Clinical White Paper

The Poinsettia Study: Improved Vision and Patient Preference for Duette™ HD Contact Lenses vs. Soft Toric Contact Lenses

February, 2013

Denise Roddy, O.D., Todd Pfeil, O.D., Steven L. Ziemba, M. Sc.
The Poinsettia Study Clinical White Paper: Improved Vision and Patient Preference for Duette™ HD Contact Lenses vs. Soft Toric Contact Lenses
Denise Roddy, O.D.¹, Todd Pfeil, O.D.², Steven L. Ziemba, M. Sc.³ © Synergeyes, Inc. February, 2013

Overview
Most soft contact lenses can be fit relatively easily with a high degree of success. However, some eye care professionals still consider soft torics to be specialty lenses because of their decreased potential for patient acceptance. In some cases, rotational instability leading to unstable vision and reduced acuity in low light or low contrast settings means soft toric lenses are not always the ideal choice for patients seeking the best possible vision. On the other hand, RGP toric or bi-toric lenses can provide great vision but wearing difficulties limit their acceptance. The ideal lens, therefore, may be one that can correct astigmatism regardless of light conditions or contrast without any worry about rotational stability while still providing a comfortable wearing experience.

In this study we examined a dual-material lens that correct astigmatism via a lacrimal lens effect that does not depend on a ballast or variable thickness optic to produce stable vision on toric corneas. The high-Dk RGP optic of the Duette lens thus produces higher quality vision while its high-Dk soft, silicone-hydrogel skirt maintains centration and ensures better comfort than an RGP.

Distance visual acuity and lens preference were examined in 50 subjects at two sites. Consecutive myopic or hyperopic subjects with <2.25D of regular corneal astigmatism and ≤0.75D of residual astigmatism, no history of corneal refractive treatment/surgery or ocular pathology interfering with lens wear or vision were enrolled. After diagnostic fitting of both lenses, PureVision 2 HD for astigmatism lenses (Bausch+Lomb, Rochester, NY) were dispensed to each subject and contact lenses-visual acuities were assessed after 2-weeks. These lenses were then discarded and Duette HD lenses (SynergEyes, Inc., Carlsbad, CA) were dispensed and the 2-week visual acuities repeated.

High and low contrast logMAR visual acuities were recorded (Bailey-Lovie LogMAR eye chart) under photopic (>120 cd/m²) and mesopic conditions (<90 cd/m²). Data was analyzed using a T-Test for Paired Samples (Microsoft Excel 2010). LogMAR values were converted to Snellen VA for presentation herein.

Results
As expected, both study lenses improved distance visual acuity compared to VA with habitual correction (photopic =20/19; mesopic=20/26) but both mean high and low contrast visual acuity under photopic conditions were significantly better (P<0.004) when subjects wore Duette HD lenses (Table 1) compared to vision with PureVision 2 HD lenses.

<table>
<thead>
<tr>
<th>Table 1: Distance Visual Acuity (Photopic)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean High Contrast Visual Acuity</td>
</tr>
<tr>
<td>Duette HD</td>
</tr>
<tr>
<td>PureVision 2 HD</td>
</tr>
</tbody>
</table>

*Difference is statistically significant (P<0.004)

Mesopic distance visual acuity also improved compared to habitual VA acuity for both lenses. However, mesopic vision in both bright and dim light conditions was significantly better with the Duette HD lenses (Table 2) compared to vision with the PureVision 2 HD lenses (P<0.001).

<table>
<thead>
<tr>
<th>Table 2: Distance Visual Acuity (Mesopic)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean High Contrast Visual Acuity</td>
</tr>
<tr>
<td>Duette HD</td>
</tr>
<tr>
<td>PureVision 2 HD</td>
</tr>
</tbody>
</table>

*Difference is statistically significant (P<0.001)

To assess the validity of these results, data was stratified for subjects whose pupils were 3-4 mm under photopic conditions (to eliminate mydriatic pupils) and 6-8 mm under mesopic conditions (to eliminate miotic pupils). The same analyses showed that outcomes remained unchanged. High and low contrast vision under both photopic and mesopic conditions were still statistically significantly better when subjects wore the Duette HD lenses.

What was known
• Soft contact lenses and Duette lenses with an RGP center and soft skirt can improve distance visual acuity.
• Toric soft contact lenses can be effective but concerns remain with them about pupillary size and visual disturbances due to lens rotation.

What this paper adds
• Distance vision was significantly better in all lighting conditions with the Duette HD lens compared to a toric soft contact lens, especially in eyes with oblique astigmatism.
• Preference for the Duette HD over the PureVision2 HD lens was related to better distance-vision outcomes with the Duette HD lenses.
At the end of the study, subjects indicated their lens preference and were given a 6-month supply of the lens they chose. Six out of ten subjects chose the Duette HD lens instead of the PureVision 2 HD lenses (Figure 3). This correlated well with visual outcomes which also favored the Duette HD. Most subjects who chose Duette HD indicated their preference was based on superior vision with that lens whereas only 8% of subjects choosing PureVision 2 HD lenses indicated they based their choice on better vision.

### Discussion

In this study, subjects wearing the Duette HD lens had significantly better vision under both photopic and mesopic conditions when viewing either high or low contrast charts, regardless of pupil size. Those positive outcomes led to the majority of subjects preferring the Duette HD lens. We enrolled subjects with a wide array of habitual correction options. However, even though none were wearing Duette HD prior to enrollment, the majority of subjects chose the Duette HD lenses to take home.

The high-Dk optics (Dk=130) on the Duette HD are intended to provide the visual outcomes expected with RGP lenses; i.e., better vision than soft contact lenses either with or without toric optics. The soft silicone-hydrogel skirt (Dk=84) of the Duette HD also allows high O₂ transmission for excellent comfort while it performs its main function of centering the optic. The fact that those design features performed as expected is evident here. Mean refractive astigmatism for all subjects was -1.37D (S.D. 0.55D) and mean keratometric cylinder was -1.53D (S.D. 0.59D). Despite residual astigmatism which the toric soft lens is designed to overcome, mean visual acuity was still superior for the Duette HD in both bright and dim light conditions as the lacrimal (tear) lens created by the Duette HD neutralized corneal cylinder quite effectively. The superior optics provide by the RGP-center of the Duette HD may be the reason for the improved vision, but some instability of the PureVision 2 HD even with only small amounts of corneal astigmatism present may also have contributed.

Analyzing outcomes after eliminating subjects with physiologic large pupils from the photopic analyses as well as subjects whose pupils could not adequately dilate from the mesopic analyses eliminated the chance for false-positive outcomes. The consistency in outcomes, regardless of pupil size, validates that the Duette HD lens can produce better visual outcomes under any lighting condition when viewing high or low contrast objects. This indicates that the Duette HD is an attractive option for patients frustrated by “good enough” vision with their soft lenses or who notice diminished acuity when driving at night. Patients who want or need to wear their lenses from sunrise to sunset, regardless of any degree of astigmatism, represent a target population for the Duette HD as a lens of first-choice.

Based on the superior outcomes with the Duette HD, this data shows that diminished VA and rotational stability with soft toric contact lenses may also have a large effect on patient satisfaction. Many eyes in this study had visually significant residual astigmatism, but the majority of subjects in this study had better visual outcomes while wearing the Duette HD lenses. Further, most subjects (60%) with significant residual astigmatism (>0.5D) still chose the Duette HD lenses. Conventional wisdom would be that residual astigmatism would spur a preference towards a soft toric lens that corrects both corneal and lenticular cylinder. In this study, subjects experienced and valued improved vision and comfort without a toric lens. Six out of ten subjects who had never worn them preferred the Duette HD lenses due to crisper vision, no concern about rotational stability, and excellent comfort; indicating that previous patient preferences can be overcome with the Duette HD lens.


Reprint requests, contact sziemba@synergeyes.com.