Clear Advantage Vision Correction Center

Informed Consent for the use of Mitomycin-C / Keratectomy

Background:

The correction of high degrees of nearsightedness (or myopia) using the excimer laser is associated with a higher chance of corneal scarring or "haze". This corneal haze may occur years after the original procedure, and can result in decreased vision.

In 1997, a practice pioneered the use of a medication called mitomycin-C (MMC) to treat patients who developed this visually debilitating condition. Since that time, we have also begun using MMC prophylactically (as a preventative measure) to decrease the possibility that corneal haze will develop after Photorefractive Keratectomy (PRK) and Laser-Assisted Subepithelial Keratomileusis (LASEK). These procedures have been associated with corneal haze in certain individuals. It is anticipated that, with the use of MMC, the likelihood of developing haze will be minimized.

Mitomycin-C

MMC is an antibiotic that has been used in the medical field for a number of decades. It has been used as an anti-cancer drug because it can stop the proliferation or growth of certain types of cells such as those seen in tumors, and also those cells in the eye which produce scarring or haze. MMC has been used in the eye since the 1980s to prevent scarring after many types of surgical procedures, such as glaucoma filtration and pterygium surgeries. The use of MMC for treatment and prevention of corneal haze is a relatively new potential indication for this medication.

MMC is very potent and potentially toxic under certain circumstances. Some of the eye-related complications that have been reported following the use of MMC (for other conditions) include, but are not limited to: conjunctival injection (redness of the eye), permanent stem cell deficiency, corneal or scleral thinning or perforation requiring corneal transplantation, corneal decompensation, cataract, and retinal vascular occlusion.

The complications listed above were seen following various types of eye surgeries, but no complications have been reported following our technique, as we have described, for corneal haze removal and prevention. Our technique uses a low dose (0.02%) of MMC delivered to the central cornea for less than 1 minute. This technique minimizes the chance of complications (compared to the types of surgeries in which MMC has been associated with such complications).

Additionally, a number of internationally renowned eye surgeons from around the world have embraced this technique and reported good results at national meetings. All

patients with haze have seen improvements in visual acuity and a decrease in corneal haze. Those patients that received preventative MMC treatment have not experienced corneal haze over an average follow up of 1 year. However, there is no guarantee that you will obtain a similar result. The possibility does exist, that over longer periods of time, corneal haze and/or unforeseen toxicity may develop in the future.

Consent:

My surgeon has indicated to me that either I have corneal haze, or that I may be more likely to develop corneal haze following PRK or LASEK. I have read and understood the above, and understand the benefits, risks, and alternatives to using MMC as described to me. I have had the opportunity to ask questions, and understand that the use of MMC is considered experimental and an "off-label" use of an FDA-approved medication. I understand that there are no guarantees as to the success of the procedure in removing or preventing haze and that toxic side effects may develop.

I give my informed consent to my surgeon (indicated below), and/or his assistants to use MMC on my Right Left Both eye(s) (circle one) as described above.

Patient's Name (printed)	Signature	Date

Witness' Name (printed)	Signature	Date

N. Timothy Peters, M.D.

Surgeon's Name (printed)	Signature	Date