Multifocal Off-Center Optics Visual Effectiveness Study (MOOVES)

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PURPOSE

Presbyopia is a challenge that almost all people face at some point in life. Some of them seek improvement in visual function through contact lenses. An issue and critical difference contact lenses have compared to spectacles is the position of the optical center of the contact lens with respect to the visual axis. Most contact lenses have a fixed position on the eye so those with multifocal optics provide simultaneous vision relying on the patient's pupil to control the optics focused on the retina along with neurosensory adaptation to perceive the focused visual stimuli. Contact lens fitting can be challenging when attempting to center the lens over the pupil in order to provide clear multifocal optics. This has been especially difficult with scleral lenses. Due to the natural physiology of the sclera's shape, large diameter lenses that land on it tend to decenter inferior temporally. The primary objective of this study is to evaluate center near multifocal outcomes using trial alignment patterns and off set near optics. This serves as a novel approach to realigning the optical center of contacts in the case of lens decentration.

METHODS

This multicenter study prospectively enrolled subjects requiring presbyopic correction of +1.75 diopters or greater and included myopia, hyperopia, and astigmatism and included both males and females. All subjects had undergone basic refraction and topography mapping if available. Data was collected over the 45 days preceding enrollment and prospectively over initial dispense and 2 follow-up visits. (1 week and 1 month). Inclusion criteria was for normal corneas, keratoconus, pellucid marginal degeneration, high ametropia, dry eye, and post-surgical subjects. Subjects with glaucoma, macular degeneration, diplopia, or visually significant cataracts were excluded.

The subjects' informed consent was obtained. Scleral lenses were fit diagnostically to achieve approximately 250 microns of central clearance and approximately 100 microns of limbal clearance. The subjects were over refracted to best correctable visual acuity and lens decentration and orientation was measured using On Point Alignment indicators on the lens. Pupil size was measured with pupil gauge and eye dominance was determined.

Scleral lenses were ordered with 2.5 mm near zones with decentration to account for position assessed during diagnostic fitting. Subjects trialed lenses in office at dispense visit and were asked to give subjective feedback on the experience. Slit lamp exam confirmed proper clearances over the cornea and scleral alignment without compression or edge lift. Visual acuity was measured and the lenses were dispensed. The subjects returned at 1 week and 1 month visits to evaluate the fit of the lenses, VA, and the subjective feedback of the lens wearing experience.

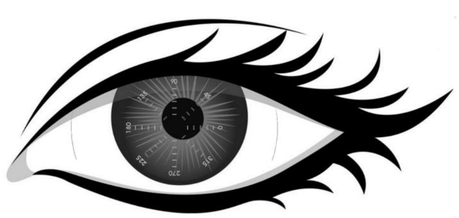

Figure 1: On Point Alignment Technology uses laser etched marks on the front surface of the diagnostic lens to determine amount and direction of decentration

RESULTS

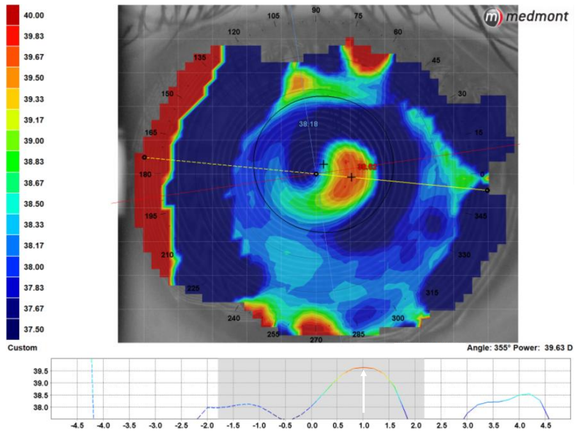

Figure 2: Tangential topography maps can be used to find the near zone of a scleral lens. Here, the zone is decentered about 1 mm temporal to the center of the pupil.

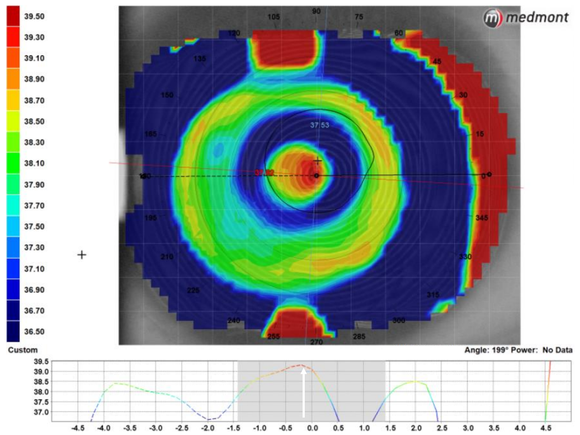

Figure 3: This map shows better centration of the near zone after applying On Point Alignment Technology. The 2.5 mm zone size is also visible on the attribute below the map.

This study had 53 subjects enrolled to date. The following data describe the results across all sites of those who completed their 1 month follow up. Four subjects exited the study because they did not want to come to follow up appointments or struggled with lens application.

The subjects include people with normal corneas, keratoconus, pathologic myopia, dry eye, and other ocular surface conditions. Average pupil size was 3.7 mm in mesopic conditions. Average decentration of the scleral lenses on eye was about 4 hash marks, approximately 1.75 mm.

Subjects gave subjective feedback on the performance of the lenses and graded them on a scale of 1 to 10 in categories of distance vision, near vision, comfort, and overall experience with both eyes, 10 being the highest. The average scores for subjects in their final dispensed lens design at the one month follow up were 8.7 for distance acuity, 9.0 for near acuity, 8.7 for comfort, and 9.0 for overall experience. The subjects were also asked to comment on subjective blur and nighttime glare in each eye with the responses 0 for absent, 1 for minimal, 2 for mild, 3 for moderate, or 4 for severe. The average rating for blur was 1.1 and nighttime glare was 1.3.

DISCUSSION

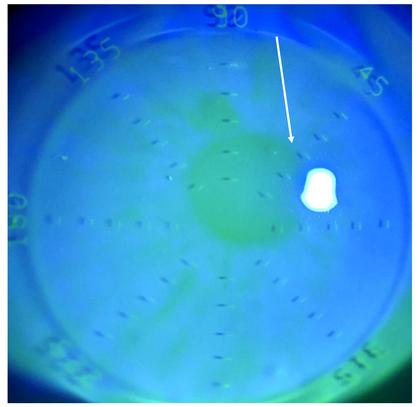

Figure 4: On Point Alignment was used to decenter the near zone based on the 3rd hash mark on the 45º meridian. The meridian is chosen based on the greatest number of marks within the pupil.

Majority of subjects in this study had at least 1.5 mm of decentration. However, many subjects were fit with only one attempt, approximately 69.2%. The most common change needed was a change in the near zone size in one or both eyes. For many this was decreasing the zone size in the dominant eye to improve the distance or increase the zone size in the non dominant eye to improve the near. Improved near acuity at the expense of distance vision is a frequent cause of failure in multifocal fitting. In this study, 77% of eyes achieved distance acuity within one line of best correctable acuity. This was enough to please subjects and so their average rating of vision at distance was 8.7 and 9 at near out of 10. This result seemed to be skewed by some keratoconus subjects that already had reduced distance acuity. Within the keratoconus subject sample of the study, 75% of them graded the average distance vision as 9, near vision as 8.7, comfort as 8.3, and overall experience as 9 out of 10.

CONCLUSION

The demand for better presbyopic correction continues to increase. Both normal and irregular cornea patients have visual needs at distance and near. Scleral lenses have the advantage of improving vision in both populations. The previous disadvantage of lens decentration can now be solved with reproducible manufacturing of decentered multifocal optic designs. This allows accurate measurement of decentration. Many patients can be successfully fit in one attempt.

Patient expectations must still be managed as the simultaneous vision experience is not perfect, and they may experience mild blur and glare at times. Pupil size plays an important role for troubleshooting vision related issues that may result. Time between follow ups and real-world experience are also important for multifocal adaptation and success.

ACKNOWLEDGMENTS

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