

# TEN COMMON SENSE REASONS WHY YOU SHOULD NOT HAVE LASIK

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After years of dealing with the hassle of spectacles and contact lenses, you've decided to reward yourself by having Lasik. You've read the glowing reports in the media about the wonders of this "state of the art" procedure and your ophthalmologist has just pronounced you "a perfect candidate."

It is at this time, more than at any other time in your life, that you must pause, stand back from the excitement of the moment, and reflect deeply on what you are about to do. Lasik will permanently alter the optics and physiology of your eyes. Most likely things will go well. But there is a significant chance, much greater than many ophthalmologists realize or will publicly admit, that your eyes will be irreversibly damaged. The results could be devastating.

One needs to take a practical approach prior to having any elective surgery and ask if the benefits truly outweigh the risks involved. You've heard a lot about the benefits, no doubt from the surgeon who stands to benefit financially by operating on your eyes. But you owe it to yourself to take a few minutes to read the rest of this document in order to become better informed about the risks of Lasik. Once you understand these risks, you may conclude that the prudent course of action is to avoid the Lasik fad until the procedure has fully matured, withstood the test of time, and been proven safe. After all, we're talking about your eyes.

## 1. The True Degree of Risk is Unknown, and Where Known is Being Downplayed.

Before surgery, patients are typically told that the risk of long-term complications from Lasik is 1%, and even lower in the hands of an experienced surgeon (such as the one trying to sell you the procedure). For starters, one must realize that the risk being referred to is for *each* eye, so the combined risk that permanent damage will occur to at least one eye is, by these figures, actually 2%. Doesn't sound so good anymore? Read on...

At the 1997 Association for Research in Vision and Ophthalmology meeting in Fort Lauderdale, Florida, researchers reported that up to 21% of patients who undergo laser correction complain of night-vision problems stemming

from reduced contrast sensitivity, glare, and halos.<sup>1</sup> According to another study, at one year postoperatively 12% of Lasik patients complained of visual disturbances at night. The figure for PRK patients was, by comparison, "only" 6%.<sup>2</sup> A more recent study presented in the *Review of Optometry*<sup>3</sup> summarized surgical (as opposed to optical) complication rates following Lasik as follows:

Interoperative Flap Complications	- 2.7%
Postoperative Flap Complications	- 4%
Epithelial Ingrowth (Farah)	- 14.7%
Epithelial Ingrowth (Wilson)	- 4.3%
Epithelial Defects	- 5%
Interface Debris	- 6.8%
Flap Wrinkles	- 5.9%

These complications often produce vision-distorting irregular astigmatism. Unlike regular astigmatism, which is correctable with glasses, irregular astigmatism cannot be corrected with glasses. New laser techniques are being developed to treat irregular astigmatism, but they are yielding mixed results. Some ophthalmologists believe that lasers will never be precise enough to correct irregular astigmatism.

Many top ophthalmologists remain in willful ignorance of Lasik's true risks, often preferring to avoid patients with post-Lasik complications because it is much less economical to treat such a patient than to operate on a fresh candidate. These doctors therefore never gain an accurate awareness of the extent of damage that is being done by Lasik. Their ignorance is compounded by their unfamiliarity with websites such as SurgicalEyes.com, which are dedicated to providing emotional and informational support to those suffering from post-Lasik complications.

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<sup>1</sup> See James J. Salz, M.D., *Night Vision and the Excimer Laser: How to Ensure Patient Satisfaction*, EYEWORLD, Nov. 1997 (available at [www.eyeworld.org/nov97/450062.html](http://www.eyeworld.org/nov97/450062.html)).

<sup>2</sup> *PRK, Lasik, Neck and Neck in Controlled, Matched Study*, OPTH TIMES, Feb 15, 1999.

<sup>3</sup> See Paul M. Karpecki, O.D. and Steven Linn, O.D., *What You Should Look for When Lasik Goes Astray*, REV OPTOMETRY, May 1999.

## 2. Lasik Technology Continues to Improve.

The refractive surgical community depends financially on the average individual's tendency to get swept up by fads and trends. This natural human tendency provides refractive surgeons and medical device manufacturers with large numbers of patients on whom they can continue to refine their surgical techniques and devices.

At present, for example, there is no consensus on what kind of excimer laser provides optimal results. Nidek's single beam laser follows a very different approach to ablating corneal tissue from that of Visx's broadbeam laser, yet both are touted as being "state of the art." Many surgeons cut the Lasik flap from side to side with the Chiron microkeratome, while other surgeons pronounce themselves experts in using the Hansatome microkeratome, which cuts a supposedly superior "up-down" flap.

The field of refractive surgery is still so new that many ophthalmologists develop and market their own surgical instruments to perform various procedures, such as cutting, lifting, or irrigating flaps. Perhaps their enthusiasm for Lasik stems partly from the goal of "creating rapid profits by promulgating sales of surgical equipment and adopting new surgical techniques," as one eminent refractive surgeon has speculated.<sup>4</sup>

In the field of marketing there is a type of consumer known as the "early adopter," who enjoys buying the latest products and technology. No harm done when one is dealing with a Palm Pilot or laptop computer. But does it make sense when we're talking about an irreversible surgical procedure on one's eyes? Dr. George Waring, Editor-in-Chief of the *Journal of Refractive Surgery*, answers this question best when he writes that "...we proceed with active teaching of hundreds or thousands of ophthalmologists to use a technique that we are simultaneously figuring out how to do -- including the identification of complications and statistical outcomes. Is it not safer for patients and more rational for the profession to proceed in a graduated manner, refining the techniques and improving the results on smaller numbers of patients (or in the laboratory), and saving our

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<sup>4</sup> See George O. Waring III, MD, FRCOphth, *A Cautionary Tale of Innovation in Refractive Surgery*, ARCH OPHTH, Vol. 117, No. 8, Aug. 1999 (available at <http://archophth.ama-assn.org/issues/v117n8/full/esa81001.html>).

mass education for the time when we have worked the bugs out of the technique and have acquired reasonably quantitative descriptions of safety and efficacy?"<sup>5</sup>

Other leading refractive surgeons concur that the Lasik procedure has not yet been perfected, writing: "As the technology and techniques improve, we should develop a better understanding of the importance of laser-tissue interactions, corneal wound healing, and the role of pharmacologic agents in modulating refractive outcomes. These advances should allow PRK and LASIK to become more predictable with fewer complications."<sup>6</sup>

Do you want your eyes to be the ones to help these doctors learn how to perform Lasik more safely and successfully?

## 3. Optical Aberrations Induced by Lasik are Poorly Understood by Ophthalmologists.

Refractive surgery focuses on eliminating spherical and cylindrical defocus, the most important optical aberrations to correct. However, such an approach ignores the fact that the eye has significant higher-order aberrations. According to Dr. Raymond Applegate of the Department of Ophthalmology of the University of Texas Health Science Center, these naturally occurring higher-order aberrations, combined with large increases in the eye's higher-order aberrations induced by refractive surgery, can decrease visual performance despite the elimination of spherocylindrical errors. Surgically-induced higher-order aberrations have received less attention than the correction of defocus errors despite their importance to optimal visual performance.<sup>7</sup>

Moreover, the normal cornea is relatively trouble-free whereas the post-refractive cornea frequently has a more aberrated optical performance. It is often unstable and its optical performance deteriorates at night or in patients with larger-than-average pupils. Contact lenses

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<sup>5</sup> George O. Waring, III, MD, FACS, FRCOphth, *Editorial*, J REFRACT SURG, Vol. 12, No. 3, Mar./Apr. 1996.

<sup>6</sup> Edward E. Manche, Jonathan D. Carr, Weldon W. Haw, Peter S. Hersh, *Excimer Laser Refractive Surgery*, WESTERN J MED, Jul. 1, 1998, Vol. 169, No.1.

<sup>7</sup> See Raymond A. Applegate, OD, PhD & Howard Howland, PhD, *Refractive Surgery, Optical Aberrations, and Visual Performance*, J REFRACT SURG, Vol. 13, May/June 1997.

and spectacles do not permanently alter the physiologic optics of the eye. Refractive surgery does. According to Dr. Leo Maguire of the Mayo Clinic, "When one alters irreversibly the most trouble-free component of the human visual system, one runs the risk of compounding the visual aberration caused by components of the visual system that characteristically show dysfunction with age (the lens and macula)."<sup>8</sup> Dr. Maguire worries about how many refractive patients who can compensate for their aberrated cornea will be able to do so when the lens and macula develop age-related changes? How much sooner will they require cataract surgery or visual aids for macular degeneration?<sup>9</sup>

Another reason why the eye's optics are degraded by Lasik is that excimer lasers were designed by engineers who assumed that the cornea is spherical rather than prolate. According to Dr. Jack Holladay, McNeese Professor of Ophthalmology at the University of Texas Medical School, these engineers further assumed that their job was to reshape a steep sphere into a flat sphere, rather than to reshape a steep prolate into a flatter prolate. As a result, excimer lasers reshape prolate corneas into oblate ones, a shape that is optically worse because now peripheral rays are bent more powerfully, causing more pronounced spherical aberrations when the pupil dilates. This problem affects every patient who undergoes an excimer laser procedure to some extent.<sup>10</sup>

A final optical ramification of Lasik that is poorly understood by most ophthalmologists is that following Lasik the eyes must focus and converge entirely unaided. However, after years of adaptation to the prismatic effect of glasses, many eyes will have difficulty working together. This problem can be compounded if either eye experiences even a slight decrease in vision due to a post-Lasik complication. If the eyes are unable to adapt after Lasik, the post-refractive patient will have difficulty reading and will experience constant eye strain.

Dr. Holladay concludes by writing that "We are actually reducing the optics of the eye when we perform Lasik. That's fine when the pupil is

<sup>8</sup> See Leo J. Maguire, Mayo Clinic, *Keratorefractive Surgery, Success, and the Public Health*, AM J OPHTH, Vol. 117, No. 3, March 1994.

<sup>9</sup> See *id.*

<sup>10</sup> See Jack Holladay, MD, MSEE, FACS, *What We Should Really Tell Lasik Patients*, REV OPHTH, May 1999.

small, but as it gets larger, such as in nighttime conditions, this becomes a problem."<sup>11</sup>

#### **4. Contrast Sensitivity is Inevitably Reduced Following Refractive Surgery.**

Most people will never know what contrast sensitivity is until they lose it as the result of Lasik. An example of loss of contrast sensitivity is that when someone is walking towards you in a situation where he is lit from behind, he appears merely as a dark silhouette, whereas previously you would have been easily able to identify his facial features. Alternatively, seeing a white rabbit against the snow would also become more difficult. Loss of contrast sensitivity is permanent and will to varying degrees affect everybody who undergoes Lasik.

A recent follow-up study performed for the London Centre for Refractive Surgery of patients 2 to 7 years after refractive surgery determined that 58% failed a contrast sensitivity test for night driving.<sup>12</sup> These results have been supported by an even larger study at Germany's Tubingen University, where more than 70% of patients failed a night vision test -- a requirement in Germany for receiving a driver's license.<sup>13</sup> Another study by the U.K. Transportation Research Laboratory of myopic people who had laser surgery concluded that as a result of loss of contrast sensitivity, 80% couldn't see a traffic sign at 55 meters, and 40% still couldn't see the sign at 15 meters.<sup>14</sup> The Canadian Medical Association has added laser eye surgery to a list of risk factors for unsafe driving, after finding a decrease of night vision in between 30 and 60% of laser eye patients.<sup>15</sup>

Why does this happen? One hypothesis is that some of the laser's energy goes beneath the targeted ablation to the corneal stroma and

<sup>11</sup> *Eye on Technology: New Procedure, Product Refines Lasik*, INTL SOC REFRACT SURG - EYE2EYE, Jul. 2000, p. 6.

<sup>12</sup> See Carol Hilton, *Studies Show Compromised Night Vision an Undetected Complication of Laser Eye Surgery*, THE MED POST, Jun. 6, 2000 (citing research performed by Dr. William Jory, Consultant Surgeon for the London Centre for Refractive Surgery).

<sup>13</sup> See Louise Elliott, *Canadian Medical Association Says Laser Eye Surgery Can Pose Driving Risk*, CANADIAN PRESS, Aug. 27, 2000.

<sup>14</sup> See *id.*

<sup>15</sup> See Elliott, *supra* note 12.

disturbs the fibrils.<sup>16</sup> However, there are other hypotheses and no clear answers.

Perhaps you are wondering why this side effect of Lasik has gone largely unnoticed in the United States. The reason is that, although contrast sensitivity tests are easy to administer both pre- and post-operatively, they consume more time than most ophthalmologists are willing to spend with their patients, and time is money. If refractive surgeons were to spend the time to perform all the recommended diagnostic tests, they would be spending several hours with each patient and the procedure would quickly become uneconomical for them. Therefore, refractive surgeons generally only spend about one or two hours giving their patients a “stripped-down” pre-operative evaluation. Issues such as the effect of Lasik on contrast sensitivity get lost in the rush to put more patients through the Lasik mill.<sup>17</sup>

### **5. Lasik Reduces the Cornea’s Structural Stability.**

Recent studies have indicated that people who undergo Lasik are at significantly greater risk of developing Iatrogenic Keratectasia (Ectasia) due to the thinning of the cornea. This weakens the cornea’s structural stability and can cause the cornea to bulge forward, resulting in distorted vision, return of myopia, and fluctuating vision. It can affect even patients with low degrees of myopia.<sup>18</sup>

The long-term weakening of the cornea has been well documented in other cases of corneal refractive surgery, including radial and arcuate keratotomy. Although the mechanism of weakening is different in incisional surgery, it

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<sup>16</sup> See *id.* See also, Maxine Lipner, *Inside Lasik - First on the Endothelial Cell Block*, EYEWORLD, Sep. 2000 (available in <http://www.eyeworld.org/sep00/0900p44.asp>) (noting recent studies indicating endothelial cell damage resulting from excimer laser radiation).

<sup>17</sup> For example, a recent advertisement by the Hillside PlusCare Network, directed at refractive surgeons eager to acquire more Lasik patients, was entitled “What do You Feed a Hungry Laser? Patients!”

<sup>18</sup> See S. Percy Amoils, Mark Deist, Petrus Gous, Philippa Amoils, *Iatrogenic Keratectasia after Laser In-Situ Keratomileusis for Less Than -4.0 to -7.0 Diopters of Myopia*, J CATARACT REFRACT SURG 2000, Vol. 26, No. 7, Jul. 2000, pp. 967-977.

may be even more profound in excisional surgery, such as Lasik.<sup>19</sup>

Weakening of the cornea following Lasik is poorly understood. According to one renowned refractive surgeon, “We have failed to ask some fundamental questions about the stability of refraction of the human eye.”<sup>20</sup>

### **6. Photophobia is a Frequent Side Effect of Lasik.**

Photophobia is the painful sensitivity to light that often results from Lasik. Though the exact causes of post-Lasik photophobia are unknown, some surgeons hypothesize that light scatter and glare resulting from post-Lasik corneal surface irregularities are the culprits. Others believe that low-grade inflammation secondary to the Lasik procedure is the true cause of the problem.

Whatever the cause of photophobia following Lasik, the result is that whereas one used to be able to walk down the street on a nice day without sunglasses, now sunglasses are a constant necessity. It is a grim paradox that while people undergo Lasik in order to reduce their dependency on glasses, now many will have increased dependency on sunglasses.

### **7. Myopia Will Eventually Be Your Friend.**

Have you ever wondered why most refractive surgeons do not have Lasik performed on themselves? One reason is that they recognize that with refractive surgery they will be simply be gaining distance vision at the expense of near vision.

In one’s later years, myopia reduces and can even eliminate the need for reading glasses, which compensate for the lens’s greater rigidity with age. This rigidity reduces the lens’s ability to accommodate in order to focus on near

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<sup>19</sup> See Richard E. Damiano, M.D., *Late Onset Regression After Myopic Keratomileusis -- Letter to the Editor*, J REFRACT SURG, Vol. 15, Mar./Apr. 1999. See also Theo Seiler, M.D., *Iatrogenic Keratectasia: Academic Anxiety or Serious Risk?*, J CATARACT REFRACT SURG., Vol. 25, No. 10, Oct. 1999

<sup>20</sup> See Chris Glenn, REV OPHTH, Apr. 2000 (quoting Dr. Daniel Z. Reinsteint, MD, MA, FRCSC, Professor of Ophthalmology at the University of Paris, Associate Professor at Cornell University, and National Medical Director for Lasik Vision Corp. of Vancouver, B.C.).

objects. Thus myopia is actually your friend in later years -- to read you simply remove your glasses, or at worst wear bifocals, which are lighter than normal glasses because the reading lens has a lighter prescription than the lens used for distance vision. Lenses for myopia also produce an effect called "image minification," which further reduces the need for reading glasses by making it more comfortable for the eye to see close-up objects.

Eliminate the need for glasses by having Lasik at the age of, say, 30, and within little more than a decade you will start having to deal with the inconvenience of carrying reading glasses with you at all times in order to read, use the computer, or do any other close-up work.

### **8. Steroid Drops, the Standard Treatment to Reduce Inflammation After Lasik, Hasten the Onset of Cataracts.**

Steroid medications such as Tobradex, Pred Forte, and FML<sup>21</sup> have been proven to induce cataracts, particularly posterior subcapsular cataracts, if taken for prolonged periods.<sup>22</sup> The production of cataracts varies based on individual susceptibility.

Though prolonged use of steroids is usually not necessary following Lasik, there are several complications (e.g., corneal abrasion, infection, haze) that require treatment using steroid drops, which in turn increases the risk of cataract formation.

### **9. Drier Eyes are Inevitable After Lasik.**

The process of cutting the Lasik flap and then ablating the cornea with the laser damages many of the nerves that signal to the eye the need to produce tears.<sup>23</sup> This is called "denervation." The Lasik patient will typically

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<sup>21</sup> PDR OPTH, 1999, p. 244. *See also, Fluorometholone-Induced Cataract After PRK*, OPTHALMOLOGICA 1997, pp. 394-96 (noting the case of a 24 year old woman who developed cataracts after using FML 4-7 times per day for 4 months).

<sup>22</sup> *Lens and Cataract*, § 11, BASIC AND CLINICAL SCIENCE COURSE, AM ACAD OPTH (noting that 50% of patients developed cataracts after receiving 765 drops of topical steroid over 10.5 months).

<sup>23</sup> *See At Issue: Tears Versus Plugs in Post-Lasik Patients*, OCULAR SURG NEWS, Jun. 1, 2000.

experience dry eyes for at least two months after Lasik surgery. Eye drops must constantly be applied, and the individual will often wake up in the middle of the night with severely dry, scratchy eyes that need to be lubricated again.

For some, this uncomfortable and often painful dry eye condition persists indefinitely because the nerves never completely heal. They must use expensive eye drops for the rest of their lives, and may even need to have punctum plugs inserted into their eyes' drainage ducts in order to reduce the outflow of the few precious tears they have left.<sup>24</sup>

According to one study, corneal sensitivity does not recover to the preoperative level by 6 months after Lasik, suggesting that cutting of the cornea during Lasik impairs corneal sensitivity and that the depth of the corneal ablation affects the extent of corneal sensitivity loss and recovery. One possible explanation is that in Lasik, because the corneal stroma is ablated after a corneal flap is created, damage is caused to deeper corneal tissue. There is also risk of damaging nerve fibers in forming a flap. Moreover, because there is a temporary gap between the corneal flap and the bed, the transfer of cells and other materials may be impeded. Such diffusion barriers affect the recovery of nerve cells and corneal tissues.<sup>25</sup>

### **10. The Long Term Risks of Lasik are Unknown**

By ophthalmologists' own admission, the long-term risks of Lasik are completely unknown. Peruse the medical literature of the refractive surgical community and you will quickly see how much is being learned about the long-term optical and physiological consequences of Lasik. Most of it isn't positive.

### **Conclusion**

Each of these ten points should be enough to give pause to anyone considering Lasik. Taken as a whole, they raise serious concerns about the safety of this procedure. These concerns have

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<sup>24</sup> The recent proliferation of artificial tear brands such as Theratears, Genteal, and Refresh is more than coincidental with the increase in refractive surgical procedures.

<sup>25</sup> *See Wan-Soo Kim, MD, PhD, Jeong-Sam Kim, MD, Change in Corneal Sensitivity Following Lasik*, J CATARACT REFRACT SURG, Vol. 25, Mar. 1999.

been raised by ophthalmologists themselves, but have been largely disregarded by refractive surgeons and the excimer laser industry, which seem more interested in maximizing profits from the Lasik fad rather than looking out for the long-term health of their patients.

Eyeglasses have been giving people good eyesight for nearly a thousand years. Contact lenses have been widely used for four decades, and, when cleaned and used properly, have proven themselves to be safe. Lasik has been performed for less than five years. *Does it make sense to risk your eyes on such a new procedure?*

## Common Lasik Complications

**Glare** is a phenomenon in which, after light has bounced off an object and into the eye, it is reflected again in the eye, producing an optical aberration. Consider a sheet of paper being illuminated by a lamp. To a normal eye it will be sharp and clear. For the Lasik patient with this side effect, the sheet of paper will now have a thin ring of white fuzziness around the edges, perhaps extending for an inch or two. Now take this disturbing visual effect from that single sheet of paper and expand it by the several hundred objects in a typical room, and you are looking through a thin white cloud of haze. Many ophthalmologists never inquire about their patients' post-operative glare, and if the patient should mention it, the ophthalmologist will give calming reassurances that it will eventually subside. Instead they focus their diagnostic efforts on their eye chart tests and applaud their patients on how well they can read these charts. They choose to ignore visual complications and instead measure a successful visual outcome as being able to read the eye chart at the 20/20 level, regardless of the fact that the light bouncing off the eye chart creates a blurred or ghosted image.

**Halo**s are related to glare but refer specifically to the fuzzy, cloudy light that surrounds moderately lit objects at night. A red stoplight, for example, will be surrounded by a large red haze. Even worse, the haze fluctuates in size as the pupils naturally expand and contract ever so slightly.

**Starbursting** is an optical effect surrounding brightly lit, sharper points of light. The Lasik patient with this symptom will see several extremely long lines extending in every direction from a light-emitting object -- like a July 4 firecracker. What's worse, the light will not be obscured by other objects that may be closer by. As with the glare and haloes, multiply this effect a hundred times and you get an idea of how an otherwise pleasant walk at night down a city street becomes what has been described as a "visual hell," or how the ability to drive at night becomes impaired.

**Ghosting** is a visual aberration that refers to a faint double vision that occurs when looking at objects in dim light. This effect is most pronounced when watching a movie in a cinema or on television -- every object gives a faint

"ghosted" image right beside it. The level of ghosting fluctuates with changing levels of light, which occurs constantly and is extremely distracting.

**Haze** - After the cornea has been ablated by the laser, it begins trying to heal itself. This healing produces microscopic scars that for several weeks produce cloudy vision at all light levels. This symptom generally abates over time but given the unpredictable healing response of each individual, for some the haze is permanent.

**Epithelial Ingrowth** - In some cases following Lasik, epithelial cells will begin growing at the interface between the cornea and the epithelial flap after the flap has been re-laid. If the cells do not stop growing, they will begin to cloud and distort vision. In severe cases, epithelial ingrowth can lead to flap melt in which stroma layer cells in the flap are destroyed, resulting in permanent loss of visual acuity. Epithelial ingrowths require a flap lift to enable the surgeon to clean out the excess cells, and more days of pain and weeks of haze as the re-laid flap heals.

**Corneal Abrasion** - Upon cutting the flap with the microkeratome, or lifting the flap, corneal cells can be dislodged, producing temporary blindness until healing takes place and requiring narcotic pain killers to reduce the severe eye pain that results.

**Map Dot Fingerprint Dystrophy** - The cornea can be traumatized by the initial process of having the epithelial flap cut. This can result in a disease in which an irregularity occurs on the corneal surface, essentially a bump occurring within the eye that ripples through to the epithelial layer, which becomes slightly raised. This will produce distorted vision as well as periodic epithelial "erosions" or ripping of the epithelial layer (also known as sloughing). When this occurs, it causes substantial pain over a two day period until the epithelial layer has had a chance to regenerate. Unfortunately, the epithelium can regenerate irregularly, causing further optical distortions.