PROFESSIONAL FITTING AND INFORMATION GUIDE

Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for Overnight Wear

CAUTION: Federal Law Prohibits Dispensing Without a Prescription
Nonsterile. Clean and condition lenses prior to use.

LCONQ-24-0103-05

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INTRODUCTION

Optimum Infinite (tisilfocon A) Orthokeratology Lenses II produce a temporary reduction of myopia by reversibly altering the curvature of the cornea. A slight reduction of the curvature of the cornea can reduce the excessive focusing power of the myopic eye. If the amount of corneal reshaping is precisely controlled, as is the objective of the Optimum Infinite (tisilfocon A) Orthokeratology Lenses II lens design, it is possible to bring the eye into correct focus and completely compensate for myopia. The lens is designed to be worn overnight with removal during the following day. The lenses must be worn at night on a regular schedule to maintain the corneal reshaping, or the pre-treatment myopia will return.

PRODUCT DESCRIPTION

Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for the Temporary Reduction of Myopic Refractive Error (Sigmoid Proximity Control Design):

Optimum Infinite (tisilfocon A) Orthokeratology Lenses II are manufactured from Optimum Infinite material (tisilfocon A). The lenses are designed to have congruent anterior and posterior surfaces each consisting of three zones:

1. The central spherical zone (BC).
2. A mathematically designed sigmoid corneal proximity “Return Zone” (W).
3. A non-curving “Landing Zone” (LZW).

The lens design also includes a convex elliptical edge terminus smoothly joining the anterior and posterior surfaces (P).

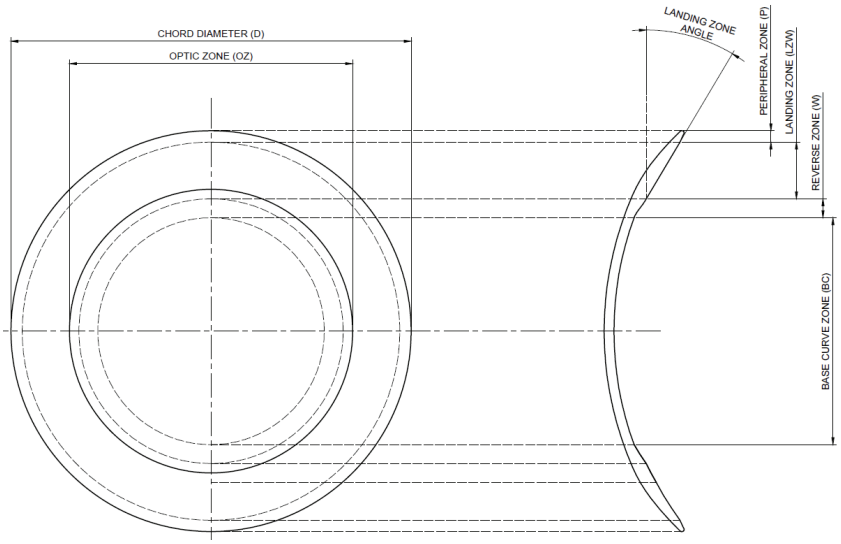
Optimum Infinite (tisilfocon A) Orthokeratology Lenses II are to be worn overnight with removal during all or part of each following day. The lens material (tisilfocon A) is a thermoset copolymer derived from fluoromethacrylate and siloxanylstyrene, bound by crosslinking agents. The lenses are available as lathe-cut contact lenses with a blue, green, red or yellow tint. The blue tinted lens contains D&C Green #6. The green tinted lens contains D&C Green #6 and D&C Yellow #18. The red tinted lens contains D&C Red #17 and D&C Yellow #18. The yellow tinted lens contains D&C Yellow #18. Also, a UV absorber (Benzophenone) is added during the manufacturing process.

Parameter	Range
Diameter (D)	9.5 to 12.0 mm
Central Base Curve Radius (BC)	6.50 to 10.50 mm
Optical Zone Semi Chord (OZ)	2.50 to 3.50 mm
Return Zone Width (w)	0.75 to 1.5 mm
Return Zone Depth (Δ)	to 1.0 mm
Return Zone Radius	to infinity
Landing Zone Angle (°)	-25° to -50°
Landing Zone Width (LZW)	0.5 to 2.75 mm
Peripheral Edge Curve Width (P)	0.04 mm to LZW
Dioptric Powers	-2.00 to +2.00 Diopters

Table 1. Optimum Infinite (tisilfocon A) Orthokeratology Lenses II Parameters

Property	Optimum Infinite (tisilfocon A) Orthokeratology Lenses II
Refractive Index (dry)	1.434
Modulus (MPa)	1416
Hardness (Shore D)	81
Specific Gravity	1.20
Surface Character	Hydrophobic
Oxygen Permeability (Dk)	180 x 10 11 (cm2/sec) (ml O2/ml x mm Hg @ 35oC)
Color Additives	Visibility Tints – D&C Green #6, Solvent Yellow #18, D&C Red #17

Table 2. Optimum Infinite (tisilfocon A) Orthokeratology Lenses II Properties



ACTIONS

The Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for overnight wear produces a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the eye, and if the amount of corneal flattening is properly controlled, it is possible to bring the eye into correct focus and completely compensate for myopia.

The posterior surface of regular contact lenses generally aligns with the central cornea and rests directly on the corneal tear layer. Regular contact lenses are designed to cause little or no effect on the cornea but Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for overnight wear is designed to purposely flatten the shape of the cornea by applying slight pressure to the center of the cornea when the patient is asleep.

After the lens is removed, the cornea retains its altered shape for all or most of one's waking hours. The lenses are designed to be worn overnight with removal during the following day. The Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for overnight wear must be worn at night on a regular schedule to maintain the orthokeratology effect, or the myopia will revert to the pretreatment level.

INDICATIONS

The Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for overnight wear are indicated for use in the reduction of refractive error in non-diseased eyes. The lenses are indicated for overnight wear for the temporary reduction of myopia up to 6.00 diopters with eyes having astigmatism up to 1.75 diopters. The lenses may only be disinfected using a chemical disinfection system.

Note: To maintain the Orthokeratology effect of myopia reduction, overnight lens wear must be continued on a prescribed schedule. Failure to do so can affect daily activities (e.g., night driving) and cause visual fluctuations and changes in intended correction.

CONTRAINDICATIONS (REASONS NOT TO USE)

Reference **"CONTRAINDICATIONS"** found in the enclosed Package Insert.

WARNINGS

Reference **"WARNINGS"** found in the enclosed Package Insert.

ADVERSE EFFECTS (PROBLEMS & WHAT TO DO)

Reference **"ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)"** found in the enclosed Package Insert.

PRECAUTIONS

Reference **"PRECAUTIONS"** found in the enclosed Package Insert.

SELECTION OF PATIENTS

Patients are selected who have a demonstrated need and desire for a refractive reduction by orthokeratology with rigid gas permeable contact lenses and who do not have any of the contraindications for contact lenses described above.

Optimum Infinite (tisilfocon A) Orthokeratology Lenses II are indicated for myopic patients who desire to have time periods during the day in which they do not need to wear their contact lenses, but still need to see clearly. Optimum Infinite (tisilfocon A) Orthokeratology Lenses II are primarily intended for patients who are within the following parameters.

Refractive error	-0.50 to –5.50 diopters with up to 1.75 diopters of astigmatism
Keratometry	37.00 to 52.00 diopters
Visual Acuity	20/20 to 20/1000

FITTING CONCEPT

Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for overnight wear are intended to be fitted so as to flatten the central cornea and thereby reduce myopia. This goal is accomplished by the lens design and the manner in which the lens is fitted.

The goal in fitting is a well-centered lens having a base curve that is flatter than the flattest meridian of the cornea by at least the attempted treatment power in that meridian. A well-fit lens will have proper sagittal depth to prevent z-axis tilt and achieve centration over the corneal apex. A well-fit lens will also have a proper sagittal depth profile to prevent bearing at the Return Zone – Landing Zone junction or heavy bearing in the periphery of the lens. The lens will demonstrate central corneal applanation, paracentral lens-cornea clearance and Landing Zone-cornea tangential correspondence.

The Optimum Infinite (tisilfocon A) Orthokeratology Lenses II fitting system utilizes the following fixed parameters:

- Optic Zone = 6.0 mm
- Return Zone Width = 1.0 mm

The optic zone and Return Zone Width may be changed in rare circumstances by means of a special order. Smaller optic zones may be appropriate in unusually small corneal diameters and in the case of target reductions greater than 5.00 diopters. For corneal diameters greater than 10.8 mm and target improvements less than 5.00 diopters, the standard parameters are recommended.

There are four primary fitting objectives:

- Provide a base curve that will reshape the underlying cornea to a resultant curvature that produces emmetropia or low hyperopia.
- Provide an initial clearance at the point of tangential correspondence of the Landing Zone and peripheral cornea that will allow the corneal apex to retreat approximately 6 microns per diopter of treatment.
- Provide a Landing Zone that has the proper angle to provide a midpoint of tangency to the underlying cornea near the midpoint of the zone itself.
- Provide a lens diameter that, in conjunction with the Landing Zone Angle, provides optimum centration.

The Optimum Infinite (tisilfocon A) Orthokeratology Lenses II in conjunction with the following fitting procedure can fulfill these objectives.

PREDICTING LENS RESULTS

Clinical studies have not established reliable methods to predict which patients will achieve the greatest corneal flattening with these contact lenses for orthokeratology. Optimum Infinite (tisilfocon A) Orthokeratology Lenses II may produce a temporary reduction of all or part of a patient's myopia. The amount of reduction will depend on many factors including the amount of myopia, the elastic characteristics of the eye and the way that the contact lenses are fitted. Average amounts of reduction have been established by clinical studies but the reduction for an individual patient may vary significantly from the averages.

CLINICAL STUDY DATA

Reference the **"SUMMARY OF CLINICAL STUDY DATA"** found in the enclosed Package Insert.

Risk Analysis

There is a small risk involved when any contact lens is worn. It is not expected that the Optimum Infinite (tisilfocon A) Orthokeratology Lenses II will provide a significant risk that is greater than other overnight wear rigid gas permeable contact lenses. Additionally, orthokeratology patients may experience episodes of blurry distance vision or visual flare and/or ghosting.

The two most common side effects that occur in rigid contact lens wearers are corneal edema and corneal staining. It is anticipated that these two side effects will also occur in some wearers of Optimum Infinite (tisilfocon A) Orthokeratology Lenses II. Other side effects, which sometimes occur in all hard lens wearers, are pain, redness, tearing, irritation, discharge, abrasion of the eye or distortion of vision. These are usually temporary conditions if the contact lenses are removed promptly and professional care is obtained. When overnight orthokeratology lenses dislocate during sleep, transient distorted vision may occur the following morning after removal of the lenses. This distortion may not be immediately corrected with spectacle lenses.The duration of the distorted vision would rarely be greater than the duration of the daily visual improvement normally achieved with the lenses.

In rare instances, there may occur permanent corneal scarring, and resulting permanent decreases in vision may occur. The risk of serious problems (such as corneal ulcers and vision loss) is greater when lenses are worn overnight. In addition, studies have shown that smoking increases the risk of corneal ulcers, for those who wear lenses overnight. The benefits and risks of overnight wear lenses should be carefully discussed with your patient. Your patient should be instructed to remove the contact lenses if any abnormal signs are present.

FITTING PROCEDURES

Note: Contact lenses for Orthokeratology should be fitted only by a contact lens fitter trained and certified in the fitting of conventional and sigmoid geometry contact lenses.

Slide Rule Calculator

Utilizing a provided slide rule calculator, practitioners will cross-reference a patient's flat Keratometric value and their vertexed Manifest Refraction Sphere (MRS) and thereby will determine a suggested diagnostic lens from an in-office diagnostic/dispensing lens system.

The slide rule will suggest a specific lens including the parameters of Base Curve, Return Zone Depth (RZD) and Landing Zone Angle (LZA) for initial evaluation by the practitioner. Based on the results of fluorescein pattern evaluation of the suggested lens, the practitioner may move to other lenses in the dispensing system to determine the best fit lens for dispensing to the patient.

The slide rule will calculate the Base Curve for 0.00 Target as follows:

Calculation Treatment Base Curve

Flat K (in diopters)
- MRS
- 0.50 Adjustment
= Base Curve

43.75 +0.00 43.75	FK TGT
-4.00 39.75	MRS (Vertexed)
-0.50	Rx = +0.50

39.25D **Base Curve**

calculated in mm of radius 8.6mm

In the above example, the slide rule will suggest the following lens from the diagnostic/dispensing set for initial evaluation.

TRIAL LENSES

Look for this lens in the Trial Set and evaluate for “Dispensability”.

39.25 BC
0.550 RZD
- 33 LZA

39.25 (8.60) B.C.

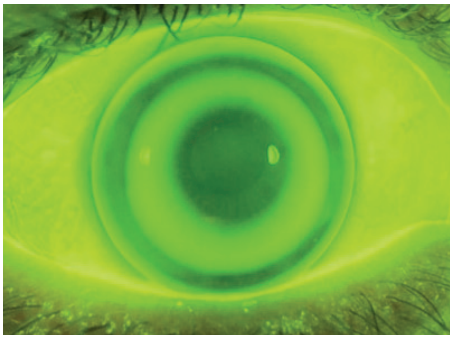
Increased sag depth Decreased angle	Increased sag depth Same angle	Increased sag depth Increased angle
Increased RZD Decreased angle	**Initial Lens** 39.25 .550 RZD -33 Angle	Increased RZD Increased angle
Decreased sag depth Decreased angle	Decreased sag depth Same angle	Increased sag depth Increased angle

Deeper ↑ Sagittal Depth ↓ Shallower

- Angle Degree +

With shallower lens in place:

1. Does it still center?
2. If yes....
3. Evaluate edge lift



39.25 (8.60) B.C.

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	**Initial Lens** 39.25 .550 RZD -33 Angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

Sagittal Depth ↕

- Angle Degree +

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39.25 (8.60) B.C.

Deeper

Sagittal Depth

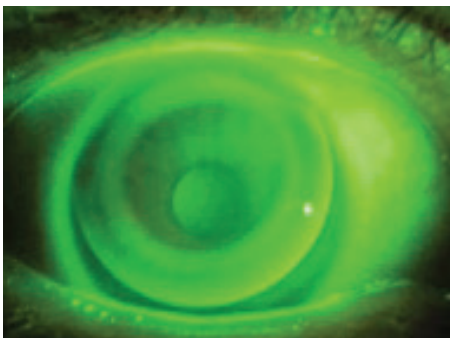
Shallower

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	**Initial Lens** 39.25 .550 RZD -33 Angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

\- Angle Degree +

With indicated lens in place:

1. If no....
2. Return to initial lens and evaluate edge lift



39.25 (8.60) B.C.

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	**Initial Lens** 39.25 .550 RZD -33 Angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

Sagittal Depth

\- Angle Degree +

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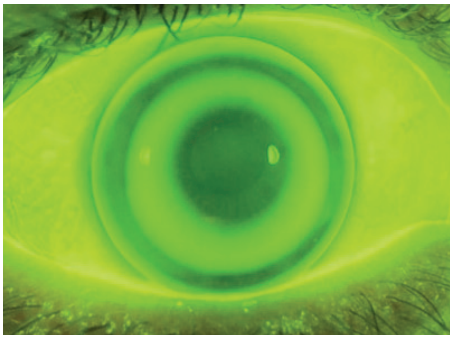
39.25 (8.60) B.C.

With **initial** lens in place:

Evaluate edge lift



39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	**Initial Lens** 39.25 .550 RZD -33 Angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

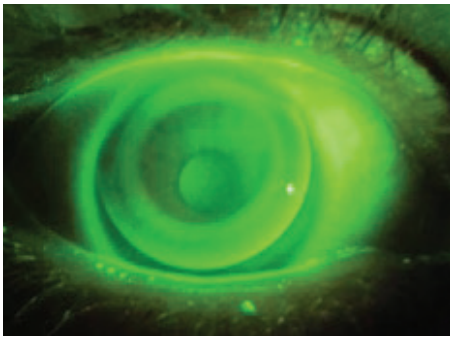
Sagittal Depth

\- Angle Degree +

39.25 (8.60) B.C.

With **initial** lens in place:

1. Does it center?
2. If no....
3. Increase RZD



39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	**Initial Lens** 39.25 .550 RZD -33 Angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

Sagittal Depth

\- Angle Degree +

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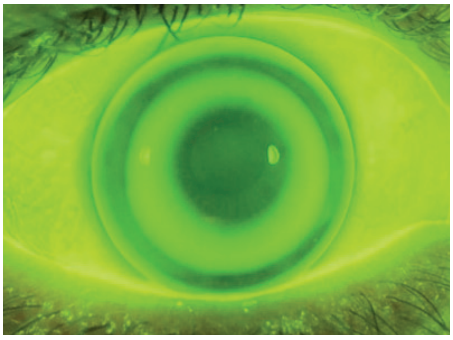
With lens in place:

1. Does it still center?
2. If yes....
3. Evaluate edge lift



39.25 (8.60) B.C.

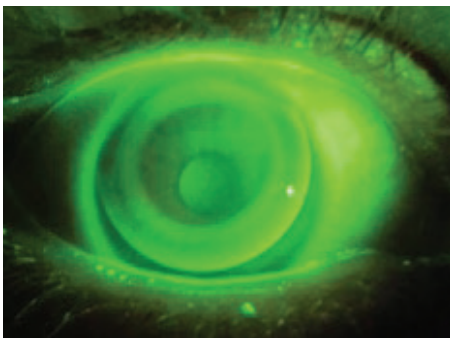
39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	**Initial Lens** 39.25 .550 RZD -33 Angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

Sagittal Depth

\- Angle Degree +

With increased RZD lens in place:

1. Does it center?
2. If no....
3. Increase Angle



39.25 (8.60) B.C.

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	**Initial Lens** 39.25 .550 RZD -33 Angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

Sagittal Depth

\- Angle Degree +

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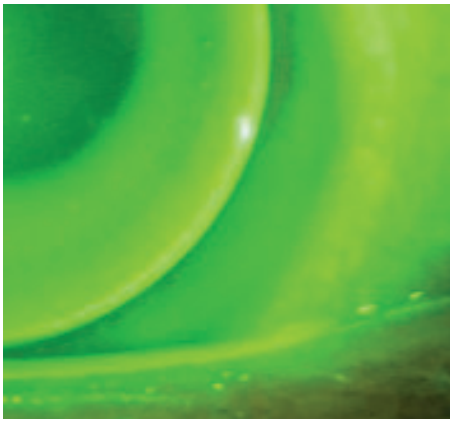
EVALUATE EDGE LIFT

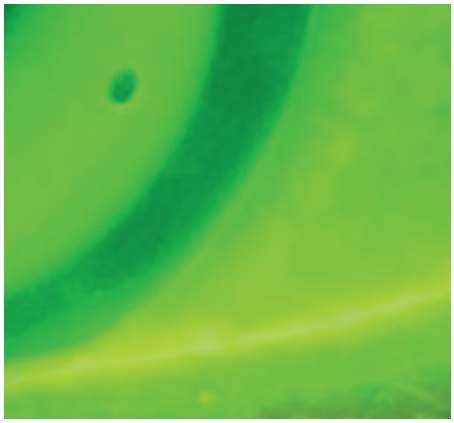
When you have found the shallowest lens that centers - Evaluate Edge Lift.

With shallowest RZD lens that centers - Evaluate Edge Lift



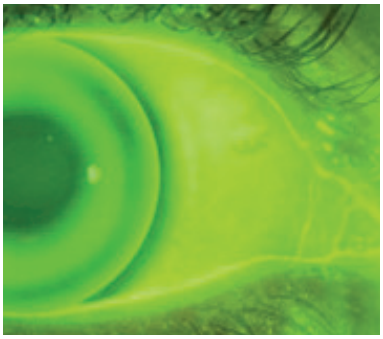
Excessive Edge Lift
Increase angle

Good Edge Lift
Dispense



Insufficient Edge Lift
Decrease Edge Lift

1. Excessive edge lift?
2. If yes....
3. Increased angle



39.25 (8.60) B.C.

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	**Initial Lens** 39.25 .550 RZD -33 Angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

Sagittal Depth

\- Angle Degree +

Shallowest RZD with centration

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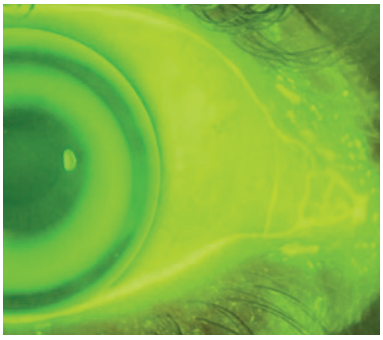
1. Good edge lift?
2. If yes....
3. Dispense



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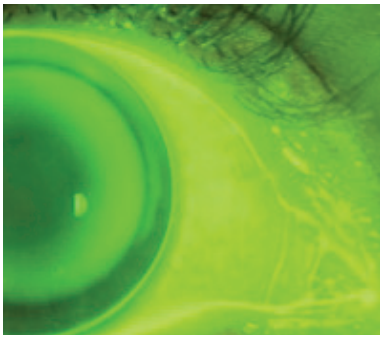
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

Sagittal Depth

\- Angle Degree +

1. Insufficient edge lift?
2. If yes....
3. Decrease Angle



39.25 (8.60) B.C.

39.25 .575 RZD -32 angle	39.25 .575 RZD -33 angle	39.25 .575 RZD -34 angle
39.25 .550 RZD -32 angle	**Initial Lens** 39.25 .550 RZD -33 Angle	39.25 .550 RZD -34 angle
39.25 .525 RZD -32 angle	39.25 .525 RZD -33 angle	39.25 .525 RZD -34 angle

Sagittal Depth

\- Angle Degree +

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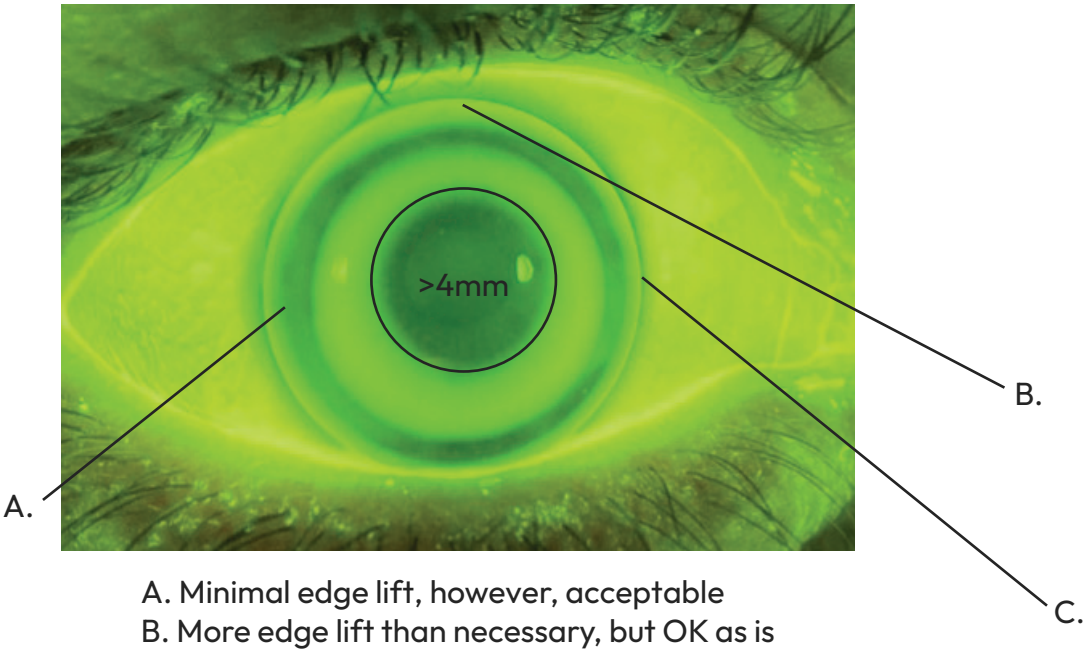
DISPENSABILITY

The lens should present with:

- 4+ mm Treatment Zone (see below illustration)
- Centered, limbus-to-limbus and in relation to pupil (see below illustration)
- Acceptable Edge Lift (note A, B, C arrows in below illustration)
- More than "Just Landed" Appearance; "JL" to moderately heavy landing is acceptable
- Fluorescein reveals a "Black, Green, Black, Green" pooling pattern



A. Minimal edge lift, however, acceptable
B. More edge lift than necessary, but OK as is
C. Optimum edge lift appearance

The Diagnostic/Dispensing system suggested an initial lens and based on observation, the clinician moves to centration, additional treatment and appropriate edge lift by moving to other lenses, if necessary, within the same Base Curve range, based on the following parameter options.

T-- C- F+	T- C F	T C+ F-
T+ C- E+	K's & RX Select Initial Diagnostic Lens	T- C+ E-
T++ C? E+	T+ C+ E	T C+ E-

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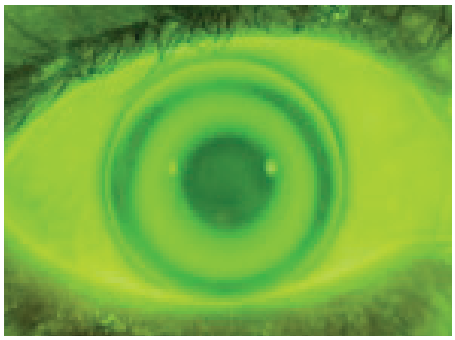
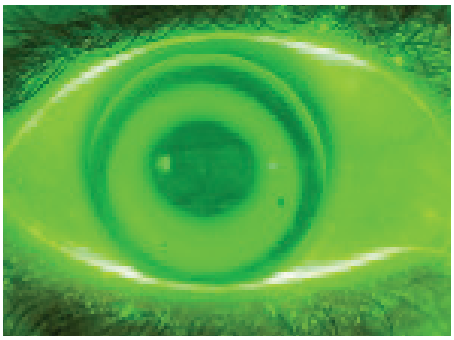
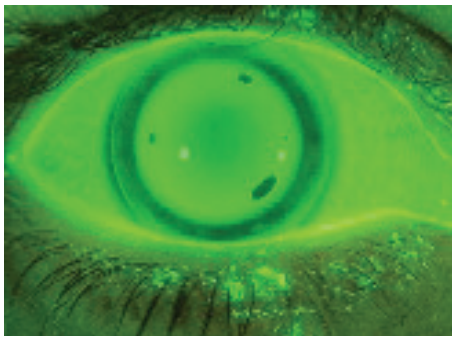
The lens is **NOT** dispensable when any of these problems exist:

- Small or NO treatment zone
- Decentered lens
- Minimal edge lift or seemingly tight periphery (LZA is excessive)

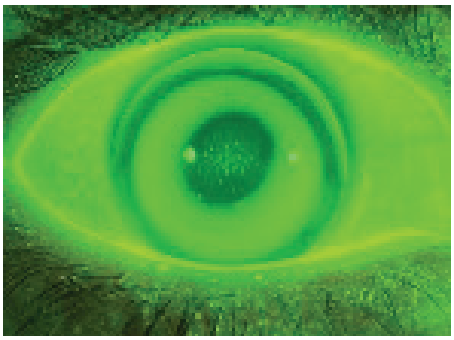




Small Treatment Zone resulting from sag too deep.



No Treatment Zone;
Excessive pooling of Fluorescein centrally resulting from sag too deep.



Oval Treatment Zone with "Just Landed" appearance resulting from sag to deep; if zone is circular, both major meridians are "treated" equally.

HOW TO FIX FITTING PROBLEMS

Small or No Treatment Zone

First Option	Decrease LZA
Second Option	Flatten Base Curve
Third Option	Decrease RZD

Decentered Lens

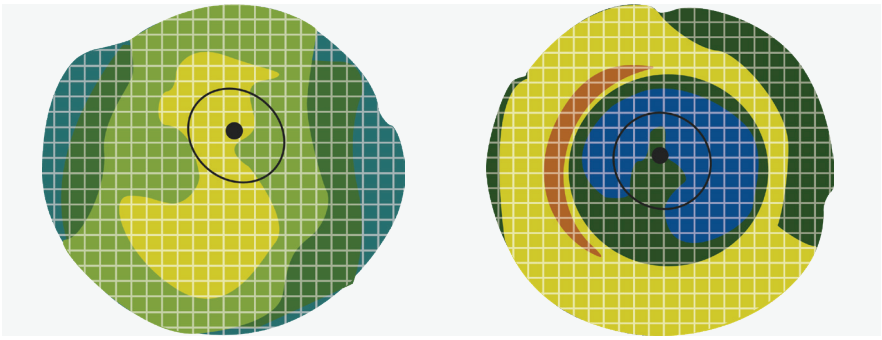
If Inferior & Nasal	Decrease LZA
If Inferior & Centered (or slightly temporal)	Decrease LZA & if remains decentered, decrease RZD
If Superior & Nasal	Increase RZD & if remains decentered, increase LZA
If Superior & Centered Laterally **	Increase LZA

Minimal Edge Lift or Seemingly Tight Periphery (LZA is excessive) **

First Option	Decrease LZA

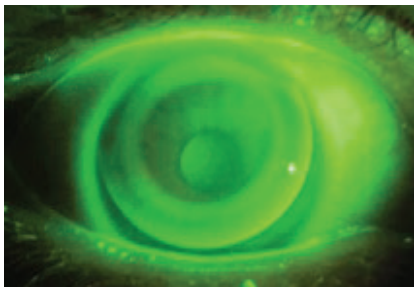
** "Z" Axis tilt may occur if the LZA is 2 degrees too great. Sometimes this will cause a superiorly decentered lens showing excessive fluorescein pooling from the RZD all the way to the edge of the lens. Decrease the LZA by 2 degrees and increase the RZD (25 to 50 microns) if this occurs.

Well-centered Lens
Before and After

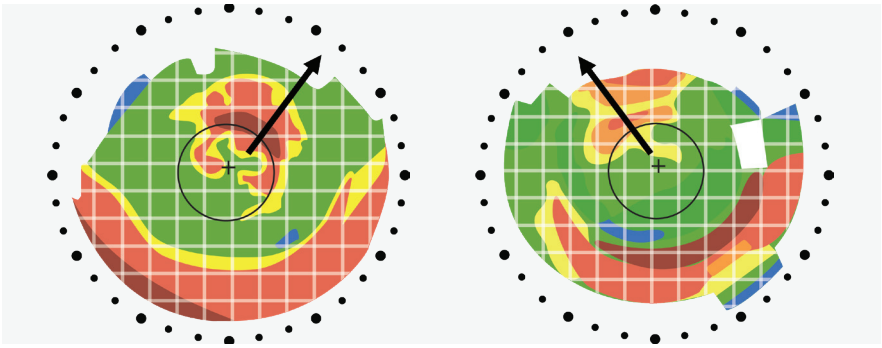


Decentered Lens Examples

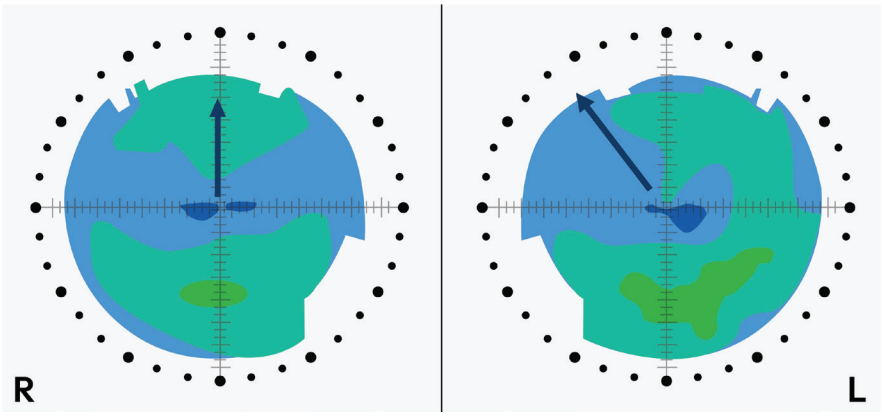
Superior Riding



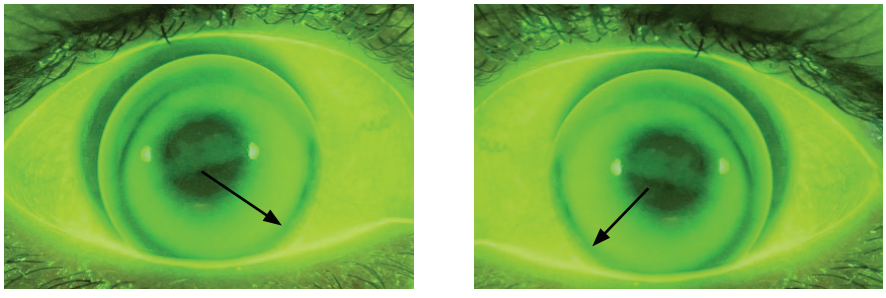
Both lenses are riding superiorly and slightly nasal, confirmed by topography.
Note the inferior and steep "smile" (epithelium being pushed inferiorly from the high riding lens) and the "up and in" displacement of the steeper central zone (central island).



The lens in the right eye is decentered slightly superiorly, whereas, the left lens not only rides high, but slightly nasally.



The lenses are riding low and nasally decentered



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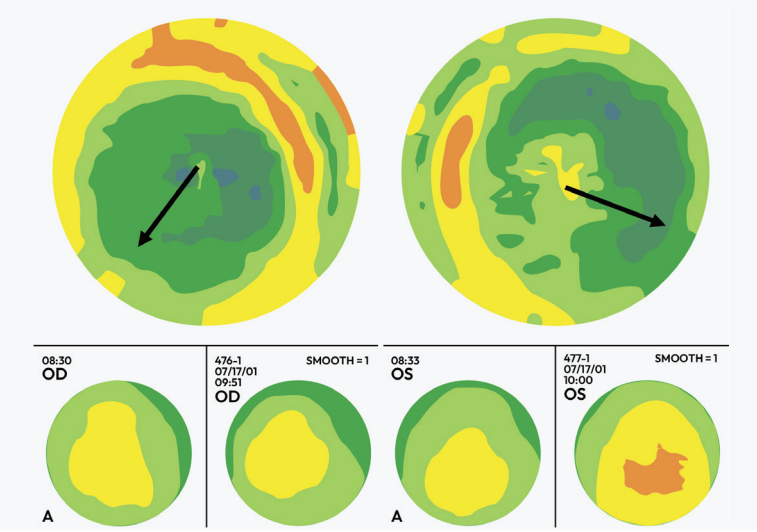
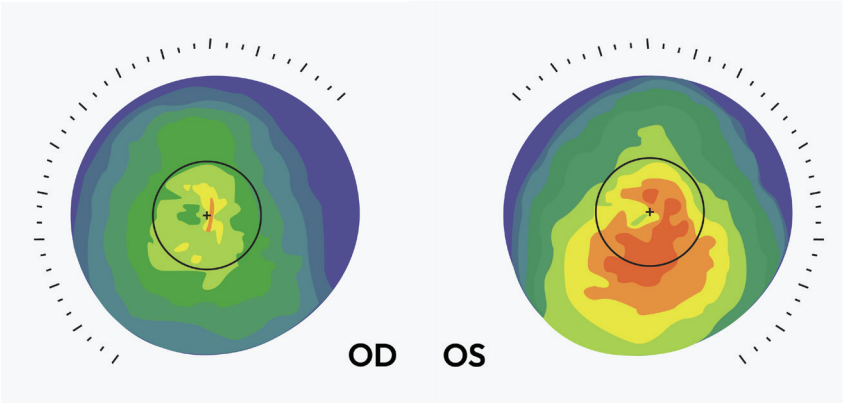
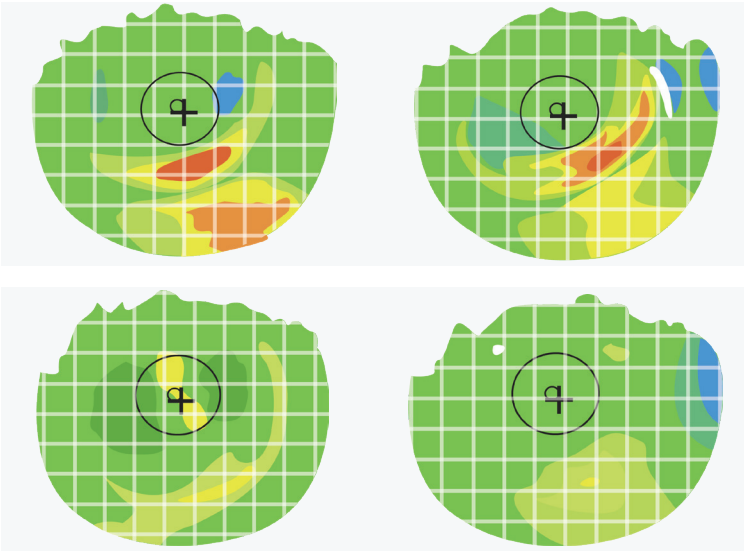
These topography “difference maps” confirm that lenses are riding infero-temporally or “down & out”.



The right topography map confirms a low riding lens that is slightly temporal or “down & out”. The left map appearance shows this lens is primarily low riding. Both topographies show “central islands” or untreated areas beneath the retainer lenses. Central islands often result from the lens sag been too deep; they may also occur in a well-centered lens or a high riding lens (with the steep zones centered or superiorly located, respectively).



A decentered lens only makes the corneal topography more misshapen if lens parameters remain unchanged (top photos). After increasing the RZD to achieve better centration, it may take months for the cornea to right itself. It is prudent to change lens parameters immediately to eliminate this form of corneal distortion. Do not expect a decentered lens to get better on it’s own accord.



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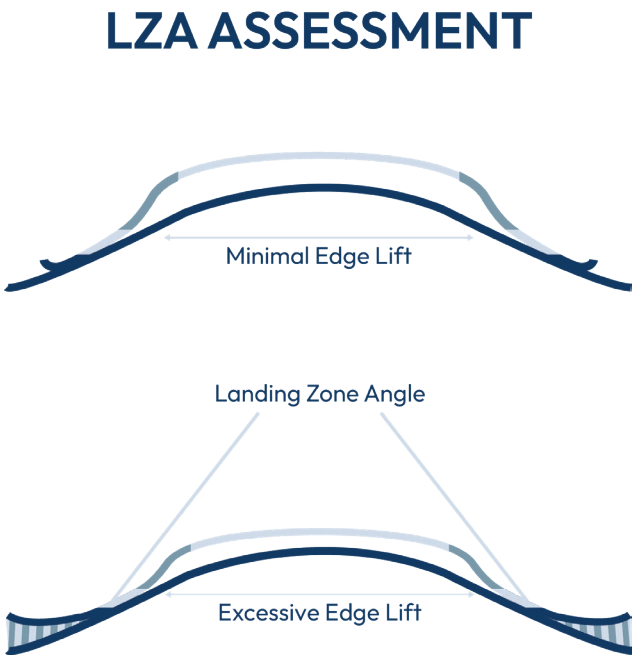
LZA Assessment

Significant edge lift may be seen when the LZA has too low an angle and will present with a “sealed off” periphery when the LZA is too steep.



Other Fitting & Problem Solving Concepts

What to do for "Under Treatment"

1) **If,**

Centered (confirmed with topography, if available)
Treatment zone is round and 5+mm in diameter
Adequate edge lift
PLANO over-refract on the lenses
No induced astigmatism in the MR

and	**then**
Have - 0.50 residual myopia	flatten base curve by 0.50D to 0.75 D
Have - 1.00 residual myopia	flatten base curve by 0.75D to 1.00D
Have - 1.50 residual myopia	reduce LZA 1 degree

2) **If,**

Centered (confirmed with topography, if available)
Treatment zone is round and 5+mm in diameter
Lack edge lift
PLANO over-refract on the lenses
No induced astigmatism in the MR

and	**then**
Have - 1.00 or less residual myopia	reduce LZA 1 degree, and increase BC by no more than 0.50D
Have - 1.50 residual myopia	reduce LZA 1 degree

3) **If,**

Centered (confirmed with topography, if available)
Treatment zone is round and 5+mm in diameter
Adequate Edge Lift

PLANO over-refract on the lenses
No induced astigmatism in the MR,
but have UNCORRECTED residual cylinder power

and
Myopia is fully treated
-or-
Have - 1.00 or less residual myopia
-or-
Have - 1.50 residual myopia

Call your eye care practitioner:
Either the LZA, RZD, BC will need to be reduced/flattened or a combination of these processes to reduce sag will be necessary.

What to do for "Over Treatment"

1) **If,**
   Centered (confirmed with topography, if available)
   Treatment zone is round and 5+mm in diameter
   Adequate edge lift
   PLANO over-refract on the lenses
   No induced astigmatism in the MR

and
Spherical power is over-corrected

then
increase the sag by steepening BC or the RZD using a 1:1 relationship per diopter in BC, or approximately 25 microns in RZD per 1.50 diopters

What to do if "Cylinder over-refraction" on the lenses

1) First, ascertain if lens base curve is warped

2) **If,**
   No warpage present
   Lenses are centered (confirmed with topography, if available)

then
source is lenticular astigmatism

Concerning Lens Appearance

If,
The Lens **Sag Is Too Great** (deep)

The lens will
- Ride low
- Undertreat
- Seal off peripherally be difficult to remove
- Ride nasally (if significantly too great/deep)
- Have Z-axis tilt (if significantly too great/deep)

If,
The Lens **Sag Is Too Little** (shallow)

The lens will
- Ride high
- Ride temporally
- Have Z-axis tilt (if significantly too great/deep)
- Create secondary corneal SPK
- Have significant edge lift

Approximate Adjustments in "Sag"
The RZD is adjustable in 25 micron steps.

Base curve changes of 0.50 D represent approximately 7 micron changes.

An LZA reduction of 1 degree (15 microns) and an increase in RZD by 25 microns represent approximate "Relative Sag," and vice versa. Therefore, changes in RZD and LZA in opposite directions are approximately a 10 micro difference in sag.

EVALUATION OF LENSES

The use of the lens prescribing system should result in a lens having a base curve that provides the desired post treatment keratometry target. This lens will also have a Return Zone Depth that will return the lens toward the cornea with enough clearance to allow the corneal apex to retreat posteriorly. The Return Zone clearance will allow for displacement of corneal volume and continued flattening through the optic zone region.

Initially the fluorescein pattern should demonstrate apical bearing over 3 to 5 mm surrounded by pooling under the return curve and initial portion of the Landing Zone. This should be surrounded by an area of tangency without heavy touch or bearing.

1) The absence of apical touch is problematic. This may be the result of the following:

- Error in calculating the base curve.
- Diagnostic lens error [lens not to package specification].
- Return Zone too deep resulting in Return Zone junction bridging [outer Return Zone bearing that lifts the optic zone off the cornea].
- Landing Zone angle too large resulting in Landing Zone bridging [Landing Zone bearing that lifts the optic zone off the cornea].

In the case of Return Zone or Landing Zone bridging, the fluorescein pattern will demonstrate a black circle of touch. For Return Zone junction bridging, the black circle will be at the outer junction of the Return Zone. For Landing Zone bridging, the black circle will be further out toward the lens edge. If the Return Zone is too deep AND the Landing Zone Angle is also too deep, the pattern will appear like Landing Zone bridging. To differentiate, first place a diagnostic lens having a Return Zone that is less deep. If the pattern still appears like Landing Zone bridging, the Landing Zone Angle must be decreased.

Keep in mind that cases of low target myopia reduction and moderate myopia reduction with high eccentricity may NOT require Optimum Infinite (tisilfocon A) Orthokeratology Lenses II. In these cases, even the shallowest Return Zone may cause Return Zone bridging. In this event, consider a conventional large diameter tri-curve RGP lens design.

2) Return Zone too shallow

If the Return Zone depth is too shallow, the lens will fail to approach the cornea outside the optic zone. The result will be a lens that teeters or tilts on the apex or decenters. When nudged to center, the lens pattern will demonstrate excessive clearance under the Return Zone and much of the Landing Zone.
Bubbles may form under the lens and the lens may easily move off the cornea.

3) Decentration and excessive clearance

Remove the lens and recheck the following:
- Base curve and Return Zone depth determination.
- Diagnostic lens error [lens not to package specification].

Note: All Optimum Infinite (tisilfocon A) Orthokeratology Lenses II are laser-marked.

The laser mark should be inspected when lenses do not demonstrate expected patterns.

If the determination and lens measurements are correct, select a lens with a greater Return Zone Depth. After placing the lens, the clearance and decentration should be reduced. If the Return Zone clearance is appropriate but the lens continues to gain in clearance toward the edge, the Landing Zone Angle is too small and the final lens order should reflect the need for a larger angle.

When initially placed and allowed to equilibrate, the well-fit lens will center and provide for a fluorescein pattern that demonstrates central bearing, paracentral clearance and peripheral alignment. After treatment, the fluorescein pattern will appear to be aligned through all zones of the lens with a low degree of paracentral clearance.

The initial pattern of a poorly fit lens may demonstrate any of the following characteristics.

- Poor centration
- Absence of central bearing
- Absence of paracentral clearance
- Excessive paracentral clearance with bubbles in the Return Zone
- Heavy bearing [black arc] at junction of the Return Zone and peripheral Landing Zone
- Heavy bearing through the peripheral Landing Zone
- Excessive clearance in the peripheral Landing Zone

The presence of any of the poorly fit patterns is followed by failure to obtain optimum treatment. A well-fit lens pattern must be achieved through diagnostic lens fitting prior to lens ordering.

UNDERSTANDING POOR FIT DYNAMICS

1) Poor Centration

Poor centration can result from insufficient fluid forces relative to lid interaction or gravity. If the lens is nudged to center and it demonstrates ideal central bearing, paracentral clearance, and peripheral tangency, the overall diameter is too small and centration should be achieved by increasing overall diameter only.

If the pattern is ideal in the central and paracentral zones but the landing zone exhibits clearance, the angle of the peripheral zone must be increased along with a possible diameter increase.

Poor centration can result from too much sagittal depth in the lens as well. If the poor centration is accompanied by either lack of central bearing, excessive return zone depth [bubble formation] or excessive bearing at the Return Zone – Landing Zone junction (junction two), the Return Zone Depth should be reduced first to see if centration is achieved.

2) Absence Of Central Bearing

A lens may fail to demonstrate central bearing for two reasons. First, the base curve selected may simply be wrong. Recheck the keratometry or corneal topography to be sure the lens selected is flatter than the corneal apex.

If the base curve has been properly selected, the cause is most always excessive sagittal depth with resultant "bridging". If the Return Zone Depth is too great, the lens will gain in sagittal depth relative to the same chord diameter of the cornea. Even a lens that has a base curve that is significantly flatter than K may vault the cornea. In this case, the fluorescein pattern should demonstrate an arc bearing outside the Return Zone.

This arc bearing is the foundation of the "Lens Bridge". The lens designed as flatter than K with a Return Zone that is too deep or too wide will span over the corneal apex instead of bearing on it.

The solution for this problem is to decrease the RZD. The lens will then be free to touch first in the central bearing zone instead of at the outside of the Return Zone.

In cases of high pre treatment corneal eccentricity it is possible for the Landing Zone Angle to also be too large in combination with the Return Zone Depth. In this case, the "bridging" starts with bearing toward the edge of the lens or the most peripheral portion of the Landing Zone. Decreasing the angle of the Landing Zone will allow the lens to increase its central bearing.

3) Absence Of Paracentral Clearance

The use of a yellow Wrattan filter is recommended to assist in detecting tear film thickness variances under the lens with fluorescein.

If a lens exhibits a uniform tear film when initially placed and the paracentral clearance zone is not apparent, you must first recheck the lens to determine that it has a proper design. Naked eye inspection of the ocular surface using the reflection of a single fluorescent lamp tube should facilitate determination of sigmoid geometry in the paracentral zone that is steeper than the base curve. This general inspection should reveal breaks in the lamp that correspond to the changes in geometry. You may also use the corneal topographer to capture and process an image of the base curve of the lens.

A lens having too much overall sagittal depth may seal off and prevent fluorescein from migrating under the lens. The result is a pattern that is uniform and without color. The lens can be nudged or partially lifted to allow the fluorescein containing tear film to travel under the lens. In this case, the pattern will significantly change and demonstrate excessive “bridging”.

Experience will result in increased judgment of the proper ratio of central bearing and paracentral clearance for a given amount of refractive change.The greater the attempted dioptric change, the greater the central bearing and the greater the paracentral clearance. For that reason, a one diopter-attempted change will not demonstrate deep or wide paracentral clearance.

4) Excessive Paracentral Clearance With Bubbles In The Return Zone

A lens with too much clearance at junction one before returning to the cornea may contain air bubbles in the optic zone and Return Zone. Check the base curve to determine it is correct for the attempted treatment. If the base curve is correct and the proper Return Zone Depth is in place and the peripheral tangency and edge lift appear good, the optic zone should be reduced to decrease the junction one elevation from the cornea. This is expected in some cases above 5.00 diopters of target treatment. In some cases, bubbles are reduced by reducing the RZD by 25 microns or the LZA by 1 degree.

5) Heavy Bearing [Black Arc] At Junction Of Return Zone And Landing Zone

If the optic zone bearing and Landing Zone tangency are good, the Return Zone is too deep and must either be reduced in width or decreased in depth. An increase in the Landing Zone Angle will also move the midpoint of the tangency out from the junction and toward the lens edge.

6) Heavy Bearing Through The Landing Zone

Once again, verify that the base curve is correct and the Return Zone is proper for the attempted treatment. If the bearing is less than full seal off but the fluorescein pattern demonstrates a uniform dark bearing instead of a light tear film clearance decrease the Landing Zone Angle one level. If the Landing Zone actually approaches seal off, decrease the RZD in conjunction with the LZA.

7) Excessive Clearance In Landing Zone

This problem is often associated with poor centration. To study the fluorescein pattern, always nudge the lens to center, while minimizing any tilting of the lens. If the lens demonstrates proper central bearing and junction two clearance but the Landing Zone progresses to too much edge lift or excessive clearance, increase the Landing Zone Angle.

PROBLEM SOLVING TABLE

Problem	Possible Cause	Solution
Apical clearance	Bridging due to excessive sagittal depth	Decrease Return Zone Depth Decrease Landing Zone Angle
Excess central bearing, lack of good centration	Base curve too flat Shallow Return Zone Depth Landing Zone Angle too small	Increase Return Zone Depth Increase Landing Zone Angle
Poor lateral centration	Inadequate sagittal depth Inadequate lens diameter	Increase depth of Return Zone Increase Landing Zone Angle Increase overall diameter*
Superficial punctate staining	Sag of lens inadequate Ocular lens surface has become soiled	Increase depth of Return Zone Decrease Landing Zone Angle Clean or replace lens
Lack of movement	Sag of lens excessive	Decrease Return Zone Depth Decrease Landing Zone Angle Decrease overall diameter*
Excessive LZ clearance	Junction two clearance is excessive Low corneal eccentricity	Increase Return Zone Depth Increase Landing Zone Angle
Over-treatment	Excessive corneal reshaping	Steepen base curve of optic zone
Under-treatment without apical pooling	Base curve too steep Poor lens centration	Flatten base curve of optic zone and increase the Return Zone Depth as needed Improve centration increase Landing Zone Angle
Under-treatment with apical pooling	Bridging	RZ bridging-decrease Return Zone Depth LZ bridging -decrease the Landing Zone Angle
Tight lens or no movement	Return Zone too deep Diameter too large	Decrease Return Zone Depth Reduce diameter
Loose lens	Return Zone too shallow Landing Zone too small Diameter too small	Increase Return Zone Depth Increase Landing Zone Angle Increase diameter
High-riding lens	Return Zone Depth too shallow Diameter too small	Increase Return Zone Depth Increase diameter
Low-riding lens (without bridging)	Landing Zone too deep diameter too small	Decrease Landing Zone Angle Increase diameter*
Flare, glare or ghosts	Return Zone bridging Poor centration	Decrease Return Zone Depth Reduce diameter
Fogging and scratchy lens	Dirty lens Improper care & handling of lenses Oily eye make-up removers	See “Lens Care”
Increase in corneal astigma-tism	Poor centration Diameter too small Return Zone too shallow	Improve centration Increase diameter* Increase Return Zone Depth
Poor VA with lenses	Poor centration Power error	Improve centration Check over-refraction/lens power
Poor VA without lenses	Poor centration Irregular corneal astigmatism Bridging	Increase LZA and/or OAD Improve centration See under-treatment solutions

*common adjustment, increase 0.5 mm in diameter up to 12.0 or 0.5 mm less than corneal diameter

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FOLLOW-UP CARE

1) Follow-up examinations, as recommended by the eye care practitioner, are necessary to ensure continued successful contact lens wear. Follow-up examinations should include an evaluation of lens movement, centration, comfort and fluorescein pattern. Lens movement will decrease as tear volume is diminishing during adaptation. The patient should also begin to feel more comfortable. An assessment of vision and eye health, including inspection of the cornea for edema and/or staining should be performed.

2) On the first morning following overnight wear, with lenses in place on the eyes, evaluate fitting performance to assure that the criteria of a well-fitted lens continue to be satisfied. The fluorescein pattern provides a guide to lens adaptation. If the cornea flattens rapidly there will be a larger area of central touch and the pooling at the lens transition will be reduced. The lens will usually show reduced movement.

3) A lens with excessive movement should be replaced with another that is larger in diameter and approaches the corneal diameter less 0.5 to 1.0 mm. Landing Zone Angle should be reevaluated to determine possible need for larger LZA.

4) If the cornea shows no flattening, this may be due to a base curve that is not flat enough or a Return Zone that is too deep, resulting in “bridging”. Bridging is caused by the outer junction of the Return Zone having a heavy touch. The result of the touch is the lifting of the base curve off the cornea. When the base curve is lifted off the central cornea, it will not flatten the cornea, even if the base curve is significantly flatter than the cornea it is covering. If the base curve has been selected to be flatter than the cornea equivalent to the attempted reduction in myopia, the failure to flatten most often resides in a Return Zone that is too deep. In this case, the Return Zone Depth should be decreased until the fluorescein pattern demonstrates a proper central bearing of 3.0 to 5.0 mm.

5) After lens removal, conduct a thorough biomicroscopy examination to detect the following:

- The presence of vertical corneal striae in the posterior central cornea and/or corneal neovascularization is indicative of excessive corneal edema.
- The presence of corneal staining and/or limbal-conjunctival hyperemia can be indicative of a reaction to solution preservatives, excessive lens wear, and/or a poorly fitted lens.

RECOMMENDED WEARING SCHEDULE

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to limit the wearing schedule recommended by the eye care practitioner regardless of how comfortable the lenses feel.

It is ideal for the patient to start with overnight wear the first night. A well fit lens provides for centration with the closed eye. The effects of lid interaction on blinking and gravity may result in lens decentration during open eye wear. Patients should be instructed to place the lens in the eye 15 to 20 minutes before going to sleep.

Patients must be cautioned; “when in doubt, take it out”. It is important that the new wearer not sleep in a lens that has a significant foreign body sensation. In the event of foreign body sensation, the patient should be instructed to remove the lens, clean and rewet it and replace the lens. If the sensation continues, the lens should not be worn.

The patient should report for follow-up evaluation the morning after the first overnight wear. The visit is best scheduled within a few hours of awakening and the patient should report with the lens in place. This visit provides an excellent opportunity to evaluate lens centration and potential lens adherence.

Upon the absence of clinical signs and complications, the patient may be instructed to continue overnight wear of the lens until the next scheduled follow-up visit.

An alternate initial daytime wear schedule may be offered at the practitioner’s discretion.

Day 1	two periods of wear not to exceed 6 hours total
Day 2	6 hours
Day 3 - Day 5	8 hours
Day 6	overnight wear with follow up visit within 24 hours

The cornea normally changes within five to eight hours of wear. The wearing schedule should be modulated to determine the MINIMUM wear required for myopic reduction. The average wearing time is between 8 and 10 hours. Determine the wearing time at which lens movement appears to stop. Attempt to maintain wearing time at this level.

MYOPIC REDUCTION MAINTENANCE LENS (RETAINER LENS) WEARING SCHEDULE

With the Optimum Infinite (tisilfocon A) Orthokeratology Lenses II, the lens used to achieve refractive therapy is usually the lens used to maintain achieved correction. The Retainer Lens wearing time begins with the same wearing time required for the last fitted Optimum Infinite (tisilfocon A) Orthokeratology Lenses II for overnight orthokeratology. After a period of several days, or when the eye care practitioner is satisfied that the patient has adapted to the first Retainer Lenses, the patient may attempt to skip a night of wear to monitor the duration of visual improvement. This may continue for as long as the patient can see clearly. When it is found that the patient experiences a visual decrement following lens removal, the schedule of overnight wear must be modulated to maintain visual performance.

Note: To maintain the Orthokeratology effect of myopia reduction overnight lens wear must be continued on a prescribed schedule. Failure to do so can affect daily activities (e.g., night driving), visual fluctuations and changes in intended correction.

HANDLING OF LENSES

Standard procedures for rigid gas permeable lenses may be used.

CAUTION: Optimum Infinite (tisilfocon A) Orthokeratology Lenses II are shipped to the practitioner nonsterile. Clean and condition lenses prior to use.

PATIENT LENS CARE RECOMMENDATIONS

Please see list of lens care products in Package Insert.

VERTEX DISTANCE & KERATOMETRY CONVERSION CHARTS

Standard charts may be used.

HOW SUPPLIED

CAUTION: Nonsterile lenses. Clean and condition lenses prior to use.
Each Optimum Infinite (tisilfocon A) Orthokeratology Lens II is supplied nonsterile in an individual plastic case. The lens is shipped dry; or, wet shipped in Boston SIMPLUS solution, or Menicon Unique pH solution. Boston Simplus Solution contains poloxamine, hydroxyalklphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%). Menicon Unique pH contains hydroxypropyl guar, polyethylene glycol, poloxamine, boric acid, propylene glycol, and is preserve with polyquaternium-1 (0.0011%), and edetate disodium (0.01%).

The case, packing slip or invoice is marked with the central base curve radius, dioptric power, overall diameter, Return Zone Depth, Landing Zone Angle, center thickness, serial number, ship date and the color of the lens. If the patient has experienced a prior history of allergy to any of these ingredients, remove the lens from the solution and soak the lens 24 hours in sterile unpreserved saline prior to cleaning, disinfecting and dispensing.

Never reuse the solution. You may store the lens in the unopened container until ready to dispense, up to a maximum of thirty (30) days from the Ship Date (see Packing Slip). When a lens has been stored for 30 days in its original packaging solution, it should be cleaned and disinfected. Follow the directions on the selected disinfecting solution regarding prolonged storage.

REPORTING OF ADVERSE REACTIONS

All serious adverse experiences and adverse reactions observed in patients wearing or experienced with the lenses should be reported immediately to the manufacturer.

Manufactured by

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APPENDIX A – INFORMED CONSENT DOCUMENT

You are being fitted with rigid gas permeable (RGP) contact lenses used for Orthokeratology. Orthokeratology refers to the use of specially designed RGP contact lenses to temporarily reshape the cornea (the clear layer on the front of the eye), allowing you to see clearly without the use of glasses or contact lenses during waking hours. The orthokeratology contact lenses must be worn on a regular basis during sleep in order to reduce the need for glasses or contact lenses during the day.

Complications and Side Effects

Orthokeratology carries the same risks as other types of contact lenses, such as swelling of the cornea, scratching of the eye, irritation, infection, unusual eye discharge, excessive tearing, dry eyes, sensitivity to light, pain, redness, and distorted vision. These risks are usually temporary if the contact lenses are removed promptly and if appropriate professional care is received. In some instances permanent corneal scarring, infection, or blood vessel growth on the cornea may occur, which can lead to reduced sight in rare cases. Although uncommon, infection of the cornea can develop rapidly and lead to loss of vision. The risk of infection of the cornea has been shown to be greater among patients who wear their lenses overnight than among those who do not sleep in their lenses.

Orthokeratology also has risks that are not typically associated with other types of contact lenses, such as blurry or variable vision, especially late in the day. The blurry vision and how long it lasts each day should decrease with time. You may also experience distortions or ghost images, particularly outside at night which may affect night driving. The risk may be increased in patients with a high degree of correction or large pupils. You may also develop a pigmented ring in the cornea. This is not noticeable, it does not change your vision, and it does not require treatment.

All risks are minimized if you follow the correct contact lens wearing schedules and care procedures. If problems occur, remove your contact lenses and report to your primary eye care practitioner as soon as possible. With any procedure, there may be unforeseeable risks. If you experience any of the symptoms listed above, remove your lenses immediately. If the condition continues after lens removal, you should immediately call for an appointment or consultation with your eye care practitioner who will provide the necessary treatment.

Lens Wear Schedule

Your doctor will recommend a wearing schedule for you to follow. The wearing time necessary for orthokeratology is typically 7 to 8 hours per night. Your doctor will also recommend a follow-up schedule to check your vision and contact lenses. **It is important that you attend every visit that your eye care practitioner recommends in order to maintain the health of your eyes.**

Alternative to Orthokeratology

Alternatives to orthokeratology include, among others, eyeglasses, traditional contact lenses, and refractive surgical procedures.

APPENDIX A – INFORMED CONSENT DOCUMENT

Pregnancy

Pregnancy could adversely affect my treatment results with orthokeratology. If problems exist during pregnancy, you may need to temporarily discontinue orthokeratology contact lens wear.

I have read and fully understand the above information. I agree to adhere to the wearing and follow-up schedules as prescribed. If I fail to return for my scheduled follow-up visits, I may forfeit my chance to continue overnight wear of orthokeratology contact lenses. All of my questions concerning my eyes and contact lenses have been answered to my satisfaction.

Patient Name: _____ **Signature:** _____

Attending Doctor/Witness Signature: _____ **Date:** _____

APPENDIX B – CHILD ASSENT DOCUMENT

I am being fitted with rigid gas permeable (RGP) contact lenses used for orthokeratology. These contact lenses reshape the cornea (the clear layer on the front of the eye) for a short time, which allows me to see clearly without the use of glasses or contact lenses while I am awake. The orthokeratology contact lenses must be worn on a regular basis during sleep so that I can see clearly during the day without glasses or contact lenses.

It is important that I agree to the following guidelines to keep my eyes healthy and allow me to wear contact lenses. Place a checkmark in each box if you agree.

- ☐ I agree to wear my lenses no more than _____ hours per night.
- ☐ I agree to wash my hands before inserting or removing my contact lenses.
- ☐ I agree to clean my lenses according to my doctor's instructions each time I remove them.
- ☐ I agree not to rinse my contact lenses in water from the sink. I will only use contact lens solutions to rinse my contact lenses.
- ☐ I agree to tell my parents or my doctor immediately if my contact lenses irritate my eyes.
- ☐ I agree to tell my parents or my doctor immediately if my eyes appear red or are painful.
- ☐ I understand that if I do not do the things listed above, my eyes may get hurt or I may not be able to wear my contact lenses.

Child's Name: _____ **Child's Age:** _____

Child's Signature: _____ **Date:** _____

APPENDIX C – INFORMED CONSENT QUIZ

Please choose the single best answer for each question.

1) If I experience red eyes, irritated eyes, excessive tearing, or light sensitivity, I should:
- A) go to the emergency room.
- B) remove your contact lenses immediately.
- C) wait for three days to see if it goes away.
- D) put a drop of artificial tears in your eyes.

2) After wearing corneal reshaping contact lenses for approximately three months, the cornea will be permanently reshaped so contact lenses will never need to be worn again.
- A) True
- B) False

3) To minimize risks associated with corneal reshaping contact lens wear, I should:
- A) follow the correct contact lens wearing schedules and procedures.
- B) remove all contact lenses if problems occur.
- C) report to an eye care practitioner if I have problems with my eyes or contact lenses.
- D) all of the above.

4) If I am not experiencing problems with my eyes or contact lenses, I do not need to attend a regularly scheduled appointment with my eye care practitioner.
- A) True
- B) False

5) The risk of infection is for patients who wear contact lenses overnight than for patients who do not sleep in their contact lenses.
- A) Greater
- B) Lower

Patient Name: _____ **Signature:** _____

Attending Doctor/Witness Signature: _____ **Date:** _____