

1 **TITLE**

2 Quality of eyeglass prescriptions from a low-cost wavefront autorefractor evaluated in rural India: results of  
3 a 708-participant field study

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19 **SYNOPSIS**

20 Eyeglass prescriptions can be accurately measured by a minimally-trained technician using a low-cost  
21 wavefront autorefractor in rural India. Objective refraction may be a feasible approach to increasing  
22 eyeglass accessibility in low-resource settings.

23 **ABSTRACT**

24 **Aim**

25 To assess the quality of eyeglass prescriptions provided by an affordable wavefront autorefractor  
26 operated by a minimally-trained technician in a low-resource setting.

27 **Methods**

28 708 participants were recruited from consecutive patients registered for routine eye examinations at  
29 Aravind Eye Hospital in Madurai, India, or an affiliated rural satellite vision centre. Visual acuity (VA) and  
30 patient preference were compared for eyeglasses prescribed from a novel wavefront autorefractor versus  
31 eyeglasses prescribed from subjective refraction by an experienced refractionist.

32 **Results**

33 Mean  $\pm$  standard deviation VA was  $0.30 \pm 0.37$ ,  $-0.02 \pm 0.14$ , and  $-0.04 \pm 0.11$  LogMAR units before  
34 correction, with autorefractor correction, and with subjective refraction correction, respectively (all  
35 differences  $P < 0.01$ ). Overall, 25% of participants had no preference, 33% preferred eyeglasses from  
36 autorefractor prescriptions, and 42% preferred eyeglasses from subjective refraction prescriptions ( $P <$   
37  $0.01$ ). Of the 438 patients 40 years old and younger, 96 had no preference and the remainder had no  
38 statistically-significant difference in preference for subjective refraction prescriptions (51%) versus  
39 autorefractor prescriptions (49%) ( $P = 0.52$ ).

40 **Conclusions**

41 Average VAs from autorefractor-prescribed eyeglasses were one letter worse than those from subjective  
42 refraction. More than half of all participants either had no preference or preferred eyeglasses prescribed  
43 by the autorefractor. This marginal difference in quality may warrant autorefractor-based prescriptions,  
44 given the portable form-factor, short measurement time, low-cost, and minimal training required to use the  
45 autorefractor evaluated here.

## 46 INTRODUCTION

47 Over one billion people worldwide suffer from poor vision that could be corrected with a pair of  
48 prescription eyeglasses.<sup>1-3</sup> These uncorrected refractive errors (UREs) are a major cause of lost  
49 productivity, limited access to education, and reduced quality of life.

50 The prevalence of UREs is generally highest in low-resource settings, due in part to the severe  
51 shortage of eye care professionals.<sup>2,4</sup> There are several national and international efforts to increase eye  
52 care capacities by task-shifting the eyeglass prescription procedure to midlevel personnel called  
53 “refractionists”.<sup>4-6</sup> However, these dedicated eye care workers still require several years of training and  
54 practice to become proficient<sup>7</sup>, and it is difficult to retain these skilled workers in poor, rural, and remote  
55 areas<sup>8</sup>. There is a need to deskill the refraction process to reduce the training required for refractionist,  
56 increase their efficiency, and improve the quality of their prescriptions.

57 Autorefractors are commonly used in high-resource settings to obtain a prescription that is used as a  
58 starting point for subjective refraction, reducing the overall time required for a refraction. However,  
59 autorefractors are conventionally considered too inaccurate to provide prescriptions without subjective  
60 refinement.<sup>9-12</sup> Previous research comparing patient tolerance and acceptance of eyeglasses has found  
61 that approximately twice as many people preferred prescriptions from subjective refraction compared to  
62 prescriptions directly from an autorefractor, even after three weeks of habituating to the prescribed  
63 eyeglasses.<sup>9,10</sup> A more recent study found a smaller gap in preferences using modern autorefractors on a  
64 young-adult, non-presbyopic population—in this group, 41% more patients preferred prescriptions from  
65 subjective refraction compared to objective methods.<sup>12</sup> Sophisticated autorefractors based on wavefront  
66 aberrometry have been explored for accurate prescriptions, enabled by algorithms incorporating both  
67 high- and low-order aberrations and advanced quality metrics.<sup>13,14</sup>

68 Despite concerns over accuracy of objective refraction, several groups have developed systems with  
69 the goal of augmenting or even substituting for eye care providers in low-resource settings. Some of  
70 these approaches include the focometer<sup>15,16</sup>, adjustable lenses<sup>15,17</sup>, photorefraction<sup>18</sup>, inverse-Shack-  
71 Hartmann systems<sup>19</sup>, and simplified wavefront aberrometers<sup>20,21</sup>. Previous work has assessed the  
72 accuracy of objective autorefractors relative to subjective refraction or conventional commercial

73 autorefractors, but these studies have limited applicability to practical use in low resource settings  
74 because: (1) they tested a small population size and age range, (2) participants were highly-educated  
75 (e.g. optometry students), (3) the device was operated by highly-trained eye-care provider or engineer,  
76 (4) the test site was a controlled laboratory without examination time-constraints, and/or (5) they excluded  
77 patients with co-morbidities such as cataracts, kerataconous, and conjunctivitis.

78 We recently introduced an aberrometer that uses low-cost components and calculates a prescription  
79 from dynamic wavefront measurements captured from a short video. Measurements from a previous  
80 study found that spherical error from this aberrometer agreed within 0.25 Dioptres (D) of subjective  
81 refraction in 74% of eyes, compared to 49% agreement of the same eyes measured with a Grand-Seiko  
82 WR-5100K commercial autorefractor.<sup>20</sup> This prototype is currently under commercial development for low-  
83 resource markets (by PlenOptika, USA and Aurolab, India). The goal of this study was to assess the  
84 prescription quality from this device under realistic constraints for applicability in low-resource  
85 environments. Specifically, we evaluated performance of this aberrometer when operated by a minimally-  
86 trained technician in a low-resource setting on a large population of patients registered for routine eye  
87 examinations at either a major eye hospital or a satellite vision centre.

## 88 **METHODS**

### 89 **Participants**

90 Institutional review board at the Aravind Eye Care System approved the study protocol. Study objectives  
91 and procedures were explained in the local dialect and verbal informed consent was obtained. Written  
92 consent was obtained from additional participants to photograph using the autorefractor and use these  
93 photographs in publication.

94 Subjects were recruited from consecutive patients visiting the general ophthalmology unit of Aravind  
95 Eye Hospital in Madurai, or a rural satellite vision centre in Thiruppuvanam. Inclusion criteria were that  
96 patients were between the ages of 15 – 70 years and within the refractive error range of the autorefractor  
97 (spherical equivalent of -6D to +10D), as determined by subjective refraction. Exclusion criteria included  
98 presence of mature cataract, any prior eye surgery, any major eye illnesses, use of systemic or ocular  
99 drugs which may affect vision. The study was completed during the Summer of 2015.

100 **Subjective Refraction Procedure**

101 Patients that completed a standard-of-care refraction and met study eligibility criteria were recruited for  
102 the study. This included streak retinoscopy and subjective refraction by an experienced refractionist.  
103 Refractions at the Aravind base hospital also included measurements by a standard commercial  
104 autorefractor before the subjective refraction. Subjective refraction was performed using a trial lens set  
105 and a digital visual acuity chart (Aurolab Aurochart) placed three meters away from the participant.

106 **Autorefractor Procedure**

107 A technician with experience in coordinating eye research studies but no training in refraction or clinical  
108 optometry was trained to use the prototype autorefractor in two two-hour sessions, followed by four-hours  
109 of practice refractions with the goal of consistently administering verbal instructions to the participants. All  
110 participants were tested by this technician. The autorefractor was calibrated at the beginning of the study.  
111 No recalibration was performed throughout the three-month study duration, which included daily packing,  
112 unpacking, and transportation. Every autorefractor measurements was performed directly after standard-  
113 of-care subjective refraction at a second station in a different room.

114 Participants were instructed to hold the autorefractor to their face, rest their elbows on a table for  
115 support, and look through the device at a back-lit visual acuity chart placed three meters away (Figure 1).  
116 The technician adjusted the interpupillary distance wheel on the autorefractor and manually adjusted the  
117 pitch of the device until the participant could see a red spot coming from the autorefractor. When the  
118 participant saw a bright red spot within, the technician turned on the visual acuity chart and began  
119 recording a 10-second video of wavefront measurements with the autorefractor. The participant was  
120 instructed to blink whenever desired and to look at the visual acuity chart during the video. After the video  
121 was acquired, the device was flipped upside down to measure the opposite eye and the procedure was  
122 repeated. The participant was then measured two additional times for a total of three measurements of  
123 each eye. After the first interpupillary distance adjustment was made, typically no further adjustments  
124 were necessary. The device computed the median of the three measurements and displayed this  
125 prescription in the same format as subjective refraction on a companion laptop.

## 126 **Prescription Quality Assessment**

127 Sphere, cylinder, and axis values were transcribed from the subjective refraction and autorefractor  
128 measurements to an electronic database, which randomly assigned them to prescriptions 'A' or 'B'. The  
129 participant was escorted to a third station for VA measurement and preference survey by an experienced  
130 refractionist that was not involved in either prior refraction. This refractionist measured the VA of each eye  
131 using trial lenses set to each prescription pair in a randomized sequence, using a digital VA chart placed  
132 3 meters from the participant. The refractionist then asked the participant which prescription they  
133 preferred: A, B, or no preference. VA and preference results were entered into an electronic database  
134 that used a de-identified numeric code to track each participant.

## 135 **Statistical Analysis**

136 For statistical comparison, prescriptions were converted to power vector parameters of spherical  
137 equivalent (**M**), vertical Jackson cross cylinder (**J<sub>0</sub>**), and oblique Jackson cross cylinder (**J<sub>45</sub>**) for subjective  
138 refraction (**M<sub>SR</sub>**, **J<sub>0,SR</sub>**, **J<sub>45,SR</sub>**) and autorefraction (**M<sub>AR</sub>**, **J<sub>0,AR</sub>**, **J<sub>45,AR</sub>**). Given that subjective refraction has  
139 significant inter- and intra-optometrist variation<sup>22</sup>, we performed a Bland Altman analysis to assess  
140 correlation, bias, and outliers between the two measurements for each power vector component. We  
141 computed the 95% limit of agreement between the two measurements using the approximation of:  
142 average difference  $\pm$  (1.96 x standard deviation) of the differences.

143 All VA measurements were converted to LogMAR units for statistical comparison. VA from uncorrected  
144 vision (**VA<sub>UC</sub>**), correction by autorefractor-determined prescription (**VA<sub>AR</sub>**), and correction by subjective  
145 refraction-determined prescription (**VA<sub>SR</sub>**) were compared using a box and whisker plot of results from the  
146 right eyes only to avoid the influence of isometropia on the independence of the samples. Differences  
147 between mean values were assessed with a Wilcoxon signed-rank test with a significance level of 0.05.  
148 The participant survey for prescription preference was evaluated using a z test of proportion with a  
149 significance level of 0.05. Both VA and prescription preference results were analysed for the entire  
150 population and within two age groups partitioned by the estimated age of onset of presbyopia of 40 years  
151 of age.<sup>23</sup>

## 152 RESULTS

### 153 Participants

154 We enrolled 506 participants from the base hospital and 202 participants from the Vision Centre. All 708  
155 participants successfully received a testable prescription from both the prototype autorefractor and the  
156 subjective refraction. Within our study population, 220 participants had presbyopia, 89 participants had at  
157 least one immature cataract, 21 participants had conjunctivitis, and 1 participant had keratoconus. The  
158 mean  $\pm$  standard deviation age of participants was  $35 \pm 13$  years, 438 participants were 15-40 years of  
159 age, 270 participants were 41-70 years of age, and 413 participants were female.

### 160 Prescription Agreement

161 We observed a strong correlation between prescriptions from subjective refraction and the autorefractor,  
162 with Pearson linear correlation coefficients of  $r = 0.94, 0.83,$  and  $0.40$  for **M**, **J<sub>0</sub>**, and **J<sub>45</sub>**, respectively  
163 (Figure 2). The smaller correlation coefficient for **J<sub>45</sub>** was likely influenced by the small range of values in  
164 the study population. The standard deviation of **J<sub>45</sub>**, measured by subjective refraction, was only  $0.12$  D,  
165 compared to  $1.46$  D and  $0.30$  D for **M** and **J<sub>0</sub>**, respectively. In the correlation plot for Figure 2 (a), one  
166 measurement ( $[-3.75, -8.25]$ ) falls outside of the viewable range.

167 From Bland-Altman analysis, we observed a bias between the subjective refraction and autorefractor  
168 measurements of  $-0.09$  D,  $0.01$  D, and  $0.04$  D, for **M**, **J<sub>0</sub>**, and **J<sub>45</sub>**, respectively (Figure 2), with the  
169 autorefractor reporting more myopic spherical equivalent values on average than subjective refraction.  
170 There was also a trend for larger magnitude measurements of both myopia and hyperopia by the  
171 autorefractor. A linear fit to the Bland-Altman data has a slope of  $0.16$  and an  $R$  of  $0.36$  (line not shown),  
172 signalling either a general undercorrection from subjective refraction, or an overestimation of refractive  
173 error power measurement by the autorefractor. The 95% limits of agreement between the two methods  
174 were  $-1.47$  D to  $1.30$  D,  $-0.35$  D to  $0.36$  D, and  $-0.19$  D to  $0.27$  D, for **M**, **J<sub>0</sub>**, and **J<sub>45</sub>**, respectively. In the  
175 Bland Altman plot for Figure 2 (a), three measurements ( $[-6.00, -4.50]$ ,  $[-3.31, -6.63]$ , and  $[-0.94, -4.88]$ )  
176 fall outside of the viewable range.

## 177 **Visual Acuity**

178 We measured a mean  $\pm$  standard deviation of  $0.30 \pm 0.37$ ,  $-0.02 \pm 0.14$ , and  $-0.04 \pm 0.11$  LogMAR units  
179 for **VA<sub>UC</sub>**, **VA<sub>AR</sub>**, and **VA<sub>SR</sub>**, respectively. VA distributions for the whole study population as well as the  
180 age-grouped populations are shown in Figure 3. VA was better after correction from both refraction  
181 methods ( $P < 0.01$ ) for all study groups. **VA<sub>SR</sub>** was also better than **VA<sub>AR</sub>** ( $P < 0.01$ ) for all study groups,  
182 by margins of 0.01, 0.04, and 0.02 LogMAR units for the younger, older, and all age groups, respectively.

## 183 **Prescription Preference**

184 Overall, 25% of participants had no preference of eyeglasses, 42% preferred prescriptions from  
185 subjective refraction, and 33% preferred prescriptions from the autorefractor (Table 1). The entire  
186 population and the older groups preferred subjective refraction prescriptions more often than autorefractor  
187 prescriptions ( $P < 0.01$ ). Within the 342 participants in the younger group that had a preference, there  
188 was no statistically significant difference in prescription preference (49% preferred autorefractor  
189 prescriptions, 51% preferred subjective refraction prescriptions,  $P = 0.52$ ).

**Table 1** Participant Preference of Trial Lens Prescriptions with Masked Origin

Age Group	Participants, No. (%)				P Value SR vs AR Preference
	All	No Preference	Preferred SR	Preferred AR	
15-40	438 (61.9)	96 (21.9)	174 (39.7)	168 (38.4)	0.52
41-70	270 (38.1)	82 (30.4)	123 (45.6)	65 (24.1)	< 0.01
All	708 (100.0)	178 (25.1)	297 (41.9)	233 (32.9)	< 0.01

Abbreviations: SR, Subjective Refraction Prescription; AR, Autorefractor Prescription.

## 190 **DISCUSSION**

191 This study found smaller differences in visual acuity and preference of prescriptions obtained from  
192 autorefraction compared to subjective refraction than previous work.<sup>9-12</sup> There are several differences of  
193 our study design and autorefractor that may contribute to this result. The refractionists used in our study  
194 specialize in high-volume refractive eye exams and have less training than optometrists or  
195 ophthalmologists used in other studies. Our study used a 3-meter refraction distance since it is the  
196 standard of care within the Aravind system, but the convention of most eye exams is a 6-meter or 20-foot  
197 distance. Our study was also conducted on an Indian population in a low-resource setting, which could  
198 have systematic differences in visual acuity preferences and compliance to subjective refraction



199 instructions. Lastly, the autorefractor tested in our study is significantly different than previous studies. It is  
200 an open-view wavefront aberrometer, that analyses wavefront data from three 10-second videos of  
201 measurements (typically 240 wavefronts), rather than a single snapshot or the average of several images.

202 This study is, to the best of our knowledge, the first that identifies a population (patients 40 years old  
203 and younger) that exhibits no statistically-significant difference between preferences of prescriptions  
204 derived from an autorefractor compared to subjective refraction. The difference in preference between the  
205 two age groups may be due to several physiological parameters that vary with age. While patients with  
206 mature cataracts were excluded from this study, 6 patients (1.4%) in the younger group were noted to  
207 have at least one immature cataract, while 83 patients (30.7%) in the older group were noted to have at  
208 least one immature cataract. Pupil size was not directly measured here, but is known to decrease  
209 significantly with age.<sup>24</sup> Both opacities in the lens and a small pupil make the projection of the wavefront  
210 beacon on the retina and the measurement of the emerging wavefront more difficult. The older group is  
211 also expected to have smaller accommodative amplitude. Closed-view wavefront autorefractors are  
212 known to cause instrument-induced myopia, leading to an overestimation of myopia.<sup>25</sup> However, the  
213 system evaluated here is open-view and the observed trend was of greater autorefractor prescription  
214 preference in the population expected to have larger accommodation amplitude. Lastly, the technological  
215 literacy and compliance to both the subjective refraction and autorefraction procedures may differ  
216 between the age groups, both of which could influence the quality of the prescriptions from each method.

217 In this study, we only surveyed participants for nominal prescription preference. Future work assessing  
218 the qualitative strength of preference and satisfaction of each prescription with ordinal surveys is  
219 underway and will provide more insight into differences in perceived quality of the prescriptions. We also  
220 assessed VA and preference immediately after the eye examination, but assessing prescription quality  
221 after several weeks of habituation to the test prescription will improve the understanding of factors  
222 influencing long-term patient satisfaction. Lastly, a new version of the prototype autorefractor evaluated in  
223 this study is currently being commercialized with a larger refractive range, improved ergonomics, and is  
224 targeted to be cost-effective for low-resource settings.

225 Participants using eyeglasses prescribed by the autorefractor operated by a non-clinical, minimally-  
226 trained technician achieved a visual acuity that was only approximately one letter worse than using  
227 eyeglasses prescribed by an experienced refractionists. Moreover, though participants preferred  
228 subjective refraction prescriptions in aggregate, participants 40 years of age and younger had no  
229 statistically-significant difference in their preference. Given the minimal training required to use the  
230 autorefractor tested here and the marginal difference in prescription quality by the refractionist compared  
231 to the autorefractor, wavefront-based objective prescriptions may be a viable substitute for subjective  
232 refraction in low-resource settings.

### 233 **CONFLICT OF INTEREST DISCLOSURES**

234 NJD, SRD, DL, and EL are inventors on patents relating to the autorefractor used in this study and have a  
235 financial interest in PlenOptika, Inc. SRD and DL are employees of PlenOptika. NJD and EL are technical  
236 advisors and collaborators of PlenOptika.

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242

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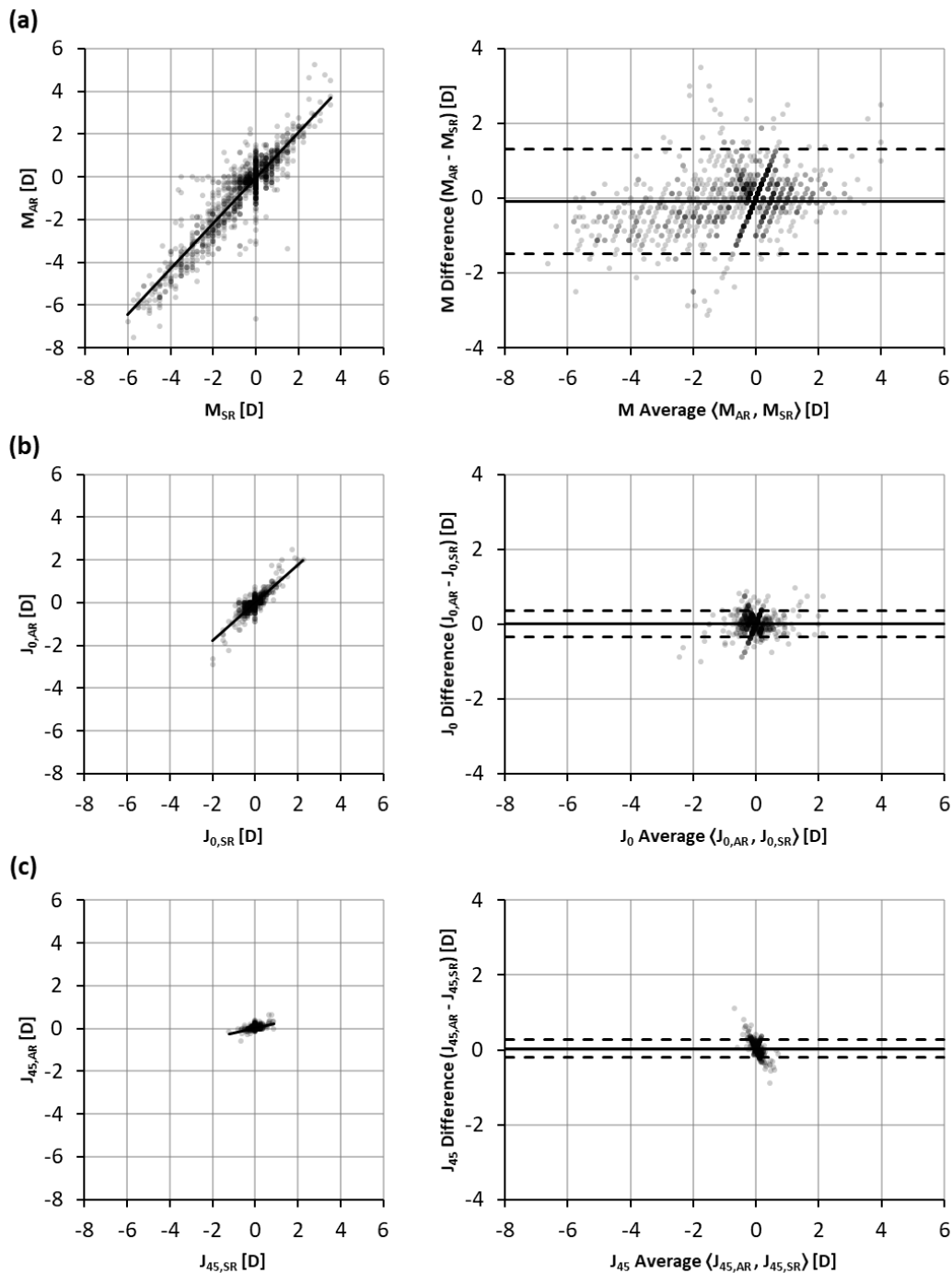
299 **TITLES AND LEGENDS TO FIGURES**

300 **Figure 1. Testing procedure for the wavefront autorefractor**



301  
302 Participants looked through the open-view wavefront autorefractor at a distant back-lit visual acuity chart,  
303 while three 10-second videos of wavefront images were recorded by the device. The autorefractor was  
304 flipped over to measure the opposite eye. After repeating three times, the system displayed the  
305 autorefractor eyeglass prescription.

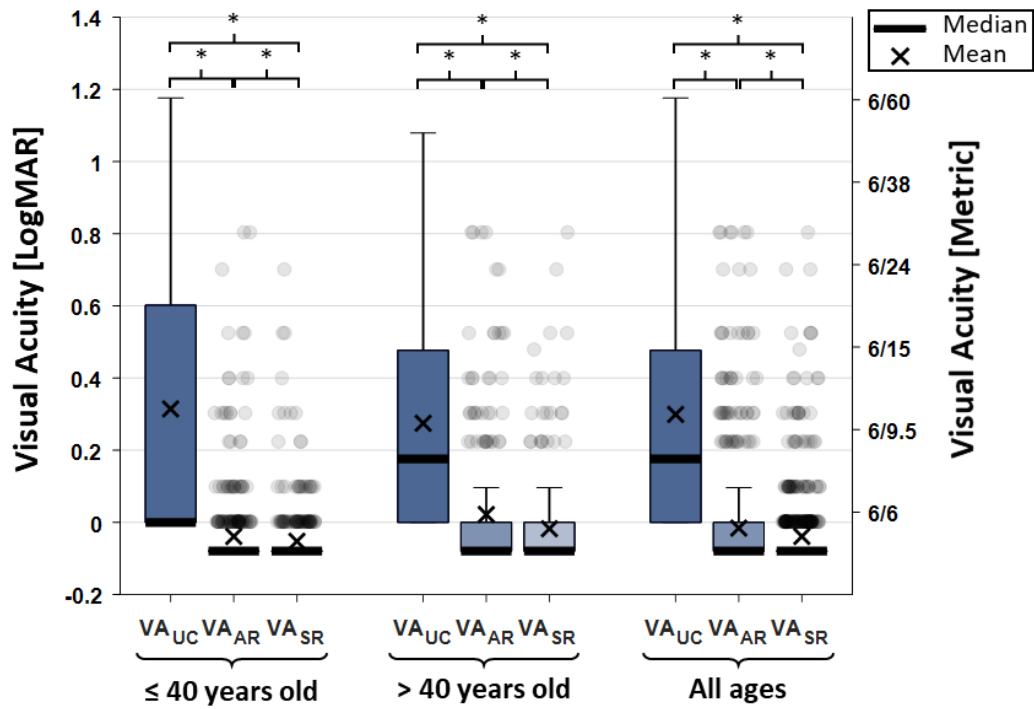
306 **Figure 2. Correlation and Bland Altman Plots of Power Vectors measured by Autorefractor versus**  
307 **Subjective Refraction**



308  
309 Correlation (Left) and Bland Altman (Right) plots comparing agreement of prescriptions measured by  
310 subjective refraction and the prototype autorefractor.

311

312 **Figure 3. Box Plot of Visual Acuity before and After Correction**



313

314 Visual acuity of right eyes without correction ( $VA_{UC}$ ), with trial lenses set to the autorefractor-determined  
315 prescription ( $VA_{AR}$ ), and with trial lenses set to the subjective refraction-determined prescription ( $VA_{SR}$ ).

316 There was a statistically-significant difference ( $P < 0.01$ ) between average visual acuity measurements

317 among all combinations within each age group.