CHILDREN'S EYE CARE
the art and science of vision

Informed Consent

Orthokeratology, Ortho-k, CRT, Corneal Reshaping

Welcome to Orthokeratology, our corneal reshaping treatment 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 consultation 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.

INTRODUCTION: WHAT IS ORTHOKERATOLOGY?

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.

I acknowledge I have read and fully understand the above-information. _____ Initial

FEDERAL DRUG ADMINISTRATION (FDA) APPROVAL:

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 Orthokeratologist, is the best method to obtain clear, comfortable vision. We will have a discussion with you about your best options for success.

I have read the above and understand that my lenses may not be FDA approved. _____ Initial

MYOPIA CONTROL:

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.

I have read the above and understand that myopia control is not FDA approved. _____ Initial

CONTRAINDICATIONS:

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 on becoming pregnant in the next 12 months).

I do not have any of the conditions listed above. _____ Initial

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. We will provide you with a series of disposable soft lenses, if necessary, to be used until you feel your vision is comfortable.

Halos. Some patients experience halos or flare around lights at night. This 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. Of particular 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 that lenses are worn between removals. Ortho-k lenses are removed daily and, if proper cleaning and disinfection protocols are observed, are safe to use for most people. Should an infection arise, calling us for prompt medical care can help avoid complications.

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 problem has been resolved. If the molding process results in dry eyes, lenses may need to be discontinued while the problem is being solved.

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.

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

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LIMITATIONS OF TREATMENT:

Permanent vision correction. Ortho-k will not give permanently corrected vision. Your prescription will revert back 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.

Resistant cornea. Some corneas will not mold appropriately. Prior to beginning the treatment process, we will be performing tests to rule out known causes for a nonresponsive cornea.

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. _____ **Initial**

CHILDREN'S EYE CARE OBLIGATIONS:

- We agree to evaluate your cornea, general health and prescription prior to beginning the treatment process. If we feel you are not a good candidate, we will not proceed with the program.
- 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 425-823-3937.

I understand the obligations of Vision Care Specialists. _____ Initial

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. Missed appointments will 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 every six months 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. _____ Initial

PROFESSIONAL FEES:

The fee for Ortho-k includes all professional services and all therapeutic lenses that are required to complete the treatment. If refit lenses are needed during the fitting process, the previous pair must be returned. Additional supplies incorporated in your program include a complete care kit and instruction on its use. Your therapeutic lenses require regular cleaning. Replacement care kits are not included in your program and can be purchased in this office or ordered online.

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The following fee is inclusive and includes all treatment lenses and office visits related to corneal reshaping necessary during the treatment period. If however, you require medical eye care, we will bill those visits to your major medical plan per our assignment of benefits agreement.

The total fee for our services related to your Orthokeratology therapy is $2600 for new fit and $1600 for refit. This fee will cover all computerized corneal mapping, lens design, retainer lenses, and all follow up care for 12 months from the date on this consent form. During the treatment, before complete myopic reduction, you may be required to temporarily wear spectacles/disposable contact lenses to correct remaining refractive error during the day time to aid vision. When the treatment is completed, you will need to continue to wear the final pair of lenses to maintain the myopic reduction effect. Regular after-care visits for new fit (1 day after wear, 1 week after wear, 1 month after wear, 3 months after wear) are still necessary to ensure the health of your eyes. Lost or damaged lenses are not included in this global fitting process. If you lose or damage a lens during the fitting process, you will be responsible for replacement at the rate of $190/lens and an additional fee of $30 for any rush order.

Other fees. We recommend that you always have a spare pair of lenses. Treatment may be compromised if disrupted by discontinued wear due to lost or damaged lenses.

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

DISCONTINUATION OF TREATMENT:

It is a rare occurrence in health care that any procedure succeeds in every case. Should either you (the patient) or Drs. Epley, Stallworth or Mai decide to discontinue treatment, it will be **NON-REFUNDABLE.**

I understand the non-refund policy. _____ Initial

MAINTENANCE AGREEMENT:

Ortho-K requires close monitoring and annual eye exams are extremely important. **The fee for the annual refitting cost is $1600, which will include the material and follow-up appointments.** This fee covers the testing directly related to Orthokeratology including both the yearly and quarterly visits. Routine and medical eye testing will be billed to insurance at the usual and customary rate or to the individual if there is no insurance coverage.

I understand the Maintenance Agreement **_____ Initial**

VOLUNTARY CONSENT:

In signing this Informed Consent, I (or my guardian) certify that I have read the preceding information and understand the contents. I understand that the treatment outcome cannot be guaranteed. I understand that treatment obtained may not eliminate my need for glasses completely. I have been informed of alternative treatments including glasses, conventional contact lenses and refractive surgery. All my questions have been answered to my satisfaction.

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Patient Name (Print) Patient (Guardian if under 18) Signature

_____

Date

_____

_____

Witness Full Name (Print) Witness Signature

_____

Date

*** Price subject to change without notice**