Instrumentation and Processes for Fitting and Manufacturing Wavefront-guided Soft Contact Lenses for the Highly Aberrated Eye.

Jason Marsack,[1] Xifeng Xiao,[2] Raymond Applegate,[1] Paul Pulaski,[2] Matt Haugo,[2] Jeff Kolberg,[2] Janine Bugno,[3] Keith Parker,[3] Frank Chinisci,[4] Dan Neal[2]

1. University of Houston, College of Optometry, Houston TX. 2. Wavefront Dynamics, Albuquerque NM.
3. Advanced Vision Technologies, Lakewood CO. 4. Consultant, Albuquerque NM.

Background

The hypothesis that lower and higher order aberrations of an eye can be corrected using a custom contact lens pre-dates the ability to quickly and objectively measure the wavefront error of the eye.[1]

The emergence of clinically viable wavefront sensors in the early 2000s saw a focus on applications for the typical eye, notably in the area of refractive surgery.

Emphasis is now being placed on measuring the lower and higher order aberrations of eyes suffering from corneal ectasias, as it enables the quantification (and therefore facilitates the objective correction) of elevated higher order aberrations.

The delivery of aberration-compensating corrections for the ectatic eye has taken the form of contact lenses, with several examples found in the peer-reviewed literature.[eg: 2-5]

Correction of higher order aberrations in a soft contact lens would be an evolution in personalized optical correction for the individual with corneal ectasia, blending the comfort/convenience of a soft lens with the optical quality afforded by wavefront-guided optics.

Purpose

To address key challenges for manufacturing and fitting wavefront-guided soft contact lenses.

Methods

This project was approved by an institutional review board, and all subjects signed an informed consent before participating.

This process starts with the fitting of a spherical, slab-off ballasted NaturaSOFT contact lens (Advanced Vision Technologies).

The NextWave aberrometer (Wavefront Dynamics) is used to quantify both a) residual wavefront error and b) on-eye rotation and translation of the spherical NaturaSOFT lens over time.[6]

Residual lower and higher order aberration corrections are implemented in a subsequent iteration of the lens sharing all of the macro characteristics of the spherical NaturaSOFT lens, resulting in a wavefront-guided soft lens.

The process diverges from typical soft lens practice, requiring:

- the development of instrumentation with the dynamic range necessary for objective quantification of the aberration structure of the highly aberrated eye with/without a lens;
- utilization of the markings in the quantification of spherical lens on-eye translation and rotation with respect to the pupil center.
- Integrating data from steps 1 and 3 into a wavefront-guided soft contact lens that can be manufactured with an ophthalmic lathe.

Results

1) Measurement of residual wavefront error

- Uncorrected and soft lens corrected eyes measured.

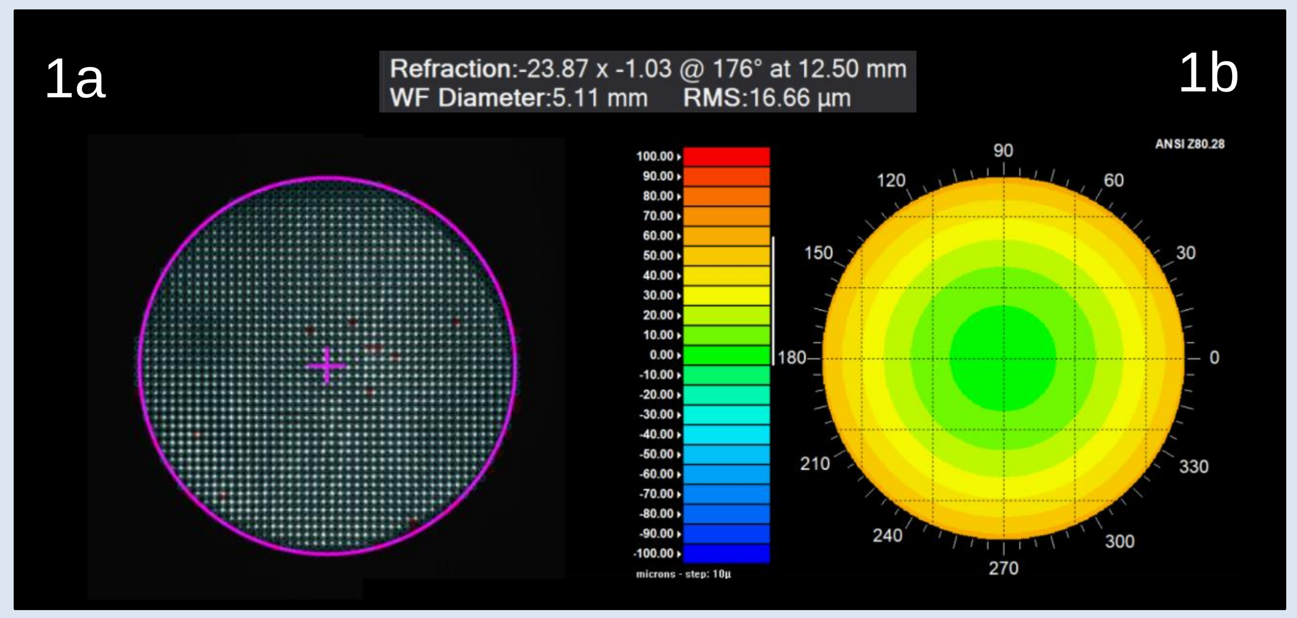

Fig 1a:Example of raw wavefront data (Shack Hartmann spots) for a significant level of myopia.

Fig 1b: Quantification of wavefront error from the spot pattern shown in 1a.

2) Quantification of spherical lens translation and rotation with respect to the pupil center.

- Markings placed on lens surface, several patterns explored.
- **Locating fiducials in NextWave images and alignment of subsequent iterations of the lens on-eye remain significant challenges.**

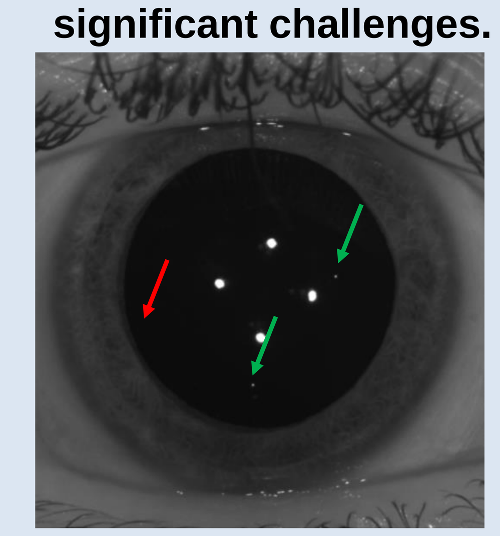

Fig 2a: Image depicting 2 of 3 markings visible on the iris camera.

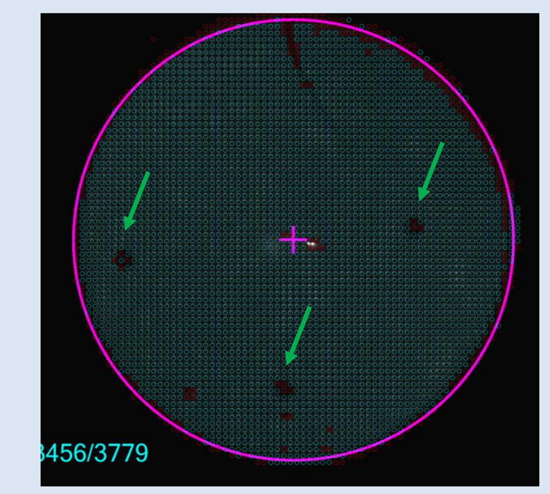

Fig 2b: The markings seen distinctly when cast against the raw wavefront data within the pupil.

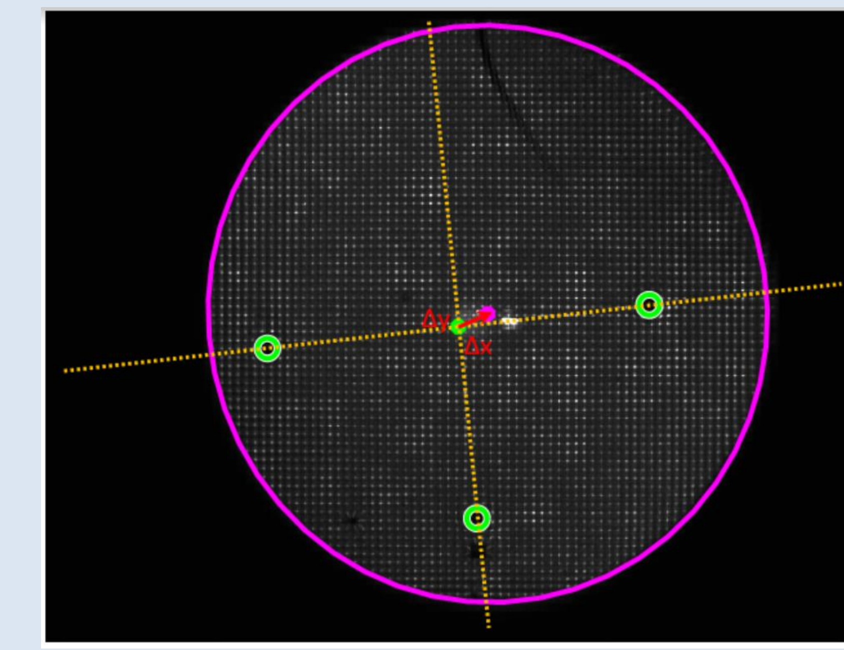

Fig 2c: Image depicting the quantification of rotation/ translation of a soft lens on the eye with respect to pupil center. Here, the rotation is Δx = 0.47mm, Δy = 0.12mm, θ = 6.4°

3) Design, manufacture and performance of spherical and wavefront-guided soft contact lenses

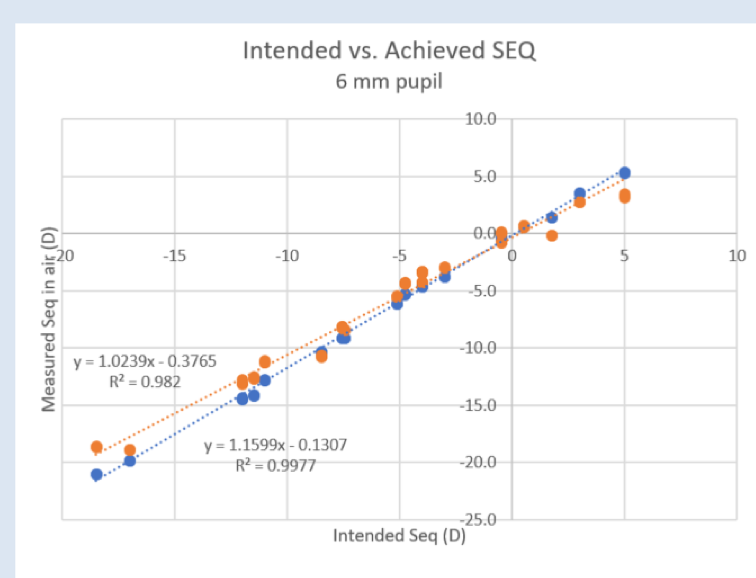

Fig 3a: Designed vs measured sphere (blue) and Seidel sphere (orange) defocus for a large range of spherical lens powers. These lenses form the base for the wavefront-guided lenses that follow in the design process. While spherical, the anterior surface of these lenses is defined via points, the same method as the wavefront-guided lenses.

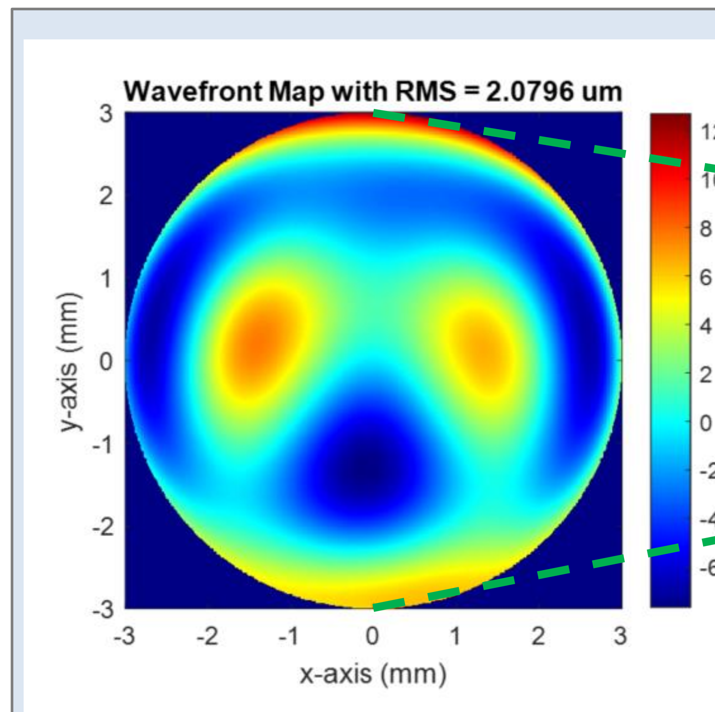

Fig 3b: Example of a desired aberration patch "HappyDog" quantified over a 6mm diameter.

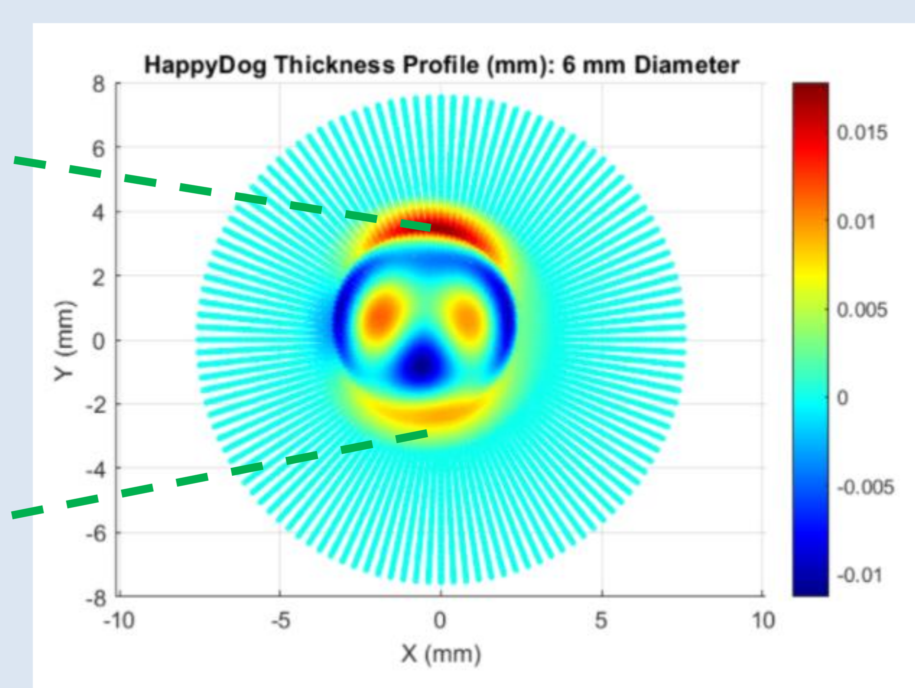

Fig 3c: The aberration structure in 3b integrated into a points file description layer. This figure shows the scale of the offset aberration patch (matching the dilated pupil) with respect to the overall 14.5mm diameter lens.

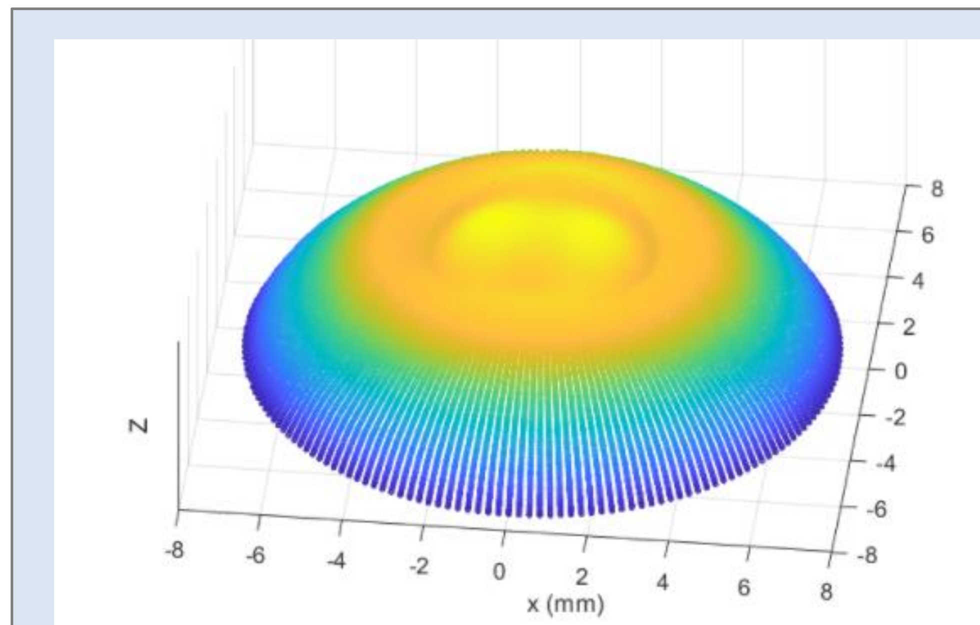

Fig 3d: aberration patch integrated into the anterior surface of a spherical NaturaSOFT contact lens design. (patch exaggerated by 20x before integration for visual effect).

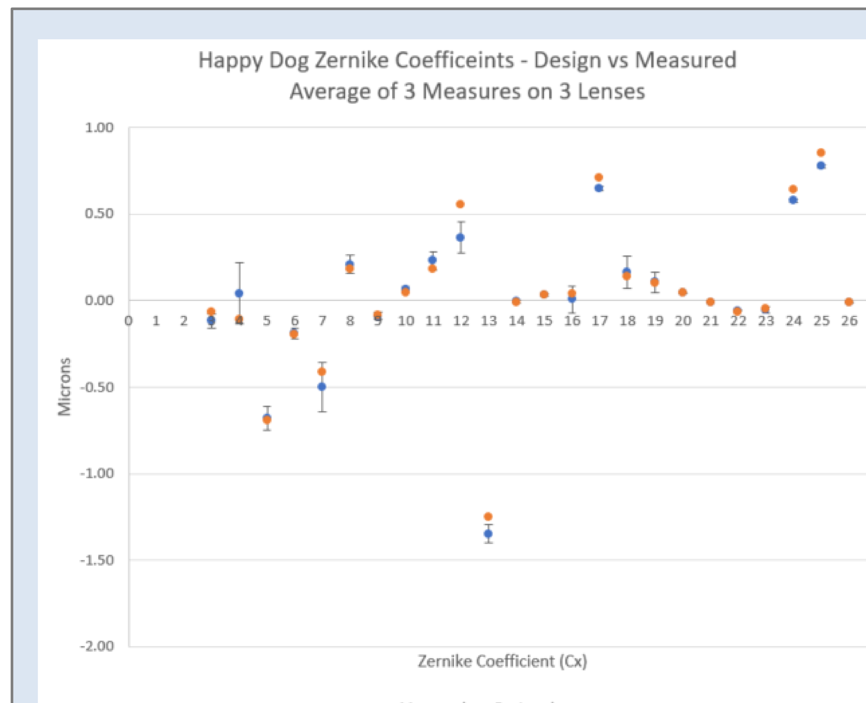

Fig 3e: Zernike coefficients for the desired aberration patch "HappyDog" as pictured in 3b (orange) and the average values for 2nd – 6th order Zernike coefficients for 3 measures of 3 lenses. Error bars represent 1 standard deviation.

Overall, the desired pattern is faithfully represented on average in the test lenses aggregate, with some overshoot/undershoot in several aberration terms.

Conclusion

- The evolution of the instrumentation and processes necessary for fitting wavefront-guided soft contact lenses is ongoing.
- Work to date demonstrates that wavefront-guided lenses can be made in a soft lens material, and that they are capable of reducing higher order aberration. Alignment of the wavefront patch with regards to the underlying pupil is presenting challenges along with methods to determine when a lens fit is acceptable and stable moving from spherical to wavefront-guided designs..
- Future work will focus on evolving the process to be feasible in a clinical environment, and reducing the number of iterations necessary to achieve success.

References

1. Smirnov MS. Measurement of the wave aberration of the human eye. Biofizika 1961;6:776-95.
2. Sabesan R, Jeong T, Carvalho L, et al. Vision Improvement by Correcting Higher-order Aberrations with Customized Soft Contact Lenses in Keratoconic Eyes. Opt Lett 2007;32:1000–2.
3. Katsoulos C, Karageorgiadis L, Vasileiou N, et al. Customized Hydrogel Contact Lenses for Keratoconus Incorporating Correction for Vertical Coma Aberration. Ophthalmic Physiol Opt 2009; 29:321–9.
4. Sabesan R, Johns L, Tomashevskaya O, et al. Wavefront-guided Scleral Lens Prosthetic Device for Keratoconus. Optom Vis Sci 2013;90:314–23.
5. Jinabhai A, O'Donnell C, Tromans C, et al. Optical Quality and Visual Performance with Customised Soft Contact Lenses for Keratoconus. Ophthalmic Physiol Opt 2014;34:528–39.
6. Neal D, Xiao X, Dunlay T, Haugo M. Evaluation of Dynamic Wavefront Aberration Measurement. GSLS 2022.

The authors thank Dr. Charlie Campbell for access to the HappyDog aberration pattern.