# MINIMUM CORNEAL VAULT NECESSARY TO A VIEW FLUORESCEIN PATTERN UNDER GAS PERMEABLE CONTACT LENSES

by

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ABSTRACT

*Background:* This research study explores the minimum corneal clearance needed to view a Sodium Fluorescein (NaFl) pattern under a gas permeable (GP) contact lens. Current literature indicates the minimum tear layer thickness necessary to view a NaFl pattern is 20 microns while in ortho-keratology lenses, the apical clearance is assumed to be 5-15 microns.[1,2,3] *Methods:* By manipulating the parameters of GP contact lenses, the minimum tear layer thickness underneath the lens needed to view a NaFl pattern, can be found using the caliper function of the anterior segment Heidelberg Optical Coherence Tomographer (OCT). A Medmount E300 Corneal Topographer was used to assess corneal curvature and predict tear layer thickness under the GP lens. The NaFl pattern was viewed using a Haag-Streit slit lamp biomicroscope with a yellow wratten filter in conjunction with the cobalt blue filter. *Results:* The minimum tear thickness needed to view NaFl patterns under a GP lens was determined to be seven microns. The Medmont Studio software demonstrated a high predictability of tear layer thickness under the GP lens. *Conclusions:* Current research indicates a tear layer thinner than 20 microns appears dark under GP contact lenses when viewed with slit lamp biomicroscopy.[3.4] Our research found tear layers as thin as seven microns can be viewed, thus indicating when no NaFl pattern is visible, the corneal clearance is smaller than previous research concludes. The Medmont software also accurately predicted tear layer thickness. The findings have a potential to change the way both GP and ortho-keratology lenses are fit in order to have the most beneficial results to the patient.

TABLE OF CONTENS

LIST OF TABLES

# CHAPTER 1

## INTRODUCTION TO MINIMUM CORNEAL VAULT NECESSARY TO VIEW A FLUORESCEIN PATTERN UNDER GAS PERMEABLE CONTACT LENSES

Fitting gas permeable contact lenses is highly dependent on viewing the Sodium Fluorescein pattern of the tear layer underneath the lens when the lens resides on the cornea. In conventional GP lenses (lenses with an average diameter of 9.4 mm), the NaFl pattern of the tear layer is utilized to determine the quality of the contact lens fit.[3] The tear layer appears green due to staining by the NaFl dye. A Wratten no. 12 filter and cobalt blue filter is used to activate the dye and allow for the NaFl pattern to be easily observable underneath the lens.[5, 6] The thickness of the tear layer is evaluated using slit lamp biomicroscopy and an optic section. Areas of NaFl pooling appear green under direct observation. Areas in which the dye is absent or the tear film is too thin to detect appears dark or black.[3, 4, 5] An area where the lens directly touches the cornea also appears dark or black.[5] Darker shades of green indicate a thicker tear layer while a lighter shade of green indicates a thinner tear layer.[3, 5] An aligned fit occurs when there is an even shade of green under the entirety of the lens. A steep fit is observed when there is excessive pooling under the center of the lens and areas of dark in the midperiphy. A flat fit is found with a central dark pattern with excessive peripheral pooling. Bearing of the lens on the cornea can lead to corneal molding and formation of a corneal abrasion.[3, 4] An adequate tear layer underneath the lens is vital to corneal health in way of sufficient tear exchange, allowing for the clearing debris out from underneath the lens and providing nutrients to the corneal tissue.[4] By evaluating the NaFl pattern the clinician can make modifications to the lens parameters to achieve the desired fitting characteristics of the lens on the corneal surface.

When fitting ortho-keretology contact lenses, a reverse geometry GP design is utilized.[1]The lens design is used to flatten the central cornea in order to decrease the power of the central cornea.[1]In order to achieve the result, a much different fitting philosophy and NaFl staining pattern is obtained when compared to conventional GP lenses. The desired pattern of the dye is a 3.00mm area of central touch or absence of visible staining surrounded by an area of thick NaFl pooling and tear layer in what looks like a "bullseye pattern."[1, 2] The alignment curve portion of the lens should exhibit another zone of absence of NaFl followed by an area of NaFl staining representing the edge lift curve.[1, 2] By careful observation of the NaFl pattern and the resulting tear layer thickness, modifications are made to the parameters of the lens to achieve the desired fitting result.

Anterior segment OCT has shown to be a reliable way to measure tear layer thickness under GP contact lenses and the results are highly repeatable. [7] Anterior segment OCT works by utilizing the time interval difference in light passing through the corneal tissue. The time interval difference provides high-resolution cross-sectional images of the corneal surface and in this case the contact lens on the eye itself. [7] Once the cross sectional image of the lens, tear layer, and cornea is found, the manual caliper function is utilized. The top section of the caliper is measured from the posterior surface of the lens and the bottom half is measured on the anterior surface of the cornea. The space in between represents the tear layer thickness. The OCT provides a measure in microns of the length of the caliper and the resulting tear layer.[7]

The Medmont Corneal Topographer utilizes placoid rings to provide a detailed map of the corneal surface then in conjunction with the lens parameters, predicts the tear thickness under the lens using the Medmont Studio software. The Medmont Studio software demonstrates a highly accurate way to predict NaFl patterns of GP contact lenses.[8] The accuracy of the Medmont Studio software is highly dependent on the quality of the placoid rings.[8] Distortions in the rings due to tear break up and corneal scarring, decreases the accuracy of the Medmont Studio's prediction capabilities.[8] In order to use the software effectively, practitioners must ensure the placoid rigs are clear and parallel.

Knowledge of the minimum tear thickness necessary to observe the pattern is needed to insure proper tear clearance under the lens in order to maintain corneal health in conventional GP lenses. This study seeks to determine the minimum tear layer thickness necessary to observe the NaFl staining pattern underneath GP lenses and evaluates the accuracy of the Medmont Studio software in predicting tear layer thickness.

CHAPTER 2

## METHODS TO MINIMUM CORNEAL VAULT NECESSARY TO VIEW A FLUORESCEIN PATTERN UNDER GAS PERMEABLE CONTACT LENSES

Two optometry graduate students from the Michigan College of Optometry where asked to participate in our study. Participants were given an informed consent letter stating the risks and benefits of the study. Once the participant signed the document, testing commenced. Each participant's corneal topography was found using a Medmont Corneal Topographer. Once the topography measurement was obtained, an initial spherical base curve of the GP lens was found. The initial lens was fit to approximately match the patient's flat keretometry value. After the initial contact lens was placed in the eye, the lens was allowed to sit for five minutes. After five minutes, the patients was taken to the Heidelberg anterior segment OCT. The patient was asked to rest their chin on the chinrest of the OCT with their forehead tight against the headrest for the duration of the scan. They were instructed to fixate on the central target, to blink before the scan, and to hold their blink for the duration of the scan. An image of the lens on the cornea was then obtained. Using the caliper function on the image (the top of the caliper residing on the posterior surface of the contact lens and the lower portion of the caliper was placed on the anterior cornel surface), the tear layer thickness was measured. The length of the caliper represented the tear layer in-between the two surfaces. The computer generated the tear layer thickness using the caliper function and the length of the caliper. The tear layer thickness was recorded for each patient along with the corresponding GP base curve. NaFl dye in the form of Flo-Glow strips was inserted into the lower canthus of the eye. The patient was then inserted into the slit lamp biomicroscope with the cobalt filter and wratten filter in place. The NaFl pattern was recorded along with areas of pooling and areas where the NaFl was not visible. Care was taken to specifically record the apical portion of the cornea where the tear thickness was calibrated using the OCT caliper function. If no NaFl staining was visible under the apical portion of the contact lens during the initial fit, the next lens fit on the eye had a base curve of 0.25D steeper than the initial lens. The tear layer measurement and evaluation was found and recorded as described previously. The subsequent lenses base curves were each steeped by 0.25 diopters until the lens showed a NaFl pattern. For patients, who's the initial lens fit showed a NaFl pattern under the apical portion of the contact lens, the base curve of the next lens tested was flattened by 0.25 diopters. The tear layer thickness and evaluation of the NaFl pattern was found using the same method as described previously. The subsequent lenses base curves were each flattened by 0.25 diopters and the tear thickness and NaFl pattern was recorded. Three trial lenses were fit on each of the two patients. The data was compiled using the tear thickness resulting in a visible NaFl staining pattern under the flattest base curve of the lens tested. This value was averaged from the two patients evaluated. The average tear thickness resulted in the minimum tear thickness needed to view a NaFl Pattern under a GP lens. Using the Medmont Studio software, the parameters of each lens fit on the patient was entered into the program and the computer generated predictive tear layer clearance for each of the trial lenses. The data was analyzed and compared to the tear layer measurements obtained by the anterior segment OCT.

# CHAPTER 3

## RESULTS TO MINIMUM CORNEAL VAULT NECESSARY TO VIEW A FLUORESCEIN PATTERN UNDER GAS PERMEABLE CONTACT LENSES

Results of study indicated a minimum tear layer thickness necessary to view a NaFl pattern under a GP lens using biomicroscopy was seven microns (Table 1). Three trial lenses displayed a tear film thickness of seven microns. In two out of the three lenses, a NaFl pattern was visible during observation with biomicroscopy (Appendix A). In the lens which displayed 15 microns of tear film thickness underneath the lens, a NaFl pattern was also visible during biomicroscopy (Appendix A). The remaining two lenses evaluated each contained a tear thickness greater than 23 microns underneath the lens and a NaFl pattern was visible during evaluation with biomicroscopy on each of the two lenses (Table 1).

By using Medmont Studio software on the Medmout E300 Corneal Topographer, the predicted central corneal tear layer thickness under the GP lens was found and compared to the tear layer thickness measured using the Heidelberg OCT. The Medmount studio program takes into account the dimensions of the GP lens as well as the corneal topography measurement. Tear thickness and vault are predicted by the Medmont Studio program based on the aforementioned values. The mean difference found between the actual tear thickness and the predicted value was 7.33 microns. The median difference between the actual and predicted tear thickness was found to be 4.5 microns with a standard deviation of 6.77 microns and a standard error of 2.50 microns. Also, when comparing actual and predicted tear layer thickness measurements, the chi squared test indicated a p value of 3.098E-07. The p value indicated a strong relationship of the Medmount's prediction and the actual tear thickness value measured using the OCT.

**Table 1. Actual vs Predicted Tear thickness Values**

| Pt. number and lens used | K Values (mm) | Base Curve Lens Tested (mm) | OCT measured central tear Thickness (um) | Medmount predicted central tear thickness (um) | Observe NaFl Pattern (Yes/No) |
|---|---|---|---|---|---|
| Pt.1 Lens 1 | 7.64/7.782@172 | 7.67 | 15 | 25 | Yes |
| Pt. 1 Lens 2 | 7.64/7.782@172 | 7.76 | 7 | 28 | Yes |
| Pt. 1 Lens 3 | 7.64/7.782@172 | 7.85 | 7 | 3 | No |
| Pt.2 Lens 1 | 7.29/7.37@167 | 7.18 | 45 | 45 | Yes |
| Pt. 2 Lens 2 | 7.29/7.37@167 | 7.37 | 23 | 19 | Yes |
| Pt. 3. Lens 3 | 7.29/7.37@167 | 7.50 | 7 | 2 | Yes |

**Table 1:** Indicates the actual measured tear layer thickness utilizing the OCT and compares the values to the predicted thickness by the Medmont Studio software.  All lenses tested contained a 10mm overall diameter with an 8mm optic zone diameter.

CHAPTER 4

# DISCUSSION TO MINIMUM CORNEAL VAULT NECESSARY TO VIEW A FLUORESCEIN PATTERN UNDER GAS PERMEABLE CONTACT LENSES

Assessing the NaFl staining pattern underneath GP lenses using slit lamp biomicroscopy is vital for contact lens practitioners in order to achieve the most optimal lens fit. Dark areas observed underneath the lens indicate corneal bearing or a tear thickness too thin to allow visibility of the dye. Dark green areas of staining underneath the lens indicate excessive tear layer thickness. An aligned fit occurs when there is an even shade of green under the entirety of the lens. When fitting ortho-keretology contact lenses, a reverse geometry GP design is utilized.[1] The desired pattern of the dye is a 3.00mm area of central touch or absence of visible staining surrounded by an area of thick NaFl pooling.[2]

Current research indicates a standard spherical GP lens on a aspheric cornea, has an ideal apical tear thickness of between 15 and 20 microns, any volume of tear thickness under 15 to 20 microns will not be visible and will appear as black.[1-5] In regards to otho-keratology lenses, the lens is assumed to have an apical clearance of 5 to 15 microns.[1] The findings of this study indicates a tear layer thickness of seven microns was viewed with slit lamp biomicrosopy in two out of the three lenses tested, exhibiting seven microns of tear thickness (Table 1). All tear layer thickness measurements greater than seven microns (found by the caliper function of the Heidelberg OCT) were easily observable with slit lamp biomicroscopy (Appendix A). Our findings indicate a drastically thinner tear layer needed to observe a NaFl pattern than previous research indicates.

Our study also sought test the accuracy of the Medmont E300 Corneal Topographer and the Medmount Studio software in predicting tear layer thickness under a GP lens. The Medmont predicted central tear thickness, based on the GP lens parameters, was compared to the actual central tear thickness measured with the Heidelberg OCT. The median difference between the actual and predicted tear thickness was found to be 4.5 microns with a standard deviation of 6.77 microns and a standard error of 2.50 microns. Also, when comparing actual and predicted tear layer thickness measurements, the chi squared test indicated a p value of 3.098E-07. The p value indicated a strong correlation between the actual and predicted results which was clinically significant.

Anterior segment OCT demonstrates a reliable way to measure tear layer thickness under GP contact lenses and the results are highly repeatable. [7] Our findings indicated anterior segment OCT imaging provided a clear view and accurate measurement of the tear layer under the lens, allowing for the thickness of the tear layer to be evaluated using the caliper function (Appendix A). The findings of our study are vital in regards to fitting ortho-keretology GP lenses where a dark area of central bearing is needed for an adequate fit. When fitting ortho-keretology lenses, the NaFl pattern is not visible in the central 3.0mm of the lens.[1] Our findings indicate anterior segment OCT imaging may be accurately utilized in the fitting process to insure central bearing and corneal chaffing is not occurring during the treatment period, thus providing a healthy lens fit. Our study also found tear layer thickness as thin as seven microns can be viewed with slit lamp biomicroscopy. Our study indicates there is a much higher probability of lens chaffing and lens bearing on the cornea when no NaFl pattern is viewed due to the tear film thickness being less than seven microns and not the 15-20 microns previous research indicates. Thus, in order to insure adequate corneal health with the lens fit, NaFl staining must be viewed with biomicroscopy. It is important to keep in mind the small sample size of our study. Additional research must be conducted to further confirm the ability to accurately determine tear thickness using OCT imaging and the minimum tear layer thickness needed to accurately observe a NaFl staining pattern.

The results from our study find the Medmont Studio software is able to accurately predict tear layer thickness under GP lenses. The topographer uses placoid rings to provide a detailed map of the corneal surface, then in conjunction with the lens parameters, predicts the tear thickness under the lens. The accuracy of the Medmont Studio software is highly dependent on the quality of the placoid rings.[8] Distortions in the rings due to tear break up and corneal scarring, decrease the accuracy of the Medmont Studio's prediction capabilities.[8] In order to use the software effectively, practitioners must ensure the placoid rigs are clear and parallel. Furthermore, GP lens manufacture designs that are not taken into account by the program can lead to irregularities in the predicted vs actual tear film thickness data. Our study only looked at standard tri-curve lens design which was included in the software, thus the latter was not a variable in the study.  In order to accurately predict tear film thickness using the software, lens manufactures must include additional lens design parameters in the prediction programs to keep up with the advances in lens technology.

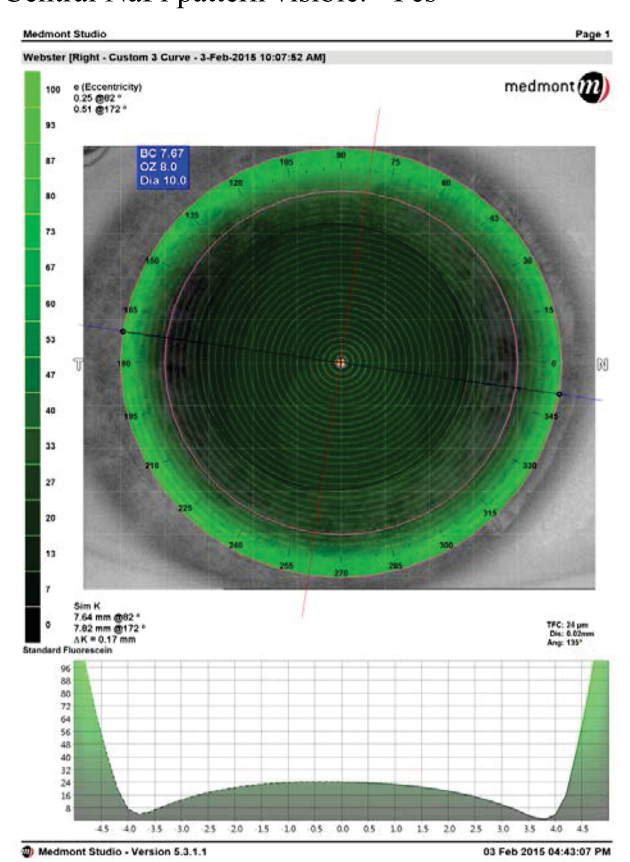
In conclusion, the minimum tear layer thickness necessary to view NaFl staining under a GP lens was seven microns contrary to previous research. Anterior segment OCT was able to accurately measure central tear layer thickness under a GP lens and the Medmont Studio soft wear was able to accurately predict the tear thickness under the lens. The software is a viable option in assessing NaFl staining prior to placing the lens on the patient’s eye, thus reducing the number of diagnostic lenses utilized before a successful fit is obtained.

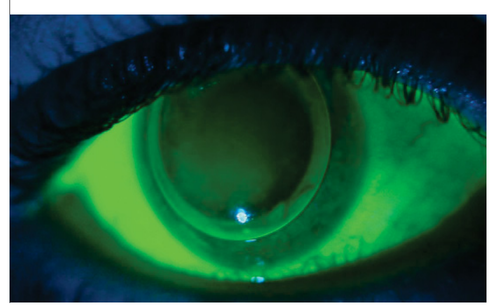
REFERENCES

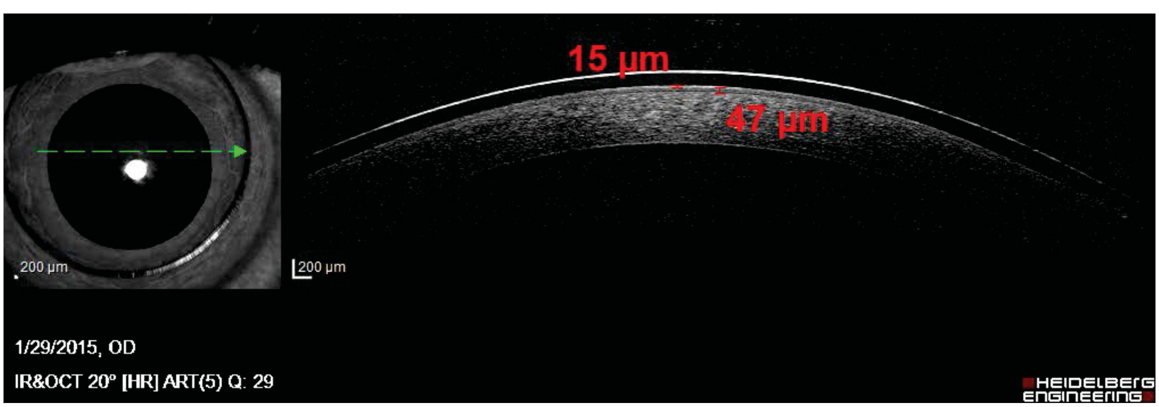

1. Mountford J, Cho P, Chui WS. Fluorescein Pattern Analysis a Valid Method of Assessing the Accuracy of Reverse Geometry Lenses for Ortho-Keratology. Clin Exp Optom 2005: 88:1:33-8
2. Mountford J, Caroline PJ, Noach D. Corneal topography and orthokeratology: Prefitting evaluation. Contact Lens Spectrum. 2002: 17: 38-44.
3. Bennett ES, Henry VA. Clinical Manual of Contact Lenses. Philadelphia: Lippincott Williams & Wilkins; 2009.
4. Guillon M, Sammons W. Contact Lens Design. Contact Lens Practice, Chapman & Hall, London 1994:87-112.
5. Young G. Fluorescein fit in rigid lens evaluation. ICLC 1988; 15: 95-110.
6. Carney LG. Luminance of fluorescein solutions. Am J Optom Arch Am Acad Optom. 1972; 49: 200-204
7. Elbendary A, Samura WA. Evaluation of Rigid Gas Permeable Lens Fitting in Keratoconic Patients with Optical Coherence Tomography. Graefes Arch Clin Exp Ophthalmol 2013: 251:6:1565-70
8. Sindt CW, Grout TK, Kojima, R. Evaluating virtual fitting for Keratoconus. CL Spectrum. 2011: 21-24

APPENDIX A. Tear Layer Thickness and Analysis

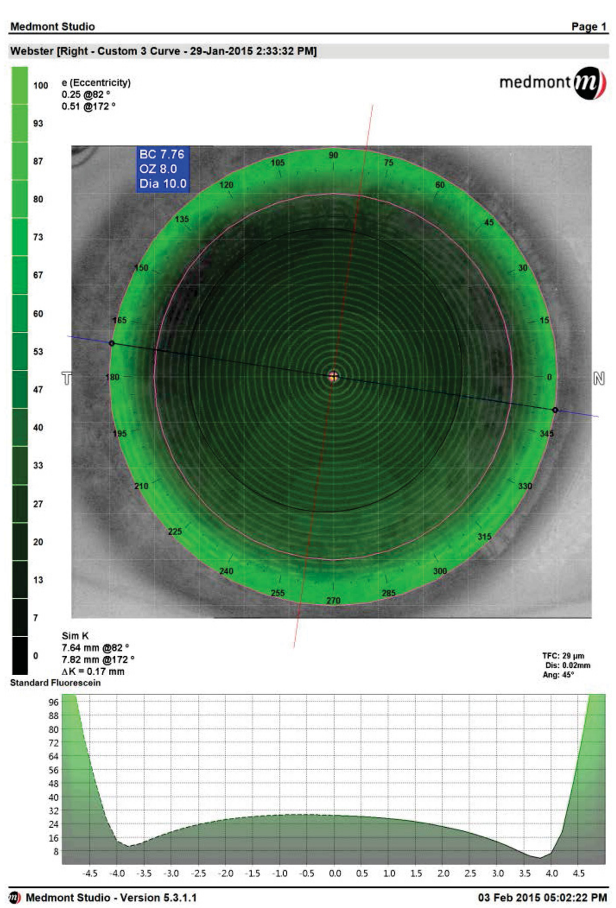
**Patient 1 Lens 1**
OD:
Sim K's: 7.64 @ 082; 7.82 @ 172
Fit with lens #1: BC 7.67mm, Dia 10mm
Predicted central corneal tear thickness: 25 microns
Actual central corneal tear thickness: 15 microns
Central NaFl pattern visible: Yes

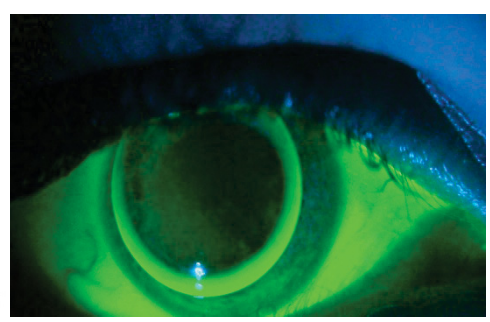


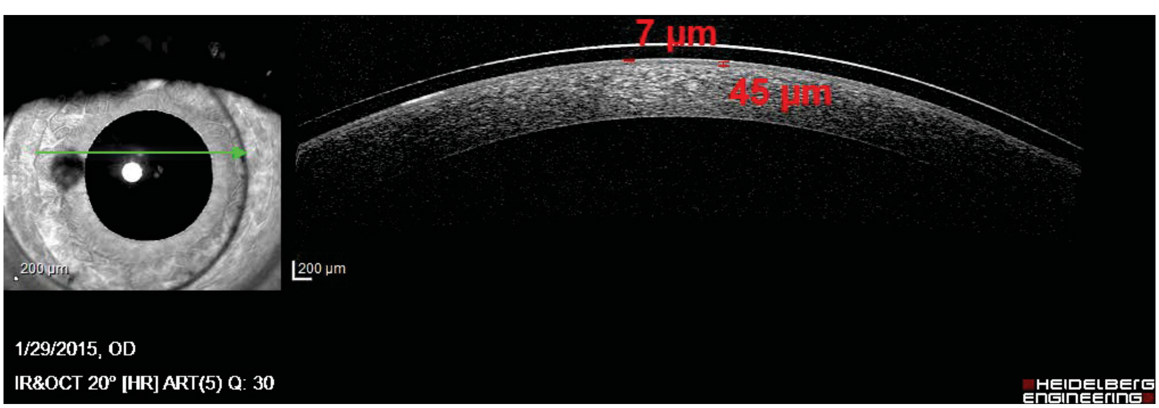





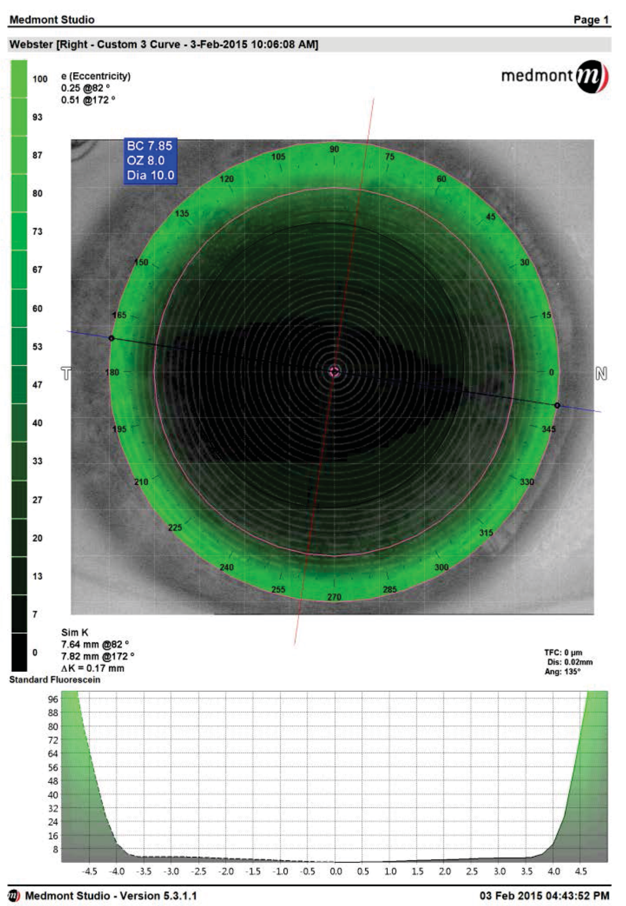
**Patient 1 Lens 2**
OD:
Sim K's: 7.64 @ 082; 7.82 @ 172
Fit with lens #2: BC 7.76mm, Dia 10mm
Predicted central corneal tear thickness: 28 microns
Actual central corneal tear thickness:  7 microns
Central NaFl pattern visible:  Yes

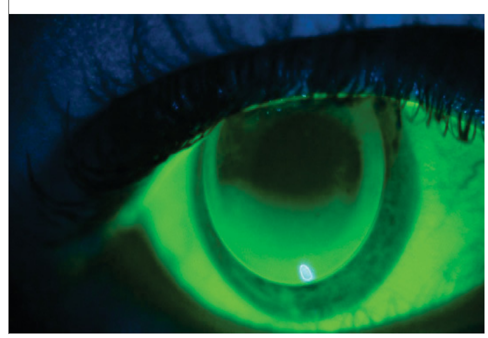


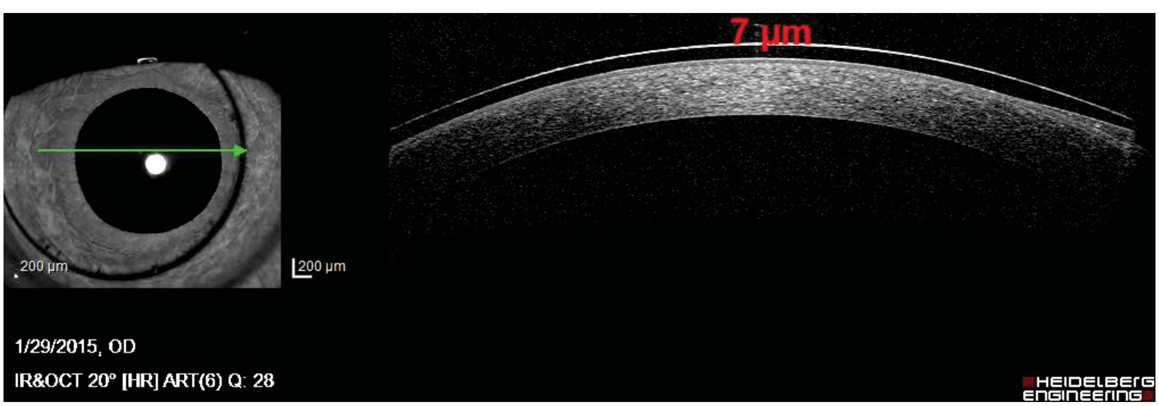





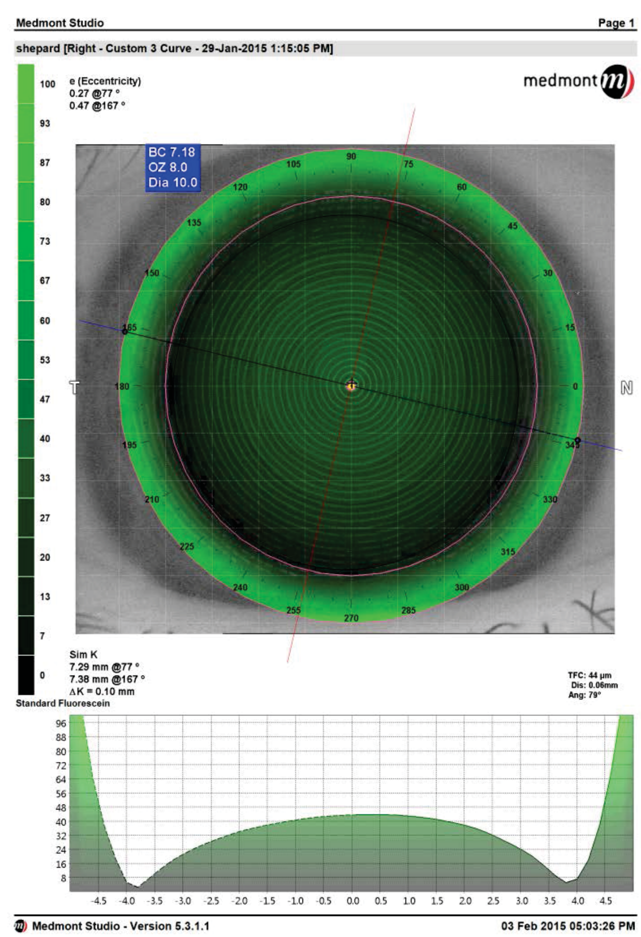
**Patient 1 Lens 3**
OD:
Sim K's: 7.64 @ 082; 7.82 @ 172
Fit with lens #3: BC 7.85mm, Dia 10mm
Predicted central corneal tear thickness: 3 microns
Actual central corneal tear thickness: 7 microns
Central NaFl pattern visible: No

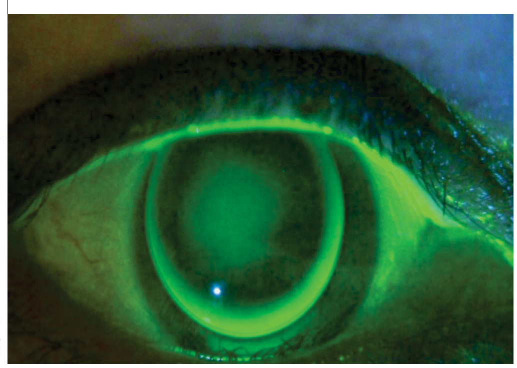


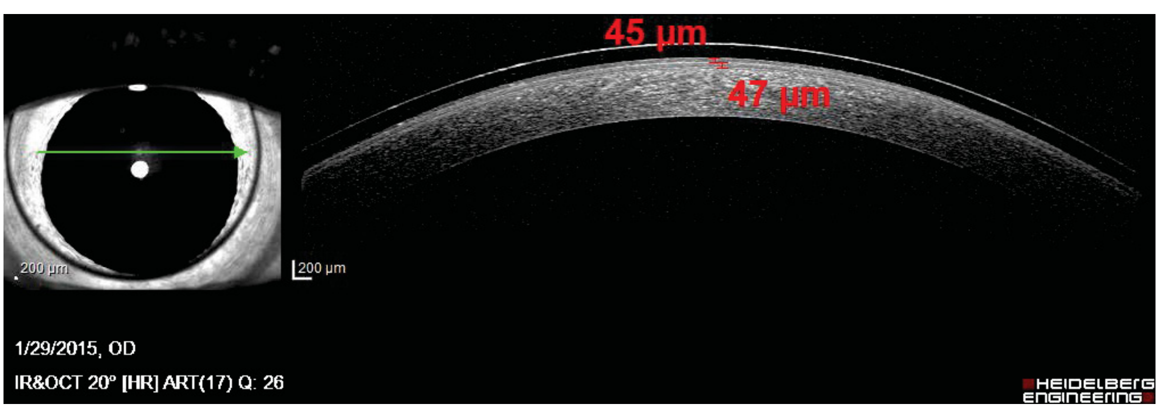





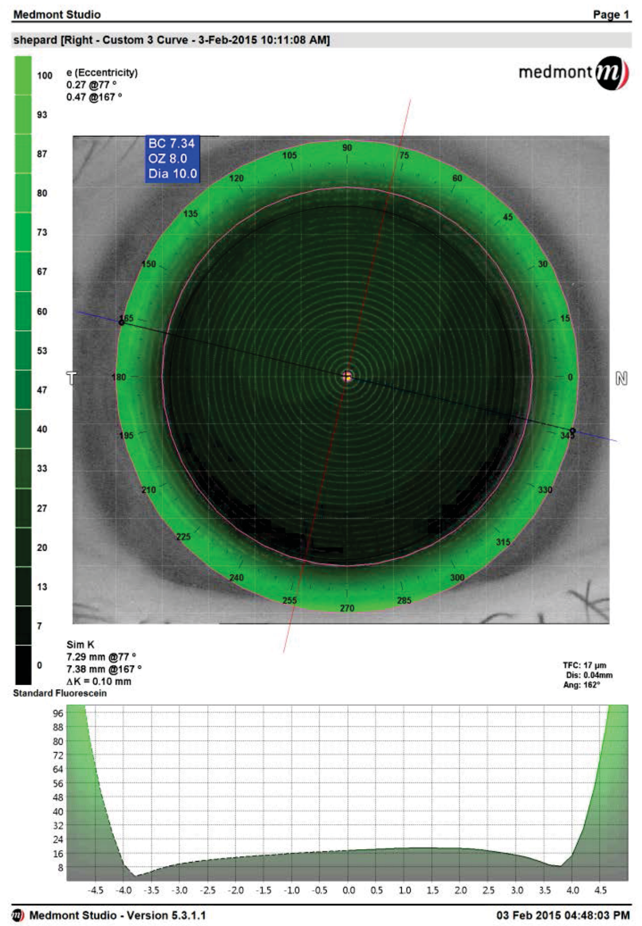
**Patient 2 Lens 4**
OD:
Sim K's: 7.29 @ 077; 7.37 @ 167
Fit with lens #4: BC 7.18mm, Dia 10mm
Predicted central corneal tear thickness: 45 microns
Actual central corneal tear thickness:   45 microns
Central NaFl pattern visible:  Yes

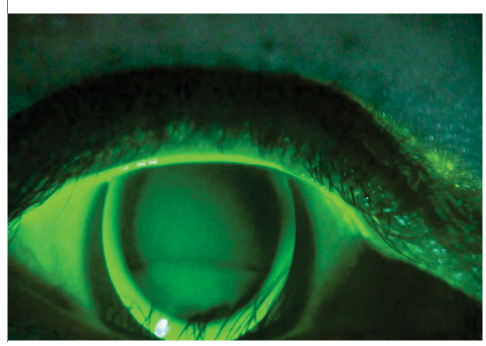


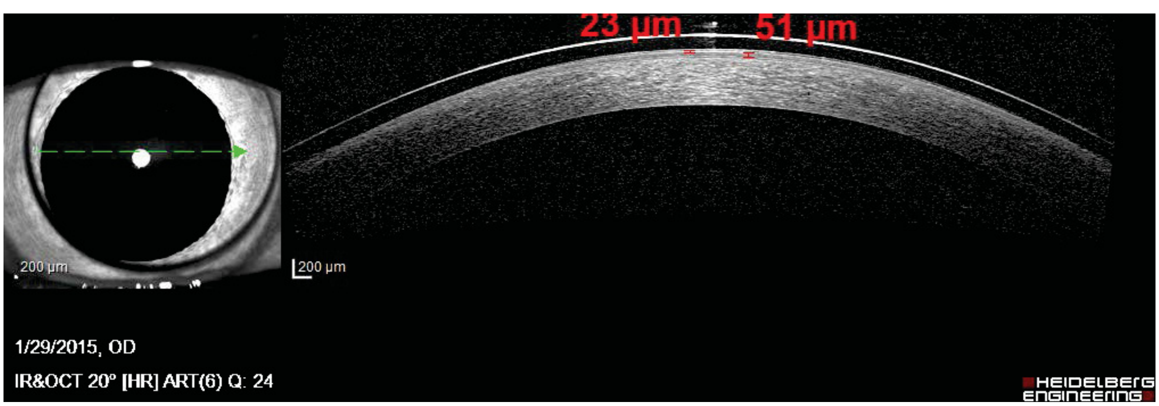





**Patient 2 Lens 5**
OD:
Sim K's: 7.29 @ 077; 7.37 @ 167
Fit with lens #5: BC 7.34mm, Dia 10mm
Predicted central corneal tear thickness: 19 microns
Actual central corneal tear thickness: 23 microns
Central NaFl pattern visible: Yes





**Patient 2 Lens 6**
OD:
Sim K's: 7.29 @ 077; 7.37 @ 167
Fit with lens #6: BC 7.50mm, Dia 10mm
Predicted central corneal tear thickness: 2 microns
Actual central corneal tear thickness: 7 microns
Central NaFl pattern visible: Yes