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Optometrist

Informed Consent Night Wear Orthokeratology

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

Patient Name: _____

Date: _____

Treatment: (circle) Right Eye Left Eye Both Eyes Monovision: Yes No

Patient Initials: _____

Pretreatment Refraction: Right Eye _____

Left Eye _____

Patient Name: _____

Introduction: It is my hope to fully inform you concerning the side effects, limitations and complications of night wear orthokeratology (ortho-K) treatment. It is important to understand that it is impossible to perform any form of treatment without the patient accepting a certain degree of responsibility and risk. This consent form in combination with the entire consultation process is designed to enhance your understanding the potential for difficulties that may be encountered during the procedure. It is not our intention to dissuade someone from pursuing ortho-K, as most of our patients will never encounter any significant complications, and the vast majority are very pleased with the improvement they achieve. We would prefer to accurately outline the associated limitations to all candidates so that they may either elect not to accept the limitations or be better prepared to deal with any unexpected side effect which may arise. Ortho-K is an elective procedure and you may decide not to undergo treatment at all. The only way to avoid all limitations is by not proceeding with ortho-K. Among alternatives are: eyeglasses; day-wear contact lenses; extended wear contact lenses; Laser in Situ Keratomileusis (LASIK), Photorefractive keratectomy (PRK), Intra-stromal corneal rings (INTACS), clear lens extraction, implantable lenses (ICL), automated lamellar keratoplasty (ALK) and radial keratotomy (RK).

Patient Initials: _____

Federal Drug Administration (FDA) approval

The FDA has determined that Ortho-K is a safe and effective procedure. To date they have approved several different company's lens designs. The ultimate decision maker as to whether a design is appropriate for a specific patient is your doctor, not the FDA. All of our designs are customized for specific patient eyes, designing lenses with fitting characteristics measured in microns. While technically this means our designs may not be FDA approved, it is a legal, off-label use of the materials. We feel this customization, in the hands of a skilled orthokeratologist, is often your best option for clear, comfortable vision. Your initials here indicate you agree that your lenses may not be "FDA approved." If you wish to only be fit with "FDA approved" designs that are not as customized, you agree to notify the doctor of your wishes and should NOT initial here.

Patient Initials: _____

Indications: Ortho-K treatment is intended for use:

- In patients who have an optical prescription less than -4.00 diopters of nearsightedness and less than 1.00 diopters of astigmatism. Although more severe forms of nearsightedness and astigmatism can be treated, it is less likely that such cases will achieve ideal results.
- In patients who are at least 8 years of age.
- In patients who have been clearly informed of all alternatives.
- In patients who want a fully reversible procedure. Ortho-K is reversible.

Contraindications (FOR ALL PATIENTS): By initialing below, you are certifying that you (or your guardian) are at least 18 years of age. You also confirm that you understand that the following conditions may present a reason not to undergo Ortho-K treatment, so you agree to disclose these medical conditions to your eye doctor:

- Keratoconus (patients with this condition may have unstable corneas)
- Herpes Simplex or Herpes Zoster virus (with previous ocular episodes)
- Unstable or uncontrolled diabetes

Patient Initials: _____

If applicable (FEMALE PATIENTS ONLY): You should understand that pregnancy could adversely affect treatment results. By initialing below, you are confirming that you are not pregnant, nursing, or plan to become pregnant in the next three months. If it is possible that you are pregnant, you agree to take a pregnancy test before undergoing the Ortho-K procedure. If you do become pregnant in the 3 months following treatment, you agree to notify the clinic immediately. The treatment has no known effect on a pregnancy but the pregnancy may affect the treatment.

Patient Initials: _____

Evaluation: The evaluation and fitting process is intended to assess a patient's suitability for Ortho-K based on a patient's optical prescription, corneal curvature and other factors, but not to identify or treat ocular disease. Ocular disease may be present prior to Ortho-K or may develop after Ortho-K. Ortho-K does not treat ocular disease. You should have a comprehensive eye health and vision examination prior to your Ortho-K treatment and at least once a year to identify and treat ocular disease.

Patient Initials: _____

Contact Lens Wearers: Patients who wear gas permeable or hard contact lenses must completely stop wearing such lenses at least (1) one month prior to the Ortho-K procedure (this may be longer for some patients.) Patients who wear soft contact lenses must completely stop wearing their soft contact lenses (1) one week prior to the Ortho-K procedure and possibly longer.

Patient Initials: _____

Confidentiality: By initialing below, you give permission for the medical data concerning your treatment and subsequent treatment to be submitted to Janice L. Glaser, O.D., to the manufacturer of the contact lenses and to regulatory authorities or otherwise used for record keeping, statistical analysis, marketing and/or quality control. Patient identity will be strictly confidential in any dissemination of such data.

Patient Initials: _____

Governing Law/Jurisdiction: By initialing below, you agree that the relationship between yourself and the doctor shall be governed by and constructed in accordance with the laws of the state of California. You also acknowledge that the procedure was performed in the state of California and the courts of California shall have jurisdiction to entertain any complaint, demand, claim or cause of action, whether based on alleged breach of contract or alleged negligence arising out of treatment. You hereby agree that you will commence any such legal proceeding in the state of California and you submit to the jurisdiction of the courts of California.

Patient Initials: _____

Risks and Complications: The majority of reactions/limitations after Ortho-K are temporary in nature and will resolve within three months after the procedure or with discontinued use of the contact lens molds. However, it is possible that some of these limitations could be longer-term or permanent with continued use of the contact lens molds.

- Lens awareness may be experienced during the waking hours that the molds are being worn. This is normal and typically resolves in two to six weeks. The lenses are specifically designed for closed lid wear so that some lens awareness may always be present while wearing the lenses when awake.

Patient Initials: _____

- Blurriness is normal during the first week of treatment as the cornea molding changes occur. There is considerable improvement in vision during this time and it generally requires 2-7 days until vision is clear enough to drive.

Patient Initials: _____

- Over-Correction/Under-Correction. While mild over-correction is optimal, there is a chance that initial Ortho-K treatment may result in over-correction or under-correction that is significant enough to cause symptoms. If this occurs, you may be eligible for an additional Ortho-K enhancement lens designed to alleviate this. If the doctor feels that further enhancements will not improve the results, eyeglasses may be prescribed for part-time wear. While an enhancement procedure does not guarantee improvement, it very often does significantly improve vision.

Patient Initials: _____

- Presbyopia/Monovision. Presbyopia, the normal aging change of the near focusing structures of the eye, naturally causes people to need reading glasses in their 40s. If you do not need bifocals or reading glasses now, you will most likely need them as you age, whether or not you have Ortho-K. Ortho-K does not stop the natural aging process. It is possible that in some patients a full correction of distance vision with Ortho-K may mean that reading glasses are needed at an earlier time than if the patient did not have Ortho-K treatment. One possible option is monovision. In monovision the aim is to have the non-dominant eye under-corrected (i.e.. not fully corrected for distance vision) in order to help reading vision. This involves giving up a little distance sharpness. Night driving glasses are more common with patients who have monovision and reading glasses may still be required for fine print or prolonged reading BUT overall dependence upon glasses is still dramatically reduced. Monovision helps with simple near tasks such as opening mail, reading price tags, or looking at one's wristwatch. Patients who desire best distance or night vision unaided, such as golfers, should avoid monovision. In our experience, people over 45 should consider monovision.

Monovision: YES NO SLIGHT **Patient Initials:** _____

- Infection. The risk of infection while wearing the Ortho-K mold is very rare. There may be an increased (over regular contact lenses) risk of infection by a small organism called acanthamoeba.

However, proper contact lens disinfection procedures and proper contact lens solutions systems should nearly eliminate this risk. Serious corneal infections may result in scarring, a permanent reduction of vision, and even complete loss of vision.

Patient Initials: _____

- Epithelial abrasions. You may experience at some point in time a superficial abrasion to the outer layer of the cornea called the epithelium. This can occur if debris gets between the lens and the eye or if the lens surface needs to be modified. Epithelial abrasions are a rare and temporary complication that will typically resolve in 3-24 hours. If you experience sudden eye discomfort, redness and light-sensitivity, remove the contact lens mold and contact your eye doctor.

Patient Initials: _____

- Regression/Other changes to the eye. Although expert orthokeratologists mostly agree that Ortho-K molds appear to retard or slow progression of nearsightedness, regression of results may occur. As a result you may experience some regression of vision results you initially obtained with Ortho-K treatment. This will certainly occur, to some degree, if you discontinue the use of your night-wear molds on a maintenance basis. Again, Ortho-K does not stop the natural aging process. In addition, Ortho-K will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts or retinal degeneration or detachment.

Patient Initials: _____

- Post-Treatment Precautions: As with refractive surgical procedures, you may experience starburst-like images or halos around lights after Ortho-K treatment, your depth perception may be slightly altered, and image sizes may appear slightly different. Some of these conditions may affect your ability to drive and judge distances. Driving should be done only when you are certain that your vision is adequate. Ask your doctor when it is appropriate for you to drive.

Patient Initials: _____

- Other Complications: it is important to note that it is impossible to list every conceivable complication that could occur with Ortho-K and that there could be a complication not listed above. Risks and complications that are considered to be unforeseeable or a long-term effect not yet known or anticipated at the present time are not discussed.

Patient Initials: _____

