Custom Aligned Optical Technology in Ampleye® Multifocal Scleral Lenses

Chad M. Rosen, OD, MBA, FAAO

Key Takeaways

- Optical alignment is an important consideration when fitting patients in multifocal lenses
- Ampleye® multifocal optics can be custom aligned to place the optics in front of the patient's line of sight
- A standard decentration angle and amount can improve the optical alignment on many Ampleye® lenses, increasing chances of success
- Practitioner measurement via slit lamp can produce similar results to measurements taken with a topographer when evaluating the angle and magnitude of decentration

Scleral Lens Centration

It is well known that scleral lenses don't center perfectly in front of the eye. Most commonly, they tend to decenter infero-temporally due to rotational asymmetries of the scleral anatomy.[1,2] Another reasoning for this decentration relates to a combination of eyelid tension, gravity, and interactions between the eyelids and lenses.[3] If there is enough decentration of a scleral lens, changes in ocular physiology can occur. One of these changes is insufficient limbal clearance, which can result in corneal touch or excessive conjunctival impingement. In these cases, adjustments to the lens parameters may be necessary to improve comfort and/or vision, as well as preserve adequate ocular health. Even though it is difficult to compare decentration data from one study to the next, this evaluation showed similar results in the direction and magnitude of decentration as other published papers with similar scleral lens diameters.

Optical Impact of Decentered Contact Lenses

In patients considered to have "normal" eyes, the main, low order aberrations can be corrected with a spherocylindrical prescription. In these individuals, approximately 10% of the eye's total aberrations are in the form of higher order aberrations (HOAs).[4] From this information, one can determine most normal individuals will have fairly sharp vision by simply providing spherocylindrical correction. This assumption can only be made if the form of correction (I.e. spectacle or contact lens) is perfectly centered on the eye. Since scleral lenses tend to decenter infero-temporally on the eye, the optics presented through the pupil will be similarly decentered.

Patients with normal eyes may not notice this optical decentration, but patients with irregular corneas benefit from customized optics. Using scleral lenses to correct vision in patients with irregular corneas has shown to improve vision and reduce ocular aberrations.[5] In addition, recent efforts have demonstrated the benefit of wavefront-guided optics and their ability to correct HOAs in patients with keratoconus to normal levels.[6,7]

Multifocal Optics of Contact Lenses

As soon as multifocal optics are added to a contact lens, it becomes even more important to align those optics in front of a patient's line of sight. Despite advances in technology, multifocal contact lenses are reported to increase measured spherical aberrations.[8,9] This can contribute to the visual "compromise" clinicians sometimes discuss with their presbyopic patients. It also may factor into the perceived challenges in fitting those patients with multifocal contact lenses.

Clinical thoughts have been presented to test patients' contrast sensitivity function in addition to traditional Snellen visual acuity. This stemmed from patients in multifocal lenses performing well with Snellen visual acuity, but stating their vision didn't have the quality they would like. Research has shown that contrast sensitivity function isn't largely impacted with center-near multifocal contact lenses when compared to single-vision contact lenses.[9]

Misalignment of Multifocal Optics

Understanding common tendencies of scleral lenses to decenter infero-temporal, the negative optical impacts of decentering spherocylindrical optics in front of the eye, and the impact of multifocal optics on aberrations, it is understandable why practitioners see fitting multifocal contact lenses as challenging. Even if a contact lens appears clinically acceptable in terms of centration, the multifocal optics may not align within the center of the pupil which can induce HOAs like coma and can translate to decreased visual acuity.[10] This demonstrates the importance of careful evaluation of lens centration, in particular with multifocal contact lenses.

Based on current knowledge, it makes sense to think proper centration of multifocal optics may improve patient satisfaction and outcomes. This has been demonstrated with intraocular lenses with studies showing rotationally asymmetric multifocal intraocular lenses can provide a wide range of visual acuity.[11] If intraocular lenses can accomplish this, surely it can also be achieved with multifocal contact lenses by decentering the optics to create the "rotationally asymmetric" multifocal.

Aging Patients and Scleral Lenses

Patients over 65 years old are the fastest growing population in many countries, with the United States expecting to see growth from 40 million to close to 90 million by 2050 in this group.[12] This increasing population will need eyecare and creates an opportunity for practitioners. Not only does this trend provide more presbyopes who will desire clear vision at all distances, but other conditions that accompany the aging eye. For instance, the crystalline lens starts to develop mild opacities as cataracts form, increasing aberrations through the eye. In addition, the prevalence of dry eye in this patient population is extremely high, with estimates of 70% of Americans over the age of 60 having meibomian gland dysfunction.[12] The high rate of dry eye disease is also considered to impact twice as many women as it does men.[12]

Scleral lenses have become an important tool in the management of dry eye disease. Many patients experience improved comfort, decreased symptoms of dry eye, more consistent and comfortable vision, and decreased compromise of the ocular surface, ultimately leading to a better quality of life.[13,14] It can range from solo therapy that brings a patient comfort throughout the day, or can be combined with other methods to combat the underlying causes of dry eye. Regardless of how they are used, practitioners have seen notable improvement in dry eye symptoms while using scleral lenses with these patients.

Custom Aligned Ampleye® Optics Provide Another Tool for Satisfying Presbyopic Patients

The quest of finding a perfect contact lens to guarantee success in patients who require an add power is a daunting one. As an industry, we have been searching for this "silver bullet" that will make practitioners' lives simpler when fitting multifocal lenses. The Custom ALigned Optics of the Ampleye® Multifocal from Art Optical helps move us one step closer in this process.

When fitting presbyopic patients in multifocal contact lenses, there are many details to gather prior to making a contact lens recommendation. This non-exhaustive list provides common details gathered to assist practitioners in fitting multifocal contact lenses:

- Add power
- Visual demand during work/avocation
- Upper/lower eyelid position & tightness
- Horizontal visible iris diameter
- Keratometry readings
- Corneal astigmatism amount, regularity, and location
- Pupil size in dim and standard room illumination
- Ocular dominance
- Presence of ocular surface disease

Even if all the above items are accounted for, it may not matter if the optics don't center in front of the eye. With the understanding that scleral lenses often decenter infero-temporal creating an optical challenge, especially with multifocal optics, Art Optical wanted to help practitioners by providing the ability to customize the alignment of the optics by placing them in front of a patient's pupil/line of sight. Before launching the ability to the general public, an evaluation was performed to validate this capability.

Evaluation Details & Results

To determine the success of custom aligned multifocal optics, 10 subjects were recruited and fitted with Ampleye® scleral lenses in a pilot evaluation. The 16.5mm diameter lens was used on all subjects except one, with a smaller diameter lens being used to help obtain an ideal fit on a smaller eye. During the initial fit, a combination of single vision and multifocal Ampleye® lenses were used to determine whether similar results could be obtained. Measurements of both direction (i.e. nasal, temporal, inferior, superior) and magnitude (measured in mm) were taken via slit-lamp and topographer. This was done in order to compare methods for validation purposes.

Once an optimal fit was achieved with the lenses on each eye, two separate lenses were created with the appropriate decentered optics. One was based on measurements obtained from the slit-lamp and the other was from the corneal topography measurements. In order to align the rotationally asymmetric optics (i.e. decentered), a black dot was placed on the manufactured lens 180 degrees from the laser-engraved R/L (Image 1). The new lenses were fitted on each subject and the same measurements and measurement methods from the initial visit were repeated.

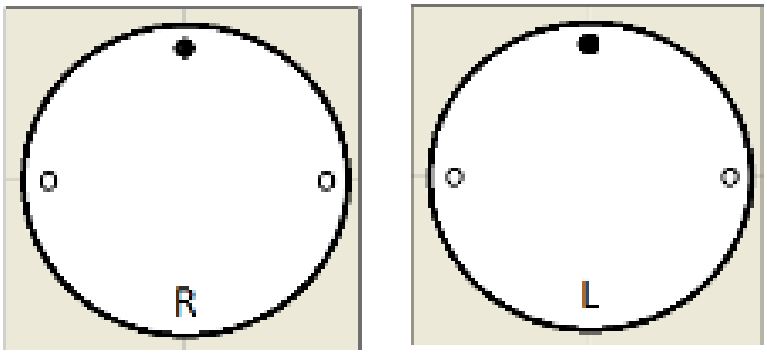

Image 1: Ampleye® laser marks at 3 & 9 o'clock, along with R/L to signify which eye the lens is made for. A black dot was placed 180 degrees from the R/L to signify how the lens should be oriented upon insertion.

A comparison of the two measurement methods (slit-lamp evaluation and topography calipers) produced similar results, demonstrating the ability to consistently obtain fitting information for reliable outputs with standard, in-office equipment. The evaluation also revealed successful decentration of Ampleye® multifocal optics (Image 3) that were better aligned in front of the pupil than the standard lens (Image 2).

Standard Optics (OS)

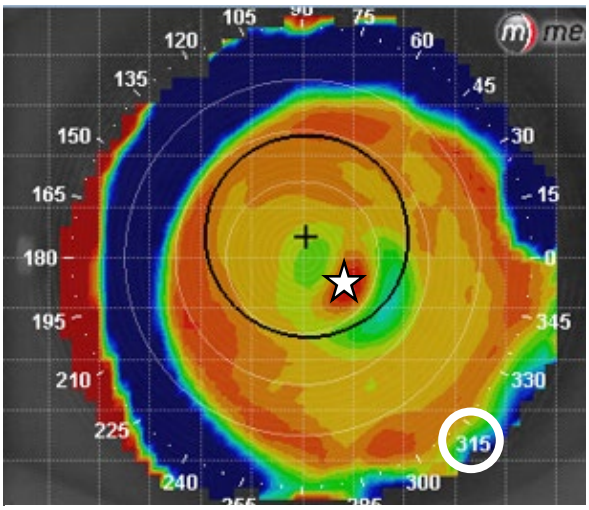

Image 2: Standard Ampleye® optics. Lens decentered inferior/temporal (toward 315°). The center of the optics (white star) are not aligned with the center of the pupil (middle of black circle).

Decentered Optics (OS)

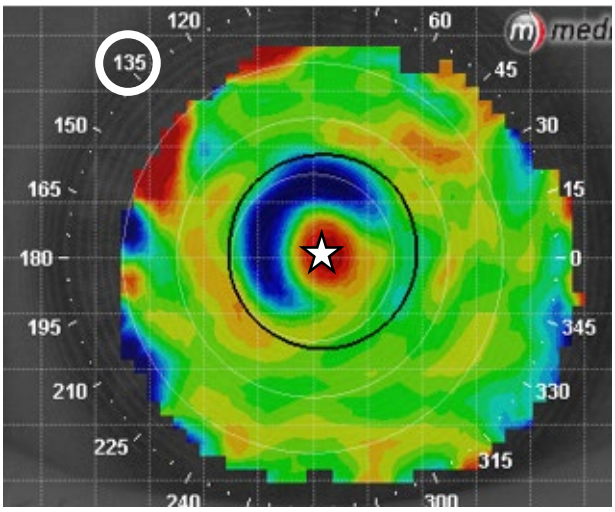

Image 3: Custom Aligned Ampleye® optics 0.75mm toward 135° (moved superior/nasal). The center of the lens optics (white star) are aligned with the center of the pupil (middle of the black circle).

Analysis also revealed a pattern in the angle of decentration and the distance from center the optics moved. As anticipated from common scleral lens tendencies, the Ampleye® lenses in this evaluation decentered infero-temporal on almost all patients in similar amounts to other studies that evaluated lenses of the same diameter. Precise measurements taken with the lenses on helped determine that most lenses decentered 0.75mm infero-temporal at a 45° angle from center (i.e. toward 225° OD and 315° OS). From this information, Art Optical created a "standard" decentration amount (0.75mm) and angle (toward 45°OD and 135° OS) as an option for practitioners when ordering custom aligned multifocal lenses.

Insights & Conclusions

Fitting presbyopic patients can be time-consuming and frustrating for practitioners. This is an often-cited reason for the large gap between those patients who desire a multifocal and the number of practitioners actively fitting them.

The nature of scleral lenses to decenter infero-temporal on the eye can present optical challenges and result in a decreased quality of vision, which can be amplified when multifocal optics are employed.[5] Despite this challenge, providing a more customized set of optics that are aligned with the patient's visual axis can improve their visual quality and satisfaction in keratoconus patients, making us believe similar results can be obtained in normal corneas.[6,7]

Since presbyopic patients often have dry eye, providing scleral lenses with multifocal optics can address two issues with one solution. It can provide quality optics from a gas permeable lens and it can alleviate some symptoms of dry eye in many patients. Utilizing commercial soft multifocal contact lenses can provide unsatisfactory vision and may increase dry eye symptoms.[15] Fitting gas permeable lenses and taking the additional step to align the optics in front of the line of sight can help cut down on some visual aberrations patients may experience, improving their overall satisfaction.

If assessment of a fit appears acceptable in all aspects outside of mild decentration, the Ampleye® multifocal has the ability to custom align the optics in front of a patient's pupil/line of sight in order to maximize visual performance. In addition, a standard decentration angle and amount was created from this data to assist in fitting these lenses. With minimal time added during a scleral lens evaluation, better-aligned optics can be obtained for our multifocal patients. These technological advances from Art Optical move practitioners one step forward in the quest of achieving successful clinical outcomes with our presbyopes.

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