

SUPPLEMENTARY MATERIAL**Supplementary Table 1.** Characteristics of Test 1 and Test 2 lenses

	Test 1	Test 2	Control
Lens Type	Single vision DOT with ~5 mm clear centre aperture	Single vision DOT with ~5 mm clear centre aperture	Standard single vision lens with tint
DOT Pattern	Pattern 1	Pattern 2	None
Tint	None	None	Light standard green tint (LTF: ~95%)
Lens Material	Trivex (impact resistant)		
Powers available for study (D)	Sphere: -0.75 to -6.00 (0.25 steps) Cylinder: 0.00 to -2.00 (0.25 steps)		

D, diopter; DOT, Diffusion Optics Technology; LTF, light transmission factor

Supplementary Table 2. Criteria for balancing randomization

Age (years)	Lower baseline SER	Higher baseline SER
6 to <7	-0.75 to -2.25 D	<-2.25 to -4.50 D
7 to <9	-0.75 to -2.50 D	<-2.50 to -4.50 D
8 to <9	-0.75 to -2.50 D	<-2.50 to -4.50 D
9 to <10	-0.75 to -2.50 D	<-2.50 to -4.50 D
10 to <11	-0.75 to -2.50 D	<-2.50 to -4.50 D

SER, spherical equivalent refraction.

Supplementary Table 3. Reasons for Discontinuation Among Subjects Dispensed Spectacles

Treatment Arm/ Subject	Age/SER Group at Baseline	Days Since Dispensing	Reason for Discontinuation
<i>Test 1</i>			
#1	9/Low	184	At the discretion of the Investigator or the Subject
#2	9/Low	189	Other - Lost to follow up
#3	9/Low	357	Other – Lost to follow up
#4	7/High	7	Other - Parent states study glasses were impeding schoolwork and ability to see normal in everyday wear and with football
#5	7/High	26	Other - Subject wants transition lenses; the provided sunglasses fell off her face; withdrew consent
<i>Test 2</i>			
#1	9/Low	29	At the discretion of the Investigator or the Subject
#2	6/Low	36	At the discretion of the Investigator or the Subject
#3	9/Low	59	At the discretion of the Investigator or the Subject
#4	10/Low	183	At the discretion of the Investigator or the Subject
#5	9/Low	3	Non-compliance to Protocol
#6	8/Low	240	Non-compliance to Protocol
#7	9/High	374	Other - 'bullying at school'
#8	9/High	3	Other - Finds it very difficult to adapt to the peripheral lens pattern and keep finding the clear central zone
#9	8/Low	210	Other - Lost to follow up
#10	8/Low	520	Other - Lost to follow up (Subject never showed up for last two visits and not answering phone calls/texts)
#11	6/Low	30	Other - Mother decided to withdraw from study based on look of lenses and comments her daughter made about "just letting her eyes be free" needing a small break. Mother had a difficult time adjusting to how the lenses changed her daughter's appearance and how she was looked at by the general public, indicated they treated her as she was special needs solely on appearance of her glasses
#12	10/Low	37	Other - Mother indicated subject was having a hard time adapting to the new lenses. Reported it was a struggle to get subject to wear her glasses on a daily basis.
#13	8/Low	162	Other - Parent and Child wanted to withdraw from the study because child does not like to continue wearing the study product.

Treatment Arm/ Subject	Age/SER Group at Baseline	Days Since Dispensing	Reason for Discontinuation
#14	6/Low	33	Other - Parents are unhappy with the lens appearance and wish to discontinue child. Child stated she'd rather have her old glasses back.
#15	7/Low	190	Other - Subject did not like the pattern on the study spectacles
#16	7/High	10	Other - subject no longer wants to be in the study, did not like glasses
#17	9/High	43	Other - Subject withdrew assent, Early Exit
<i>Control</i>			
#1	6/Low	30	Subject does not meet eligibility criteria
#2	10/Low	78	Subject does not meet eligibility criteria

SER, spherical equivalent refraction

Supplementary Table 4. Parent Questionnaire Responses

Variable	Baseline			12-month		
	Test 1 88	Test 2 75	Control 95	Test 1 78	Test 2 56	Control 91
Habitual user?						
Yes, n (%)	79 (89.8)	66 (88.0)	83 (87.4)	78 (100)	56 (100)	91 (100)
Days typically worn during the week, mean (SD)	4.8 (0.71)	4.9 (0.32)	5 (0.25)	4.9 (0.47)	4.9 (0.53)	5.0 (0.00)
Daily wearing time (hrs) during the week, mean (SD)	12.7 (4.17)	13.3 (3.88)	12.9 (4.26)	12.8 (2.37)	12.9 (2.37)	13.6 (2.20)
Days typically worn during the weekend, mean (SD)	1.8 (0.36)	1.9 (0.35)	1.9 (0.34)	2.0 (0.16)	2.0 (0.19)	2.0 (0.00)
Daily wearing time (hrs) during the weekend, mean (SD)	11.9 (4.83)	12.6 (4.70)	12.3 (5.37)	12.8 (2.60)	12.4 (3.52)	13.5 (2.51)
Spectacles removed for near vision activities?						
Yes, n (% of habitual users)	15 (19.0)	15 (22.7)	21 (25.3)	15 (19.2)	23 (41.1)	17 (18.7)
If Yes, which activities? n (% of habitual users)¹						
Reading/Writing	5 (6.3)	12 (18.2)	11 (13.3)	9 (11.5)	13 (23.2)	5 (5.5)
PC/Tablet/Phone	4 (5.1)	6 (9.1)	4 (4.8)	3 (3.8)	7 (12.5)	7 (7.7)
Sports	5 (6.3)	1 (1.5)	6 (7.2)	4 (5.1)	2 (3.6)	3 (3.3)
TV	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Recess/Play Time	2 (2.5)	0 (0)	1 (1.2)	0 (0)	0 (0)	1 (1.1)
Other	3 (3.8)	0 (0)	2 (2.4)	2 (2.6)	3 (5.4)	2 (2.2)
How often does your child complain about glare? (0=Never, 1=Occasionally, 2=Quite often, 3=Very often)						
Mean (SD)	0.3 (0.47)	0.3 (0.54)	0.3 (0.61)	0.2 (0.38)	0.2 (0.40)	0.1 (0.22)
How severe is your child's glare? (0=Not at all, 1=Mild; 2=Moderate; 3=Severe)						
Mean (SD)	0.2 (0.49)	0.3 (0.55)	0.3 (0.55)	0.2 (0.39)	0.2 (0.48)	0.1 (0.37)
How often does your child complain about halos? (0=Never, 1=Occasionally, 2=Quite often, 3=Very often)						
Mean (SD)	0.1 (0.27)	0.1 (0.43)	0.1 (0.44)	0.1 (0.39)	0.2 (0.47)	0.1 (0.31)
How severe are your child's halos? (0=Not at all, 1=Mild; 2=Moderate; 3=Severe)						
Mean (SD)	0.1 (0.35)	0.1 (0.41)	0.1 (0.35)	0.1 (0.37)	0.2 (0.52)	0.1 (0.28)
How often does your child complain about hazy vision? (0=Never, 1=Occasionally, 2=Quite often, 3=Very often)						
Mean (SD)	0.3 (0.56)	0.3 (0.56)	0.2 (0.48)	0.2 (0.40)	0.2 (0.47)	0.1 (0.31)
How severe is your child's hazy vision? (0=Not at all, 1=Mild; 2=Moderate; 3=Severe)						
Mean (SD)	0.3 (0.65)	0.2 (0.49)	0.2 (0.45)	0.1 (0.35)	0.2 (0.46)	0.1 (0.28)
¹ Opened-ended question, more than one activity may have been mentioned						

Supplementary Table 5: Summary of AL and cycloplegic SER change by visit (observed) - mITT Subjects.

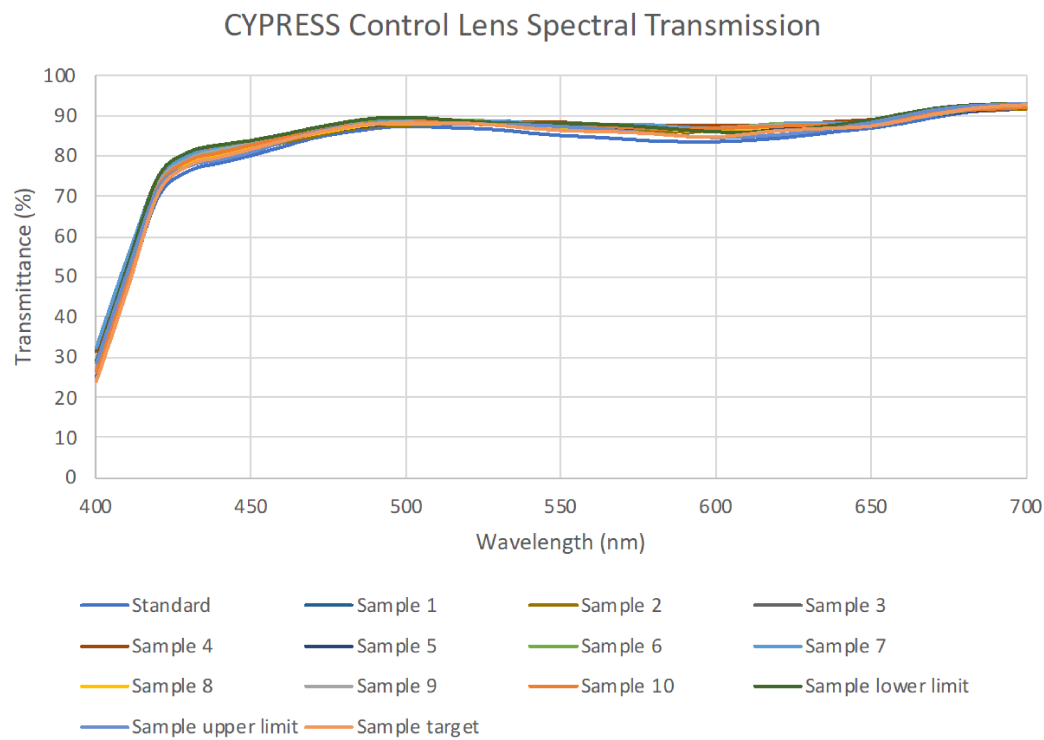
Variable	Test 1	Test 2	Control
AL			
<i>Baseline</i>			
No. of Subjects	88	75	93
Mean (SD)	24.1 (0.82)	23.9 (0.70)	24.0 (0.78)
<i>Month 12</i>			
No. of Subjects	79	56	91
Mean (SD)	24.3 (0.89)	24.2 (0.77)	24.3 (0.78)
<i>Month 12 Change from Baseline</i>			
No. of Subjects	79	56	91
Mean (SD)	0.15 (0.15)	0.18 (0.21)	0.30 (0.17)
cycloSER			
<i>Baseline</i>			
No. of Subjects	88	75	93
Mean (SD)	-2.00 (0.93)	-1.85 (0.91)	-1.95 (1.02)
<i>Month 12 cycloSER</i>			
No. of Subjects	78	56	91
Mean (SD)	-2.15 (1.08)	-2.10 (1.09)	-2.45 (1.09)
<i>Month 12 Change from Baseline</i>			
No. of Subjects	78	56	91
Mean (SD)	-0.15 (0.39)	-0.23 (0.49)	-0.53 (0.46)

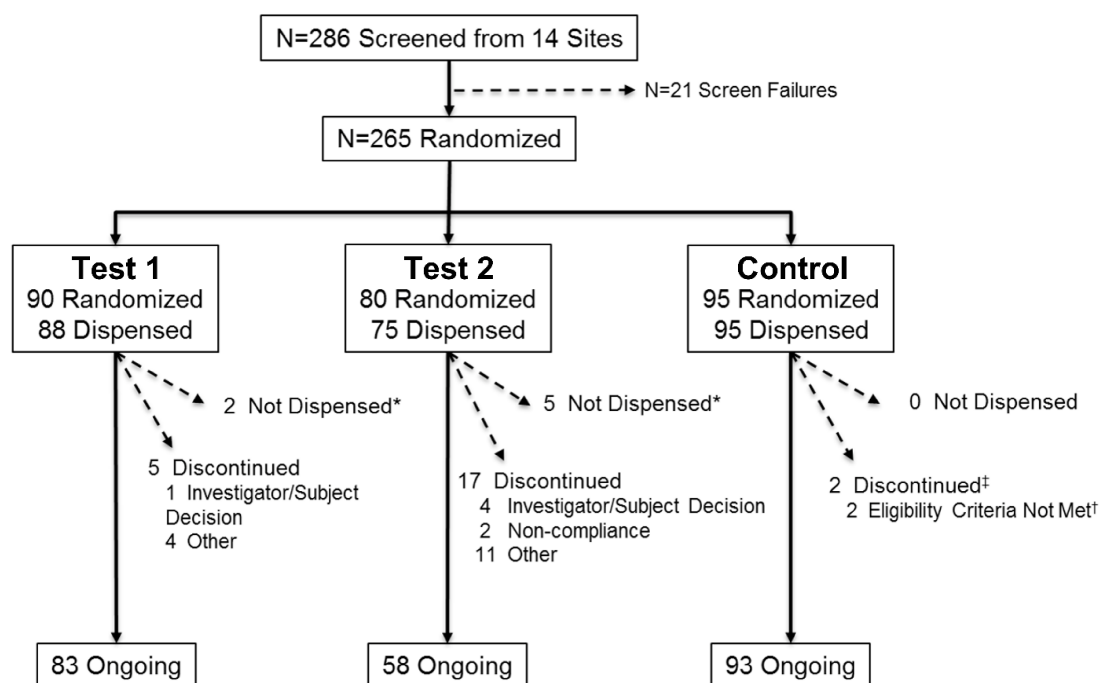
AL, axial length; mITT, modified intent-to treat; SER, spherical equivalent refraction

Supplementary Figure 1. Diffusion Optics Technology (DOT) spectacles



Supplementary Figure 2. Validated spectral transmission data: control lenses



Supplementary Figure 3. Subject disposition.

* Not dispensed due to investigator/subject discretion (two in Test 1), noncompliance (1 in Test 2) and other (2 each in Test 1 and Test 2)

†Two Control subjects were identified as hyperopic for the cycloplegic autorefraction at baseline.

Supplementary Figure 4. Plot of uncorrected axial length (A) and spherical equivalent refraction (B) at baseline and follow-up by treatment group

