

Orthokeratology Fitting/Care Agreement & Informed Consent Contract

It is important that you read this document very carefully. Be sure you understand each portion of this form before signing it, and if you have any questions, please ask your doctor or the staff. This document explains a specialty treatment process commonly referred to as "Orthokeratology", where custom contact lenses made from a rigid gas permeable material are used to reshape the cornea while the patient sleeps, and through this process provide acceptable unaided distance vision while the patient is awake. The Orthokeratology effect is temporary and reversible with the cornea returning to its original form usually within two weeks after lens wear has been discontinued. To provide the best treatment, it is necessary to wear the shaping lenses as prescribed by your doctor. The quality of the Patient's unaided vision is dependent on the amount of the internal astigmatism present in the Patient's eyes, which is not always predictable and cannot be altered. If the results are found to be unacceptable, the process will be reversed by discontinuing the program. It is our intent to fully explain all the side effects, limitations and complications of orthokeratology, and it is important to understand that it is impossible to perform any treatment without the patient accepting a certain degree of responsibility and risk. This document in combination with the consultation and training process are designed to educate you regarding any potential risks, however please realize that very few patients will ever encounter any serious problems. Orthokeratology is an elective procedure and other alternatives include: eyeglasses, conventional contact lenses or refractive surgery (adults only).

Contraindications:

The following conditions present a reason not to undergo orthokeratology treatment. By signing below, you certify that you do not currently have or previously had any of the following: keratoconus, ocular herpes, extreme dry eye, corneal dystrophies/disorders, anterior chamber infection/inflammation or pregnancy.

Limitations:

Prescriptions exceeding the normal range of orthokeratology may take longer to mold and therefore longer to achieve ideal vision. It is possible that full correction may not be able to be achieved. Additionally, some corneas will not reshape as desired leading to less than optimal unaided distance vision. Prior to beginning the treatment process, we will be performing tests to determine your candidate status for Orthokeratology. With recent advancements in Orthokeratology, even some of the most difficult patients can find a lens design that can work for them. Another point to consider is that some patients cannot sleep for the 7 hours per night required for treatment, which may limit the ability to mold the cornea, and full treatment may not be achieved. Orthokeratology will not provide permanently corrected vision, because the cornea will revert to its original shape and your prescription will return to its original amount if your treatment is terminated for any reason.

Risks and Complications:

The shaping lenses may feel scratchy and irritating if they are worn during waking hours, as they are designed for closed-eye wear. With time, this scratchiness will usually lessen. However, we advise minimizing your use of the shaping lenses during waking hours as this may compromise your treatment. During the first week of treatment, reshaping may be incomplete and you may experience some blurred vision. If necessary, we will provide you with a series of disposable soft lenses to be used until you feel your vision is comfortable. In most cases, the initial Orthokeratology shaping lens will achieve optimal vision, however, occasionally over or under treatment may occur. New shaping lenses may need to be ordered to correct this problem. If the new lenses cannot achieve optimal treatment, eyeglasses may be prescribed for part-time wear. Some patients experience halos or flare around lights at night, which usually becomes less noticeable within a few weeks. If it does not subside, we will attempt to redesign the lenses to create a larger treatment area. However, in some cases, these haloes may not completely disappear. The risk of infection while wearing Orthokeratology lenses is very rare, however, there is a slight risk of infection caused by Acanthamoeba (found in tap water). Your recommended lens sterilization program should eliminate this risk and you will receive extensive training in the care of your lenses along with our informational handout on proper handling and care of your Orthokeratology lenses. **Under no circumstances should you rinse your shaping lenses with tap water or modify your sterilization regimen without consulting the office.** Serious infection from Acanthamoeba can result in corneal scarring, a permanent reduction of vision, and/or possibly a need for a corneal transplant. Additionally, you may experience a superficial abrasion to the cornea, which can occur if debris gets trapped between the eye and the lens if the lens is not cleaned properly, if the disinfectant is not rinsed from the lens, or if you sleep with your eyes slightly open. These are rare and temporary. Call the office if you wake with a painful eye that does not resolve in 30 minutes. Another consideration is that some people do not produce sufficient tears, which can make Orthokeratology treatment difficult. We will perform tests to determine your tear quantity and quality, and if dry eyes are diagnosed prior to treatment, we will not start the program until the problem has been resolved. If the Orthokeratology process results in dry eyes then the shaping lenses may need to be discontinued while the problem is being solved. Orthokeratology shaping

lenses attempt to slow or stop the progression of myopia (nearsightedness). Nevertheless, regression of treatment may occur at some point, which may require a redesigning of the lenses to again achieve optimal vision. It is impossible to list every conceivable complication that could occur with wearing Orthokeratology lenses. Complications that are considered to be unforeseeable or unknown at this time are not discussed, but should be considered when electing to proceed with the Orthokeratology program.

The Second Half of Life:

Presbyopia is the normal aging of the eyes, which results in blurred vision when reading or doing near work. Presbyopia occurs because the crystalline lens within the eye loses its ability to change shape which is what allows us to focus at near. Presbyopia usually emerges around age 40. If you have presbyopia or borderline presbyopia you have a few options: 1) wearing reading glasses when doing near work 2) monovision Orthokeratology, where one eye is focused for distance and the other for reading, or 3) multifocal Orthokeratology. Reading glasses are a small inconvenience, but can provide very sharp vision at near while your Orthokeratology effect provides adequate distance vision. Monovision on the other hand may cause you to give up some visual sharpness and depth perception, but allows you to remain free of glasses. Most people find this to be a small compromise and enjoy their reduced dependence on reading glasses. Finally, multifocal Orthokeratology can provide both good distance and near vision if the patient is able to adapt. However, this third option is a relatively new process that involves shaping the inferior cornea slightly different than the central and superior corneas. It may take more fitting visits to obtain success both at distance and near, but could potentially be the best option for you depending on your lifestyle.

Professional Fees:

Initial Consultation and Training: Includes a detailed evaluation of refractive status, corneal topography, HVID (horizontal visible iris diameter) measurements, and determination of the Patient's status as a candidate for Orthokeratology. After the initial lenses have been determined, the Patient will set an appointment for training on insertion, removal, handling and care of the shaping lenses, and the Patient will be given an educational sheet that reviews instructions given during the training. These services are separate and distinct from the annual comprehensive exam, which is part of annual preventive health care. This Consultation and Training has a one time fee of **\$200**, payable at the time of the appointment.

Fitting and Modification: Includes analysis of the shaping lens parameters, early morning evaluation(s) of the refractive changes, topography changes, and physiological changes of the cornea along with evaluating the fit of the diagnostic lenses both before and after wearing the lenses for the recommended period of time. Decisions will be made whether to continue treatment, and whether to alter either the type, brand, or parameters of the shaping lenses. This Fitting and Modification covers all visits related to determining the proper lenses for one year, and has a one-time fee of (**\$400 / \$600 / \$800**), payable at the time of the appointment. The fee chosen will be based on the complexity of the treatment program, when significantly more time and effort will be necessary to establish acceptable vision (such as with mono vision, multifocal, or lenses for astigmatism). Note - this does not include the annual comprehensive exam, or any necessary medical visits.

Shaping Lenses: Includes one pair of custom ordered shaping lenses. **\$TBD** (payable upon receiving the lenses). Additional lenses can be provided at a discounted price of 80% of the initial lens cost. It is highly recommended to order two sets of lenses in case something would happen to your initial set of lenses.

Refund Policy: As with other health care treatment programs, if either you (the Patient) or the doctor decide not to proceed with Orthokeratology, we will provide a refund as follows:

- **Initial Consultation and Training: (\$200) Non-refundable**
- **Fitting and Modification: (\$400/\$600/\$800)**
 - Within one week of initiating wear of the lenses, the Patient will be refunded **75%** of the fee.
 - Between one week and the end of the warranty on the lenses (90 days), the Patient will be refunded at **50%** of the fee.
 - After the warranty expires, no refund will be issued.
- **Shaping Lenses: (\$TBD)**
 - Before the expiration of the warranty on the lenses (90 days), the Patient will be refunded the full amount and treatment will be discontinued. This refund is contingent upon prompt return of the undamaged shaping lenses to our office.
 - After the warranty expires, no refunds will be issued.

Our Obligation:

- 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 need.
- We will carefully educate you in the wearing, caring and sterilization of your shaping lenses.
- The doctor will be available during normal business hours
- In the event of an emergency and the doctor is not available, please call the emergency city wide call number (1-800-888-1433)

The Patient's Obligation:

- I agree to never use tap water to rinse my shaping lenses.
- I agree to handle, clean and sterilize my shaping lenses in the manner instructed and never deviate from those instructions unless I consult with the office.
- I agree to call the office immediately if I have pain, discharge, light sensitivity, redness or have consistent difficulty removing my retainers 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 ASAP in advance to reschedule.
- If I am a current contact lens wearer, I agree to discontinue wearing my current contact lenses for time prescribed.
- Lost or damaged shaping lenses are not included in the global fitting process. If I lose or damage a lens during the fitting process (12 months), I will be responsible for replacements at the replacement rate.
- After my initial treatment phase (12 months), I agree to return every six months, so the health of my corneas can be examined, my shaping lenses can be deep cleaned, and I can be updated on any new advances in the care of my shaping lenses.
- I acknowledge that failure to show up to follow-up exam(s) or any fitting evaluations as scheduled by the clinic office disqualifies me from Our Obligation discussed above.
- In the event of an emergency and the doctor is not available, I agree to seek medical attention in a timely manner.

Voluntary Consent:

I have read all of the above information regarding Orthokeratology lenses, and by 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, and that the treatment obtained may not be eliminating my need for glasses completely. I have been informed of alternative treatments including glasses, conventional contact lenses and refractive surgery. All of my questions have been answered to my satisfaction. Although it is impossible for the doctor to inform me of every possible complication, the doctor and the clinic staff have answered all my questions to my satisfaction and will answer any further inquiries I may have. Should any complications occur, I agree to contact the doctor immediately. If for any reason I am unable to contact the doctor, and I am experiencing an emergency situation, I will seek other medical attention as soon as possible.

Patient Name: _____

Address: _____

Date: _____ Phone: _____

Signature(Patient or Parent/Guardian*): _____

*If patient is under 18 years old, a parent or guardian signature required.

Name of Parent/Guardian: _____

Relationship to Minor: _____