

INFORMED CONSENT

MONOVISION LASER VISION CORRECTION

INTRODUCTION

This document is provided to obtain your informed consent for laser vision correction. It contains important information detailing the risks and benefits as well as alternative treatments available. Laser vision correction is an elective procedure and you are choosing it because you want to, not because you must.

It is important that you thoroughly read and understand everything, and only sign once you have read, understood, and have had all questions answered to your satisfaction enabling you to make an informed decision.

INSTRUCTIONS

- Your vision correction coordinator will review this document with you.
- Take as much time as needed to read, understand, and have all questions answered prior to signing.
- This document must be completed prior to any treatment.
- You may request a copy of this document at any time.

Name	MRN	Date

Email Address	Witness

Procedure	Near Eye	Trial Lenses	Trial Contacts
Monovision			

ID: AG01 REV:20180713

MONOVISION / MENUVISION (MV) PROCEDURE CONSENT

INDICATIONS AND PROCEDURE

Vision-correcting surgery such as LASIK, LASEK, and SMILE can precisely and accurately correct fixed focal errors of the eye such as nearsightedness, farsightedness, and astigmatism. These optical conditions are fundamentally different than presbyopia, the loss of adjustability of focus for near viewing. Presbyopia is the reason that reading glasses (magnifiers) become necessary, typically in the 40's, even for people who have excellent distance vision. For those that require prescriptive correction to see clearly at distance, bifocals or separate (different prescription) reading glasses become necessary to see clearly at close range.

For some individuals, wearing a contact lens in one eye for distance vision, and a contact in the other eye for reading, affords a reasonable solution. This is called monovision (mono for one; one eye for distance, one eye for near vision). "Menuvision", or modified monovision, is a similar, but much milder application of the same principle which preserves depth perception and reduces the disparity between eyes. This is collectively referred to as monovision (MV).

If a person enjoys and functions well with monovision in contact lenses, the same option can be created on a more permanent basis with vision-correcting surgery such as LASIK, LASEK or SMILE. If you are contemplating such correction for yourself, it is important to understand the advantages and drawbacks of such care.

AT THIS TIME THERE IS NO PERFECT TREATMENT OR CURE FOR PRESBYOPIA, IT IS A COMPROMISE

The typical solutions described above are all some extent a compromise of one form or another. For many people, wearing eyeglasses for distance is troublesome enough, and wearing bifocals is even less pleasant. Many people dislike bifocals with a distinct line visible in the lenses, and are willing to sacrifice some degree of sharpness and clarity to eliminate the line (progressive lenses, for example). With increasing use of computers in our home and work, additional problems arise because we view computer monitors at a different distance and a different angle (from the horizontal) than typical written material.

ALTERNATIVES

There are several options available to those who are presbyopic, besides monovision including: wearing bifocals or separate distance and reading glasses or contact lenses. For example, contact lenses can be worn for distance correction in both eyes, and reading glasses can be put on to read. Similarly, during refractive surgery both eyes can be fully corrected for distance, and reading glasses be put on to read.

RISKS AND COMPLICATIONS:

REDUCED DEPTH PERCEPTION

For most people, depth perception is best when viewing with both eyes optimally corrected and balanced for distance. Eye care professionals refer to this as binocular vision. Monovision can reduce depth perception to some extent, because the eyes are not focused together at the same distance. Because monovision can reduce optimum depth perception, it is recommended that this option be tried with trial lenses or contact lenses (which are removable) prior to contemplating a surgical correction (which is permanent).

OCULAR DOMINANCE, AND CHOOSING THE DISTANCE EYE CORRECTLY

Ocular dominance is similar to right- or left-handedness. Typically, eye care professionals believe that for most individuals, one eye is the dominant eye for viewing. Several tests can be performed to determine which eye, right or left, is dominant in a person. Conventional wisdom holds that if contemplating monovision, the dominant eye should be corrected for distance, and the non-dominant eye corrected for near. While this is a good guideline, it should not be construed as an absolute rule. A very small percentage of persons may be co-dominant, and in rare circumstances a person may actually prefer using the dominant eye for near viewing. The methods for testing and determining ocular dominance are not always 100% accurate; and there is some subjective component in the measurement process. Be sure you understand this and have discussed with your surgeon which eye should be corrected for distance, and which for near. If you have any doubts or uncertainty whatsoever, surgery should be delayed until a very solid comfort level is attained. Under no circumstances should you consider undertaking monovision surgical correction before you are convinced it will be right for you. Once surgery is performed, it is not always possible to undo what is done, or to reverse the distance and near eye.

OFF LABEL TREATMENT

The Food and Drug Administration (FDA) approves medical devices for specific treatment profiles (Indications), and laser vision correction has not been indicated by the FDA for monovision or menuvision treatments. FDA approval for the excimer lasers were based upon specific treatment constraints and monovision treatments were not included as part of the FDA study or approval. I understand that this is considered an off-label procedure and there may be both short term and long term risks either now, or in the future, not studied by the FDA that may be related or unrelated to an off-label treatment.

VISUAL CONSTRAINTS AFTER TREATMENT

Monovision is a compromise. You will need glasses at times for distance vision since both eyes are not fully corrected for distance. Some examples of this may include driving while it is dark and raining, or watching a movie from the back row. Conversely since both eyes are not fully corrected for near vision there will be times where you will need reading glasses. Some examples of this would be reading an entire newspaper, or reading a contract with small print, especially in dim lighting or small print. For most patients these strenuous visual activities make up a small percentage of their waking time and do not require any corrective glasses for the majority of their day. In selecting a monovision treatment you should fully understand this compromise and be satisfied with the risks and benefits.

REVERSAL

A small percentage of patients are not satisfied with monovision. Most monovision treatments may be reversed. This is accomplished by treating the monovision eye fully for distance. Once reversed both eyes will be corrected for distance and you will require reading glasses, just as you would had you not undergone monovision treatment. Monovision may only be reversed after the initial treatment has stabilized and you have allowed a period of time to adjust to monovision correction. This time period will be determined by your surgeon, however is typically six months. Reversal of monovision carries all of the risks of the original procedure and reversals are not covered under treatment fee and additional costs may apply. Since a reversal of monovision requires correcting both eyes fully for distance once reversed it will be permanent and you will need reading glasses to correct your near vision.

SELECTION OF NEAR EYE POWER

I understand the importance of selecting the correct power and near eye. I have been encouraged to take as much time as needed and try as many different powers of correction until I am satisfied with monovision. I have been given the opportunity to try monovision for an extended period of time through the use of contact lenses or temporary corrective lenses.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

I have read and understand the above risks and benefits of monovision, and I understand that this informed consent does not include every possible risk, benefit and complication that can result from monovision.

I understand that monovision is off-label treatment and the long-term risks either now, or in the future, have not been studied by the FDA.

I understand that monovision is a compromise and that I may need glasses for distance or near vision.

I understand the importance of selecting the dominant eye and the near eye power and have been given the opportunity to try these choices through the use of trial lenses or removable contact lenses.

I have read and understood the information presented above about the risks, benefits, and alternatives to monovision treatment. I understand that there are no guarantees as to the success of the procedure. I have had the opportunity to ask questions and have them answered to my satisfaction.

OFF-LABEL LASER VISION CORRECTION ADDENDUM

PROCEDURE OR LASER PARAMETERS OUTSIDE OF FDA APPROVED INDICATIONS

When a drug or device is approved for medical use by the Food and Drug Administration (FDA), the manufacturer produces a label to explain its use. Once it is approved by the FDA, physicians may use it off-label for other purposes if they are well-informed about the product, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effects.

I understand that there may be both short term and long-term risks either now, or in the future, not studied by the FDA that may be related or unrelated to an off-label treatment.

The following sections describe off-label usage that may apply to your treatment and consent is required for treatment.

MONOVISION PROCEDURE

I understand that monovision and menuvision is an off-label procedure. Nevertheless, I wish to have laser vision correction with monovision or menuvision performed on my eye(s).

INFORMED CONSENT

By signing the below, I certify the following to the best of my knowledge:

All 5 pages of this document have been given to me in its entirety.

All of my questions regarding monovision have been answered to my satisfaction allowing me to give my informed consent.

I understand that during the course of the proposed procedure(s) unforeseen conditions may be revealed requiring the performance of additional procedures, and I authorize such procedures to be performed at my physician's discretion.

I understand my treatment is off-label, as outlined in *Off-Label Laser Vision Correction Addendum* (page 4), I have read, understand, and hereby consent to *Off-Label Laser Vision Correction Addendum* (page 4).

I understand that no warranty or guarantee has been made to me regarding the result, cure or safety.

I understand that all or part of my procedure may not be covered by my insurer and accept responsibility for all out-of-pocket expenses.

I give my permission for Laser Eye Institute to videotape or photograph my procedure, for purposes of documentation, education, research or training of other health care professionals. I also give my permission for Laser Eye Institute its employees and agents to use data about my procedure and subsequent treatment to further understand refractive vision correction. I understand that my name will remain confidential, unless I give subsequent written permission for my identity to be disclosed outside of Laser Eye Institute.

MY SIGNATURE BELOW CERTIFIES THAT I AM NOT UNDER THE INFLUENCE OF ANY NARCOTIC, ALCOHOL OR ANY OTHER DRUG, OR SUBSTANCE THAT MAY IMPAIR MY JUDGEMENT, OR MY ABILITY TO UNDERSTAND THIS CONSENT. I FURTHER CERTIFY THAT I WAS ABLE TO READ AND UNDERSTAND THIS INFORMED CONSENT AND ANY QUESTIONS I HAD REGARDING THE ABOVE PROCEDURE(S), RISKS, BENEFITS, AND ALTERNATE PROCEDURES HAVE BEEN EXPLAINED TO MY SATISFACTION ALLOWING ME TO GIVE MY INFORMED CONSENT FOR THE ABOVE PROCEDURE(S).

Name	MRN	Date

Monovision Consent: I consent to having a Monovision treatment.

Patient Signature	Monovision Near Eye (Write in RIGHT or LEFT)

Patient Declines Monovision Contact Lens Trial

Patient Signature