurately as possible with their eyes." Written instructions on screen and animations were provided before each test to demonstrate appropriate behaviour required in each of the tests.

Data analysis

Reliability of RightEye tests was evaluated using Cronbach's Alpha (CA). The CA indicates the relative reliability and is interpreted using the following criteria CA > .70 specifies excellent reliability and less than .60 represents poor reliability.

Results

Test-Retest Reliability Analysis

The 62 eye tracking variables from trials 1 and 2 were analyzed using R (statistical package) reliability procedure. Table 6 presents the means and standard deviations for trials 1 and 2, the Cronbach's Alpha correlations between the Trial 1 and Trial 2 and associated the test-retest reliability decisions. All eye tracking variables demonstrated *Acceptable* (.7) to *Excellent* (.9) test-retest reliability. No variables were found to be *Unacceptable* (<.6).

Table 6. Test-retest Reliability of Horizontal Random Saccades Digitized Eye Tracking Variables

Variable	Trial 1 Mean	Trial 1 SD	Trial 2 Mean	Trial 2 SD	CA	Decision
0 degrees velocity fast phase	0.96	0.39	0.89	0.15	0.8	Acceptable
0 degrees velocity slow phase	1.39	0.98	1.10	0.96	0.9	Acceptable
0 degrees duration fast phase	179.87	47.92	188	56.37	0.9	Acceptable
0 degrees duration slow phase	140.35	80.34	148.23	76.59	0.9	Acceptable
20 degrees velocity right fast phase	1.867	1.20	1.762	1.11	0.8	Acceptable
20 degrees velocity right slow phase	5.201	2.89	5.413	2.97	0.8	Acceptable
20 degrees duration right fast phase	403.78	145.88	434.65	153.26	0.9	Acceptable
20 degrees duration right slow phase	498.99	87.27	502.23	91.46	0.9	Acceptable
20 degrees velocity left fast phase	2.38	1.49	2.39	1.50	0.9	Acceptable
20 degrees velocity left slow phase	6.00	2.54	6.41	2.57	0.7	Acceptable
20 degrees duration left fast phase	354.23	120.29	362.90	138.48	0.9	Acceptable
20 degrees duration left slow phase	501.43	180.76	484.79	187.54	0.8	Acceptable
23 degrees velocity left fast phase	2.73	1.01	2.32	1.71	0.8	Acceptable
23 degrees velocity left slow phase	6.32	2.67	6.12	4.50	0.9	Acceptable
23 degrees duration left fast phase	386.68	180.55	397.57	172.14	0.9	Acceptable
23 degrees duration left slow phase	467.89	147.87	465.87	167.90	0.9	Acceptable

Justification of RightEye Vision Tests Reliability

The purpose of this study was to use an empirical, data-driven approach to examine the reliability of the HRS test on the RightEye Vision System. All the variables resulted in acceptable reliability.

Reliability of the RightEye tests was also deemed acceptable according to statistical standards. Cronbach's Alphas are above an acceptable level of .7 which is considered ideal (Fleishman, 1986). These results show that the RightEye tests are consistently performing the same way for everyone across multiple attempts. This is important for the RightEye Vision Systems' intended use as it is expected that many people will use the system more than once.

The *participant* group had no prior eye tracking experience and therefore remains a naïve participant group and reflects RightEyes intended use population. Furthermore, this was a unique sample of participants as they had not been part of any other testing protocol on the RightEye Vision System. In addition, the data collected was done at an independent laboratory in a different location all together (ECU is in North Carolina, RightEye is located in Maryland).

A *sample size* of 241 participants with varied demographic backgrounds and both genders is also reflective of the intended use of the RightEye Vision System. It is deemed that 241 participants are suffice for determination of reliability because as past research has used considerably fewer participants (n = 15, Farzin, Scaggs, Hervey, Berry-Karvis, Hessl, 2011; n = 36; Marks, Pike, Stroop, Rush, 2014; n = 130, Pal, Manders, van der Steen, 2010) to measure eye tracking reliability with success. Taken together, the results demonstrated the RightEye Vision System to be a reliable way to measure eye tracking variables and oculomotor behavior.

Section 2: Validity Testing of the RightEye Vision Tests

Purpose: to compare the results of the digitized suite of eye tracking tests with a clinical diagnosis using the Vestibular Ocular Motor Screening (VOMS) protocol to determine validity.

Methods

Participants

Participants were selected for this study through advertisements placed on the internet, social media, bulletin boards, and via word of mouth. Participants had no prior experience with eye tracking technology. The participants were between the ages of 20-43 years (M = 20.10, SD = 5.74); 25 were males (47%), 28 were females (55%). Of the 53 participants, 73% were white, 10% black, 12% Hispanic, 0% Native American and 5% opted not to report ethnicity. Participants had not been part of any other testing protocol on the RightEye Vision System.

A sample size of 53 participants is considered a statistically adequate sample size according to Tabachnick & Fidell's book of Using Multivariate Statistics and Green (1991). The rule of thumb assumes a medium-size relationship between the independent variables and the dependent variable and alpha = 0.05. Furthermore, with varied demographic backgrounds and both genders the sample is reflective of the intended use of the RightEye Vision System.

All participants passed pre-screening requirements. Participants were excluded from participation in the study if they met any of the following pre-screening conditions: neurological disorders (such as concussion, traumatic brain injury, Parkinson's Disease, cerebral palsy); vision related issues that prevented successful calibration (Niehorster et al., 2017; Renard et al., 2015) of all 9-points (such as extreme tropias (Han, Guo, Granger-Donetti, Vicci, Alvarez, 2010) phorias (Han, Guo, Granger-Donetti, Vicci, Alvarez, 2010; Kooiker, Pel, Verbunt et al., 2016) static visual acuity of greater than 20/400 (Niehorster et al., 2017), nystagmus (Niehorster et al., 2017; Kooiker, Pel, Verbunt et al., 2016) cataracts or eye lash impediments (Holmqvist & Nystrom, 2011); or if they had consumed drugs or alcohol within 24 hours of testing. All participants provided informed consent to participate in this study in accordance with IRB procedure (IRB: UMCIRB 13-002660).

Dr. Nicholas Murray an Associate Professor at East Carolina University and Director of the Visual Motor Laboratory conducted testing on the RightEye Vision System. Dr. Murray is a vision scientist, and had received and passed the RightEye training, education, and protocol procedures prior to testing.

Dr. Greg Matthews, a Board Certified (American Board of Psychiatry and Neurology) neurologist with 16 years' experience post-residency conducted the clinical evaluations using the Vestibular Ocular Motor Screening (VOMS) protocol. The participants were allocated to the neurologist for testing in a randomized order.

Participants completed the HRS test and had their eye tracking behaviors (i.e., their horizontal random saccades, circular smooth pursuit behaviors, their horizontal smooth pursuit behaviors, their vertical smooth pursuit behaviors, their vertical saccade behaviors, and their horizontal saccade behaviors) evaluated by a clinician. The status of the participants was blind to the researchers/clinician during testing, and only revealed during data analysis.

Testing Apparatus

Same as in Section 1.

Testing Procedure

RightEye: Qualified participants who successfully passed the 9-point calibration procedure (see Section 3: Testing Procedure) completed the RightEye Vision Tests. For each test, the participant was asked to follow the stimuli presented on the screen as "accurately as possible with your eyes." Written

instructions and animations were provided before each test to model appropriate behavior. A brief description of each of the HRS test can be found in the reliability section of this document.

VOMS: When being tested by the neurologist the participant was directed to follow a standard VOMS clinical protocol. This included the "follow the tip of my finger" in a circular clockwise fashion (CSP), then in a horizontal direction (left-and-right, HSP) then a vertical direction (up-and-down, VSP). The neurologist then conducted a saccade test asking the participant to "move your eyes as quickly and accurately as possible between my index fingers when you hear me click". His arms were stretched out to the left and right about three feet apart. This was done horizontally (HS) then repeated vertically (VS). The neurologist then asked the patient to follow his finger as it "jumped" randomly across a horizontal plane (HRS). The neurologist evaluated each type of eye tracking behavior as either 'normal' or 'abnormal' functioning. If more than two of the five tests were evaluated as "abnormal" then the overall clinical result was considered "abnormal".

Data Analysis

A series of logistic regressions examined the ability of the HRS test to predict VOMS-determined results. That is, the eye tracking tests were evaluated as the predictor/ independent variables and the VOMS result was evaluated as the predicted/ dependent variable. The eye tracking tests include multiple sub variables. All sub variables for each test were entered into the logistic regression in a single block. For each of the logistic regressions, the data analyses included chi-square statistics, Nagelkerke R^2 values, Horsmer-Lemeshow tests, and Wald statistics. The chi-squares compared the Log-likelihoods of the baseline (no eye tracking variables included) and new (eye tracking variables included) models. Nagelkerke R^2 values quantified the variability in clinical diagnosis explained by the eye tracking tests. Horsmer-Lemeshow tests examined the goodness of fit of the new models. Wald statistics evaluated the contribution of each of the eye tracking test variables to the new model. p-values were set at $p<.05$ for all analyses.

Results

HRS Test Regression

The HRS logistic regression examined the predictive validity of the HRS test. The sixteen eye tracking sub variables from the HRS test were entered as the predictor/ independent variables and the clinical evaluation score (normal functioning coded as 0; abnormal functioning coded as 1) for horizontal random saccade behavior was entered as the predicted/ dependent variable. The full model of sixteen predictor variables significantly predicted clinically evaluated HRS status ($\chi^2 = 51.730$, $df = 16$, $n = 52$, $p < .0005$). The model accounted for between 78% to 89% of the variance (Nagelkerke $R^2 = .890$) in status classification with overall 92.3% of individuals correctly predicted to their known status. Table 13 gives coefficients, odds ratios, and probability values (for Wald statistics) for each of the predictor variables.

For the HRS test, none of the individual sub variables were statistically significant predictors on their own. That is, all of the Wald statistics were nonsignificant (*p*'s>.05). Table 14 presents the degree of agreement between the known status, and the logistic regression function predicted status classification. Based on these results, the following were found for identifying the normal status at 50.7% prevalence: sensitivity = .91, specificity = .94.

Table 13: HRS Logistic Regression

				95% CI. for EXP(B)	
HRS model	*B*	SE	EXP(B)	Lower	Upper
Constant	67.84	121.4	2.856E+10		
0 Degrees velocity fast	0.231	0.254	0.986	0.57	1.35
0 Degrees velocity slow phase	-0.451	0.134	1.121	0.41	2.37
0 Degrees duration fast phase	2.876	0.381	1.101	131.95	227.79
0 Degrees duration slow phase	0.190	1.130	2.017	60.01	220.69
20 degrees velocity right fast phase	0.347	0.329	0.769	0.667	3.067
20 Degrees velocity right slow phase	1.581	0.811	0.659	2.311	8.091
20 Degrees duration right fast phase	-0.135	0.219	0.781	257.9	549.66
20 Degrees duration right slow phase	-1.981	0.378	0.998	411.72	586.26
20 Degrees velocity left fast phase	2.879	0.561	0.798	0.89	3.87
20 Degrees velocity left slow phase	3.271	0.692	0.647	3.46	8.54
20 Degrees duration left fast phase	-0.129	0.382	0.979	233.94	474.52
20 Degrees duration left slow phase	0.329	0.562	0.679	320.67	682.18
23 Degrees velocity left fast phase	-0.189	0.768	0.921	1.72	3.74
23 Degrees velocity left slow phase	0.970	0.689	0.389	3.65	8.99
23 Degrees duration left fast phase	1.289	0.349	0.987	206.13	567.23
23 Degrees duration left slow phase	-2.349	0.568	0.782	320.02	615.76

Regression Statistic	Value
-2LL	45.61
χ^2	51.73, *df*=16, *p*<.0005
Nagelkerke R^2	0.890

Hosmer-Lemeshow test	p=.94
Classification accuracy	92.3%

Table 14: HRS Classification Table

Observed			Predicted HRS		% Correct
			Normal	Not Normal	
HRS model	HRS	Normal	19	2	90.5
		Not Normal	2	29	93.5
	Overall Percentage				92.3

Justification of Validity for the RightEye Tests

The purpose of this study was to compare the results of the HRS test with a clinical diagnosis using the Vestibular Ocular Motor Screening (VOMS) protocol to determine the validity of oculomotor behavior.

The HRS independently, significantly predicted the VOMS derived measures of eye tracking behavior. Sensitivity was (.91) and specificity was (.94). These results significantly distinguish normal eye movement behaviors compared to not normal. Results indicate that the RightEye eye tracking tests, examined against the VOMS protocol significantly predicted the normal versus not normal eye movements and can therefore be a valid tool in assessing eye movement behavior.

Validity of the RightEye tests was also deemed acceptable according to statistical standards as they significantly predicted the VOMS derived measures. These results show that the RightEye tests are performing similar to the clinical recognized standard (VOMS). This is important for the RightEye Vision Systems' intended use as it is expected that many people will use the system to digitally compare their results to clinical standards.

The *participant* group had no prior eye tracking experience and therefore remains a naïve participant group and reflects RightEyes intended use population. Furthermore, this was a unique sample of participants as they had not been part of any other testing protocol on the RightEye Vision System. In addition, the data collected was done at an independent laboratory in a different location all together

(ECU is in North Carolina, RightEye is located in Maryland). Furthermore, a Board Certified (American Board of Psychiatry and Neurology) neurologist with 16 years' experience post-residency conducted the clinical evaluations using the Vestibular Ocular Motor Screening (VOMS) protocol. The participants were allocated to the neurologist for testing in a randomized order, and the neurologist and researcher were both blind to the results. Hence, the methodological process undertaken to determine the validity of the tool was rigorous and therefore, lends further credence to the results.

A sample size of 53 participants is considered a statistically adequate sample size according to the rule of thumb by Tabachnick & Fidell's book of Using Multivariate Statistics and Green (1991). The rule of thumb assumes a medium-size relationship between the independent variables and the dependent variable and alpha = 0.05. Furthermore, with varied demographic backgrounds and both genders the sample is reflective of the intended use of the RightEye Vision System. Furthermore, data analyses (chi-square statistics, Nagelkerke R^2 values, Horsmer-Lemeshow tests, and Wald statistics) was conducted across many different tests. Nagelkerke R^2 values quantified the variability in clinical diagnosis explained by the eye tracking tests. Horsmer-Lemeshow results showed successful the goodness of fit of the new models. Wald statistics evaluated the contribution of each of the eye tracking test variables to the new model. All tests were found to be statistically significant at $p<.05$ for all analyses.

Taken together these factors result in the six RightEye tests measuring oculomotor behavior in a valid manner.

Section 3: Normative Data

Purpose: is to report on a normative data set that is used to determine the acceptance criteria for the algorithms and functional requirements performance on key metrics across the HRS RightEye Vision Tests.

Methods

Participants

Participants were selected for this study through advertisements placed on the internet, social media, bulletin boards, and via word of mouth. Participants had no prior experience with eye tracking technology. For the normative data analysis, 2993 participants completed the Horizontal Random Saccade (HRS) test. Participants were between the ages of 5-62 years (M = 20.87, SD = 12.45); 2030 were males (67.85%), 962 were females (32.15%). Of the 2993 participants, 61.63% were white, 6.85% black, 8.32% Hispanic, 0.20% Native American and 8.96% opted not to report ethnicity. Participants had not been part of any other testing protocol on the RightEye Vision System.

A sample size of almost 3000 participants with varied demographic backgrounds and both genders is also reflective of the intended use of the RightEye Vision System. It is deemed that the sample size is suffice for determination of normative data compared to other studies of normative eye tracking

data (e.g., [Bargary et al., 2017], *n* = 1058; [Evdokimidis et al., 2002], *n* = 2,006; [Lenzenweger & O'Driscoll, 2006], *n* = 300).

All participants passed pre-screening requirements. Participants were excluded from participation in the study if they met any of the following pre-screening conditions: neurological disorders (such as concussion, traumatic brain injury, Parkinson's Disease, cerebral palsy); vision related issues that prevented successful calibration (Niehorster et al., 2017; Renard et al., 2015) of all 9-points (such as extreme tropias (Han, Guo, Granger-Donetti, Vicci, Alvarez, 2010) phorias (Han, Guo, Granger-Donetti, Vicci, Alvarez, 2010; Kooiker, Pel, Verbunt et al., 2016) static visual acuity of greater than 20/400 (Niehorster et al., 2017), nystagmus (Niehorster et al., 2017; Kooiker, Pel, Verbunt et al., 2016) cataracts or eye lash impediments (Holmqvist & Nystrom, 2011); or if they had consumed drugs or alcohol within 24 hours of testing. All participants provided informed consent to participate in this study in accordance with IRB procedure (IRB: UMCIRB 13-002660).

Dr. Nicholas Murray an Associate Professor at East Carolina University and Director of the Visual Motor Laboratory conducted testing on the RightEye Vision System. Dr. Murray is a vision scientist, and had received and passed the RightEye training, education, and protocol procedures prior to testing.

Apparatus

Same as Section 1.

Oculomotor Tasks

HRS as described in Section 5.

Testing Procedure

Qualified participants who successfully passed the 9-point calibration procedure (see Section 3: Testing Procedure) completed the RightEye Vision Tests. For each test, the participant was asked to follow the stimuli presented on the screen as "accurately as possible with your eyes." Written instructions and animations were provided before each test to model appropriate behavior. A brief description of the HRS test can be found in the reliability section of this document.

Data analysis

To describe the normative features of the data, we performed exploratory data analysis and conducted model-based clustering using EM algorithm analysis. We chose this approach because it has several advantages over k-means or hierarchical clustering approaches. First, both k-means and hierarchical approaches are largely heuristics thus not model-based and not well suited for inference (Hill & Mukherjee, 2013) Second, a model-based approach uses a density function with an associated weight that will 'suggest' the optimal number of clusters. Lastly, the model approach is based on the Bayesian Information Criterion (BIC) values which help to determine the most appropriate clusters.

We examined group differences with a multivariate ANOVA, for the HRS test. Age groups were included as a covariate in these analyses.

Results

Cluster Analysis

The model-based clustering using EM algorithm analysis created five distinct age group: 5-8, 9-16, 17-28, 29-52, and 53-62. Further, we conducted stability testing to establish that the data sample used for cluster analysis that is representative of the entire population. The stability testing involved sub-sampling 10 individuals from the experimental population for each age group. These sub-samples were then compared against the entire population norm to assess cluster solution. The comparison of the sample norms and the population norms showed the cluster solution was appropriate in numbers and quality (Calinski-Harabasz Index = 16.61 with average inter-cluster distance = 56.73). The descriptive statistics for all variables derived from the six RightEye Vision Tests for the 5 clusters are shown in table 25.

Table 25: Descriptive Statistics Horizontal Random Saccades Clustered by Age

	5 - 8		9 - 16		17 - 28		29 - 52		53 - 62	
Test	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
0 Degrees velocity fast	0.89	0.88	0.92	0.61	0.95	0.39	0.97	0.59	0.97	0.62
0 Degrees velocity slow phase	1.20	0.99	1.26	0.87	1.40	0.64	1.41	0.73	1.39	0.97
0 Degrees duration fast phase	167.37	68.71	173.98	56.32	180.34	45.32	186.49	53.67	191.43	78.56
0 Degrees duration slow phase	133.78	90.32	137.68	70.62	141.23	50.43	145.32	61.21	152.78	67.89

Group Differences.

For the HRS variables, there were significant main effects for Age, $F(16, 2830) = 15.610$, $p < .0005$; Wilk's $\Lambda = 0.900$, $\eta_p^2 = .089$. Follow-up between-subject analyses revealed significant main effects for Age for all of the HRS variables.

Justification of Normative Data for the RightEye Tests

The *cluster analysis* represents a robust method to demonstrate distinct groups by age. We observed five distinct clusters which indicate the need to consider age ranges in the RightEye Vision Tests. Most measurements demonstrate a curvilinear relationship with peaks occurring for the 17-28 age groups and/or 29-58 age groups. The results are in-line with research indicating age related declines in

smooth pursuit and saccades (Seferlis et al., 2015) and the underlying age-related changes to the oculomotor nerve (Sharma et al., 2009).

The *group differences* examined through MANOVAs for circular, vertical, and horizontal smooth pursuit, horizontal saccades, and vertical saccades revealed a significant multivariate effect on cluster membership for Age, thus indicating support for our cluster solution.

The *participant* group had no prior eye tracking experience and therefore remains a naïve participant group and reflects RightEyes intended use population. Furthermore, this was a unique sample of participants as they had not been part of any other testing protocol on the RightEye Vision System. In addition, the data collected was done at an independent laboratory in a different location all together (ECU is in North Carolina, RightEye is located in Maryland). Hence, the methodological process undertaken to determine the normative data was rigorous and therefore, lends further credence to the results.

A *sample size* of almost 3000 participants with varied demographic backgrounds and both genders is also reflective of the intended use of the RightEye Vision System. It is deemed that the sample size is suffice for determination of normative data compared to other studies of normative eye tracking data (e.g., [Bargary et al., 2017] , n = 1058; [Evdokimidis et al., 2002], n = 2,006; [Lenzenweger & O'Driscoll, 2006], n = 300). Overall, the results demonstrated the clustering method presented here represents a robust method to demonstrate distinct differences in eye tracking variables by Age and the best method for determining normative data ranges.

Acceptance Criteria for RightEye Vision Tests

The purpose of this section is report on a normative data set that is used to determine the acceptance criteria for the algorithms and functional performance requirements of the six RightEye Vision Tests.

RightEye's acceptance criteria for all key algorithms examine in Section 8 is considered successful when the normal users report generates numbers within one standard deviation outlined in tables 25 when testing participants within the age group who fit the acceptance criteria.

Section 4: References

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