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ADDENDUM
MITOMYCIN-C (MMC) WITH REFRACTIVE SURGERY

INDICATIONS AND ALTERNATIVES
The correction of high degrees of nearsightedness (or myopia) using the excimer laser is associated with a higher chance of developing corneal scarring or "haze." This corneal haze may develop years after the original procedure and can result in decreased vision. Refractive surgeries such as Photorefractive Keratectomy (PRK), Laser-Assisted Subepithelial Keratomileusis (LASEK), and Advanced Surface Ablation (ASA) have been associated with corneal haze in some individuals.

Since 1997, a medication called Mitomycin-C (MMC) has been used to treat patients who develop corneal haze. Several studies have shown that the use of MMC decreases the likelihood of developing haze after PRK, LASEK, and ASA. For this reason, ophthalmologists are also using MMC prophylactically, as a preventive measure.

MMC is an antitumor antibiotic that has been used in the medical field for a number of decades. It is 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. It also stops cells in the eye which produce scarring or haze. MMC has been used in the eye since the 1980's to prevent scarring after many types of surgical procedures, such as glaucoma filtration and pterygium surgery. The use of MMC for the treatment and prevention of corneal haze is a newer use of this medication.

COMPLICATIONS
MMC is very potent and, under certain circumstances, potentially toxic. Eye-related and vision-threatening complications that have been reported when using MMC for other conditions include, but are not limited to: secondary glaucoma, corneal edema, corneal or scleral thinning or perforation requiring corneal transplants, permanent stem cell deficiency, sudden onset mature cataract, corneal decompensation, corectopia (displacement of the pupil from its normal position), iritis, scleral calcification, scleral melt, retinal vascular occlusion, conjunctival irritation (redness of the eye), and incapacitating photophobia and pain.

Although the complications listed above have been seen in various types of eye surgeries, **no significant complications have been reported using the low-dose technique described below for corneal haze removal and prevention in refractive surgery.** This techniques uses a low dose (0.02%) of MMC delivered by placing a small, circular shaped sponge on the central cornea for one to two minutes. This technique minimizes, but may not eliminate, the chance of developing MMC-related complications.

Patients who received preventive MMC treatments have shown improvement in visual acuity and a decrease in corneal haze. No corneal haze developed during an average follow-up period of one

year. However, there is no guarantee that you will obtain a similar result. Over long periods of time, corneal haze or unforeseen toxicity may develop, which may require additional treatment.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

My surgeon has indicated to me that I either have corneal haze, or that I may be more likely to develop corneal haze following PRK, LASEK, or ASA. I have read and understood the information presented above about the risks, benefits, and alternatives to using MMC for both treatment and prevention of corneal haze. I have had the opportunity to ask questions and have them answered to my satisfaction.

I understand that administering MMC for treatment and prevention of corneal haze is considered an "off-label" use of an FDA-approved medication. 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 a medication 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 are no guarantees as to the success of the procedure for removing or preventing haze and that toxic side effects may develop.

I give my informed consent to my surgeon (indicated below) and/or his or her assistants to use MMC on my _____ eye (patient should write in right, left, or both).

_____	_____	_____
Patient's name (printed)	Patient's signature	Date
_____	_____	_____
Witness name (printed)	Witness's signature	Date

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