Crossover Comparison of Two Novel Comfilcon A Lens Designs

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PURPOSE

This study compares subjective experiences and visual performance of subjects with symptoms of Computer Vision Syndrome (CVS) using two novel comifilcon A lens designs, one of which is specifically designed for digital device use.

INTRODUCTION

The AOA defines CVS as Computer Vision Syndrome (also referred to as Digital Eye Strain) as a group of eye and vision-related problems that result from prolonged computer, tablet, e-reader and cell phone use.[1] Many individuals experience eye discomfort and vision problems when viewing digital screens for extended periods. The level of discomfort appears to increase with the amount of digital screen use."[2] Self-reported symptom prevalence rates exceed 65%, with a suggestion women may be affected more often than males due to higher prevalence rates of dry eye.[3] Multiple ergonomic, environmental and ocular factors play a role in the evolution of symptoms but a consensus is lacking on causative mechanisms.[1,2,4-10] Vision status including visual acuity, refractive status, focusing and motility are used in establishing a diagnosis.[3,4-9,11]

At least one contact lens manufacturer promotes it has attempted to effectively address some symptoms associated with smart device use through creation of a novel design.[12]

METHODS

This is a pilot study using a randomized, double-masked, cross-over design. A series of subjects symptomatic for computer vision syndrome were randomly assigned to wear either the Biofinity or then the Energys (Cooper Vision, Scottsville, NY) silicone hydrogel contact lens in a single vision design for one month. They were then crossed over after a 3-day washout period to the opposing design for a second month before exiting the study. This study complied with the tenants of the Helsinki accords and was approved by the IRB committee at Southern College of Optometry.

INCLUSION CRITERIA

- Score >6 on CVS-Q
- Male or female
- >18 years of age
- Experienced contact lens wearer
- Spherical equivalent refractive error between ±6.00D with astigmatism <0.75D
- Subjects had normal stereopsis and binocular vison, defined as having no strabismus on unilateral cover test and 40" arc or better with no suppression measured with Randot® SO-002 (Stereo Optical, Chicago, IL).

EXCLUSION CRITERIA

- Monovision
- History of refractive surgery
- Binocular vision abnormalities
- Allergies exacerbated by contact lens wear

Symptoms were assessed at baseline and exit of each design using the validated Computer Vision Syndrome questionnaire (CVS-Q)13-15 This questionnaire assesses frequency and intensity of symptoms including

- Burning
- Itching
- Feeling of a foreign body
- Tearing
- Excessive blinking
- Eye redness
- Eye pain
- Heavy eyelids
- Dryness
- Blurred vision
- Double vision
- Difficulty focusing for near vision
- Increased sensitivity to light
- Colored halos around objects
- Feeling that eyesight is worsening
- Headache

PRIMARY OUTCOME MEASURES

- Binocular logMAR (Hi-Lo contrast) visual acuity at 6M and 40cm
  - » The M&S Technologies Smart System II (M&S Technologies, Niles, IL) has been shown to be comparable to ETDRS and Pelli Robson charts,[16,17] Computer tests have been shown to a reliable, capable way of assessing vision.[11]
- Subjective assessment of accommodation was assessed by plotting a binocular defocus curve over-refraction at 6M (-3.00 to +3.00D in 0.50D steps) in phoropter while wearing contact lenses.[17] Room luminance was controlled and subjects viewed optotypes through a standardized 4 mm aperture to reduce confounding effects on retinal defocus.[18] Lenses were presented in a randomized order.[17,19]
  - » Subjective assessment of amplitude of accommodation by "push-up method" tends to overestimate accommodative levels.[17,20-22]
- Objective assessment of accommodation Multiple studies support quantitative and qualitative changes in accommodation may be associated with asthenopia.[22-24] The Grand Seiko WR 5500 (AIT, Bensenville, IL) has been shown to be capable of reliably measuring objective accommodation.[20,24-27]

STATISTICS

Sample size calculations a priori suggested a minimum of N=27 subjects is necessary to sufficiently power a study. Allowing for a 10% drop-out rate a reasonable estimated sample size was N=30 subjects.

Descriptive statistics and graphs were prepared using Microsoft, Excel 2016 MSO ver. 16.0.4498.1000 (Microsoft Corp., Santa Rosa, CA). Analytical statistics compared Biofinity and Biofinity Energys for statistically significant differences using Friedman matched pairs test after exiting each design using Analyse-it for Microsoft Excel 4.81 (Analyse-It Software, Ltd., Leeds, UK).

RESULTS

Subjects (N=9; F=7, M=2) age 26.6 ±3.2 years (22 to 33 years). Data was not normally distributed and parametric statistics were applied. Median values were compared with all significance levels set at p=0.05.

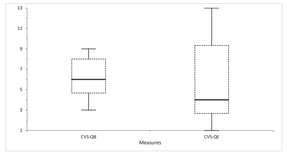

FIGURE 1: *CVS-Q Questionnaire measurements with standard error bars taken at the exit visit of each contact lens (N=9) after 1 month of wear. Symptoms were not statistically different than each other (p=0.739).*

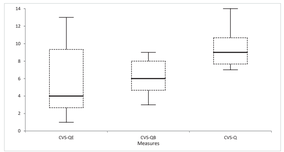

FIGURE 2: *Comparison to baseline for CVS-Q scores at exit after one month of wear. Only Biofinity reached statistical significance on Friedman test (p=0.005) and Biofinity Energys (p=0.096).*

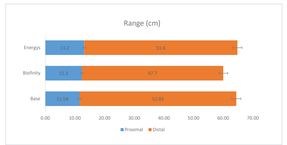

FIGURE 3: *Proximal and distal range of clear vision (ROCV) with standard error bars after one month of wear (N=9). Comparisons on Friedman test were not statistically significant (p>0.05).*

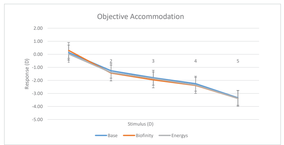

FIGURE 4: *Log MAR acuity with standard error bars after one month of wear (N=9). Comparisons on Friedman test were not statistically significant (p>0.05).*

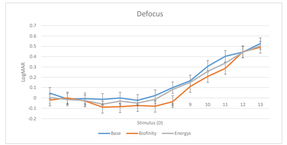

FIGURE 5: *Log MAR distance visual acuity with standard error bars after one month of wear (N=9). Comparisons on Friedman test were not statistically significant (p>0.05).*

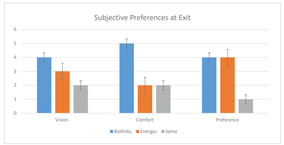

FIGURE 6: *Frequencies with standard error bars across the three dimensions surveyed. (N=9).*

There was no statistically significant difference between lens designs for CVS-Q *(Figure 1)* at exit, but there was a statistically significant improvement in symptoms for the spherical design compared to baseline *(Figure 2)*. There was no statistically significant change in proximal or distal range of accommodation *(Figure 3)*, objective accommodation as assessed using Grand Seiko WR5500 *(Figure 4)*, or subjective accommodation *(Figure 5)* plotted as a defocus curve (except with a +0.50D, p=0.02), or LogMAR visual acuities at any distance.

DISCUSSION

This limited pilot study suggests there is little difference between these two novel lenses based on symptoms and measures of accommodation or visual acuity. Both designs demonstrated subjective improvements in comfort and vision among symptomatic wearers compared to baseline. *(Figure 6)*

This is in contrast to the increase in symptoms among contact lens wearers compared to non-wearers.[29] A double-masked design minimizes expectation bias.

Various studies have divided etiologies of CVS (or DES) into two broad categories.

- External (associated with dryness) or Internal (associated with accommodative/ binocular vision related[13]
- Dry eye related and accommodation[19]

OUTCOME MEASURE	BIOFINITY	BIOFINITY ENERGYS	P-VALUE
CVS- Q	6.2 ± 2.0	6.0 ± 4.1	0.739
High contrast logMAR DVA	-0.12 ± 0.075	-0.071 ± 0.08	0.096
Low contrast logMAR DVA	0.01 ± 0.060	0.060 ± 0.09	0.317
High contrast logMAR NVA	-0.11 ± 0.093	-0.124 ± 0.040	0.739
Low contrast logMAR NVA	-0.02 ± 0.08	0.018 ± 0.07	0.739
Proximal range of clear vision (cm)	12.3 ± 2.15	13.17 ± 2.47	1.000
Distal range of clear vision (cm)	47.7 ± 13.48	51.61 ± 13.35	0.739
Objective Accommodation 0.0D	0.30 ± 0.34	0.026 ± 0.41	0.096
Objective Accommodation 2.0D	-1.43 ± 0.37	-1.396 ± 0.42	0.480
Objective Accommodation 2.5D	-1.96 ± 0.30	-1.863 ± 0.28	0.739
Objective Accommodation 3.0D	-2.39 ± 0.35	-2.354 ± 0.30	0.739
Objective Accommodation 4.0D	-3.38 ± 0.32	-3.384 ± 0.39	0.739
Defocus: +3.00 DS (logMAR DVA)	0.49 ± 0.13	0.504 ± 0.22	0.739
Defocus: +2.50 DS (logMAR DVA)	0.45 ± 0.15	0.442 ± 0.15	0.739
Defocus: +2.00 DS (logMAR DVA)	0.29 ± 0.15	0.338 ± 0.15	0.317
Defocus: +1.50 DS (logMAR DVA)	0.21 ± 0.11	0.258 ± 0.15	0.317
Defocus: +1.00 DS (logMAR DVA)	0.11 ± 0.09	0.151 ± 0.10	0.480
Defocus: +0.50 DS (logMAR DVA)	-0.04 ± 0.10	0.082 ± 0.09	**0.020**
Defocus: 0.00 DS (logMAR DVA)	-0.08 ± 0.06	-0.013 ± 0.10	0.096
Defocus: -0.50 DS (logMAR DVA)	-0.07 ± 0.08	-0.049 ± 0.07	0.480
Defocus: -1.00 DS (logMAR DVA)	-0.03 ± 0.08	-0.084 ± 0.06	0.158
Defocus: -1.50 DS (logMAR DVA)	-0.09 ± 0.06	-0.060 ± 0.07	0.158
Defocus: -2.00 DS (logMAR DVA)	-0.03 ± 0.08	-0.024 ± 0.09	0.480
Defocus: -2.50 DS (logMAR DVA)	0.00 ± 0.18	-0.016 ± 0.07	1.000
Defocus: -3.00 DS (logMAR DVA)	-0.02 ± 0.10	0.004 ± 0.07	1.000

TABLE 1: *Within subject comparisons of symptoms and primary outcome measures at exit after one month of wear of each lens. CVS-Q, high and low contrast LogMAR distance (DVA) and near visual acuities (NVA), proximal and distal ROCV, objective accommodation, and defocus data. Values represent (mean ± SD) and the statistical significance (p-value) of the difference.*

The subjects in this pilot study were symptomatic on the validated CVS-Q.[13,29] Screening excluded obvious binocular issues and did not assess subjects for signs of ocular surface disorders. The questionnaire does assess subjects for symptoms related to dry eye.[13] Females outnumbered males, 7 to 2, creating a gender bias. Females are known to experience dry eye at higher frequencies than males.[5,31,32] The bias was minimized since all subjects were screened for a symptom score of 6 on the CVS-Q and by using within subject comparisons in a cross-over design. A validated dry eye questionnaire and assessment for signs of dry eye might have provided additional insights on causes of subject symptoms, but the similarity of designs would predict equivalent palliative responses.

The lens bulk and surface properties are identical, varying only in anterior asphericity of the Energys version which contributes a nominal add effect of +0.50D to +0.75D. *(Table 2)* This controls for lens surface and bulk contributions to comfort, leaving only design differences.[33]

PARAMETER	BIFONITY	ENERGYS
Material/H2O content	comfilcon A/48%	comfilcon A/48%
Base Curve (mm)	8.6 mm	8.6 mm
DIA(mm)	14.0 mm	14.0 mm
Sphere Powers	+15.00D to -20.00D	+15.00 to -20.00D
Design	Asphere	Multiple front-surface aspheric curves
Dk/t (at -3.00D)	160	160
Replacement Interval	Monthly	Monthly

TABLE 2: *Comparison of bulk and design attributes of the two novel contact lens designs used in this study.*

Subjects were excluded if they failed a brief screening for binocular dysfunction. The multiaspheric anterior surface design of the Energys lens might differentially influence outcomes for subjects with accommodative infacility, insufficiency or high AC/A ratios. Future studies should consider this group.

The range of subject refractive errors was limited to exclude influences from presbyopia and/or astigmatism.[33-35]

Other factors[1] not considered in this study which may influence outcomes include

- Critical flicker-fusion frequency effects,
- Blinking or squinting,
- Pupil diameter and reflex,
- Blue light exposure

CONCLUSION

This small pilot study suggests there is little subjective or objective clinical difference between lens designs in a case series of subjects symptomatic for computer vision syndrome. Additional prospective studies of sufficient power are necessary to determine which factor(s) best measure and differentiate which contact lens design attributes most impact computer vision syndrome.

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