Arise™: a streamlined orthokeratology (Ortho-K) lens fitting system

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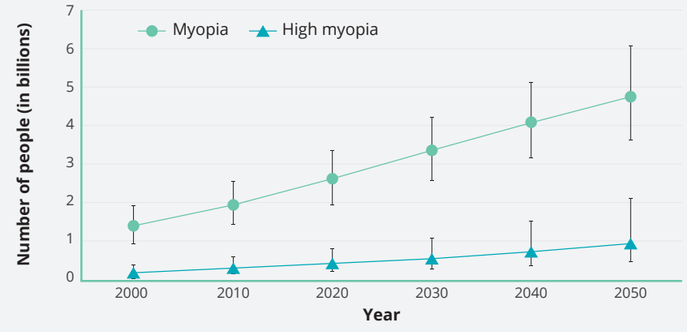
"From early experience, we have found the Arise platform easy to use in practice. The cloud-based fitting library, which compares a given topography to a library of topographies, makes the design process easy, even for new users, and also reduces the need for a live consultation call"

– Brooke Messer

Myopia, or near-sightedness, is the most common ocular disorder in the world, and a leading cause of vision impairment.[1] The prevalence of myopia is on the rise, with the number of people affected by myopia worldwide estimated to increase from ~2 billion (~28% of the world's population) in 2010 to more than half the world's population (~5 billion people) by 2050 (**Figure 1**).[1,2] Vision correction options for myopia include spectacles, contact lenses, or refractive surgery.[1]

Figure 1. Current and projected worldwide prevalence of myopia and high myopia[2]



Graph showing the number of people estimated to have myopia and high myopia for each decade from 2000 through 2050. Error bars represent the 95% confidence intervals. Myopia was defined as −0.50 D or less and high myopia as −5.00 D or less. Adapted with permission from Holden 2016.[2]

Orthokeratology

Orthokeratology, or Ortho-K, is a non-surgical vision correction option for myopia.[2] It works by temporarily flattening the curvature of the cornea with precisely designed gas-permeable contact lenses, worn while sleeping, to achieve unaided vision correction during waking hours.[2] This can be a valuable alternative to spectacles, daytime contact lens wear (soft, gas permeable, or hybrid), or refractive surgery.[2]

Traditional Ortho-K uses corneal gas-permeable lenses with reverse geometry curvatures.[2] Reverse geometry lenses have a base curve flatter than the central radius of the cornea, a mid-peripheral zone (reverse curve) that is deeper (steeper) peripherally compared with the central area, an alignment zone that follows the shape of the peripheral cornea, and a peripheral zone to provide edge lift for tear exchange under the lens (**Figure 2**).[2]

Improvements in lens design and materials, along with advancements in diagnostic and manufacturing technologies, have increased and expanded the contemporary relevance of Ortho-K in recent years.[2,3]

The Arise™ Ortho-K system

The Arise system is an Ortho-K platform that uses cloud-based technology and direct integration with a topographer to algorithmically create highly customized Ortho-K lens designs accounting for eccentricity and asphericity (**Figure 3**). The lenses are indicated for overnight wear for the temporary reduction of myopic refractive error up to −5.00 D and astigmatism up to 1.50 D.[4] It is the first US Food and Drug Administration (FDA)-approved Ortho-K lens design with clinical evidence supporting the use of their toric/non-spherical posterior peripheral curves to improve corneal alignment on non-spherical corneas.[4,5] The platform confers a number of benefits to practitioners. It provides an efficient system to record baseline findings, and by utilizing a cloud-based fit library, it enables the design of a custom Ortho-K lens without the use of a diagnostic fitting set, which can potentially reduce chair time.[5]

The Arise Ortho-K system is the first FDA-approved Ortho-K lens design with clinical evidence supporting the use of their toric/non-spherical posterior peripheral curves.

Figure 2. Representation of reverse geometry Ortho-K lens design[2,4]

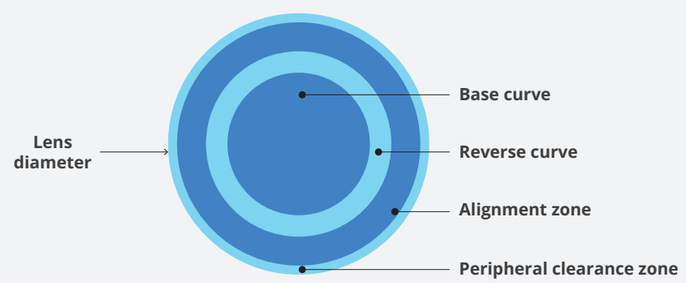


Figure 3. The Arise platform fitting process[6]

1 Capture

Upload corneal images from a compatible topographer.

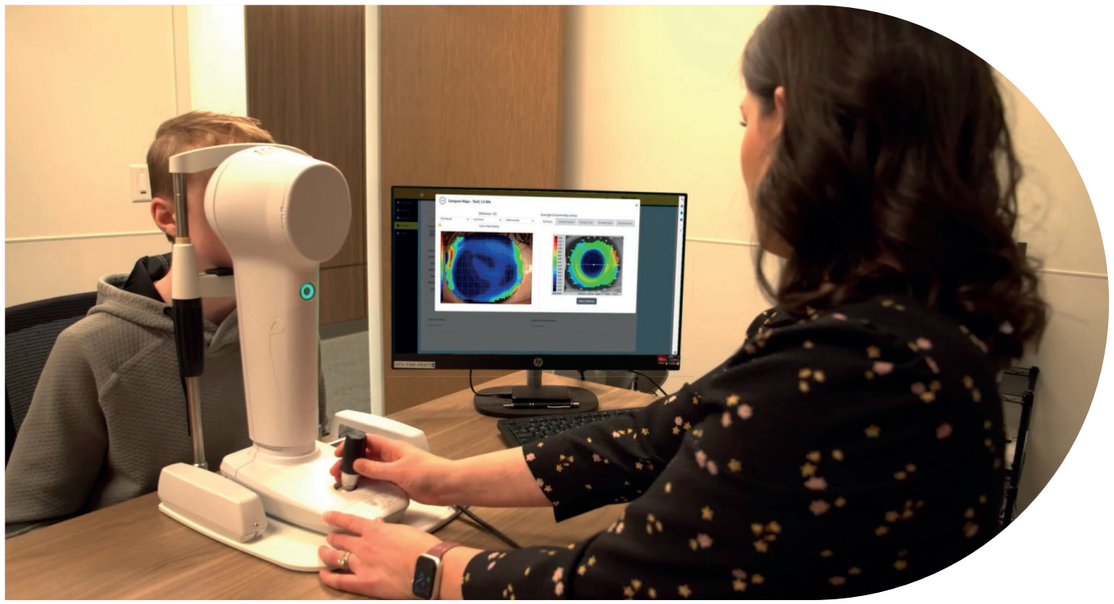
2 Design

The Arise platform algorithmically recommends custom Ortho-K lens designs.

3 Evaluate

If necessary, use the Overnight Outcome Map Library to guide the refit process.

Instructions on how to fit Arise with a non-integrated topographer are available through a Bausch + Lomb representative.



Key clinical study data

A multicenter, single-arm, open-label study was conducted to assess the safety and effectiveness of the Arise system over a 3-month period.[7]

Patient population

- Ortho-K lens-naïve patients ≥12 years of age, with myopic refractive error (spherical refractive error between plano and −5.00 D, astigmatism ≤1.50 D, and a corneal topography sagittal height differential of ≥30 µm).

Key effectiveness outcomes

- **Primary effectiveness outcome: following 3 months of overnight lens wear, 93.3% of patients achieved a monocular high-contrast uncorrected distance visual acuity (UDVA) of 20/40 or better (95% CI: 82.1%, 97.7%; n=45 patients).**
- Improvements in UDVA line change were observed at each follow-up visit compared with baseline.
  - » Mean (SD) UDVA line change from baseline at the 3-month follow-up visit was 5.9 (3.3); n=90 eyes.
- Acceptable lens fit was reported for 96.1% of eyes at the first dispensing visit (n=152 eyes).
- Following the first night of overnight wear, acceptable lens fit assessments were reported for 95.5% of eyes (n=132).

Key safety outcomes

- **Primary safety outcome: no serious adverse events were reported throughout the study, including treatment-emergent serious adverse events.**
- The safety profile was consistent with previous studies of overnight Ortho-K lenses, with no new potential safety risks identified.

These findings were in line with those of an earlier multicenter, 9-month study of oprifocon A lenses in 191 patients (374 eyes) with myopia ≥18 years of age.[8]

Arise clinical trial insights

The investigators' perspective

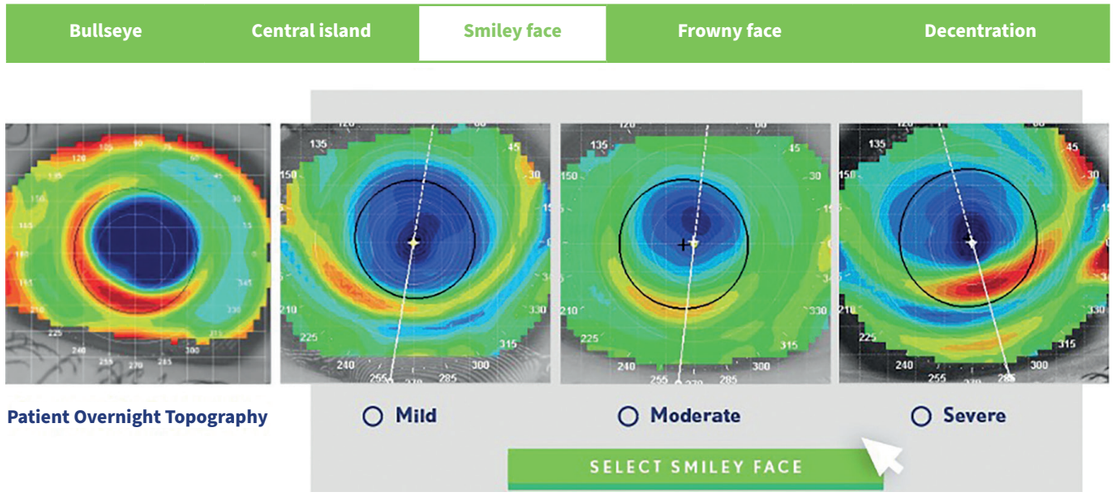
Drs Zachary Holland, OD, and Jennifer Harthan, OD, clinical study investigators for the 3-month Arise system study, provide their perspectives on the study findings and discuss their experience with the lenses during the trial.

To be eligible for inclusion in the study, the threshold for the sagittal height difference between the principal meridians of the cornea was ≥30 µm at an 8 mm chord diameter.[7] This is also the threshold for consideration of toric peripheral curves in the Arise fitting system.[4] In real-world practice, for eyes falling under this threshold, a spherical peripheral curve can be used.

In our experience, we've observed that utilization of toric peripheral curves tended to translate to better centration for corneas with greater sagittal height differences. This is in line with findings in the literature, where the incorporation of toric peripheral curves is indeed associated with better centration.[3] This emphasizes the value of utilizing a system that can design Ortho-K lenses with appropriate levels of toricity.

Almost half of the total cases screened qualified for a lens with toric peripheral curves, reaffirming that there is a significant clinical need for this option in Ortho-K lens designs.[7]

Figure 4. Sample view of the Overnight Outcome Map Library



"Clinical data affirm that Ortho-K with Arise is safe and effective, including with toric peripheral curve designs."

– Zachary Holland

"When a patient understands that their exact topography is being uploaded and it really is designing a lens for them, they appreciate and value the lens they are receiving."

– Jamie Kuzniar

Clinical pearls

For ease of use

When uploading corneal images from a compatible topographer to the Ortho-K lens platform via the CloudLink software, it is advised to take multiple image captures to ensure a high-quality "baseline map" is obtained. This baseline topography map is the foundation of the fitting process. The platform will automatically recommend custom lens parameters based on analysis of the map data points and inputted patient data (e.g., age, pupil size, refractive error). The system automatically adjusts the optic zone diameter according to the age of the patient; however, this is also manually customizable as needed. Peripheral curves are also automatically suggested as appropriate (per topography input) and can be further manually modified if required. The Overnight Outcome Map Library (sample view shown in **Figure 4**), built within the Arise platform, analyzes thousands of data points to create outcome examples and can be used to provide comparisons for help with troubleshooting and redesign. By selecting the closest match to your patient, the system algorithmically calculates the suggested lens design parameters. **With these efficiencies, it is possible to design and order a lens within seconds.**

The cloud-based system utilized by the Arise platform can also be used to facilitate collaboration between practice staff, including a comment-based communication system between teams (office and laboratory). It can also create other workflow efficiencies in the process. For example, while the technician is uploading topography data, the eye care professional can collect the necessary patient information and input the parameters into the system. The system itself keeps a clear record of designed lenses and their outcomes, effectively serving as a tracking system for existing cases as well.

For integration into practice

Arise Ortho-K lenses are a suitable option for many patients with low or moderate myopia, with a few exceptions (e.g., very high astigmatism).[4] The clinical data demonstrating the fitting success rates with the Arise lens are consistent with our real-world practice experience to date. If a high-quality baseline scan is obtained, there is limited need for troubleshooting or re-fits – an important consideration for busy practices. The cloud-based system can also act as a teaching tool for eye care professionals working with a variety of staff, students, and other practitioners, with the difference map feature being a particularly useful means to understand where and to what degree the cornea has changed. This can even be useful in explaining the process to patients.

The latest versions of the fitting system are compatible with several corneal topographers: Medmont, CSO, Keratograph, Pentacam®, and Keratron Scout.

"The Arise platform and Ortho-K lenses have been a great addition to my practice."

Novice and experienced Ortho-K providers can benefit from the software features and built-in efficiencies."

– Brooke Messer

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"Successful fitting with the Arise platform is translating from the clinical data to real-world practice."

– Jennifer Harthan

Conclusions

The Arise platform aims to make the process of fitting Ortho-K lenses more efficient for eye care professionals. It enables a streamlined fitting process, utilizing sophisticated algorithms to interpret corneal topography images and recommend appropriate lens parameters based on patient data.

It is also the first FDA-approved Ortho-K lens design with clinical evidence supporting the use of their toric/non-spherical posterior peripheral curves. This is a significant clinical need in Ortho-K lens design.

The Arise system's efficient and effective performance, as evidenced in clinical data, is now translating into real-world clinical practice.

Author biographies

Dr Brooke Messer is a distinguished optometrist and residency director at Vance Thompson Vision, West Fargo, and specializes in managing patients with keratoconus and those requiring post-surgical cornea care. She has a special interest in myopia and orthokeratology. She is a member of several optometric organizations and has received numerous awards and honors throughout her career.

Dr Jennifer Harthan is a professor at the Illinois College of Optometry and chief of the Cornea and Contact Lens Center for Clinical Excellence at the Illinois Eye Institute. She is a founding member of the SCOPE (Scleral Lenses in Current Ophthalmic Practice Evaluation) research team, and has numerous publications on the topics of complex contact lens fits and anterior segment disease.

Dr Zachary Holland is the owner of the Cornea and Contact Lens Institute of Minnesota. He actively participates in multiple FDA clinical trials and is published regularly on the topics of myopia, scleral lenses, keratoconus management, corneal crosslinking, and practice management.

Dr Jamie Kuzniar is the owner and founder of Elevate Eye Care + Eyewear, Rochester Hills. She is a graduate of Michigan College of Optometry, and completed a cornea and contact lens residency at Indiana University. She enjoys lecturing about keratoconus, specialty lenses, and practice management.

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Disclosures

Brooke Messer, Jennifer Harthan, Zachary Holland and Jamie Kuzniar are consultants for Bausch + Lomb.

Scan for more information

IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE

Boston Orthokeratology (oprifocon A) shaping lenses for overnight wear are indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lenses are indicated for overnight wear as part of the Bausch + Lomb Vision Shaping Treatment VST® process for the temporary reduction of myopia up to 5.00 diopters with eyes having astigmatism up to 1.50 diopters. The lenses may only be disinfected using a chemical disinfection system.

SAFETY INFORMATION

CONTRAINDICATIONS

DO NOT USE the Boston Orthokeratology (oprifocon A) shaping lenses when any of the following conditions exist:

- Acute and sub-acute inflammations or infection of the anterior chamber of the eye
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
- Severe insufficiency of tears (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity)
- Any systemic disease which may affect the eye or be exacerbated by wearing contact lenses
- Allergic reactions of ocular surfaces or adnexa which may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
- Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for your Boston Orthokeratology (oprifocon A) shaping lenses
- Any active corneal infection (bacterial, fungal, or viral)
- If eyes become red or irritated

WARNINGS

The risk of ulcerative keratitis has been shown to be greater among wearers of extended wear lenses than among wearers of daily wear lenses. The risk among extended wear use users increases the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. Smoking increases the risk of ulcerative keratitis for contact lens wearers. Wearing the lenses continuously (extended wear) presents increased risk, which increases with the number of consecutive days the lenses are worn between removals. Although the safety risks of overnight wear with removal upon wakening may not be as great as with extended wear, there is still increased risk beginning with the first overnight period.

PRECAUTIONS

When selecting an appropriate lens design and parameters, the eye care practitioner should consider all factors that affect lens performance and the patient's ocular health; including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

ADVERSE EVENTS

A total of 378 eyes (191 patients) were enrolled in a clinical study. There were twelve significant lens-related adverse events reported in ten subjects. All eyes that showed acuity reductions were documented as returning to normal vision, except two eyes of one subject with severe corneal staining that showed ≥2 lines loss of BSCVA. The return to pre-treatment VA was not recorded for this subject, although the subject returned to soft contact lens wear and verbally reported that vision was normal. All adverse events resolved without further complications.

A separate clinical study evaluated the effect of non-spherical (toric) peripheral curves on 45 astigmatic patients who were orthokeratology lens-naïve. Among the dispensed subjects, no significant adverse events were reported.

ATTENTION: Refer to the package insert for a complete listing of indications, warnings and precautions, clinical trial information, etc.

CAUTION: Federal (USA) law restricts this device to the sale by, or on the order of a licensed practitioner.

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