# 1 Use of a binocular optical coherence tomography system to

# 2 evaluate strabismus in primary position

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## 26 Running Head:

27 Automated, quantitative assessment of strabismus using binocular OCT

## 28 Keywords:

- 29 Binocular
- 30 Optical coherence tomography
- 31 Automated
- 32 Diagnostics
- 33 Strabismus

## 34 **Abbreviations**:

- 35 APCT Alternating Prism Cover Test
- 36 OCT Optical Coherence Tomography
- 37 LoA Limits of Agreement
- 38
- 39 Figures:
- 40 2
- 41
- 42 **Tables:**
- 43 1

# 44 Key Points

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46	Question: Can a new form of optical coherence tomography (OCT) known as
47	'binocular OCT' be used to measure the size of strabismus?
48	Findings: This study included 15 participants with strabismus and 15 healthy
49	individuals. Binocular OCT imaging correctly revealed the type and direction of the deviation
50	in all participants, including both horizontal and vertical deviations. The size of strabismus
51	measured with binocular OCT had fair agreement with the alternating prism cover test.
52	Meaning: Binocular anterior segment OCT imaging can provide clinicians with a
53	precise measurement of strabismus, which may be useful for diagnosis and monitoring.

#### 54 Abstract

55 56 **Importance:** Current clinical methods for assessing strabismus can be prone to 57 error. Binocular OCT has the potential to assess and quantify strabismus objectively and in 58 an automated manner. 59 **Objective:** To evaluate the use of a binocular optical coherence tomography (OCT) 60 prototype to assess the presence and size of strabismus. 61 Design, Setting, and Participants: Fifteen participants with strabismus recruited 62 from Moorfields Eye Hospital NHS Foundation Trust, London, UK, and fifteen healthy 63 volunteers underwent automated anterior segment imaging using the binocular OCT 64 prototype. All participants had an orthoptic assessment including alternating prism cover test 65 (APCT) prior to imaging. Simultaneously acquired pairs of OCT images, captured with one 66 eye fixating, were analysed using ImageJ to assess the presence and angle of strabismus. 67 Main Outcomes and Measures: The direction and size of strabismus measured 68 using binocular OCT was compared to that found using APCT. 69 **Results:** The median age for participants with strabismus was 55 years (interguartile 70 range 33-66.5 years), and 50 years (interquartile range 41-59 years) for healthy group. The 71 median magnitude of horizontal deviation was  $20\Delta$  (interquartile range  $13-35\Delta$ ), and  $3\Delta$  for 72 vertical deviation (interguartile range  $0-5\Delta$ ). Binocular OCT imaging correctly revealed the 73 type and direction of the deviation in all 15 strabismus participants, including both horizontal 74 and vertical deviations. APCT and OCT measurements were strongly correlated for both 75 horizontal (Pearson's r = 0.85, 95% confidence interval (CI) 0.60-0.95; P < 0.001) and 76 vertical (r = 0.89, CI 0.69-0.96; P < 0.001) deviations. In the healthy cohort, 9 participants 77 had a latent horizontal deviation on APCT (median magnitude  $2\Delta$ , range 2-4 $\Delta$ ). Six were 78 orthophoric. Horizontal deviations were observed on OCT imaging in 12 of the 15 79 participants, and a vertical deviation was visible in 1 participant.

80 Conclusions and Relevance: These findings suggest that binocular anterior
81 segment OCT imaging can provide clinicians with a precise measurement of strabismus.
82 The prototype can potentially incorporate several binocular vision tests that will provide
83 quantitative data for the assessment, diagnosis, and monitoring of ocular misalignments.

### 84 Introduction

85

Strabismus is a common condition that can affect both children and adults.<sup>1, 2</sup> Clinical 86 87 assessments designed to measure ocular misalignment often require specialist orthoptic 88 expertise and good patient cooperation. An alternating prism cover test (APCT) is most 89 commonly used, however, the endpoint of such testing can be subtle or variable, and is prone to inter- and intra-observer error, particularly in less cooperative children.<sup>3, 4</sup> Electronic 90 91 instruments that use infrared light to track eye position of both eyes simultaneously such as video goggles<sup>5</sup> and gaze trackers<sup>6</sup> have been developed to increase the precision of 92 93 measurement but are mainly used for research purposes. 94 Optical coherence tomography (OCT) devices are becoming ubiquitous to eye clinics 95 as they provide objective and quantitative data about ocular structures to aid the diagnosis 96 and monitoring of eye disease. In this report we demonstrate an application of a prototype 97 binocular optical coherence tomography system (Envision Diagnostics, El Segundo, CA) that 98 acquires anterior segment images of both eyes simultaneously, even with one eye fixating, 99 and in an automated manner. By analyzing simultaneously acquired pairs of anterior 100 segment images, the presence of strabismus can be identified. We evaluate the use of 101 anterior segment OCT as a method of assessing strabismus and measuring the angle of

102 deviation.

### 103 Methods

104

105 Participants with strabismus were prospectively recruited from clinics at Moorfields Eye 106 Hospital NHS Foundation Trust, London, UK, as part of the EASE study (ClinicalTrials.gov 107 Identifier: NCT02822612). Healthy volunteers were recruited from staff members at the 108 hospital. Written informed consent was obtained from all participants in the study. All 109 participants were required to have no significant hearing impairment that would affect their 110 ability to respond to instructions delivered by the device. A conversational level of English 111 was required for users to understand the instructions, and to be able to communicate with 112 the device via an English language voice recognition system. No participants were excluded 113 based on disease status to ensure our cohort consisted of everyday users of eye care 114 services. All underwent orthoptic assessment prior to binocular OCT examination, including 115 visual acuity measurement and APCT at distance in primary position, with habitual refractive 116 error correction if appropriate. Approval for data collection and analysis was obtained from a 117 UK National Health Service Research Ethics Committee (London-Central). The study 118 adhered to the tenets of the Declaration of Helsinki.

119

#### 120 **Binocular OCT examination**

All participants underwent binocular OCT examination as described elsewhere.<sup>7</sup> Briefly, this is an automated prototype device that acquires OCT images of the anterior and posterior segments of both eyes simultaneously using a tunable swept-source laser without requiring an operator. The device uses a Maxwellian view system to simulate distance fixation. The fixation target was presented to the non-deviating eye in the strabismus group, selected manually prior to examination. Therefore, the primary deviation was measured on OCT. For healthy participants, the target was presented to the dominant eye (right eye in all participants). The spherical equivalent of the user's habitual refractive error is correctedwithin the device.

130

#### 131 Measurement of angle

132 A volume comprising 128 B-scans of the anterior segment was acquired by the device in the 133 horizontal and vertical planes. Only a single central anterior segment image was used for 134 each plane for analyses. The central image can be deduced by the visualization of the 135 corneal vertex reflection in the fixing eye.<sup>8</sup> This hyperreflective line was used as a surrogate 136 for the visual axis. The image captured at the same time point was used for the fellow non-137 fixing eye. The images were adjusted to 16.5x14.9 aspect ratio as they are acquired at 138 16.5mm width and 14.9mm depth. ImageJ, a widely use open-source Java image analysis 139 program was used to measure the difference in angle in degrees between the fixing and 140 non-fixing eye. A line was drawn between the pupil margins at the posterior epithelium of the 141 iris for both eyes. These landmarks were chosen as they were visible in both horizontal and 142 vertical scans. The angle between the lines was calculated as the angle of deviation (Figure 143 1).

144

#### 145 **Outcome measures**

1461. The direction of the deviation was determined by the direction of the fellow eye with147respect to the fixating eye in both horizontal and vertical scans. This was compared

148 to the direction of the misalignment found using APCT for distance fixation.

149 2. The size of the misalignment was compared to that found using distance APCT.

150 Values in prism diopters ( $\Delta$ ) were converted to degrees using the following formula:<sup>9</sup>

151 degrees =  $tan^{-1}(\Delta/100) \times 180/π$ 

#### 152 **Results**

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154 Twelve participants had concomitant strabismus, one of which had glaucoma and 155 strabismus. One participant had a decompensated strabismus as a consequence of loss of 156 vision after a retinal detachment. Two participants had an acquired restrictive incomitant 157 strabismus related to sphenoid wing meningioma, and thyroid eye disease. These are 158 described further in Table 1. The median age was 55 years (interguartile range 33-66.5 159 years). Thirteen subjects were Caucasian, and two subjects were Asian. Seven of the 15 160 subjects were female. The median magnitude of horizontal deviation was 20<sup>(</sup> (interguartile 161 range 13-35 $\Delta$ ), and 3 $\Delta$  for vertical deviation (interquartile range 0-5 $\Delta$ ). Mean spherical 162 equivalent was  $+0.53D \pm 2.19$  (range sphere -2.50 to +5.50DS, range cylinder 0 to -3.50DC). 163 The cohort of healthy participants had no manifest deviation. Nine healthy participants had a 164 latent deviation for distance, and 6 were orthophoric. The median age of this group was 50 165 years (interquartile range 41-59 years). Twelve healthy participants were Caucasian, two 166 were Asian, and one subject was Black. Eight of the healthy participants were female. Mean 167 spherical equivalent for this cohort was -0.51D ±1.45 (range sphere -3.50 to +2.75DS, range 168 cylinder 0 to -2.50DC). All participants understood the examination and were cooperative, as 169 discussed further in a usability study of the device.<sup>7</sup>

170

#### 171 Direction and size of misalignment

Orthoptic assessment revealed five participants in the strabismus group had a horizontal
deviation only, one participant had a vertical deviation only, and nine participants had both
horizontal and vertical deviations. A torsional element was not detected in any participants.
Binocular OCT imaging correctly identified the direction of misalignment in all 15 strabismus
participants, including both horizontal and vertical deviations. Three out of the five

participants assessed as having a horizontal deviation only using APCT were also found to
have an additional vertical deviation on binocular OCT imaging (Table 1).

179 There was a strong correlation between the measurement of strabismus using APCT 180 and the measurement calculated from the OCT images for both horizontal (Pearson's 181 r=0.85, 95% confidence interval (CI) 0.60-0.95; P<0.001) and vertical (r=0.89, CI 0.69-0.96; 182 P<0.001) deviations. The confidence intervals indicate a strong relationship between the two methods. Bland-Altman<sup>10</sup> plots show heteroscedasticity where the agreement between the 183 184 methods decreases as the size of the deviation increases. There was a mean difference of - $0.30^{\circ}$  (~ -0.52 $\Delta$ ) for horizontal misalignment and -2.20° (~ -3.84 $\Delta$ ) for vertical misalignment. 185 186 The 95% limits of agreement (LoA) for horizontal misalignment were between 9.55° (~ 16.82 $\Delta$ ) and -10.16° (~ -17.55 $\Delta$ ). For vertical misalignment the limits of agreement were 187 188 narrower between 2.66° (~ 4.65 $\Delta$ ) and -7.06° (~ -12.38 $\Delta$ ). Regression on the Bland-Altman 189 plots show no significant proportional bias for horizontal misalignments (P=0.957), however 190 show a significant relationship for vertical misalignments (P=0.007).

191 In the healthy cohort, 8 had an exophoria (median magnitude  $2\Delta$ , range  $2-4\Delta$  (1.15-192 2.29°), one participant had an esophoria measuring  $2\Delta$ , and 6 participants were orthophoric, 193 measured using distance APCT. One participant had a vertical deviation on near APCT. No 194 other participants in this group had a vertical or torsional component at distance or near. In 195 the 8 exophoric participants, 6 had a misalignment corresponding to an exo-deviation on 196 OCT (median magnitude 5.25° (~ 9.19 $\Delta$ ), interquartile range, 2.63-6.49° (~ 4.59-11.38 $\Delta$ ), 197 one had an eso-deviation on OCT measuring  $8.61^{\circ}$  (~  $15\Delta$ ), and one participant had no 198 deviation on OCT. From the 6 orthophoric participants, 3 had an exo-deviation on OCT 199 (range 2.93-6.38°) and 1 had an eso-deviation (4.09°). The single participant with an 200 esophoria did not have any measured deviation on the binocular OCT. Two participants 201 measured as orthophoric on APCT was also orthophoric on binocular OCT. A vertical 202 component corresponding to a left hyper-deviation was identified in 1 healthy participant on 203 OCT measuring  $2.26^{\circ}$  (~  $3.95\Delta$ ). This participant did not have a vertical latent deviation on 204 distance APCT, but did have a left hyperphoria measuring 5∆ on near APCT. A weak

205 correlation was observed between APCT and OCT measurements for horizontal deviation in

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206 this group (Pearson's r=0.06, P=0.830, CI 0.14-0.85).
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### 208 **Discussion**

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210 In this paper we explore OCT-derived quantification and assessment of strabismus angle

211 using a novel prototype binocular OCT system.

212 The device was able to correctly identify the direction of the deviation in the 213 strabismus group, including both horizontal and vertical elements. The device also indicated 214 a vertical deviation ( $<4\Delta$ ) in three participants who were recorded as vertically orthophoric. 215 Small deviations ( $<2\Delta$ ), particularly vertical deviations, may not be reliably perceived by the unaided eye on cover testing<sup>11, 12</sup> but may be visible on the OCT. The binocular OCT 216 217 identified a horizontal deviation in 12 participants of the healthy cohort. In 9 of these 218 participants, the direction of the deviation on OCT was the same as the latent deviation 219 found on APCT. This suggests that the binocular OCT is measuring both manifest and latent 220 components.

221 In horizontal misalignment, the agreement between the methods tended to decrease 222 as the size of the deviation increased. A similar heteroscedastic pattern was found for 223 vertical misalignments however our sample was skewed towards smaller deviations. The LoA were larger than the inter-examiner variability found by de Jongh et al.<sup>13</sup> for horizontal 224 225 deviations (10 $\Delta$ ). This would suggest that our method is not in strong agreement with APCT. 226 However, a larger sample is required to confirm inferences from Bland-Altman plots. 227 Differences between the methods may be partly attributable to the limited scale of prism 228 diopters - as the deviation becomes larger, the difference in degrees between each prism 229 diopter also increases. In addition, increments between diopters in prism bars increase as 230 the power increases. For example, between  $1-10\Delta$ , prism power increases in increments of 231 1 diopter, whereas between 20-50 $\Delta$ , power increases by 5 $\Delta$  increments, forcing the 232 orthoptist to choose the closest prism that neutralises the misalignment. Whereas, the 233 binocular OCT is able to measure strabismus angle more precisely using a scale of degrees 234 instead of diopters. A longitudinal and repeatability study is required to validate this method

and to investigate whether OCT-derived measurements are valuable for monitoring thechange in size of misalignment over time.

237 There are several limitations of the device at present, however it is likely that these 238 can be overcome in future iterations. A significant limitation of the device includes the 239 inability to ascertain whether a heterophoria or heterotropia is present. We observed 240 deviations in both the healthy and strabismus cohorts. It is likely that the device is reliably 241 identifying manifest vertical and horizontal components in the strabismus group. However, if 242 the device was used as a screening device for manifest strabismus, it may have a high false 243 positive rate particularly for horizontal deviations as observed in the healthy cohort. The 244 unique features of the binocular OCT could potentially be extended to perform a cover test 245 by switching the fixation between the eyes to differentiate between these entities. In the 246 present study, all strabismus participants had a constant deviation. Those with intermittent 247 deviations may not be identified using the current prototype setup. Real-time video OCT with 248 3D-rendering would also aid measurement of torsional deviations. By bringing the fixation 249 target closer to the eyes, the device has the capacity to simulate near fixation to measure 250 deviation at various distances. In addition, the current prototype setup performs ocular motility testing by displaying the fixation target at different locations of the screen.<sup>7</sup> 251 252 Strabismus with varying gaze or motion, in addition to alternating fixation, may help discern 253 between primary and secondary deviations in incomitant strabismus.

254 The prototype currently corrects a mean spherical equivalent of the user's habitual 255 correction to aid visualization of the fixation target. Refractive error can affect the size of the 256 deviation, and the inability to correct cylindrical error may contribute to the differences 257 observed between the methods. Additionally, although the device simulates distance 258 fixation, proximal convergence may attribute to differences between APCT and OCT 259 measurements. In one exophoric participant, a significant eso-deviation was found on OCT. 260 Monocular viewing conditions has been shown to cause accommodative convergence which may affect these results.<sup>14</sup> In subsequent devices with binocular viewing conditions this may 261 262 be reduced. Some users of the device may naturally fixate closer than distance fixation, and

this could explain the larger exo-deviations found on OCT compared to APCT in the healthy
cohort. This may also explain the vertical component found in the one healthy participant
who had a vertical deviation at near.

266 Our method of using the pupil margin as a reference plane for tilt may contribute to 267 error. An anatomical landmark such as Schwalbe's line may be less variable as this cannot 268 change dynamically like the iris, but may be less discernible, particularly in vertical scans 269 due to occlusion of this landmark by the eyelids. Visual axis data could potentially provide 270 more accurate measurements of strabismus. This could be determined by using retinal OCT 271 images of the fovea that are also acquired using the device. The device currently does not 272 measure axial length which prevents mapping the retinal and anterior segment images to 273 each other to determine the visual axis. However, if axial length data could be obtained, the 274 visual axis could potentially provide a reliable method of measuring strabismus using OCT, 275 particularly in strabismus with normal retinal correspondence.

In summary, we present a novel application of OCT imaging to detect and measure 276 277 ocular misalignment. The advantage of this method is the ability to detect subtle differences 278 in the size of strabismus that may not be visible to the naked eye. This is encompassed 279 within a device that can perform several functional tests in addition to whole-eye imaging. 280 The automated manner of the device means a highly skilled specialist is not required to take 281 measurements of the deviation, therefore making it ideal for screening purposes. As 282 discussed, measuring strabismus using prism bars has limitations particularly at larger 283 angles. The binocular OCT can provide a more precise measurement of this angle using 284 degrees (with out without converting back to prism diopters). This may be useful for 285 measuring strabismus over time, before and after surgery, or for patients undergoing 286 botulinum toxin injections. Although the current setup has many caveats, future iterations of 287 the binocular OCT may allow quicker and more accurate assessments of strabismus 288 particularly where orthoptists are limited with huge patient volumes. In addition, the device 289 can output objective quantitative data for ocular misalignments as well as for other 290 diagnostic tests,<sup>7</sup> aiding the diagnosis and monitoring of eye disease.

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312	R.C., P.J.M., R.S.A., P.A.K. were involved in the study setup
313	R.C., V.K.T. collected the data for the study
314	R.C. analysed the data
315	R.C., P.J.M., V.K.T., R.S.A., P.A.K. wrote the manuscript
316	
317	Access to data:

- R.C. had full access to all the data in the study and takes responsibility for the integrity of the
- 319 data and the accuracy of the data analysis.

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- 347 agreement of the alternate prism cover test (APCT) measurements of strabismus
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**Table 1.** Orthoptic assessment and binocular optical coherence tomography measurements for fifteen participants with strabismus. Vertical deviation measurements obtained using OCT are indicated as hyper- or hypo- with respect to the strabismic eye (i.e. the eye with a horizontal deviation if present).

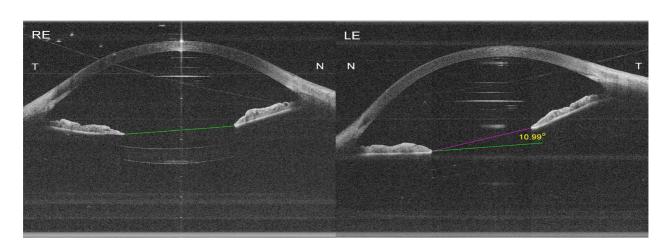
Part icip ant	Clinical diagnosis	Binocular status in primary position	Age	Visual acuity (logMAR)		Mean spherical equivale	Distance prism cover	Prism cover test - equivalent angle in degrees		Angle measured on OCT (degrees)		OCT angle converted to prism
				Right	Left	nt (both eyes) (DS)	test (6 metres)	Horizo ntal	Vertical	Horizont al	Vertical	(rounded to nearest diopter)
1	RE consecutive exotropia (prior strabismus surgery for childhood esotropia)	No diplopia, RE suppress ion	35	0.60	0.00	0 (unaided)	12∆BI 5∆BD R/L	6.84	2.86	6.14 (exo)	11.13 (RE hyper)	11∆BI 20∆BD R/L
2	LE/Alternating esotropia (Duane's syndrome)	No diplopia, LE suppress ion	24	-0.10	-0.10	-0.63	45∆BO	24.23		18.67 (eso)	2.23 (LE hyper)	34∆BO 4∆BD L/R
3	RE fully accommodative esotropia	No diplopia, binocular	23	0.62	0.02	+2.88	6∆BO 4∆BD R/L	3.43	2.29	6.17 (eso)	4.87 (RE hyper)	11∆BO 9∆BD R/L

		single vision										
4	RE consecutive exotropia (prior strabismus surgery for childhood esotropia)	No diplopia, RE suppress ion	63	0.00	0.16	+5.38	45∆BI 3∆BD R/L	24.23	1.72	29.34 (exo)	2.93 (RE hyper)	56∆BI 5∆ R/L
5	RE consecutive exotropia (prior strabismus surgery for childhood esotropia)	No diplopia, RE suppress ion	50	0.18	-0.02	-0.06	25∆BI	14.04		19.83 (exo)	2.28 (RE hypo)	36∆BI 4∆BD L/R
6	LE childhood esotropia	No diplopia, LE suppress ion	47	0.16	0.76	-2.44	25∆BO	14.04		11.08 (eso)	0.00	20∆BO
7	LE longstanding distance esotropia	Diplopia	74	0.00	0.00	-1.25	14∆BO 4∆BD L/R	7.97	2.29	12.96 (eso)	2.18 (LE hyper)	23∆BO 4∆BD L/R
8	LE myopic esotropia	Diplopia	74	-0.10	0.00	-0.5	25∆BO 2∆BD R/L	14.04	1.15	23.74 (eso)	3.48 (LE hypo)	44∆BO 6∆BD R/L
9	LE hypertropia (secondary to thyroid eye disease)	Diplopia	62	-0.10	0.00	+1.25	20∆BD L/R		11.31	0.00 (ortho)	18.15 (LE hyper)	33∆BD L/R

10	RE residual esotropia with hypertropia (prior strabismus surgery for childhood esotropia)	No diplopia, RE suppress ion	31	-0.08	-0.12	+3.13	14∆BO 5∆BD R/L	7.97	2.86	2.07 (eso)	5.89 (RE hyper)	4∆BO 10∆BD R/L
11	RE exotropia with hypertropia (decompensated after loss of vision from a right retinal detachment)	Diplopia	31	0.78	-0.20	0 (unaided)	45∆BI 3∆BD R/L	24.23	2.29	16.97 (exo)	2.02 (RE hyper)	31∆BI 4∆BD R/L
12	LE exotropia with hypotropia (secondary to left sphenoid wing meningioma)	Diplopia	74	-0.04	0.30	+1.25	20∆BI 25∆BD R/L	11.31	14.04	14.75 (exo)	14.26 (LE hypo)	26∆BI 25∆BD R/L
13	LE residual exotropia (prior strabismus surgery for childhood exotropia)	No diplopia, LE suppress ion	55	0.00	0.48	0 (unaided)	60∆BI 6∆BD R/L	30.96	3.43	26.33 (exo)	6.30 (LE hypo)	49∆BI 11∆BD R/L
14	RE age-related distance esotropia	Diplopia	68	0.16	0.00	-1.50	6∆BO	3.43		1.33 (eso)	0.00	2∆ВО
15	LE myopic esotropia (and glaucoma)	Diplopia	61	-0.10	0.10	-0.25	16∆BO	9.09		10.99 (eso)	1.54 (LE hyper)	19∆BO 3∆BD L/R

## 1 Figures and Figure Legends

### 



#### 

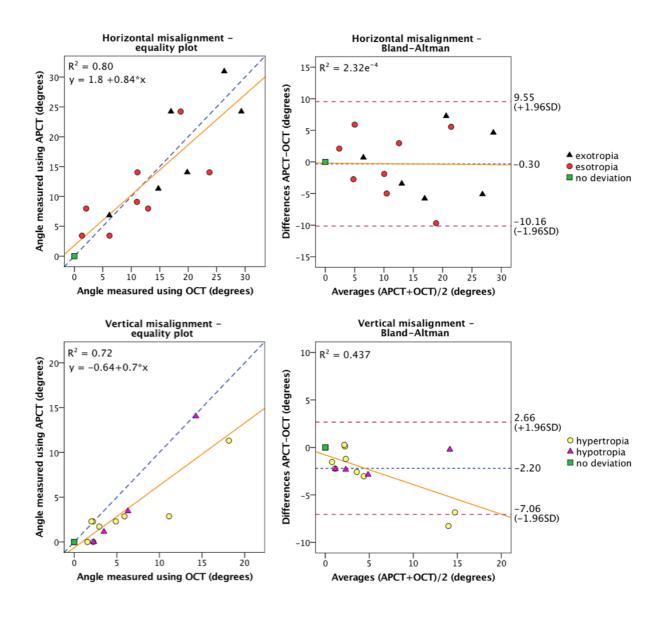
## 5 Figure 1.

- **Title:** Simultaneously acquired pair of anterior segment optical coherence tomography
- 7 (OCT) images obtained for Participant 15.

**Caption:** The right eye is the fixating eye, and the left eye is the strabismic eye. The angle

- 9 of the deviation is calculated by measuring the tilt of the eye with respect to the fixating eye.
- 10 The pupil margins are used as landmarks to measure tilt. This pair of images indicate a left
- 11 esotropia. (N = nasal, T = temporal)

- •



23 24

#### 25 **Figure 2**.

Title: Equality and Bland-Altman plots comparing agreement of measurements obtained
 using APCT and binocular OCT.

**Caption:** Measurements for horizontal misalignments vertical misalignment are presented in the top and bottom plots respectively. For vertical deviations, pink triangle markers represent a hypo- deviation with respect to the strabismic eye. Green indicates no measured deviation with either method. Regression lines are represented in orange. For the equality plots the dashed line represents perfect agreement. The reference lines on the Bland-Altman plots show the mean and 95% limits of agreement (LoA). The LoA were  $\pm 9.85^{\circ}$  from the mean for horizontal misalignments, and  $\pm 4.86^{\circ}$  for vertical misalignments.