

ORTHOKERATOLOGY MYOPIA CONTROL PROGRAM

Welcome to Orthokeratology, our myopia control program. You are beginning an exciting program designed to reduce and/or eliminate your dependency on eyeglasses or contact lenses during the day. The process reduces your refractive error by wearing corneal molding retainer therapeutic lenses that will gently and non-surgically reshape your corneas as you sleep.

This document in combination with the entire program and training process is designed to educate you regarding any potential risks. It is important to understand that it is impossible to perform any treatment without the patient accepting a certain degree of responsibility and risk. Ortho-K is an elective procedure and the alternatives are: eyeglasses, conventional contact lenses or refractive surgery (adults only).

We appreciate the confidence and trust you have placed in us for your treatment and care. Please read this contract in its entirety and feel free to ask any questions you have. It is very important that you read this document carefully. Please initial where indicated. Do not sign this form until you have read and understand each section. If you have any questions, please write them on the back so you won't forget them.

INFORMED CONSENT AND INTRODUCTION

Introduction	<p>Orthokeratology or Ortho-K is the science of changing the curvature or shape of the cornea to change how light is focused on the retina at the back of one's eye. It works each night while you sleep. You put specially designed molding retainer lenses on when you go to bed and remove them when you wake up. Your vision is clear during the day, without glasses or contact lenses.</p> <p>_____ ✍ I acknowledge I have read and fully understand the above information.</p>
FDA Approval	<p>There are several Ortho-K lens designs on the market - Some of the designs have specific FDA approval and some do not. All lenses used are made in an FDA approved lens material, however, some of our designs are customized and allow us to use multiple curves and/or diameters measured in microns. Because customized retainer lenses are made to fit your individual eye, there are no "standardized" designs for these lenses. In addition, FDA approvals are based on the amount of power being corrected. If your power falls outside the range of FDA approval, your fit will be considered "off label". Off label use of medications and medical devices is common in modern medicine as the FDA cannot possibly approve every condition for these drugs or devices. Ortho-K is a unique and customizable treatment and therefore, your case may be considered "off label" as it may be the best option for a successful fit depending on your distinctive corneal topography and strength of prescription. We feel this customization, in the hands of a skilled practitioner, is the best method to obtain clear, comfortable vision. We will have a discussion with you about your best options for success.</p> <p>_____ ✍ I have read the above and understand that my lenses may not be FDA approved.</p>
Myopia Control	<p>Myopia (nearsightedness) control is an "off label" use of Ortho-K. Ortho-K is FDA approved as a safe and reversible procedure to temporarily reduce dependency on spectacles and daytime contact lenses. It is not specifically approved to slow down the progression of myopia. Multiple scientific studies have proven Ortho-K to be a safe and effective method for controlling myopia, but no such FDA approval exists at this time.</p> <p>_____ ✍ I have read the above and understand that myopia control is not FDA approved.</p>
Contraindications	<p>The following conditions present a reason not to undergo Ortho-K treatment. By initialing, you certify that you do not currently have any of the following: keratoconus, previous ocular herpes, corneal dystrophy, degeneration or disease, pregnancy (or planning to become pregnant in the next 12 months).</p> <p>_____ ✍ I do not have any of the conditions listed above.</p>

Risks and Complications

Lens Awareness - As the lenses are designed for closed-eye wear, they may feel scratchy if they are worn during waking hours. With time, this scratchiness will usually lessen. However, we advise minimizing your use of the lenses during waking hours as this may compromise your treatment.

Initial Blurriness - During the first week of treatment, molding may be incomplete, and you may experience some blurred vision. On average it takes 7-10 days for treatment to take full effect. If necessary, we will provide you with a series of disposable soft lenses to be used until you feel your vision is comfortable.

Halos - Some patients experience halos or flare around lights at night. This phenomenon usually becomes less noticeable within a few weeks. If it does not subside, we will attempt to re-design the lenses to create a larger treatment area if possible. However, in some cases, these halos may not completely disappear.

Infection - As with the use of any contact lens, there are potential risks of eye infections. Areas of concern are microbial keratitis and corneal ulcers. The risk of these conditions increases among users of extended wear lenses and increases with the number of consecutive days those lenses are worn between removals. Ortho-K lenses are removed daily and are worn for far fewer hours a day than traditional contact lenses and have a higher oxygen permeability value than most soft contact lenses, so the risk of infection becomes lower.

As with all contact lens wear, there is a slight risk of developing an infection caused by acanthamoeba (found in tap water). We have designed a lens sterilization program that should eliminate this risk and you will receive extensive training in the care of your retainer lenses. **Under no circumstances should you rinse your lenses with tap water or modify your sterilization regimen without consulting the office.** Acanthamoeba infections are very serious and can result in scarring, a permanent reduction of vision and even complete loss of vision requiring corneal transplantation.

Abrasions - At some point during treatment, you may experience a superficial abrasion to the cornea. This can occur if debris gets trapped between the eye and the lens, the lens was not cleaned properly, disinfectant was not rinsed from the lens, and/or you slept with your eyelids slightly parted. Fortunately, abrasions are rare and temporary. **Call the office if you wake with a painful eye that does not resolve in 30 minutes.**

Dry Eye - Some people do not produce sufficient tears. We will perform tests to determine your tear quantity and quality. If dry eyes are diagnosed prior to treatment, we will not start the program until the issue has been stabilized. If the molding process results in severe dry eyes, lenses may need to be discontinued either temporarily or permanently.

Other - It is impossible to list every conceivable complication that could occur with orthokeratology. Complications that are considered to be unforeseeable or unknown at this time are not discussed.

If you require medical eye care we will bill those visits to your major medical plan per our assignment of benefits agreement, or at a discounted private pay fee.

_____  I understand the risks and complications of Ortho-K treatment process.

Limitations of Treatment

Permanent Vision Correction - Ortho-K will not permanently correct vision. Your prescription will revert to its pre-fit status if your treatment is terminated for any reason.

Regression - Ortho-K retainer lenses attempt to slow or stop the progression of myopia (nearsightedness) and hyperopia (farsightedness). Nevertheless, regression of treatment may occur at some point. This may require a re-designing of the lenses to again achieve optimal vision.

Over- or under-correction - In most cases, the initial Ortho-K retainer lenses will achieve optimal vision. On occasion over or under treatment may occur. New lenses will be ordered to correct this problem. If new lenses cannot achieve optimal treatment, eyeglasses may be prescribed for part-time wear.

Out of Range Prescriptions - Prescriptions exceeding the normal range of Ortho-K may take longer to mold and therefore, it may take longer for ideal vision to be achieved. It is also possible that full correction may not be able to be achieved.

Insufficient Treatment Time - Some patients cannot sleep for the 6+ hours per night required for treatment. This may limit our ability to mold the cornea. Full treatment may not be able to be achieved.

Presbyopia - Orthokeratology does not correct or prevent presbyopia, the normal aging process of the crystalline lens of the eye which causes blurred vision when reading or doing close work. Presbyopia usually occurs around age 40. If you have presbyopia or borderline presbyopia you will be given two options:

- Reading glasses when doing near work; OR
- Monovision treatment where one eye is focused for distance and the other for reading. Monovision may cause you to give up some visual sharpness and depth perception. Most people find this a small compromise and enjoy their reduced dependence on reading glasses.

_____  **I understand the limitations listed above.**

Provider Obligations

- We agree to evaluate your cornea, general health, and prescription prior to beginning the treatment process. If we feel you are not a suitable candidate, we will not proceed with the program, and you will be responsible only for the \$100 consultation fee.
- We will choose the highest quality, most appropriate lens for your particular treatment needs.
- We will carefully educate you in the wearing, caring and sterilization of your retainer lenses.
- One of our doctors will be on call 24 hours each day, 7 days each week (including holidays) to handle emergency care or phone consultation. Report all treatment-related emergencies immediately at 206-527-2987 during regular business hours or after hours.

_____  **I understand the obligations of the provider.**

Patient Obligations

- I agree to never use tap water to rinse my lenses.
- I agree to handle, clean, and sterilize my lenses in the manner instructed and never deviate from those instructions without the prior approval of the office.
- I agree to call the office immediately if I have pain, discharge, light sensitivity, redness or have consistent difficulty removing my lenses in the morning.
- I agree to return to the office for every scheduled follow up visit. If I cannot make a visit, I agree to call 24-hours in advance to reschedule. Chronically missed and rescheduled appointments may be charged.
- If I am a current contact lens wearer, I agree to discontinue wearing my current lenses for the time prescribed.
- After my initial treatment phase (6 months), I agree to return for my annual eye exam, and annual Ortho-K eval so the health of my corneas can be examined, my lenses can be deep cleaned, and I can be updated on any new advances in the care of my lenses.

_____  **I understand my obligations.**

Professional Fees

Ortho-K Consultation and Initial Fitting:

This fee includes your initial consultation with the provider to answer any questions you might have, all computerized corneal mapping, lens design, first set of lenses with a 90-day warranty, complete care kit and Ortho-K follow up care for 6 months from the date on this consent form. The non-refundable consultation fee of \$100 will be applied to the fitting fees outlined below if you proceed with the Ortho-K Treatment Program.

- Tier #1 Fee: Eyeglass prescription less than -3.00 diopters - \$2,450 (includes two sets of lenses)
- Tier #2 Fee: Eyeglass prescription -3.00 to -5.00 diopters - \$2,850 (includes two sets of lenses)

Annual Ortho-K Evaluations and Maintenance:


\$1,000 (includes annual evaluation and a set of lenses)

This fee covers the testing related to orthokeratology.

Ortho-K Lens Fees (materials):

- **Replacement Lenses:** \$250 per lens
- **Lost or Broken Lenses:** If lenses are lost or broken within 90-days of purchase a one-time replacement price of \$125 per lens will be given.

The full treatment fee should be paid in full at the time of the first fitting. Payment options include cash, check, MasterCard, Visa, and Care Credit.

_____  **I understand and agree to the fee terms and conditions above.**

Discontinuation of Treatment

It is a rare occurrence in health care that any procedure succeeds in every case. Should either you (the patient) or the practitioner decide to discontinue treatment within the first three (3) months of this agreement, then we will refund your money as follows:

- Within seven (7) days of initiating treatment: full refund minus \$100 consultation fee.
- From Day 8 to Day 90 of initiating treatment: full refund minus \$750.

Each of the above refund policies is contingent upon the prompt return of the undamaged retainer lenses to our office upon discontinuation of the fitting process. Failure to return the lenses will result in a diminished refund of current lens fee.

_____  **I understand the refund policy.**

