



## **Preliminary clinical validation of a new picture-based visual acuity test in children with amblyopia: a comparison of The Auckland Optotypes and crowded logMAR letters**

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1 **Preliminary Clinical Validation Of A New Picture–Based Visual**  
2 **Acuity Test In Children With Amblyopia: A Comparison Of The**  
3 **Auckland Optotypes (Tao) And Crowded Logmar Letters**

4  
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20  
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22 **Author Contributions:** Emma McVeigh and Siobhán Ludden had full access to all the data in the study  
23 and take responsibility for the integrity of the data and the accuracy of the data analysis.

24 Concept and design: Ludden, Dahlmann-Noor.

25 Acquisition of data: Emma McVeigh (London), Siobhán Ludden, (London) Sahra Mohamed (Bedford)

26 Analysis/interpretation of data: All authors.

27 Drafting of the manuscript: McVeigh, Ludden (joint first authors).

28 Critical revision of the manuscript for important intellectual content: All authors.

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31 Administrative, technical, or material support: Mulholland, Dahlmann-Noor, Shah. Supervision:

32 Mulholland, Shah, Dahlmann-Noor.

33

34 **KEYWORDS:** Amblyopia, Visual Acuity, The Auckland Optotypes, COMPlog, ETDRS, Picture acuity

35 test

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43 **ABSTRACT**

44 **Background/aims**

45 Amblyopia is the most common visual deficit in children and accurate visual acuity (VA) assessment is  
46 essential for diagnosis. While ETDRS high-contrast logMAR VA is the reference standard test for adults,  
47 less agreement exists for pre-literate children. A new picture optotype acuity test (The Auckland  
48 Optotypes; TAO) has shown favourable comparison to letter acuity charts but has not yet been evaluated  
49 in children with amblyopia. This study aimed to compare visual acuity (VA) obtained using TAO to  
50 crowded logMAR letters in children age 5-8 years with amblyopia.

51

52 **Methods:**

53 Children with amblyopia (n=54 [20.37% strabismic, 18.52% anisometric, 61.11% mixed], mean age  
54  $78.30 \pm 11.72$  months) were recruited from paediatric ophthalmology/orthoptic clinics at Moorfields Eye  
55 Hospital NHS Foundation Trust, London, and Cambridge Community Services NHS Trust, Bedford.  
56 Best corrected VA was measured in both the amblyopic eye (AE) and fellow eye (FE) using TAO and a  
57 crowded letter acuity chart. Bland-Altman analysis was used to measure 95% Limits of agreement (LoA)  
58 for VA measures captured (AE, FE and interocular difference [IOD]).

59

60 **Results:**

61 Good agreement between TAO and letter VA measurement was observed (mean bias: AE -0.01, FE 0.01,  
62 IOD -0.02). For AE measures 95% LoA were from -0.25 to 0.24 logMAR, this being similar for FE (-  
63 0.24 to 0.25) and IOD measures (-0.30 to 0.27).

64

65 **Conclusion:**

66 TAO and letters elicited similar VA in children with amblyopia. TAO could be a useful picture-based  
67 chart for paediatric vision assessment.

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71 **INTRODUCTION**

72 Accurate measurement of visual acuity (VA) is central to the detection of amblyopia, the most common  
73 vision deficit in childhood, and the monitoring of treatment efficacy. Measuring VA in children is  
74 difficult and requires age-appropriate tests and experienced clinicians. The Early Treatment Diabetic  
75 Retinopathy Study (ETDRS) chart is the reference standard VA test for adults however, it is not suitable  
76 for pre-literate children. Picture-based vision charts have been designed to address this; however, these  
77 often have their own limitations, for example, overestimation of VA compared to letter optotypes (1-4).  
78 In the UK, in pre-literate children the Kay Picture test (1) is widely used. Clinical validation has shown  
79 that it overestimates visual acuity by 0.10-0.20 logMAR, compared to crowded letter tests (2, 3). In  
80 children with amblyopia, Kay Picture values have been found to differ from ETDRS measurements by  
81 around 0.20 logMAR. There has also been a suggestion of proportional bias, with increasing VA  
82 overestimate with worsening levels of VA (4). The Kay Pictures subsequently have been redesigned to  
83 address some of these issues but with limited validation (5).

84 Recently, a new picture optotype test, The Auckland Optotypes (TAO) has been developed (6). TAO are  
85 an open access set of psychometrically robust, picture optotypes. It consists of 10 optotypes which have  
86 a consistent stroke width, 1:1 aspect ratio and are fully enclosed with limited acute angles (figure 1).  
87 Existing evidence suggests that VA obtained with TAO is comparable to that obtained with ETDRS in  
88 adults. Similarly, strong agreement has been found between TAO and Sloan letters as well as Lea  
89 symbols in visually normal children (6-8). Such agreement is promising and suggests that TAO could  
90 enhance the accuracy of VA assessment in pre-literate children and potentially fulfil the criteria for a  
91 picture optotype test suitable for use in clinical trials. However, before TAO could be advocated for  
92 clinical or research use, validation in children with visual difficulties and in particular amblyopia is  
93 required.

94

95 The aim of this study was to examine the agreement of VA measurements obtained using TAO to that of  
96 the reference standard VA test for children with amblyopia –crowded logMAR letters (HOTV/Keeler  
97 Crowded logMAR).

98

99 **METHODS**

100 **Participants**

101 Fifty-four children aged 5-8 years (mean  $\pm$ SD, 78.30  $\pm$ 11.72 months) with unilateral amblyopia were  
102 recruited to this study between the 13<sup>th</sup> June 2019 – 27<sup>th</sup> February 2020. Amblyopia was defined as an  
103 interocular difference  $\geq$ 0.20 logMAR, with fellow eye acuity of 0.20 logMAR or better. Children with a  
104 history of intraocular surgery, current ocular surface inflammation, glaucoma, cataract or developmental  
105 delay were excluded. Due to screen size limitations, participants with VA  $>$ 1.40 logMAR were excluded.  
106 Ethical approval was obtained from the Research Ethics Committee London – Surrey (19/LO/0519).  
107 All procedures adhered to the tenets of the Declaration of Helsinki. Informed parental consent was  
108 obtained prior to study procedures and children also provided written assent where appropriate.

109

110 **Psychophysical procedure**

111 Study procedures were undertaken at Moorfields Eye Hospital NHS Foundation Trust, City Road,  
112 London (site 1) and Cambridgeshire Community NHS Trust, Bedford (site 2). At both sites, a consistent  
113 clinical testing room, was used for test presentation i.e., both optotype acuity tests were presented under  
114 the same room illumination and the test chart brightness was  $>$ 80 cd/m<sup>2</sup> for all measures. Testing order  
115 of acuity tests was randomised using simple block randomisation.

116 At site 1, both TAO and letter (HOTV) tests were presented on a 19” GNR TS902 LCD monitor (pixel  
117 resolution 1280x1024, refresh rate 60Hz) via the COMProg computerised system calibrated for a 3.5m  
118 viewing distance. The COMProg testing algorithm employs an initial range finding phase whereby a  
119 single crowded optotype is presented in 0.20 logMAR steps until a single reversal is obtained. Threshold  
120 VA was then measured by presenting a single line of five optotypes, separated by half an optotype width  
121 and surrounded by an overall crowding box, decreasing in 0.10 logMAR intervals. If all five optotypes  
122 could not be simultaneously presented due to limitations in screen size, the lines were broken into smaller  
123 numbers of optotypes such that a cumulative total of five optotypes were presented for each line size.  
124 This was the case for both TAO and letter tests. The simultaneous presentation of five optotypes per line

125 could occur from 0.80 logMAR. Testing was terminated once all optotypes at a given VA level (i.e., a  
126 whole line) were incorrectly identified.

127 At site 2, TAO and letters were presented as hand-held tests at 3m distance. TAO was presented on a  
128 hand-held Microsoft Surface Go 10-inch tablet (screen resolution: 1800 x 1200, refresh rate: 60 Hz) via  
129 COMProg, as above. Letter acuity was assessed using hand-held Keeler Crowded Acuity Cards in a  
130 similar two-stage process. Initially participants were asked to identify either the second or third letter on a  
131 line, decreasing in 0.20 logMAR steps until one letter was incorrectly identified. Threshold VA testing  
132 then began from the last correct response, decreasing in 0.10 logMAR intervals. Testing was terminated  
133 once all optotypes on the line were incorrectly identified.

134

135 Data collection was undertaken by experienced orthoptists/paediatric optometrist. An opaque occluder  
136 was used for uniocular testing; the amblyopic eye was always tested first. Participants were instructed to  
137 name the optotypes aloud; a matching card was permitted if required. A forced-choice procedure was  
138 employed in all cases to minimize the effect of observer criterion, i.e., if children were unsure of the  
139 optotype presented at threshold they were encouraged to attempt/guess before termination. Optotype  
140 presentation duration was unlimited and, in all cases, single optotype scoring was applied. VA was  
141 recorded in standard logMAR notation. A scaling factor (-0.216 logMAR) was applied to TAO measures  
142 to account for a different bounding box to stroke width ratio compared with Sloan letters (SC Dakin,  
143 personal communication, 2019). The stroke width / total optotype ratio for TAO is 1:8.23, compared to  
144 1:5 for Snellen, 1:7 for Lea Symbols and 1:10 for Kay pictures. Therefore; such a scaling factor is  
145 required to achieve equivalence between different optotype sets (6).

146

## 147 **Data Analysis**

148 Analysis was conducted using MATLAB 2020a (The MathWorks Inc., USA). Bland-Altman Limits of  
149 Agreement (LoA) analysis was used to measure agreement between the VA tests. The upper and lower  
150 95% LoA and associated 95% confidence intervals were calculated. Proportional bias was evaluated using  
151 Pearson's correlation and ordinary least squares linear regression analysis. VA measures in the amblyopic

152 eye (AE) and fellow eye (FE), in addition to interocular difference (IOD) were evaluated separately.  
153 Equality plots were also constructed for AE, FE and IOD comparisons between charts, with paired  
154 samples t-tests being undertaken to determine if there were statistically significant differences in these  
155 measures with each chart form. A three-way ANOVA with the fixed effects of chart type and testing site,  
156 together with the random effect of amblyopia severity was performed to examine what experimental  
157 factors may influence the IOD measures captured in this study. For the purposes of this analysis  
158 amblyopia severity was determined by logMAR letter acuity in the amblyopic eye. AE acuity  $<0.6$  was  
159 considered moderate amblyopia and  $\geq 0.6$  severe amblyopia (9, 10). An  $\alpha$  of 0.05 was considered  
160 statistically significant with holm-Bonferroni correction being applied to p-values where necessary.

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175 **RESULTS**

176 All participants successfully completed both TAO and logMAR letter VA tests. Participant characteristics  
177 are detailed in Table 1.

178 Bland-Altman analysis indicated good agreement between TAO and crowded logMAR letters (Figure 2 a-  
179 c). LoA for FE measurements were  $\pm 0.25$  logMAR, with similar values for AE ( $\pm 0.24$  logMAR) and  
180 IOD ( $\pm 0.32$  logMAR). A paired t-test (with Holm-Bonferroni correction) also revealed there to be no  
181 statistically significant differences in either FE (P=0.49), AE (P=0.79) and IOD (P=0.45) measurements  
182 with either test examined. No statistically significant proportional bias between chart forms was observed  
183 for AE ( $r^2=0.04$ ,  $p=0.16$ ) and FE measures ( $r^2=0.06$ ,  $p=0.07$ ), but was evident for FE measures ( $r^2=0.08$ ,  
184  $p=0.04$ , fig. 2c) whereby IOD measures appeared to be underestimated by TAO relative to letter acuity  
185 measures when amblyopia was more dense. A similar trend may be observed from the equality plot  
186 examining the relationship between IOD measures with TAO and logMAR letter acuity (fig. 2e). Further  
187 examination also revealed there to be statistically significant interaction effects between study site and  
188 amblyopia grade ( $F_{(1,107)}=8$ ,  $P=0.005$ ) on IOD values. No other interaction effects were observed. Post-  
189 hoc analysis (fig. 3) revealed there be markedly lower IOD values in participants at site 2 compared to site  
190 1 ( $P<0.001$ , fig. 3c), this reflecting the fact relatively fewer patients with severe amblyopia were recruited at  
191 this site compared to site 1 (Table 1).

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199 **DISCUSSION**

200 Good agreement was established between TAO and letter VA (Figure 2 a-c), indicating that TAO appears  
201 to be an equivalent measure to letter VA in children with amblyopia. The 95% LoA established in this  
202 study in the AE ( $\pm 0.24$  logMAR) and FE ( $\pm 0.25$  logMAR) were similar to, albeit slightly wider than,  
203 previously reported comparisons between TAO and logMAR letters in visually normal children ( $\pm 0.20$   
204 logMAR) (7, 8). The LoA observed in this study are also in line with those for well-established and  
205 widely used picture acuity charts. For example, in a paediatric population the agreement between Lea  
206 Symbols and ETDRS has been shown to be in the region of 0.30 to -0.20 logMAR (11). While LoA  
207 between Kay Pictures and Keeler crowded logMAR charts, both of which have fewer optotype  
208 alternatives than TAO, has been reported as (0.225 to -0.030 logMAR) (3, 11, 12). However, TAO does  
209 appear advantageous as the mean bias observed in this analysis is lower than that reported for other  
210 picture acuity charts indicating closer agreement with VA measures with the reference standard ETDRS  
211 chart (3, 11, 12).

212

213 While there was no overall influence of study site on observed trends for IOD measures with each chart  
214 form (fig. 3a), site 1 did exhibit higher overall IOD values in children with severe amblyopia (AE  $\geq 0.6$   
215 logMAR, fig. 3c). We hypothesise that this observed difference in overall IOD (across both chart forms)  
216 is a result of differences in the cohorts recruited at each study site, rather than any systematic differences  
217 between tests, investigators or study procedures at each site. Indeed, it may be seen from fig. 3c that a  
218 greater number of patients with dense amblyopia (as defined using logMAR letter VA) were recruited and  
219 tested at site 1 compared to site 2.

220

221 While we observed good agreement between TAO and letter VA, TAO appeared to underestimate IOD  
222 relative to letters in severe amblyopia ( $\geq 0.6$  crowded letter logMAR, figures 2a, 3b). This underestimation  
223 is somewhat surprising as the agreement between amblyopic and fellow eye acuity using TAO compared  
224 to letter optotypes was a good level and similar LoA were found for either eye. We propose that this  
225 underestimation of IOD in severe amblyopia is a result of differences in TAO design compared to letters.

226 For example, TAO, consisting of 10 optotypes, contains more possible alternatives than the letters used  
227 in paediatric letter charts considered in this study. It has been demonstrated that the number of  
228 alternatives in a forced choice (AFC) test is inversely related to VA threshold measures (13, 14); the letter  
229 tests used in this study being truncated (COMPlog: 4-AFC, Keeler: 6-AFC) relative to TAO (10-AFC)  
230 which could contribute to lower IOD in severe amblyopia as there is increased probability of an incorrect  
231 “guess” at threshold with TAO. TAO optotypes also lack acute angles which could potentially increase  
232 their difficulty relative to letters at threshold (15, 16). Further examination of the equality plot comparing  
233 TAO and letter VA for the FE in the cohort examined (fig. 2e) would suggest that such issues appear to  
234 bias measures primarily at the higher VA range (better than 0.20 logMAR). It is also possible that this  
235 trend could also be attributed to the small participant sample within this VA range (n=14) or increased  
236 measurement variability in severe amblyopia. As this was an unexpected finding in this sample, further  
237 work with an appropriate sample size would be beneficial to specifically determine if IOD varies with  
238 amblyopia severity when examined with TAO and conventional tests. Further work incorporating inter  
239 and intra-test variability would also be useful to evaluate the precision of cross-sectional and longitudinal  
240 VA measures with TAO in amblyopia.

241

242 No proportional bias was observed with AE measures, this being evident in both the Bland-Altman (fig.  
243 2a) and equality plots (fig.2d). This is particularly relevant in amblyopia as poorer AE VA triggers  
244 increased patching doses; thus, any VA overestimation could result in insufficient treatment for the  
245 severity of the condition. Therefore, TAO could be advantageous in the accurate estimate of AE acuity  
246 in pre-literate children.

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252 **CONCLUSIONS**

253 This study describes the first comparison of TAO to logMAR letters in children with amblyopia. Good  
254 agreement was found between the tests, using a clinical testing protocol, suggesting that TAO could be  
255 appropriate for clinical VA measures in children with amblyopia. We recognise that this is a preliminary  
256 study and a larger sample size would be advantageous to expand on these findings. Further investigation  
257 of TAO VA measures in younger children and in severe amblyopia would be advantageous.

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260 **COMMERCIAL DISCLOSURES:**

261 **Mulholland PJ** - Heidelberg Engineering & LKC Inc. (Research support)

262 **Shah N** - The Moorfields Acuity Chart (Co-inventor)

263 - COMplog Clinical Vision Measurement Systems Ltd (Research support)

264

265 **Dahlmann-Noor A** – Santen Inc (Medical Advisor)

266

267 **AUTHOR CONTRIBUTION STATEMENT:**

268 SL was responsible for the initial study design and concept, protocol development, BIPOSA funding  
269 application, ethics application, recruitment of participants and drafting the final manuscript.

270 EMcV was responsible for the College of Optometrists funding application, assisting with ethics  
271 application, recruitment of participants and drafting the final manuscript.

272 NS was responsible for assisting in the College of Optometrists funding application and editing the final  
273 manuscript.

274 PJM was responsible for assisting in the College of Optometrists funding application and editing the final  
275 manuscript.

276 SM was responsible for the recruitment of participants at site 2.

277 ADN was responsible for the initial design and concept of the study, NIHR Biomedical Research Centre  
278 grant application, ethics application, overseeing the study and editing the final manuscript.

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283 Research Centre based at Moorfields Eye Hospital NHS Foundation Trust and UCL Institute of  
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<b>Gender – n</b>	
Male	28
Female	26
<b>Age (months) – Mean <math>\pm</math>SD</b>	<b>78.30 <math>\pm</math>11.72</b>
<b>Ethnicity – n</b>	
White	30
Asian/British Asian	10
Black/Black British	7
Mixed	4
Other	3
<b>Type of Amblyopia – n (%)</b>	
Strabismic	11 (20.37%)
Anisometropic	10 (18.52%)
Mixed	33 (61.11%)
<b>Refractive Error SE – Median (IQR)</b>	
<b>Amblyopic Eye</b>	<b>4.32 (-0.19 to +6.75)</b>
<b>Fellow Eye</b>	<b>1.88 (+0.19 to +4.35)</b>

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345 **Table 1:** Participant Characteristics. Where data is normally distributed mean  $\pm$  standard deviation (SD) is  
 346 reported. Where data was not normally distributed median (interquartile range) is reported.

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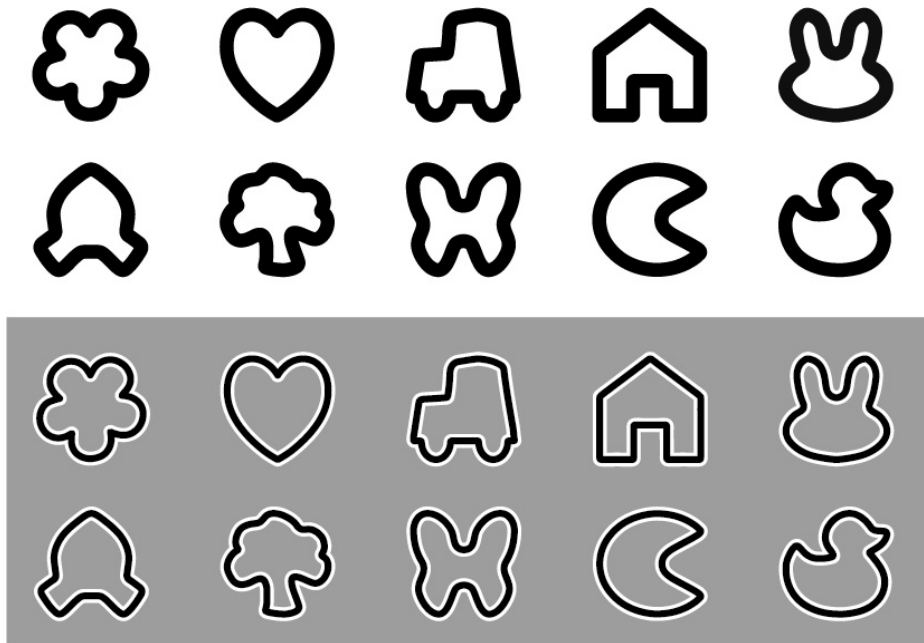
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353 **FIGURES:**

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**Figure 1.** An illustration of The Auckland Optotypes in both regular and vanishing forms.

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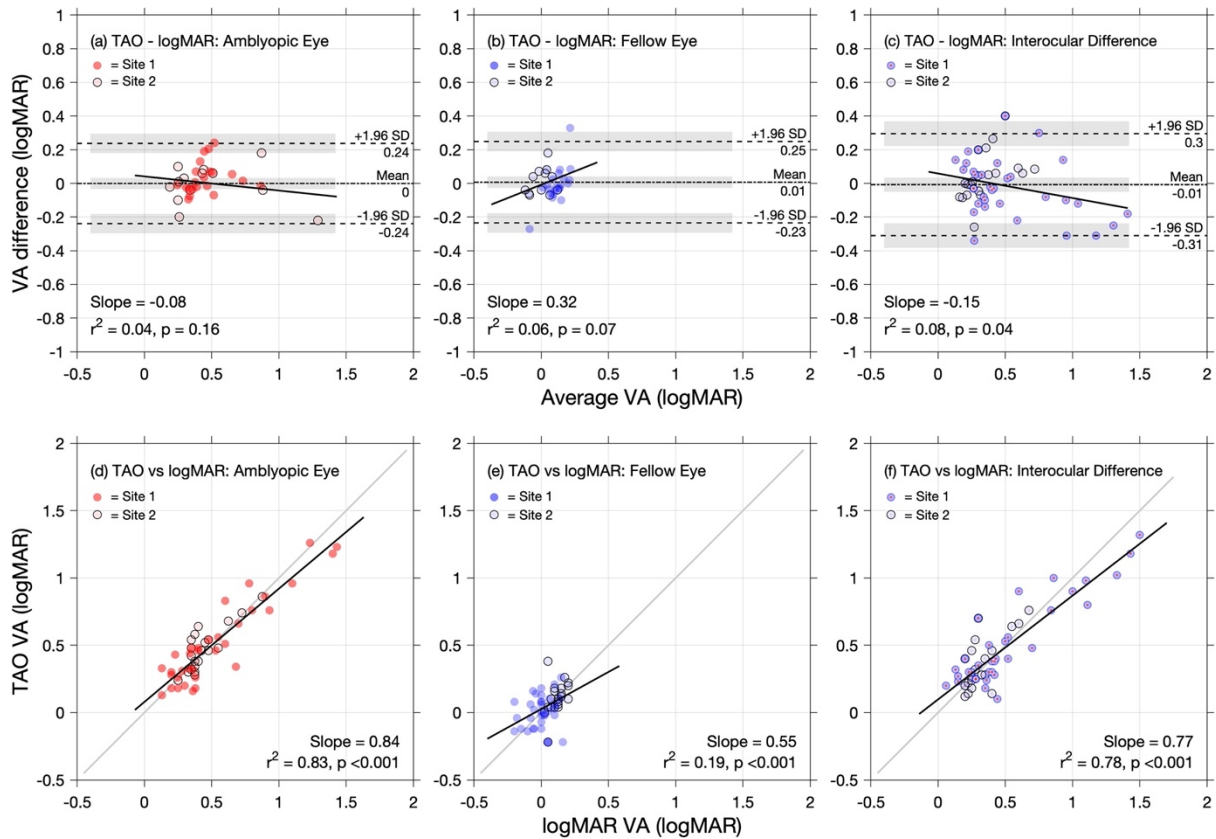
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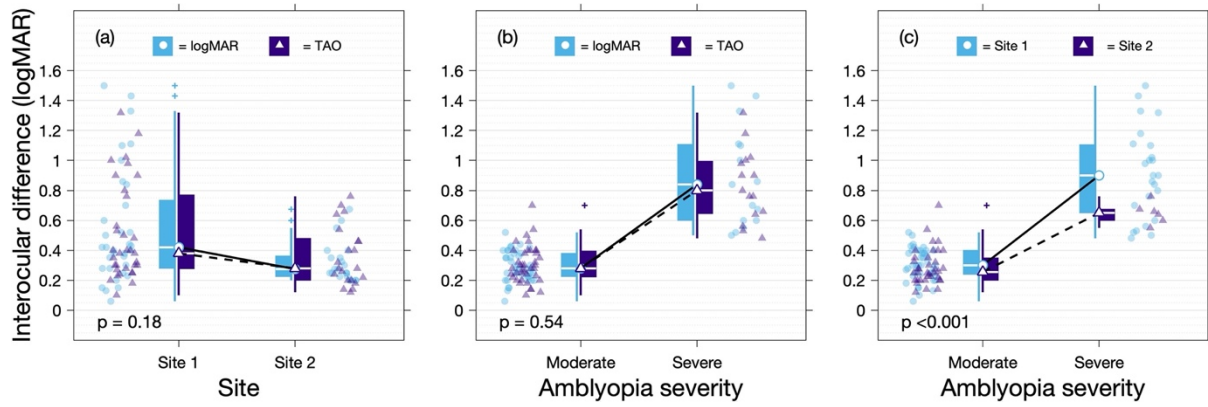
**Figure 2.** (a-c) Bland-Altman LoA plots indicate good agreement between TAO and crowded logMAR letters for the amblyopic eye (a), fellow eye (b) and interocular difference measures (c). 95% confidence intervals surrounding the 95% LOA are represented by grey shading with different plot markers for each test site. (d-f) Equality plots comparing TAO and logMAR. Ordinary least-squares linear regression line is included (black) along with an equality line (grey).

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**Figure 3.** Interaction plots examining the effect of (a) experimental site and chart form, (b) logMAR letter VA level in the amblyopic eye (amblyopia severity) and chart form, and (c) logMAR letter VA level in the amblyopic eye (amblyopia severity) with test site on IOD values.