To Compare the Effectiveness of 3 Different Types of Lens and Lens Coating in Eliminating Symptoms for Children With Prolonged Visual Symptoms Due to a Concussion. (SLICK)

2/25/2018

Inclusion/Exclusion Criteria

Inclusion:

1. 9-17 years of age
2. Minimum BCVA: 20/25 OD and OS at distance and 20/30 both eyes at near
3. Stereopsis minimum: 500"global at near
4. CISS $\geq$ 16
5. Refractive error: at least $\pm$ 0.50D sphere or cylinder
6. Concussion $\geq$ 4 weeks $\leq$ 16 weeks
7. Ability to clear $\geq$0.5cpm MAF/BAF (+/-1.50)

Exclusion:

1. Diplopia from nerve palsies
2. Retinal pathology
3. Previous treatment (ADD, base in prism) since concussion
   a. Vision therapy $\geq$ 6 weeks since concussion

3 randomized (block randomization, SAS 9.4) groups (all lenses sponsored by Essilor):

- (30) Single Vision (for distance) polycarbonate
- (30) Single Vision polycarbonate (for distance) with antireflective coating (Crizal-alize)
- (30) 0.85D add (Eyzen) with antireflective coating (Crizal Alize)

SLICK Protocol

Enrollment visit:

1. CISS
2. CISS-CON
3. VAs with habitual cc or sc at distance (OD and OS)
4. VAs with habitual cc or sc at near (OU)
5. Cover test at distance and near
6. EOMs
7. Stereo at distance and near
8. MEM
9. Amplitude of accommodation (push up x 3) (OD and OS)
10. NPC x3
11. Monocular accommodative flipper (+/- 1.50) each eye using 20/30 accomm rock card
12. Binocular accommodative flipper (+/- 1.50)*
13. Vergence ranges at distance and near
14. Vergence facility 3BI and 12 BO*
15. NRA/PRA
16. DEM
17. Repeat CISS-CON

*with suppression check – red/green

(Not for study data but part of protocol)

1. Dry retinoscopy
2. Dry manifest refraction
3. Dilation: 1 gtt practitioner's preference on anesthetics then 1% cyclopentolate, 1% tropicamide, wait 4 minutes then 1 gtt more drop of 1% tropicamide
4. After 25 minutes of gtts, can start doing BIO retina exam
5. After 30 minutes of gtts, wet retinoscopy and wet refraction

Spectacle Correction (based off of combination of wet retinoscopy and refraction and dry refraction)

1. Full correction of anisometropia
2. Full correction of astigmatism
3. Full correction of myopia
4. Full correction of hyperopia or symmetrically under corrected by no more than +1.00 from wet retinoscopy or refraction

At dispense of study glasses:

1. CISS-CON
   Wait 5 minutes
2. Repeat CISS-CON

Study visit #1 (masked examiner) 5 weeks +1 from dispense of glasses:
ALL done with study glasses

1. CISS-CON
2. BCVA at distance (OD and OS)
3. BCVA at near (OU)
4. Cover test at distance and near
5. Stereo at distance and near
6. MEM

7. Amplitude of accommodation (push up x 3) (OD and OS)
8. NPC x3
9. Monocular accommodative flipper (+/- 1.50) each eye using 20/30 accomm rock card
10. Binocular accommodative flipper (+/- 1.50)*
11. Vergence ranges at distance and near
12. Vergence facility 3BI and 12 BO*
13. NRA/PRA
14. DEM
15. Repeat CISS-CON

Study visit #2 In office, 3 month from dispense CISS

1. CISS-CON
   Wait 5 minutes
2. Repeat CISS-CON

OVERVIEW OF STUDY FOLLOW-UP

All patients will have the following study visits/interactions after the enrollment visit:

- If patient providing own outside frame, return within 1 week of enrollment for fitting
- Randomization (at day of glasses fitting)
- Dispense glasses when arrive from Essilor, followed by CISS-CON same day *(masked)*
- 5 weeks ± 1 week after dispense of lenses visit *(masked)*
- 12 weeks after dispense visit *(masked)*

SUMMARY OF TESTING PROCEDURE (In Order)

Tests		Visits (from dispense)		
	Enrollment	Dispense	5 weeks ± 1 week	16 weeks
CISS-CON	X	ME	ME	ME
BCVA at distance (OD and OS) at near (OU)	X		ME	
EOMs	X			
Cover Test at distance and near	X		ME	
Randot Stereoacuity at distance and near	X		ME	
Near Point Convergence (3x)	X		ME	
MEM	X		ME	
Amplitude of Accommodation (3x)	X		ME	
Monocular accommodative flipper (+/- 1.50)	X		ME	
Binocular accommodative flipper (+/- 1.50)*	X		ME	
Horizontal vergence ranges at (near) x 2 and (distance) x 1	X		ME	
Vergence (3BI and 12BO) Facility *	X		ME	
NRA/PRA	X		ME	
Developmental Eye Movement Test	X		ME	
CISS-CON repeat	X	ME	ME	ME

*with suppression check

ME stands for masked examiner

FLOW CHART

Enrollment Testing Procedures

- CISS-CON x 2
- Visual acuity
- Cover Test
- EOMs
- Stereopsis testing
- NPC (3x)

- MEM
- Push up AA (3x)
- MAF and BAF (+/-) 1.50
- NRA/PRA
- Horizontal vergence ranges at (near) x 2 and (distance) x 1
- Vergence Facility
- DEM

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Fitting for glasses

Patient to return with personal frame ≤1 week from enrollment visit

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Randomization

⇩   ⇩   ⇩

| Single Vision w/o AR | Single Vision w/AR | Eyezen lens w/AR |

⇩   ⇩   ⇩

Dispense of glasses (timeline at discretion of lens arrival from Essilor):
CISS-CON x 2

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Masked exam (all testing through study lens)
5 weeks +1 week after dispense of lenses

- CISS
- Visual acuities
- Cover Test
- Stereopsis
- NPC x 3
- MEM

- Amplitude of accommodation x 3
- MAF and BAF (+/- 1.50)
- NRA/PRA
- Horizontal vergence ranges at near x2 and distance x1
- Vergence Facility
- DEM

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Failed treatment criteria? CISS increase ≥ 10

⇩   ⇩

Yes

Investigator intervenes with preferred treatment

End of study for patient

No

Continue study lens wear

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12 weeks from dispense

Masked examiner office visit