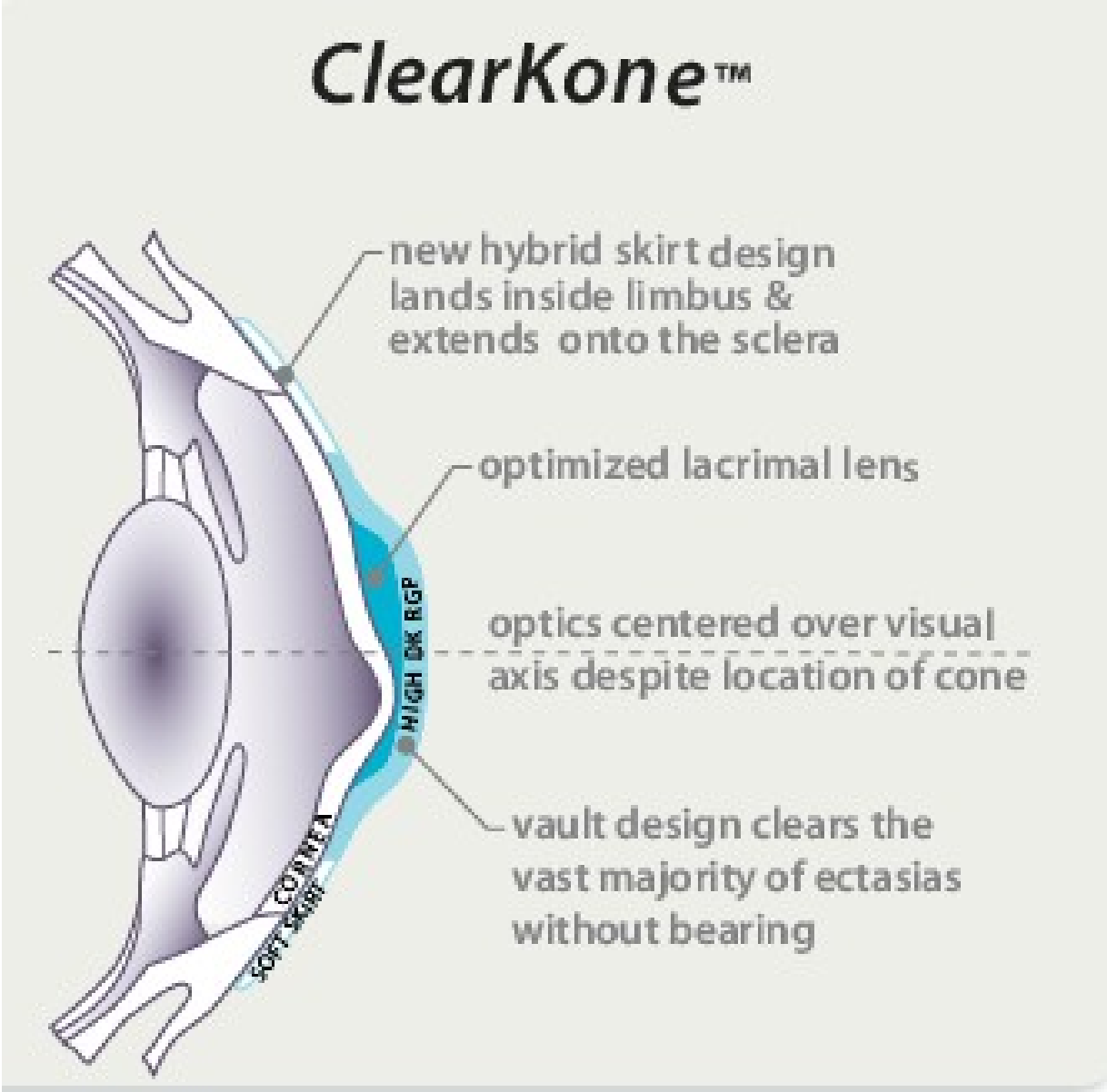
Clinical Fit Training

ClearKone™
Restoring vision. Changing lives.™

Product Overview

Lens Design


ClearKone™
new hybrid skirt design lands inside limbus & extends onto the sclera
optimized lacrimal lens
optics centered over visual axis despite location of cone
vault design clears the vast majority of ectasias without bearing
HIGH DK RGP
CORNEA
SOFT SKIRT

Patent-pending Vault design

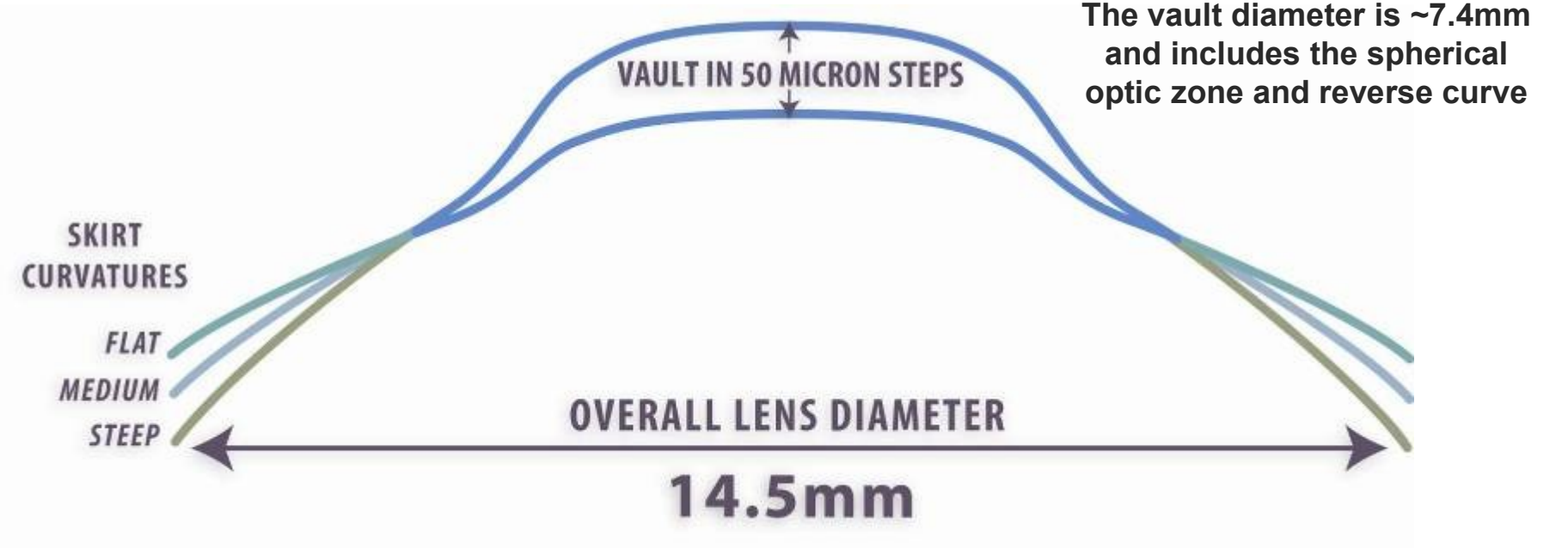
- The vault value describes the overall relative depth of the lens on the cornea.
- The goal is to determine the appropriate vault that provides complete apical clearance.
- Design gives the ability to “vault” over the vast majority of ectasias without bearing
- Design results in substantially lower lens power:
  - Closer lens alignment to the cornea in conjunction with the lacrimal lens results in significantly lower powers
  - Enhances optical quality and improves Visual Acuity for the patient
  - Lower lens power in conjunction with superior centration substantially reduces coma and minification

New Hybrid Skirt Design

- *ClearKone* incorporates a new reverse geometry hybrid design that:
  - Promotes all-day tear flow and movement
  - Facilitates ease of removal
  - Provides all-day comfort and corneal health
- The lens lands on both the soft, defined as Outer Landing Zone (OLZ) and rigid, defined as Inner Landing Zone (ILZ) materials. The landing area is divided by the junction of the hybrid lens.

Vault and Skirt Curvature

ClearKone is available in 11 different vaults of which each can be ordered in 3 different skirt curvatures; flat, medium and steep.



The vault diameter is ~7.4mm and includes the spherical optic zone and reverse curve

The fit of the vault is independent of the fit of the skirt curve. Each should be fitted separately.

ClearKone Diagnostic Set

22 lens diagnostic set:

- 11 Vaults: 100 – 600μ in 50μ steps
- 2 Skirt Curvatures for each Vault: Medium and Steep
- DMV scleral cup inserter
- NaFL illuminating cobalt pen light
- Wratten filter
- Fitting Guide

Each Dx lens has laser markings that indicate its lens type, vault and skirt curvature

Streamlined Fitting Process

- Linear vault fitting process minimizes chair time
  - Power of Dx lenses are calibrated to change at the same rate as the vault
  - All lenses within the fitting set will require the same over-refraction
    - Calculations that are normally needed with other lenses are unnecessary
    - Once the over-refraction of a Dx lens has been determined, every other lens in the set will take the same over-refraction
- Requires no topography

Fitting *ClearKone* is both consistent and predictable and requires minimum chair time and remakes.

Patient Candidates

ClearKone is Ideal for:

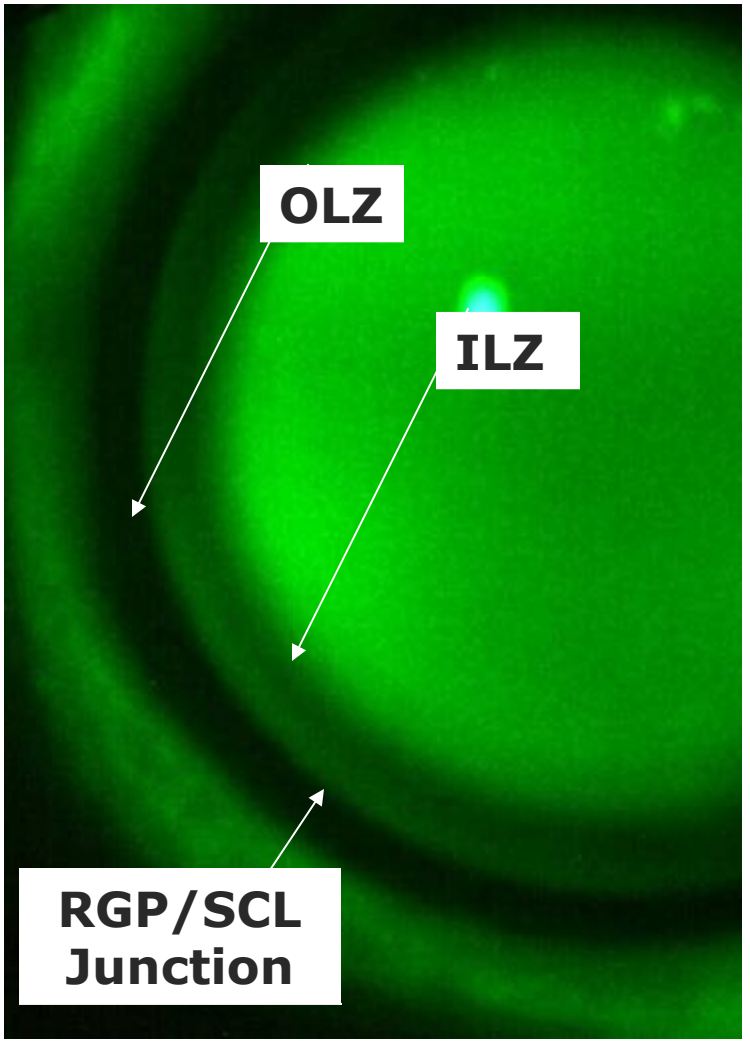
- Oval/nipple keratoconus (emerging to advanced)
- Central and the majority of decentered cones

Fitting success may be possible for:

- Globus
- Pellucid Marginal Degeneration
- RK, PRK, LASIK induced ectasia
- Most irregular corneas

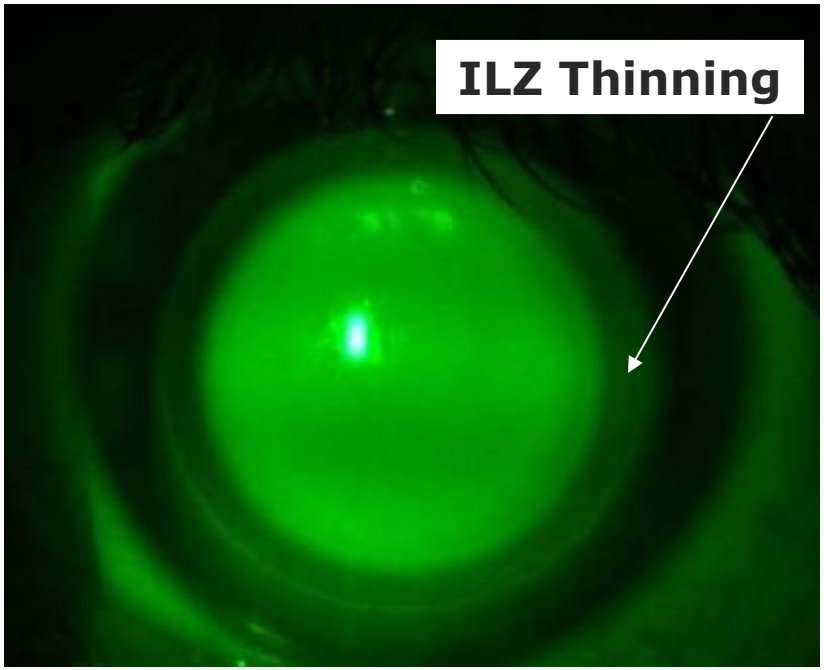
ClearKone Terminology

- **Vault** - The vault value describes the overall relative depth of the lens
- **Outer Landing Zone (OLZ)** - Portion of the lens that lands on the soft material
- **Inner Landing Zone (ILZ)** – Portion of the lens that lands on the RGP material



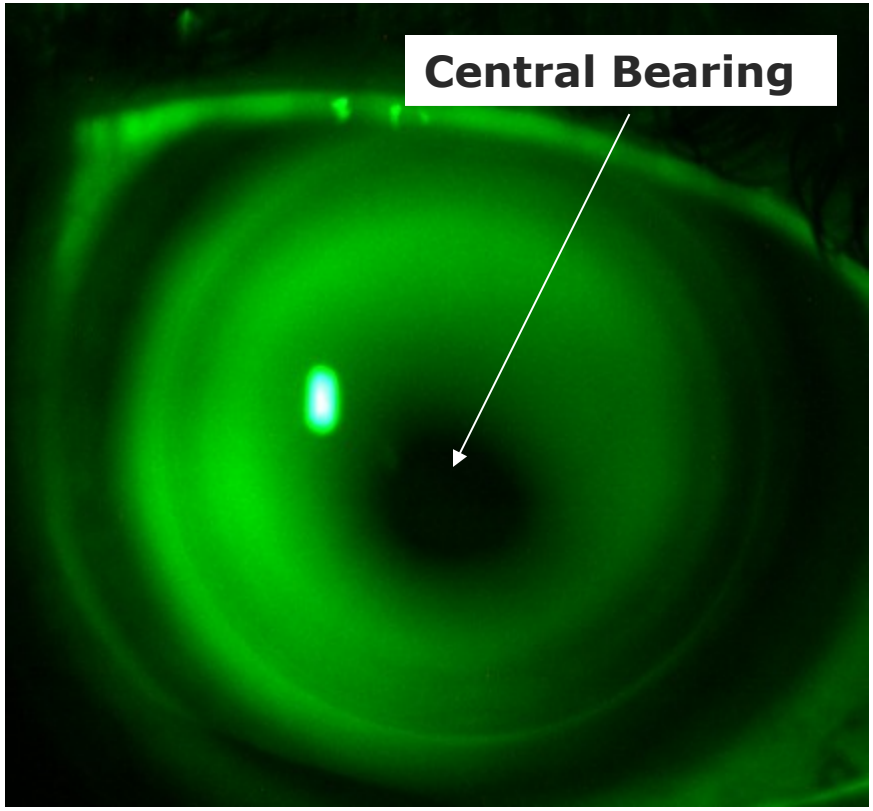
ClearKone Terminology (con't)

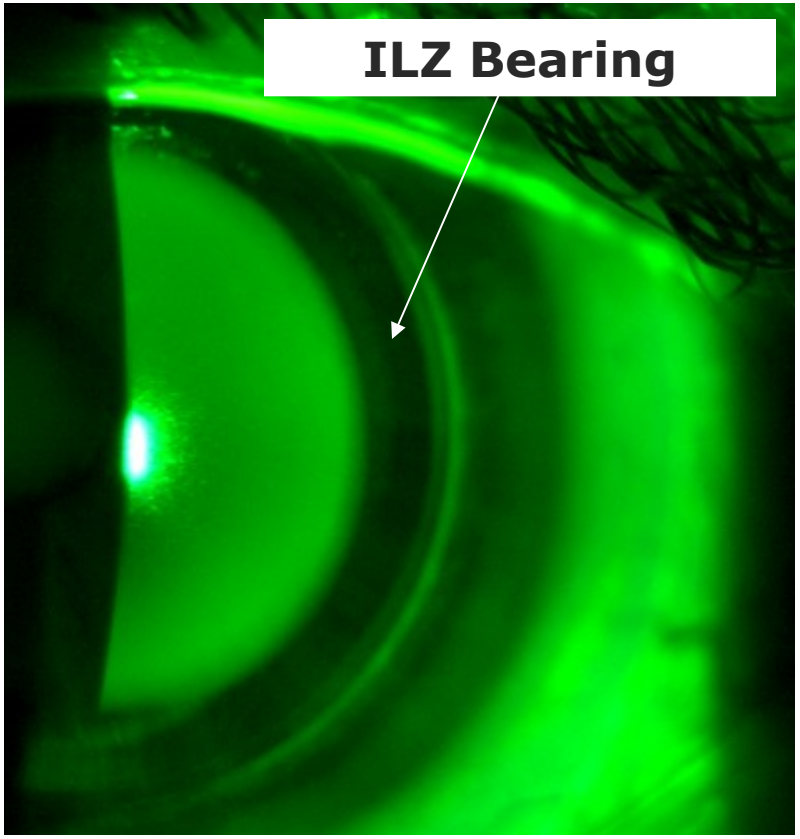
- **NaFL Thinning** – refers to the appearance of a NaFL pattern in a lens with apical clearance to the cornea. A decrease of thickness of the tear layer will cause a decrease in fluorescence, resulting in an area of NaFL having a darker appearance than the area around it (Not black as with bearing)



ClearKone Terminology (con't)

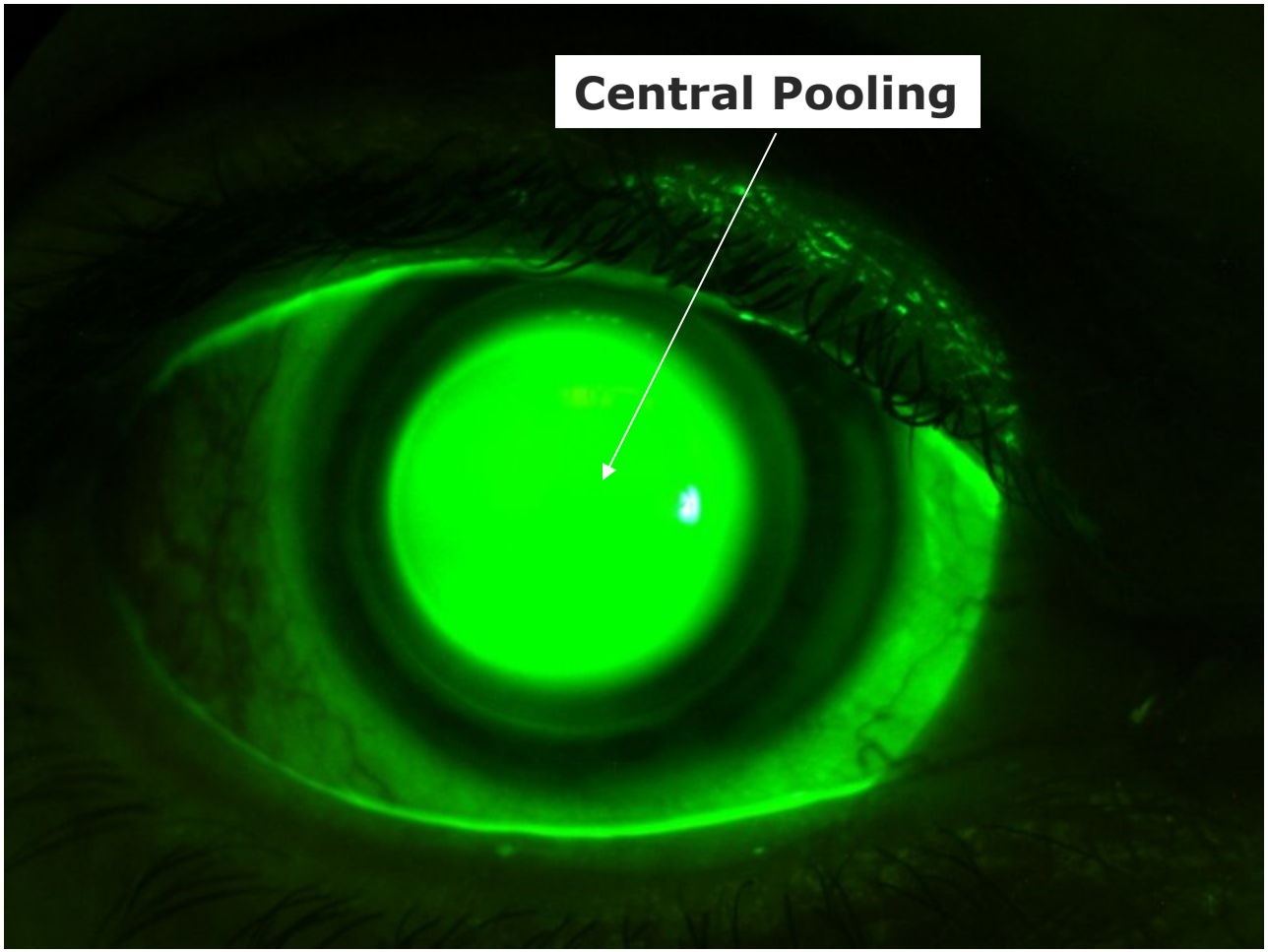
- **Bearing** – a black appearance as a result of contact of the cornea with the posterior of the lens, eliminating the presence of NaFL and the possibility of any fluorescence.





ClearKone Terminology (con't)

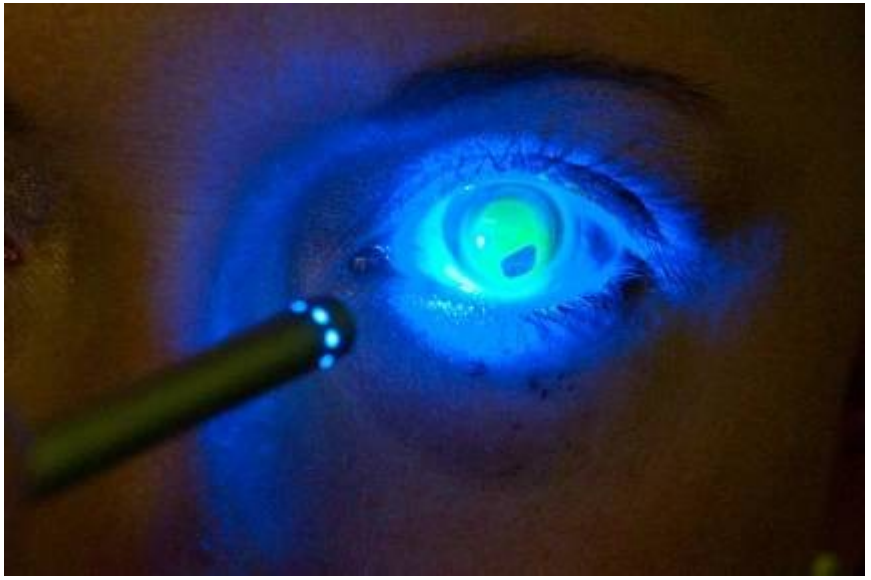
- **<u>Pooling</u>** – complete uniform appearance of the NaFL layer (no variation in brightness)



Fitting Process

Bubbles

- Areas within the optic zone could result in trapped air bubbles if lens not inserted properly
- Air bubbles affect the appearance of NaFL pattern - critical to eliminate them prior to evaluating fit
- Bubbles are ALWAYS representative of an insertion error – NOT a fitting error
- Must remove lens and re-insert – making certain bowl of lens is filled to the TOP with solution



Proper Insertion Process

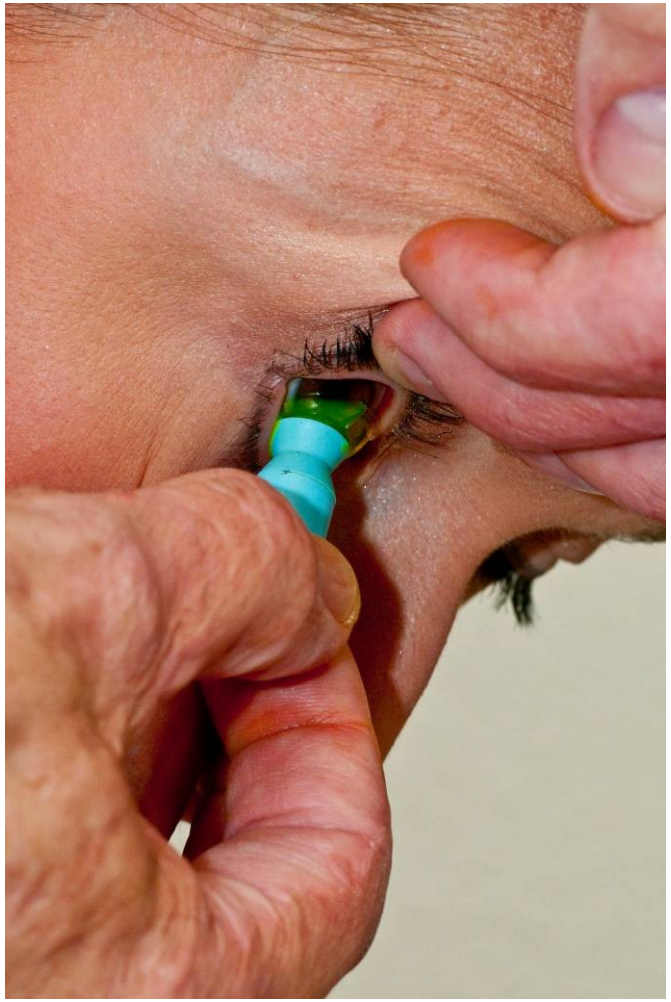
- To increase the comfort of the fluorescein and to minimize insertion bubbles, fill the bowl of the lens with 1 drop of fluorescein and fill the remainder of the bowl completely to the top with non-preserved saline.

Proper Insertion Process (con't)

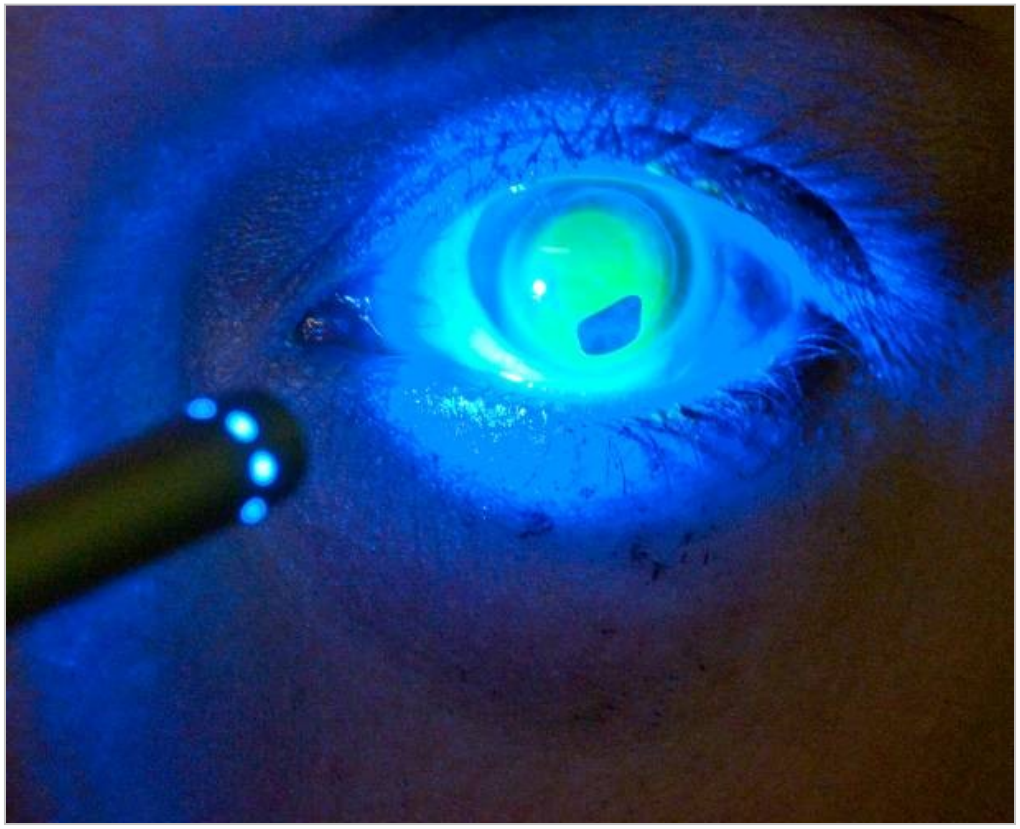
- Fill the lens while holding it horizontally on the DMV scleral cup (included in the Dx set).
- Have the patient lean forward and tuck their chin to chest. Nose perpendicular to the floor.
- Bubbles are less likely to occur if patient maintains fixated gaze straight to the floor.

Proper Insertion Process (con't)

- Retract the upper and lower lids and elevate the lens onto the center of the cornea, displacing the saline.
- **Be careful not to push the lens too forcefully upon insertion**.
  - This can induce corneal suction resulting in edema



Proper Insertion Process (cont.)



- Check for bubbles under the lens with the NaFL illuminating cobalt pen light (provided in Dx set)
- **Bubbles cannot be displaced by lens manipulation – must remove and re-insert**

Practitioner Insertion Video

Key Fitting Principles

- The fitting of *ClearKone* is based on the concept of fitting on overall sagittal depth rather than varying the base curve in relation to the irregular cornea.
  - The fit of *ClearKone* depends upon the depth of the lens clearing the elevation of the cone, rather than a match in curvature
- The fitting process involves individually fitting two different areas of the cornea:
  - Central – determining the appropriate vault needed to clear the cone and provide complete apical clearance.
  - Peripheral – determining the skirt curvature that places the proper distribution of support within the landing zones.

Evaluating NaFL Patterns

- The key to determine the proper *ClearKone* fit is to evaluate the lens/cornea relationship using high molecular weight NaFL (i.e. FluoreSoft®)
- NaFL evaluation must be done within 3-5 minutes after insertion, because the tear flow will thin the NaFL and give a false appearance/interpretation. (Should not let patient sit in waiting room for 15+ minutes)
- Critical to eliminate any central touch when fitting. Even the lightest touch or “feather touch” can cause patient discomfort.
- Critical to use a Wratten filter (provided in Dx set) to enhance the contrast of the NaFL pattern. Makes fine tuning the skirt curve much easier and will save chair time.

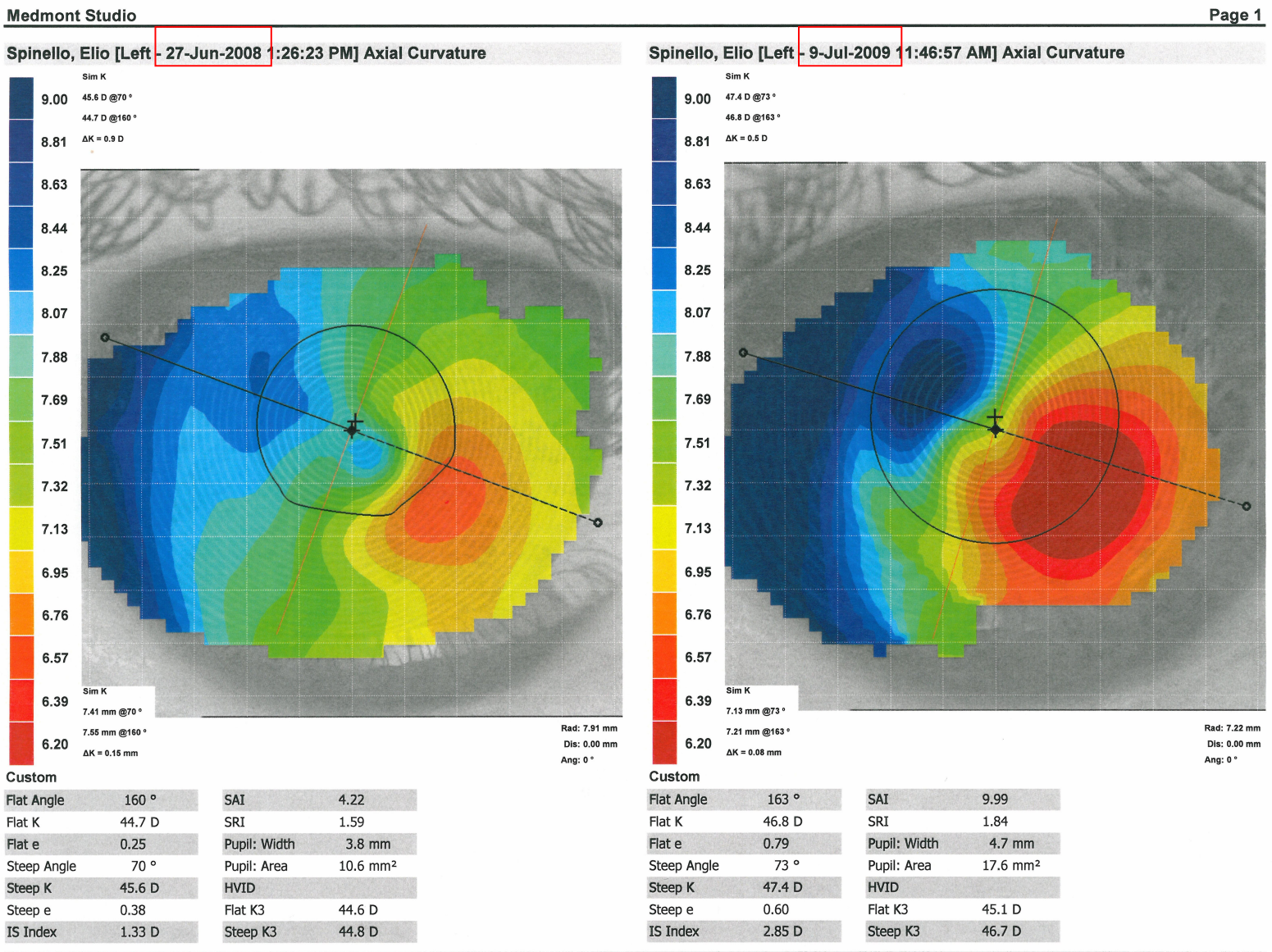
Corneal Changes

- For patients who are being re-fit from RGPs, *SynergEyes A, KC or PS (*and sometimes even soft/soft torics)
  - Once the pressure of the predicate lens is removed, the cornea will most likely return to its natural shape
  - You should expect topographical changes
  - Critical to have complete apical clearance on first fit lenses
  - On follow-up if patient complains of discomfort or reduced wear time – check for central bearing
    - May need to re-order deeper *ClearKone* lenses

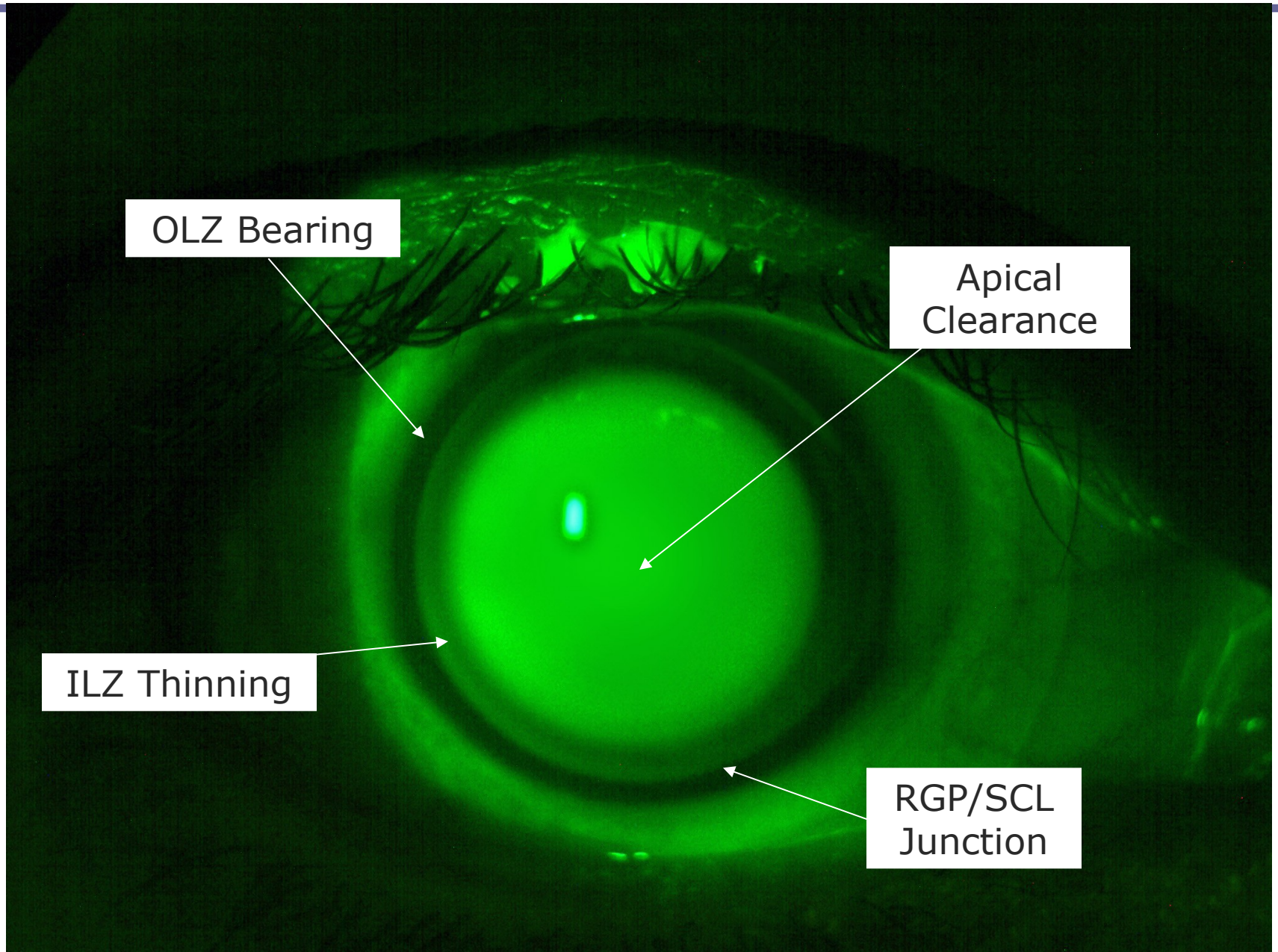
Example Topo Changes of *ClearKone* Patient

Predicate Lens: *Rose K*

Successfully Wearing *ClearKone* for over 1 year

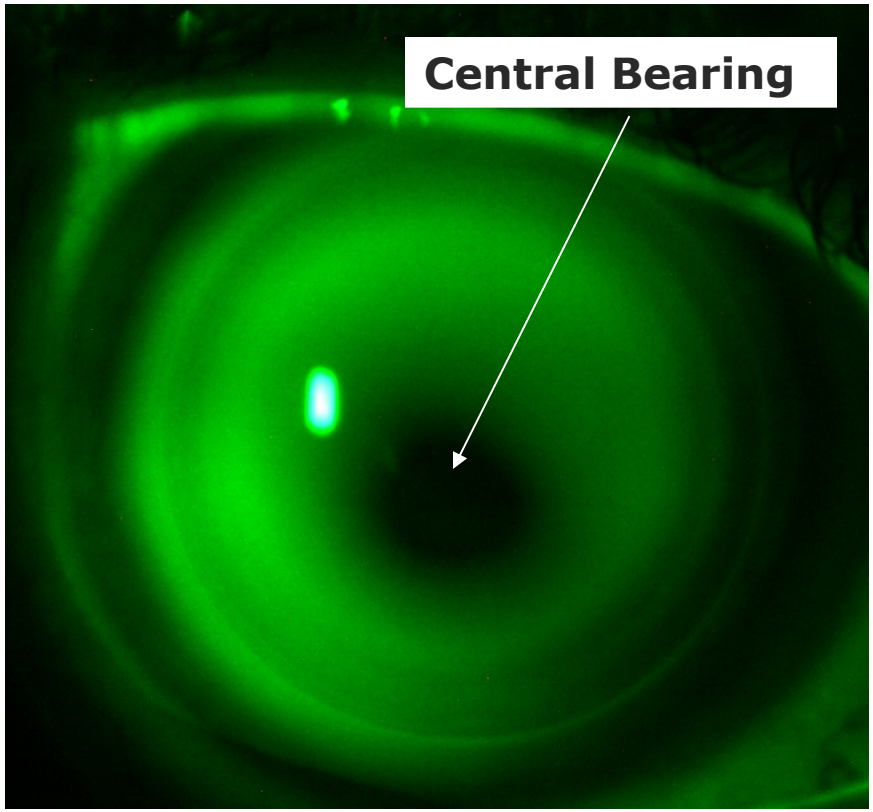


Ideal *ClearKone* Fit

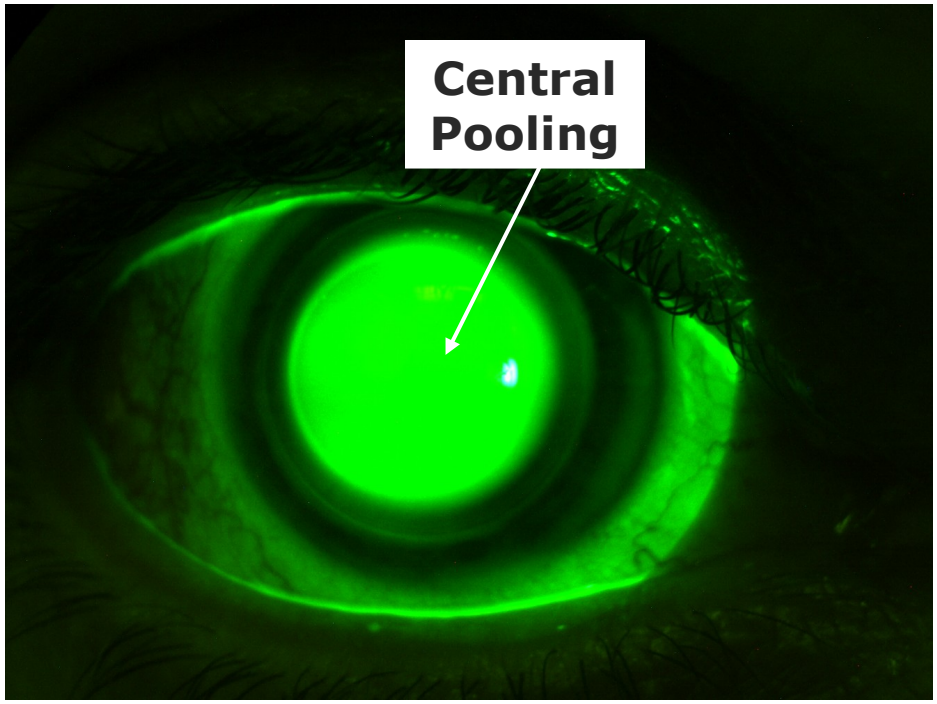


Step 1: Determine Vault

To determine the proper vault, begin with the 250μ Vault value in the Medium skirt curve and check for:

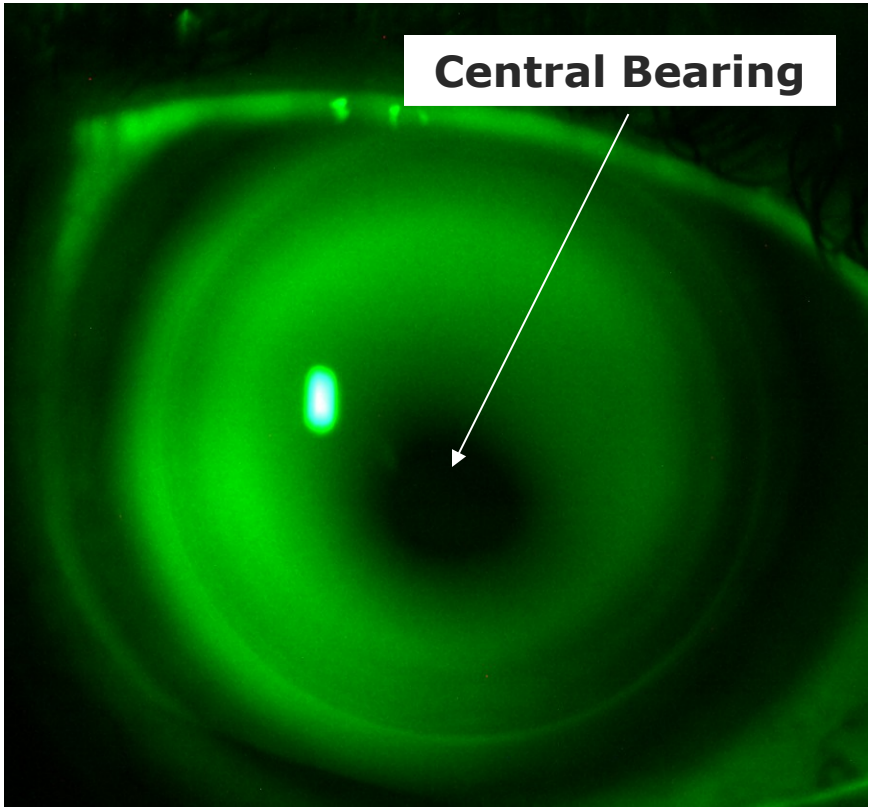


OR



Step 1: Determine Vault

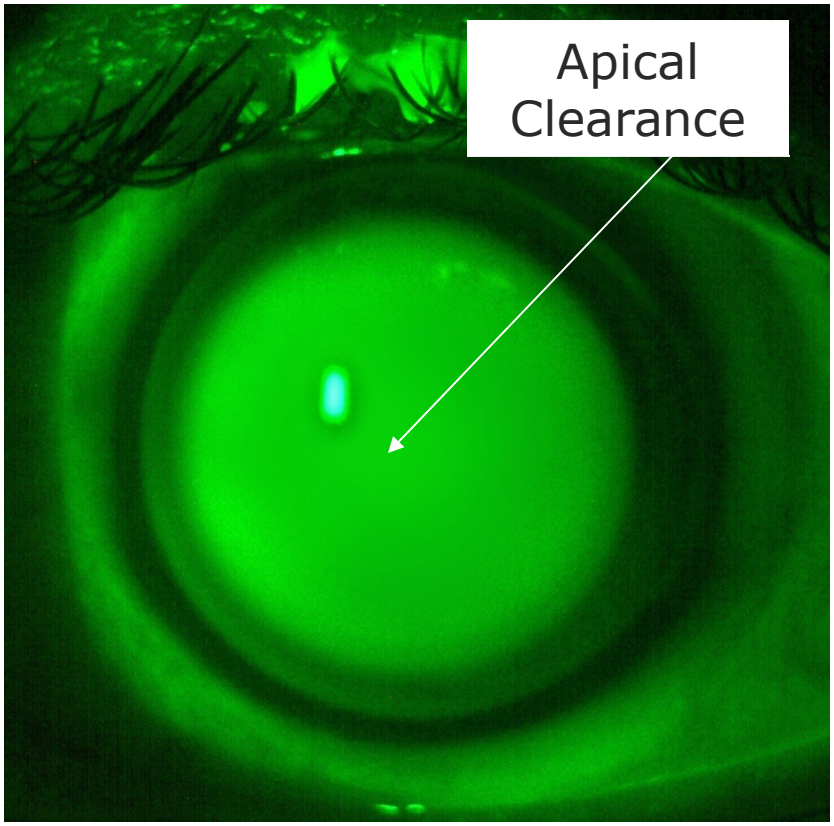
Starting point is the 250μ / medium skirt Dx lens.



Vault too shallow

If central bearing is seen, increase the vault in 100μ increments, until apical clearance is achieved.

Step 1: Determine Vault



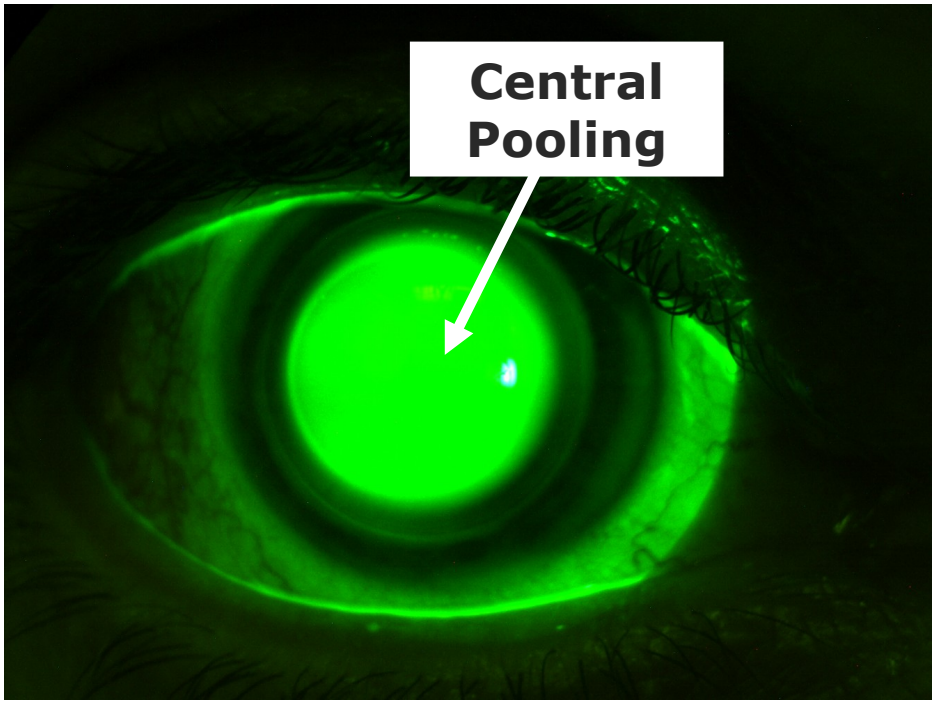
Ideal Vault Fit

- Ideal vault fit = 100µ over first bearing
- Complete apical clearance
- Remember: Even the lightest touch or “feather touch” can cause patient discomfort

After a few minutes of wear, the patient will tell you if you have bearing because the lens will not be comfortable.

Step 1: Determine Vault

At the 250μ / Medium starting point.

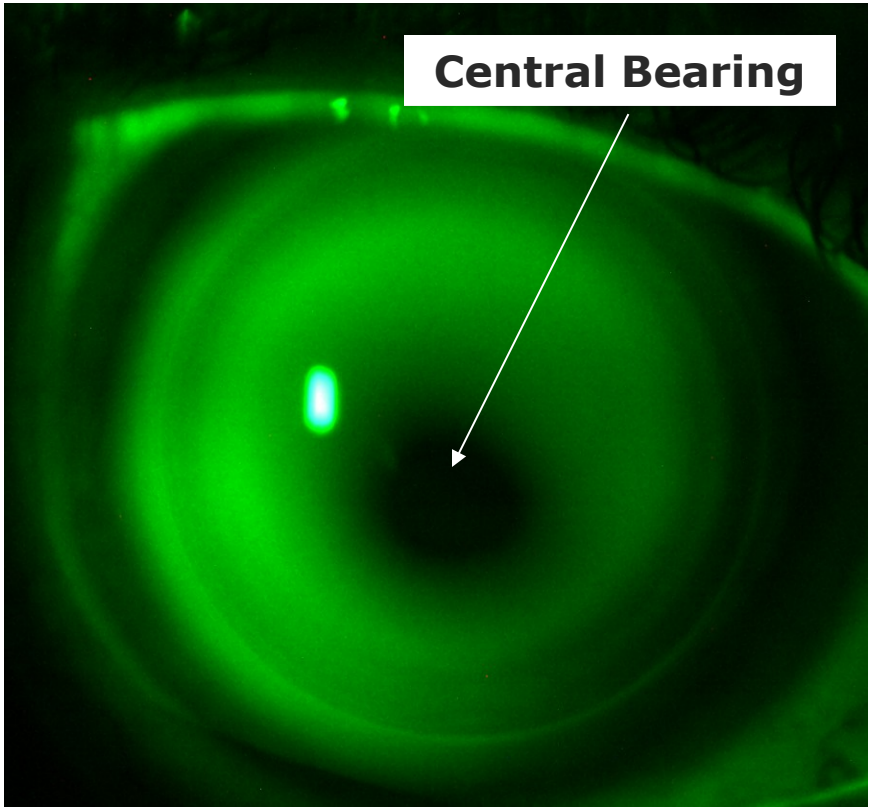


Vault too deep

If pooling is seen, decrease the vault in 100μ increments until the first bearing is observed.

Step 1: Determine Vault

Vault decreased 100µ

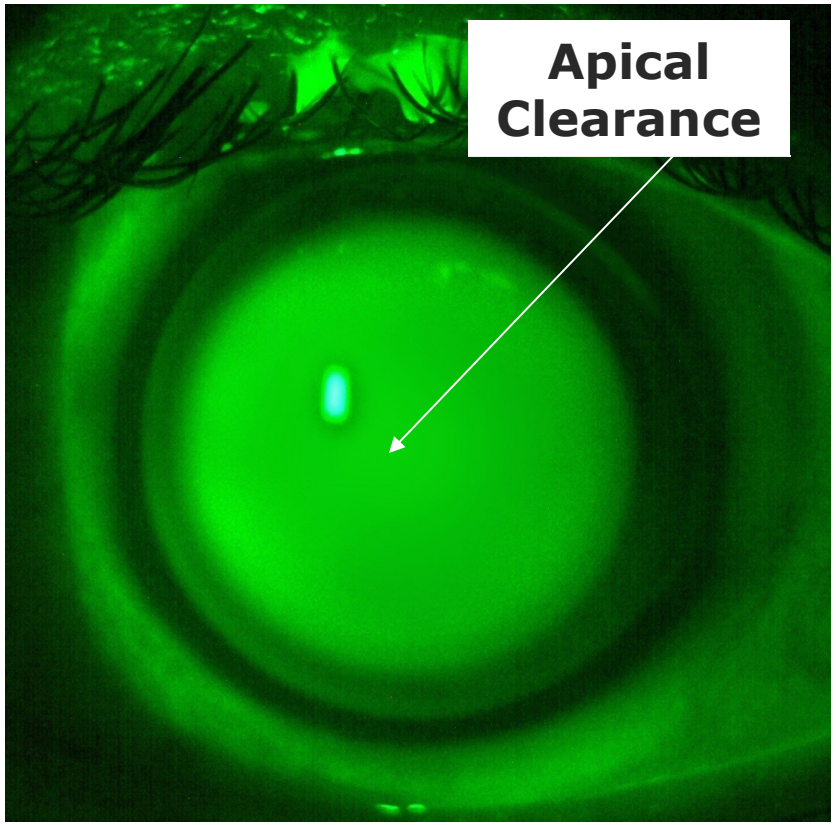


Vault too shallow

When first bearing is observed – increase the vault by 100µ and re-evaluate the corneal clearance for apical clearance.

Step 1: Determine Vault

Vault increased 100µ



Ideal Vault Fit

If the increased vault now results in apical clearance, you have reached the endpoint.

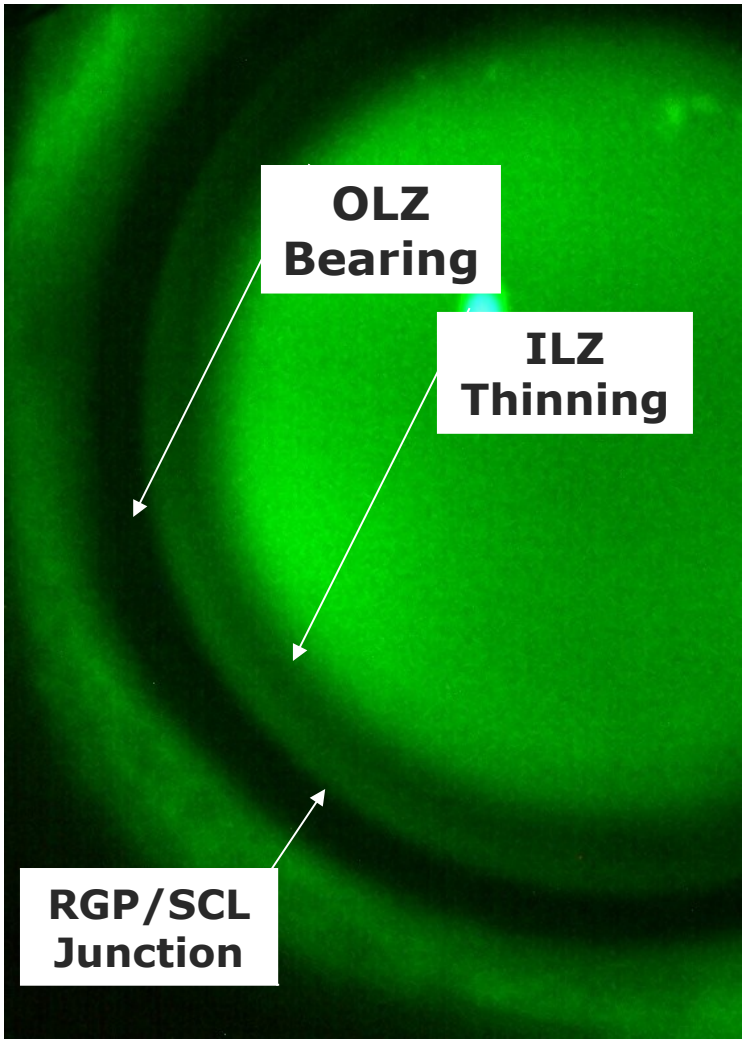
If the increased vault still results in bearing, increase the vault 100µ to reach the fitting end-point.

After a few minutes of wear, the patient will tell you if you have bearing because the lens will not be comfortable.

Step 2: Determine Skirt Curvature

- Evaluate skirt only after proper vault determined and is on eye
- GOAL: on most patients, best fit landing area achieved when NaFL thinning is observed in ILZ and bearing in the OLZ.
- Lens will exhibit movement very similar to soft lens.

Ideal Skirt Curve Fit

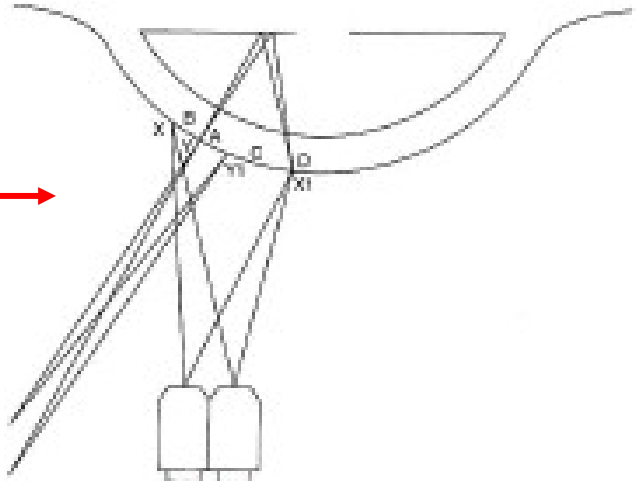


Patient comfort will greatly validate final fit

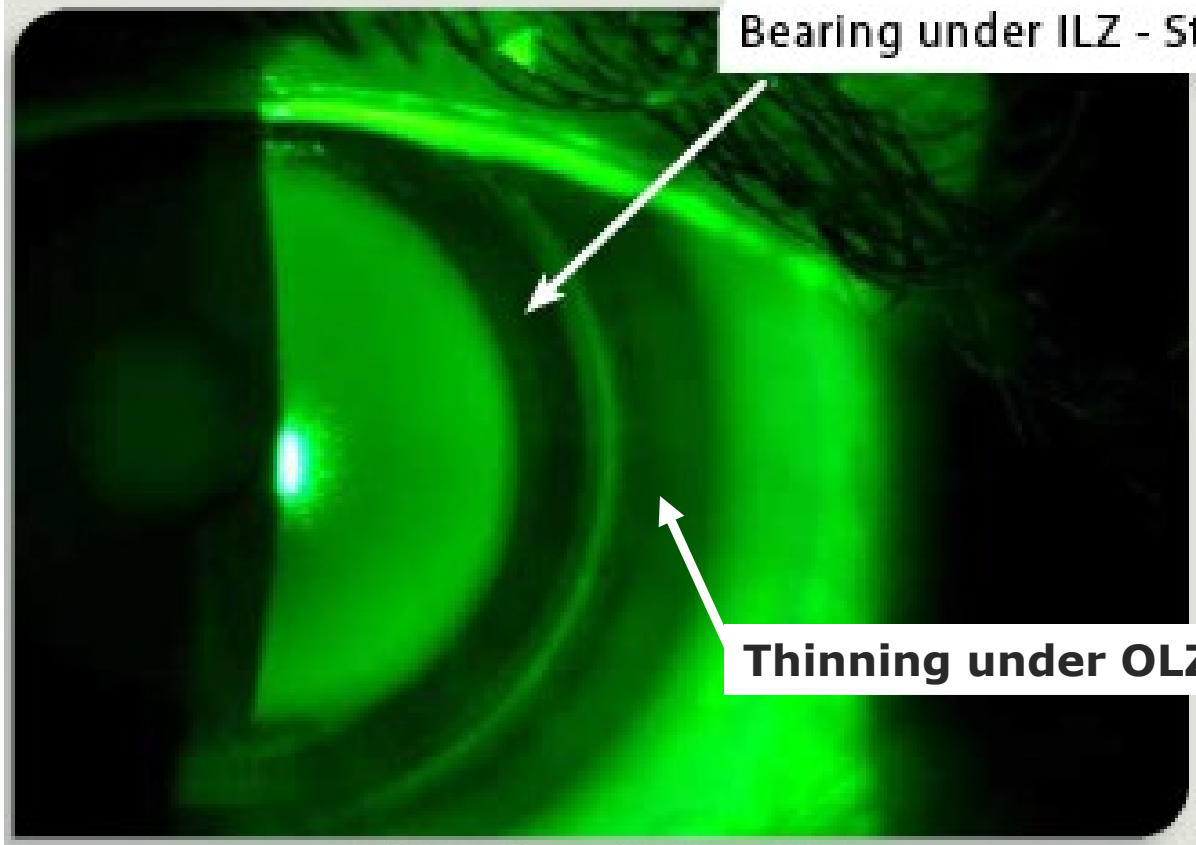
Step 2: Determine Skirt Curvature (con't)

- Start with the Medium skirt curve
- Evaluate landing area at 3 and 9 o'clock positions with the slit beam perpendicular to the area being observed
  - It is critical to have the slit beam positioned perpendicular to the area being observed in order to properly illuminate the area for evaluation

Slit beam is positioned perpendicular to the 9 o'clock position to effectively evaluate the landing zone

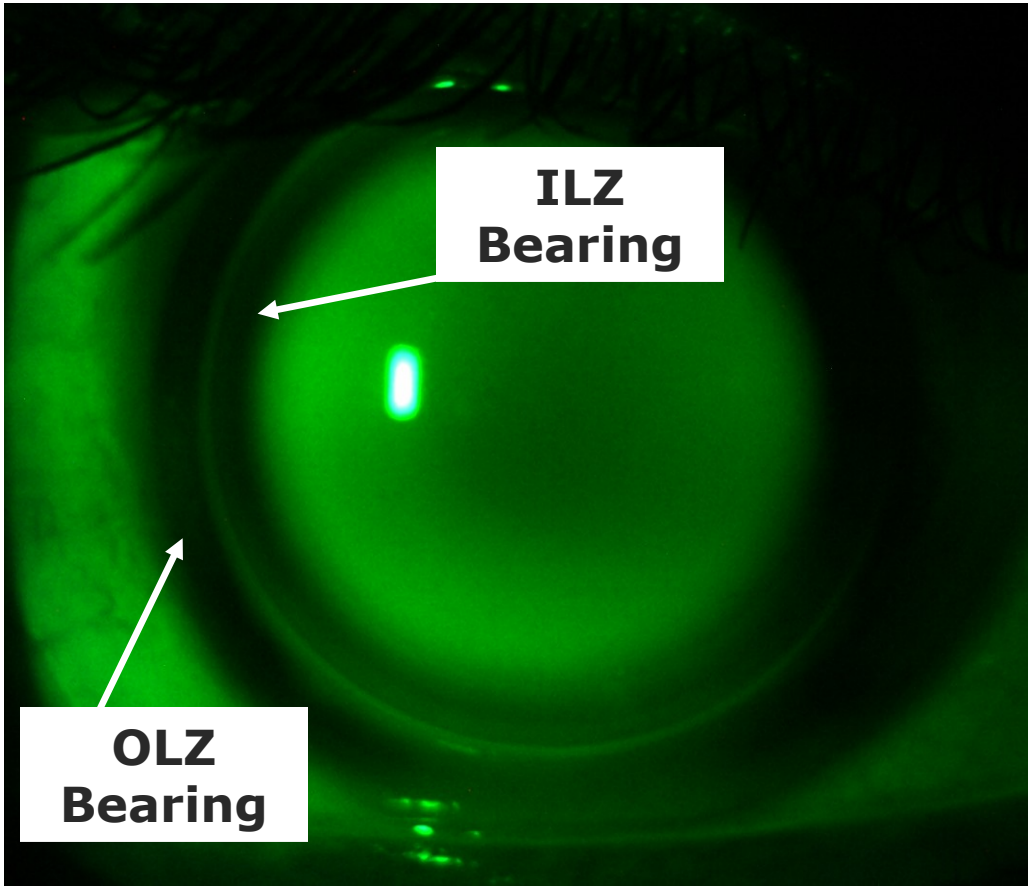


Skirt Curve too Flat



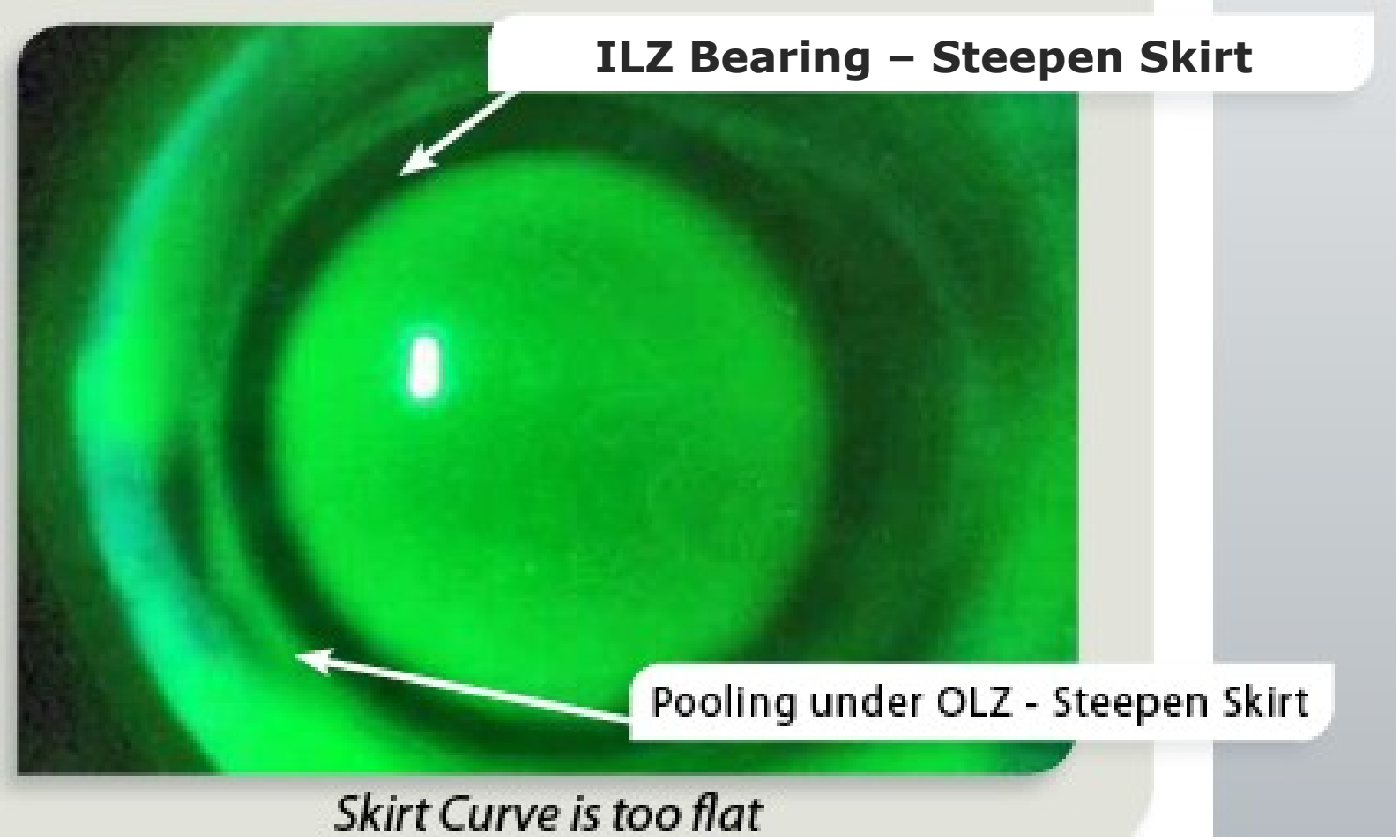
If bearing observed under ILZ and thinning observed under OLZ – change to the STEEP skirt curve

Skirt Curve too Flat



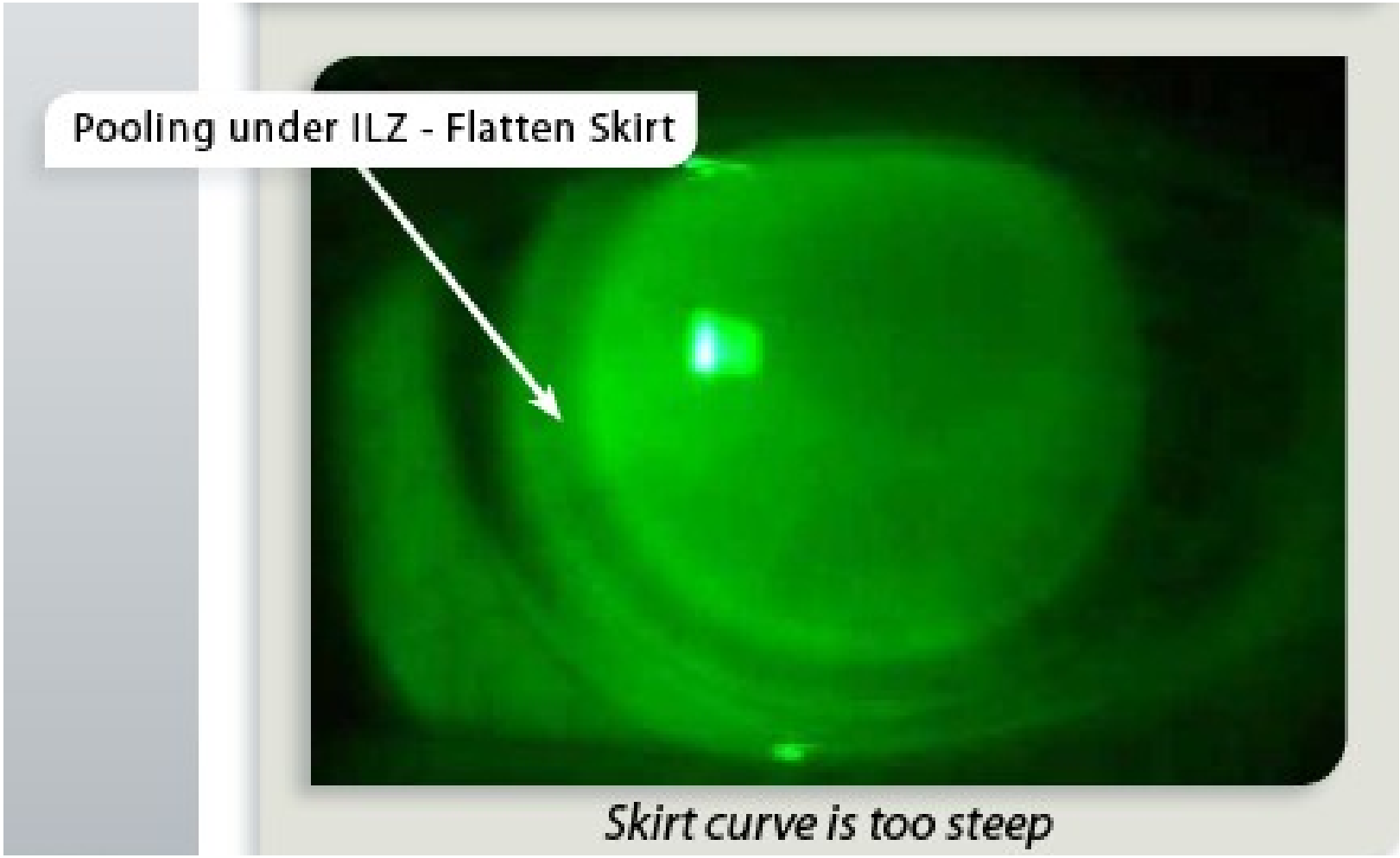
If equal bearing observed under both ILZ and OLZ – change to the STEEP skirt curve

Skirt Curve too Flat



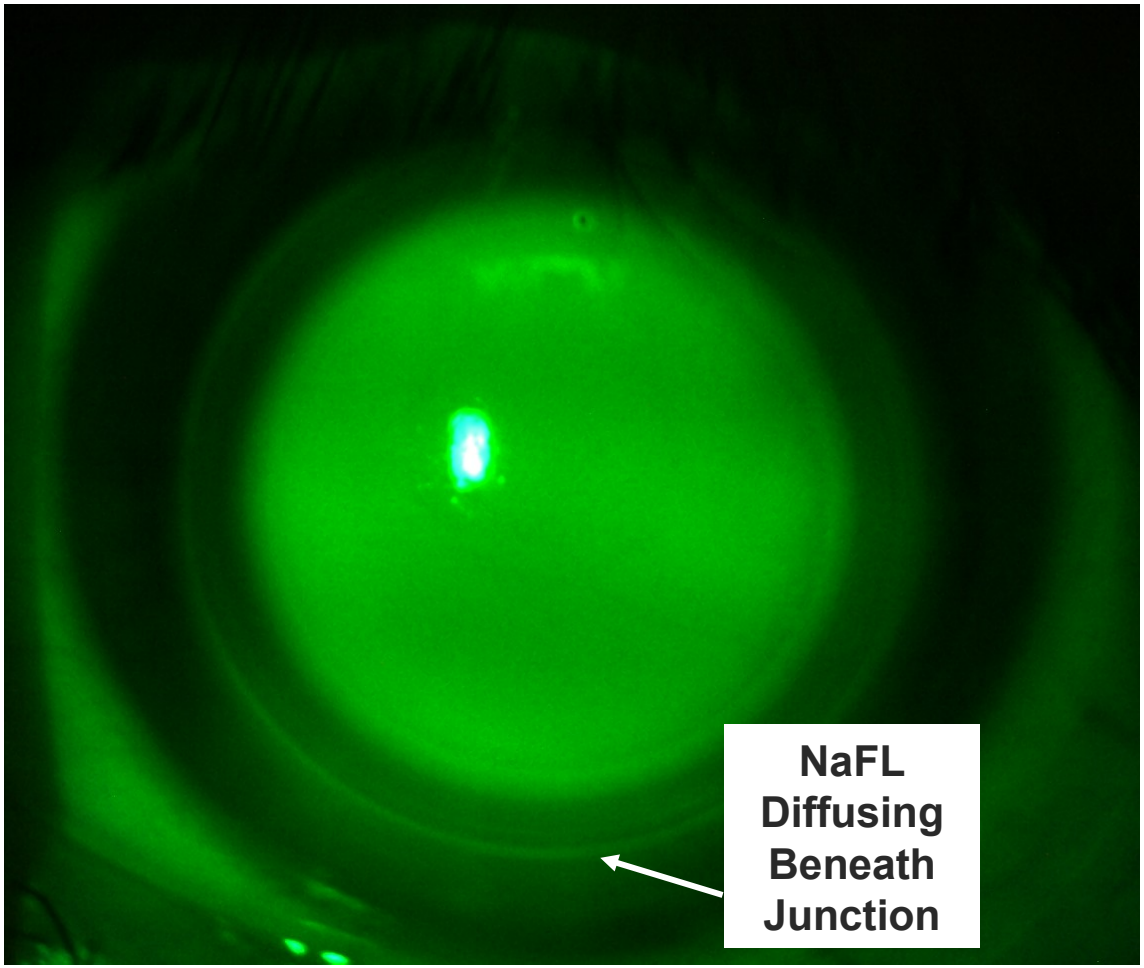
If pooling observed under the OLZ, and bearing is observed under ILZ – change to the STEEP skirt

Skirt Curve too Steep



If pooling observed under the ILZ–
order the FLAT skirt curve

Determining Proper Skirt Curvature



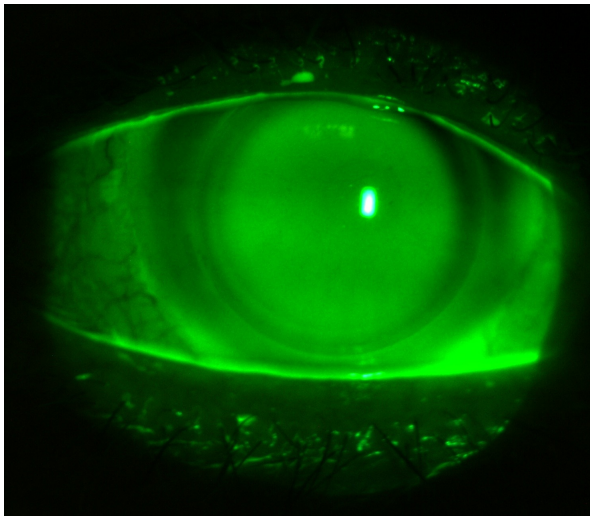
Patient comfort is optimized when NaFL pattern shows slight diffusing beneath the rigid/soft junction

Step 3: Determine Final Lens Power

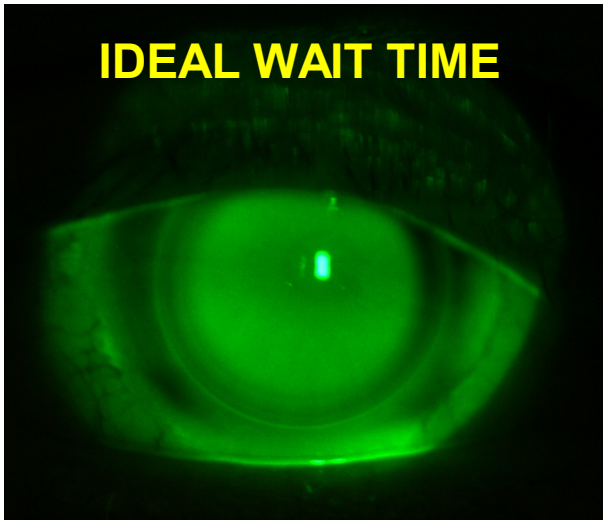
- When an ideal NaFL pattern is achieved, over-refract to determine final lens power
- If the over-refraction is greater than 4.00D, adjust for vertex distance.
- Lenses in the fitting set vary in power from -1.00D to -14.50D sphere power depending on the vault depth selection.
  - A laminated card is provided in the Dx set indicating the power of each lens

Tips for Achieving Success

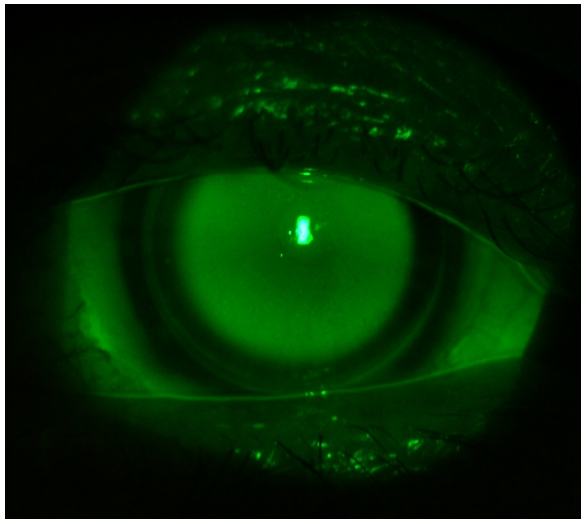
Evaluating NaFL Patterns – Timing is Critical!



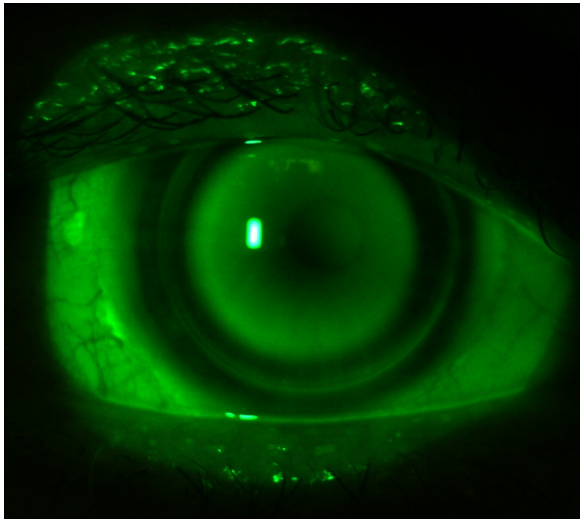
1 minute after insertion



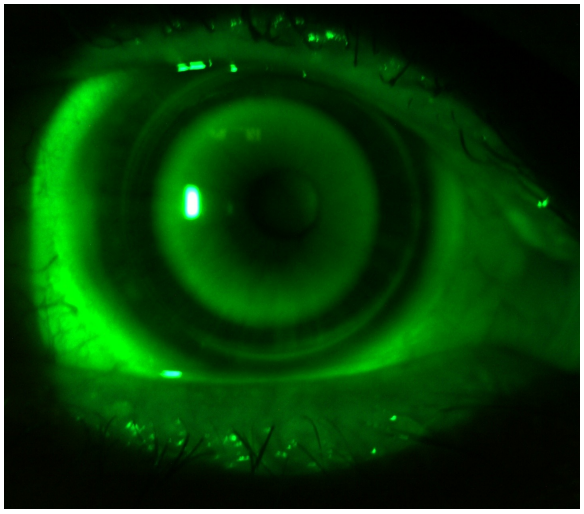
3 minutes after insertion



7 minutes after insertion

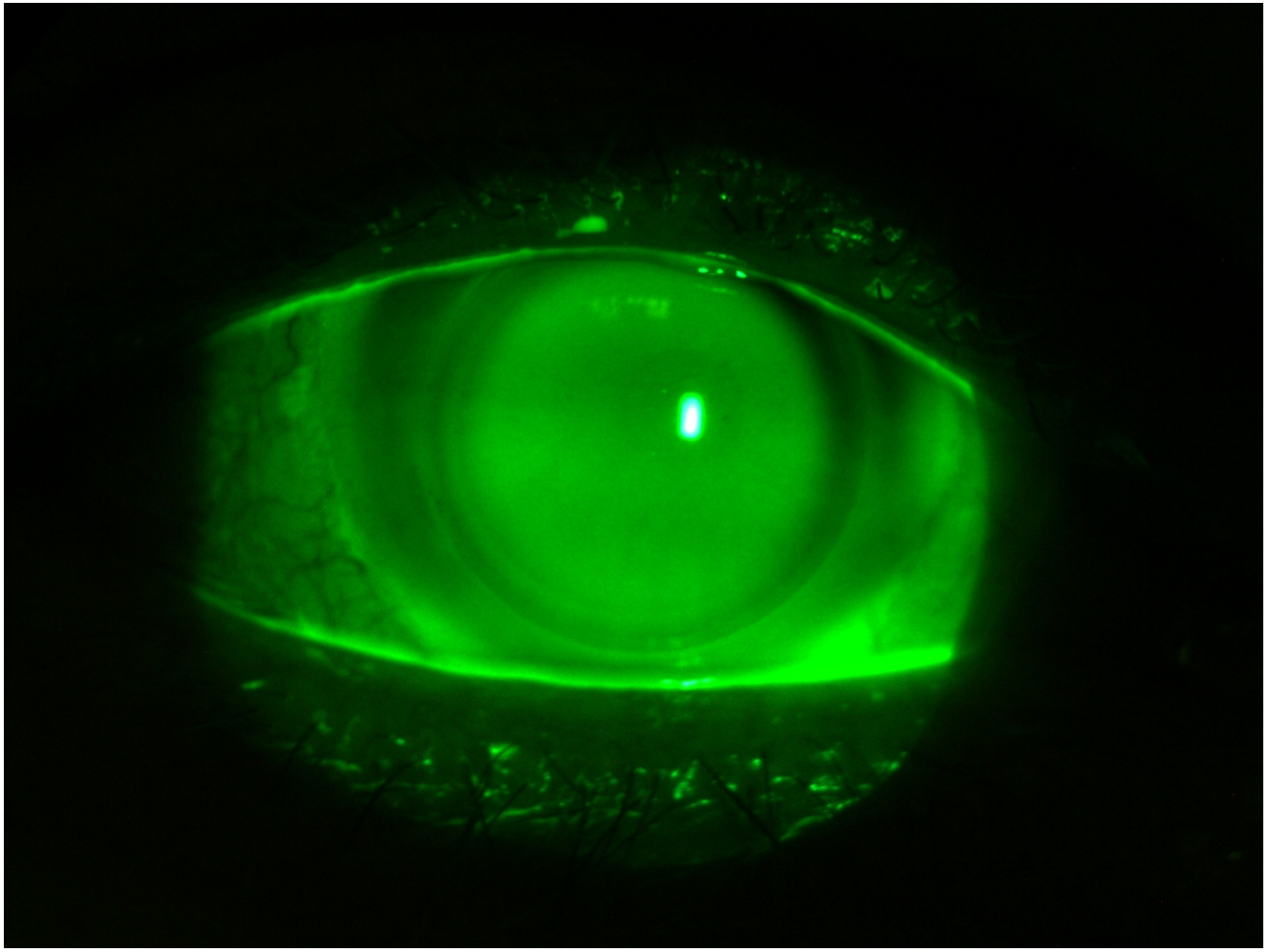


16 minutes after insertion



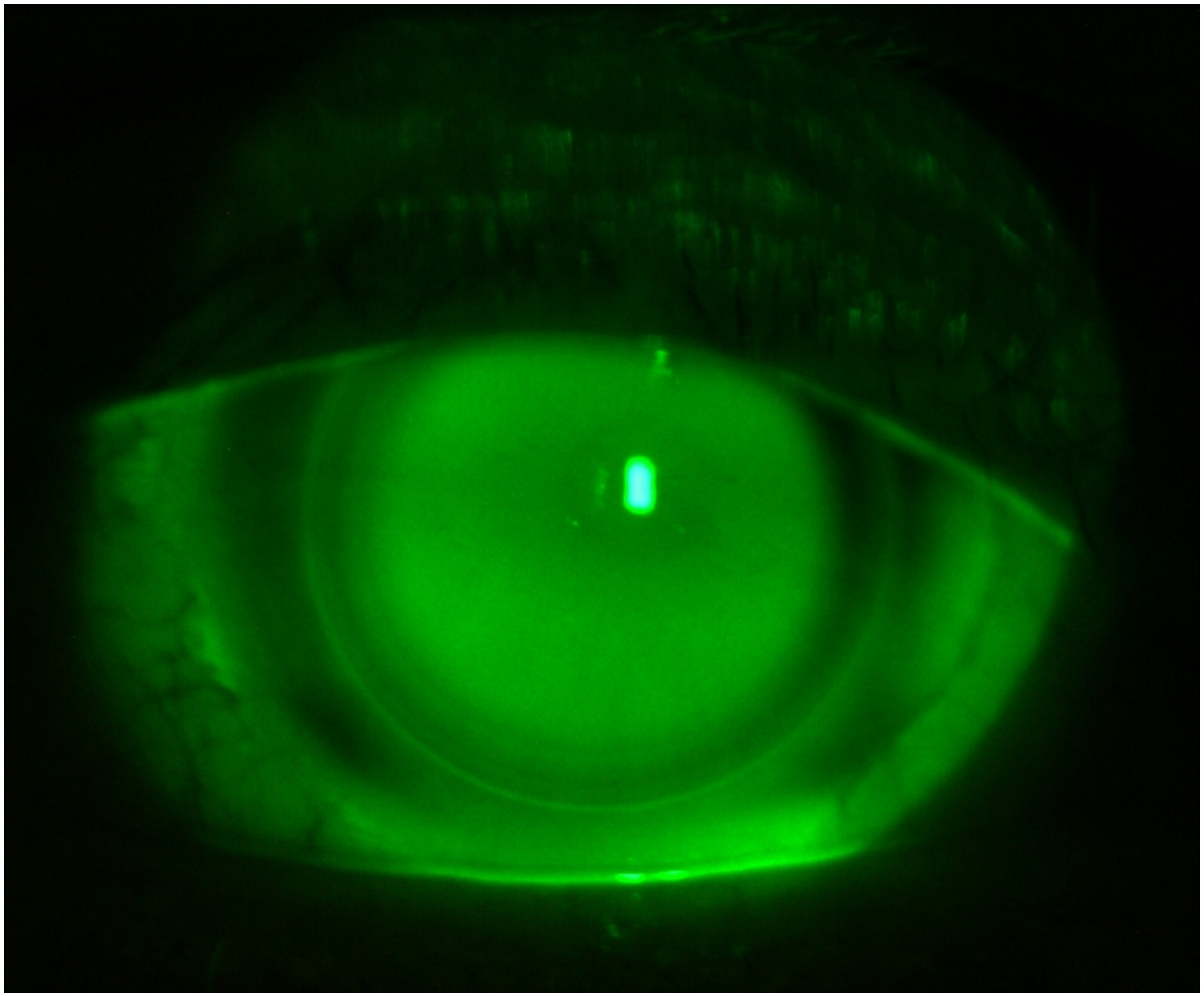
31 minutes after insertion

NaFL Pattern 1 Minute after Insertion



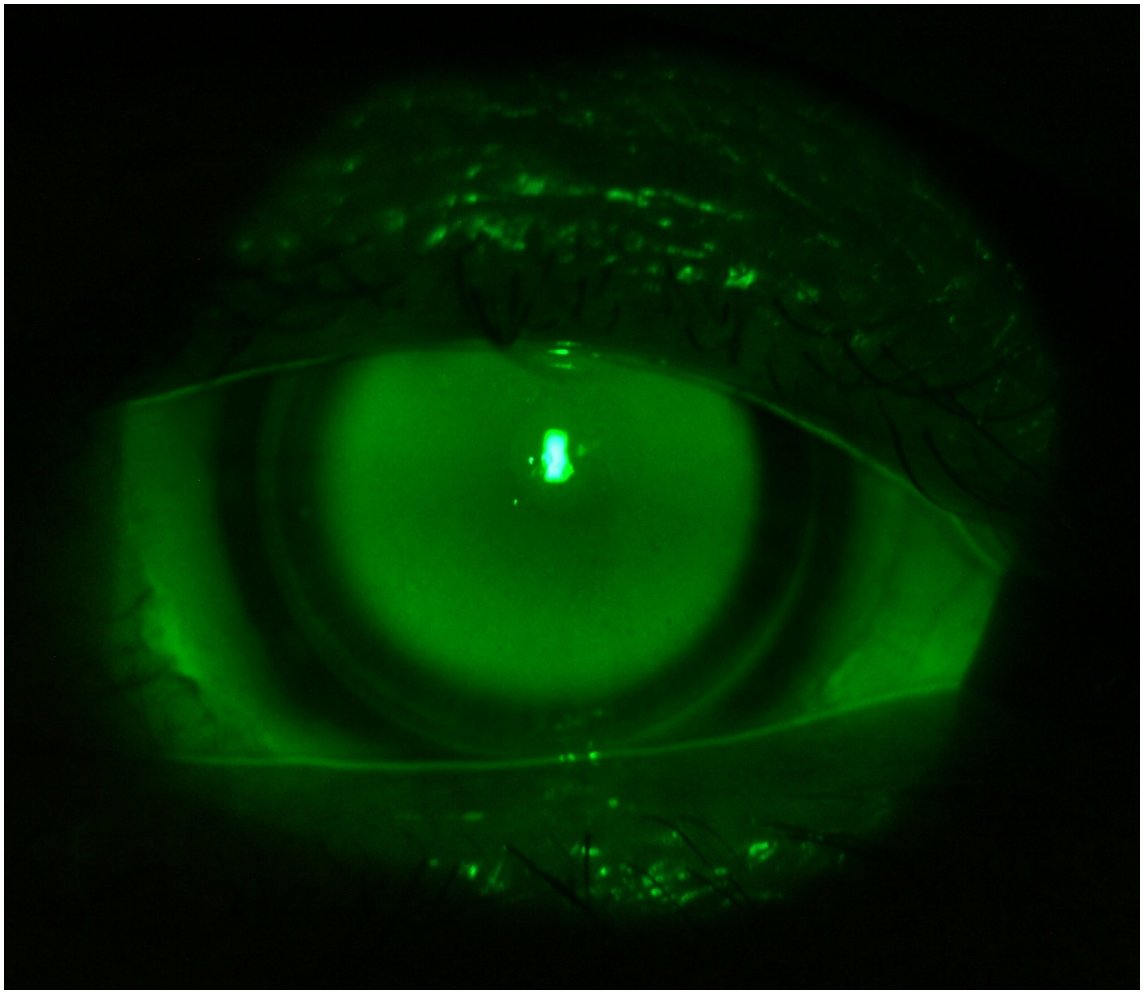
NaFL pattern 1 minute after insertion – lens still settling

NaFL Pattern 3 Minutes after Insertion



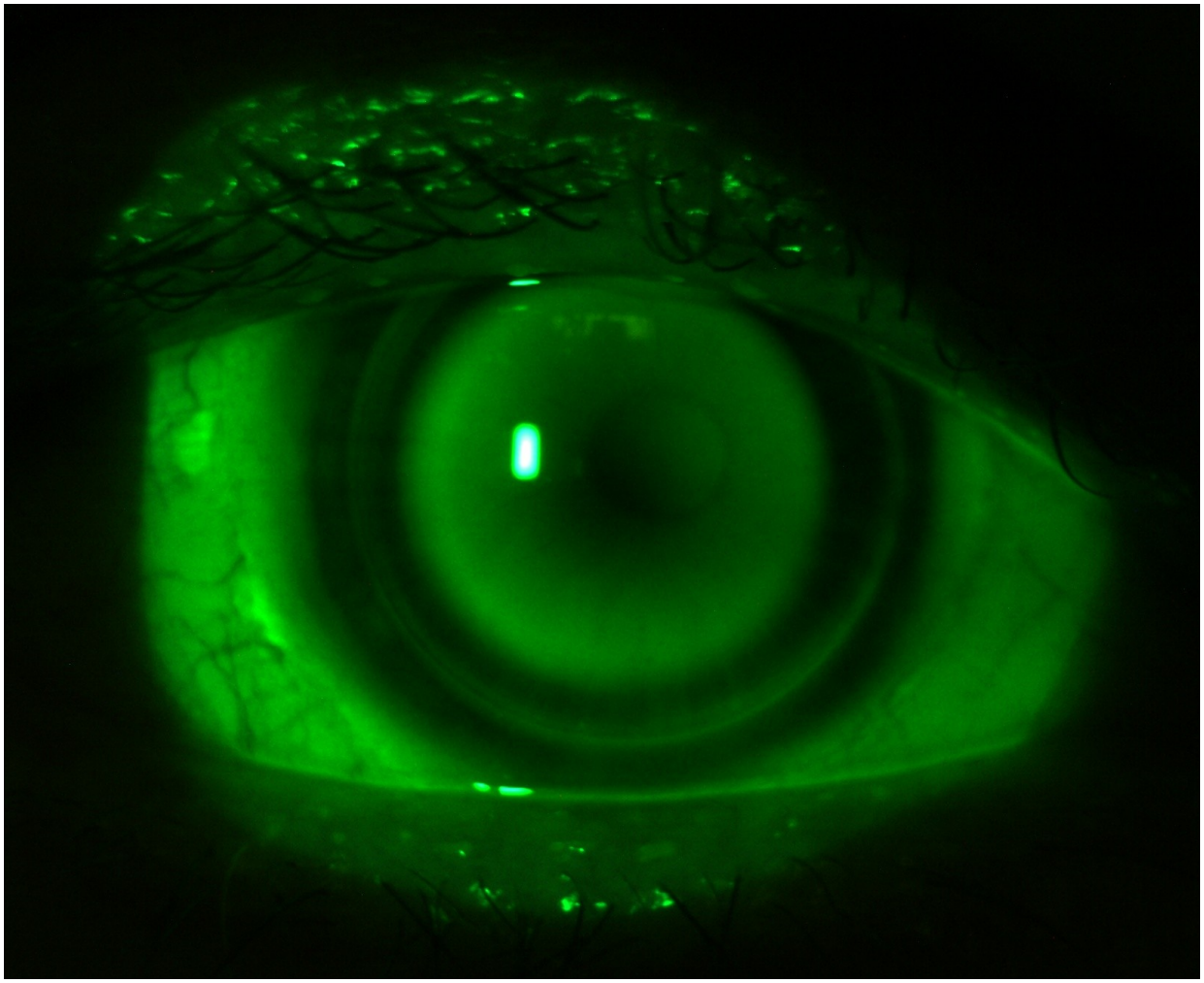
NaFL pattern 3 minutes after insertion – ideal amount of fluorescein to evaluate the fit

NaFL Pattern 7 Minutes after Insertion



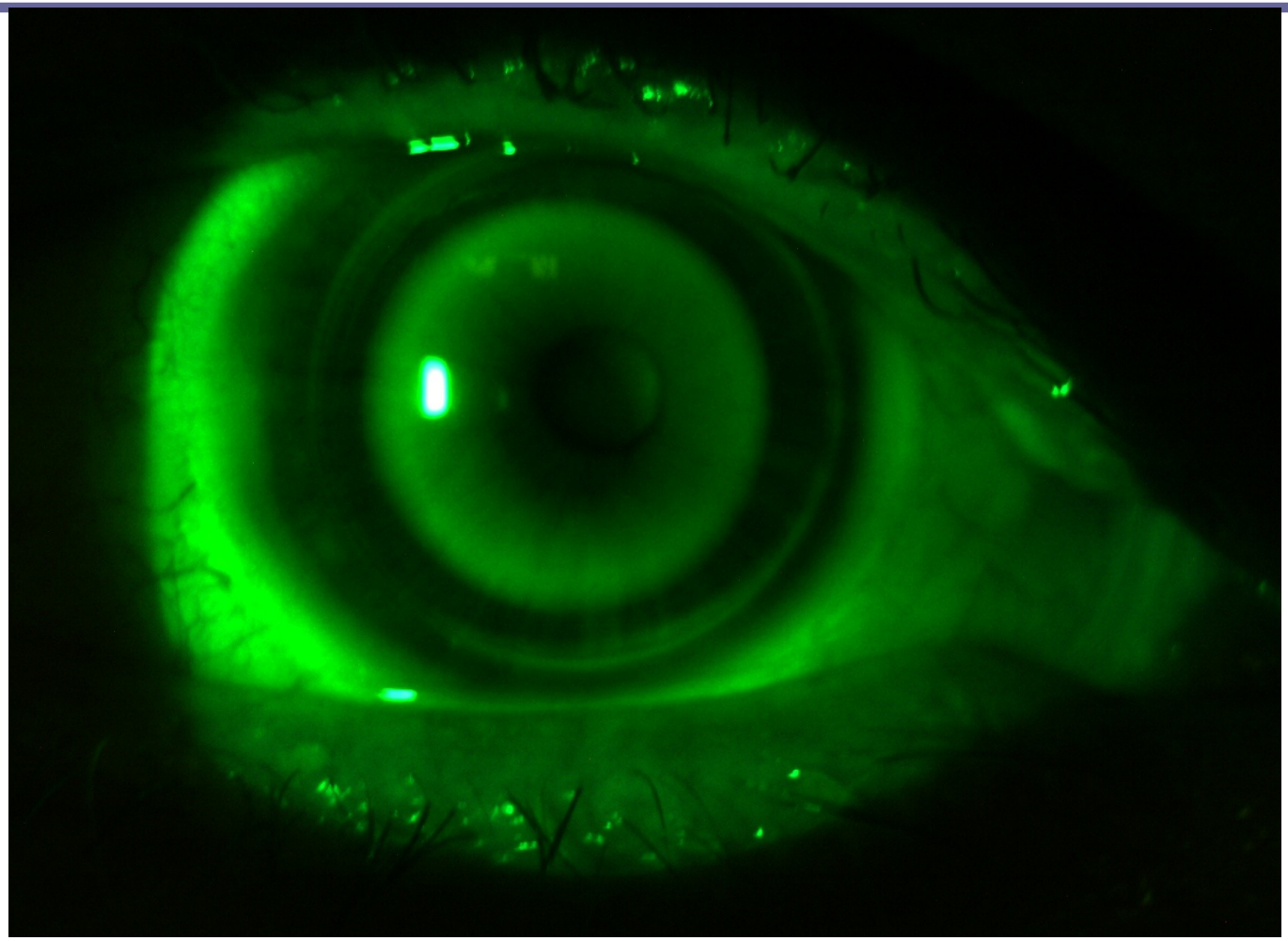
NaFL pattern 7 minutes after insertion – tear flow has thinned the NaFL and gives a false indication of bearing

NaFL Pattern 16 Minutes after Insertion



NaFL pattern 16 minutes after insertion – fluorescein dissipated even further

NaFL Pattern 31 Minutes after Insertion

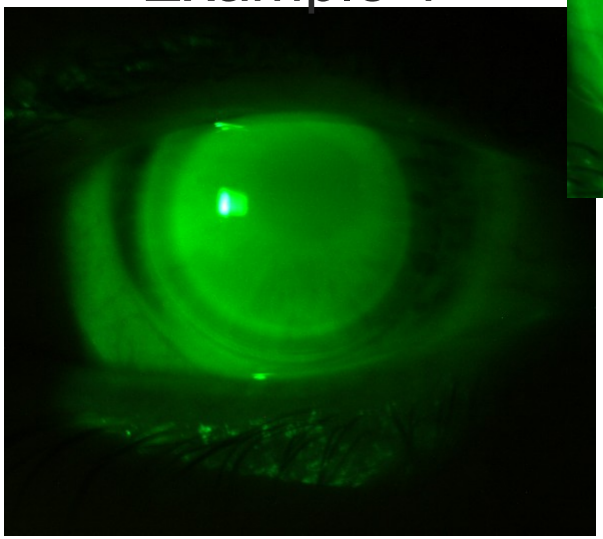


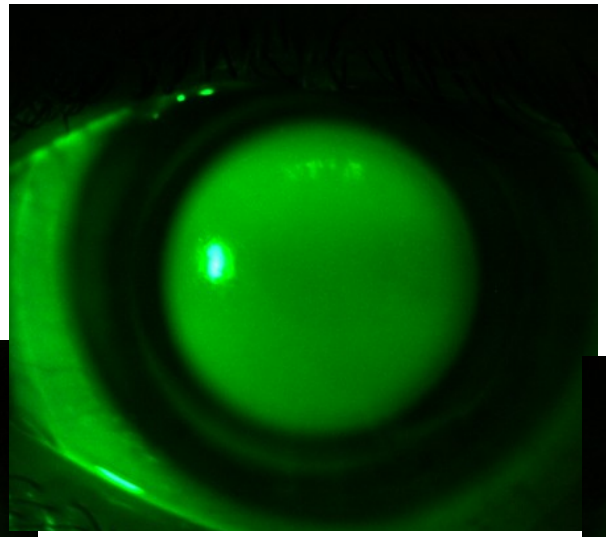
NaFL pattern 31 minutes after insertion – fluorescein almost completely dissipated. The difference in fit of the ILZ & OLZ can no longer be determined.

Subtle NaFL Pattern Differences - Skirt

Subtle differences in NaFL patterns affect lens fit. Which of the following is the ideal skirt curve?

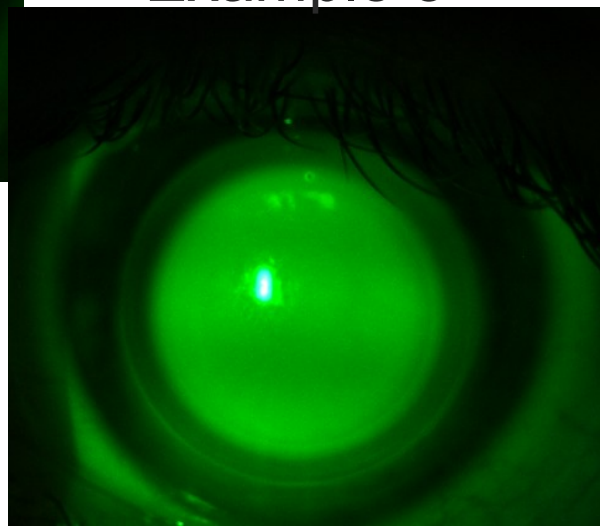
Example 1





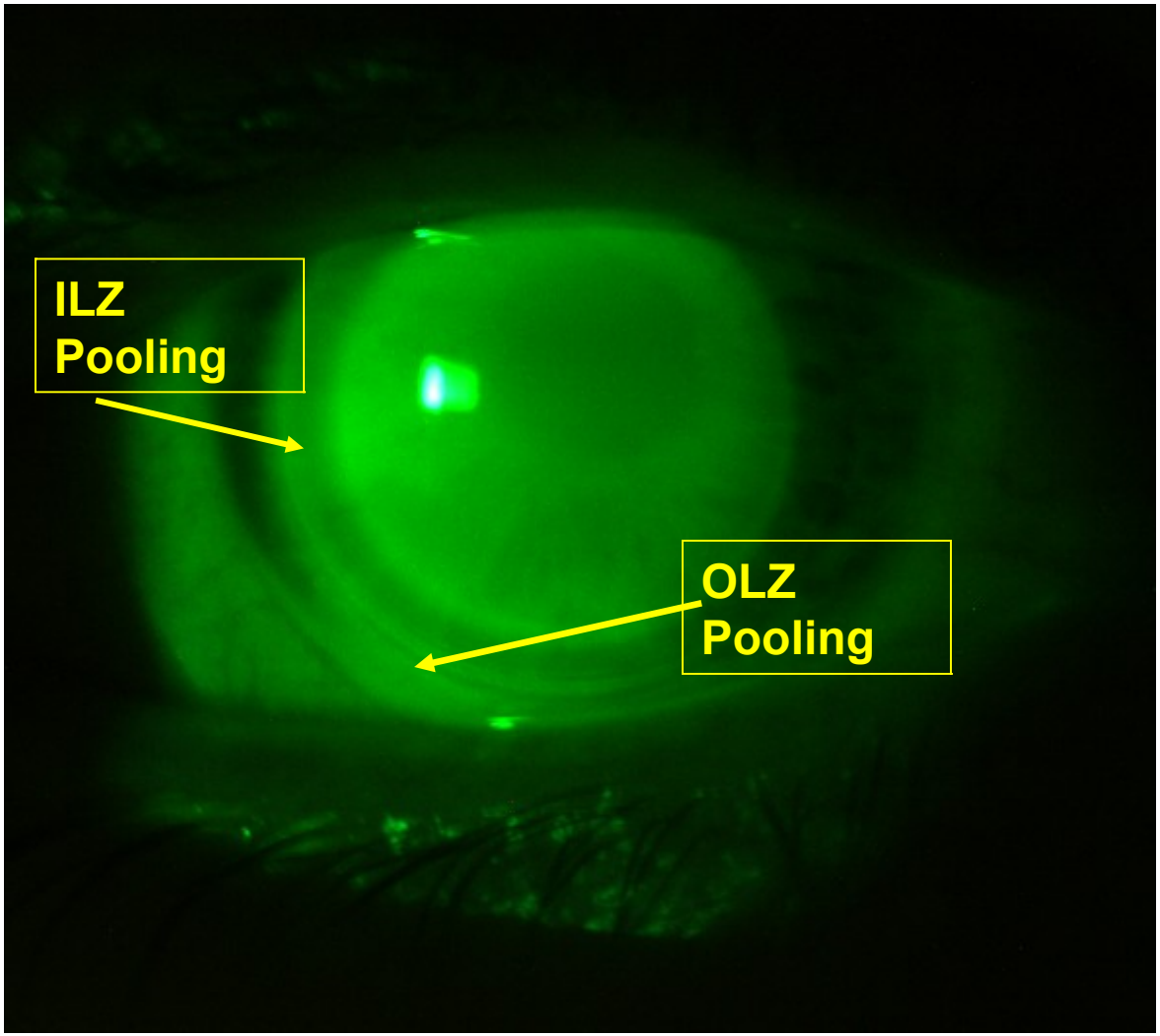
Example 2

Example 3



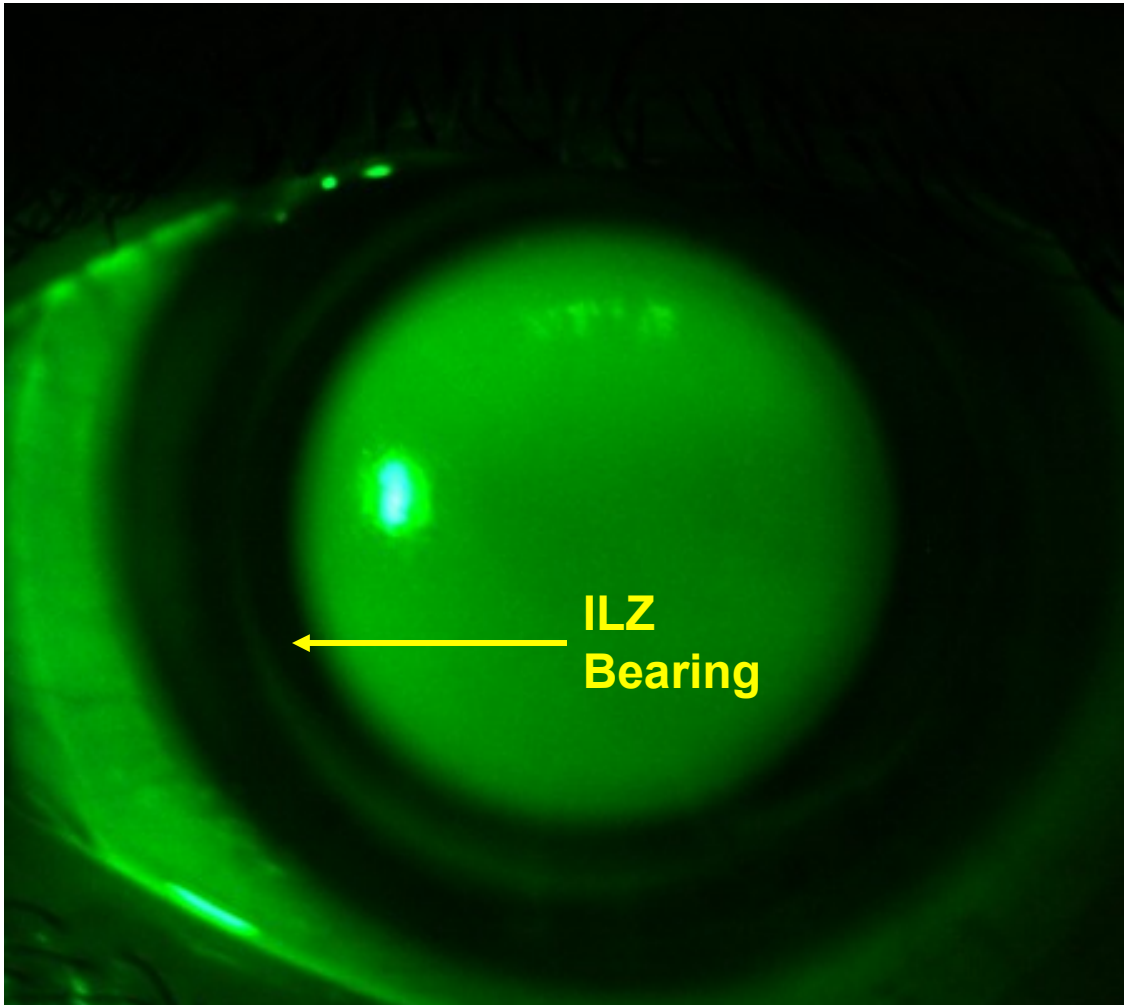
Subtle NaFL Patterns – Example 1

Example 1: Skirt Curve too Steep



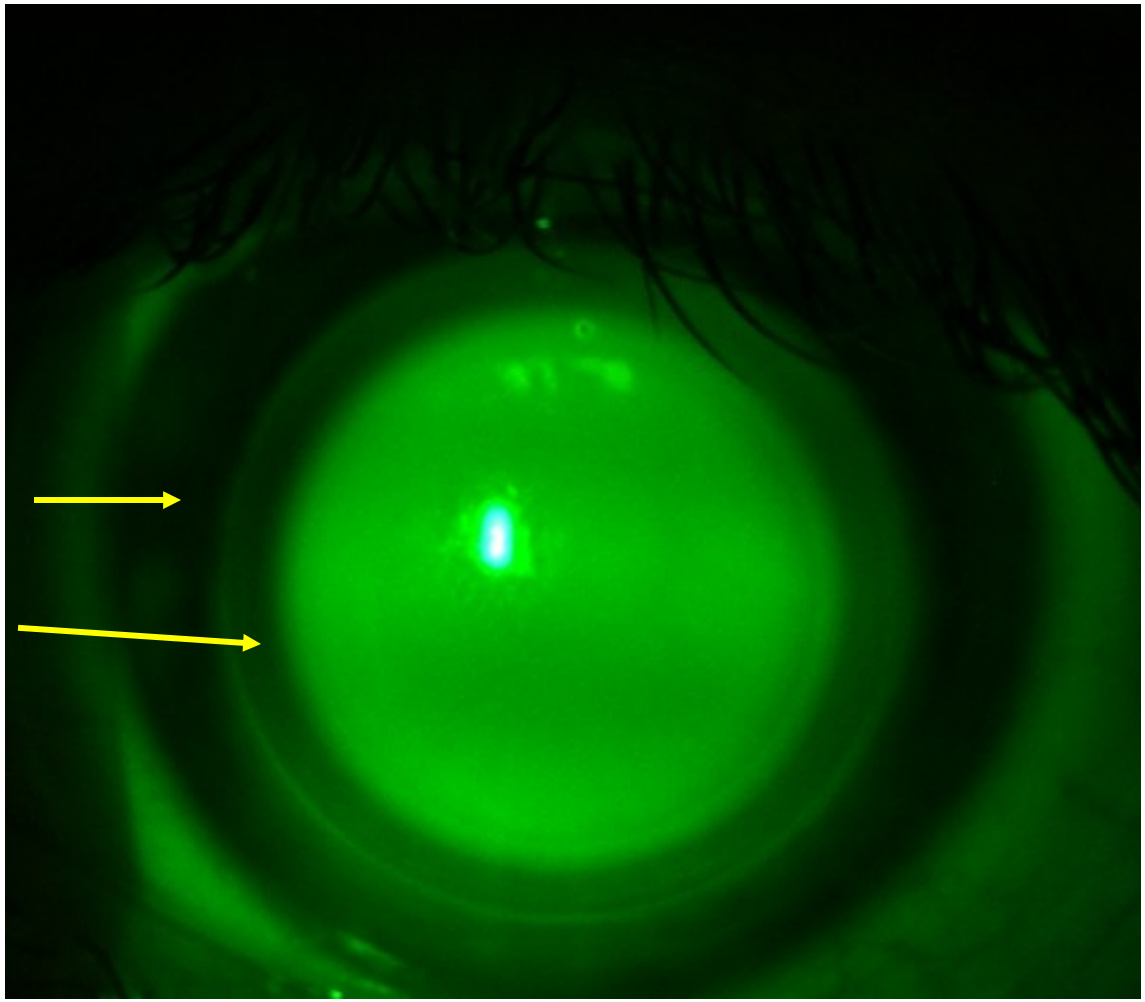
Subtle NaFL Patterns – Example 2

Example 2: Skirt Curve Too Flat



Subtle NaFL Patterns – Example 3

Example 3: Ideal Skirt Curve



Making Changes at Follow-Up

- If a vault change is needed at follow-up, the lens power will also need to be adjusted
- The chart included in the Dx set lists the Rx for each vault – add/subtract the required change in lens power by determining the Rx with the new vault
  - Example: Change vault from 300µ to 350µ – difference in Rx is -1.50D.
  - The Rx on the 350µ lens is -1.50D greater than the Rx on the 300µ.

Vault (µ)	Rx (D)
100	-1.00
150	-2.00
200	-3.00
250	-4.50
300	-5.50
350	-7.00
400	-8.00
450	-10.00
500	-11.00
550	-13.00
600	-14.50

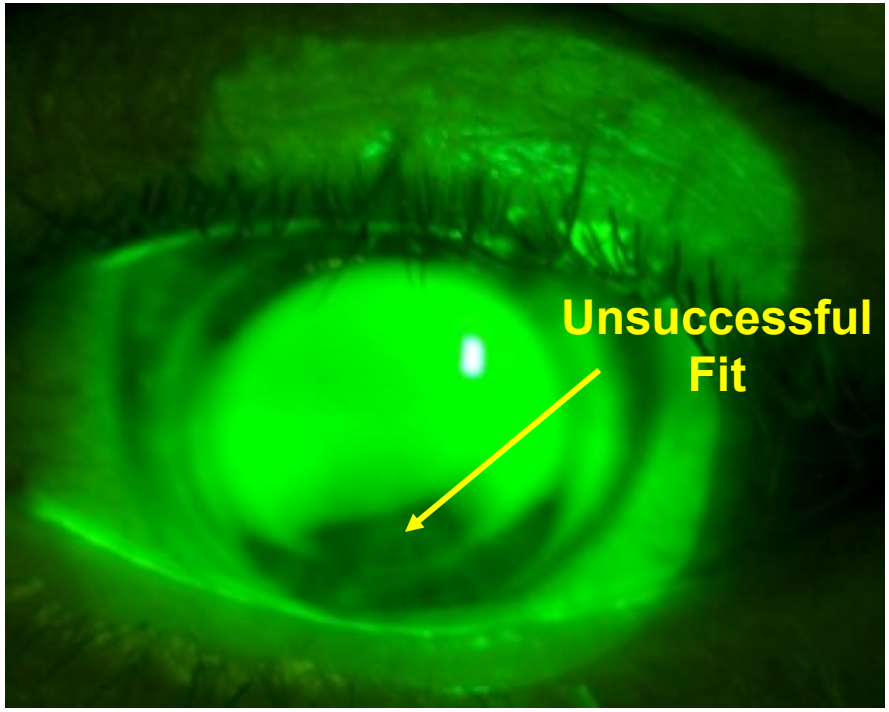
Making Changes at Follow-Up (con't)

- If a power change is required in addition to a vault change, the power change must be added to the power change required by the change in vault
  - Example: Change vault from 300μ to 350μ and need an additional -.50D
    - New lens power is -2.00D from original lens power

Vault (μ)	Rx (D)
100	-1.00
150	-2.00
200	-3.00
250	-4.50
300	-5.50
350	-7.00
400	-8.00
450	-10.00
500	-11.00
550	-13.00
600	-14.50

Fitting challenges

- Ectasia extends beyond landing zone
- Irregular landing pattern – unable to achieve an even distribution of landing zone
- Post-graft patients – fitting success can be possible but landing zone may fall on the graft-host interface
- Highly irregular or asymmetric landing pattern
  - Often seen in advanced PMD patients



Final fit and ultimate success is not always predictable purely based on corneal topography

Where to start

- Fitting *ClearKone* is **different** than any other KC lens – including *SynergEyes KC*
  - Disregard all conventional fitting methods and commit to learning curve
- After ~3-4 patient fits, the fitting process will go very quickly and be straightforward / predictable
  - Give yourself some extra time initially
- **Don't start with the most extreme patients who have failed with every other product** instead, we suggest
  - Newly diagnosed patients
  - RGP patients wanting better comfort/acuity
  - Piggybacks wanting improvements
  - Failed *SynergEyes KC* patients

Things to remember

- Critical to eliminate any central touch when fitting. Even the lightest “feather touch” can cause patient discomfort.
- For patients being re-fit from RGPs, *SynergEyes KC, A, PS* or even soft lenses
  - Cornea will most likely return to it’s natural shape once the pressure of the predicate lens is removed
  - May need to re-order deeper lenses after the cornea re-normalizes
- Patient comfort greatly validates final fit in *ClearKone*
- Patient training is critical
  - Proper insertion
  - Removal easier than KC lens but still requires training
  - Proper lens care critical (ONLY Non-preserved products)
  - Proper wear time - daily NOT extended
  - Build wear time over 5-7 days

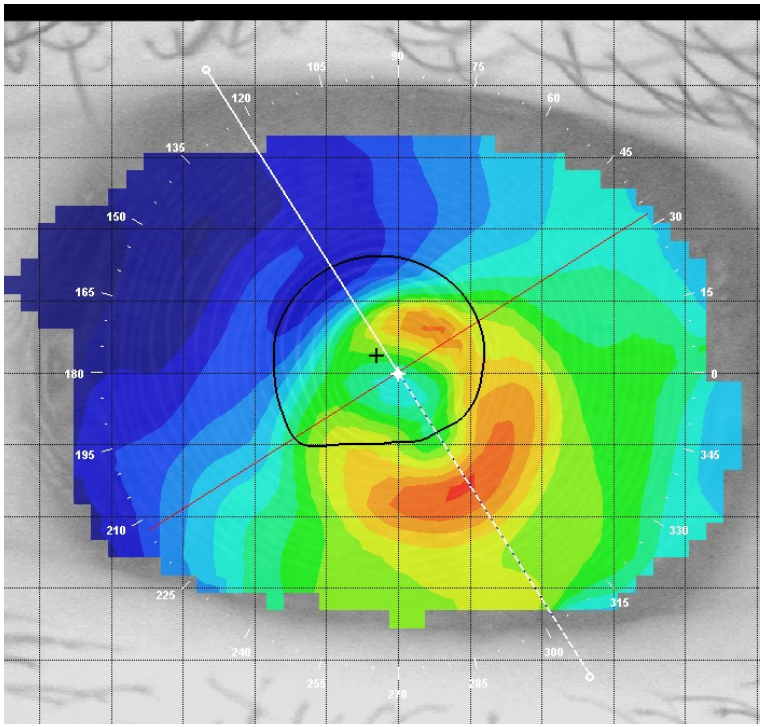
Case Study

ClearKone Case Study

- Patient JS
- Diagnosis: keratoconus
- Contact lens history:
  - RGP's since 1959 (most recent: Rose K)
  - Re-fit into *SynergEyes KC* in 2006 and was able to wear for 8 hours per day
- Goal:
  - Increase comfort OU
  - Increase wear time

ClearKone Case Study (cont.)

OD

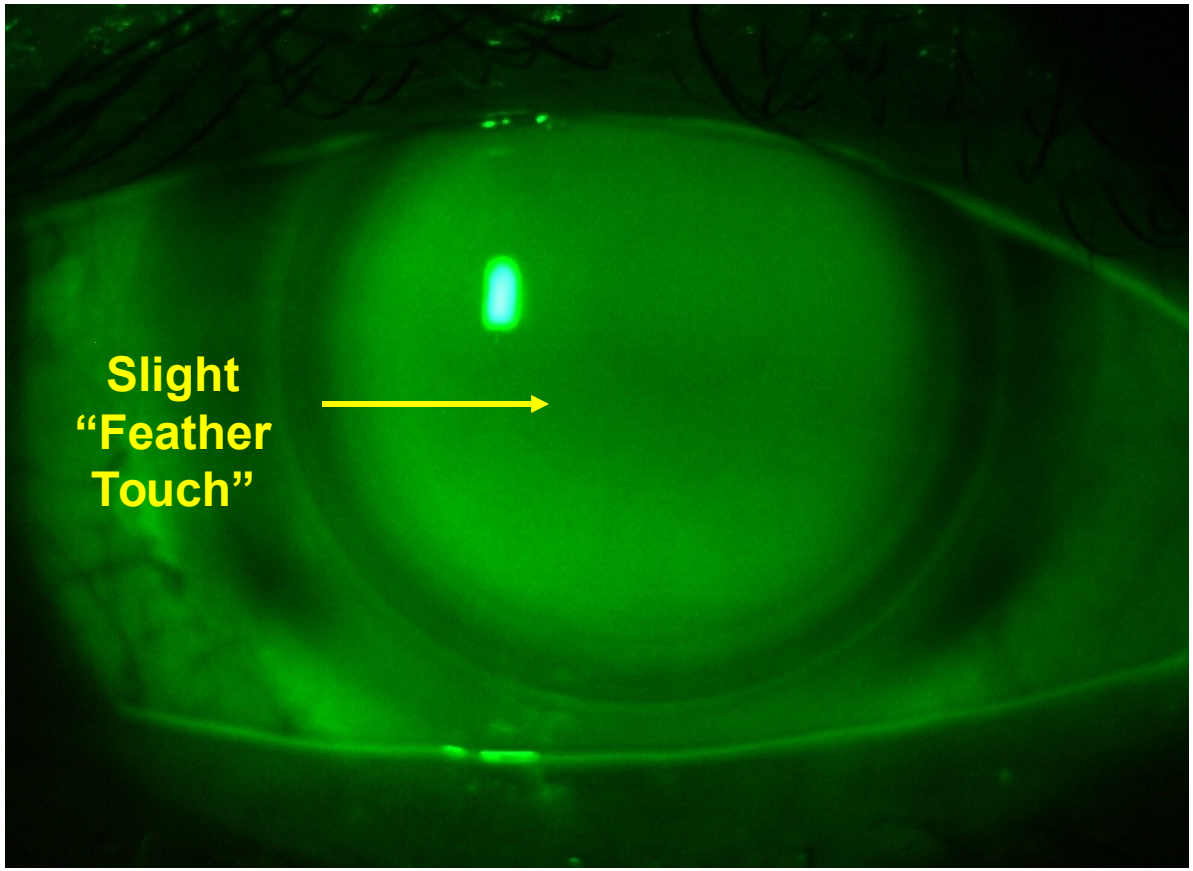


K's 48.40 x 43.20

ClearKone Case Study (cont.)

Vault Selection

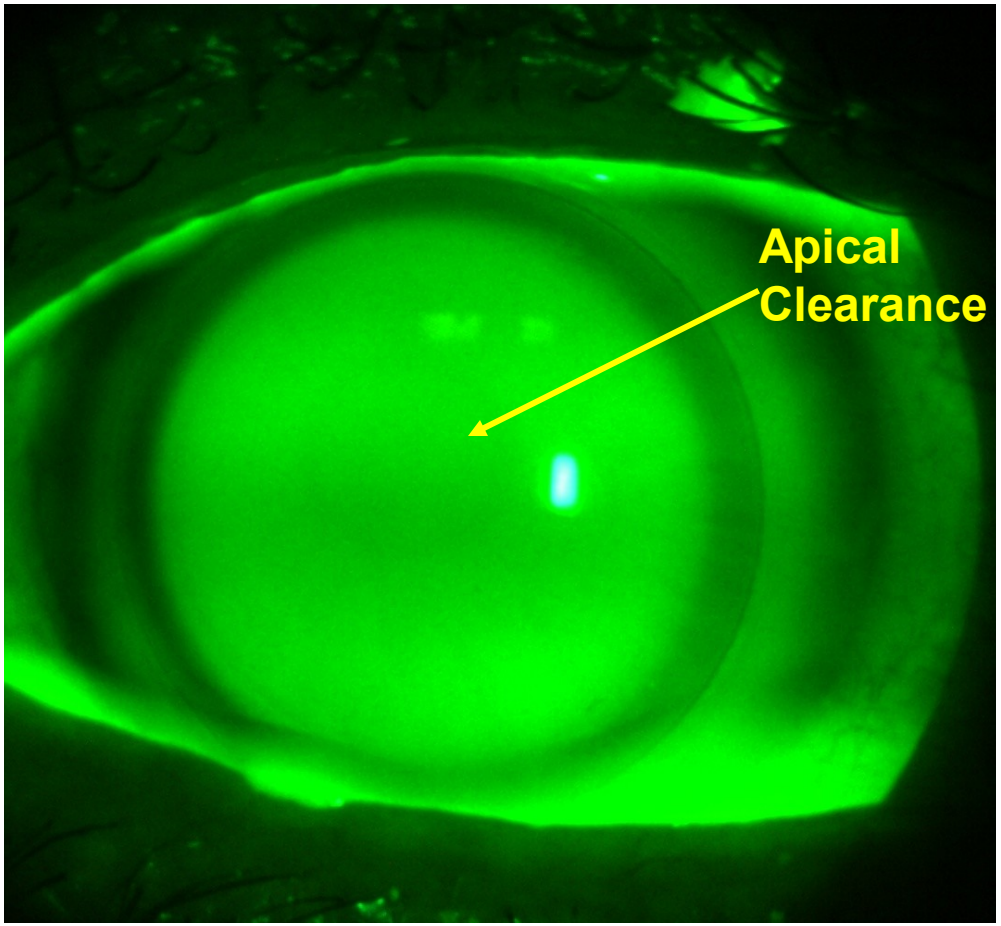
- 250µ vault



ClearKone Case Study (cont.)

Vault Selection

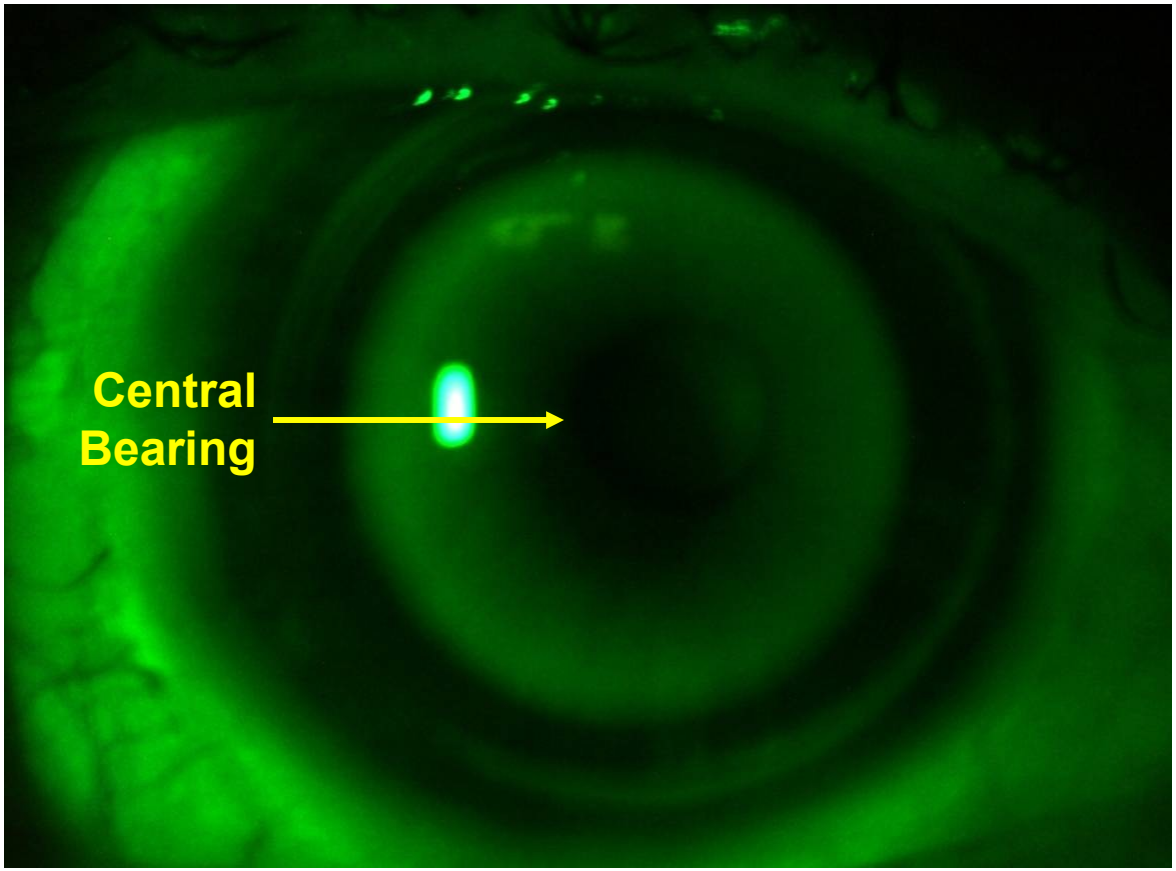
- 350µ vault – Ideal Fit



ClearKone Case Study (cont.)

Vault Selection

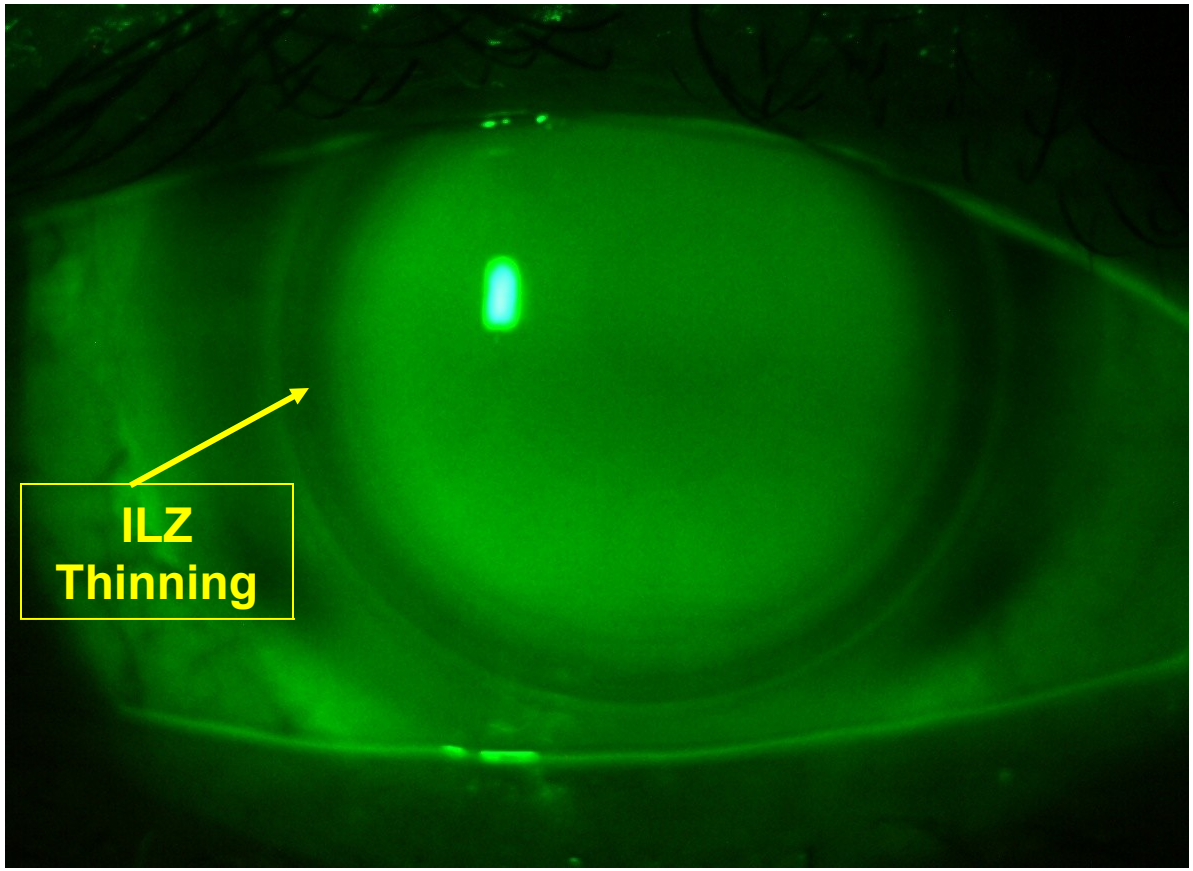
- 150µ vault



ClearKone Case Study (cont.)

Skirt Selection

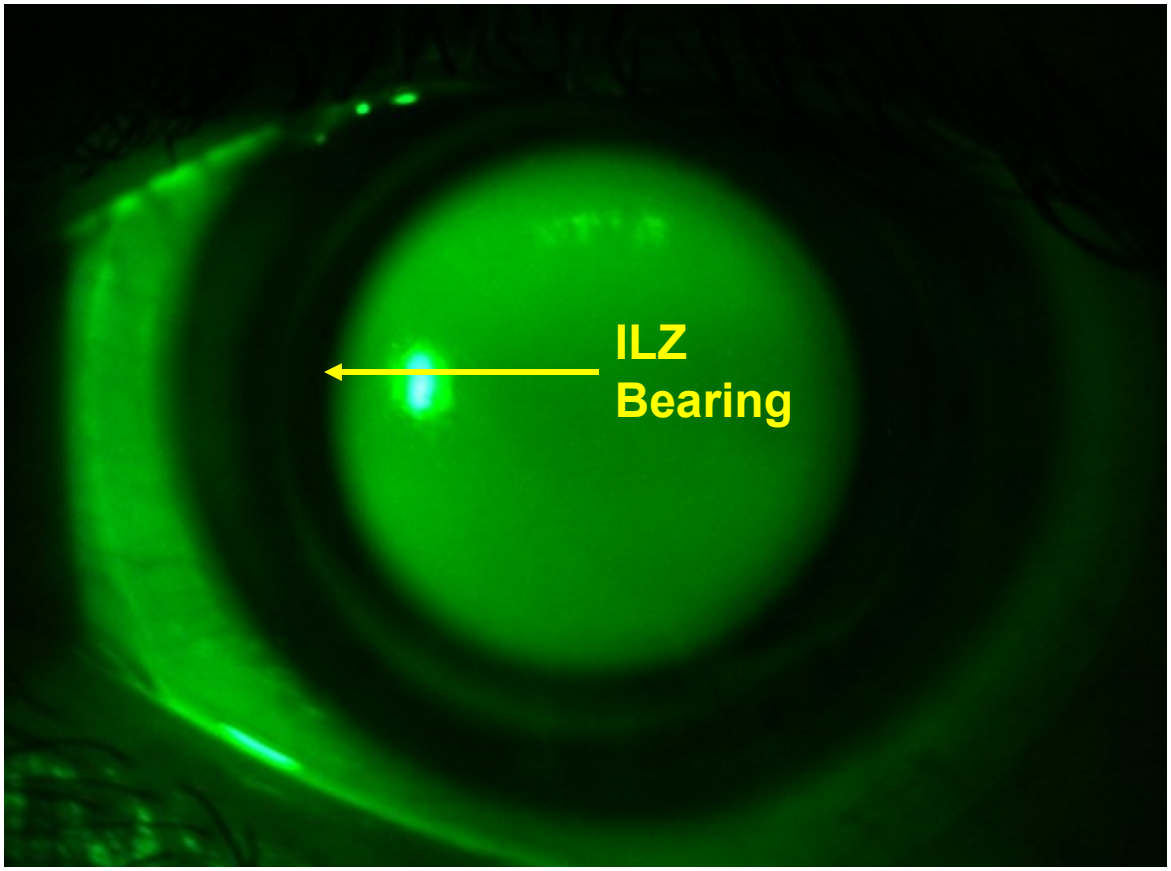
- 350μ vault with Medium skirt



ClearKone Case Study (cont.)

Skirt Selection

- 350μ vault with Flat skirt



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Restoring vision. Changing lives.™

Patient Insertion and Removal Instructions

Lens Insertion: Patient Instructions

- Fill the lens with preservative-free saline while holding it horizontally on a SynergEyes® DMV® inserter OR by stabilizing the lens between your index and middle finger. (SynergEyes® DMV® Inserters can be purchased via your eyecare professional or www.dmvcorp.com).

- It is critical to fill the lens bowl completely to the TOP with saline to avoid insertion bubbles. The DMV inserter allows the completely filled lens to be well balanced so you can easily place the lens on the eye. You will know if you have an insertion bubble if you notice an irregularity in your peripheral vision.

Lens Insertion: Patient Instructions (cont.)

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- Lean forward and tuck your chin to your chest. Your nose should be perpendicular to the floor. It may be helpful to place a mirror flat on the counter to look into as you insert the lens.

- Pull up on your upper eyelid by placing the fingers at the base of the lashes. Pull down on the lower lid with the ring finger of the hand holding the lens, and insert the lens.

Lens Insertion: Patient Instructions (cont.)

- As the saline is displaced, the lens will gently settle onto the surface of the eye. **IT IS VERY IMPORTANT NOT TO PUSH THE LENS TOO FORCEFULLY ONTO THE EYE.**

Lens Removal: Patient Instructions

1. Wash and dry hands.
2. Hands must be completely dry for successful removal.

3. Do not use lubricating drops prior to removal.
4. Make the “OK” sign with the thumb and forefinger.

Lens Removal: Patient Instructions (cont.)

5. Look straight ahead.
6. Grasp the lens at the 6 o'clock position.
7. Allow air underneath the soft skirt of the lens.
8. Lift lens away from eye.

Every patient should view the insertion & removal video at
www.synergeyes.com

Lens Care: Patient Instructions

- Patients must digitally clean their lenses each day prior to overnight storage for disinfection.
- For rinsing use only a preservative free saline solution such as Unisol®4.
- For disinfection use Clear Care® or Oxysept® Ultracare® Formula Peroxide Disinfection System.

Lens Care: Patient Instructions (cont.)

- To clean the lenses, place the lens bowl-side up in the palm of the hand and apply a few drops of saline.
- With the pad of the finger gently rub the entire lens in a circular motion against the palm of the hand.
- Be sure to thoroughly clean the entire lens and then rinse it well in a steady stream of saline.

ClearKone® Parameters

Material	Paflufocon D center (hemiberfilcon A skirt)
Dk	100
Water Content	27% (soft skirt)
Diameter	14.5mm
Vault	100 – 600 in 50µ steps
Skirt Curvature	Steep, Medium, Flat
Sphere Power	+2.00 to -8.00 in 0.25D steps -8.50 to -20.00 in 0.50D steps +2.50 to +5.00 in 0.50D steps
Wear Indications	Daily Wear
Recommended Replacement	6 Months
Lens Care	Hydrogen Peroxide
Delivery	1-2 Weeks

The unique design of the *ClearKone*® lens allows for the majority of the power to come from the lacrimal lens which substantially lowers lens powers to further enhance optical performance.

The streamlined fitting process makes the *ClearKone*® lens one of the simplest keratoconus products to fit, while delivering the best possible vision and comfort for the widest spectrum of patients.

see. change. enjoy vision.

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