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Introducing the New DigiForm 16.6 Scleral Lens

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Scleral Lens Indications

Irregular corneas:

- Keratoconus, pellucid marginal degeneration, keratoglobus, post-surgical (corneal transplant, post-lasik, postRK), ectasias, corneal scars…

Ocular surface disease and dry eye patients:

- Steven's Johnson Syndrome, Sjogrens, Graft vs Host, Exposure, Keratoconjunctivits Sicca…

Normal cornea:

- High ametropias, high astigmatism, GP intolerant…

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Scleral Lens Advantages

Comfort

- Edges tuck under lids, no touch on cornea

Large Diameter

- Stability (won't pop out), no FB entrapment
- Large optical zone

Fluid Reservoir

- Vision doesn't fluctuate, comfortable wearing time
- Moisture held over eye

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One scleral design for all corneal conditions

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16.6 DigiForm Design Advantages

One diameter/one set for all corneal conditions

Simple to fit and easy to communicate with lab and consultants

Ultimate control over fit and optics

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One Diameter

16.6mm is a mini-scleral lens:

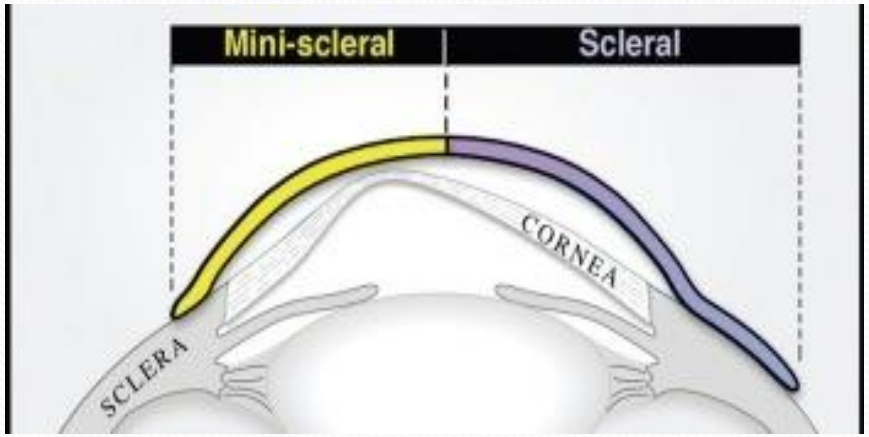
Easier handling for patients

- Smaller opening required for application

Less trouble shooting issues compared to full scleral designs

- less lens de-centration
- less likely to require toric haptics
- less fogging/debri due to lower clearance needed

Mini-scleral lens: up to 6.00mm larger than HVID



http://www.clspectrum.com/articleviewer.aspx?articleid=104748

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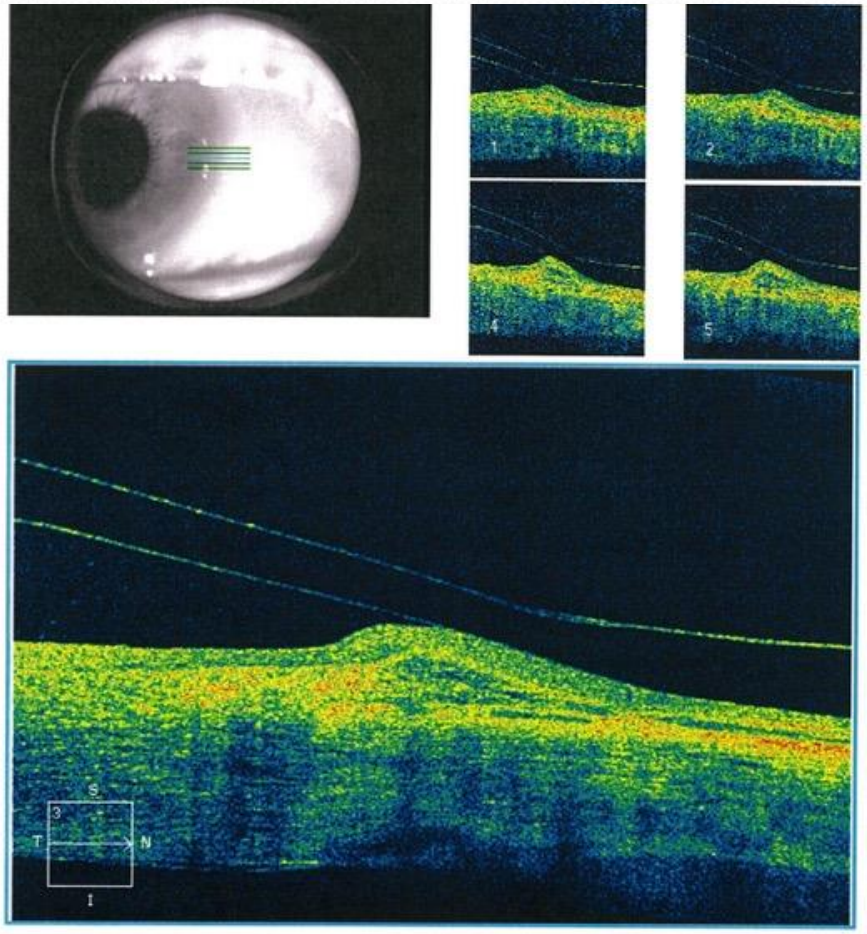
One Diameter: 16.6mm

Improved limbal coverage especially helpful for successful fits in:

- Pellucid Marginal Degeneration (PMD)
- Corneal Transplants:
  - Proud grafts, high graft junctions
- INTACs
- Large Corneas
- ect…



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One set for all corneal conditions

15 trial lens set:

- Extensive range:
  - BC 6.00mm- 9.50mm
  - Sag depth 4.31mm-5.62mm
- Both prolate and oblate shapes depending on base curve
  - Oblate shapes have reverse curves to optimize clearance
- Ability to find best fit within trial set

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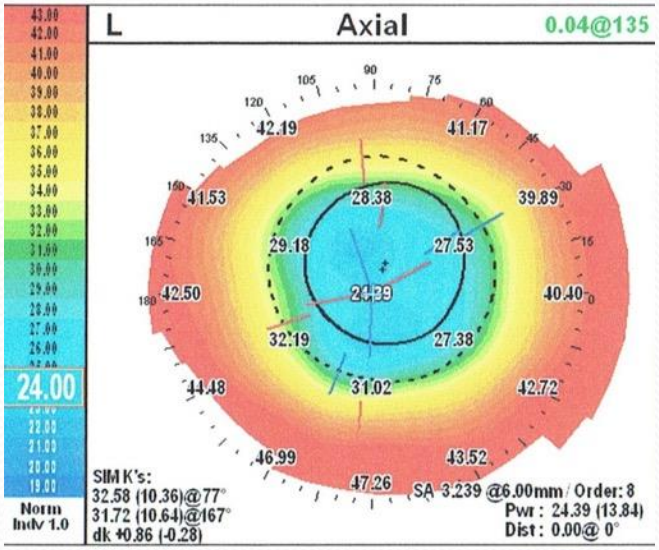
The DigiForm 16.6 Trial Lens Set

Lens#	BC	Diop	Sag	Shape (Default)
1	6.00	56.25	5.65	Prolate
2	6.25	54.00	5.49	Prolate
3	6.50	51.92	5.35	Prolate
4	6.75	50.00	5.22	Prolate
5	7.00	48.21	5.10	Prolate
6	7.25	46.55	4.99	Prolate
7	7.50	45.00	4.89	Prolate
8	7.75	43.55	4.80	Prolate
9	8.00	42.19	4.72	Oblate
10	8.25	40.91	4.64	Oblate
11	8.50	39.71	4.56	Oblate
12	8.75	38.57	4.50	Oblate
13	9.00	37.50	4.43	Oblate
14	9.25	36.49	4.37	Oblate
15	9.50	35.53	4.31	Oblate



Oblate shapes help to address flat zones on the cornea

- example post-Lasik, post-RK, corneal transplant

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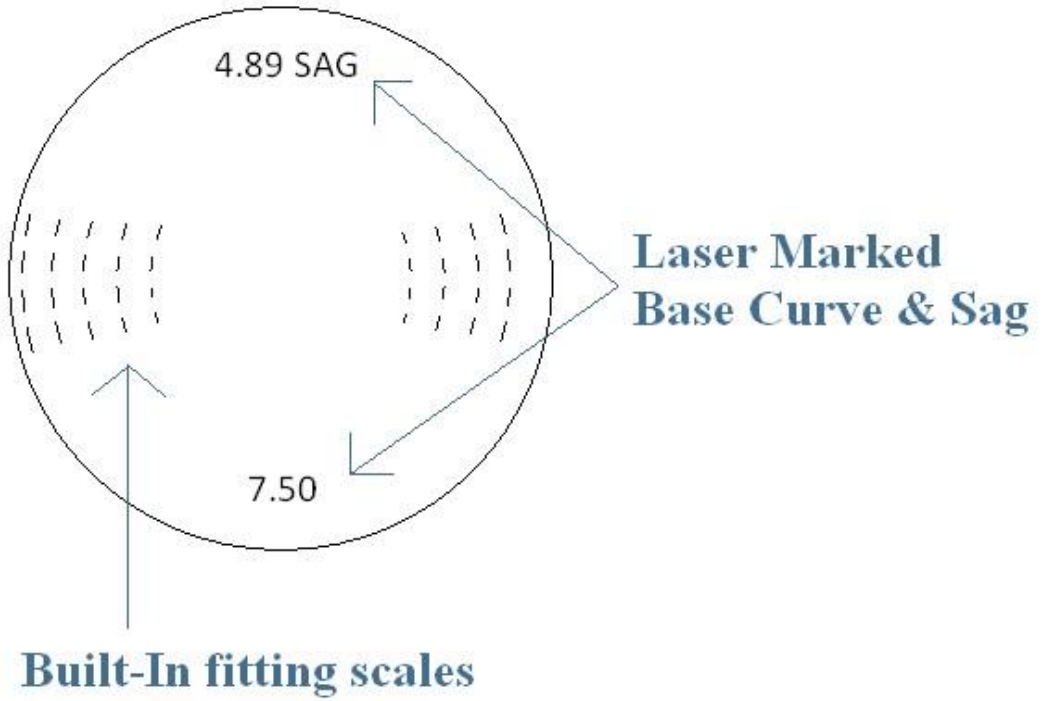
Simple to fit &
Easy to Communicate with Lab

Design:

- Central base curve and 8.0mm optic zone
- 5 additional curves to optimize fit
  - 8-10mm, 10-12mm, 12-14mm, 14-15.8mm, 15.8-16.6mm
- Lenses are laser engraved and easy to read



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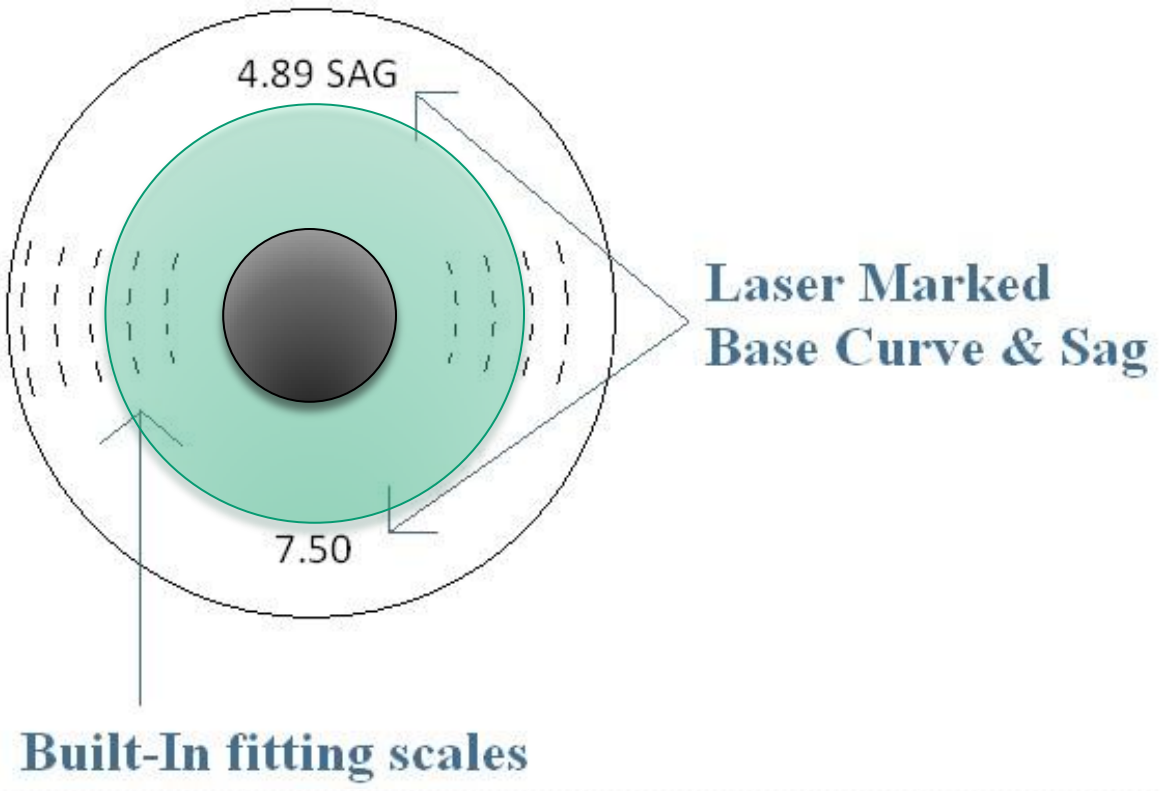
Simple to fit & Easy to Communicate with Lab

Markings:

- Measure HVID using markings
  - Smaller than 3nd hash= <12.0mm
  - Larger than 3rd hash = >12.0mm
  - Each hash mark = 1mm



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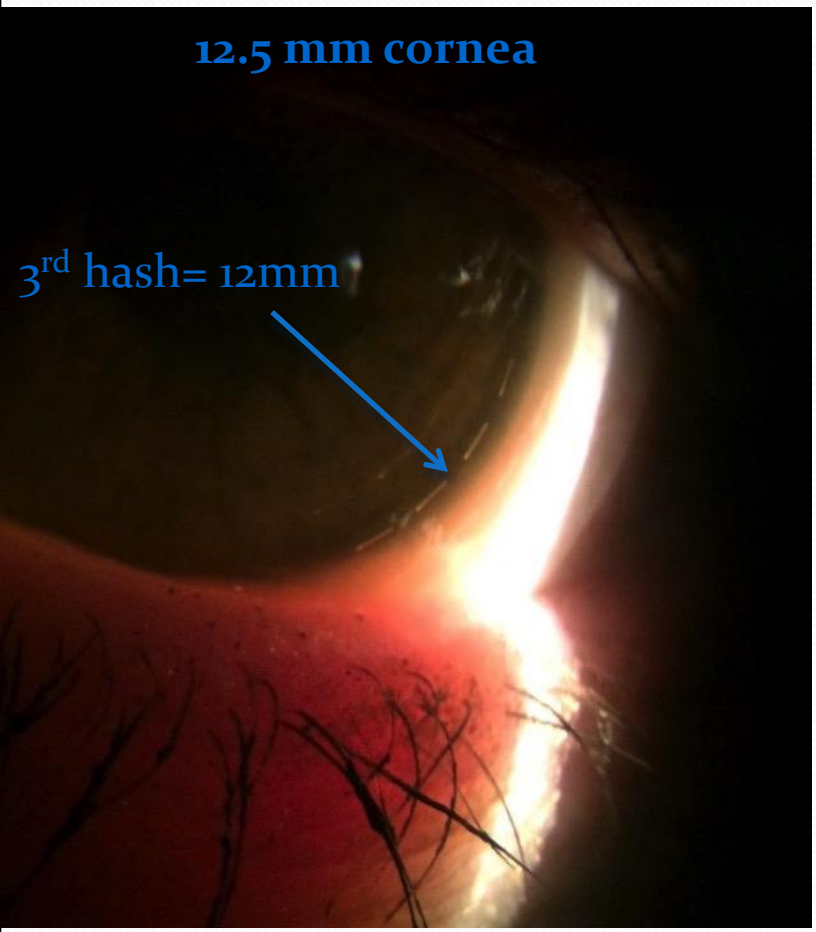
Simple to fit &
Easy to Communicate with Lab



Why is HVID important?

- HVID defines which curves are limbal curves
  - <12.0mm 2nd curve is the limbal curve
  - >12.0mm 3rd curve is the limbal curve
  - Allows lab to make best adjustment to address limbal issues vs edge issues

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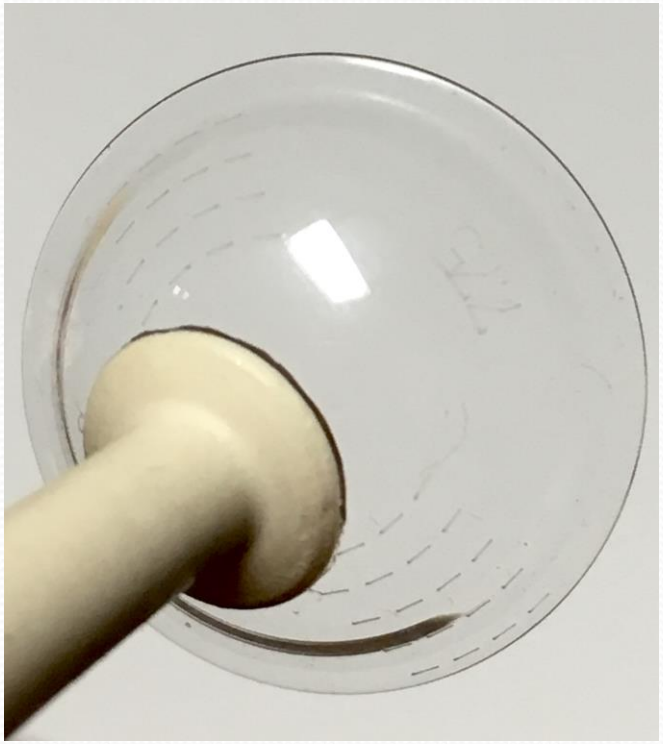
Ultimate control over fit



Design:

- Central base curve (8mm OZ)
  - 5 additional curves to optimize fit
    - Each zone is clearly marked
- Can modify any part of the lens to achieve best fit
  - Make bi-toric or quad specific changes
  - Prolate or Oblate
  - Notching available

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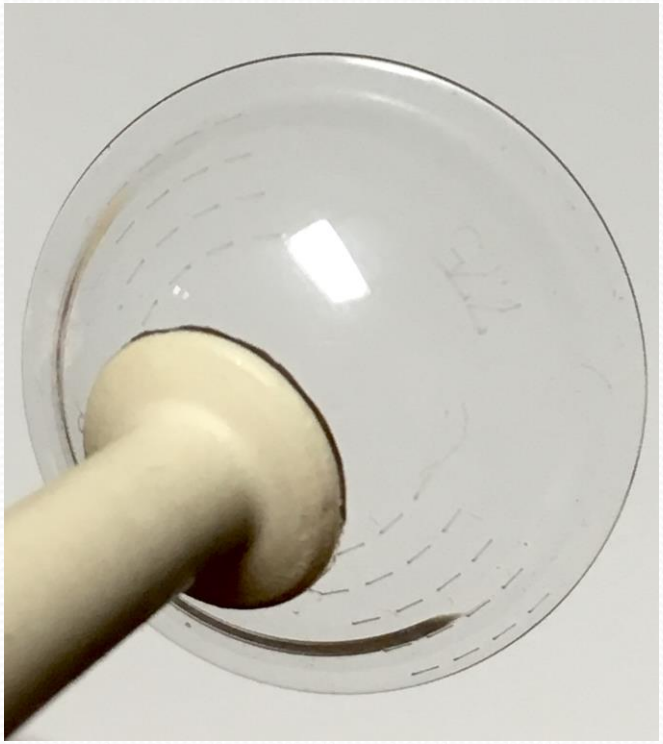
Ultimate control over fit



Lens Modifications

- Made in micron units
  - Minimum change: 25-50µm
  - Moderate change: 75-150µm
  - Aggressive change: >200µm

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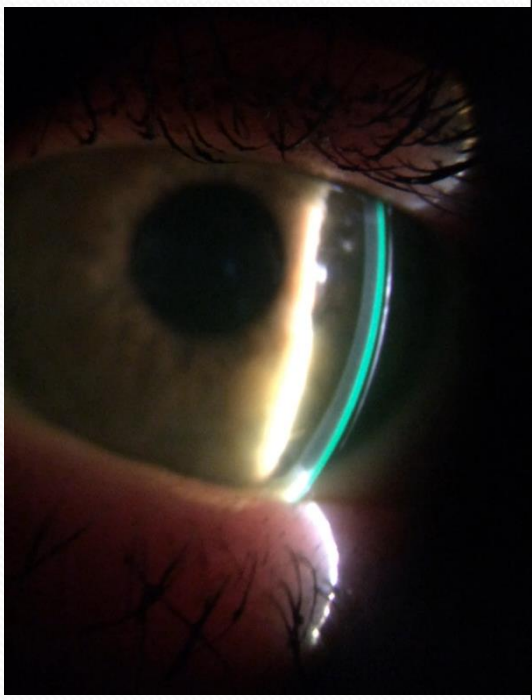
Optimized Optics

All options use the same fit set:

- Spherical
- Front-Toric
  - Markers of one dot or two dots at 12 o'clock
- Multifocal optics:
  - Similar to fitting soft multifocal lenses
    - Center near design
    - Control zone size and add power



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16.6

digiform™

covering your eye with comfort

Base Curves	**4.25mm-10.00mm**
Sagittal Depth	7940µm-4208µm
Power	-30.00 - +30.00 diopters
Options	• Fit: bi-toric changes, quadrant specific changes, notching • Optics: Spherical, front-toric power, center-near multifocal
Materials	Optimum Extra (*available with tangible hydroPeg*), Tyro 97, Boston XO, Boston XO2, Menicon Z, HDS 100

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OPTIMUM | tangible™ HYDRA-PEG

- 30-40nm coating of Polyethylene Glycol (PEG) polymer
- Improves surface wettability and reduces lens deposits
  - Increases tear break up time and helps with dryness issues
- Warranted 1 year against non-wetting

*Clean with non-abrasive/ alcohol free cleaners such as peroxide bases systems or Unique PH
  - Avoid Boston, Lobob or Progent cleaners

Step By Step Fitting

1. Select initial trial lens
2. Evaluate central clearance
3. Evaluate limbal clearance
4. Check edge landing 360°
5. Over-refract and order

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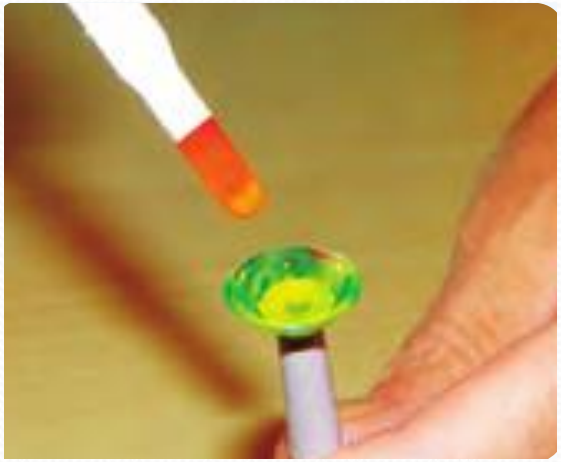
1. Select Initial Trial Lens

Initial Base Curve Selection	
Keratoconus	1.0 D flatter than average K
Normal Corneas	On Flattest K
Post Lasik	4.0 D steeper than Flat K
Post RK	5.0 D steeper than Flat K



Insert lens with NaFl and check for bubbles

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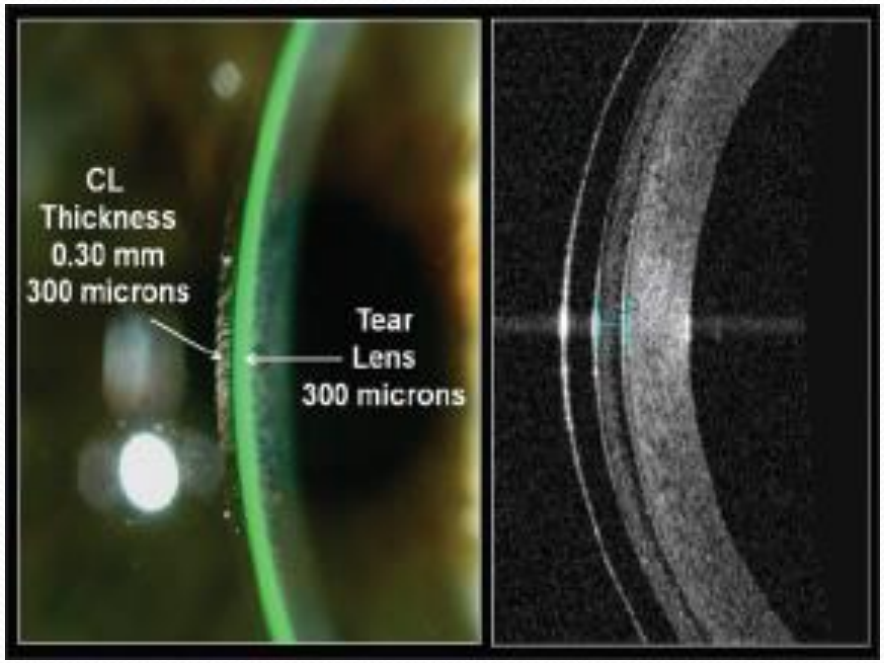
2. Evaluate Central Clearance



- Thinnest slit beam of white light at 45°
- Compare clearance with known lens thickness
  - Corneal thickness varies significantly

Measure clearance over highest elevation

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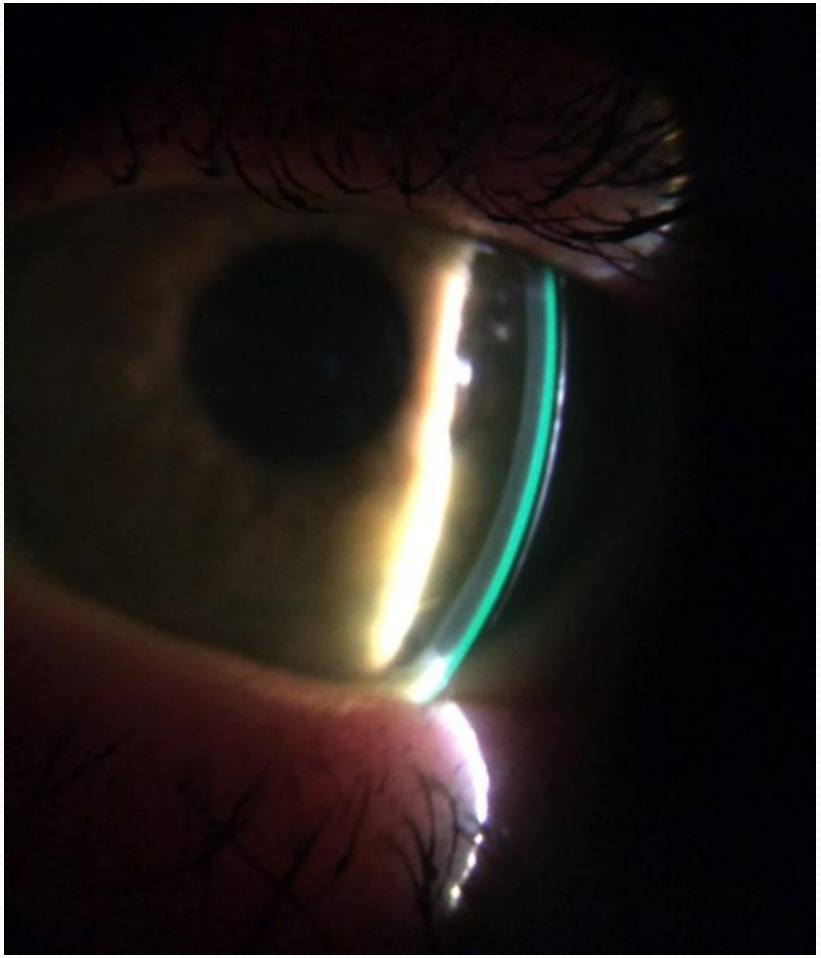
2. Evaluate Central Clearance



Lens settling:

Central clearance will decrease slightly as lens settles:

- Aim for **300µm upon initial insertion**

Recheck lens after 30 minutes

- **200-250µm is ideal after settling**

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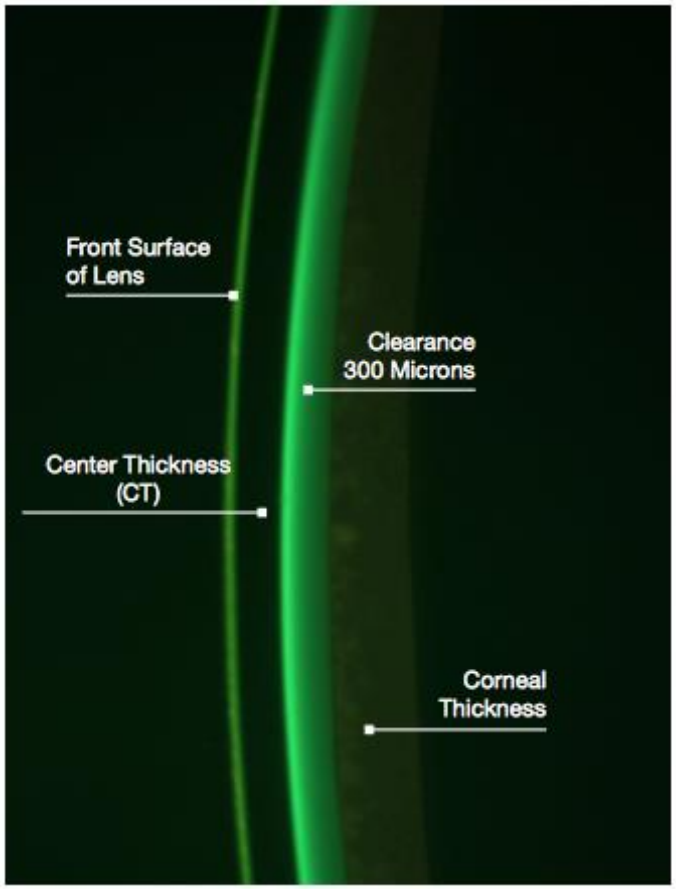
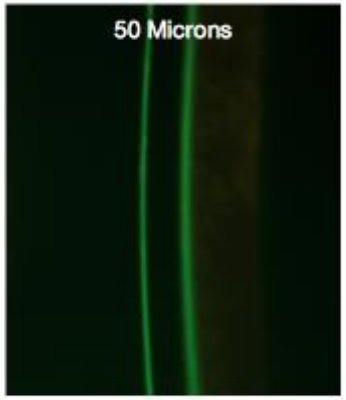
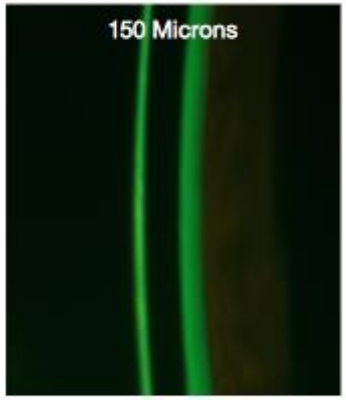
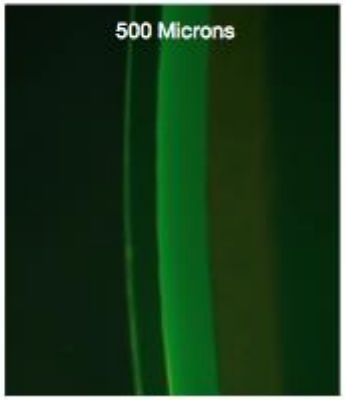
2. Evaluate Central Clearance

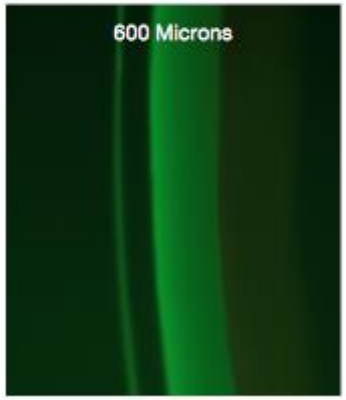
Ferris State Scleral Lens Grading Scale











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12	8.75	38.57	4.50	Oblate
13	9.00	37.50	4.43	Oblate
14	9.25	36.49	4.37	Oblate
15	9.50	35.53	4.31	Oblate

Lens 7 → Lens 5 = 200µm more clearance

Adjust base curve until desired vault achieved:

- Steeper base curve → INCREASES vault
- Flatter base curve → DECREASES vault

Fit set lists lenses in base curve but also sagittal depth

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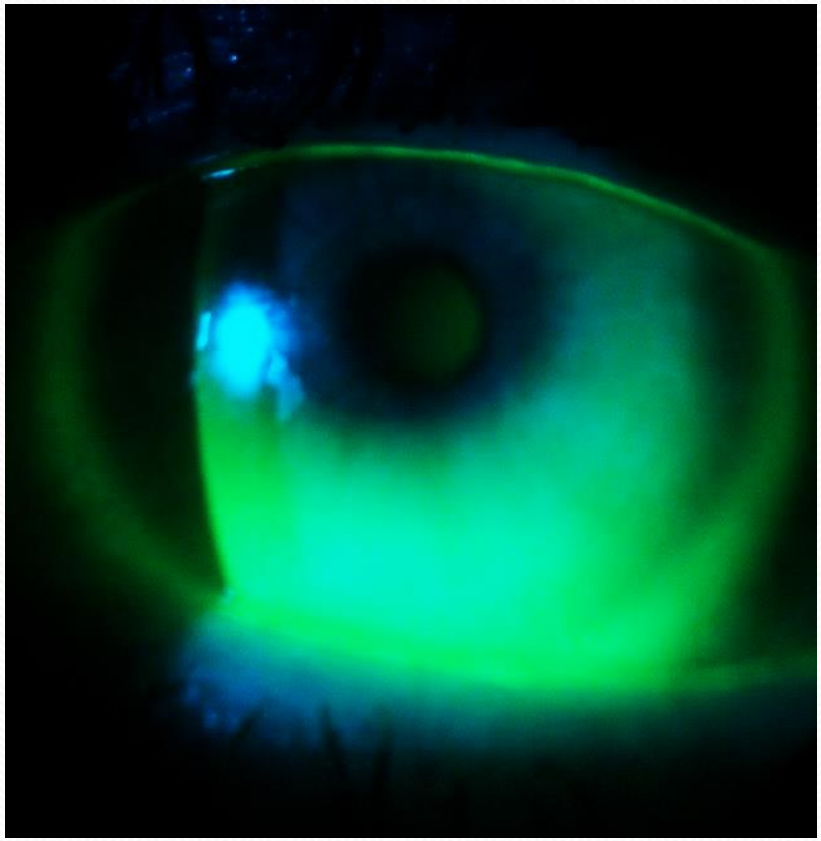
2. Evaluate Central Clearance



Cobalt blue light can be used to double check for touch

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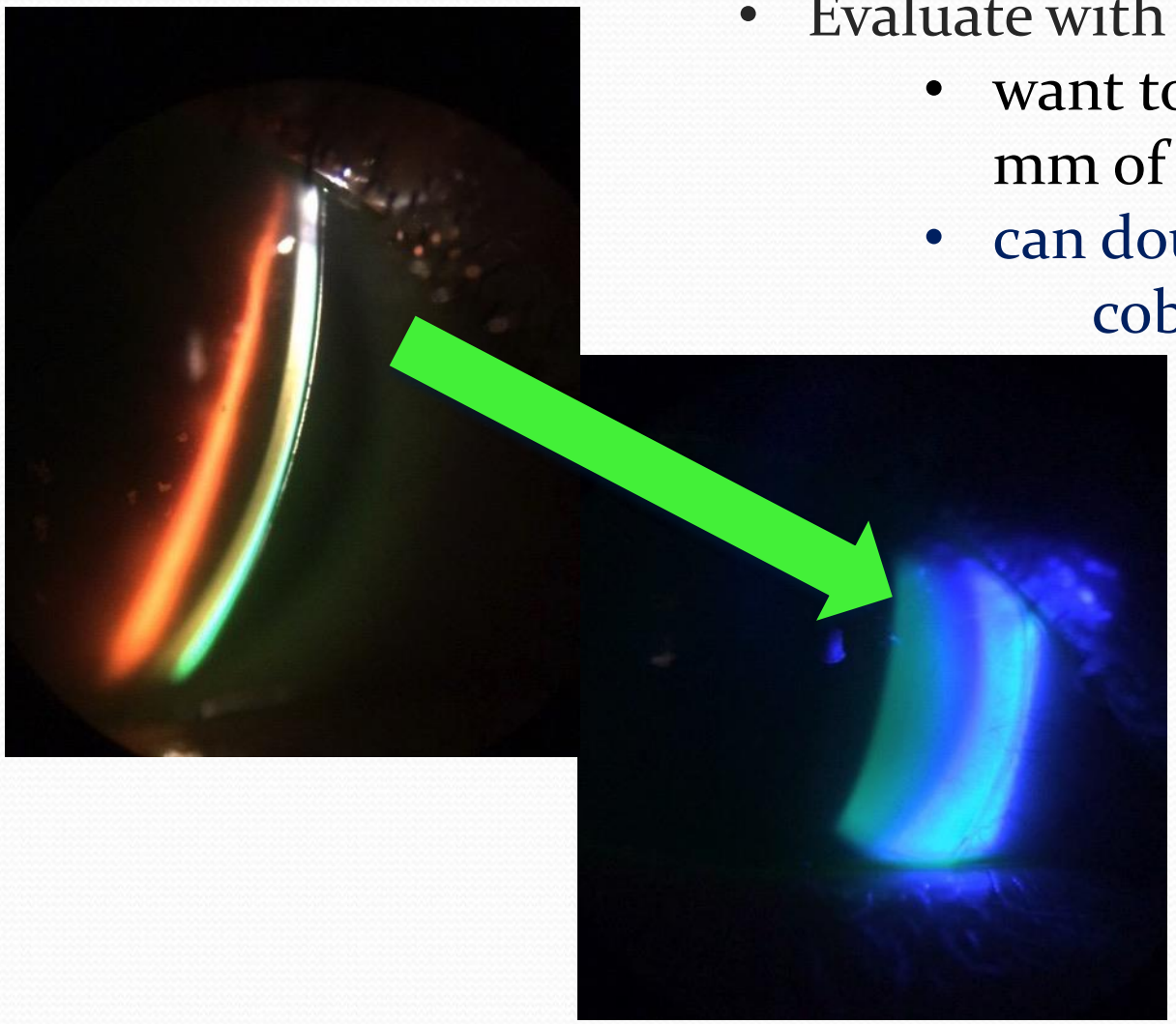
3. Evaluate Limbal Clearance



- Evaluate with white light,
  - want to see green within 1 mm of limbus
  - can double check with cobalt blue
    - Need to completely vault the limbus without bubbles

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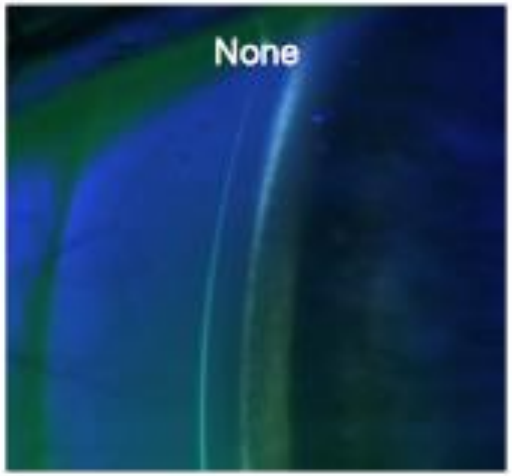
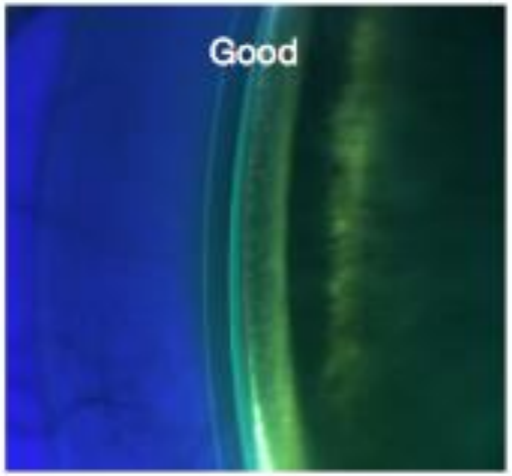
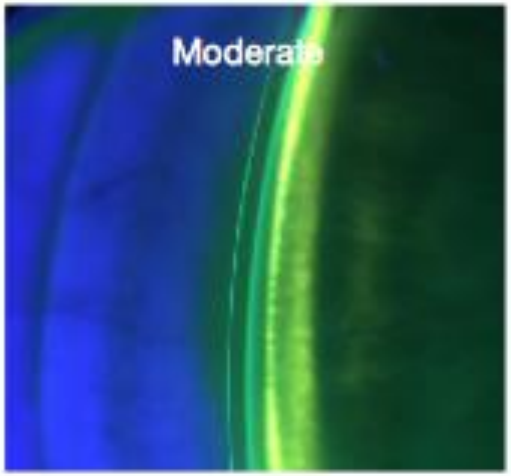
3. Evaluate Limbal Clearance

Ferris State Scleral Lens Grading Scale







4. Evaluate Edge Landing

- Look for compression of blood vessels or edge standoff

- Evaluate edges 360
  - Glaze induced blanching
    - recheck area of blanching in primary gaze

IDEAL aligned fit without compression

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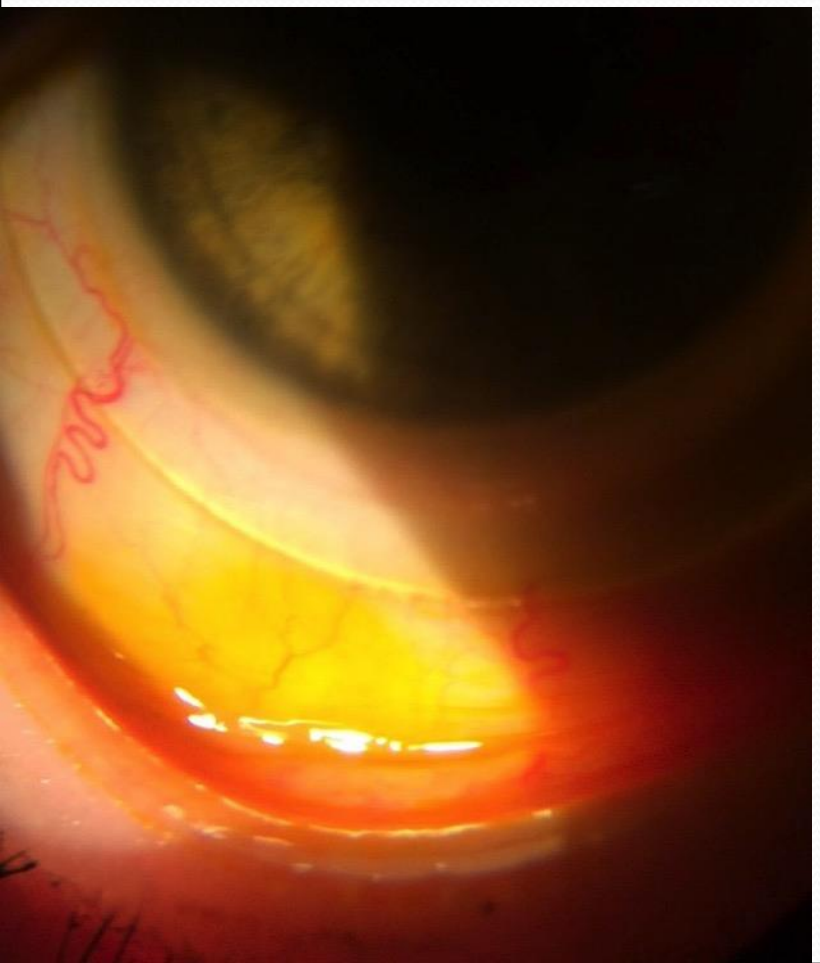
4. Evaluate Edge Landing



Evaluate 360°

- Are bi-toric or quad specific changes needed?

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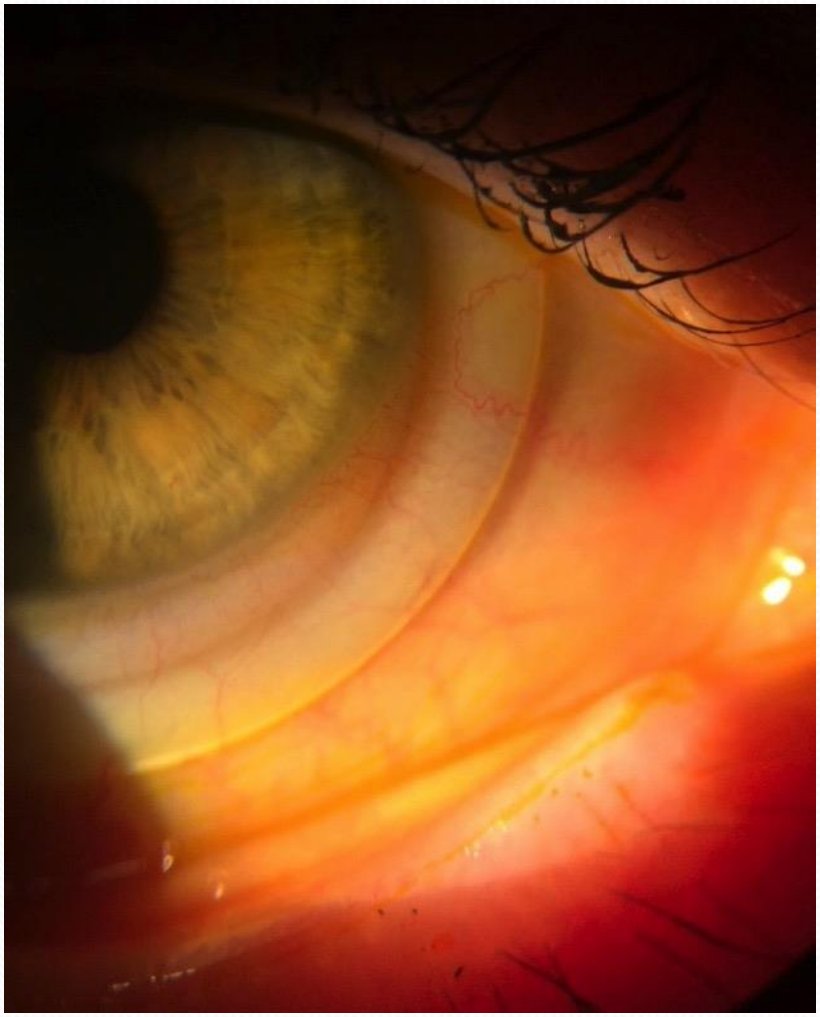

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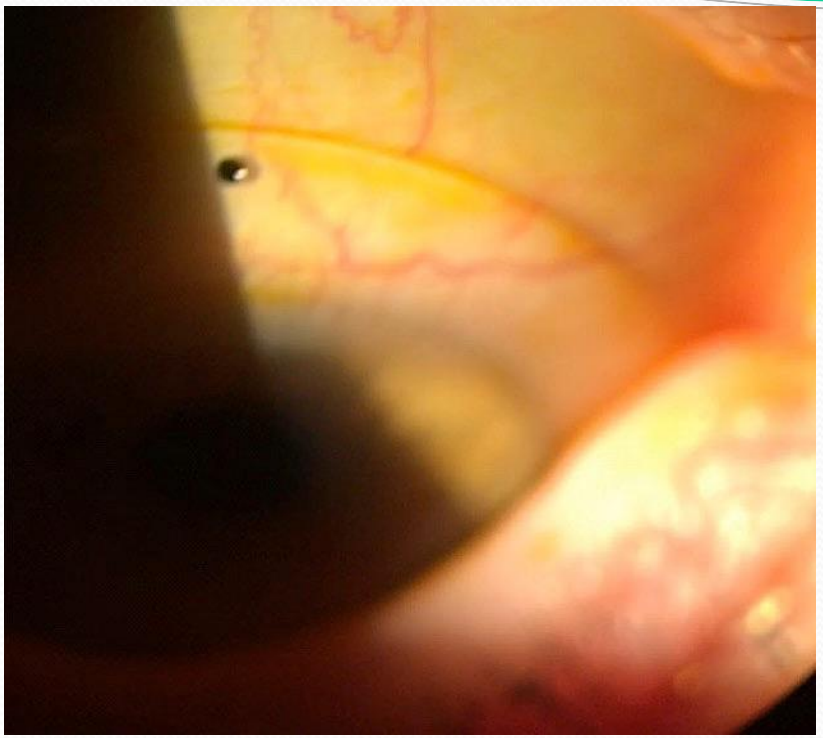

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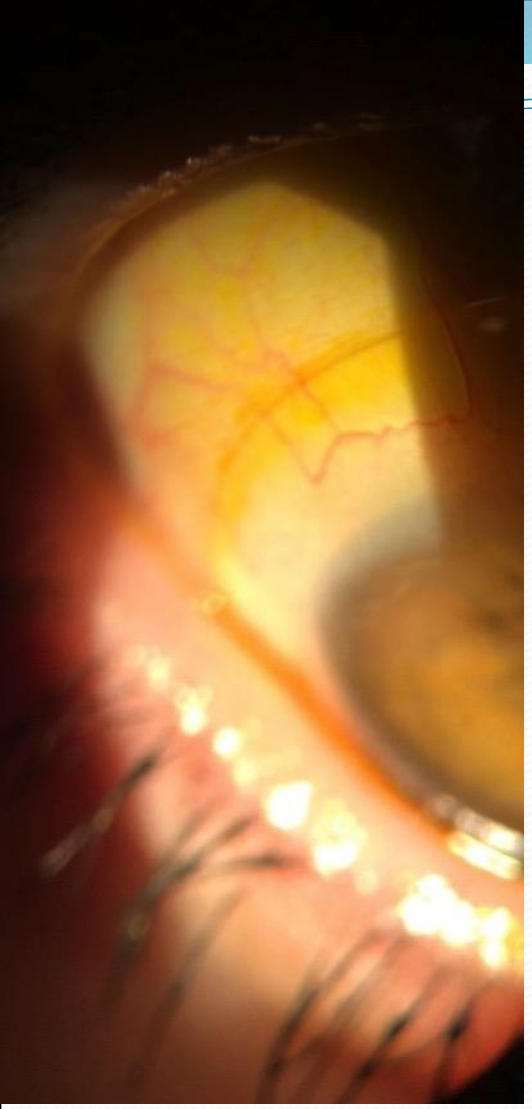

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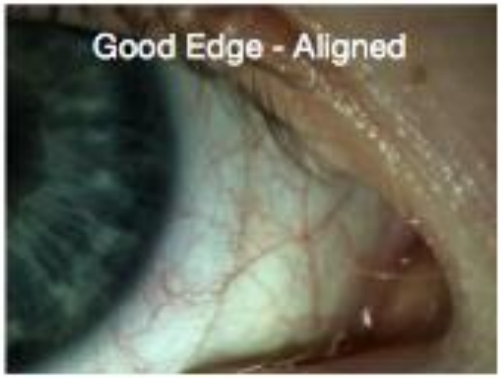
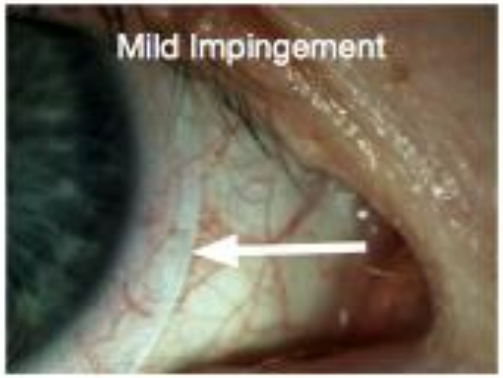
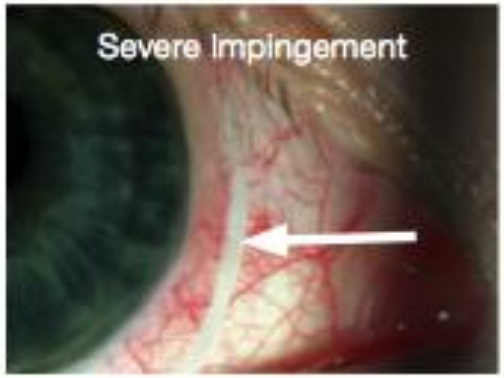
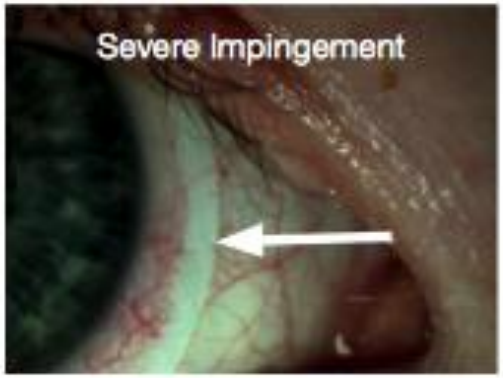
Ferris State Scleral Lens Grading Scale

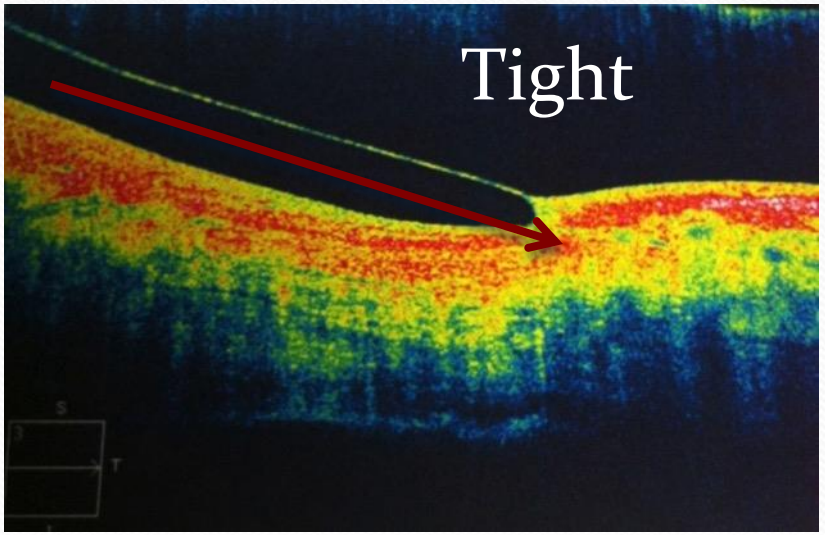


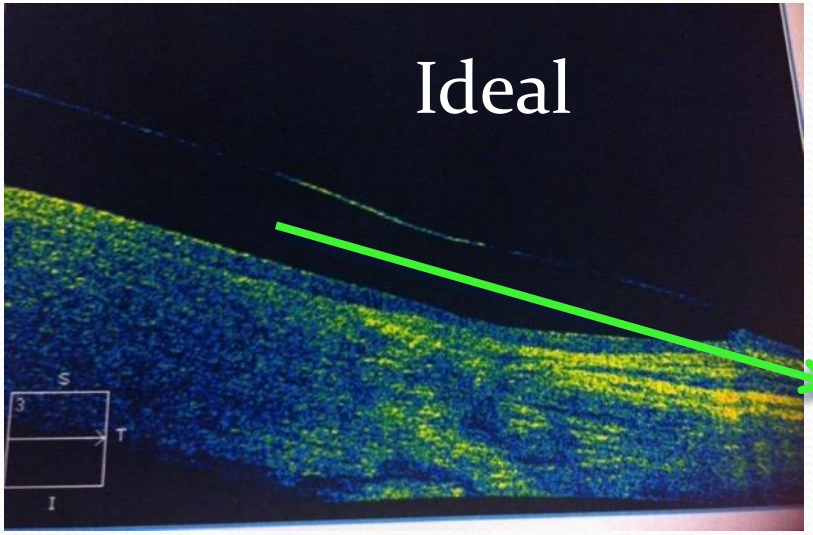


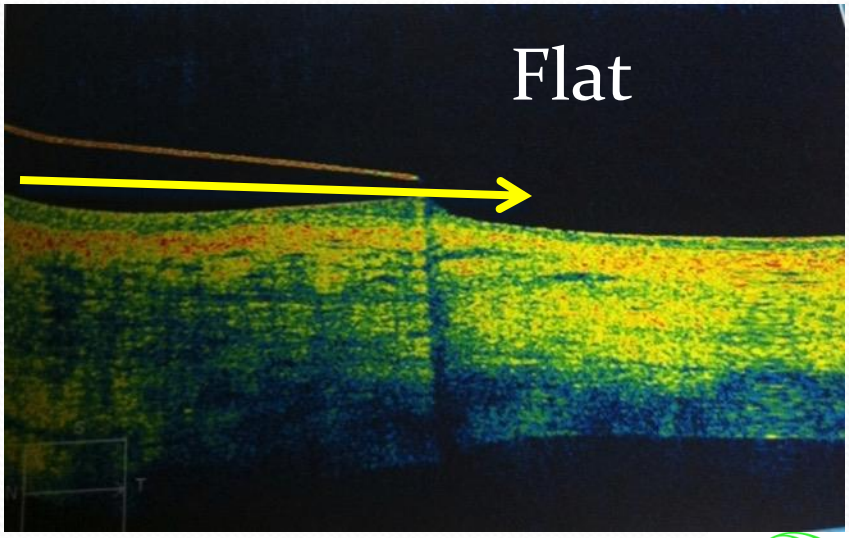




OCT Images of Edges







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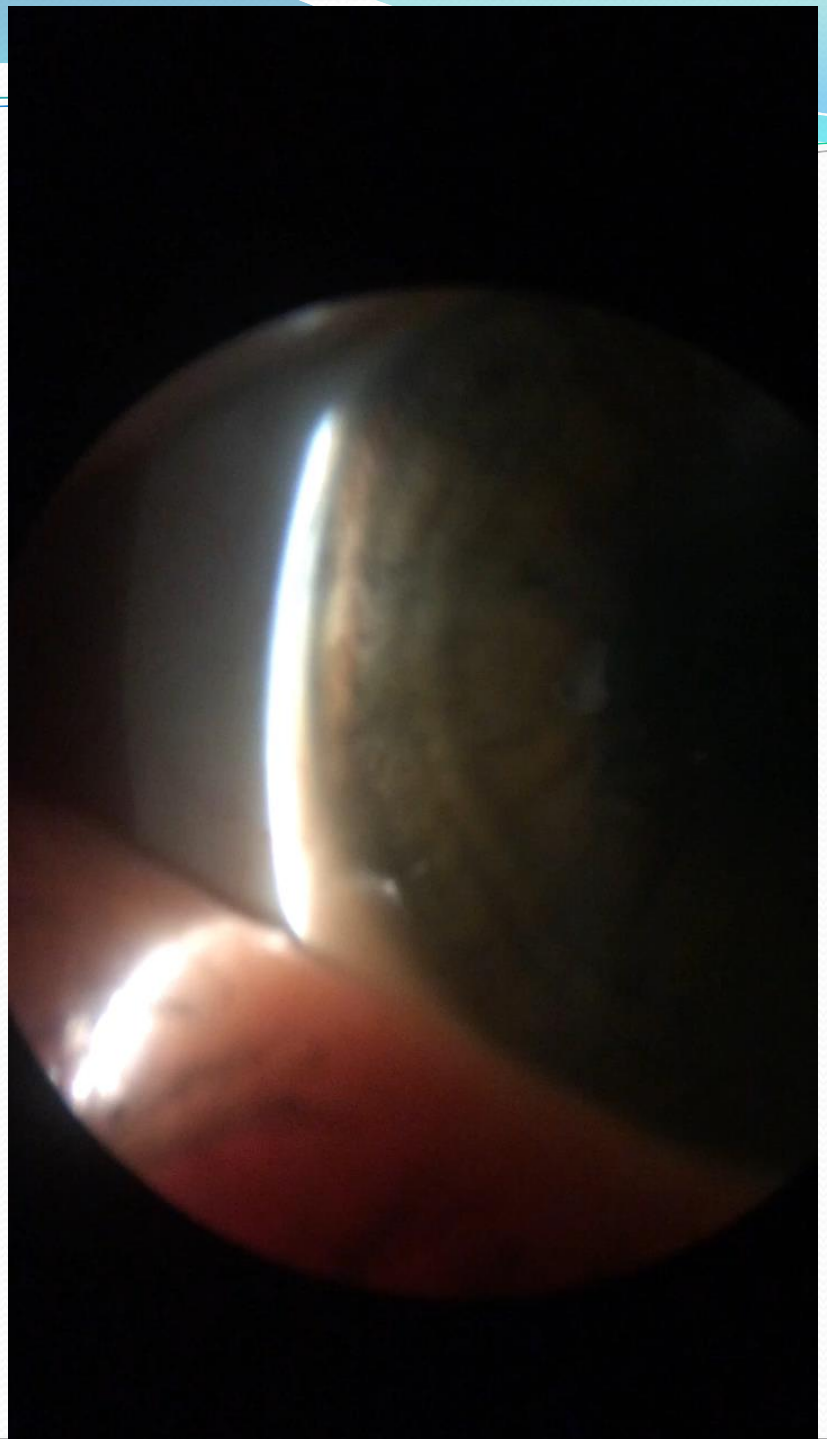

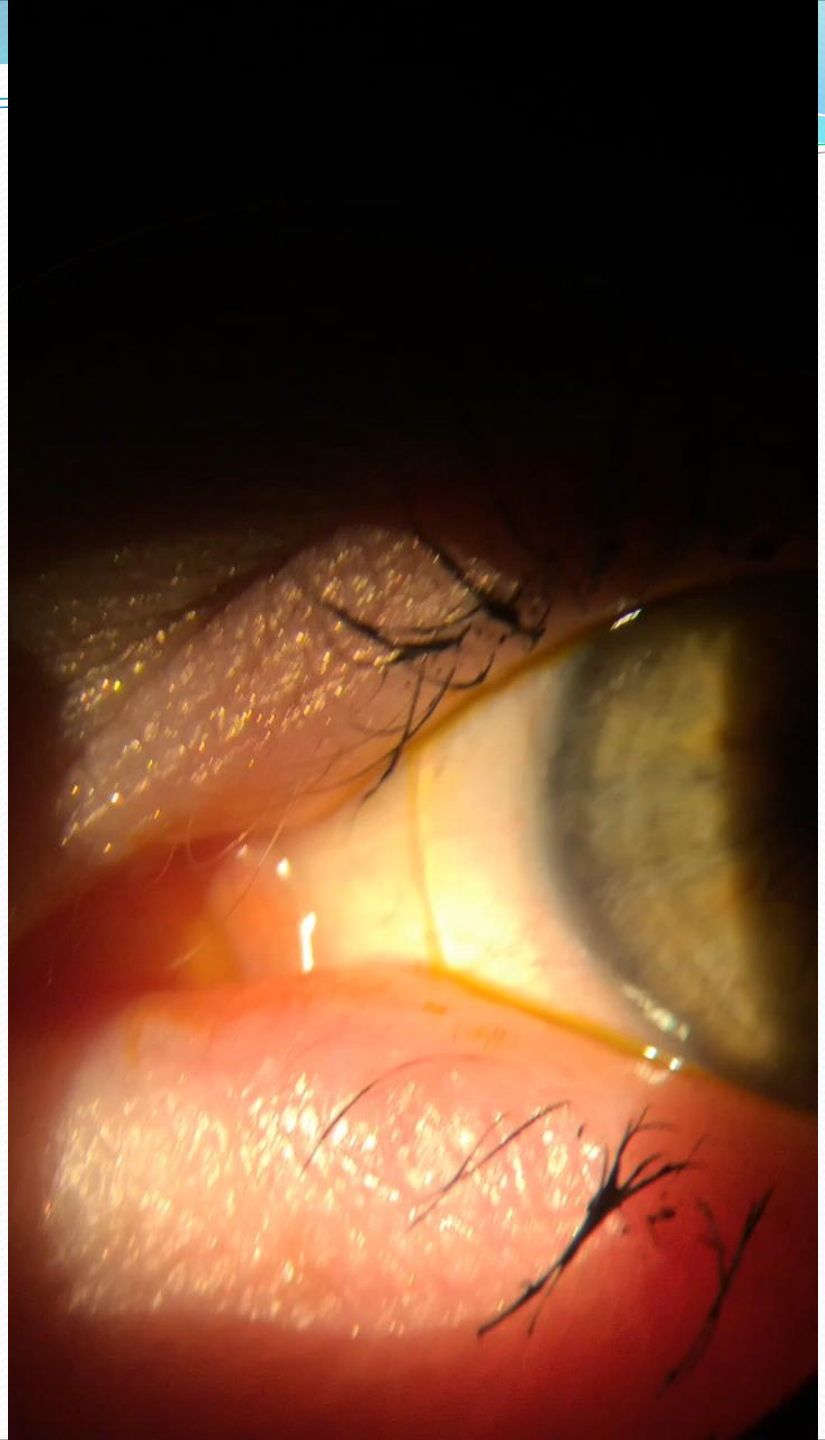

Extra Check: Look for resistance

- Have the patient look up and try to spin the lens
- Should be little to no resistance (can see the engravings move)
- If resistance look again for touch (central or limbal)

Is the patient comfortable?

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5. Over-refract and Order

- Spherical refraction first
  - Cylinder only if best VA not achieved with spherical
  - Retinoscopy or auto-refraction helps
- If cylinder correction needed check for <u>lens flexure</u>
  - Increased thickness can resolve flexure
  - Residual astigmatism: order front toric design

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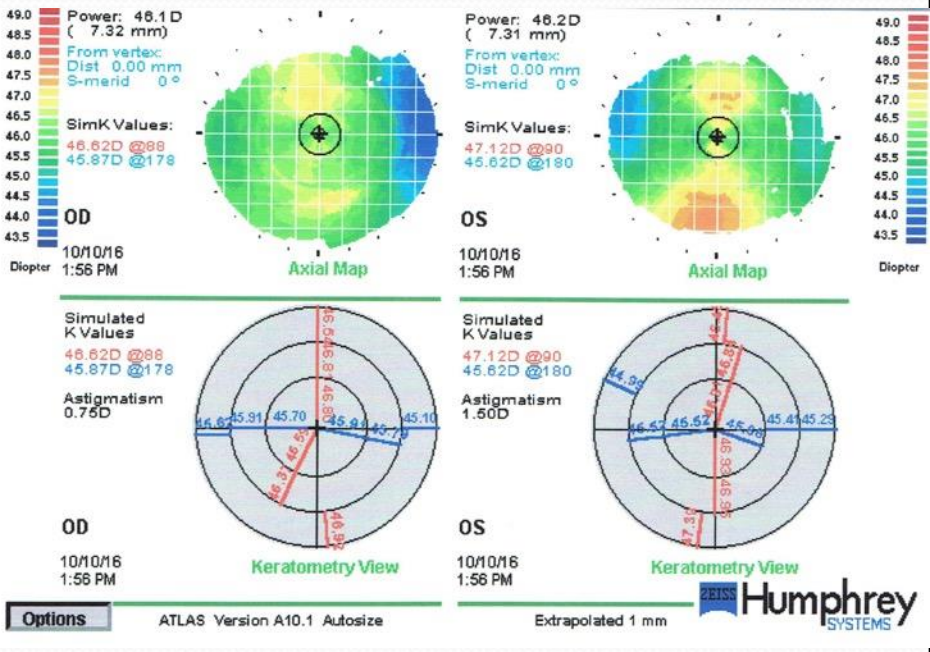
Case Study: Christy

41 year old female, medical assistant

- Complains of constant burning due to dryness, fluctuating vision that is never crisp
  - Previously fit in scleral lenses:
    - feels relief from dryness
    - unable to wear due to discomfort after several hours



Manifest:

OD: -1.00-1.00x105 to 20/25+

OS: -0.75-0.50x005 to 20/25+

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Fitting visit

Lens#	BC	Diop	Sag	Shape (Default)
1	6.00	56.25	5.65	Prolate
2	6.25	54.00	5.49	Prolate
3	6.50	51.92	5.35	Prolate
4	6.75	50.00	5.22	Prolate
5	7.00	48.21	5.10	Prolate
6	7.25	46.55	4.99	Prolate
7	7.50	45.00	4.89	Prolate
8	7.75	43.55	4.80	Prolate
9	8.00	42.19	4.72	Oblate
10	8.25	40.91	4.64	Oblate
11	8.50	39.71	4.56	Oblate
12	8.75	38.57	4.50	Oblate
13	9.00	37.50	4.43	Oblate
14	9.25	36.49	4.37	Oblate
15	9.50	35.53	4.31	Oblate

First trial:

OD: **Lens 8:**

- ~125µm central clearance (5 minutes after insertion)

OS: **Lens 7:**

- ~200µm central clearance (5 minutes after insertion)

Best trial lens for both eyes is Lens 6

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Trial Fitting

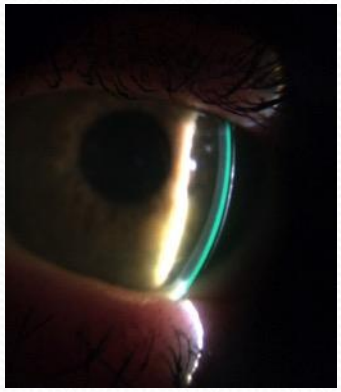
Second trial:

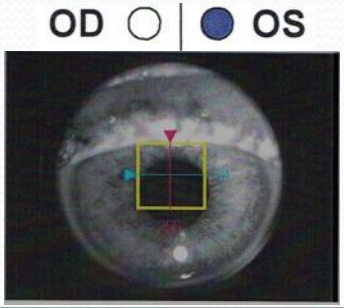
OD: **Lens 6:** Pwr: -6.75DS

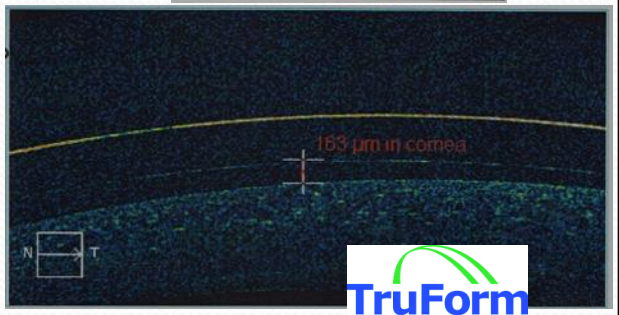
- ~300µm central clearance (5 minutes after insertion)
- ~220µm central clearance after settling, clears over the limbus, moderately flat edges 360°

OS: **Lens 7 :** Pwr: -5.25DS

- ~150µm central clearance after settling, clears over limbus, moderately flat edges 360°







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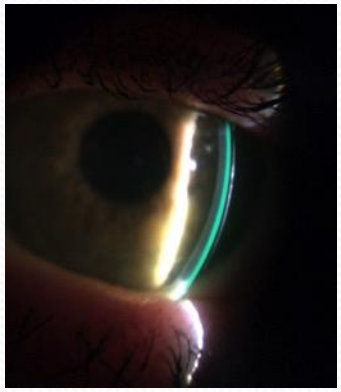
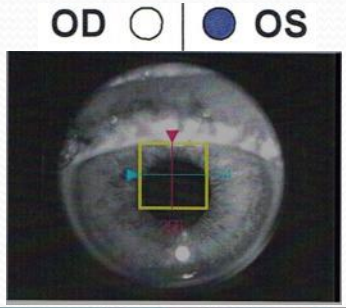
Trial Fitting



Second trial:

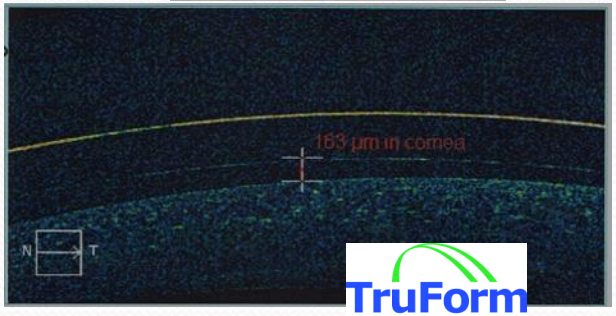
OD: **Lens 6:** Pwr: -6.75DS

- ~300µm central clearance (5 minutes after insertion)
- ~220µm central clearance after settling, clears over the limbus, moderately flat edges 360°



OS: **Lens 7 :** Pwr: -5.25DS

- ~150µm central clearance after settling, clears over limbus, moderately flat edges 360°



Over-refraction

OD: +5.25-1.50x100 to 20/20 “crisp”

OS: +5.25-1.50x075 to 20/20 “crisp”

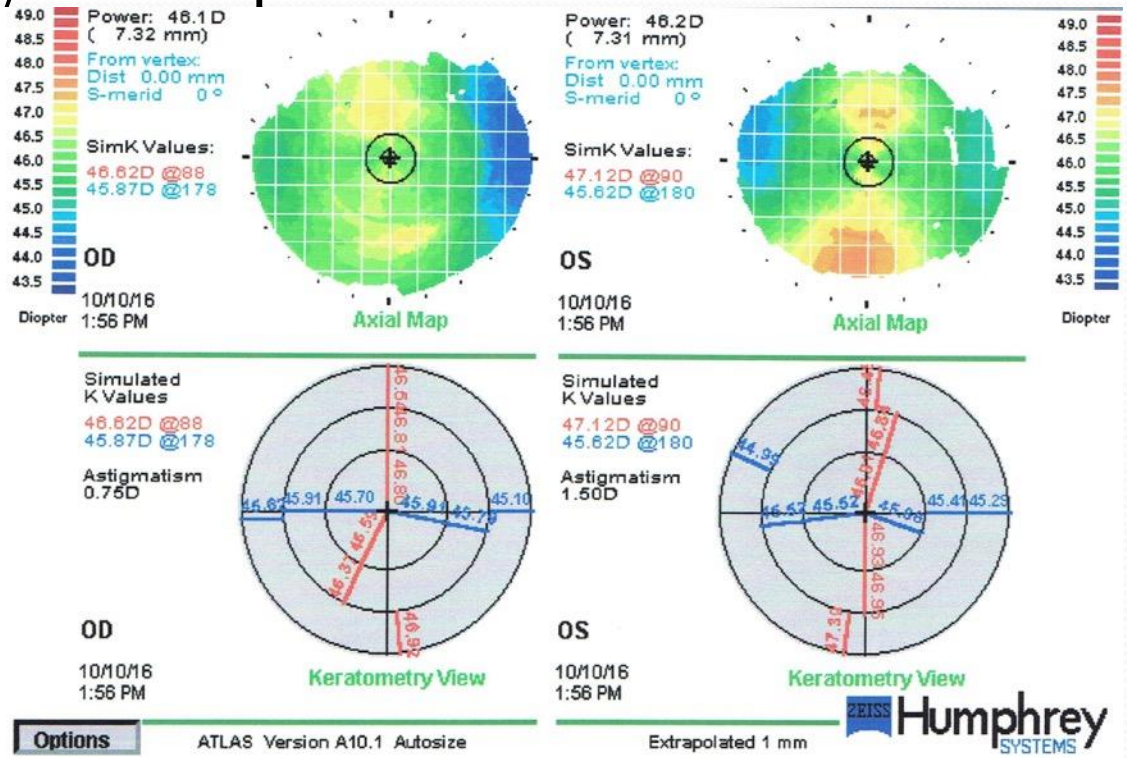
Unexpected astigmatism

Over-refraction
OD: +5.25-1.50x100 to 20/20 “crisp”
OS: +5.25-1.50x075 to 20/20 “crisp”

Manifest:
OD: -1.00-1.00x105 to 20/25+
OS: -0.75-0.50x005 to 20/25+

→No flexure over lenses

Internal astigmatism
(likely lenticular)



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First Order

DigiForm 16.6 Scleral Lenses- Front Toric

OD: BC 7.25 Sag 4.99 Pwr -1.50-1.50x100
→ 100µm steeper edge 360°

OS: BC 7.25 Sag 4.99 Pwr -1.25-1.50x075
→ 100µm steeper edge 360°

Lens Modifications

Minimum change: 25-50µm
Moderate change: 75-150µm
Aggressive change: >200µm

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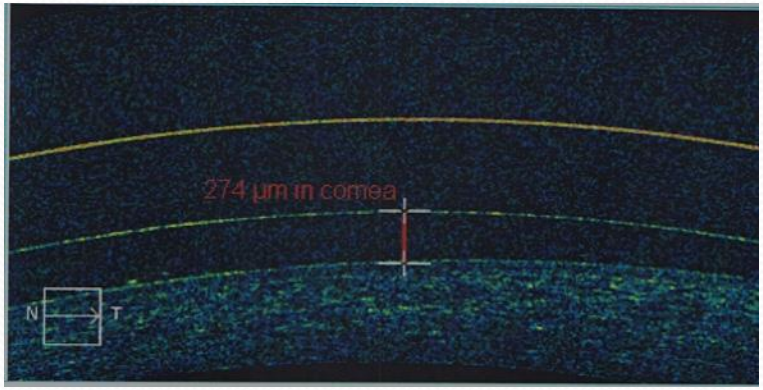
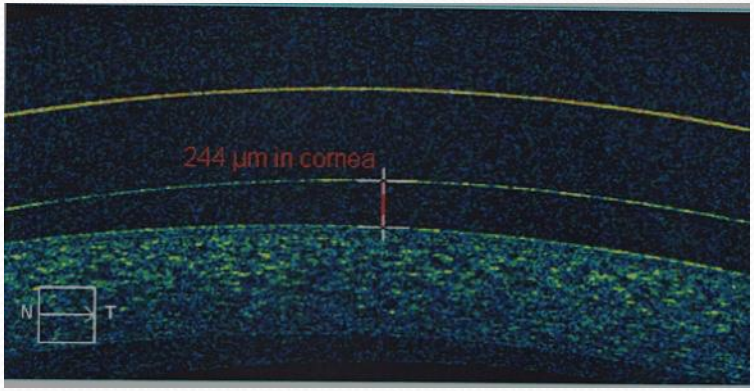
Dispense visit

"Amazing vision and comfort!
Better than all my previous lenses"





Vision:
OD: **20/20** OR: +0.75-0.75x100 to crisper 20/20
OS: **20/20** Plano to 20/20
OU: **20/15**

Evaluation (after 10min):
OD:~300µm central clearance, clears over limbus, good edges
OS: ~250µm central clearance, clears over limbus, good edges

Lenses dispensed, return 2 weeks for recheck (in the afternoon)

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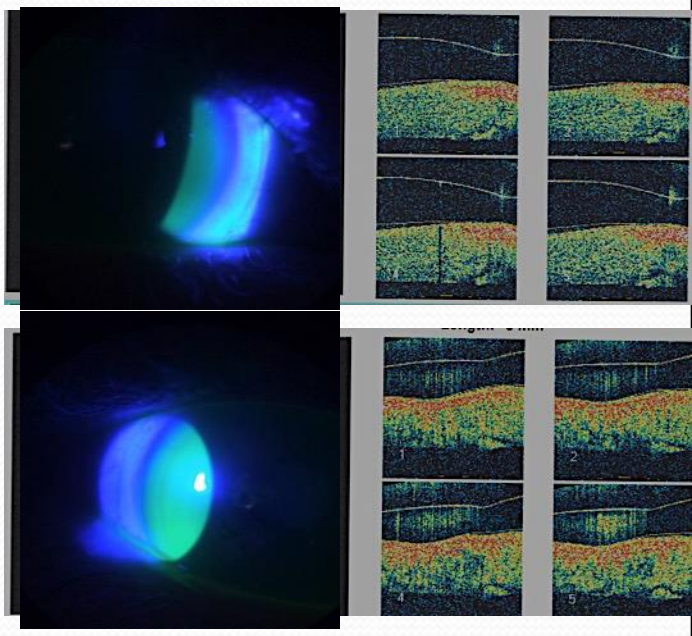
2 week follow up

"Eyes get red after 4-6 hours, feel sore but vision is so great"

Vision:
OD: **20/20** OR: +0.75-0.75x100 to crisper 20/20
OS: **20/20** Plano to 20/20
OU: **20/15**



Evaluation (4 hours wear)

OD:~250µm central clearance, touch over limbus nasal, flaring of edges 360
OS: ~200µm central clearance, touch over limbus nasal, flaring of edges 360

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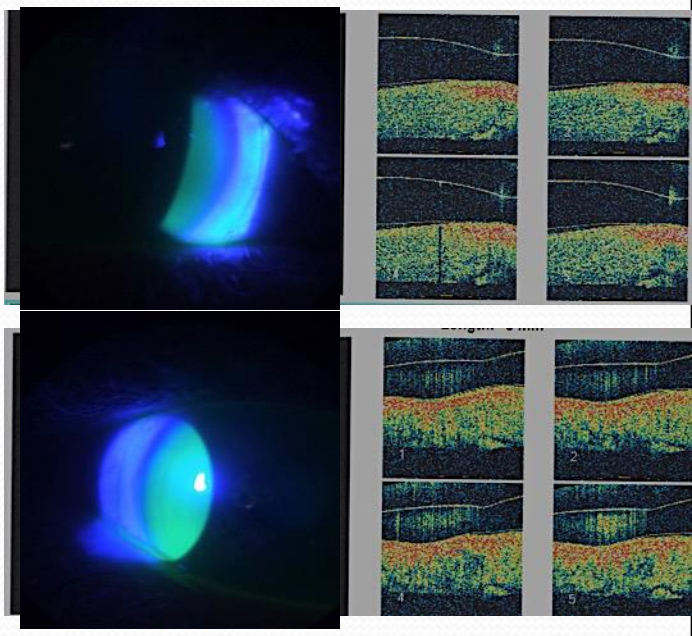
2 week follow up

"Eyes get red after 4-6 hours, feel sore but vision is so great"

Evaluation (4 hours wear)

OD:~250µm central clearance, touch over limbus nasal, flaring of edges 360

OS: ~200µm central clearance, touch over limbus nasal, flaring of edges 360



Lenses re-ordered:

OD: BC 7.25 Sag 4.99 Pwr -0.75-2.25x100

→ 75µm flatter in curve 3
(limbal curve for 12.5mm HVID)

OS: BC 7.25 Sag 4.99 Pwr -1.25-1.50x075

→ 75µm flatter in curve 3
(limbal curve for 12.5mm HVID)

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Final Lenses

"Wearing lenses all day with no problems. Vision finally feels equal and balanced"

Vision:

OD: **20/20+2** OR: Plano to 20/20

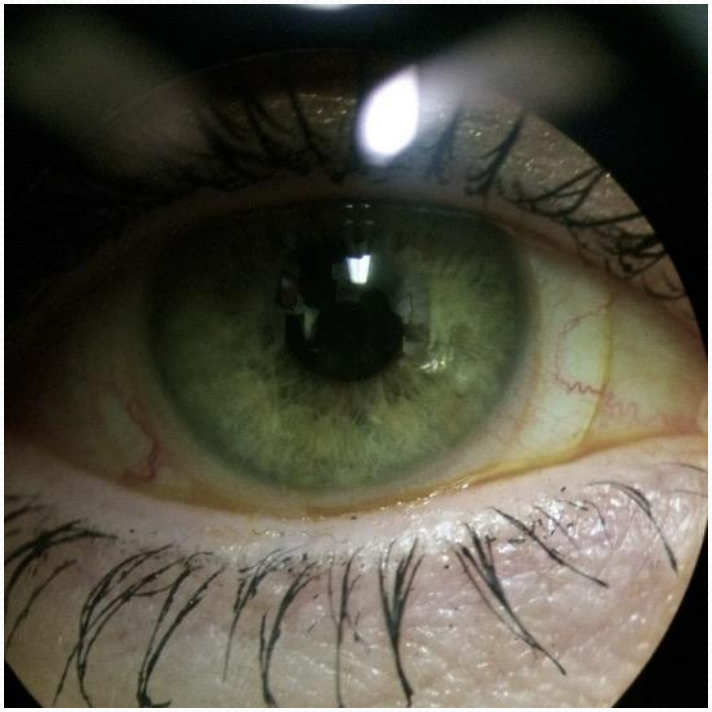
OS: **20/20** Plano to 20/20

OU: **20/15**

Evaluation (6 hours wear)

OD:~250µm central clearance, clears over limbus, good edges

OS: ~225µm central clearance, clears over limbus, good edges



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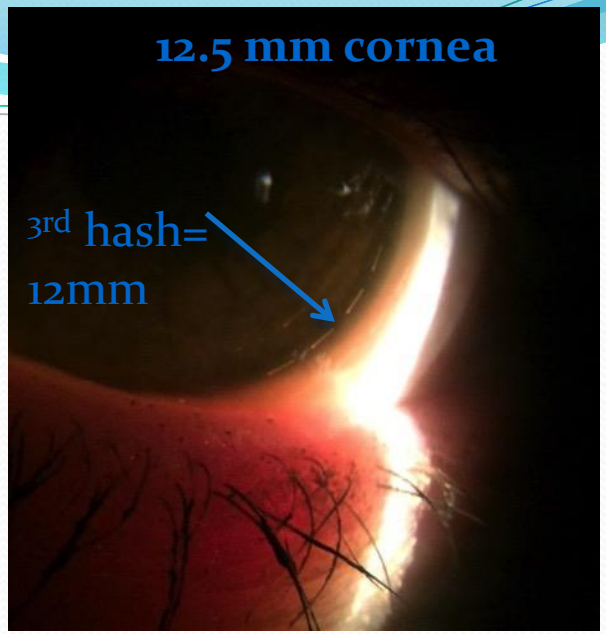
Tips for success



- Measure HVID
  - Helps define limbal vs edge curves
- Find best lens out of trial set before ordering
  - Helps minimize re-makes
- Allow lens to settle 30 minutes or more
- Check edges 360° to see if toric or quad specific curves needed

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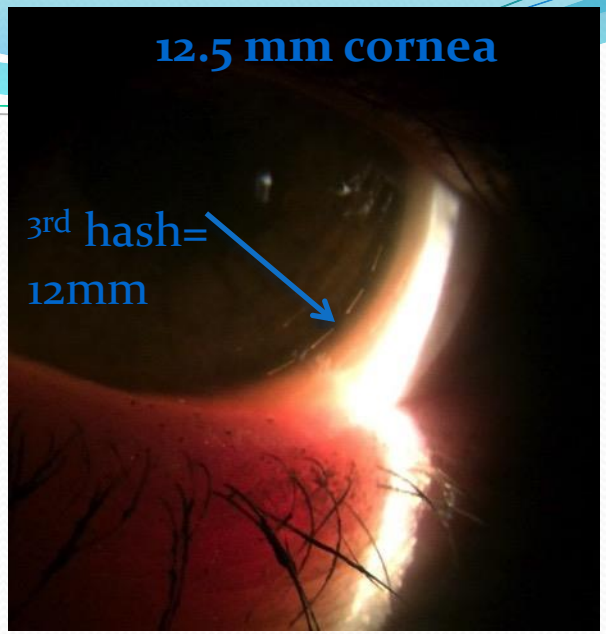
Tips for success



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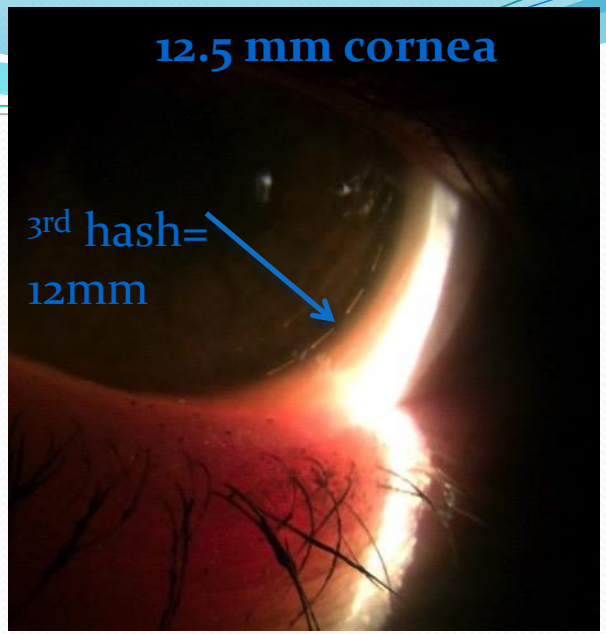
Tips for success



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Truform Optics Lab

Family business that was established in 1976

- Long time member of the Contact Lens Manufacturers Association (CLMA)
- 24-48 hour turnaround service

Dedicated to providing superior customer service:

knowledgeable consultants and

state-of-the-art lab equipment

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16.6 DigiForm Design Advantages

One diameter/one set for all corneal conditions

Simple to fit and easy to communicate with lab and consultants

Ultimate control over fit and optics

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Thank You for Your Time

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