METRO EYES
Doctors of Optometry and Ophthalmology

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Orthokeratology Fitting and Care Agreement & Informed Consent Contract

It is very important that you read this document very carefully. Please initial where indicated. Do not sign this form unless you have read and understand each section.

This document is supplemented by an Orthokeratology (Ortho-K) pre-treatment evaluation, about Ortho-K and care of Ortho-k shaping lenses, which I have read and understood. All questions that I have were answered by Dr._____. This program involves the patient wearing specially designed gas permeable reshaping lenses overnight (while sleeping) that reshape the cornea(s) in order to provide enhanced vision. I understand that the Ortho-K effect is temporary and reversible and that it may be necessary to wear my shaping lenses longer to maintain satisfactory distance vision, especially if I fail to wear the Ortho-K shaping lenses as advised. I further understand that the quality of the unaided vision that I achieve is dependent on the wearing of the shaping lenses as prescribed by the doctor and on that the overall quality of my visual acuity will be based on the degree to which my ocular astigmatism is present in my eye(s). I also understand that changing in my astigmatism is not always predictable. If I do not find the results acceptable, the process will be reversed by discontinuing the wearing of the Ortho-K shaping lenses or by replacing the shaping lens/lenses with the wearing of rigid gas permeable or soft contact lenses for approximately three weeks.

1. Introduction: It is our intent to fully inform you of the side effects, limitations and complications of Ortho-K treatment. 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 entire consultation and training process is designed to educate you regarding any potential risks. Very few patients will ever encounter any serious problems. Ortho-K is an elective procedure and is an alternative to: eyeglasses, conventional contact lenses for children/ adults or refractive surgery for adults only. **I have read the above and elect to proceed with Ortho-K treatment.**_____(initials)

2. Approval. Ortho-K is a safe and effective procedure and is an FDA approved polymer material. For some patients, an alternative off-label design may be required due to customization limitations._____(initials)

3. Contraindications: The following conditions present a reason not to undergo Ortho-K treatment. By initialing, you certify that the patient does not currently have any of the following: keratoconus, previous ocular herpes, extreme dry eye, corneal dystrophy and pregnancy.
I do not have any of the conditions listed above._____(initials)

4. Limitations: *Out of range prescriptions:* Prescriptions exceeding the normal range of Ortho-K may take longer to mold and therefore longer to achieve ideal vision. It is possible that full correction may not be achievable at all.

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

Insufficient treatment time. Some patients cannot sleep for the 7 hours per night required for treatment. This may limit our ability to mold the cornea. In these cases Full treatment may not be able to be achieved.

Permanent vision correction. Ortho-K will not provide permanently corrected vision. Your prescription will revert to its original shape if your treatment is terminated for any reason.

I understand the limitations listed in part 4 (above)._____(initials)

5. Risks and Complications:

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

Initial blurriness:

During the first week of treatment molding may be incomplete blurred vision may be experienced. We will provide you with a series of disposable soft lenses to be used until the patient feels their vision is comfortable.

Over or under correction:

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

Halos:

Some patients experience halos or glare around lights at night. This usually becomes less noticeable within a few weeks. If it does not subside, these haloes may not completely disappear.

Infection:

The risk of infection while wearing Ortho-K molds is very rare. However, there is a slight risk of 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 molds. **Under no circumstances should the retainers be rinsed with tap water and the sterilization regimen should not be modified without**

consulting the office. Serious infection can result in scarring, a permanent reduction of vision and even complete loss of vision.

Abrasions. At some point the patient 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; you slept with your eyes slightly parted; etc. They 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, retainers may need to be discontinued while the problem is being solved.

Regression.

Ortho-K mold retainers attempt to slow or stop the progression of myopia (nearsightedness). Nevertheless, regression of treatment may occur at some point. This may require a redesigning of the retainers to again achieve optimal vision.

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

I understand the potential risks and complications of the Ortho-K treatment process. _____(initials)

6. Metro Eyes Optometrists Office Obligations.

a. 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.
b. We will choose the highest quality, most appropriate lens for your particular treatment need.
c. We will carefully educate you in the wearing, caring and sterilization of your mold retainers.
d. Our doctors will be available during working hours including some holidays to handle emergency care or phone consultation.
e. In the event of an emergency and our doctors are not available I will seek medical attention in a timely manner.
f. Your fee will cover all corneal mapping, lens design, one pair of mold retainers, follow up care as well as contact lens related emergency care for 12 months from the date of this consent form was signed.

I understand the obligations of Metro Eyes Optometrists._____(initials)

7. Patient Obligations.

a. I agree to never use tap water to rinse my retainers.
b. I agree to handle, clean and sterilize my retainers in the manner instructed and never deviate from those instructions unless I consult with the office.
c. 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.
d. 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 appointments may be charged.
e. If I am a current contact lens wearer, I agree to discontinue wearing my current contact lenses for the time prescribed.
f. I understand that once the shaping lenses have been dispensed to me that I am required to wear the lenses that same night and as part of the initial "Global Fitting" process I am obligated to return for a follow-up visit with 24-48 hours for evaluation. Failure to return within this time-frame may result in an office visit charge. Unless otherwise instructed by the Doctor.
g. Replacement of Lost or Damaged shaping lenses are not included in the global fitting process. If I lose or damage a lens during the fitting process (initial 12 months) I will be responsible for replacement at the rate of **$475.00 per lens.**
h. After my initial treatment phase (12 months), I agree to return every six months so the health of my corneas can be examined, my retainers can be deep cleaned and I can be updated on any new advances in the care of my retainers.

I understand my obligations._____(initials)

8. Initial Consultation Fee:

Initial Consultation **($250.00 payable at time of consultation)**. Includes your comprehensive evaluation of refractive state, corneal topography, and determination of diagnostic Ortho-K shaping lens parameters.

9. Treatment Program: Includes one pair of customized shaping lenses and a TOTAL of 4 follow-up evaluation visits for the first year.

The cost ranges from $2800-$3000 and is based on customized shaping lens parameters and fit complexity. Payment is required at time of service.

Where a prescription range is -5.00 or Higher and/or requires a dual axis fit, additional fees (up to **$600**) will be charged.

10. Lens Remakes / Lens Changes During 90-Day initial Fitting: Although we do our best to achieve first fit success, occasionally the initial custom lens may need to be modified and an additional lens will be designed. There are No Charges for Lens modifications made during the

initial 90-Day fitting & warranty period. After 90-Days the warranty period expires and a **$370.00-$450.00 fee per lens will apply** for any lens changes, remakes or reorders.
I understand and agree to the Lens Remake / Change Fees_____(initials)

11. **Backup or Replacement Lenses:** It is recommended that a backup pair of lenses be purchased to avoid issues related to non-wear in the event lenses are lost or damaged. If purchased with initial order the fee per lens will be reduced **from $475.00** per lens to **$275.00-$350.00.**

12. Global Fitting Period & Required Visits:
(24-48 hours after lens dispense, 1-week, 1- month, 6 month). The global fitting period of 1 year includes a total of 4 office evaluation visits. If additional visits are required based on the patient's request, an **Office Visit Fee of $75.00 per visit will be charged.**
I understand and agree to the Required Visits and Additional Visit Fees._____(initials)

13. After first Year: Annual exams are recommended to re-check the status of the eyes and monitor the health of the internal/external eyes. Your vision or medical insurance may be applied to the annual exam. Fees associated with Deductibles and/or Coinsurance may apply.
The annual refitting fee for Ortho-K varies between **$1400-$1600** and includes new customized lenses, and 4 follow-ups for the year.
I understand and agree to Annual Refitting Fees._____(initials)

14. Discontinuing Mold Therapy & Refund Policy: It is a rare occurrence in health care that any procedure succeeds in every case. Should either you (the patient) or our doctor(s) decide to discontinue treatment within the **first 90 days** of this agreement, you will receive a refund the lenses minus a restocking/shipping fee of **($575.00**) contingent upon a 72-hour return of the undamaged Shaping Lenses to our office. Failure to return the Lenses in the time prescribed will result in a diminished refund of **$300 per** lens. **I understand the Refund Policy._____(initials)**

10. Voluntary Consent
I have read all of the above information regarding Ortho-K shaping lenses. 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. Although it is impossible for my eye care practitioner to inform me of every possible complication, Metro Eyes doctors and staff have answered all my questions to my satisfaction and have assured me that they will advise me of new risks if they develop and will answer any further inquiries I may have

about this treatment or wearing this type of lens. Should any complications occur, I agree to contact Metro Eyes Optometrists immediately at: **(703)-255-1502** or seek medical attention immediately.

Patient Name:_____
Patient Date of Birth: _____

Signature: _____
Date:_____

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

Signature (Parent/Guardian):_____

Relationship to minor:_____ Date:_____