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MOONLENS™
BY KATT DESIGN GROUP

PROFESSIONAL FITTING GUIDE

Overnight Orthokeratology Contact Lens System

MYOPIA MANAGEMENT MADE EASY

ORIGINAL Boston® MATERIALS

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INDEX

INTRODUCTION

The MOONLENS Orthokeratology (Ortho K) Contact Lens System for Overnight Wear is described in this guide. This is a unique contact lens product with a progressive lens design and fitting system that helps manage and temporarily correct myopia, as well as mild astigmatism. The Ortho K MOONLENS is meant to be worn overnight. It works by altering the curvature of the cornea while the patient sleeps, which thereby reduces the excessive focusing power of the myopic eye.

Created by Orthokeratology pioneers and lens design experts at KATT Design Group (KATT DG), this lens design includes a myopia management feature allowing customization for a wide range of patients, from children to adults. The MOONLENS offers vision correction to early-mid myopes that may be astigmatic patients too.

Additionally, the MOONLENS Ortho K fitting software creates custom designed individual lenses for individual eyes, simply and efficiently.

MOONLENS offers eyecare practitioners a unique, comprehensive Orthokeratology lens and fitting system to treat a wide array of myopic patients.

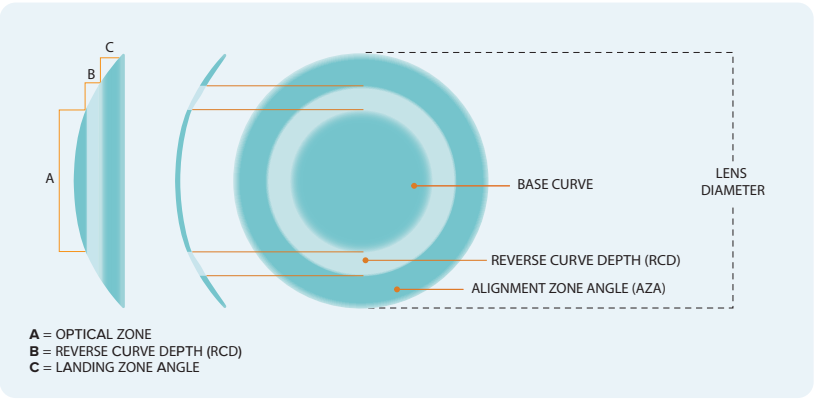
LENS DESIGN DESCRIPTION & FEATURES

The MOONLENS is a progressive Orthokeratology lens design that is simplified into three principle fitting zones for the eye care practitioner to consider:

1 - Base Curve: As with other Orthokeratology designs, the base curve creates the mold or desired shape of the cornea following overnight wear. Another feature of MOONLENS is the unique lens design incorporating a proprietary algorithm which creates the exact tear film forces for correction of each individual eye, Rx and optical zone size. Additionally, the optical zone can be reduced in size to create better control of myopia with kids or enlarged to reduce aberrations with adults.

2 - Reverse Curve Depth (RCD): The reverse curve or RCD is used to control the sagittal depth of the MOONLENS lens. This important zone links the deep fluid reservoir created by the base curve and optical zone with the landing of the lens. The MOONLENS allows the RCD to be altered in increments as small as 1 micron to control the apical clearance and depth of the lens.

3 - Alignment Zone Angle (AZA): The centration and fit of the MOONLENS is controlled by the AZA. This zone is controlled and labeled according to its cone angle which is the closest matching tangential surface to each individual eye shape. Additionally, the MOONLENS uses a unique edge contour to maximize tear exchange, performance and comfort.



Representation of the MOONLENS Overnight Orthokeratology Lens Design

ADDITIONAL LENS DESIGN FEATURES

Symmetric Versus Toric: The MOONLENS can be constructed in a symmetric landing for spherical corneas and low corneal astigmatism. In cases of higher corneal astigmatism, the MOONLENS can be constructed as a toric landing to best align to different depths between the principle meridians of the eye.

Optical Zone Size: One of the principle features of the MOONLENS is the ability to construct a standard Orthokeratology lens design for adults as well as a dedicated lens for myopia management with children. When building lenses for adults, the proven 6mm optical zone is employed which provides a large treatment area and reduced aberrations. However, when prescribing Orthokeratology for kids to slow down eye growth, a smaller optical zone is selected. The smaller optical zone produces a reduced treatment zone size.[1,2] This produces increased spherical aberration which has been shown to result in better management of myopia progression.[2,3,4]

The MOONLENS is made with BOSTON Equalens® II gas permeable material by Bausch + Lomb, approved by the US FDA for overnight Orthokeratology.

1 Rosencrans et al., Modern Aspheric Orthokeratology Lens Design of Varying Optical Zone Diameter, Poster: Vision by Design, April, 2018

2 Kojima et al., Orthokeratology Treatment Zone Size and its Relationship to High Order Aberrations, Poster: Global Specialty Lens Symposium, January, 2018

3 Hiraoka T, Kakita T, Okamoto F, et al. Influence of ocular wavefront aberrations on axial length elongation in myopic children treated with overnight Orthokeratology. Ophthalmology 2015;122:93-100

4 Lau et al., Ocular higher-order aberrations and axial eye growth in young Hong Kong children, Scientific Reports, Volume 8, Article number: 6726, 2018

FITTING STEPS

STEP 1
Patient Candidacy

- Myopia -5.00D or less
- Refractive Astigmatism -1.50D or less
- Ocular surface free of inflammation, infection or ectasia

STEP 2
Pre-Orthokeratology Exam

- Refraction
- Slit Lamp Exam
- Keratometry Readings
- Corneal Topography
- Corneal Diameter (Visible Iris Diameter)

STEP 3
Data Collection

- Refraction
- Apical Radius (or K Readings)
- Eccentricity (recommended but optional)
- Visible Iris Diameter

MOONLENS CALCULATOR

STEP 4
Initial Lens Determination

- Access the MOONLENS Calculator: **http://moonlens.kattdesigngroup.com/**
- Choose the desired Optical Zone Size (5.0mm, 5.5mm or 6.0mm)
  - See "Optical Zone Selection Table" below
- Enter the Patient's Rx
  - Use the spherical component of the Rx and vertex where necessary
- Enter the Flat Apical Radius (Ro) If this value is unavailable, then choose the flat keratometry reading
- Enter the Flat Eccentricity (E) In your corneal topographer, analyze this value over an 8mm chord.

  If a toric MOONLENS is desired, enter both the Steep and Flat Apical Radius (Steep and Flat Ro) and Steep and Flat Eccentricity (Steep and Flat E). If these inputs are left empty, a symmetric MOONLENS will be calculated.
- Order MOONLENS from your Authorized KATT DG Partner

OPTICAL ZONE SELECTION TABLE

Rx	Child/Youth	Adult
≤-3.75	5.5	6.0
-4.00 to -5.75	5.5	5.5
≥-6.00	5.0	5.0

Hint – Symmetric or Toric construction? Using your corneal topographer, analyze the flat and steep meridian sagittal depth over a chord diameter of 8mm. When the difference in height between both meridians is ≥30 microns, then enter the "Steep and Flat Apical Radius" and "Steep and Flat Eccentricity" to generate a toric. If your instrument does not provide sagittal depth, then choose a toric when the eccentricity difference between the flat meridian and steep meridian is ≥0.15.

INSTRUCTIONS FOR USING MOONLENS CALCULATOR

OZ: Determine the appropriate optical zone based on patient age (for myopia management with children or adult Ortho K), magnitude of spectacle Rx and pupil size. See "Optical Zone Selection Table" on page 8.

Rx: Enter the patient's spherical component of the spectacle Rx. Vertex powers -4.00D and above. It is not recommended to use a spherical equivalent when cylinder is present.

Flat Apical Radius: Many topographers provide the Flat Apical Radius value or Flat Ro. Use this reading when possible for the optimal MOONLENS results. However, if the Apical Radius value is not available, use the Flat keratometry reading.

Flat Eccentricity: Most topographers will provide the eccentricity of the principle meridians. This is the measure of the rate of corneal flattening of the eye from the center to periphery. The MOONLENS Calculator uses this value to determine the height of contact lens required. Where possible, calculate the eccentricity over an 8mm chord. If eccentricity is not available, the MOONLENS calculator will default to 0.50e which is the mean of normal eye shapes.

Steep Apical Radius: When a toric MOONLENS is desired, provide the Steep and Flat Apical Radius or Steep Ro. If these values are unavailable, then use the Steep and Flat keratometry reading.

Steep Eccentricity: Enter the Steep Meridian Eccentricity calculated over an 8mm chord when a toric MOONLENS is required. If the Steep Eccentricity value isn't available, refer to the MOONLENS online calculator: **http://moonlens.kattdesigngroup.com**

MOONLENS CALCULATOR

Example 1

	OD	OS
OZ (5.0, 5.5, 6.0)	6.0	6.0
Rx	-3.00	-3.00
Flat Apical Radius	7.80	7.85
Flat Eccentricity	0.50	0.55
Steep Apical Radius		7.75
Steep Eccentricity		0.35

Above Image: In this example, the data suggested on the right eye (OD) indicates a request for a 6.0mm optical zone and an Rx of -3.00D. The "Flat Apical Radius" and "Flat Eccentricity" have been entered which will generate a symmetrical MOONLENS lens. By comparison on the left (OS), both the flat and steep fields have entered data which would generate a toric MOONLENS lens.

This easy to use online calculator tool is used to generate the initial MOONLENS lens parameters.

From your computer, tablet or phone, go to:
http://moonlens.kattdesigngroup.com/

MOONLENS CALCULATOR

Example 2

	OD	OS
Rx	-3.00	-3.00
Base Curve	8.50	8.50
RCD	0.540	0.520
AZA	32	32
RCD Steep		0.540
AZA Steep		0.32
Design	Symmetric	Toric

Above Image: The Results window provides your authorized Spectrum consultations with the parameters to order the lens. The Patient Rx will determine the Base Curve in combination with the entered Flat Apical Radius.

The Reverse Curve Depth (RCD) and Alignment Zone Angle (AZA) is individually calculated for each eye based on the entered corneal shape data. The software will calculate either a symmetric or toric based on the entered corneal shape data.

INITIAL DISPENSE

STEP 5

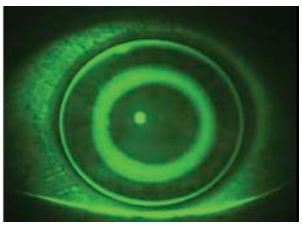
Lens Dispense and Evaluation

- Prepare the MOONLENS for dispensing by cleaning, rinsing (no tap water) and conditioning the lenses with approved contact lens solutions.
- Apply the lenses and perform a slit lamp exam
- Instill fluorescein and evaluate the pattern for:
  - Appearance of central touch
  - Circular reservoir of fluorescein surrounding the center
  - 360 degree landing throughout the Alignment Zone
  - Acceptable edge lift 360 degrees around
- The lens should center well between blinks
- Assess visual acuity
- Confirm comfort level is acceptable

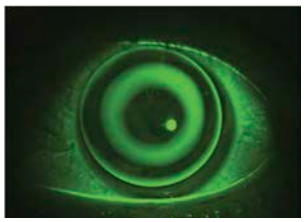
If the fit and comfort are acceptable, train the patient on application and removal. Schedule the patient for overnight wear to evaluate the outcome after one night of wear.

FLUORESCEIN EVALUATION

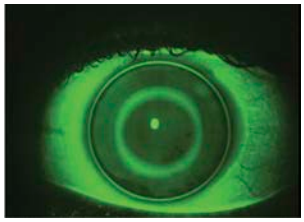
The MOONLENS is worn while sleeping so its performance is best evaluated the following morning. However, it is important to assess the fit of the lens prior to dispensing. The following slit lamp images provide a range of principle outcomes seen in MOONLENS practice and methods to optimize the fit where needed.



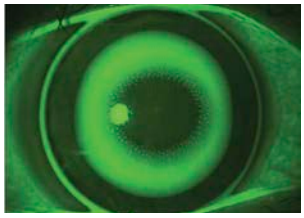
Optimal: This ideal MOONLENS fluorescein pattern shows a lens with near touch in the center, a ring of pooling in the optical zone/RCD junction area, 360 degrees of alignment or landing in the AZA as well as a healthy edge lift.



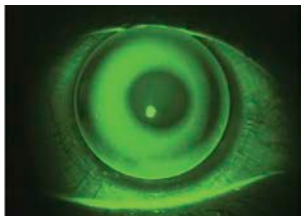
Flat: This image illustrates a high riding MOONLENS lens with an excessive edge lift. To resolve a flat fitting lens, increase the AZA one degree to tighten the peripheral alignment and improve centration. In cases of severely high riding lenses that may also be bearing on the central cornea, increase the AZA one degree and increase the RCD 10 microns (0.010mm).



Steep: This image illustrates a slightly low riding MOONLENS with a tight edge. To resolve a steep fitting lens, reduce the AZA by one degree. For severely steep lenses with excessive apical (0.010mm).



Dimple Veiling: This image illustrates a lens with an excessively deep fluid reservoir resulting in bubble formation. A periphery that appears tight with a lack of edge lift is also present in this image. Reduce the AZA by one degree to decrease the sag 12.5 microns, which will lower the reservoir depth and increase edge lift.



Inadequate Toricity: This image illustrates a symmetric MOONLENS on an astigmatic cornea. Note the landing along 3 and 9 o'clock but a complete lack of alignment along the vertical/steep meridian of the eye. Switch to the toric MOONLENS by employing a deeper "Steep RCD" value. For mildly toric eyes (1.50D corneal cylinder), use a RCD Steep that is 20 microns deeper than the RCD Flat. For moderate astigmatism (2.00D corneal cylinder), use 30 microns deeper and for highly astigmatic eyes (>2.00D), use 40 microns or higher as a RCD Steep value.

POST-WEAR ASSESSMENT

STEP 6

Patient Evaluation After 1 Night of Wear

- Evaluate in the morning after 1 night of wear
- Lenses may or may not be worn in for the exam (practitioner preference)
- If worn in for the exam, check for movement prior to removal
- Assess the cornea and conjunctiva for any presence of SPK/staining
- Check the visual acuity
- See page 16 for Topographical Responses
- Determine the next step in treatment (continue with the present lens or discontinue and modify parameters)

Following the initial night of treatment, it must be determined if the patient should continue with the same lens, or discontinue and order a lens with new parameters.
If the vision, topography and corneal response is satisfactory, then continue with wear and evaluate the patient after a week.

Improvement should be seen after each night as the lens reaches full effect. However, if the vision does not improve and the corneal response is poor (> grade 1 staining) and the topography is showing a decentered treatment effect, then discontinue wear. Alter the parameters per the Problem Solving section on page 15 or discuss the fit with your consultant at your Authorized KATT DG Partner.

RECOMMENDED FOLLOW-UP SCHEDULE

1 DAY
1 WEEK
1 MONTH

Then every 6 months follow-up

PROBLEM SOLVING

VISION

Under-correction: Flatten base curve in diopters equal to the spherical under-correction plus an additional -0.50D.

Over-correction: Steepen the base curve in diopters equal to the spherical over-correction.

Poor Acuity: If the lens has achieved full effect (7-10 days) but the patient has poor visual acuity even with the over-refraction, check the corneal topography for decentration of the effect or a inadequate treatment zone size in relationship with the pupil.

EPITHELIAL RESPONSE

Central Staining: If the lens is in touch with the central epithelium and staining is present, increase the RCD 10 microns (0.010mm).

Dimple Veiling: If dimple veiling is present due to bubbles in an excessively deep reservoir, then decrease the RCD 10 microns (0.010mm).

Peripheral Staining: If the lens edge is tight and producing staining on the peripheral cornea, limbus or conjunctiva, then decrease the AZA to increase edge lift.

EXCESSIVE MOVEMENT

Excessive Edge Lift: Excessive edge lift could result in a loose or sloppy fit. Increase the AZA one degree to tighten the alignment and edge lift.

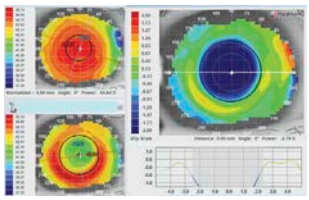
Diameter: A small diameter on a large cornea can result in a loose fit. Increase the diameter 0.3mm or within 0.5mm of the Visible Iris Diameter. Similarly, a large diameter on a small cornea can impinge on the peripheral cornea or limbus. Decrease the diameter 0.3mm if the lens appears too large for the eye. The ideal diameter is 0.8mm smaller than the Visible Iris Diameter.

INAPPROPRIATE EDGE LIFT

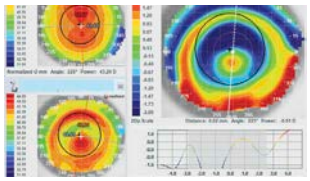
Excessive Edge Lift: An edge lift too wide or deep can cause lid awareness. Increase the AZA one step to reduce the edge lift.

Inadequate Edge Lift: If the lens exhibits a lack of edge lift, then the fit may be too tight and impinging on the cornea. Decrease the AZA one degree to increase the edge lift.

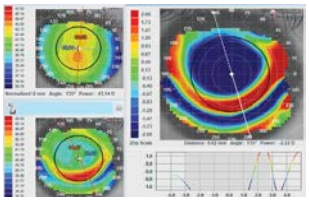
TOPOGRAPHICAL RESPONSES



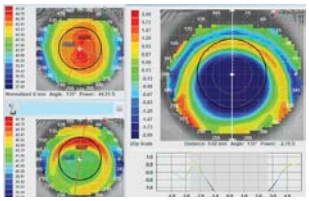
Bulls-Eye: This is the ideal topographical response in terms of centration. When an under or over-correction is associated, adjust the base curve when necessary as described above.



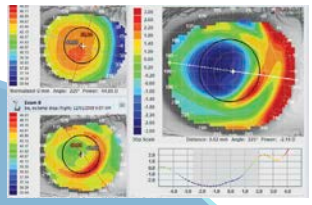
Central Island: This outcome is characterized by apical steepening and generally a low position of treatment. Additionally, the visual acuity is often reduced even with the over-refraction. In such cases, decrease the RCD 10 microns (0.010mm) and decrease the AZA one step.



Smiley Face: This outcome describes a high riding lens with a blue treatment zone decentered high on the axial map and usually an inferior "smile" of steepened epithelium. The tangential map will exhibit red and blue rings of effect that are decentered high. Increase the AZA one degree to tighten the fit. If the Smiley Face also exhibits central corneal staining from inadequate sagittal depth, then increase the RCD 10 microns (0.010mm) along with a one step increase in the AZA.



Frowny Face: This outcome appears much like a bulls-eye response, however, the axial subtractive map shows a blue treatment zone low in relationship with the pupil. A superior "frown" of steepening above the treatment zone is usually visible. Decrease the alignment zone one degree to loosen the peripheral alignment and promote improved vertical centration.



Lateral Decentration: This outcome is characterized by a treatment zone that is either nasal or temporal of the pupil. This generally is caused by a lens with inadequate sagittal depth. In mild cases, increase the AZA to tighten the fit. Alternatively, if the lens is bearing on the central cornea then increase the RCD 10 microns (0.010mm). Additionally, if the lens appears small on eye, increase the diameter 0.3mm or to within 0.5mm of the Visible Iris Diameter.

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