May 8, 2015

Stephen Ostroff, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Citizen Petition FDA-2011-P-0022

Dear Dr. Ostroff:

This letter with 1,073 signatures (Attachment A) is to request that the Food and Drug Administration (FDA) reopen for reconsideration the above referenced citizen petition.

On January 6, 2011, former FDA chief of ophthalmic devices, Morris Waxler, Ph.D. filed a citizen petition (Exhibit 1) calling for withdrawal of FDA approval of all LASIK eye surgery devices and issuance of a Public Health Advisory with a voluntary recall of LASIK devices “in an effort to stop the epidemic of permanent eye injury caused by lasers and microkeratomes used for LASIK eye surgery.”

In the extensively documented petition, Dr. Waxler says the approval was based on data that were “dominated by LASIK surgeons working hand-in-glove with LASIK manufacturers.” Says Dr. Waxler, “Data recently brought to light exposes this partnership for what it was: a classic example of the fox guarding the henhouse, wherein the primary arbiters of safety and effectiveness of LASIK devices were the device manufacturers and its collaborators.”

Dr. Waxler asserts that LASIK manufacturers and their collaborators successfully pressured FDA to classify surgically-induced vision problems (halos, starbursts, ghosted images, and glare) and chronic dry eyes as mere “symptoms” so that manufacturers could claim that the adverse event rate is less than 1%. “The true adverse event rate six months or more post-LASIK is at least 20 times the FDA approvable rate of 1%,” he says.

Moreover, Dr. Waxler expressed concern about universal adverse effects of LASIK, including permanent biomechanical weakening of the cornea with risk of late onset corneal structural failure known as corneal ectasia, which may lead to need for corneal transplantation. Small patient populations and short-term follow-up in FDA-required clinical trials were insufficient to detect post-LASIK corneal ectasia and other delayed complications. Since the introduction of LASIK in the U.S., thousands -- likely tens of thousands -- of people, have developed post-LASIK corneal ectasia.
Coincidentally, the FDA is currently considering a new drug application (NDA 203324) submitted by Avedro, Inc. for a drug/device combination product called corneal collagen crosslinking, a proposed treatment for corneal ectasia following LASIK. Clearly there is a problem.

Although corneal ectasia is a serious, sight-impairing complication of LASIK, eye surgeons do not report ectasia cases to the manufacturer or the FDA as required by the Medical Devices Reporting regulation. They do, however, keep secret files and private databases of cases of corneal ectasia after LASIK, which the FDA has been made aware of, but turns a blind eye to.

Furthermore, Dr. Waxler cites the following adverse effects of LASIK in 100% of eyes treated:

- The corneal flap never fully heals, exposing patients to life-long risk of traumatic flap dislocation.
- Intraocular pressure measurements are falsely low after LASIK, leading to possibility of vision loss from undiagnosed glaucoma.
- LASIK causes error in calculation of lens power for cataract surgery, exposing patients to poor vision after cataract extraction.

On June 23, 2014, the FDA denied Dr. Waxler’s petition, presumably at the direction of the current FDA ophthalmic devices chief, Malvina Eydelman, M.D., an ophthalmologist with a working relationship with many of the same industry leaders identified by Dr. Waxler as having pressured the agency to approve LASIK devices under his watch.

Eydelman has a history of protecting industry interests over public health. In 2006, Eydelman dropped an important patient-protection requirement from LASIK excimer laser approval letters, which required eye surgeons to provide prospective LASIK patients with a copy of the laser patient labeling prior to undergoing LASIK. The labeling contains data from FDA-required clinical trials, which show that approximately 20 percent of patients report dry eyes, double vision, starbursts, halos and night driving problems six months after LASIK.

It is clear that under the leadership of ophthalmologist Malvina Eydelman, M.D., the FDA division that oversees LASIK devices has been ‘captured’ by industry.

The FDA has failed to take action on several other citizen petitions asking for a variety of actions against LASIK, several reports of LASIK-related suicides, numerous letters and emails from the public concerning LASIK problems, countless false and misleading LASIK ads promoting specific LASIK devices, and hundreds of LASIK-injury reports filed with the agency by LASIK patients through MedWatch.

Consistent with the high incidence of dry eyes and night vision problems cited by Dr. Waxler, double digit rates of problems were found in the recently completed (2014)
clinical arm of the FDA’s LASIK Quality of Life Collaboration Project. At the 3-month endpoint, up to forty-five percent (45%) of subjects who had no visual symptoms before LASIK reported visual symptoms (halos, starbursts, glare, and ghosting) after LASIK, and up to thirty percent (30%) of subjects with no symptoms of dry eyes before LASIK reported dry eye symptoms after LASIK.

LASIK is medical fraud, which has become a leading cause of preventable vision loss. It serves only to enrich LASIK practitioners and LASIK device manufacturers.

Eighty percent of the sensory information the brain receives comes from our eyes. Performing LASIK is playing Russian roulette with patients’ eyes. No one would be harmed if LASIK were stopped, but countless people will be spared a life-time of impaired vision, chronic dry eyes and eye pain. For these reasons, the tolerance for complications should be virtually zero.

What seems to be lost in the LASIK controversy is the simple fact that LASIK is unnecessary. Visual refractive error is not a disease requiring surgical treatment. Safer alternatives – namely glasses and contact lenses – are widely available.

We, the 1,073 signatories, support Dr. Morris Waxler’s petition. Please reopen the petition for reconsideration. Thousands of American lives and families, and many more worldwide, will be spared by withdrawing the FDA’s stamp of approval on harmful LASIK devices.

Sincerely,

Paula Cofer

Cc:
The Honorable Lamar Alexander
Peter Lurie, M.D., M.P.H., Associate Commissioner for Public Health Strategy and Analysis, FDA
Attachment A
To the Food and Drug Administration Commissioner

We the undersigned support the Citizen Petition to

1. Withdraw FDA approval (PMA) for all LASIK devices
2. Issue a Public Health Advisory with a voluntary recall of LASIK device

submitted to the FDA, on January 6, 2011, by Waxler Regulatory Consultancy, in order "to stop the epidemic of permanent eye injury caused by lasers and microkeratomes used for LASIK eye surgery".

We thank you for taking the time to read this letter.

1. I have friends whose eyes have been permanently disfigured and lenses marred by this surgery - resulting in chronic dry-eye and irreparable poor vision.

2. I suffered permanent, life-altering complications from LASIK. I know of thousands of people who also had a bad outcome from LASIK. Medical studies demonstrate that LASIK "side effects" are common, and that adverse effects are universal. LASIK surgeons do not fully inform potential patients, and are engaged in a cover-up. Clinical trials that the FDA relied upon were tainted by dishonest investigators.

3. I had LASIK on 10-23-10. Since then ( and prior to! ) had dry eyes. Burning in my one eye. Starbursts and halos too... It's important to stop this cause of present problems and future unknown problems! My doctor said I was a good candidate. Well I was not and he doesn't wanna hear about my "problems".

4. My eyes were ruined from lasik

5. Lasik took away my night vision & left me scarred for life with unbearable starbursting.

6. my brother’s vision was severely and permanently damaged by lasik

7. I am permanently disabled as a result of Lasik. My vision is 20/20 according to the ophthalmologist who mutilated my corneas. He tells me the procedure was successful;

(continues on next page)

Name From Comments

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Page 1 - Signatures 1 - 8
8. however, while viewing an object I see six (6) ghost images, starbursts and halos around EVERY light source and the severe dryness negates the 20/20 correction. My quality of life has been RUINED, thanks to LASIK.

9. Almost 2 years ago my son had Lasik for hyperopia. The surgery left him with irreparable damage, double vision, that can not be corrected even by custom gas permeable lenses.

10. Lasik nearly ruined my life. Only got it back after finding a great set of expensive, custom contact lenses.

11. Many complications appeared a few years later after having lasik on both eyes. Good result at first doesn't mean it will continue for life. I hope lasik ops can be stopped and a cure will be developed for lasik victims.

12. because my life has changed in a negative way since i got a botched EPI surgery. the dr. took NO responsibility for what happened...AND did surgery without a signed consent form. pure arrogance.

13. Now you know why lasik doctors dont give FDA lasik booklet patient information to patients.

14. I underwent LASIK in 1999 and suffered many negative results to include: neuropathic pain, halos, diminished vision and a sensation of severe dry eyes. Currently, I am going through a period of severe photophobia and cannot drive or perform any activity in lighted conditions. I would also like to make the point that it is not only LASIK that needs to be re-evaluated but the physicians' themselves that perform LASIK and provide no follow up care or responsibility to their patients that have negative and debilitating results.

15. Feel deceived because of lack of proper information regarding a permanent, irreversible elective procedure with all kinds of unnecessary side effects. It has been a financial and psychological burden that I carry ever since.

16. Too many people's health is being irreparably damaged by this procedure. Complications are extremely common (albeit the true rate is often covered up.) Patients with bad outcomes are ignored. This mass mutilation must stop.

17. I am fully aware of the harm Lasik causes to all eyes it is performed on - there simply is a mountain of science that proves so. I had Lasik performed on both of my eyes and despite having been told I had a fairly good result, even by optometrists who are against Lasik, I know the quality of my vision and health of my eyes have suffered as a result of Lasik.
19. My husband was injured by Dr. Herbert Nevyas when he performed unauthorized especially when my husband was not a candidate. My husband was butchered by this doctor, who also threatened to sue me for telling about my husband's experience on my web site.

21. Need to stop damaging perfectly healthy eyes. People are not informed of the true risk and side effects.

22. My cousin was harmed permanently by this surgery

23. As a LASIK casualty I experience the inadequacies of the FDA's lack of protection on a daily basis. With my websites (lasikdecision.com), I see a tremendous amount of traffic by those seeking help to correct the problems by doctors who don't abide by established rules and procedures. Too many people are needlessly damaged.

24. Electing to have Lasik was absolutely the worst decision of my life. I went from crystal clear vision with glasses to chronic dry eye, redness, inability to focus and vision that is uncorrectable with glasses.

25. I've had my life ruined by lasik on 5-6-2009 by the latest lasik available. I was completely lied to about the safety of Lasik and destroyed. I'm now on Disability. Please stop destroying lives and warn the public of this horrible lasik procedure. PLEASE STOP LASIK AND HELP LASIK CASUALTIES. I need your help I've been injured so badly.

26. I had LASIK performed in 1999. Had good vision for about a year then it started to decline to bad night vision, double vision, ect. Virginia Eye Institute, who did the procedure, had me returning every 3 months for 8 years for checkups and I was told that nothing was wrong. I finally went to a different vision specialist who says he cannot correct the damage done by LASIK but fitted glasses to help some. My prescription has to be changed every 6 months to try to gradually get my vision back the best it can be. I will always have vision problems since I had LASIK.

28. Because of my unfortunate knowledge of doing anything to the eyes permanently which result in pain and less visible spectrum.

29. Like the previous posters Lynn Hamilton and James Burke, I am disabled from my chosen profession by the "temporary side effects" of this surgery which have lasted for years. As a direct result of this surgery, I no longer can see to drive at night and my night vision is obscured by huge starbursts and haloes. I also have permanent double vision in one eye due to a decentered ablation. This (continues on next page)
surgery also induced very painful dry eyes as well as a loss of multiple lines of best correctable vision due to induced irregular astigmatism. Despite all these permanent unfixable complications, I am still considered a success by industry standards.

31. I am a physician who had LASEK done about 4 years ago. It has ruined my life. I cannot do what I studied my whole life for because of it. I am limited to certain services that I can provide because of my eyesight behind LASEK. People don't realize how long the rest of your life is if you have a bad outcome from this surgery. Above and beyond that, it is the most unethical procedure in the world.

32. I had LASIK in September, 2010. Prior to the surgery, I was a happy, healthy (in every way) young professional. I will never be that person again. Due to unbearable side effects - I have suffered from all the typical side effects (halos, starbursts, night vision problems) - plus severe depression, and even thoughts of suicide - something I never even thought myself capable of thinking of. I hope to God that this tragedy can be prevented for others.

33. My girlfriend of 3 years has had her life turned upside down by this awful surgery. She scouted one of the top locations in the region and paid top dollar only to be left with seemingly permanent after effects. Down with LASIK and my support to your petition.

34. People are unnecessarily being harmed by Lasik. Anyone who makes their living caring for others vision knows this.

35. I've communicated with over 300 people who've expressed a desire to end their life because of LASIK. Much of this is related to dry eye and night vision complaints. Victims all say the same thing: That their surgeon lied to them about the severity of complications, and continued to lie when they experienced a bad outcome. Time for this to stop.

36. I had Lasik 2 1/2 years ago, and I am now visually disabled and cannot work or live my life free from pain. My eyes are so light sensitive that I can barely go outside, let alone use a computer or watch tv or be under non-natural lighting. No one seems to be able to help me in my condition either. I just keep getting told that this condition shouldn't have lasted this long (TLSS), as if that somehow addresses the issue. We need more research so this and other side effects don't keep happening.
40. I am having many complications as a result of LASIK.

41. My son had LASIK twice in the last year and is suffering from daily discomfort and horrible night vision and starbursts.

42. I had lasik done on my left eye and it is permanently damaged and no vision left in it. There are too many unscrupulous doctors lying to people about the lazy LASIK and they should all be in prison because they are criminals! They don’t give a hoot about their patients, they only care about making huge profits and they know they are ruining their patient’s life for EVER but keep on convincing people the LASIK is safe....

The media is just as corrupted as these so-called doctors because they advertise LASIK on TV and promoting it for these low life doctors.

I have no respect for these bastards nor do I trust any of these money hungry charlatans and the same goes for the FDA who approved such dangerous surgery.

44. haven’t had lasik but had lasek. supposed to be the "safer" way to go. still suffer chronic dry eye for 5 years already.

46. I had Lasik done in 1999 and it was the worst decision of my life. To say I have dry eye would be an understatement. I live on eye drops. I also see halos and star bursts at night. If I could go back to the way I was before Lasik I would do it.

48. This petition is important to me because I have watched the pain and suffering of a dear friend who received lasik surgery.

49. Because the world has been duped, the LASIK industry used falsified studies using only the good outcomes, and throwing away the bad outcomes, in order to get FDA approval...they cited lies that "there were no known long-term damages from LASIK" when they knew every flap never heals, kills vital corneal nerves needed to generate tears, further thins out corneas which progressively ages the eye causing/inducing irregular higher order aberrations then needing corneal transplants, all while causing it’s victims escalated depression and some suicidal tendencies because there is no cure.
LASIK surgery was supposed to improve my quality of life. Instead, it has deteriorated the quality of life for not only me, but my family as well. I would give almost anything to go back. That in itself should say enough. Please discontinue this dangerous procedure until the long term side effects and additional corrective technologies can be developed. Thank you.

I, like so many others, is a victim of LASIK surgery. I am now legally blind in both eyes and need a cornea transplant. PLEASE stop the butchering of healthy eyes.

How can patients sign an Informed Consent document if the side effects are not honestly shared?

I got LASIK in 2006 (at age 23) and it has ruined my life. I suffer from disabling pain that will most likely last forever. With no end in sight, I am becoming more and more suicidal with each day that passes. I don't truly want to die, but I do not want to "live" like this anymore. I can't.

My friend, Colin Dorrian, took his own life after years of suffering negative outcomes of a LASIK procedure.

I have been left with compromised vision after LASIK. I have multiple images, halos, glare, loss of contrast sensitivity, and can no longer use a microscope. The side-effects of this surgery were downplayed and my negative results were not reported as part of the study that was ongoing at the time of my surgery. My university faculty surgeon calls me "functional" and considers my outcome acceptable. My worst decision was to have trusted him and the FDA with my vision. The FDA needs to admit and rectify its mistakes.

I had lasil 6 months back and frankly speaking, my lasik doctor conned me giving all the false promises, if he wanted money so badly i would have donated money, atleast my priceless eyes would not have been compromised for ever, how can FDA approve an irreversible procedure?now i am suffering from poorer quality vision,loss of contrast, ghosting, haloes and starbursts, people who are promoting and helping to promote lasik are worst than devils.

my brother had severe eye damage after having lasik surgery and was not a good candidate for the surgery in the first place.

I have dedicated 20 years of my professional life as an optometrist to solving the problems of botched refractive surgery.
Lasik surgery has been devastating to my son!
Laser kills Cornea!!
This issue is important to me because my nephew took his life when he was unable to live with the outcome to his eyes of lasik surgery.
We have to ask ourselves "do we really need LASIK now that we have a new and improved non-surgical vision correction procedure called OrthoKeratology (Ortho-K)."
Thousands of people in this country and around the world are choosing Ortho-K over Lasik; and still it is not being heavily advertised here in the U.S. My guess is that 98% of the people who are having problems with Lasik were not given the option of Ortho-K.
The public must know they have options.
Doctors, start offering this procedure to your patients. To get updated/educated/training on the modern advancements of Ortho-K, visit online the OrthoKeratology Academy of America.

have been in optical field past ten years and our eye sight and eye health is of the most importance. Who wants to loose their vision or even risk the possibility. This is something you can't buy if its not good.!! Please Agree and sign if you care.

One of my closest friends had this surgery and she was so excited....until it completely changed her life and now she suffers everyday. She talked me out of doing LASIK and now I want everyone else to know that it is unnecessary and dangerous! Say yes to glasses and contacts and no to lasik!!!

My nephew took his own life, tortured by the unbearable after-effects of LASIK surgery.
My friend has daily pain thanks to Lasik as well as other challenges. When will the well being of people trump corporate greed? Enough is enough!
I developed corneal ectasia in the left eye post Lasik plus have severe image distortion at night with halos, double vision and depth misperception. Now I wear RGP contact in the left
77. I am left permanently disable due to PRK surgery triggering the late Zoster Virus in my body. This has the potential to cause damage to a great many people. The doctors don’t even speak poorly about each other, buiy222, Tid

78. LASIK Surgery has ruined my vision. At the day of the LASIK surgery, she applied excessive pressure to my eye to block my vision. Under normal circumstances, the eye is able to see the laser treating the eye. She masked half of my cornea (topographies). I have a triple vision; at 12, 3 and 6 o’clock with the real image at 3 o’clock all connected with a glare. No laser in the World is designed to treat only half of cornea. She penetrated to the center of my cornea getting into and pulled my vitreous from my retina (topographies).

79. I believe my eyesight has been permanently damaged by PRK, performed by one of the most respected doctors in the industry. I also believe that many websites currently touting the procedure are very misleading. I believe most doctors are aware that the results are not what they verbally indicated them to be. I now have painful eyes, and distorted vision 24/7 - which was not the case prior to the 3 surgeries I have had to "correct" my vision.

80. I am suffering tremendious after a lasik operation in 2000. It is effecting my life situation in a highly negative way. I get no help and have been meet by suspicion from opticians and eye doctors that I have meet - like they are questioning my sanity... It is such a hard problem to describe and as it is changing depending on degree of light, air quality (humidity) and personla health condition (everything is connected). Eyes are the gateway oin to the soul and to take in the impressions via a damaged eye is creating stress and discomfort. Please take us serious and listen. Friendly regards from Lena. Hoping that there will be a cure some day

81. Because I had Lasik in 2000. I have suffered with blurred vision, halos, terrible night vision, ghost vision, scarring, etc. I have had Lasix twice on my right eye and it is no where near 20/20. Wear contacts now and still can not see perfectly. I live with headaches and daily eye strain. If what they are doing is illegal, I would like to see it stopped !!!!!!!

82. I had lasik 7 years ago and I am left with horrific problems. I have not slept though the night for 7 years. I hope that this can stop others from making a serious mistake that will affect their life.
83. I have a friend who had the surgery and the nerves have never grown back and they have not been able to do anything to help her.....she has no tear ducts now and her eyes are at risk.

84. I suffer from post-LASIK complications

85. Lasik devices ruining too many people's eyesight permanently

86. I had LASIK in 2000, and have horrible night vision, and spend a lot of money on correction and vision that I never had to spend before. All of my friends who had LASIK now try to avoid driving at night. The MD who did the treatment did not care about my being able to function--only that I could read letters on his eye chart.

87. I presented at the FDA's Ophthalmic Devices Panel meeting April 2008 to report on the behalf of damaged lasik patients. This petition highlights the alleged intellectual dishonesty of the researchers which occurred during the PMA approval process, as well as criminal activity when active lawsuit information was withheld. The FDA should take immediate action to withdraw the PMA for the lasers and prosecute criminal activity.

88. After reading the issues, I decided that this petition was worth signing to protect the health of patients.

89. My cousin committed suicide after suffering from the effects of LASIK surgery.

90. I don't want people to undergo terrible things just because the "solution" created messes them up even more, if they were not sure of the side effects why try them on people?

91. Because it is the right thing.

92. BECAUSE I HAVE SEEN THE PROBLEMS A GREAT FRIEND OF MINE HAS BEEN HAVING DUE TO THIS LASIK
I suffer from this condition

Two of my close friend's eyes were damaged by Lasik

My friend had a terrible experience after having Lasik. She has to wear contacts to see things without being distorted, all objects have a "glow" around them, starbursts in night vision, and constant dry eye.

A member of my family suffered adverse events as enumerated on page 2, paragraph 3 of the petition, with devastating consequences.

Friend's vision damaged by LASIK

Lasik surgery has permanently damaged my eyes. I have been suffering for 10 years now on a daily basis. I strongly support the petition to withdraw all LASIK devices in hoping to prevent further eye damage to innocent victims.

Blinding people to make a buck is very bad karma.
Eyeglasses rule!

Because my practice rehabilitates vision when LASIK goes bad.

A good friend of mine had Lasik surgery and has had serious complications, including the inability to function as an attorney due to these complications.

I had LASIK surgery 5 years ago and now have chronic dry eyes which I have suffered with ever since the surgery. I have been to many eye specialists which say they can do nothing to help me. I use 140 eye drop vials a week to alleviate my constant dry eyes. I miss being able to do outdoor activities with my family and friends. I feel that I have been severely handicapped due to the dry eyes and if I could go back in time would not have done the LASIK surgery. I would never wish what I have endured on my worst enemies.

I was not given the FDA-mandated Patient Information Booklet. I was a very poor candidate for LASIK, with multiple contraindications. However, greed on the part of my optometrist, and the surgeon willing to pay him the (continues on next page)
119. (continued from previous page)

highest comanagement fee, prevailed. The result was
disastrous and I am now more nearsighted than I was prior
to LASIK, but I am not correctable with glasses or soft
contacts. Thanks to my complications I see multiple
images. Because I can see well with hard contact lenses, I
am considered one of the "lucky ones".

The Stop to Corruption and Greed at the Expense of Good
People's Eye Site and Quality of Life are Way Over Due.
Lasik is Mutilation, Plain and Simple.

Unhappy with my result. People are not getting good
informed consent. These doctors need to be stopped.

120.

I now have Keratoconus due to LASIK. The laser has
made me blind.

121.

I had LASIK and then later cataract surgeries. Any
research about their relevance?

122.

I have suffered permanent damage to my right eye as a
result of Lasik. I have spent thousands of dollars but
unable to fix it. My vision continues to degrade.

There are serious problems with a lack of informed
consent due to inaccurate, misleading and incorrect
information being provided to those that are considering
LASIK. I now suffer from very poor near vision that I now
realize was entirely predictable for someone of my age. I
also suffer from dry eyes. Why do they not inform the
public that the cornea never heals anywhere near the
strength it was prior to LASIK?

Because my friend was blinded by the surgery.

123.

After undergoing LAZIK surgery 8 months ago I now see
worse than when I had either contacts or glasses. I see
halos, starbursts, have poop contrast sensitivity and am
near sighted in one eye and far sighted in the other. Yet
the optometrist that performed the surgery considers me a
success saying that my "brain needs to adapt to it's new
visual reality". The way the legal disclaimer is worded
gives no indication that even with a "successful surgery"
you may have difficulty seeing things clearly and crisply. I
do not feel I was properly informed of the risks of the
surgery before going ahead with it. The FDA should
reconsider it's position with regards to LAZIK.

124.

I saw a perfectly healthy, happy man lose everything due
to this surgery.

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131.
Comments

Because my husband suffers long term ill effects from his Lasik surgery.

I had LASIK that resulted in painful dry eye syndrome and a vitreous detachment that left me with a floating mass of haze and a large black floater mass that together cause a 20% blind spot. My vision fluctuates and cannot be corrected with glasses. LASIK is a nightmare.

2 years ago I was butchered by LASIK. I now am far sighted in one eye, near sighted in the other, have double vision in one eye, triple in the other, different colors take on shapes of their own, starbursts, halos, contrast issues and dry eye to name a few. I have spent thousands in a effort to correct my vision including rigid lenses and Sclerals to no avail. I struggle to keep my job and at one point contemplated suicide for several weeks. My vision continues to get worse and who knows what the future has in store for me.

The major portion of my professional practice is devoted to helping patients who have lost quality vision due to refractive eye surgery regain what was lost.

I made the worst mistake of my life by having LASIK. LASIK damages a person's most vital sensory organ. Ruin a person's eyes and you ruin that person's life. It's that simple. The FDA should withdraw approval of LASIK and stop ruining many people's lives all for the sake of not wearing glasses or contact lenses. LASIK is not safe and effective. It's risky and deceptive. Why doesn't the FDA do it's job?

Because I had LASIK surgery 11 yrs ago and it has had a severely adverse effect on my life. It has basically ruined my life, I am never comfortable. My vision fluctuates. I will be going for ocular surface reconstructive surgery in 2 months, which I have to pay for out of my own pocket. I live in Canada and have to go to Florida for this surgery.

not proven to be a successful procedure

My vision was ruined by the procedures Lasik Plus did. They maintain I have 20/20 binocular vision. So now I have traded one pair of corrective lenses for 2 pair; one for intermediate and one pair for distance. Lasid does not work long term!!!!! Presbyopia gets everyone eventually.
I am a surgeon who has seen a "top" eye surgeon destroy my wife's eyes with "state of the art surgery". Having now looked into it deeper the ethics of approval, consent and full disclosure are clearly not being met. So far there are three suicides in the petition related to this....how many more are there? I am concerned that the FDA have been misled and would also welcome a US department of Justice investigation into the relationship between the industry and the surgeons. It has been done in Orthopaedics and opened a very large can of worms...and $ multimillion dollar fines for what was said to be all above board. The FDA need to relook at this now.

A total triumph of marketing, greed and arrogance over common sense.

A dear friend of mine had Lasik surgery and has had major problems since having the surgery.

I am a casualty of Lasik. Progressive corneal ectasia was triggered by the procedure consequently leading to a corneal transplant. My visual challenges /difficulties remain ongoing and will do so for life. My wish is that others be spared the pain and diminished quality of life the lasik procedure has brought me.

Some of the adverse outcomes from LASIK surgery are outlined in this petition. What has not been examined here or elsewhere is how these outcomes impact patient's lives. What impact do high order aberrations have on an individual's ability to process visual information? What impact do visual distortions have on the psychological health of an individual? Following the FDA hearing in April of 2008 the public was assured that practitioners heard LASIK patients who have been damaged by this procedure. But what has changed? No efforts have been made to understand or address the problems that LASIK patients encounter.

I may require eye surgery in the future

The doctors who need to pay for their LASIK devices are perpetuating a fraud on the American people. They all wear glasses. The "success rate" for LASIK includes everyone with 20/20 vision--including those in constant pain, who have to wear goggles, who see seven moons at night, who can no longer use a computer, who are suicidal, etc., as a result of this surgery.

I had LASIK in 2002. That was the greatest mistake in my life. It has basically changed my life. I suffer from halos, starbursts, double vision, diminished contrast sensitivity (continues on next page)
and photophobia. LASIK is a nightmare and should be immediately stopped to prevent further tragedies.

The risks are extremely high and this is not emphasized. The result is permanent injury from elective surgery.

LASIK clinical trials data that were the basis of FDA approval of the procedure are both incomplete and massaged to create the appearance that LASIK is safer than it is. As a scientist I felt I did my due diligence by reading the clinical trials data summary prior to my own surgery, only to find out that I and every other American who has undergone LASIK, was deceived. As a result, my eyes and the eyes of millions of Americans are permanently damaged by LASIK.

Lasik ruined my eyes.

My husband's cousin committed suicide after having a botched lasik.

After PRK surgery I had to give up my art teacher profession. I am overcorrected +3 dpt, the ablation zone is heavily decentrated >1 mm, I lost 70% vision and I have permanent doublevision, halos, lost of stereovision, headache, heart problems. My cause still is in process since 12 years even 3 experts affirmed malpractice and manipulated documents as well as wrong information of treatment. Even all that experts evidences I dont have a last sentence. The doctor of the clinic eureeey is accused because of betray. (manipulated documented)

It is ridiculous that Lasik is sold as a no risk operation or low risk...piece of cake when many people experience debilitating eye problems afterward. There HAS to be a warning issued regarding the true safety of Lasik. Public health is at risk.

My life has been ruined because of lasik. Glasses or contacts can't fix my eyes because of lasik. My eyes are messed up forever. This lasik procedure needs to be stopped now, before more people have their eyes ruined. Lasik surgeons are more interested money than telling the truth about how badly lasik can damage your eyes. I have sparklebursts, bad vision in low light and dark, starbursting, double and triple vision, severe glare, halos, light sensitivity, dry eyes, contrast loss, floaters that are worse since lasik. I have been on depression and anxiety medication since right after having lasik over four years ago. Please stop lasik from causing more people lives to be ruined!
LASIK damaged my sight and gave me dry eye.

A procedure that has a failure rate as high as LASIK (some studies report from 1% to 10% of severe complications, with much higher numbers for "minor" complications, whatever "minor" means when talking about vision), with consequences as severe as blinding people, and yet, is still marketed as safe and simple. This must be stopped!

I have a friend who had to go on disability because of lasik surgery. He and his family have suffered physically, emotionally and economically. The future for them is uncertain at best.

My good friend had this surgery and has had horrible, debilitating eye pain ever since.

I know people who have had improper lasik and now suffer the same vision impairment I have from severe keratoconus. No one should have to go from eyeglasses to what I deal with every day! It is a crime. Period.

My brother is suffering from chronic dry eye due to his lasik surgery.

-5 Myope in my better eye. Was considering LASIK until going home one day and hearing the FDA wanted stronger warnings and read of all the problems with LASIK.

Stop Lasik It destroys peoples lives forever

My 26 year old son had a retinal detachment in one eye within a month of having lasic surgery. He had retinal reattachment surgery and he now has a permanently scarred retina. There is significant scientific evidence that the suction applied to the eye during lasic surgery can cause a tearing of the retina by pulling on the vitreous humor in the eye.

My husband had LASIK in 2006, the suction broke as the laser was making a pass over the cornea, thus destroying it. He has endured years of surgeries as a result, including 2 corneal transplants, not to mention the loss of vision and pain. Our life revolves around this disability now. We have to plan trips carefully and be aware of where we might get help if needed while away from home. Our lives have been totally turned upside down by LASIK.

I was diagnosed with LASIK Induced Trigeminal Neuralgia and put in a medical journal for speculum damage.

My wife has had this surgery twice and she is almost blind she has to wear one contact lense to see it ruined her eyesight
177. I had this surgery twice. Have lost my night vision, in constant pain, dry eyes, prescription worse now than before surgery. Was an expensive scam I fell for.

178. I had it done two years ago, Severe eye damage, constant pain and PVD's with many eye floaters and guess what, I still need glasses! It is so dangerous, please put an end to it! I will never be the same, it has ruined my life and my wife's life.

179. My cousin Dom Morgan was damaged by lasik surgery by Dr. Nevyus when he wasn't a good candidate.

180. such a long story to tell, but bottom line is i had LASIK 10 year ago and as a result I have permanent dry eye syndrome ever since, and my best corrected vision is now worse than pre LASIK. The "safe and effective" data being presented to the public is just plain false.

181. My colleague who had LASIK surgery 5 years ago is now legally blind. It's ethically wrong for eye surgeons to ruin the lives of perfectly healthy people just so they can make a few thousand dollars.

182. Because my life has forever been impaired by the complications from LASIK surgery and I don't want an elective surgery to be able to continue its harm and devastation. Totally unnecessary!!!

183. Had PRK by the awful Dr. Wright, and lasik w/"enhancements." Both corneas perforated and saw 7 of everything for 3 yrs. Numerous surgeries after that not only didn't help first problem but each surgery caused a new problem. Lasik caused cataracts. Enormous problems after cataract surgeries at age 48, with permanent hazing in left eye. Had to quit working, can't drive at night, filing for disability. On anti-depressants. Spent at least $20K on corrective surgeries over 14 yrs. that haven't worked.

184. Because Lasik destroy my life.

185. My life has been negatively changed forever. I suffer from chronic dye eye which is physically, emotionally, and financially debilitating. The public needs to be aware of the risks and the hazards associated with this elective surgery.

186. As far as the doctors who sell this surgery are concerned, the potential revenue of this surgery has always eclipsed the community of people who might suffer from it. Do some good science for once on this surgery... make 'em start over.
189. My eyes have been ruined by Lasik. I can hardly drive at night, eyes burn every day, I see 6+ ghost images of everything in my left eye and 3 in my right. My vision is far worse then when I started and all corrective surgery has just made things worse. I'm now suffer depression and anxiety because every waking minute I'm reminded of the damage that was done to my eyes.

Lasik ruined my eyes,

The procedure goes against the Hippocratic oath--first do no harm--and it's medically unnecessary. More time and money should be spent towards finding the genetic causes of myopia/hyperopia/astigmatism than on performing this barbaric procedure.

Eleven years ago, Lasik created "dry eye hell" for me. The surgery correction was perfect, but the side effects (dryness) took away my sight! The pain was unbearable! Drops and meds and plugs don't work! There's no cure for dry eye! Stop inducing dry eye into people. When they get older, it will haunt them!

I have lived in Lasik eye hell for over 10 years. Parched eyes (repeat corneal erosions) and horrible vision (starbursts, distortion, halos). Cannot drive at night. Daily suffering. Glasses do not fix my vision issues, and eyes are too parched to wear RGP contact lenses, even scleral.

Received 1,000% incorrect laser to right eye which result in blindness. Lasik is extremely dangerous and very unsafe

I had botched lasik procedures - 7 - that's right 7, on my right eye and am left with poor vision, and a wrinkled corneal flap. The doctor was Donald Rogers in Albuquerque, NM. The same thing happened with a friend who also saw him.

Too many people have been conned by these butchers, playing on their vanity. Glasses versus permanent side effects...glasses are the safer choice.
Since LASIK surgery in May, 2010, my eyes continue to be very dry, to the point where I can't see. The sloughing of dead tissue, as well as my vision, has not improved since the surgery. And now, I can't even use prescription eye glasses to fix my vision. I wish I would have known about serious and common these complications can be.

ruined my eyes ... one of "best" doctors lied to me and did procedure I was NOT a good candidate for and he knew it! My eyes are ruined for life! I'm not disabled.

I believe all lasers should be banned except for NECESSARY medical procedures. Far too many people are being injured due to LASIK and IPL/LASERS used for cosmetic purposes. People's faces, health and eyes are suffering permanent damage and lives/families are being ruined. http://iplandlaserdamagesupport.prophpbb.com

Laser for medical and cosmetic use are too unpredictable. I had an extremely bad outcome from an IPL that will forever change my appearance and health.

My vision was ruined by LASIK.

I had LASIK in 2006 and diagnosed with keratoconus (post LASIK ectasia) 9 months later. I suffer from starbursts, halos, glare, and multiple ghost images. My life and that of my family now revolve around this disability. I feel I was not properly informed of the risks and side effects. The FDA should immediately withdraw the approval for LASIK so that no one else ever has to experience this.

I had lasik done and immediately needed reading glasses afterward. I was 40 at the time and the dr. said I may need reading glasses (like most other aging adults he said) as I get into my 40's. I needed reading glasses immediately following the surgery! I am now having further vision problems with blurriness and eye pain.

I developed a buldging cornea as the surgery was being preformed. It was diagnosed as kerataconous. I spent many miserable years until I finally had a cornea transplant.

I have a friend who has suffered chronic dry eye and other injury from LASIK surgery. His is now disabled; his life - and that of the family he is trying to support - has been completely disrupted. He was not aware that this "side effect" of the surgery is so common. Few people are aware that this so-called 'simple procedure' can ruin lives.
Name From Comments

216.  
Lasik really ruined my life. I hate my lasik doctor that he butchered my healthy corneas. I am contact lens intolerant and I told him that yet he callously continued with this surgery. I have to wear moisture chamber goggles for life and spend $300 a month on eyedrops for life. I can never read the computer without pain and reading hurts my eyes. I don't enjoy reading for pleasure anymore. I find my vision deteriorating due to the host of problems lasik has caused me.

217.  
I have severe chronic dry eye due to my lasik procedure in June of 2005.

218.  
My wife has severe dry eye following lasik.

219.  
I now have life long problems with my cornea, that i had no idea would happen. This isn't worth any vanity or concerns about wearing glasses.

220.  
Lasik is a quick fix and it si WRONG!

221.  
As an R.N. and dry eye sufferer, consumers need protection from the harm caused by Lasik.

222.  
I am a fan of Kathy Griffin. On her website she warns her fans that she has been partially blinded by LASIK, but that the media backed by big money will not report on her story. No one should suffer the complications reported here. We must hold the media accountable for its failure to report the truth.

223.  
I had a bad lasik vision surgery

224.  
I am a French lasik victim. I have decided to sue the surgeon because of the misleading information he provides to his clients.

225.  
I am a LASIK victim.

226.  
I had thought of lasik 5 years ago and for my son as well later if it went well but after he turned 20. I knew eyes are probably the most important part of our lives and our jobs depend on them. I did a lot of research on the internet at that time and saw many negative comments and I postponed the idea until newer, better machines come up. But reading through all this now I thank God that I took time to make this decision and not go for LASIK. All these doctors are still advertising that it is safe and sound. Where is the greed leading to us? (continues on next page)
Not being able to drive at night? Not being able to go out in light? Constant dry eyes and pains? Multiple images? What else can they ruin to your life?

had lasik done took me 2 years to get back to work due to severe dry eyes better now but still have problems with dry eye and nerve pain.

I have permanent 20/80 vision as a bad Lasik procedure. I wish I had never had it done.

I am supporting this petition as I have seen the adverse effects of LASIK surgery that some friends of mine now have to endure for the rest of their lives. This has spurred me to support this cause in order to stop LASIK surgery until a through and truthful evaluation of LASIK surgery can be completed. I support this to prevent the maiming of any other person.

Had LASIK in 1998. Enhancement 1 in 1999. Enhance 2 in 2000. Both eyes developed ectasia. Right eye so damaged can only wear Scleral Lens. RGP in left. Corrected visual acuity worse than before surgery. Appears surgery was too aggressive as my corneas are so thin there is irreparable damage. Need resources dedicated to prevention of future adverse results and especially to assisting in development of safe treatments for those of us with unsatisfactory LASIK outcomes.

FDA illegally certified the procedure

I am permanently disabled for 7 years now following lasik. I have 10 complications and constant dizziness. No doctor i saw would admit my complications until after statutes were over.

I got worse floaters to my eyes after lasik and suffer from dry eyes and glare.

My vision is permanently distorted. My eyes hurt. There are no effective cures or treatments. These injuries do not heal They are progressive. This is all due to LASIK. If the industry can withhold information and manipulate the results of FDA studies then imagine their power to deceive prospective patients. Unfortunately, people injured by LASIK don't have to imagine. We live it every minute of our lives.

Because my dad killed himself because of LASIk when I was 15.
To prevent blindness; you can use your eyes without surgery and perfectly be cured

While LASIK may have some applications in the treatment of refractive errors, I am supporting this petition because there is a greater need and responsibility to stop and assess the iatrogenic damage caused worldwide not only by LASIK, but also PRK, RK, ALK, and many other heavily marketed but inadequately followed-up corneal refractive procedures. It is time for the practice of ophthalmology to come to terms with the damage it has created in my opinion.

LASIK ruined my sister's vision
I have glare and dry eyes due to LASIK.

Laser vision correction destroyed my life
Corneal Ectasies, risc of not discovering ocular tension glaucoma, glare, reduced optimum VA, nightglare/myopia, dry eyes, mislocated/wrinkled flaps which never "heales" or grow completely together with the tissue it lay on.

I know people who have suffered greatly, this is a dangerous procedure for cosmetic reasons (unnessary), ive seen it ruin many lives. One lady just committed suicide because lasik caused such extreme dry eye. The only people who bennifit is the industry.

LASIK should be banned because they are lying and deceptive in the most egregious nature stating a phony 95.4% patient happy rate, knowing that every eye is permanently damaged with long term known incurable injuries, a permanent flap which never heals and is open to infection for life, a loss of cells (keratocytes). Yet the physicians aren't telling this important fact, they only tell you the benefits to sell it. Their commissioned corrupt staff follows. Lastly, here's the biggest problem. Most/ALL LASIK Ambulatory Surgical Facilities (ASFs) are supposed to be following the MDR regulation, but are instead NOT following it. That is why they continue to lie to patients telling them they suffer only temporary dry eye, glare, halos, contrast issues, when instead they should be telling them they are permanently injured, which would then require them to issue a Medwatch case for the injured patient. They are choosing to AVOID this paper trail which would send up a RED FLAG to the FDA, and end their millions...

No one can understand how bad dry eyes can be until they cannot be cured.
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<th>Name</th>
<th>From</th>
<th>Comments</th>
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<tbody>
<tr>
<td>252.</td>
<td></td>
<td>I was screened inappropriately as a candidate for LASIK and now suffer the consequences of dry eye, higher order aberations, astigmatism.</td>
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<tr>
<td>253.</td>
<td></td>
<td>I had LASIK seven years ago and have had chronic dry eye, redness and discomfort since.</td>
</tr>
<tr>
<td>254.</td>
<td></td>
<td>8 years after LASIK, my dry eye syndrome has substantially ruined my way of life. Something as simple as watching a movie is now painful. Beyond that, I'm now wearing glasses again anyway as my vision has changed as I age. So what was the point?</td>
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<td>255.</td>
<td></td>
<td>my first husband killed himself due to permanent eye injury from lasik</td>
</tr>
<tr>
<td>256.</td>
<td></td>
<td>I had Lasik surgery in the mid 1990’s and started having severe eye pain about three years ago. Have had some improvement through a daily regimen of warm compresses and medications. However, I'm sure this is just a part of my life now.</td>
</tr>
<tr>
<td>257.</td>
<td></td>
<td>I would give anything to have my &quot;old&quot; life back. I have suffered with dry eye syndrome since Lasik surgery two years ago. I wanted to quit wearing contacts and not wear glasses but I traded them for a miserable life. AND, you cannot find a doctor that knows anything about dry eyes. All they know about is money! LASIK needs to be banned!</td>
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<td>258.</td>
<td></td>
<td>I had Lasik 5 years ago and am still suffering the consequences of severe and debilitating dry eye, though I have been working with several doctors to alleviate symptoms. This is a debilitating condition which has taken away my 20s. I was not properly and thoroughly screened nor informed of such likelihood of risk. I found out later I barely passed the pre-screening. They should have ran a second test, but the profit is too great to turn anyone on the fence down.</td>
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<tr>
<td>259.</td>
<td></td>
<td>Lasik gave me dry eye and floaters. This surgery is dangerous and can ruin people lifes.</td>
</tr>
<tr>
<td>260.</td>
<td></td>
<td>A very close friend of mine has been suffering from severe dry eye for many years after having underwent LASIK procedure. She was not properly informed of the risks of the procedure before undergoing the surgery.</td>
</tr>
<tr>
<td>261.</td>
<td></td>
<td>I have tear dysfunction syndrome that is so debilitating, it has irrevocably changed my life. I don't want anyone to suffer with my problems because they had LASIK.</td>
</tr>
<tr>
<td>262.</td>
<td></td>
<td>Severe dry eyes caused by RK and lasik</td>
</tr>
<tr>
<td>263.</td>
<td></td>
<td>I feel that my quality of life has been diminished after having Lasik eye surgery.</td>
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</table>
LASIK industry spokesmen say that complications do not occur with newer LASIK technologies. That is absolutely false. The FDA has an extensive database (MedWatch/Maude) of medical device-related injuries, which contains numerous reports of LASIK injuries with the latest LASIK devices. It’s important to note that 99% of LASIK patients do not know that they can report their bad outcomes to the FDA. The FDA has been "captured" by Big Ophthalmology.

My eyes were permanently damaged due to LASIK eye surgery. Not a single day goes by that I don’t regret having the surgery done!

My friend who required two corneal transplants after her failed LASIK is too afraid to speak on her own behalf. All the local LASIK surgeons who saw her for second opinions covered up her ectasia diagnosis. She became SUICIDAL.

My life was ruined in 1993 by RK, the refractive surgery done before LASIK. I'm on social security disability. The doctor who did this bore zero responsibility for the constant pain, dryness, and recurrent erosions of the scars he gave me. He is a respected corneal surgeon in Indianapolis who continues to ruin people's lives with LASIK.

I had surgery and it did not go well. Eyes in worse shape now than before, has caused me to have depression and my life is not the same after Lasik.

I have residual vision problems after lasik surgery 9 years ago. This procedure is inherently dangerous to the long term stability of your vision.

Have had lasik in 2009. Since then terrible ghosting, despite retreatments. Also very dry eye, which makes it hard to continue my work. No doc can improve my situation!

I had lasik surgery 4 years ago with Dr. Jeffrey Singer in Louisiana. Not only did he stretch the upper eyelid, he overcorrected me and now I suffer from severe dry eye. Besides that, I have floaters, a cataract, halos, starbusts, light sensitivity, and pain. This unnecessary procedure has ruined my life and my family's also. Sad thing is that many doctors I went to see afterwards said they would have never done the surgery because I was 52 and had great eyeseight for my age. The worst thing of all is that he showed no remorse for what he did to me. I hope no one ever hurts his children or other family members in this way. I don't wish this on my worst enemy. It has changed a great life into a miserable one and has taken the best years of my life away. For anyone reading this: NEVER HAVE SURGERY ON YOUR EYES UNLESS IT IS ABSOLUTLEY NECESSARY TO KEEP YOUR VISION!
274. 4 years after having Lasik surgery I have severe dry eyes and struggle each day to maintain comfort so that I can get through each day at work. I wish I had never gotten the surgery and would not recommend it to anyone. If the surgeons had been honest about the severe side effects, I would have never gotten it done.

275. My wife had the LASIK procedure about 10 years ago. As a result she suffers from severe dry eye, star bursts, halos and other untreatable cronic conditions. This surgery is not the 10 minute miracle it is touted to be and has unpredictable outcomes.

276. As an optometrist I unfortunately see many cases of unhappy patients after lasik. Problems ranging from dry eyes poor vision to several cases of corneal ectasia. There are also many cases of "good" =20/20 vision who complain of poor vision which can be clearly measured on a contrast sensitivity chart.

277. I have sjogrens syndrome and it can cause blindness!

278. I am supporting a friend whose legal opinions I trust.

279. I've had Lasik-induced dry eyes for 4 years now. No longer able to work full-time.

280. My wife has severe dry eyes due to her PRK surgery. LASIK doctors define success only in terms of visual acuity. It's like saying I've fixed your stuttering problem - by cutting out your tongue.

281. I have severely dry eyes from having LASIK surgery. I wear goggles all the time and have to be very careful about how I manage my eyes. This has been the situation for over three years.

282. Because I got injured in a LASIK surgery.

283. I have dry eyes and know what the challenges are like dealing with this issue. Also, a close friend of mine has suffered the consequences from LASIK eye surgery and now has to wear goggles every day.

284. I have a friend who suffers from dry eyes as a result of this procedure. I do not believe the potential side effects were emphasized before she had the procedure.

285. I have a grand daughter who had this procedure done her eyes are worse than before.

286. Someone I care about has suffered from severe dry eyes from the surgery.
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<tbody>
<tr>
<td>288.</td>
<td></td>
<td>I have a good friend whose LASIK surgery has since given her chronic and painful dry eyes. It upsets me terribly that this happened to her, and I wouldn't wish this upon anyone, even my worst enemies.</td>
</tr>
<tr>
<td>289.</td>
<td></td>
<td>My eyes have been burning since my LASIK surgery eight years ago. I battle severe dry eye symptoms every single day. Side-effects were minimized by my LASIK surgeon, and there was clear evidence of poor tear film due to dry eye feelings prior to surgery and 100% contact intolerance.</td>
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<tr>
<td>290.</td>
<td></td>
<td>Because one of my good friends has suffered terrible dry eyes since she underwent surgery and there should be some way to prevent this terrible side effect from happening.</td>
</tr>
<tr>
<td>291.</td>
<td></td>
<td>Consumers not fully aware of risks</td>
</tr>
<tr>
<td>292.</td>
<td></td>
<td>I only had eye problems after my lasik surgery.</td>
</tr>
<tr>
<td>293.</td>
<td></td>
<td>I have a friend who was not diagnosed with dry eyes prior to her LASIK procedure, and now has to wear goggles every day of her life. She can't do any of the outdoor activities she loves, and she's literally constantly in pain. All of this could have been prevented - please withdraw your approval of all LASIK devices!</td>
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<tr>
<td>294.</td>
<td></td>
<td>My sister has been in pain with dry eye since she had the surgery over 10 years ago.</td>
</tr>
<tr>
<td>295.</td>
<td></td>
<td>I also have dry eyes after my lasic procedure and if I had to do it all over again I would not. It's risky business as there is nothing they can test you for before the procedure to see if you would be one of the unlucky ones and have this problem after the procedure!</td>
</tr>
<tr>
<td>296.</td>
<td></td>
<td>I have had chronic and painful dry eyes since my surgery 10 years ago. My eyes become easily fatigued to the point where I am unable to read. This condition has adversely affected my career in IT. In my pre-op interviews with Dr. Manger and staff, I stated dry eyes as the main reason I wanted lasik surgery. I thought wearing contacts was the problem. They did not tell me the surgery greatly exacerbated the condition. I learned this afterward. My vision has deteriorated since to the point where I wear contacts or glasses all the time. I regret my decision and urge reform of this industry.</td>
</tr>
<tr>
<td>297.</td>
<td></td>
<td>Dr. Wong did my left eye, and my vision was terrible. He did it a second time and I am now legally blind. My right eye is also much worse off. Without contact lenses, I would not even be able to drive.</td>
</tr>
</tbody>
</table>
I have been visually disabled and suffer relentless agonizing pain due to severe ocular surface disease (dry eye) and multiple visual abberations that resulted from LASIK surgery.

A friend who underwent LASIK surgery has been in extreme discomfort ever since. Please recall these devices.

I had lasik almost 8 years ago and it changed my life dramatically for the worse! I now have severe night blindness (to the point where I can barely drive at night AT ALL), severe dry eyes, halos and pus oozing from my eyes every morning. My eyes are always hurting and red & blotched looking. If I had ever known the extent the surgery would affect my quality of life...I would NEVER have gotten it done. It should be illegal what happened to me and, obviously by the messages below, to so many others as well.

My eyes were damaged.

I had Lasik surgery in 2001. I developed Chronic Dry Eye right after the procedure. I have been to several eye Drs. in the last 10 years with no relief in sight. I am all for with drawl of FDA approval and a Public Health Advisory

My eyes were damaged and my quality of life has been severely diminished. I have to deal with this everyday. I don't want others to experience this.

It was the worst decision I ever made. They never told me that correcting my vision for distance would ruin my reading vision. I had bi-focals before the procedure and still have bifocals after lasik. In addition I have permanent dry eyes.

A friend experienced chronic dry eyes after Lasik. She was not properly notified of the potential risks before the surgery nor given appropriate care by the attending doctor when she started to experience problems. Her ability to work and do the things she loves like read/write has been severely limited by the inability to properly moisture her eyes.

Lasik ruined my life
I had no problems prior to LASIK surgery; now both eyes are severely dry, and the "standard" treatment (Restasis) does not help. I would never have gotten LASIK if I had known I would live the rest of my life suffering with dry eyes.

I have family and friends whose lives have been ruined by Lasik and are not in constant severe pain from their procedure.

I have a friend who has suffered for more than 2 years after having lasik surgery, surgery that was performed without her full knowledge of the fact that she had dry eyes and that she could suffer ill effects from the surgery. She was diagnosed with dry eyes prior to surgery, but not told that she had dry eyes, nor that there could be long term eye pain because of this condition. Please stop the epidemic of permanent eye injury caused by LASIK eye surgery.

Why isn't the FDA protecting us? Why do they continue to ignore the dangers of LASIK?

My nephew's vision is permanently damaged due to lasik.

A friend of mine has daily severe headaches since Lasik surgery. Doctors have no answers.

After two enhancements I'm still not 20/20 (even with glasses and contacts) so I did not want a third. I feel that my stigmatism may be LASIK induced. I have starburst efffect at night and some dry eye when using contacts.

Causing damage to people's eyes with a FDA approved device is criminal just as it is allowing unsafe drugs that kill people such as the COX-2 inhibitors to remain on the market! FDA should be ashamed of themselves.

Lasik ruined my husbands eyesight. It nearly ruined our lives. He has traveled throughout the U.S and Canada in search of a soultion. Currently, a collection of eye glasses and unique custom made contact lenses are his only hope for a "normal" life.

Had Lasik surgery with complications. Can't see clearly and have eye pain. Prior to surgery, asked surgen about possible keloid problems and was told no correlation. I believe that with my past medical history, I should have been told that may be contraindactions for surgery, and given realistic numbers of complications (told less than 2% have problems!!).

My Left eye has bad cornea scarring and I need a cornea transplant which costs around $35,000 that I don't have. I have to close my left eye while I see with my right one or (continues on next page)
the bad sight overlaps with my right eye. I now have one good eye.... And glasses don't help. Contacts hurt after 4 hour in my left eye, so I can't wear them all day. Also my left eye is 20/100 with double vision and very bad light streaks at night. I just want my left eye taken out; it bothers me when I try to see with my other 20/30 right eye. I got laid off two months ago and it probably will be harder with one eye to keep any decent job. I had four operations (enhancements) that caused trauma to my left eye and started herpes simplex which caused damage to my left eye. The place where I had operations at will not help me at all with money because they say I can't prove that the lasers caused the virus. I am very mad, but can't do anything about it. By the way, I did not have herpes before the operations.

I have a best friend who has been damaged by LASIK surgery that could have been avoided.

I have researched this thoroughly and these machines simply are NOT safe for general use. Although many people have reasonable outcomes, nobody should be encouraged to gamble with their only eyes.

I have three friends who have had LASIK surgery and those three have chronic issues related to it.

My daughter had Lasik surgery & lost vision in one of her eyes had to have 3 surgeries & she is still going through pain & emotional stress due to Lasik surgery

After telling me to my face that I was “a perfect candidate” for Lasik, the surgeon wrote in the chart that I had blepharitis (a serious contraindication to Lasik) and that he had fully discussed it with me. Lasik left me with double vision, impaired visual acuity, and chronic eye pain. Since I have started speaking out about the ethical failure of the medical profession to confront fraudulent advertising and incompetent surgeons, I hear Lasik horror stories on a regular basis – and my typical audience consists of medical professionals.

Dr. Dishler in Colorado should not have performed LASIK surgery on me. He knew I was not a good candidate for the surgery for several reasons. My vision is worse than ever. I had a RETINAL DETACHMENT as a result and had to have emergency surgery. I've seen 5 specialists.... I live in constant fear of losing my eyesight now.
Do to a "mix-up" at the front desk, I received the wrong prescription in both eyes. My corneal tissue is now only about 430 microns thick in each eye --- too thin to have LASIK repeated safely --- and my corneas are now too flat for regular contacts --- so I've had to be fitted by a specialist for reverse geometry lenses (which gives adequate, but not totally clear vision).

because a friend of mine suffered vision loss, poor night vision, and chronic dry eyes after LASIK

Because LASIK permanently crippled my vision and I want to prevent the same thing from happening to others.

I know several people who have had permanent damage from this procedure which has resulted in a major negative effect on their lives as well as the lives of their love ones.

The agony of dry eye from medically necessary surgery nearly cost me my sanity. To run the risk, however small of inflicting this curse upon anyone from an optional and mendaciously advertised procedure is simple wickedness. This is commercialised medicine at its worst. First do no harm?

I had Lasix and now wear glasses with a prescription 3x stronger than before the surgery. And...dry eye, halos, starburst, impaired night vision.

It is important to me because friends and family have experienced serious problems that should have been recognized prior to surgery.

My niece was hurt by lasik

Lasik altered my night vision and how i see light. Very sensitive to bright light and glare is an annoying problem. Wish someone had warned me about these issues beforehand.

During the pre-screening I told the eye professionals I could not use monovision or see using the contacts but lasik was performed anyway. I experienced a month of vomiting due to nausea after the surgery. I overcame that, but now deal with glasses 24x7 for everything except far site, have painful dry eye, halos, glare, and increased sensitivity to light. No eye professional since the surgery has been able to fit me properly for midterm sight (computer) in glasses or contacts.

A friend, whose judgement I trust, asked me to sign this petition.
Eyes have been permanently damaged.
Complications from Lasik severe dry eyes and halos.

My eyes were irreversibly damaged and my vision destroyed. My PRK and Lasik procedures in 1997/98 caused decentration, severe dry eyes, glare, halos, starbursts, decreased contrast sensitivity, etc. My quality of life and work capacity has suffered tremendously. Reading causes daily headaches and vision fluctuations. I cannot pursue higher education, cannot work efficiently, it is extremely taxing to drive at night, and the list goes on. It causes fatigue and depression...

A person that I care about has been injured by LASIK.

A family member had both of his eyes irreparably damaged. He will forever see only blurry, fuzzy vision. This should happen to no one. One’s eyesight is precious and should be protected from this frivolity. It ruined my nephew's life.

My daughter, who has a sister that is blind, was trying to improve her vision. She was not told of all the horror stories that had happened to individuals. Just because she can read an eye chart they say her surgery is a success. She has smearing, halos, starbursting and cannot drive at night. She is very young and will have to deal with this for the rest of her life. It has mentally hurt her so much.

My bother suffers daily from further worsened blurred vision, night spots and "halos" around light sources at night. It has caused much depression and a serious claim against unethical Doctors who practice LASIK on candidates who should NOT be treated with this surgery!

To tout something as progress in eye care, and have it severely injure so many unsuspecting people, is unconscionable. The FDA was designed to be watch dogs for our health. I have eye injury caused by neurosurgery for something very different, which I was also not forewarned about. This is something huge, which must be stopped now.

I was a victim to lasik. When I had My operation in june of last year I was told that I was a great candidate and the Dr has the latest machines the would reshape my corneas to get 20/20 vision. All lies, not only my vision in not 20/20 I have HOA in both eyes preventing my from seeing at night. Lasik operations should be stop all over the world.

I had Lasik is 2000 and since then have had problems with my vision. My eyes became severely dry. I experience blurred vision, halos, glare and don't like driving at night (continues on next page)
especially in the rain with the glare, halos and starbursts. My eyes can be fine one day and then I will have problems for weeks, not knowing each and every day what to expect.

This issue is important to me because it has drastically reduced my life quality as well as of others! My operation took place back in 1999. Since then I have had serious problems with blurred vision, halos, double vision, and a very troublesome and stressful focusing ability. And no acceptance or knowledge of these sideeffects of the profession. And no cure! My life is now dividet into two; before and after the operation....

I've never had lasik surgery, yet as a severe dry eye sufferer I feel this issue affects me significantly. I live in a small city and a large private eye hospital monopolises ophthalmology in our city. This hospital focuses on lasik eye surgery and other lucrative surgeries, with heavy advertising of lasik. Patients who need urgent eye care must wait for months, whilst potential lasik victims get an immediate, free consultation. Despite the fact that this lasik center creates so many new dry eye cases every year, the "doctors" there know nothing about dry eye nor are they willing to learn. These doctors refuse to provide me with even the most basic dry eye care, and because they have eliminated all the small ophthalmologists from the city I have nowhere to go. Even if I get a corneal ulcer, I am completely on my own, because a doctor at their facility dumped me as a patient for pleading with him and crying to please try something, anything to help me. The lasik doctors are cruel and heartless and without ethics.

My wife had PRK surgery three years ago and suffers from chronic eye pain and severe dry eye syndrome as a result which has greatly impacted both of our lives.

My 16 yr old daughter wants it and I keep telling her NEVER mess with your eyes. She is under the impression the procedure is now perfected. There are too many horror stories out there. It is NOT worth the risk!!!

I had Lasik and suffered dry eye syndrome.

I have had Lasix procedure twice! I suffer from halos and double vision

I had Lasik done 5 years ago and have regretted it ever since. I have been suffering from horrible dry eye (I'm afraid to be without eye drops) and pterygium in both eyes. I've seen two doctors and both have told me "this is all a normal part of Lasik". If only they had mentioned it before!
Lasik has destroyed my quality of life and left me in constant pain.

It has been my experience that Lasik procedures are being done too casually by doctors. Mistakes get made all too often. Your eyes are far too precious to risk all that mine have been through - and have even more to endure inorder to restore my sight.

I think Lasik is overrated and to hurried. Even though they "show" you all the so called complication before you get the procedure done, I really think they should have given me more time to have a second thought. They are too quick to do the procedure. Even the day I got my procedure tone, they asked if I was ready and I said no partly because I was afraid and partly because I wasn't 100% convinsed. They said, "I'll take that as a yes". But every body I had talked to said it was great so I thought it was just me being afraid. I have not been happy since I had lasik on both eyes in 2007. Lots of glare, shadowed vision, dry eye, sore eyes from the incision that doesn't ever heal closed. I panicked when I lost my glasses once and I was very near sited. I ran to get lasik because of the scare and now I wish I could go back to just wearing my glases again. It has caused problems with my driving and work. Good luck with this petition

I had Lasik in 2008 and suffered severe dry eye afterwards.I was never told that this could not be cured, I never had TBU test or Schirmers preformed. Why don't you require that these tests are preformed.Wy doen't more people know about all the risks? And how severe they are, and that there is no cure. Ans what about RCE. I never even heard about these until weeks after my Lasik. Why? I was never told the flap does not heal completly, why was I not told that?

I had lasik done many years ago, still could not see clearly, so I needed contact lenses, and still could not see clearly. My son also had it done, and his eyes have been ruined for life. He found out after the surgery, that he was NOT a candidate and should NOT have had the procedure. Now he suffers daily and will never be able to see clearly!

BECAUSE IF THE DAMAGE IT HAS CAUSED MY NEPHEW

I had lasik surgery ten years ago,left eye has never been clear

Helping a friend

I don't want any others to be injured!
377. Name
   From
   My little sister had PRK surgery 3 years ago. Due to the chronic dry eye and excruciating pain her lifestyle has been dramatically altered. She now is on prescription medication to control the pain, has to use eye drops, wear goggles, and apply moist heat compresses twice daily (which when trying to enjoy her love of the outdoors makes things very cumbersome). What is really disgusting was the way she was treated postop by the surgeon, ophthalmologist and office. This is just a small synopsis of what she and her husband have had to go through. It has been hard for all her loved ones to watch her go through this.

378. Name
   From
   My son had lasik surgery when he was 21 years old by one of the top lasik surgeons in the country. Because of this surgery my son developed corneal ectasia and had to have a cornea transplant in one eye and is legally blind in the other. He now needs another transplant. Please stop lasik surgeons from hurting another patient and their families. I also think these doctors need to be reprimanded in some way for not reporting bad results to the FDA. Hold them accountable and withdraw FDA approval of all lasik devices!!

379. Name
   From

380. Name
   From

381. Name
   From

382. Name
   From

383. Name
   From

384. Name
   From

385. Name
   From

386. Name
   From

387. Name
   From

   My sister's retina detached after Lasik surgery and her eyesight continues to deteriorate.
   I have a LASIK complication

   My whole family's life is ruined because of deceptive lasik surgery. I now have uncorrectable blurry vision, constantly painful dry eyes, massive depression and anxiety. I'm unable to function as a wife, mother or friend. This should be a criminal offense; I should have never been a candidate because of dry eyes and high myopia. I will most likely end up with corneal ectasia. How can you continue to allow this to happen? How many people must commit suicide or have to get on disability before you take action? This is an absolute travesty. May God help those of us who are suffering and may our attempts to stop this butchering of corneas be successful.

   My son was severely handicapped as a result of this surgery.
   we should not suffer
I was not a candidate for PRK due to thin cornea, high myopia and large pupils. Doctor downplayed effects as healing. Night time problems don't happen anymore he says. Says he never had a problem my brain will adjust. My total ablation zone smaller than my pupil in dim light (never mind dark light) He says this is not a problem. How come we can all do the math and the doctor cannot. I will starbursts at night now and the moon will never look the same. It all seemed too simple before.

my boyfriend can't see anymore because of lasik please do not allow any surgeries that can damage a person's vision and thereby life just for cosmetic reasons. My life has been a total nightmare, due to Lasik.

I had LASIK surgery in 1998. I now have problems with starbursts, halos, double images, etc. These problems have continued to get worse. If I could go back and undo the surgery I would. I have had a difficult time coping with my vision. I don't want others to suffer what I have experienced. If nothing else, there needs to be much tighter FDA restrictions on LASIK. We have laws that protect consumers from eating unhealthy food. Shouldn't we have some laws that help protect us from the negative consequences of having our cornea's sliced open. This is not a minor procedure. I entered into it too lightly. Please help others avoid this mistake.

Thank you,
Bryan

LASIK is the worst thing going on in the medical community and the doctors know it. They are more focused on making money than anything else. Not many doctors out there who want to "help" people, so watch your back. LASIK ruined my vision, my vision is fuzzy, my eyes are constantly dry, red, irritated. LASIK makes the entire medical profession appear to be charlatans. Doctors know LASIK is a quagmire, they just can't help themselves because the cash is quick. Very unfortunate situation, many lives ruined by such a needless surgery. Stick with your glasses, don't let someone ruin your life.

Butchering human cornea merely for able to see more, is rediculous.

I was going to have Lasik performed until I read the several pages of possible complications and was very disturbed by it.
400. Name From Comments

4 months on disability. Vision slowly improving after 6 months. Dry eyes continue. Mandate full verbal disclosure of risk., not just sign a consent the day of surgery!

401. I have been permanently damaged by Lasik. I have significant GASH/HOAs and Dry Eye. Dry eye was never mentioned as a complication but is the most difficult to deal with. I have lost my fiance and am alienated from my family because they don't understand the pain, guilt and self loathing that accompanies the decision to pay someone thousands of dollars to permanently ruin your vision and your life. I have suicidal thoughts now which I never had before Lasik. As time and my disease progress I feel more and more hopeless, helpless and naive ...

402. Although I have never had Lasik, I have suffered from severe dry eye syndrome for over 10 years. It affects my quality of life on a daily basis. I do not want others to suffer this agony if it can be avoided.

403. LASIK has totally screwed my life up and I find it hard to cope in most situations. Can't drive, hard to see movies. Total glare, haloes, funny feeling in eyes, dry eye, I have most of the adverse side effects of lasik.

404. My mother was injured by a LASIK surgery.

405. Because people's lives are being ruined----with no hope for recovery--too many lies--too much deceipt--a barbaric and flawed practice that exceeds greatly, the limit for failure of devices (lasers in this case) set by the FDA itself. And still, the FDA does NOTHING. Because they are bought and owned by the Medical "profession"-

406. a good friend was greatly harmed by this.

407. I had lasik eye surgery on Sept 24, '10 and have suffered 6 complications and have permanent corneal scars, have lost my night vision and suffer from extreme dry eyes. I am back to wearing glasses now and deeply regret my decision to have this procedure. Lasik MD has only said that these are all risks and that is the reality of the surgery. I feel I have made my sight worse and the damage cannot be undone.

Jodi Barnett

408. I am currently suffering from complications of PRK performed in 1994 via the excimer laser. If I knew then what I know now, I would never have done it.
This is a very important issue to me because my vision is worse now than it was before LASIK. I have had several issues with this it is NOT worth it!

Lasik has ruined my daughters eyes and is making her life horriable!

I just went to the eye dr after 5 1/2 years after lasik and now the effects have declined and have been advised by dr that i need bifocals and the close/near vision is of a 48-50 yr old and i am 43.. I now need glasses for both close (which i knew would occur) but now need for distance which i did not know would happen.

I had lasik on July 2,2010 at Key Whitman Eye Center in Dallas, Texas. Ever since my procedure I've had starbursting, halos, horrible night vision, low light vision issues, ghosting, increase in floaters, and other various issues. Until October of 2010 I had lost all hope in dealing with my issues. I came in contact with Dr. Gemoules in Coppell, Tx to be fitted with custom scleral contacts. As of this day they have reduced my issues by 80-85%. So life is pretty much back to normal. My pupils were measured at 8.5mm after I already had my lasik procedure. On my charts they put my pupil was measured at 6mm, which they were never measured in the first place.

2 years after LASIK, I was told informed for first time that my 'unlimited' enhancements must be limited, because each enhancement increases chance of drying the eyes. 4 years after surgery, I started making mistakes at work and realized I needed glasses again for distance. Multiple opticians have said that 4-5 years after surgery, people who had Lasik often begin needing glasses again. I have not been able to achieve the same level of vision improvement with glasses that I could before the surgery. It affects my performance at work. Before surgery, glasses cost $150 per 2 years. Now specialized glasses cost $800-$1000 per 2 years!

I had surgery scheduled for the 15th of this month. HAD. After reading about all the problems people have had, and realizing I am a horrible candidate for this procedure, despite what the eye doctor claimed, I am appalled.

I was contemplating about lasik

This procedure is criminal, period. It’s assault. There is no ethical reason for a doctor to slice open a healthy cornea and then fry it with a laser. The only reason anyone would to this to a fellow human being is greed. These "doctors" are playing on people's vanity to get rich while destroying patients' vision for life. I've worn specs since I was 15, and (continues on next page)
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yes, they're a pain in the neck sometimes, but I would never, ever try something this foolish and dangerous. I've never even tried contacts due to the potential for infection and scarring. DO NOT MESS WITH YOUR EYES - THEY ARE IRREPLACEABLE!

Cause it has affected my best friend drastically--and several others I am close to. Now I am having severe eye issues since brain surgery #3--and I know what NOT to do.

Lasik seems "dangerous" at best

Please know that every person's vision is priceless. Until refractive surgery is reversible, all elective refractive laser eye surgery should stopped by every state government to show that they care for their tax payers and want to stop any more people becoming disabled.

I am an optician and do not like lasik at all.

I am living with permanent vision complications and dry eye as a result of LASIK surgery. Because of this my quality of life has suffered. The risks outweigh the benefits when it comes to refractive surgery - and once it is done, it is not reversible.

I had LASIK 5 years ago. My doctor assured my he was good (he was the first in my state to perform the surgery) and that I would have no complications. Every single day since LASIK my eyes hurt. Sometimes it's unbearable and interferes with my daily life and I am miserable. I regret ever getting LASIK. I wish someone would have warned me.

I had LASIK in 2003 and I thought I was told that I may need an enhancement but otherwise I should be good for 7 - 10 years. I went into surgery at -3.50 in both eyes. In 2007, I had to get glasses. -1.25 in one eye, -1.75 in the other. My doctor wanted me to pay $1300 for an enhancement. I saw a different doctor yesterday for contacts and now my distance is worse -1.75 in both eyes but my close/reading vision is awesome. So, I need bifocal contacts or one for far, one for distance or cheap reading glasses when I wear contacts. Since 2007, I have been wearing glasses.

I know of relatives, friends and aquatints that the LASIK did not work out as advertised, some are suffering years after the treatment. Pull the plug.

I pay for a lifetime guarantee lasik surgery.I was never informed of any complications And I have had a dry eyes since the surgery. the lasik Dr. Told me when I went in for (continues on next page)
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Comments

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my second surgery that there were complications with cells growing under my flap. This was never discussed on my original surgery.

cauze lasik made me night blind.....

I have adverse side effects from my LASIK procedure performed over 10 years ago and regret it. Wish they had disclosed more warnings about side effects prior to surgery. I would have opted to not have it done. I don't want others to make the same mistake.

FDA should recall all lasers used in PRK and LAZIK.

Cornea Never Heals.. Laser is very harmful to cornea.

Complications are really suffering! i could hardly read the letters on the screen clearly!

I've had friends and a relative who had bad outcomes

Any laser eye surgery is like a gamble of success to failure, unfortunately there are more failures. Most people don't put in/have the time to do their research and second opinions before making the life changing decision. Many doctors are most looking out for their own best interest and don't care to compensate for their failures to patients who have to live with their doctors mistakes, or commit suicide to stop the suffering.

My brother has been practically blinded by LASIK surgery. He lives in chronic pain.

I had LASIK, and I wish I could turn back the clock to undo my life altering MISTAKE!!

We came way too close to risk destroying our daughter's eyes with this procedure. I pray they recall the lasik devices and outlaw the procedure.

Am now left with huge floaters constantly in my vision as a result of LASIK; a totally unnecessary practice

Because my life has changed forever. And because I have to start it afresh. And that is not easy.

This issue is VERY important to me as I am one of the 20% of people with disastrous Lasik results. I have extremely dry eyes, starbursts, double vision, and severe depression. I can't see my husband across from me at 12 feet or so. Can't drive safely night or day. I'm am sick that I (continues on next page)
was mislead regarding the chances of something like this happening.

i had Lasik in 1995 and was advised that because i was in my 40's that i might need reading glasses but within the last few years my eyes are extremely dry especially the cornea and when i went back to the surgeon and ophthmologist they told me i had blesparitis and this not true. Im an artist and do computer work and because my eyes are so dry and painful, i cannot work as long as i used too, because my eyes get very blurry due to the dryness and feel the lasik surgeon was very dishonest and so was my ophthamologist. I have tried drops and followed my eyedoctors remedys and it doesn't help

Lasik surgery ruined mine and my families lives. This procedure should be banned!

My doctor in New York, Harry Koster, has ruined my life. He was completely misleading before the procedure, and I would have never done this surgery if I knew the life-altering risks involved. I want the FDA to withdraw its approval so others don't make the same mistake as me.

I had Lasik in 2009 on newest SHWIND AMARIS, and still im suffering from dry eyes, starbursts and halos. Lasik disaster must be stopped.

I know a young lady that feels her life has been ruined because of severe side effects of her Lasik

Prevent more terrible outcome and lifetime suffering from side effect!!!!!!

My boyfriend had Lasik done (in his early 40's) and has a permanent blur in one of his eyes which gets worse while night driving. The doctor can't do anything about it. They said a 2nd Lasik it too risky.

I did an unsuccesful Lasik and was at no time informed about the inherent risks, despite I asked for it.

I had Lasik 5 years ago and have had painful dry eye ever since. I have spent thousands trying to control the symptoms, but there is no cure.

safety is important
It is disappointing to see certified doctors putting their patients' sight, lives, and state of mind at risk.

I am suffering daily due to corneal ectasia after my botched lasik eye surgery. I am going to get to the bottom of this crisis. Godspeed.

On June 29 2011 I will be visiting with a Cornea Specialist to see how bad my eyes have gotten. I had Lasik Surgery in February 2000 my vision was good till about 2005. At that time I saw an eye doctor and was told I had a bad astigmatism and the only think that would correct it was RPG's. I've seen a second Doctor and she said the same. About a month ago I lost a contact and tried to get in to see my Doctor she was unavailable, so I ended up seeing a partner of hers. He took one look in my eyes and send me immediately to the Cornea specialist. Not sure if intacs will work could end up with Cornea transplants due to Lasik Surgery and to uniformed Doctors. Get the news out.

I definitely decided to have lasik surgery, after reading those who had complications, I see that there is no B plan, I hope all of these people get well soon. Thanks for warning other people.

The FDA should consider what would happen if they're life or that of a family member was ruined by a surgery. Why would you support something risky. At least make a recall on it for a couple of years until you catch all the surgeons responsible for the tragedies. Quit supporting something that not only has destroyed but caused suicides.

I now suffer horrible, debilitating night glare after a lasik procedure in January 2005.

LASIK has changed my wife's life forever. We need to bring awareness to it's dangerous.

How the surgery effected someone I know and my surgery did pretty well but I was under the impression that if my eyes had any kind of trouble in the future they would fix my (continues on next page)
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### Comments

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eyes. Not true the insurance I paid extra and alot for does very little to keep my eyes good in the future.

I'm a LASIK disaster victim myself and I don't want others to suffer the same fate as I had!

6 mon post lasik with LasikPlus, floaters poor night vision undercorrected left eye. LasikPlus refuses to do anything to correct my complications.

So many ForProfit organizations today take advantage of the people. We the public want accountability to be enforced.

RK surgery a failure

My eyes are ruined for life. Because of their lies.

My cornea is thin and bulging and I csntnsee out of my right eye after lassie

I don't agree with the method in witch doctors explane this procedure to there Patients !

If the Laying LASIK Doctors saw as I See after LASIK, They would stop ding LASIK because simply they couldn't do it.

I know a few people who have had problems with lasik as well

My dear friend had complications and prior to surgery was told she was the "perfect candidate" for lasik, which was not the case at all! I believe providers are not being fully open about the side effects and are testing the patients properly to make sure they are the right candidate for lasik.

I suffer from chronic dry eyes ever since my surgery in 2003. And I am back on glasses. Having LASIK has been the worst decision I have made in my life. I regret it every second. Please don't get LASIK. Wear glasses.

Had a friend who was suffering mentally and physically from LASIK complications!

I have very large pupils and was planning on undergoing lasik. Fortunately I was made aware that I was not a candidate and did not go through with it.

I had a bad Lasik experience
500. I have dry eye

501. I am a post-lasik patient from China mainland. I have suffered some complications such as dry eyes & starbursts for 8 years. Nowadays in China, many public hospitals have Lasik surgery. And a great number of teenagers who wearing glasses want to do this surgery. They even never ever heard about Lasik complications!! Therefore, I hope FDA of US could withdraw the approval and Chinese physicians stop doing Lasik immediately!!!

502. Because My husbands life has been destroyed by LASIK.

503. My life has been negatively altered by this procedure. Today, I was given back some hope after being initially fitted with specialty lenses that adress higher order aberration and corneal ectasia. My eyes have become a disability. I also suffer from severe dry eye that wakes me up at all hours of the night. If the specialty lenses turn out to work, I am going to go public with my story. I do not want anyone else to suffer in the way I have. I am a very strong person; however, I totally understand why some have sought to end their life over the significant negative side effects from post-refractive complications. As well, the arrogance on the part of some ophthalmologists is appalling!

504. too risky and potential for long-term problems with the eyes -- too precious to take a chance with

505. LASIK surgery has complicated my life. I am no longer able to enjoy the hobbies that I once engaged in, and I am now severely depressed. Now after nearly 1.5 years and two surgeries on each eye I am still unable to correct my vision to a level it was at with only a $10 pair of disposable soft lenses. I was lied to about the type of procedure I was to receive as well as given incomplete information regarding the surgeries and risks involved.

506. I had lasik eye surgery (Sept 2010) and deeply regret that decision as it has ruined my eye sight and quality of life. I have suffered 7 major eye complications, 4 of which are now permanent.

507. My husband was in the early 90s trials and the same thing happened to him. The FDA was notified and yet 20 years later, nothing has changed. He has dry eyes, halos, headaches, etc. It was done 3 times on his eye. Never did the 2nd eye. In 1994 asked the FDA for info to help and was turned down. They said legal dept. said no. Why do trials if no one heeds the warnings of side effects.
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**Comments**

510. had Lasik in 2008. I now have starbursts and halos, regression in both eyes. I was told before surgery I would be able to wear contacts if I still needed them. but "why would I want them". I can not be fitted in contacts.

511. I had lasik which has given me terrible dry eyes. I had the bladeless procedure which I was told was top of the line and side effects were rare. During my pre examining I was never checked for quality tear production. My Dr. Told me there may be a little dry eye in early healing but would go away, that most everyone experienced this. After that I told her that I was contact intolerant. She didn't seem to be bothered by this. I wish I could go back in time. I would take my glasses back any day to get rid of this dry eye. Hope this helps.

512. Lasik surgery has changed my life in the most negative way. I had PRK July 2011, since then I've lost my night vision, suffered from dry eye and constant pain. I am now severally visually compromised.

513. Affects a friend

514. I had a LASIK Surgery at Dr. Marguerite M. McDonald. Half of my right cornea was treated, and Penetration to the center of my right eye getting into the interior of my right eye resulting in Posterior Vitreous Detachement.

515. because something that can make your eyesite worse than it was is wrong

516. was told I was an excellent candidate for Epi-LASIK surgery by McDolald Eye Associates in Fayetteville and have suffered since that time. I had enhancements done on each eye and now wear contacts. My vision is horrible! I suffer daily!!

517. Permanently injured by prk

518. I do not want more people's vision and lives destroyed.

519. it is a nightmare, worst thing ever done. Not able to sleep. have developed floaters and my doctor does not give me any response

520. destroy lives

521. Six days after iLASIK with Dr. Boutrous I noticed many floaters in my vision, and was diagnosed with PVD at a follow-up. However, everyone at the practice denies that (continues on next page)
this is a complication of LASIK. I have been given many excuses: that it's normal, age-related (I was 34), they've always been there, that only notice them because I'm paying more attention to my vision, that the floaters will "settle down after a while", that I'll get used to them. It's been 17 months and they're not gone. I was never this unhappy with my pre-op nearsightedness. I would take back my pre-op eyes in a heartbeat, if only I could, but the floaters aren't treatable. I also have some night glare. I'm sure my surgeon counts me as a "success" when advertising his LASIK mill to prospective patients. If the LASIK surgeons deny and dismiss the complications they caused for past patients, how can their future patients make informed decisions? I feel my surgeon violated my trust and his ethical obligation to first do no harm.

Lasik practitioners do not disclose all risks of lasik: dry eye PAIN, depression, loss of income, cost of follow up treatment (drops, glasses, scleral lenses), loss of contrast sensitivity, loss of ability to see at night. The list could go on. Who in there right mind would go through with the procedure if they knew what the real risks were?? Until a non industry funded report can be done to assess the true gravity of complications, Lasik needs to be stopped. Enough people have already had their lives and the lives of their children torn apart.

Because too many patients are suffering irreparable harm due to this unnecessary surgery. These are real complications--not "side effects". If a medication had this safety profile, the FDA would withdraw it in a heartbeat. Addressing the advertising is not enough. There has to be a full investigation by the FDA into the safety and efficacy of Lasik. In a large percentage of patients, it has proven neither safe not effective. Furthermore, those providing the safety data at present have inherent conflicts since they stand to lose huge profits by exposing the dangers of this surgery. Ditto the instrument companies involved. This requires a similar investigation to that done for Celebrex. It is a scourge on the medical profession and will go down in history as that. The USFDA can truly do something and must act without further delay.

Because I had Lasik surgery 4 months ago and my eyes still feel tired, irritated and dry. I wish I could go back in time.
I had done a LASik and now I am suffering with almost lost vision.

In December when I was 34 I had lasik done in both eyes. For the last ten months my entire family has suffered financially and emotionally. I regret the day I ever had lasik done and wish more than anything that it could be undone. I will never let anyone I love have lasik done to them. My two young daughters were almost left motherless because of lasik. I am blessed that I still have one good eye so I can drive my children to their activities and read them their homework.

It makes life unbearable if you suffer the side effects and yet they call it a success.

My dad wants to have the surgery soon and he's getting his eyes checked tomorrow by a doctor who's done LASIK on one of our relatives. I'm trying to talk him out of it. His doctor might not tell him the risks involved. (Prayin')

Had lasik done in 2003. It was great at first but only lasted about a year. Now my vision in some ways is worse than it was before. Had I known it would not last that long or the other problems that were to come. I would not have had it done to me. It was expensive and not worth the risk.

Lasik has ruined my eyes and my life. I have been suffering from severe eye pain and headaches since lasik. My doctor was extremely ill-prepared to deal with my injuries from lasik, or I should say, COMPLETELY CLUELESS! They should not be doing these surgeries, when they have absolutely NO idea how to treat the patients after they are injured.

I was thinking to do this surgery, but I'm so glad I did the research before. While doctors are making millions of dollars millions of patients suffer. STOP mutilating our souls and hopes to have a better vision. If a driver pass a red light and have point in licence it will lose the privilege to drive 4 awhile. Why not the same should happen to the doctors?

I hate Lasix and all the doctors that prescribe such dangerous drug, is a death sentence for patients! NO I am not taking it however I know of some that I care about is taking it and I have to force them to stop!
545. Name From Comments
546. i had a quack ophthalmologist destroy my right eye in surgery. i had to have it removed years later.
547. To save health of eyes
548. This kind of surgery is dangerous and unnecessary but still ophthalmologists still do it even hiding complications but then if you have floaters and need a vitrectomy to regain good vision they will not operate you even if you need it...
549. DO NOT GET THIS PROCEDURE. IT HAS RUINED MY LIFE. MY EYES ARE BURNING, DRIED OUT, AND HURTING. POST SURGERY SIX YEARS AND PRAYING FOR A SOLUTION.
550. I was not informed of the risks of lasik before having the procedure done
551. This is a horrible condition and we thought that since it has been around for 20 years there would be a safe version. Glasses are better than dry eye any day!!!
552. because I care about health of people whethernknown or unknown to me
553. Had Lasik done in 4/2010. Now many issues(floaters, night problems)
554. i also have glasses an m not ready to take risk .we got only 2 eyes for life time with out them we r waste.ask them who dont have eyes from birth.
555. My eye has been permanently damaged by LASIK. I need to wear a double lens to correct my vision which is inconsistent and problematic.
556. My friend got it done now his eyes are messed up!
557. affects a friend
558. I am having dry eye, halos, glare, starbursts and loss of contrast sensitivity after lasik. I was told at the clinic that these go away in 3 months, they lied. They all promise perfect vision, this has really affected my life, Anxiety and depression is more severe now, even thought about suicide beacuse I blame myself for this decision.
559. Lasik destroyed my life.
560.
my friends' lives were destroyed by lasik

I had LASIK done nearly 10 years ago when I was 22 years old. From day one I had severe dry eyes and poor night vision. I ended up having my right eye "enhanced" one month after the initial procedure due to not correcting my astigmatism enough. Today I am on Restasis for dry eyes and recently have gone back to glasses. I am trying to wear contacts but my eyes are so dry my doctor is not sure I will be able to. I wish I would have never had LASIK done.

I had Lasik five years later i have to wear glasses, pretty sure i am going blind now

After I have read many testimonialas on many sites, I adore my contact lenses.

I am 35 years old, was very active and fit, and am negatively affected by lasik...Had a thin flap cut on my left eye and an aborted procedure. They had already done my right eye. I am not eligible for more surgery to correct due to this complication. I am optically imbalanced for life which severely limits my depth perception, night driving ability, and basically all other daily and recreational activities (I am 20/2000 in that eye). I have halos, starbursts, and floaters in the eye they did perform surgery on "successfully". In that eye, I have regressed to 20/50 vision in a fairly short time, suffer extreme dry eye and now have to wear glasses AND contacts simultaneously to have any semblance of normal vision. I too wish I had not done this procedure. BTW the doctor classified my surgery as a success even though they totally screwed up the flap cut on my left eye. How is this possible, who is taking a kickback? Come on FDA, look out for the public!

I'm interested in this field because i have been living with blindness on my left eye and myopia on my right eye through my whole life. The way, that LASIK surgery corrects the refraction problems is not addressing the core issue. The surgery is dangerous and should be banned.

I did my Lasik 7 years ago. I went to two LASIK centers and my eyes' doctor. They all said I was an ideal candidate and would not have any side effect. But it wasn't true. After the surgery, my eyes were sensitivity to light, very dry, and have a difficult to drive at night. All my problems are gradually happen and getting worst. I really don't want anyone like me to have this problems. Please stop LASIK.
I had Lasik surgery on both eyes in 1996 and 1997. Since having the surgery I have had extreme problems with dry eyes and night vision. In particular star bursts when looking at lights meeting cars. I have discussed this with my eye doctor over the last five years and he said it was cataracts. I asked to have the cataracts removed but they refused. They said having them removed would worsen my eyesight. I have had my tear ducts permanently plugged and use eye drops every day yet my eyes are painfully dry. During my last visit I overheard my doctor talking with an assistant about my eyes damaged by Lasik. When he came back into the room I insisted he tell me if that was what is causing my problems with glare and dry eyes. He said it was and put me on two additional medications for the eyes. I have researched this problem and discovered Lasik has damaged millions of patients eyes. This procedure should not be allowed. I'm only 62 and have 20/15 vision yet I cannot see at night when meeting cars or looking at lights. The results of this procedure are not reversible and patients, like me, would have never had this done if we knew this would happen to us.

RK ruined my eyes and life. I have the same complications as lasik. In the near future, the FDA will look back and realize that Lasik ruined more lives than any other operations in the history, and the sad part is that it is totally a cosmetic surgery.

I've had 2 lasic Surgery's done in the past 2 yrs and it had stolen my life and i can't get any answers from them, so scared!!

I have severe night vision complications, abberations, which the lasik surgeons greatly downplayed prior to surgery. After surgery and complications I have been basically told tough rocks. I cannot believe I was conned into this procedure.

My eyes have been irreparably damaged following Lasek @ Optimax UK. Not enough info is provided by clinics re the very real & very likely problems suffered after surgery.

Had it done 18months ago, worst thing I have ever done, my experience has been shocking!

Was always interested in Lasik but had too much astigmatism and too little cash to get it done. A chat with my informed, optician-trained colleague tells me this was good fortune!

It is so wrong to playabout with poor peoples eyes for money and it cost the person there job and ruined there life, i know as my wife had iol surgery and her life is ruined (continues on next page)
so I would like to stop eye surgery unless it is for medical reasons only.

I do not want the LASIK industry to dominate people’s mindset. This is an elective surgery, and the risks should be clear before-hand.

Underwent LASIK surgery thinking that there is a 3% chance of complication whereas the truth is that there is a 100% chance of complication with a 3% chance that I would not complain about them.

Now that I know the dangers of LASIK, I support this petition to withdraw the approval for all LASIK devices and its kinds.

I had LASIK done in NYC at a purportedly advanced facility. Dr. Wu of LaserOne (101 Park Ave) performed a “negative clearance” procedure (I figured this out, after the fact, on my own), 6mm std LASIK on (very large) 8.3 & 8.5mm pupils which results in horrible & dehabilitating higher order aberrations. Night blind now, can’t drive or see in mid- to dark rooms. The left eye ended up half corrected (think yin/yang, top/bottom), leading to double vision. 1 yr post surgery and depressed; a good part of my life is ruined & social situations are very difficult. I definitely understand those who have considered extreme measures. Apparently the Dr. considers my surgery a success too...

Dr. simply asked if I had any questions during pre-op. Trusted he wouldn’t perform something that would compromise my quality of life. Wrong. I am miserable and now realize it’s for life. Coping and trying to keep a good attitude...

I had lasik surgery in 2002. I was not a candidate for this surgery, but the surgeon convinced me to proceed. I'm a graphic designer, and he ruined my career, and many aspects of my quality of life. My only option left at this point, it seems is cornea transplants. These eye doctors are ruining people vision, and because the injury can not be seen by others... they get away with it.

I would like people to be informed prior to a Lasik procedure what could possibly happen. I had cataract implants put in a year and half ago and then had ‘recommended’ lasik ‘tweaking’ a month or so later. My vision has gotten worse since the surgeries and my eyes also feel miserable. I have severe dry eye. Not only is my
(continued from previous page)

vision poor in low light which causes dizziness, but also, they hurt. This has taken such a toll on my life as you can imagine. If I had known that this was going to be a major problem in my life, I never would have had the surgery done. I could see better BEFORE I had the cataracts removed. I'm only 55. Am I going to be blind by the time I'm 70?

People need to realize that their eyes are way more important and why risk healthy eyes for vain reasons? It's not worth it!

They told me I was the perfect candidate when my pupils were almost 8mm. I asked him repeatedly about this and was told that there I would be fine. Well I'm not fine. I suffer from GASH - DAY and NIGHT, loss of contrast sensitivity, night blindness, dry eye, and photophobia. They knew that the laser could not treat an area that large and did it anyway, lied to me about it the whole time, and refused to scan my cornea outside the treatment zone. It was criminal and this procedure should be banned immediately and the surgeons need to have their licences revoked. I found some one willing to do the scan and it showed how much damage they did. Stay away from google me -> lasik surgery in piedmont atlanta at a place that promises better vision <--

To prevent innocent people from enduring permanent eye injury caused by these procedures. They are NOT safe and have serious side effects that diminish quality of life.

I do not anyone to ever suffer the emotional and physical pain as I am suffering.

They made it sound so easy and wonderful. I still wear glasses, only now my vision worsens at the day progresses. I no longer drive at night...the glare is blinding. And hey, the dry eye never went away. This was approved by the FDA?

It ruined my life. Take a perfectly healthy and successful person and lie to him about how easy it is to get rid of his glasses and by covering up all complications and stating that there are no side effects. There can be no greater evil than to make commerce out of peoples health by risking their lives and especially all that depends on it i.e. their
normally healthy eyes. This is the biggest fraud by the medical fraternity all over the world amidst many as its the most debilitating and it just takes the life out of otherwise normal and healthy people leading normal happy lives. For gods sake its peoples "eyes", this is not a hair transplant or a hair removal or whatever other cosmetic surgeries are to be able to deal with an adverse outcome. And if people choose to risk their eyes then they should be allowed to do so by the Doctors explaining to them the plethora of possible complications that exist and if the patient can actually cope with such an out come and if such a realist outcome is really worth the idea of "getting rid of his/her glasses". Instead people are lied to and butchered. What a waste of lives, nothing can be more traumatic to go into the op-theater trusting the doctor and knowing later that nothing can be done to reverse your condition no matter if you spent any amount of money or if upi won a law suit or if you were offered a Billion Dollars. Your eyes are gone forever!

I was considering not knowing the risks.

My sister had LASIK eye surgery a year ago, and while she has obtained 20/20 vision, she was not informed of the long-term risks including possible eclasia and difficulties with any future cataract surgery by her surgeon. It is unethical to withhold or downplay such risks to prospective patients for surgery. As someone who mainly utilizes a bicycle for transportation (including at night), I am nervous for my own safety. As LASIK remains popular, there will be an increasing post-LASIK drivers with impaired night vision... this affects everyone. LASIK is a public health disaster in the making. As a public health professional and current PhD student, I believe the current actual risks of short- and long-term complications and "side effects: of LASIK are much to high in both frequency and possible severity to allow for this ELECTIVE surgery to be a good idea. It is a conflict of interest that laser eye centers themselves are providing the patient with information and consent forms. I am certain that if prospective LASIK patients were properly informed of the actual risks and the possible severity of these complications, they would elect to NOT have the surgery done.

I have undergone lasik surgery and suffered from ectasia.

I've had "rare" complications.
606. [Redacted] This procedure ruined my life. It left me with severe dry eyes. Corneal erosions. Starburst and halos at night. My night vision is ruined and I have vitreous detachment in both eyes. The non stop pain caused me to attempt suicide at age 32. I lost my job, house car and future. This could of easily been prevented if I was given proper VERBAL warning about 3 conditions that SHOULD of eliminated me from the procedure. I went to The Lasik Vision Institute. Warning to all.

607. To Stop The Needless Mutilation Of Healthy Eyes By Excimer Lasers

608. I just got the idea today to get lasik. I am so sick and tired of glasses, until i started researching lasik eye surgery. I am so thankful for finding out the facts FIRST. For those who weren't so lucky, I am truely sorry.

609. I Had Lasik surgery five years ago. To this day, I still suffer from dry eye, eye strain and severe floaters in both eyes. I filed a lawsuit against my ophthalmologist with the understanding that in all likelihood I would lose, but with the satisfaction of knowing that I won't be silenced, or bow quietly into that good night.

610. I got severe chronic dry eye and my eyes hurt constantly. This is the biggest mistake I made of my life.

611. I had Lasik surgery at a very reputable center about 5 years ago. Since I was already over 40 it was suggested that I have mono-vision done so that hopefully I wouldn't need reading glasses for a very long time, if ever. I'm 49 and now need reading glasses. I've had three surgeries on my left eye, one to treat a condition before I even had Lasik (this should probably have been a warning sign to the doctor), one for the initial Lasik and one to "fine tune" the eye (the dominant eye) afterwards. I've had problems with severe dry eye in the left eye periodically and it's now becoming worse and quite frequent. I'm also beginning to have some of the same symptoms, except for the "foreign body" sensation (which is maddening!) in my right eye. I'm fearful of where my eyes will be in a few years.

612. After hearing about the results of her surgery, I became quite excited about getting rid of my myopia and being able to look at my son in the mornings without having to wear glasses. So I went to get Lasik, with supposedly one of the best Lasik surgeons in Austin at the time, Stephen Dell. I deemed the surgery a miracle. Within minutes I had 20/10 (continues on next page)
vision in my left eye and 20/20 vision in my right eye. Sadly within 2 years of the surgery, I developed mild astigmatism. At that time Dr. Dell said that I was ready to get a surgical enhancement. He recommended that I had the surgery with “a new machine that corrected astigmatism” for an additional $1,000 or for free with the old machine since my initial surgery was guaranteed for life. I declined a second surgery because I wanted to use the new machine and did not have the $1,000 at that time. On my 3rd year after lasik, I was ready to have a 2nd surgery. however, when Dr. Dell did the pre-surgical test, he said, “you are no longer a candidate for an enhancement. The Shape of your cornea has changed, probably because you rub your eyes or due to hormonal changes.” He did not tell me 1) that the astigmatism was caused by the surgery and 2) that I had developed ectasia. Instead he prescribed eye drops for glaucoma because according to him the drops could change the shape of my cornea, making me a good candidate for surgery again. Luckily, I had a severe adverse reaction to the glaucoma eye drops, and urgently went to see one of Dr. Dell’s associate, Dr. Sargent. She was clearly put off by the glaucoma treatment as well as the suggestion that I could have Lasik again by using glaucoma eye drops, and strongly suggested that I forget about Lasik. I did forget about Lasik and my vision continued to degenerate at a slow rate. I would get a new prescription every 2 years. Whenever, I asked why is my vision worse than before Lasik, the Dell associate kept saying that it must be because I was rubbing my eyes in my sleep. Not undergoing the second surgery most likely saved my sight, my uncle remarked as well as Dr. Wang. Nevertheless, the process of Ectasia could have been delayed if I had worn appropriate contacts early on. In other words, Dell Associates knew what was going on and didn’t diagnose me.

I suffer from serious post lasik complications.

Eye is the most sensitive and important organ in the human body; and under no circumstances experiments with it for the purpose of doing business is tolerable.

I underwent Lasik surgery on one eye only about 3 months ago and it has been hell ever since. My vision has not improved one bit, in fact, it has gotten much, much worse. I now have halos/glare in low-lighting whenever my pupil size gets larger. While I don’t always have dry eye, I do still
(continued from previous page)
feel discomfort in my eye from time-to-time and need to use eye drops.
I was never told that I was at a greater risk having this procedure. In fact, I never even saw the surgeon until a few minutes before having the procedure. Don't do it whatever you do. Dr. Whiting was my surgeon in Saint Louis Park, MN.

Tuve una operación LASIK en el 2009 y desde entonces mi visión se ha deteriorado y lo peor de todo es que no puedo ver de cerca, cuando antes mi visión cercana era perfecta, todo ha sido un desastre, mi vida cambió y el lasik arruinó mi manera de ver el mundo. Simplemente lo peor, no se lo recomendaría a nadie. Ojalá pudieran sacar a LASIK del mercado en todos los países, para evitar muchos más desastres en la visión de quienes tan solo desean ver mejor y ponen seguridad en manos de oftalmo logo que piensan que van a curar su miopía o astigmatismo a través del lasik. Por eso apoyo el retiro oficial del LASIK. LASIK me ha arruinado por completo la visión, y ahora tengo que ver la manera de poderlo solucionar, espero poder ver mejor en un futuro y corregir lo mal que me dejó esta catastrófica operación.

Read so many horror stories about this surgery, and it needs to be outlawed. I feel so bad and sad for everyone who has had complications from this surgery:(

Lasik suicide. My one and only child committed suicide after 1.5 years of struggle with bad Lasik job. He was only 22. His night vision became very poor. Please have FDA pull this off the market at all cost. How many people have to die?

I have severe permanent pain as result of LASIK. The doctor is still do surgeries.

I got my lasik eye surgery from Grewal Eye Institute, Sector-9 by Dr. S.P.S. Grewal, Chandigarh, India & i am not satisfied with Dr. Grewal & surgery result at all.
LASIK ruined my eyes and quality of life.

January 12, 2005. A day that I wish I can erase from my life. The day that will hunt me forever until my life has run it's course. This is the day I got "Custom Lasik" which should have been called a Custom Nightmare that will last a life time!! I suffer from bad GASH. I see dayburst, starburst, double vision, Glare, Halo's, Light sensitivity, loss of contrast, dry eyes, headaches, fluctuation vision. Opting to "throw away my glasses" has been the worst decision of my life by far. LASIK destroyed my promising life and career. Suicide cross my mind less than a year after I got LASIK. I had to learned how to beat this and coupe with it. I couldn't believe what was going on with my life, it totally took a 180 for the worst. I really can go on forever about this dreadful surgery but I'm not going too b/c the damage is done and cannot be fix. Because of LASIK, my trust in doctors are at 0 percent. I can't see a doctor w/o asking a thousand and one questions. So I leave you all with this. If you are an eye doctor I have not forgotten, my eyes will not allowed it. This surgery is senseless and inhumane and you all need to be ashamed of yourselves. You are lower than dirt, you are by far worst than the world maddest serial killer. You guys are the worst type of criminal. You may have taken my healthy eyes from me, but you gave up your integrity, dignity, and oath to protect the public for a few bucks that you will not be able to take to your grave as well as your judgement. Oh yeah and I was only -1.75 in both eyes and my eye doctor recommend I get this painless surgey. "Painless My Ass". A 10 min surgery that equal a life time of pure pain. I do believe in karma. If you doctors have an ounce of humanity in your heart, give up the ghost.

I am an ophthalmologist who is appalled at the unacceptable complications of this cosmetic procedure.

My right eye developed Keratoconus after 3 attempts to improve my vision with Lasik. I've had multiple surgeries on the eye with the last one in 2007, where intacs were inserted in my eye. My next procedure, which will cost $3,900, is scheduled in June of 2012, and this is called cross-linking to solidify the cornea. Lasik has been a nightmare for me and has ruined my life.

My husband suffered retinal tears x3 followed by a retinal detachment and finally a retinal re-detachment 5 weeks after Lasik
My vision is permanently damaged because of LASIK and I have the latest custom Wavefront technologies applied. This is horrible.

I have seen too many of my friends and family suffer from LASIK. It needs to stop as it is causing so much more harm than good.

the fact that the FDA continues to ignore the disaaster that is Lasik, is appalling.

I have been very frustrated with my vision which does not seem corrected with contacts or glasses and looked into Lasik, even though from the start of it years ago, i knew it was too good to be true and wondered what the long-term consequences might be. These reports are so disturbing and it just goes to show that if it sounds to good to be ture, it probably is. I dont trust FDA on anything anyway; they have the proof of the problems and yet this surgery continues. Our country is a mess and here’s one more example. My heart goes out to those injured

My daughter was almost talked into it until I found your website. Thank you for alerting us to it.

complications due to lasik surgery, dry eyes and partial loss of color vision

Had LASIK 5 years back and suffering since then from pain in the eyes, dry eyes and vision fluctuations.

More than 6 months have passed i got my intralase lasik surgery done from Grewal eye institute at Chandigarh, India but even till date vision of my left eye is not perfect. I got my eye-sight tested from some other doctor & as per his report i still have no. in both eyes.

My Post-lasik no. after 6 months time duration is:
Right Eye SPHERE: +0.250 & CYLINDER: -0.50 ASIS-015 & for
Left Eye SPHERE: +0.50 & CYLINDER: -1.00 AXIS – 005.

Before lasik surgery my no. was:
Right Eye SPHERE: -1.50D & CYLINDER: -2.50D ASIS-180 & for
Left Eye SPHERE: -0.50 & CYLINDER: -2.50D AXIS – 170.

Sir i choosed for best institute, best doctor & best option i.e. bladefree (custom) as suggested by him. Inspite of this my eyes didn't got perfect due which i feel depressed/tensed.
LASIK eye surgery is 100% misleading. 1 month after the surgery, I was already experiencing symptoms like dry eyes, and halos. I have acquired more symptoms after 6 years of wondering what’s coming next for my eyes. I have distorted vision, halos, tired eyes, headaches, and a weird blur that never goes away. These are the symptoms obvious to me, but I’m frightened to know what the future holds for my eyes and my life. The fear of going blind and not being able to see my children terrifies me. I paid LASIK to RUIN my life... I regret the 1 month of zeal after the surgery because I recommended LASIK to everyone I could. Now, I wonder how many people took my advice and let LASIK destroy their eyes also.

I had Lasik almost 3 years ago and pain and dryness and now refered nerve pain from this long term chronic issue continues to dominate my life and reduce my enjoyment of everything and affect those close to me as well. I have felt suicidal with it, I struggle find the strength to carry on. I was an energetic positive person running my own business, I was looking to remove the ‘hassle’ of glasses and contacts. It makes me feel sick to think back. I have forgotten who I was. I am trying to seek compensation for what it’s worth (more to make the point so I’m not another one of their positive statistics) but it’s like dealing with robots. This procedure is dangerous and life ruining for some people. My surgery was deemed to go well (in their view), my eyes were suitable, I was young and v fit and healthy...

I have dry eye disease from wearing contact lenses and I do not think anyone should ever risk their eyes for any reason especially not for cosmetic purposes.

ince my lasik surgery in 2010, I have a lot of complications; black points, starbusts, dryeyes. I don’t recommend this surgery.

As a new glasses/contact wearer, I have been reading up on LASIK surgery and I am shocked to find all the associated risks and potential complications. I believe that LASIK needs to be stopped, and another alternative should be found.

I have friends of mine that have had this cosmetic procedure and are very sorry they did. God gave us one pair of eyes and for a doctor to mislead patient for a profit is a crime and should be charged as one.

I think that’s a great aggression to the cornea, the only transparent tissue of our body. I see on my practice, many eyes with problems caused by theses surgeries.
my experience with laser surgery is not so good. i undergone through laser operation in jan 2002. my glasses power was -7.5 in both eye after operation left eye glass power was -1.0 and right eye was nil(6/6), but after 1-2 years both eye again got the number close to -1.75 with some cylindrical power, now after 10 years my glasses power are -4.5 and -4.0 with cylindrical. so i have to completly rely on glasses. i dont know whether this number will go on increaing

after listening to a story of lasik gne wrong

Because Lasik surgery has caused me so many problems with my eye sight to the point that I am gonna need cornea transplants (both eyes). Further, I cannot see at night so I cannot drive. Turned into a handicapped after Lasik surgery

After reading all about this, im glad I have not went throught witht the procedure. Otherwise I would have made the biggest mistake of my life. I think they should outlawed, and should be sued. Patients are putting their trust to a stranger, and risking their lives for better vision. Thats at their own risk.

I had lasik and now have extensive floaters and vision is deteriorating and I'm only 35 years old

I'm so mad!!! I've been living with such rotten vision since 2006., I was messed up day one and it just got worse.!! No ONE said it could be this bad!!! Swervy world, loss of contrast, ghosty line around people. squares aren't square, circles aren't round., things aren't clear... and it costs a boatload of money to get any contact that even help. It doesn't fix it all, but helps,, and I will have to worry about being fit for lenses for the rest of my life..! My irregular corneas cannot be fit with regular hard or soft lenses.. But only with contacts that overall cost thousand of dollars and add more cost every couple years to get replacements.. And The emotional trauma I went through and the daily PAIN I go through still (cuz you can't escape it) every day.. You can't heal from it, because it's right in front of you every waking minute. This needs to be banned.. I've met too many others personally myself that have been harmed. If I am only ONE person and meeting so many, you know (continues on next page)
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how many others are out there, besides the one on this petition. Not every harmed know there is a petition. And think of those who really NEED corneal transplants.. we can't donate our eyes, and some of us have to use the transplants that others could have, because now our eyes are so totally damaged. I'm just sooo angry!!!! And pray that it is stopped!!! I am so sorry to all of you who have been through what I have. So sorry!! We need doctors to help those of us harmed, in finding some way to repair the damage without causing more damage.. Too many people are suffering!

I am 45 yrs and have been wearing glasses for almost 30 years. I was just about to get a consultation for LASIK when I came across this website. I am a pharmacist so I KNOW how unscrupulous the FDA can be. I appreciate others sharing their stories, as now I have decided to forgo the procedure. I might investigate Ortho-K, which is non-invasive and temporarily reshapes your cornea.

i was thinking of getting it, but now it seems unsafe. i have been getting spammed by lazik vision institute which seems too a lot of damage (now that i have googled them) via KCG Marketing, PO Box 27002, West Vancouver, BC Canada's unwanted SPAM.

No idea how it will effect my vision as I age..

Within 3 yrs post LASIK, my vision began to change with the left I changing more than my right eye. Extreme dry eye and having a steep yet blunted eye made soft contacts difficult. Having different acuity in each eye also makes reading difficult. I have had ductile plugs to help ease the extreme dry eye, but those did not alleviate the problem. I am frustrated that optometrists are not educated in treating the issues of the post LASIK eye.

I have severe corneal ectesia after getting LASIK in 1999 and if I could go back in time I would skip the LASIK.

i am a victim of poor outcome to lasik

Wavefront Lasik has ruined my quailty of life. Anyone thinking about this procedure should be very careful. I would outlaw it.

Lasik has ruined so many lives. This is the worst scam I have ever heard of.
lasik has severely altered my ability to function

After 4 years & eight thousand dollars later my left eye has gone blurry & double vision. ghost like tv screen. I have been back to the wanker in maroochydore who did the stuff up only to be told that it is normal. 1 month after the initial op he had to have another go at it. at my expence. I would not recomend getting it done to anyone. God only knows what it is going to be after another 4 years. these con men ought to be put out of action.

thanks jim for the info....never going to get lasik now!!

unnecessary permanent eye injuries are occurring due to negligence of the manufacturer, the FDA, and the doctors not informing the patients of ALL the problems with this procedure.

do not do lasik! the chances of becoming blind are high

I am left with double vision and will need both scleral lens and glasses, permanent nerve and muscle damage, distortions, and peripheral vision loss.

I am extremely furious that a doctor allowed me to undergo LASIK when I was only 20, with a lot of red flags such as a thin cornea, mild astigmatism, dry eye problems...etc. As somebody else mentioned this is criminal. Only 3 years after I began experiencing severe vision distortion from ectasia, which has no conceivable solution or cure, and will only keep advancing. I am terrified that my eyes will be useless before I am even 30. DO NOT GET THIS SURGERY, IT IS NOT WORTH IT!!

After doing extensive research concerning LASIK, I am appalled that this travesty continues without being stopped. My God, we are talking about EYES. The evidence is overwhelming that LASIK should be stopped. The FDA has know this for years, but continues to be part of the problem instead of being part of the solution like they’re supposed to be in matters like this. Another classic example of a federal government agency gone amuck, and everyday citizens just get lost in the shuffle. People are not being informed enough about the serious complications of LASIK that occur more often than they are being lead to believe when they inquire about having this procedure done. Like Dr. Waxler stated in his last open letter on the web in April, “There is no informed consent for a medical coverup”.

Personal experience of suffering post Lasix chronic dry eye. I feel I was not made sufficiently aware of the risks and subsequent to the problem presenting indifferent (continues on next page)
response of doctor. Feel completely disillusioned with the medical professions as a result.

I have friends who have had serious eye injuries from lasik surgery

I had lasik done at the age of 23 and i am 26 now . I have develop several problems such as astagmitism and still no one telling me what are the problems . i am so scared , feeling depressed , anxiety and confused all the time . Withing 6 months my eye sight has flucuated a lot and i dont know still whats going to happen next . please never do this my prescription was very less but i needed for the police job which i never got . i feel like to cry

I had wavefront lasik and totally and utterly regret it. My eyes are so dry and painful and my vision is really poor. My life has changed completely since. I would tell everyone not to have it done.

My lasik surgery consultation did NOT make clear the potential risks of this surgery. They dismissed them.

Had I been told of all the risks to lasik, I would have happily wore my contacts. My vision started to get poor and needed to wear glasses again after only about a year. My night vision is also poor (with glasses on). I see glares and it does tire my eyes out after awhile. I have a friend who had a terrible experience with his surgery and had to get a second one. FDA needs to look closely at the failed surgeries and everything in between. Successful surgery should not include dry eyes, vision regression or night vision glares either. Thank you.

Successful surgery should not include dry eyes, vision regression or night vision glares either. Thank you.

I had Lasik done in 2008. I suffered with Dry Eye for about 8-9 months after surgery. It was not worth doing the surgery considering the discomfort and frustration caused by dry eyes.

My eyes were ruined by lasik eye surgery in June 2011 in London. Search "OPTIMAX" on YouTube & my video is number one!! www.youtube.com/watch?v=DUFzAK0XmEc
The surgeon left my eyes de-centered & me with major problems! Including Starbursts, ghosting, MGD - which I DID NOT have prior to surgery. I can prove negligence & am taking legal action.
I support Sasha Rodoy's UK campaign calling for for (continues on next page)
708. **Name**
    
    **From**
    
    **Comments**
    (continued from previous page)
    government legislation to regulate this dangerous industry! THEY NEED TO BE STOPPED!!!
    www.epetitions.direct.gov.uk/petitions/28629
    
    More people need to know about this. I have moderate myopia (-4.00 in my right eye, -4.50 in my left), and mild astigmatism (0.50 in my right eye, 0.25 in my left), and I was honestly so desperate for my eyesight to stabilise so that I could have LASIK. I didn't care how much it would cost, and I have a friend who had it about 7 years ago who said it was great, but for some unknown reason that is starting to make sense now she never really wants to talk about it. I am SO glad I've done my research, I suffer with anxiety and depression right now that is bad enough to stop me working, so if the outcome wasn't perfect, it would ruin my life. I would want to kill myself. I just want to say thank you to all the people who have shared their stories so that other people like me can know the truth, it just breaks my heart that I can't help you. :'(
    
    In 2011 my eyes were damaged following Lasek in the UK. My subsequent obsessive research discovered countless others also damaged, most staying silent thanks to depression/PTSD etc... whilst many others silenced with pay offs linked to 'gagging' orders.
    I launched the UK campaign for government legislation in February 2012 & fully support Morris Waxler & anyone else fighting for the truth to be told & this industry stopped from ruining people’s eyes & lives!
    Sasha Rodoy: info@mybeautifuleyes.co.uk
    
    My daughter told me she is scheduled to have it done. I researched it because I did not think it is a bright idea, and I learned a tremendous amount of unnecessary problems that will afflict many unknowing people including my daughter.
    
    For a few years now I have been reading about the lives destroyed by LASIK. As these patients age, their chances of complications will increase. Stop the damage!
    
    I had a successful "permanent" procedure done 11 years ago. My eyesight is now worse than at that time and I wear glasses full time.
    
    Went for a consultation and was told I was a perfect candidate (-4.50 and -5.00). Set up the appointment to have it done and then chickened out thank god. I'll stick to my soft contact lenses.
    Especially after reading this!!! So this petition is working.
I have personally had a bad LASIK outcome due to the incorrect information given to me about the risks of the procedure.

I'm an ophthalmologist, employed in Clinical Contact Lens department. I meet the patients with the post LASIK complications very often. It is a very good period for the refractive surgeons in my country now. Everybody wants to do LASIK!

I only want that the patients get honest and real information about everything which that method could bring to them and that official institutions, like FDA, make a real limits for the fotorefractive surgery.

I was affected by the bad outcomes of LASIK eye surgery in 2004 at the age of 19. I had horrible dry eyes that severely affected how I functioned. Even four years after my surgery I had to quit a job working in a lab due to my inability to be exposed to the chemicals I needed to use to perform my tasks. This surgery is truly a disappointment for many and hope it is band before others get hurt.

I had LASIK a month ago thinking that its been around for a long time and is established. I now find out that it is unsafe. I have double vision, spots in vision, dry eyes, a permanent flap cut in my eyes (that I was told would heal, but it won't), terrible night vision with starburst, halos and hard time seeing in darker areas and headaches. This has caused massive depression and anxiety and I am now in constant fear of having more severe eye problems. It makes my job much much harder since I work on computers for 8 - 12 hours a day. Worst mistake of my life by far. I was misinformed or had the severity of issues with LASIK down played by the doctor. If I had known how it really was, I would never have had this procedure done.

I had Lasik in 2005, and I have had complications ever since. I've experienced and am currently experiencing dry eyes, fluctuating vision, regression of vision, and more. I am scared that I soon will not be able to drive to work to support my family. This elective surgery had stolen the person I should be. My family and I suffer everyday. Please stop this ELECTIVE surgery from ruining more lives!

I had lasik done 15 years ago, big mistake... I have a big problem on my right eye.

Having Lasik ruined my eyesight
So other people don't get misled by how good this surgery is supposed to be-I have nothing but regrets for doing it and a lower bank account-Still wearing glasses.

I did my lasik 10 years back. my sight was fine for just 3 months post lasik...then it slowly deteriorated. I had only -1.5 and -2. Now i have got cylindrical power also. Now i can wear neither soft lenses nor spectacles. My power is so much that spectacles cant be made. Only option i had was hard lenses...which is REALLY HORIBLE to wear and maintain. Now i have started to have keractomus as well....so plssssss....be happy with ur soft lenses and specs...

being a doctor i realise the kind of vested interests lasik surgeons hav

keratocone post lasik des 2 yeux suite internetion sur grenoble , crosslinking oeil droit en, 2009 et gauche en 2012

I had rk on my left eye in the early 70's. It is continuing to deteriorate with no apparent solutions. Is anyone out there receiving help from ophthomologists?

I had Lasik 7 years ago to correct nearsightedness and no other problems and now need glasses for blurred farsightedness vision!

FDA must face life prision, they have destroyes many people eyes and lifes

These surgeons performing Lasik eye surgery who work for private clinics, should no longer be considered surgeons, but entrepreneurs. They let profit and greed cloud there professional judgement, resulting in Lasik surgery being performed on high risk patients, leading to serious side effects and complications. They are ruining the lives of innocent patients and must be stopped. These highly unethical acts are unacceptable. STOP ALL LASIK PROCEDURES!

I incurred huge loss of vision and quality of life from having Lasik surgery done to me in 2010. This procedure needs to be banned. My life is basically destroyed from this.

Herzig Eye institute in Toronto lied to me. Before my procedure, they never told me all the risks and the severity of the risks. After my surgery, I experienced severe pain, halos, starbursts, conjunctiva hemorrhaging, and dry eye. (continues on next page)
They said these side effects would go away. I had the surgery 5 months ago and eyes still burn throughout the day. I constantly need eye drops. I am too afraid to drive at night. I was also undercorrected. People need to stop falsely advertising lasik. It destroys peoples' lives. I regret the decision everyday. I constantly feel depressed. I am 22. I am in dental school and I need my eyes. Lasik has ruined my life.

I'm a RK survivor. The ophthalmology community has been aware of the complications of RK and Lasik for many years, but do nothing to stop it because there is so much money to be made from treating the side effects from the surgeries. Shame on the ophthalmic and medical professions for butchering for profit.

After a Lasik-Monovision procedure 18 months ago, I have worse vision than pre-Lasik. On a recent second opinion I was told that I was not even legal to drive. My issue is that since the Lasik gave me severe dry eye in which I can't seem to heal from making my vision fluctuate--they won't correct the vision until the dry eye from Lasik heals (it's been 18 months) and legally I can't drive? I am a working mom with 2 kids--this was not communicated to me in a well-balanced fashion! Not to mention the severity of what chronic dry-eye means, i.e wake up in the morning with eyes shut until I put drops in, pain, blurred vision and what seems to be a permanent need for eye steroids to survive.

A letter for help
January 2007. After graduating from college, I accept to do LASIK myopia surgery. 1200 degrees of myopia before surgery. After surgery the abnormal dry eyes. A month after the surgery, my left eye began to be uncomfortable together. The left side of the head is not comfortable, that will get better over time, but did not, and it is more and more serious. That time the eyes eyelids feel no serious tear of lubrication left eye than the right eye. But not in pain, eyelid not broken, so that time does not particularly care about. Never know what is dry eye. Because dry eye phenomenon never had before surgery. The postoperative corneal a neurotomy perception reduce corneal did not feel dry and hot. But the upper and lower eyelids often becomes inflamed, bloodshot. Six months after surgery eyes slowly began to ache. The eyes are very dry eyes like a stinging pain morning, and almost earned not open our eyes. Even worse is very serious pain in the left eye, and along with the left side of a headache. The left eye often tears, and often pain blinded. Eyes closed, lying on the
bed, his left eye is still very uncomfortable. Every day, there can not be normal learning and working. How can not get out when feeling left cornea and left eye, upper and lower eyelid and the left side of the head daily pain, like a knife bar from the eyes to the head, like a left eye eyes inside a small stone mill to rub off. Time every day, can not sleep, frequent insomnia, can not rest, eyes closed, unable to relieve pain. Sleep until 3 o'clock to 4 o'clock every day will be the left eye pain and headache to wake up, and could no longer sleep. The left side of his head is feeling the same pain like cramps. Headache until today left eye pain and left the light weight, serious when there is no way to be alleviated only hard with the palm of your hand to press the left eye and squeeze the left cornea. Serious when trying to dig out the left eye to freed. Often feel eyes closed roll his eyeballs sometimes more than open eyes uncomfortable. Blink more painful than not blink. That time often check my eyes and the upper and lower eyelids. Because the left side of the lower eyelid dry eye, left eye damage and ulcers. Left eye eyelid is more than the right eye redness. The eyelids also very swollen. And headaches that may have a direct relationship. Left eye pain and headache then to now has not been much improvement. Until August 24, 2011, there were some changes. Since that day I did lasik the secondary left eye corrective surgery. The left cornea eccentric irregular asymmetrical get a little bit of correction, but after surgery to improve pain and dry eye effect. The postoperative left eye pain and headache alleviate. Although left eye morphogenetic get a little improvement after the second surgery, left eye pain and headaches improved than before, but corneal shape has not been fundamentally changed. The problem persists - my left eye is still pain and accompanied by a headache, but lighter than before. 8 months after corneal morphology rollback. The curvature of the cornea above seems to increase. Schirmer coating seems to have problems, aggravate dry eyes and headaches. The pain remains a serious problem affecting my life - during the day and does not work learning, the night is not normal sleep. Sleep around 5:00, I will be left eye pain and headaches wake-up to, and can no longer sleep in pain every day. Although pain than the previous three or four o'clock in the morning we wake up stronger. But the whole body is still getting worse, the body immunity getting worse. From 2007 to today, my life has been unable to take care of themselves, have been required family members to take care of every day still does not sleep. Although the daily difficulties and eye pain and headaches affect sleep sleep, will not be able to work and

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learn. From 2007 to today, the binocular vision is very bad. Poor night vision. The nighttime glare very serious, was able to go out walking and driving. More do not know the road, at night is very difficult depending on the material. Now the left eye is still about 150 degrees of hyperopia and astigmatism of more than 150 degrees.

I have a love of philosophy and art. Young people a love of life and thinking. I once wrote a philosophical treatise of thirty thousand words "Art, the presence of vitality." Has a profound insight into the human vitality. I had a dream to be a philosophy professor. But in January 2007, everything changed. The postoperative left eye pain and headaches so I have no way Rethinking macro-proposition of the life of the universe. Able to survive normal eating and sleeping is my proposition. If the instinct of these people need to be very difficult, then what is contributing to society? Everything thinking around my disease. I was seeking a variety of ways to just quickly put my cure. From 2007 to August 2011. Four years, traveled to hospitals across the country for medical treatment. Help many many doctors doctor. Help over including ophthalmology, sinus Division, Department of Neurology, Neurology, Immunology, liver and kidney Branch spine Branch, dental, etc.. Systemic done several checks, including full-body CT repeatedly, the brain CT multiple sinus CT several immune five checks several times, rheumatic detection times, blood urine test repeatedly, spinal X-rays, chest X-ray optic nerve detection, head of neurological tests many times and so on, without any problem. Even try to do the sinuses abscess surgery. Since then left eye pain and headache thought it was a sinus cysts cause, so do unnecessary surgery. No improvement at after regret. Order the cure spent nearly 300,000 yuan of money, but still to no avail. The left eye pain on the left headache still not seen any improvement. Although the body has done repeatedly over the checks are no problem, but the eye examination several times to check out the dry eye and eccentric cutting. Eyes in each hospital to check his eyes after LASIK dry eye. Wenzhou Eye Hospital check: the bottom of the right cornea often punctate staining, the bottom of the left cornea sustained punctate, strip, sheet stained. The binocular eye conjunctiva nipple hyperplasia, such as conjunctiva small follicles. The double tear film is incomplete. The binocular basal tear test right eye for the 7mm, 4mm left eye. Tear film breakup time right eye but = 1 second left tear film breakup time but = 0 seconds; checks, Beijing Tongren Hospital: eyes the basal tear test right eye 7mm, left eye 5 mmBut the left tears membrane is not complete; the Guangzhou Zhongshan Ophthalmic (continues on next page)
Hospital test: corneal limbus below the left and right side the visible large number of point-like staining FL (+); ENT Hospital of Fudan University, checks, experts believe that my left eye after LASIK surgery irregular eccentric cutting, so the cause of dry eye symptoms. The Professor of Beiyisanyuan think my left eye pain and headaches and visual fatigue. Hyperopia, astigmatism, glare can cause a recurring visual fatigue and headaches discomfort; doctor thinks double cornea after my LASIK surgery asymmetric index is high. Than before surgery, the cornea was more irregular asymmetric morphology. Partial left eye cornea center cutting can cause eye fatigue can also lead to severe dry eye; doctors think I corneal nerves has not yet returned to normal levels, they believe that the general postoperative year corneal nerve basic recovery, but some people need to longer; doctors believe excimer cutting more than 1,000 degrees of myopia center of the cornea is too flat, too steep surrounding. Reduction of central corneal curvature and increased peripheral corneal curvature, the tension and Pressure of the eyelids on the cornea concentrated in the periphery of the cornea, rather than central. So the eyelid no better oppression central corneal makes central corneal sensitivity reduced sensitivity to reduced tear secretion. This is more apparent in the corneal topography of the comparison of the left-eye and right-eye. Combined with the left eye eccentric Consumers cut the lead to severe dry eye caused by tear film coating uneven. Some The doctor thinks my left eye corneal topography on top of curvature change too suddenly. Curvature of the cornea soon change from 43D to 33D. The transition from the short and not likely to cause the upper eyelid blink uneven corneal tension and tear coating uneven. Plus the central cornea perception lower decrease in tear secretion. The periphery of the cornea steep, easily eyelid to form a larger tension and friction of the cornea steep, easy to aggravate dry eye symptoms and headaches.

In short, this non-human suffering all day torment haunt me, I can not stand. I do not want to die relief. Do not want to put their own eye dug to relieve the pain. I have always felt that there is still hope. Is blind Well than this pain. Is replaced the cornea also did not like me so painful ah. At least not like me because of left eye pain and headache, there dry eye seriously affect sleep ah! I traveled all over the country to find a lot of doctors, they do not have a good way, The doctor will say: like me, only to find the first time you do lasik surgery doctor to help you solve. They would say: do the surgery in which hospital you go to which hospital they give you. I find many of my surgeon and his
hospital, they did not have any way, and very irresponsible to tell me: My question and their operation does not matter. I really have nowhere to get consultation and treatment desperation. So request you kindly doctor to help me, I really have the heart of the removal of the eye. I hope that doctors consider surgery to help me solve the problem, including lamellar keratoplasty surgery. I hope to restore some of the central corneal thickness and central curvature doctor who can help me to save my eyes, no matter what way. If the surgery can be restored. Then surgery all risks and consequences to be borne by the patient himself, can a lawyer do notary. I hope the doctor who canceled the concerns and worries. Help me to improve central corneal morphology. Now because of eye problems, because the night unable to sleep, the body is getting worse, trance memory decline. My immune system is getting worse each organ problems, it seems there are problems with the body's metabolism. My wife is very good, she was always there for me to take care of me and help me. The more so the more I feel guilty. Her into trouble because of my illness. Sometimes I really want to walk away from the pain. But I am worried that my family would feel sorry for me. Worried about my wife alone and helpless. The family always encouraged me to let me brave and strong in the face of difficult! I remind myself all the time my illness is getting better. But again and again the active treatment and in exchange fail again and again. Again and again to seek medical treatment, but in exchange for a second doctor who cold-shoulder treatment. I hope to win and beliefs do not know how long it can hold?

My sister has also done a lasik surgery for myopia. We do the surgery in a hospital. 600 degrees of myopia before her surgery. After her surgery and some dry eye syndrome. But after six months to disappear soon improved. My cousin did the lasik surgery for myopia, myopia 500 degrees before surgery. The basic symptoms of dry eye after surgery. Many of my friends also done lasik myopia Surgery. Their pre-operative are basically 500-600 degrees of myopia, 100-200 degrees of astigmatism. Within one year after surgery, dry eye symptoms have disappeared. I was the only the highest myopia, up to 1100 degrees. Postoperative only my dry eye has not improved. And getting worse. From 2007 to today, the past five years, I have used countless ways to the treatment of left eye pain headache and dry eye. The doctor's advice with lot many ways no better but to no avail. Over the past five years including the use of a variety of artificial tears. Including imports of preservative-free artificial tears. Ten minutes with artificial
tears. For example the Carboxymethylcellulose Sodium Eye Drops times contingent, Dextran70Eye Drop, Refresh, URSAPHARTM Arzne Hycosan bought countless but the effect is minimal. Has been used the lacrimal embolism - including tears of the Smart Plug and tear duct plugs used many times and no improvement. There are contact lenses, with the the the zero mirror and RGP protect the cornea Medical, the result is more wear worse, can not be tolerated. Has always insisted on using eyedrops - including a variety of anti-inflammatory drugs and surrounded neomycin improved, used hundreds of anti-inflammatory drugs, but with much more dry eyes. Oral medications - with Chinese medicine including western medicine to stimulate tear secretion and Yin and enrich blood effect. Only slightly ease the symptoms of dry eye, but not of much help to alleviate the left eye pain. Moreover, long-term medication appears significant side effects, and a threat to other organs. Eat traditional Chinese medicine has been insisting for nearly two years. Dry eye pain, but can not solve the problem. Health care products - always insisted on eating a variety of vitamins and lutein, as if no effect. Adhere eaten for some time, analgesic drugs and psychotropic drugs - including various antidepressant anxiolytics and Western medicine and traditional Chinese medicine to promote sleep, in addition to the brain unresponsive, eye pain and therefore alleviate. Contrary eat these drugs more dry eyes. The treatment of dry eye include Chinese acupuncture and fumigation by grinding and eye - including eye acupuncture and body acupuncture conditioning, but no substantial improvement in the left eye pain and headache problems. However, I seem to comfort. Also include a variety of physical therapy, the left eye ocular anti-inflammatory therapy, the effect is very short-lived. The above method can not improve pain problems. The left eye pain and left headache and still can not be mitigated. Serious still use the palm of your hand to press the cornea and the eye to relieve the pain and headache. Submandibular gland transplant ever wanted to do to ease the most frustrating case. It is a major surgery, the mouth is very dry after transplantation. Doctors do not recommend that I do so, because of the lacrimal gland and tear secretion is good. They think my problem is that the shape of the cornea. The fact that, as they say my question exactly corneal shape.

On August 24, 2011, I do left eye secondary lasik surgery. It is guided treatment of hyperopia and astigmatism, corneal topography (T-CAT) LASIK surgery. Corneal shape after only a little change, but it was to improve left eye pain and headaches as well as to improve the effect of 

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dry eye is very obvious. Sleep also improved a lot. Later, I proposed to the doctor again lasik surgery. Vision, I do not consider. 1200 degrees of myopia even back to 2007 years ago, I was very happy. I am also very pleased to wear thick glasses. The key is to corneal shape. But the doctor said I corneal thickness has few remaining. In this case, I think a to do corneal stroma microlens filled surgical implantation. Femtosecond lenticule re-implantation transplant a lenticule. Is to cut the corneal supplemented back. Although it is not possible to completely do as morphology before lasik surgery back in 2007. But I think if you restore some form of increased central corneal curvature can be a good solution to my problem. To correct a little eccentric cutting. Lamellar transplantation the corneal technology has been very mature, allograft the corneal rejection probability is very low, not to mention micron calculate the thickness of the cornea corneal microlens. I want to fill my original corneal flap corneal microlens to improve my cornea forms a 600-800 degrees. As before people do 500-600 degrees of myopia lasik surgery, very few people will have to dry eye, corneal topography and central corneal curvature and has not changed much. Problem will do lasik surgery myopia above 1000 degrees. As the doctor said central corneal curvature is too low causes the eyelid tension and pressure is concentrated in the periphery of the cornea, rather than central. Restore central corneal curvature to reduce peripheral curvature fundamental improvements in tear distribution. If filling ineffective also can take down. If you fill really solve my problem until it becomes better and better, then my life is no longer a tragedy! Future and hope no longer slim! Moreover, this method can help more people who need help!

2007年1月。大学毕业后,我接受做LASIK近视手术。手术前1200度近视。手术后双眼干燥异常。手术后一个月,我的左眼开始难受起来。左边头部也不舒服,以为过段时间就会好,可是没有,而且是越来越严重。那个时候双眼眼睑感觉无泪液润滑左眼比右眼严重 ... 虽然每天很困顿,但眼睛疼和头疼影响的就是睡不好觉,更无法工作和学习。从2007年到今天,双眼视力也非常不好。夜晚的视力很差。夜间眩光非常严重。无法外出行走和开车。看不清楚路。夜晚视物非常困难。现在左眼仍有有150度左右的远视和150多度的散光。

我曾经是一个热爱哲学与艺术。一个热爱生命与思考的青年。我曾写过三万字哲学论文《艺术、存在、生命力》。对人类生命力有着深刻洞悉的人。我曾梦想做一名哲学教授。但是一切都在2007年1月份被改变了。术后的左眼疼痛和头疼使我无从再思考生命宇宙之类的宏观 ... 点状,条状,片状染色。双眼眼睑结膜乳头增生,结膜小滤泡等。双眼泪膜不完整。双眼基础泪液测试右眼为7mm,左眼为4mm。但泪膜破裂时间右眼but=1秒,左眼泪膜破裂时间but=0秒;北京同仁医院检查为:双眼基础泪液测试右眼为7mm,左眼为5mm,但左眼泪膜不完整;广州中山眼科医院测试为:左右侧角膜下方巩缘可见大量点状染色FL(+);复旦大学五官科医院检查后专家认为我的左眼LASIK手术后有不规则和偏中心切削。所以造成干眼不适症状。北医三院教授认为我左眼疼痛和头疼与视疲劳有关。远视、散光 ... 膜地形图上边曲率变化过于突然。角膜曲率从43D很快转变到33D。距离短没有过渡,容易造成上眼睑瞬目对角膜张力的不均衡和泪液涂布的不均衡。加上角膜中央知觉降低泪液分泌减少。角膜周边陡峭处容易与眼睑形成较大张力和摩擦,容易加重干眼和头疼等不适症状。

总之,这种非人类的痛苦整天折磨着我纠缠着我,使我无法忍受。我不想以死解脱。也不想把自己眼球挖出来来缓解疼痛。我一直觉得的还有希望。就是眼睛瞎了也要比这种痛苦好啊。就是换过角膜的人也没有像我这样这样痛苦啊。至少不会像我一样因为左眼疼痛和头疼还有干 ... 家人会为我难过。担心我的妻子会孤独无助。家人总是鼓励我让我勇敢坚强的面对困难!我每时每刻都在提醒自己我的病会好转起来。可是一次次的积极治疗然后换回一次次的失败。一次次的求医问药却换回一次次医生们的冷漠对待。我那必胜的希望和信念不知还能坚持多久?

在2011年8月24日,我做了左眼二次lasik手术。那是个治疗远视和散光的角膜地形图引导的(T-CAT)LASIK手术。术后角膜形态虽然只有一点改变,偏心得到一点纠正。但当时改善左眼疼痛和头疼还有改善干眼效果却非常明显。连睡眠也改善很多。后来 ... 角膜周边而不是中央。恢复角膜中央曲率降低周边曲率会根本改善泪液分布情况。如果填充效果不好的话还可以取掉。如果填充后真能完全解决我的问题直至变得越来越好,那么我的人生就不再是一个悲剧! Future and hope no longer slim! Moreover, this method can help more people who need help!

I am experiencing chronic dry eye 2 years after my lasik procedure! I have never had this condition before previously.

I had Lasik eye surgery in 2001. My right eye was under corrected, therefore, had an enhancement in 2003 resulting is good vision for several years. In 2012, I noticed I could not see to drive or read. I have now been diagnosed with Keratoconus and Corneal Ectasia after lasik. I am very depressed.
I had IR Customvue Lasik Laser Vision correction on December 15, 2010. On checking i was found to have a refractive error of RE -4.75 DS / -1.50 DC x 40 and the LE was -4.50DS/-2.75DC-140. The corneal topography was normal and the central corneal thickness was 530 microns in the right eye and 521 microns in the left eye. The fundus, anterior segment and adnexa were within normal limits.

After this i had halos & starbust. Again i had lasik on june 2011 & dr. Increased my optical zone but my halos-starbust hvnt gone. They still there.

Then again i had lasik a on 6th January 2013 on left eye. Dr. Increased my zone to 8 mm & they said its maximum zone they can do but my halos starbust are still there & now i cannot read near things. I got nearsightedness problem also. Im very tensed & disappointed. If you have any solution please let me know. Dr saying your pupil size is large that is why you having these issues. I am very depressed, annoyed, frustrated and sad. What I really want is to get back a normal vision

I had all lasik surgery from Dr. Vipin Buckshey, Visual Aids Centre, 8, Ring Road, Lajpat Nagar – IV, New Delhi -110024.

Awaited reply.

Regards,
Deepak Kapoor
+91-98990-29700
deeppakkapoor297@yahoo.com

I believe the long term risks of lasik are not being exposed. I also dont want to be a blindo by the time I am 50.

I dont want vulnerable and ignorant people to get hurt.

what is side effect of lasik laser

I had LASIK and bad outcome

My friend had a bad outcome and is now struggling everyday.

I had the LASIK surgery with very bad outcomes (starburts, hellos, dry eye, distorted vision, headaches etc). Overall quality of life is reduced with this procedure. Its side effects are described by doctors as 'nothing permanent' yet they are. This operation is very dangerous and should be banned. Doctors must start saying the truth about this surgery to patients.

I am a physician. I had bilateral LASIk surgery 7 years ago, everything went well. i had the "obvious" side effects: glares, halos, difficult night vision, dry eye, neovascularity, sensibility to light. I did not mind that, at least i was free of
753. Name From Comments
(continued from previous page)
using glasses. I started to have floaters in my left eye 5 months ago, I am young, healthy and had no previous trauma. My myopia was mild before surgery. There is no explanation to what the ophtalmologist found out this week: I had floaters, retina damage (superior) in both eyes, probable posterior vitreous detachment (left) and need laser photocoagulation, urgently so I could avoid retinal detachment. I suspect is all derived from the lasik surgical procedural in my eyes.
I would urge you to reconsider the safety of lasik procedure, for the sake of patients health, not minding all the money and enrichment that would be lost.

754. Name From Comments
Too many disasters have happened to many people that are permanent!

755. Name From Comments
After having LASIK in 2011, I have dry eyes and my vision is worse at night. I believe the risks were not adequately discussed.

757. Name From Comments
I have undergone LASIK and my near vision has become blurry after the surgery.

759. Name From Comments
Son is 39 years old and now suffers from star bursts and halos at night resulting in severe headaches and other problems. Do NOT recommend Lasik to anyone.

761. Name From Comments
I have post lasik estacia due to Lasik in 1999. I wouldn’t recommend it!

762. Name From Comments
Failed lasik operation at Visual Aids Centre, 8, Ring Road, Lajpat Nagar – IV, New Delhi - 110024. Now I am suffering from Keratoconus and need to go for C3R / CXL surgery to prevent my cornea. Vision has already dropped a lot to what it was before lasik.

763. Name From Comments
stop this

764. Name From Comments
I am seeing advertisements where they say 99% is safe and that even nasa is doing it.................please stop this......

765. Name From Comments
I have developed ectasia after LASIX five years ago.

766. Name From Comments
my eyes were damaged

767. Name From Comments
Health nurse
Because I have halos, no night vision, and major depression ever since I had this done in 1999. I wish I was not alive.

Having difficulty after lasik surgery.

A Dallas Dr. blinded me in my left eye with this procedure and damaged my right eye which is getting worse over time.

It makes me furious that doctors, especially in the United States, where we believe we have the best educated and ethical, would do this procedure without really understanding the risks, and acting like we were signing on to do a routine procedure! I had this procedure done almost 15 years ago, and today I fear I'm going blind soon! I'm in constant pain and pressure, with severe headaches resulting from it. I'm truly depressed about this.

My parent had LASIK with many complications (bad night vision, floaters, halos, and close focus problems) and has developed cataracts which prevents reading -- one of the great joys of life.

We now know that LASIK eye surgery was not fully tested, is improperly regulated for safety concerns, and is now proving to have been too dangerous for long-term eye health. STOP LASIK surgery now.

I agree with the FDA Citizen Petition to:
1. Withdraw FDA approval (PMA) for all LASIK devices
2. AND, to issue an immediate Public Health Advisory with a voluntary recall of LASIK devices.

We must stop the eye LASIK industry from permanently harming even more individuals' eyes in the coming years.

I had LASIK and have never gotten rid of my glasses, have chronic dry eye which was never a problem prior to LASIK, have night vision issues and have now developed cataracts. My vision since LASIK has been a fluctuating nightmare. I could never wear prescription glasses after the surgery as my vision changed from day to day. This procedure should be BANNED.

I thank God I never had this procedure. It is made to sound so safe and, from what this petition says, it is anything but. It should be banned before more people's eyesight is ruined.
I had laser eye surgery exactly 6 years ago. I was told by the surgery “I was an excellent candidate” and “could expect an excellent outcome”. I queried the fact I had large pupils and dry eyes as I was concerned this could impact on the outcome, and they said it was nothing to worry about and wouldn’t affect the outcome. I foolishly believed them and proceeded with the surgery. I’ve been suffering with severe dry eye ever since and I’m left with permanent horrific night aberrations. Like a lot of people my eyesight also fluctuates greatly from day to day – a side effect that is yet to be taken more seriously. I receive very little sympathy from the surgery and at times they’ve been very reluctant to help. Do not believe a word these surgeons tell you – at the end of the day it’s a business, they’re there to make money, and they don’t care what the consequences will be for you! It needs to be banned...NOW!!!

Personal Post Lasik Complications

The poor outcomes are simply bearable. It’s sad to see that so many people might get hurt for the rest of their lives.

I got lasik done through Vipin Buckshey of Visual Aids centre Delhi, India. He did not take my pupil size and other measurements properly and did the Lasik in a haphazard manner. Later I found that he is not a surgeon, he does not even have a basic doctors degree. He forced me to get Lasik done but I was not right candidate He was in a hurry to get me under the blade and make fast money. Now I have glares in the mornings and halos at night and have blurred vision. I will never be able to drive. I am almost blind after Lasik.

I developed monocular diplopia in the left eye (actually triplopia with visual smearing and blurring) which began within less than three (3) years following the Lasik procedure and worsened until recently. My ophthalmologist examined my eyes in June of 2012 and stated that my vision in the Left eye was about 20/60 (it had been approximately 20/30 before Lasik and sharp & clear in both eyes). I left his office WITHOUT A PRESCRIPTION OR ADVICE ON ANY THING THAT COULD BE DONE, EVEN THOUGH I HAD ASKED.
I am a sufferer of post-Lasik ectasia. Nobody deserves to suffer because of an unnecessary surgery being sold by medical practitioners without any ethics.

because i want to stop them to not take peoples visual. i love all human beings when they are not feeling how could i feel good.

my eightsight is not terrible, but I was dreaming of having the perfect eyesight. Being a researcher by nature, i had to read fully about this surgery. My aunt had it 14 years ago and now her vision deteriorated and she wears glassess again. I heard about some guy who see on his left eye somthing like a hair all the time.I stumbled upon many websites that warned of the danger of lasik. I was horrified, especially that I have a scar on my eye due to using eye lenses which tore and scratched my eye. I could have been blinded. Doing the lasik might cause me severe eye damage because of the scar.I kept my glassess and I changed my mind. I prefer glassess. Thanks from all my heart to all the people who shared their stories.

Had LASIK 5 years ago and am legally blind on one eye. This is a dangerous procedure since any small error actually results in losing the eye forever - no glasses can help.

MY EYES ARE PERMANANTLY DAMAGED FROM LASIK. I WOULD NEVER LET ANYONE GO THROUGH THIS PROCEDURE WITHOUT INFORMING THEM OF THE HARM IN THE LONG RUN.

Visual Aids Center Delhi made me blind. Visual Aids Centre Delhi ruined my life through Lasik. It is run by bunch of Idiots with no ethics. The surgeon is a complete ass. After ruining my eyes doctor at Visual Aids Center has tuned his back towards me. Do not get Lasik done and never from Visual Aids Centre Delhi, India. I would like to repeat this once again loud and clear - Visual Aids Center Delhi made me blind. Visual Aids Centre Delhi ruined my life through Lasik. Be happy with your spectacles, atleast you can see using them. I am willing to pay my lifetime of saving to undo my Lasik and get my spectacles back.
The advertisement is not telling the truth. I do want other people to dall into the trap that they cannot undo the effect and have to live a miserable life.

cause now life is a martyrdom

We have created in France an association requiring the supervision of lasik surgery and the rights for the patients to be clearly informed about the danger of lasik eye surgery.

We are sharing the same willing and we want to show that we are all acting as one.

Sign also our petition on http://lesdanglersdulasik.com/petition/

Friends and Family eye injury.

The laser companies pressurise you into having a consultation and putting a deposit for surgery on the day of your consultation and they do not explain the risks that involve with laser to the patient. They are more interested in getting as many patients as they can, most people cannot find the risks of laser themselves and when the are pressurised to have surgery it is too late then as there is no going back once it is done.

Has effected my eyesight

atleast, risks and complications should be the first thing, which needs to be told public or future customers. I don’t think optimum education is provided for these procedures, which is a big safety hazard. Eyes are eyes and eye tissue once scarred cannot be regrown as natural.
823. Name From

Comments

Was thinking of doing LASIK by one of the best doctor and Eye hospital in India. Have a prescription of about -5 in both eyes along with axis and cylinder. Hated glasses throughout my life and wanted to get rid of it, thinking I would be a more successful person without glasses. The doctor sounded genuine and all the tests positive in order to do the surgery. It surgery sounded TOO GOOD TO BE TRUE. Visited another doc and he too told me to go ahead and let him know my condition after 2 months. Internet has saved my life coz that's how I found about the long term adverse after effects of this procedure, the maintenace costs seems life long. Thank you all 4 saving me with your real life opinions and my sincerest sympathies for all those suffering today !!!

I totally support this cause of banning Lasik. I have lost most of my vision after a failed lasik done at Visual aids center in delhi. Since then I have spent tons over doctors and lenses but nothing has helped. Surgeons are not sure why the outcome of the Lasik was a disaster while others say that my measurements were taken incorrectly during the procedure. Lasik has ruined my professional, personal and social life. I can hardly see at night (and day) and might never be able to drive/ride again in my life. Would take legal/criminal action if this does not get better. Would advice people to boycott Lasik unless you hate your eyesight.

The surgeon never told me he created a button hole when creating the flap. Instead of waiting like a professional would he continued on with the LASIK. When he was done he said well I never had that happen before never told me what had happened. Fast forward years later going to a dr for severe dry eyes I'm finally told I have a button hole. I have scarring built up and now my vision has changed that am blind in that eye. I now have to have surgery to see if they can remove the scarring if that doesn't work I will be in line to have a cornea transplant. Don't have LASIK wear glasses or contacts.

I did laisk 2 ys ago & now developed post laisk hypermetropia in the left eye with sharp diminution of vision thats diagnosed as keratectasia now Im asking for treatmnt

I was a bit moved when my friend who had just undergone LASIK operation a few days ago. She told me that the staff in the clinic told her only 0.1% of patients need enhancement surgery after LASIK. But, luckily I decided to surf the net to research more about the side effects, and gosh, for every common complications (e.g. dry eyes, (continues on next page)
827. (continued from previous page)
cataracts) it is almost around 20% of the patients will suffer from it, which is, 1 in 5 patients! 1 in 5! this is not "rare". Thanks to those who bravely posted out their conditions and reveal the truth behind LASIk, I have decided not to risk my eyes and am contented with my specs and contact lenses. We need to bring this awareness to more people as this surgery is irreversible.

830. The eye doctors are not informing customers of the real risks being involved. The flaps are cut too thin, to thick often times all the way through. The eye doctors are not scheduling follow up visits. There are often too many permanent complications.

831. I had complaints of dry eye while wearing contact lenses. My ophthalmologist recommended Lasik surgery may eliminate this issue, When I was evaluated for the surgery the RN who did my preliminary exam was shocked at how dry my eyes appeared on a simple measurement test of eye dryness performed during pre surgery assessment. The RN said she needed to check with the doctor to see if they could still do Lasik with me. She wasn't sure they would still do the surgery because my eyes were so dry. She also told me she had very dry eyes on this test but, not as dry as mine. My RN shared with me that she had Lasik and just used eye drops a few times a day(for approx. 2yrs). After checking with the doctor she said my eye dryness would not prevent me from having Lasik. The doctor came in and, said my eye dryness would not be an issue for the procedure. Furthermore, the doctor said I would not be bothered with dry eye after Lasik and, after a short recovery period I would not need eye drops at all. Basically she(the doctor) looked me straight in the eye and lied to me just to make more money.

832.

833.

834. Dr. Diane Tanabe ruined my L Eye with Laser, Flap was Stuck, Complaint to State Medical Board www.bmp.state.mn.us to NO Avail www.sharon4mnag.blogspot.com Scrool 3rd Post down also read Sharons Mayoral Profile www.eastmetrovoterguide.com

835.

836.

837. A physician I know had lasik and now has iatrogenic corneal ectasia and is legally blind in one eye.
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<tr>
<th>Name</th>
<th>From</th>
<th>Comments</th>
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<tbody>
<tr>
<td>838.</td>
<td></td>
<td>Still need glasses, it's a rip off.</td>
</tr>
<tr>
<td>839.</td>
<td></td>
<td>Because I got lasik done one year ago and it caused me to develop cataracts on both eyes. I don't want this to happen to anyone else.</td>
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<td>840.</td>
<td></td>
<td>have multiple large atrophic holes in both eyes along with floaters after LASIK. LASIK companies are DECEPTIVE about the percentage rate of harm resulting from LASIK.</td>
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<td>841.</td>
<td></td>
<td>I have had both Lasik and Lasak and now they are saying I need a lens replacement operation which I have refused. I have been left with many problems and wish I had never had laser eye surgery</td>
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<td>842.</td>
<td></td>
<td>My vision is very blurred and distracting after Lasik.</td>
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<td>843.</td>
<td></td>
<td>Corneal Ectasia!!!</td>
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<td>844.</td>
<td></td>
<td>I developed ectasia 4 years after Lasik. At this point, I am wearing &quot;piggyback&quot; (hard over soft) lenses with marginal tolerance with decent correction, but with every optical aberration you can imagine. My condition is progressing despite crosslinking which I will probably have repeated. Having Lasik was the single worst decision of my life and has resulted continuous pain and suffering. I was never told that my complication was a possibilty. If I had, I would not have had the procedure done.</td>
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<td>845.</td>
<td></td>
<td>I work in the medical industry and I am very well aware of the risks of Lasik. Put a stop to this scandal!</td>
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<td>846.</td>
<td></td>
<td>I got lasik done through Vipin Buckshey &amp; Dr. Anuj Singh of Visual Aids centre Delhi, India. I have lost most of the vision post lasik. I am as good as a blind person with light sensitivity, glare, halos and star bursts. And have been gifted with contrast loss and dry eye. Lasik was a disaster and other surgeons say that my measurements and procedure was not correct. And these issues are permanent. Lasik should be banned.</td>
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<td>847.</td>
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I had lasik monovision less than two months ago and it's been a disaster from day one. Prior to the surgery, I was told there was a "brief period of adjustment". At my first follow-up after surgery, I was told that I could expect "months of misery" until my brain adjusted. My vision is SIGNIFICANTLY worse than it was prior to surgery and my surgical eye is so dry it's painful.
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<th>Name</th>
<th>From</th>
<th>Comments</th>
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<tbody>
<tr>
<td>854.</td>
<td></td>
<td>Because I have had this surgery now my life is basically ruined from the terrible dry eye. Biggest regret of my life!</td>
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<tr>
<td>855.</td>
<td></td>
<td>I had lasik and have suffered from many side effects that were not explained adequately to me.</td>
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<tr>
<td>856.</td>
<td></td>
<td>I am a long sufferer from myopia and could not imagine ruining what little sight I have. I was so close to getting LASIK after being carried away by the promise of perfect vision in the blink of an eye. Research and patient testimonies convinced me to reconsider.</td>
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<td>857.</td>
<td></td>
<td>I am blind in my left eye and suffering greatly due to lasik eye surgery performed in 2005. I have post lasik ectasia. This is a very unsafe surgery and is even causing people to commit suicide because of the loss of sight and unbearable pain.</td>
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<td>858.</td>
<td></td>
<td>I am a Lasik survivor. I will never let someone I love have this done to them. It was 2010 when I had it done and I will live with this until the day I die. I regret having it done. Sadly I learned to late that it was all about lining doctor's pockets. My children almost had to grow up without a mother because of this. I have filed a complaint with the FDA about my experience. I lost out on valuable time as I was hospitalized afterwards. I also spent much more money than my Lasik fees trying to regain my vision.</td>
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<td>859.</td>
<td></td>
<td>Because although costly, results were not as expected and service thereafter has been less than satisfying.</td>
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<td>860.</td>
<td></td>
<td>I have been recently diagnosed with corneal ectasia.</td>
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<tr>
<td>861.</td>
<td></td>
<td>I had Lasik in 2009, in 2013 I was diagnosed with corneal ectasia from Lasik. My eyesight is ruined.</td>
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</table>
I had wanted to get the surgery and a respected friend told me not to; he regretted ever having done it. I saw a post on his LinkedIn about how threatening this really is. I'm glad I listened. But this needs to be stopped! Especially for those that aren't aware.

Too many false promises... the industry of LASIK is almost like EZ-CHECK CASHING business!

I had Lasik myself 2 years ago. It was a graduation present for graduating with a degree in photography. I have since quit photography and have not taken a photo in 2 years. I have been to 6-7 doctors including corneal specialists. They all say everything is fine after 1-2 visits which is complete bull as the issues persist and sometimes are even worse. This has destroyed my life. the FDA needs to come up with a solution to fix everyone NOW!

one of my close friends got lasik and now her eye sight is worse!

My daughter was just beginning her life as an adult and a photographer when I gave her the most horrible gift I could have given... LASIK. Her young life has now been irrevocably altered as a result.

The procedure as with many money-making services, appears to be done in a caveat emptor fashion. Let the buyer beware. Disclosures, if any, are small. Risks are not fully discussed with the patient to allow for a fully and clear understanding of potentially serious repercussions. Patients are typically not medically trained and are thus unduly influenced by their trust of the provider and his or her "credentials." Full assessments of the potential risks with individual patients, based on careful examination, don't appear to occur with enough vigor, or are discounted. If someone has a dysfunction prior to surgery, the surgery will likely only exacerbate the problem. Meibomian gland dysfunction is a good example. Until this procedure is perfected, or all potential repercussions are fully vetted, understood and projected patient by patient, this procedure should be suspended. It has changed my daughter's life, and while she is a resilient and talented individual, this procedure has adversely affected her ability to utilize her education and pursue her professional passion.
I had lasik in 2001 and it never worked for me. I developed ectasia and keratoconous subsequently. Now living with this irreversible damage.

the complications are not told upfront, I went to some consultations, this procedure was made to appear completely safe. Yet I hear too many horror story from other people.

had lasik 7 yrs ago. typical complications. paid for my ignorance and naivity and belief in the integrity of human nature with my eyes

TLC messed up my sight with Lasik surgery on both eyes. I have heavy fog like effect, multiple images and starbursts in both eyes. The left eye was re-lasered with custom PRK. It just moved the multiple images to up close. The right eye (not relasered) has the multiple images at a distance. My night vision and resolution (both day and night) have been reduced by half. The TLC personnel and the eye surgeon (Dr. Louise Doyle) kept telling me that my corneas were healing ok and that the problems were temporary and would go away. The problems just got worse over time. Then vice president of customer relations at TLC, Dr. John Potter, called me and emailed me many times, but he had ordered the Columbus Ohio TLC branch to NOT relaser my eyes, which he later recinded after I had asked for a copy of my records. I am now considering cornea transplants to attempt to fix the vision problems create by the laser vision surgeries. Also, the multiple images are returning in my left eyes vision, making that eye nearly useless.

It's my life .I suffer severe dry eye I can not lead a normal life

I think surgery in general is the last thing, that people must do only in cases of emergency.

Before lasik, I was such a happy person. I led a normal life and was planning on getting married. I never had a dry eye issue with my glasses before lasik. Now, I am in pain everyday. I can no longer work. I have spent tens of thousands of dollars attempting to correct my chronic dry eye. The money is meaningless to me, I just want to not be in pain anymore and go back to how things were. I am considering suicide. I hate how people can say one (continues on next page)
incident cannot cause a person to commit suicide. Here’s the thing, lasik was a one day thing, but the burning and the pain is every day. Every single day, almost all day for me. Can that cause a person to want to commit suicide? It has for me. I wish everyone who is pro lasik could be afflicted with burning and pain in their eyes like I have everyday. Would they still then tout lasik? This is torture. If you call dry eye a side effect when it prevents you from working, prevents you from enjoying life, and causes you to keep your eyes closed for 10 to 16 hours a day when before you were a happy person, you cannot distinguish the difference between a side effect and an injury. Why doesn't the FDA go ahead and call blindness and every other injury a side effect too? That way lasik could have a 0% injury rate and only side effects.

Because I am going blind. I had Lasik in 1996, or what I thought I had done. Come to find out, they did RK in both eyes. I then needed an enhancement 2 years later. Since then my eyes have gotten so bad, I can’t see to put on makeup. 1 1/2 yr ago, I had cataract surgery in my right eye, right over the RK incisions, I now have found out that is a definite no no. I feel like I am looking through petroleum jelly, and it keeps getting worse each day. I am seeing an optomologist on Monday 1/27. I want him to tell me, no holes barred what is happening to my eyes. I will be doing research to see what I can do, or if I have any recourse.

because i do not want others to ruin their life .......

I had the surgery - I have severe eye pain and have to wear corrective glasses for double vision. This surgery has made me legally blind due to infections. My body began attacking the infection triggering an autoimmune disease of the eyes. The ‘doctors’ don’t tell you the incisions never completely heal, leaving the eyes open for the rest of your life to infections & gritty sand in eye feeling. I have to take daily pain medication for the eye pain. Even in my sleep I have pain, in which I dream about my eyes. I lost my job in an art dept due to loss of color vision. Why is this sadistic surgery still allowed? I hear it advertised on the radio & TV as being so wonderful and for the "health" of your eyes. There must be a lot of money involved with lobbyists who outweigh the warnings of credible physicians. Once the surgery is done, it can never be undone. I warn as many people as I can about this. Please put an end to this dangerous procedure.

http://www.reiser.net/lasik
901.

Lasik was the worst decision of my life.

Unsuspecting, trusting people are having their precious eyes mutilated for life. They must be protected by stopping the merchandisers of the ophthalmic quackery known as LASIK.

902.

LASIK has more complications it ruins your eyes some people after the surgery have gotten eye pain so severe that they killed themselves

to discourage people from having this injurious type of treatment

I have to raise 2 children, suffering depression due to eye pain and floaters. Hopeless. I should have been lived full life, having more children. But lasik has ruined everything.

903.

I had complications from the surgery and have spend the better part of the past two decades trying to find a solution via rigid contact lenses with no success.

904.

I had complications and every contact lens specialist I've seen who treats post lasik patients tells me that lasik is a bad idea.

905.

Lasik has ruined my life! And it's really unfair that I have no legal recourse because of the statute of limitations.


906.

I was considering lasik after reading and hearing all the promising results; after doing some research and stumbling across the truth of all potential permanent side effects, I will stay with my contacts and glasses. Everyone should be warned!

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922. I am not satisfied with the LASIK procedure that I went through. I was not warned about the side effects of the procedure. Now, I see Halos, star bursts and double vision. When I told my Doctor about my problem, he said, the side effects will wear off over time and I do not need to worry about it! It has been an year and I see no improvement! This is the biggest regret of my life. I am not happy with my new eyes!

923. I had LASIK in 2004 and I now have post LASIK estasia. My eyesight has progressively gotten and it is unable to be corrected w/ glasses or soft contacts. I recently got hard gas perm contacts, but the irritates my eye so bad I can hardly wear them. The Dr. said the next step would be a cornea transplant. I don't want to have another surgery due to the potential side effects.

924. After a extensive research about whether I should take a LASIK surgery I realized that it is a risk that is not necessary for most of us. It is an awesome technology but not supposed to be marketed.

927. Any thing unethical should be removed from the society.

929. I was diagnosed with corneal ecstasia after LASIK

930. had lasik one year ago was misinformed diagnosed with coma high order abberations.1 year post lasik lasikn md are monsters.they will not provide me with my copy of my chart .in canada u cant sue drs im suing these bastards for comrimising severely so .my eyesight .lasik md will be held accountable .im severely depressed.

931. I wear glasses since more than 20 yrs , i did my research on internet ....many many ppl are suffering from lasik complication ....it is un needed risk .... wearing glasses is not that bad

932. Stop eye damage.

934. Had LASIK in 2000 - rapid deterioration in left eye vision in 2013. Diagnosed with iatrogenic ectasia. Left Eye CXL procedure, right eye being monitored for possible CXL

935. I have been thinking about getting Lasik for a while now but with all of these comments have decided against it! Thank you all for sharing and saving me. Who knows what could have happened
I would have wanted a LASIK surgery but thanks to all the people who testified, I can now be sure that I won’t be playing Russian roulette with my eyes. I’m really grateful and supportive to the victims of this shameful method.

I think it ruins a person’s life completely; I was so active before surgery. Now I can hardly do anything; I am only 22.

I suffered 13 years of indescribable pain and terrible vision problems resulting from LASIK. The only thing that saved me was a regime of the most powerful pain medications under a pain management doctor, plus updating my distance and near-vision glasses prescription every year since LASIK!! It nearly destroyed my life!!!

I got operated with Lasik and this caused retinal damages, floaters, light sensitivity and many other serious problems which affect my life.

Реклама "восстановления зрения" с помощью LASIK не соответствует действительности. Получается некое подобие "постоянных контактных линз", которые никогда нельзя снять. Мне приходится использовать плюсовые очки вблизи, ИНАЧЕ НИЧЕГО НЕ ВИДНО

My wife and I almost had the surgery, if it wasn’t for sites like lasikcomplications.com, I could be suffering as well. Fortunately, we never had the search done and still wear daily contacts and glasses... better than destroying our entire lives!

I want to further the crusade to inform the FDA that it should not allow this very costly price tag on our citizens. Can you imagine how many are now hurting and on disability that we all have to pay for because of these high price quick surgeries making surgeons millionaires in only a few years?

Isn’t it interesting that so many doctors doing the surgery never had it done to themselves. I find that very interesting! It’s all about the quick money, even if it ruins the lives of those that didn’t do their due diligence research. Like the (continues on next page)
Internet, never believe everything you hear. The FDA is certainly not on your side,

I had lasik on 09/05 this year and now I'm suffering severe glare/halo/starburst side effects.

too risky too costly will ruin your life dont go by other people's results we are all made differently. its like any surgery it has complications. is just simply not worth it. 5 minutes can become years of regret and misery.

I am seeing multiple images with my eyes and scared to death of possible side effects now that I was never told and was stupid enough not to do my home work. This is serious surgery on eyes and it should only be done as a last measure. Kiss your glasses and contacts and thank God if you have avoided LASIK or other vision correction surgery.

I dont want people to lose their sights! The eye-care industry is corrupt and the fail to see the truth.

I am suffering life changing problems - Severe Dry Eye, Constant eye pain, Recurrent Corneal Abrasions, Fluctuating Vision, very poor intermediate vision, blurring, floaters, persistent headaches and migraines, all leading to anxiety and depression

They blinded my left eye. Right has to be redone another £5000

I had LASIK eye surgery in 2005 I can no longer drive as a result . 9 years later and I still have all the side effects mentioned I have had years of going to a eye hospital . Before I had the laser surgery my eyesight was not good I was long and short sighted but was assured that I was suitable for the procedure I feel that not enough checks are done on each individual they are to quick to take your money

Though I thought I was well informed of the various risks from lasik, I was in fact not. I suffer several of the more common sideeffects (starbursts, multiple images, halos) and
now realize how difficult it is to explain to someone how serious this is in terms of its degrading effects on quality of life. This Expected value of this surgery I suspect is in fact negative.

LASIK ruined my brothers life

One year ago I was pretty determed to do this...However I'm glad that i spent A LOT OF TIME studying about this operation. I've asked people, friends who have family doctors and who were explained why it's really dangerous. 2 ore things that stopped me from doing this: the fear of childbirth, and possible damage to the eyes and my active lifestyle, with sport and so on - i couldn't give up on this for months to come... So i'm glad i didn't do this :)

Lasik destroyed by life. Severe dry eye, pain, smeared lights in my vision, starbursts, double vision, haloes. With scleral lenses I trade some quality of vision for excruciating pain and dryness. Its a real scandal that this so called medical procedure is permitted.

After about 12 yrs. my eyes are painful and the distance between each eye is horrible for wearing glasses. NO LASIK

my Husband had PRK on his right eye approximately 7 weeks ago, with very poor results, He will absolutely not do the other eye. The risks of Laser surgery were not raised or communicated to him at all by either his optician or the surgeon, although they had multiple opportunities to do so. If they had been, it would have prompted more research by him prior to the surgery and he would never have had it done. I don't want others to fall into the same mis-representative marketing trap.

Worst decision of my life to have Lasik

because, i am victim of operation LASIK and advertisment aboutit. In 1999, when LASIL was in the begging of operations, the advertisment was very extanded, in relation with the secret effects.
a Metropolitan Eye Center physician, if he can call himself that, has done irreversible damage to my husbands eyes. He should be held accountable.

Hundreds of thousands of people are being dubbed by the "hype" of LASIK surgery as a safe "medical procedure" when in fact it is not as safe as they believe. Most people place too much trust in doctors and Medical Equipment Manufacturers. Doctors are human and Medical Equipment manufacturers are looking for the all mighty dollar and/or their stock holder profits. It is our responsibility to utilize our own intelligence to make medical decisions, it does not fall upon doctors or corporate executives.

LASIK made my eye hurts and dry

This issue is important to me, because I cannot bear to see a money hungry industry that ends up ruining patients' vision and life. It's sad to see these patients remain helpless.

I am myself a victim of this surgery, suffering from a severe dry eye.

It's been 3 years since my surgery which ruined my life. Severe dryness, Ghost images, floaters, star bursts what not every side effect. I am living in a hell now

I had Lasik in 2011.
I recently read an article where a producer of laser equipment stated that only 2% of one of their market researches reported seeing or reading something about lasik and FDA, referring to the thousands of FDA testimonies of harmed people....basically has declared satisfied that the rest of 98% are not informed of the horror outcomes and immense risks of lasik.....this defines the market for which a 5% of bad outcomes is considered collateral damage...

I spent the first 6 months in an incredible pain both physic and psychic, not being able to take care of my little girl who back then had 6 months. Today I still cope with this chronic (continues on next page)
pain, it needs a lot of strength and patience. Lasik is easy money gained by equipment producers, doctors, pharma, on one side..... by ruining people eyes and lives. This is atrocity encouraged by the authorities that should protect people health.

Doctors choose ophthalmology as a residency because easy money are gained, surgeries are easy, not messy, take only 20 minutes and are very expensive....I quote the same doctor that performed my surgery ruining my eyes, the same doctor that gave me no after care, treating me like scum and brutally suggesting to turn on the lights when I complained of not being able anymore to see a proper contrast in dim lights and giving me some dry eyes drops to treat my excruciating pain, the same doctor that decided to have me had Lasik instead of Lasek (a less invasive procedure) because he knew better, didn't he? After all he was the doctor, so I trusted him cutting my eyes open.

They failed to diagnose or more probably decided to ignore an obvious chalazion, a clear indication of non performing lasik, one of the many conditions that higher the procedural risk, a risk that however is huge for a "cosmetic procedure". Days after procedure I was told that were others with similar outcomes and that they managed their condition with drops. I soon realized that this was not possible.....but they had important stuff to do, many other Lasik surgeries that day, many other high likely possibilities of future destroyed lives. Proper screening would drastically reduce the number of "good candidates" and this isn't in the best interest of the industry.

I've waited patiently the moment of the procedure since high school, I did it at 32 years being convinced that a procedure performed for so many years must be safe. I made the mistake to search on the internet for risks and not for complications, so I didn't see the bad and horrible outcomes, but only the misleading information of those who promote Lasik.

Prior the procedure I was told that the slight dryness will last for 2 months and then back to normal....this was 3 years now and I am nowhere near normal....punctal plugs inserted....let alone the glare, starbursts, lack of contrast, eye fatigue, special ugly glasses that I have to wear to protect the little tears that I still produce.

There is no cure, I tried everything out of despair. This is life condition, a iatrogenic one.

FDA should do its job and stop this crime! Better late than never. "Primum non nocere", right?
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<td>I had RK and 20 years later way too many bad issues. Eyesight is diminishing quickly along with very painful recurrent corneal erosion in both eyes daily. My daughter had RK surgery done and it is giving her problems now. I am a recent victim. This surgery is ruining people and we are being silenced afterwards! I worry about the younger kids not knowing the truth and destroying their lives! This surgery makes us completely desperate and hopeless. Stop LASIK NOW!! Post-LASIK Kerectasia, diplopia</td>
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<td>lasik ruined my life ! i cant work at security or lifeguard ! i had depression and thinking on suicide ! theres no way to fix this !</td>
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<td>Accountability on all across the board peddling Lasik eye surgery. After the fact, an independent optometrist provided by the Medical Board to investigate my (continues on next page)</td>
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Page 92 - Signatures 995 - 1,019
complaints and do tests on me, had expressed to me and the Medical Board that I did not require surgery in the first place. No action has been taken by the Medical Board or the Hospital that leases an office/theatre to the Surgeon which both are still benefitting from unsuspecting patients.

I am against LASIK because I have heard from my friends of the long term consequences that seriously worsen their quality of life

Because refractive surgery is not well regulated, not reported all the risks and possible sequels, and relevant measurements pre and postoperative visual quality either performed.

Lasik ruined my life.

LASIK has ruined too many eyesights and lives already!

My Daughters eyes have been damaged by this surgery & has caused her mental trauma that no one needs.

Basically Lasik destroyed my life

Because I am a victim of this industry. They lied to me and now i am suffering the consequences. A hit rate of 20-30% in an unnecessary operation can not afford
it is terrible harm to eyes

Hay que eliminar esta técnica

My results are that I have double vision, very uncomfortable dry eyes, horrible vision in one eye that can't be corrected by glasses, halos and horrible night vision. I wish I had never done this.

My initial eye damage was from lasik causing occupational loss. I want no one to go thru this horrible life changing experience

My sister was blinded by LASIK.
Eye Dr and hospitals should honestly inform their patients on the short term and long term complications of lasik. My Dr told me about dry eyes, and I was told to sign an agreement prior surgery, however how could a patient knew about those complications.

I am affected by many symptoms after lasik, my life is dictated by my new symptoms and I feel that everyday I have half day to live, once the day is dark I cannot do a normal life and I become depressed. I work in front of a computer and can bare more than three days working, it unbearable but have not option than to keep going make a living. No one can imagine how bad is to live under these circumstances. Please stop immediately this surgeries, please.

Porque desde que me operé la calidad visual cada vez empeora, con sequedad, picazón y cada vez menor agudeza visual, es la peor decisión que he tomado en mi vida, todos los doctores le quitan importancia a estas secuelas, y consideran un éxito sólo por eliminar el defecto refractario.

Experiencing same situation. Worst decision I ever made and so unnecessary for me. W
Exhibit 1
January 6, 2011

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Dear Sir or Madam:

Waxler Regulatory Consultancy LLC submits the attached Citizen Petition under Sections 201, 301, 510, 513, 519, and 520 of the Food Drug and Cosmetic Act and 21 Code of Federal Regulations to request the Commissioner of Food and Drugs to withdraw FDA approval (PMA) for all LASIK devices and issue a Public Health Advisory with a voluntary recall of LASIK devices in an effort to stop the epidemic of permanent eye injury caused by lasers and microkeratomes used for LASIK eye surgery.

Please contact me if you have questions.

Respectfully submitted,

[Signature]

Morris Waxler, Ph.D.
President

Attachment
CITIZEN PETITION

Waxler Regulatory Consultancy, LLC submits this petition to the United States Food and Drug Administration (FDA) under 21 Code of Federal Regulations (CFR) § 10.30, and sections 201, 301, 510, 513, 519, and 520 of the Federal Food, Drug, and Cosmetic Act (FDCA) to ask FDA Commissioner Dr. Margaret Hamburg to stop the epidemic of permanent eye injury caused by lasers and microkeratomes used for LASIK eye surgery. Data are provided as factual grounds in support of this petition, and requests fall under FDA jurisdiction under 21 CFR, Part 5.10. The urgency and enormity of the threat of LASIK devices to public health and safety indicate further need for involvement of FDA’s Office of Criminal Investigation (OCI), the House Energy and Commerce Committee's oversight and investigations subcommittee and other congressional leaders in this matter.

Many thousands of eyes have been damaged beyond repair by LASIK devices since the 1990s. Approximately 700,000 eyes will receive refractive surgery with LASIK devices by the end of year 2011. Thus, more than four thousand six hundred (4,630) are projected to face blindness due to surgically thinned and bulging corneas (keratectasia). This is an addition to the many thousands of LASIK patients already suffering from keratectasia. In addition, more than 70,000 LASIK patients (140,000 eyes) will suffer by the end of 2011 with persistent adverse effects including but not limited to night vision disturbances, dry eye, glare, and halos. These LASIK-induced adverse events have occurred from using both early and late model LASIK technologies. Also, upwards of 43 percent of LASIK patients will be wearing corrective lenses 6 to 12 months after surgery and in about 7 years fifty-five percent will be unhappy with their vision and the number of eyes that lost 2 or more lines of visual acuity will have doubled.

I. ACTION REQUESTED

I, Morris Waxler**, am the former Branch Chief in charge of FDA approvals of LASIK devices between 1996-2000. I request FDA commissioner, Dr. Margaret Hamburg, take the following actions:

❖ Withdraw FDA approval (PMA) for all LASIK devices
❖ Issue a Public Health Advisory with a voluntary recall of LASIK devices

II. FACTUAL GROUNDS

Manufacturers and their collaborators (including but not limited to clinics, refractive surgeons, and agents) withheld and distorted safety and effectiveness data (Section A) submitted to the Food and Drug Administration (FDA) so that LASIK devices would appear to have:

- A FDA-acceptable adverse event rate of ≤1%, rather than the true rate of at least 20%*
- Only temporary adverse effects when, in fact, some persist for 6 months to many years†
- >90% effectiveness when the true rate is approximately 57%‡

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* Keratectasia rate of 0.66%. See Section B5
† Adverse event rate of 20.0%. See Sections A1, A2
‡ See Section A4
§ See Section B8
** Waxler Regulatory Consultancy LLC
†† Table 1

Waxler Regulatory Consultancy LLC
1/6/11
Starting during my tenure, FDA decision-making on LASIK devices was dominated by LASIK surgeons working hand-in-glove with LASIK manufacturers. Data recently brought to light exposes this partnership for what it was: a classic example of the fox guarding the henhouse, wherein the primary arbiters of safety and effectiveness of LASIK devices were the device manufacturers and its collaborators. Surgeons used LASIK devices in violation of required manufacturing quality controls (21 CFR 820), patient protections (including but not limited to 21 CFR 50; 54; 56; and 812), and reports of adverse events (including but not limited to 21 CFR 803; 812; and 820) when they manufactured and distributed LASIK devices in interstate commerce within the United States as:

- Homemade lasers (“black boxes”)
- Imported investigational lasers (“grey boxes”)
- Illegal key cards (“Bermuda cards”) and
- “Off-label” photorefractive keratectomy (PRK) lasers

As a consequence the FDA was deprived of knowledge of the full extent of LASIK injuries prior to and during FDA reviews of documents submitted in support of the safety and effectiveness of LASIK devices under 21 CFR 812 and 21 CFR 814. In addition, LASIK manufacturers and their collaborators withheld safety and effectiveness information from their investigational device exemption (IDE) reports to the FDA. In addition, they hid LASIK injuries from FDA within the context of out-of-court settlement of innumerable lawsuits. Clinic-sponsored IDE studies cherry-picked, withheld, and hid data from FDA that clearly showed LASIK with excessive adverse event rates (greater than 1%). These activities were an industry-wide effort, organized wholly or in part by the manufacturers and their collaborators in order to circumvent FDA law and regulation. I will submit CONFIDENTIAL information on these matters separately to FDA’s Office of Criminal Investigation.

Published scientific data shows LASIK devices induce an average adverse event rate of about 22% that persists beyond six months to five or more years. Moreover, the published data (Section B) shows that LASIK devices transform healthy corneas into sick corneas that:

- Never completely heal
- Are permanently weakened, vulnerable to trauma and inflammation
- Cause neuropathic dry eyes
- Have pathology that progresses annually
- Are vulnerable to blinding corneal bulging (keratectasia)
- Compromises night vision
- Have unstable vision corrections that regress
- Require eye care that otherwise would not be needed
A. PMA Applicants Withheld and Distorted Safety Data In Submissions to FDA

Figure 1 is a LASIK industry graph\(^1\) falsely showing that dry eyes, night vision, glare, and halos do not occur six months after LASIK. FDA reproduces the manufacturer’s graph on its website without attribution or identification of the evidence upon which it is based.\(^2\) Visitors to the LASIK manufacturer’s website\(^3\) are sent to FDA’s LASIK website to view the graph as if it was FDA’s. Manufacturers knew (and know) that these adverse events occur with a frequency much higher than 1% at 6 months post-LASIK.

Figure 1 is an example of untruthful and inaccurate information submitted to the FDA by manufacturers and their collaborators in support of premarket applications (PMA) for LASIK devices (P970005, P990010, P970053, P970043, P900016, P980008, P930016, P020050, P030008, P930008, P060004). These manufacturers and their collaborators have been engaged in, and still are engaged in, a pattern of falsifying, misrepresenting, manipulating, and withholding safety and effectiveness data from FDA to make their LASIK devices appear safer than they are.

Figure 1. LASIK Industry Graph Showing False Data
From: http://www.agingeye.net/lasik/lasik.php
1. Falsified and Misrepresented Data in Submissions to FDA

LASIK manufacturers and their collaborators made and are making false statements to FDA when they report and label their devices with an adverse event rate of less than 1%. Figures 2-7 show that the manufacturers knew (know) that the adverse event rates are much higher than 5% and persist for at least 12 months. The vertical axis on each of these figures is percent post-LASIK vision changes compared to pre-operative values. The horizontal axis on each figure is the follow-up (FU) month post-LASIK at which data was collected. These data are taken from manufacturers documents submitted to FDA and identified in Table 1.*

![Figure 2 – LASIK Induced Adverse Events](image_url)

The vertical axis is percent post-LASIK vision changes compared to pre-operative values. The horizontal axis is the follow-up (FU) month post-LASIK at which data was collected.

* The source documents for these data are identified in Table 1A, Appendix.
Figure 3 - LASIK Induced Adverse Events
The vertical axis is percent post-LASIK vision changes compared to pre-operative values. The horizontal axis is the follow-up (FU) month post-LASIK at which data was collected.

Figure 4 – LASIK Induced Adverse Events
The vertical axis is percent post-LASIK vision changes compared to pre-operative values. The horizontal axis is the follow-up (FU) month post-LASIK at which data was collected.
Figure 5 – LASIK Induced Adverse Events
The vertical axis is percent post-LASIK vision changes compared to pre-operative values. The horizontal axis is the follow-up (FU) month post-LASIK at which data was collected.

Figure 6 – LASIK Induced Adverse Events
The vertical axis is percent post-LASIK vision changes compared to pre-operative values. The horizontal axis is the follow-up (FU) month post-LASIK at which data was collected.
The vertical axis is percent post-LASIK vision changes compared to pre-operative values. The horizontal axis is the follow-up (FU) month post-LASIK at which data was collected.

The data shown in Figure 2-7 clearly show substantial adverse effects beyond six months post-LASIK. The following section shows that manufacturers and their collaborators pressured FDA to not count these adverse effects in the “adverse event rate”.

2. Manufacturers Pressured FDA to Not Count Certain Adverse Events

FDA originally counted glare, halos, dry eye, night driving difficulties, and similar problems after excimer laser refractive surgery as adverse events, e.g. page 16 of the Patient Information Brochure for P970053c says “…adverse events beyond the first few months: night vision difficulty (48.1% at six months)...glare (34.4% at 6 months)...” LASIK manufacturers and their collaborators successfully pressured FDA to classify these problems as mere “symptoms” so that manufacturers could claim that the adverse event rate is less than one percent. FDA required an adverse event rate of less than one percent of eyes. In 2009 FDA publicly acknowledged that “…halos, glare, night vision problems, and dry eye from LASIK should be reported to FDA...”, in other words that these problems are “reportable events” and thus adverse unless proven unrelated to LASIK. The result is that the true adverse event for LASIK devices is much higher than 1%.*

* I will submit CONFIDENTIAL information on these matters to FDA’s Office of Criminal Investigation.
In addition to falsifying and misrepresenting these adverse events the manufacturers and their collaborators withheld significant adverse event data from FDA.

3. Manufacturers Withheld Safety Data

Table 1 shows that LASIK manufacturers withheld an average of about 30% of the follow-up data on adverse events, including but not limited to dry eyes, night vision problems, glare, and halos (see Table 1A in the Appendix for sources of the data). Manufacturers asserted that the missing data was not submitted because vision outcomes were so good that subjects would not come back for post-operative visits. They repeatedly made this claim in meetings with FDA.

Table 1 – Percent Adverse Events Data Withheld by Manufacturers

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Follow-Up (months)</th>
<th>% Data Withheld</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kremer LASIK</td>
<td>12</td>
<td>79.9</td>
</tr>
<tr>
<td>Kremer LASIK</td>
<td>12</td>
<td>39.7</td>
</tr>
<tr>
<td>VISX LASIK</td>
<td>3</td>
<td>62.1</td>
</tr>
<tr>
<td>Nidek EC-5000</td>
<td>12</td>
<td>41.5</td>
</tr>
<tr>
<td>LADARVision</td>
<td>6</td>
<td>57.9</td>
</tr>
<tr>
<td>VISX Star S2, S3</td>
<td>6</td>
<td>29.4</td>
</tr>
<tr>
<td>LaserSight</td>
<td>6</td>
<td>88.2</td>
</tr>
<tr>
<td>LaserSight</td>
<td>6</td>
<td>73</td>
</tr>
<tr>
<td>VISX</td>
<td>6</td>
<td>4.3</td>
</tr>
<tr>
<td>LADARVision 4000</td>
<td>6</td>
<td>68.1</td>
</tr>
<tr>
<td>VISX Star S4</td>
<td>6</td>
<td>22.3</td>
</tr>
<tr>
<td>Allegretto Wave</td>
<td>3</td>
<td>7.6</td>
</tr>
<tr>
<td>Allegretto Wave</td>
<td>6</td>
<td>10.3</td>
</tr>
<tr>
<td>LADARVision 4000</td>
<td>3</td>
<td>29.9</td>
</tr>
<tr>
<td>VISX Star S4</td>
<td>6</td>
<td>1.1</td>
</tr>
<tr>
<td>VISX WaveScan</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>VISX Star S4</td>
<td>6</td>
<td>41.8</td>
</tr>
<tr>
<td>Allegretto Wave</td>
<td>6</td>
<td>12.3</td>
</tr>
<tr>
<td>LADARVision 4000</td>
<td>6</td>
<td>20.2</td>
</tr>
<tr>
<td>LADARVision 4000 &amp; 6000</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Allegretto Wave</td>
<td>3</td>
<td>4.2</td>
</tr>
<tr>
<td>Allegretto Wave</td>
<td>3</td>
<td>6.4</td>
</tr>
<tr>
<td>MEL-80</td>
<td>6</td>
<td>2.2</td>
</tr>
<tr>
<td>Nidek EC-5000</td>
<td>12</td>
<td>5.2</td>
</tr>
<tr>
<td>VISX Star Wave</td>
<td>12</td>
<td>9.4</td>
</tr>
</tbody>
</table>

Sum = 724
N= 25
Mean = 29.7

Manufacturers and their collaborators withheld more than 10% of the adverse event data from 13 of the 25 studies, more than 20% from 12 studies, and more than 40% from seven studies. In addition, they withheld information from FDA about LASIK injuries that resulted in lawsuits and out-of-court
settlement that occurred during investigational studies and during FDA review of the PMAs. Manufacturers and their collaborators did not report these adverse events to FDA during my tenure at FDA.\(^7\)

The “true” adverse event rate is more than 1% at 6 months post-LASIK (Figures 2-7). For example, the manufacturers reported to FDA that dry eyes occur at ~21% (Figure 7, Table 3A), night vision problems at ~11% (Figure 6, Table 3A), glare at ~12% (Figure 6, Table 3A), and halos at ~14% (Figure 7). However, the published literature shows that these four adverse event rates are approximately 22%, 16%, 20%, and 19% respectively (Table 2). Thus the “true” adverse event rate six months or more post-LASIK is at least 20 times the FDA approvable rate of 1%.

Table 2. Adverse Event (AE) Rates at \(>6\) Months After LASIK

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Published Adverse Event Rates</th>
<th>Adverse Event Rate (%) Reported by Manufacturers to FDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry eyes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reported %</td>
<td>Mean %</td>
</tr>
<tr>
<td></td>
<td>46.0(^8)</td>
<td>~22</td>
</tr>
<tr>
<td></td>
<td>9.0(^9)</td>
<td>~20.6</td>
</tr>
<tr>
<td></td>
<td>35.3(^10)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>12.5(^11)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>20.8(^12)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>27.0(^13)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4.0(^14) 5 years post-LASIK</td>
<td></td>
</tr>
<tr>
<td>Night vision problems</td>
<td>6.19(^15)</td>
<td>~16</td>
</tr>
<tr>
<td></td>
<td>5.15(^16)</td>
<td>~10.9</td>
</tr>
<tr>
<td></td>
<td>10.3(^17)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7.1(^18)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4.7(^19)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>29.5(^20)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>29.0(^21)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11.7(^22)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>33.8(^23) 24.0(^24) 5 years post-LASIK</td>
<td></td>
</tr>
<tr>
<td>Glare</td>
<td>12.0(^25)</td>
<td>~20</td>
</tr>
<tr>
<td></td>
<td>16.3(^26)</td>
<td>~11.6</td>
</tr>
<tr>
<td></td>
<td>27.2(^27)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>24.5(^28)</td>
<td></td>
</tr>
<tr>
<td>Halos</td>
<td>24.7(^29)</td>
<td>~19</td>
</tr>
<tr>
<td></td>
<td>30.0(^30)</td>
<td>~14.1</td>
</tr>
<tr>
<td></td>
<td>3.0(^31) 5 years post-LASIK</td>
<td></td>
</tr>
</tbody>
</table>

LASIK manufacturers and their collaborators emphasized “patient satisfaction” to divert FDA attention from continuing LASIK-patient complaints about glare, halos, dry eye and night driving problems. Reports by refractive surgeons that most patients are satisfied\(^32\) with LASIK even as they report dry eyes and night vision impairment are suspect. Perhaps patients did not have these adverse events when they were asked if they were satisfied. Or, perhaps it was because post-LASIK complications surfaced months thereafter.\(^33\)

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\(^*\) See Table 3A, Appendix

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Waxler Regulatory Consultancy LLC
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or years after LASIK surgery. Or the patient may report high satisfaction because of a need to justify to have LASIK in the first place.

LASIK manufacturers continue to falsely label their LASIK devices as having an adverse event rate of \( \leq 1\% \) (see manufacturers’ patient brochures\(^3\)). To this moment they and their collaborators have been successfully engaged in a pattern of falsifying, misrepresenting, manipulating, and withholding safety and effectiveness data from FDA to make their LASIK devices appear safer than they are.

4. **Manufacturers Distorted Effectiveness of LASIK Device**

Table 3 shows manufacturers knew that about 43\% of LASIK patients’ visual acuity could be improved by wearing spectacles 6-12 months after surgery. The manufacturers and their collaborators distorted this evidence.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>FU (mos)</th>
<th>Spectacles May be Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kremer LASIK</td>
<td>12</td>
<td>32.7</td>
</tr>
<tr>
<td>Kremer LASIK</td>
<td>12</td>
<td>39.9</td>
</tr>
<tr>
<td>VISX Star S2</td>
<td>6</td>
<td>54.1</td>
</tr>
<tr>
<td>Nidek EC-5000</td>
<td>12</td>
<td>48.9</td>
</tr>
<tr>
<td>LADARVision</td>
<td>9</td>
<td>67.3</td>
</tr>
<tr>
<td>LADARVision</td>
<td>9</td>
<td>43.4</td>
</tr>
<tr>
<td>VISX Star S2, S3</td>
<td>6</td>
<td>48.1</td>
</tr>
<tr>
<td>LaserSight</td>
<td>12</td>
<td>51.8</td>
</tr>
<tr>
<td>VISX Star S2,S3</td>
<td>6</td>
<td>61.8</td>
</tr>
<tr>
<td>LADARVision 4000</td>
<td>6</td>
<td>17.3</td>
</tr>
<tr>
<td>VISX Star S4</td>
<td>12</td>
<td>27.9</td>
</tr>
<tr>
<td>Allegretto Wave</td>
<td>12</td>
<td>87.4</td>
</tr>
<tr>
<td>Allegretto Wave</td>
<td>12</td>
<td>67.5</td>
</tr>
<tr>
<td>LADARVision 4000</td>
<td>6</td>
<td>22.9</td>
</tr>
<tr>
<td>VISX Star S4</td>
<td>6</td>
<td>61.8</td>
</tr>
<tr>
<td>VISX Star WaveScan</td>
<td>12</td>
<td>27</td>
</tr>
<tr>
<td>VISX Star WaveScan</td>
<td>12</td>
<td>28.1</td>
</tr>
<tr>
<td>Allegretto Wave</td>
<td>6</td>
<td>69.4</td>
</tr>
<tr>
<td>LADARVision 4000</td>
<td>9</td>
<td>9.4</td>
</tr>
<tr>
<td>LADARVision 4000 &amp; 6000</td>
<td>9</td>
<td>20.4</td>
</tr>
<tr>
<td>Allegretto Wave</td>
<td>6</td>
<td>40.3</td>
</tr>
<tr>
<td>Allegretto Wave</td>
<td>6</td>
<td>42.9</td>
</tr>
<tr>
<td>MEL-80</td>
<td>6</td>
<td>33.4</td>
</tr>
<tr>
<td>Nidek EC-5000</td>
<td>12</td>
<td>1.1</td>
</tr>
<tr>
<td>MEL-80</td>
<td>6</td>
<td>92.7</td>
</tr>
<tr>
<td>VISX Star Wave</td>
<td>12</td>
<td>12.7</td>
</tr>
</tbody>
</table>

Sum = 1110.2

N = 26

Mean = 42.7
Initially, one of the FDA effectiveness measures used in the approval of excimer laser refractive surgery was the percent of post-LASIK patients that would not need spectacles or contact lenses (e.g., P930016S10 Patient Brochure). However, the manufacturers and their collaborators successfully lobbied FDA to eliminate labeling that would indicate the number of patients who might need corrective lenses post-LASIK, instead using percent uncorrected visual acuity less than or equal to 20/40. Candidates for LASIK are not informed that they have only about a 57% chance of getting rid of their spectacles or contact lenses but instead are told that there is a 95% chance that they will see better than 20/40. The manufacturers own data (Table 3) also showed that about 43% of patients’ vision could be improved with spectacles at 6 – 12 months after surgery.

Published evidence confirms a persistent double-digit adverse event rate for LASIK, and there has been no significant trend for improvement in night vision problems and dry eyes with changes in laser technology. The evidence from the PMAs show that the LASIK adverse event rate is at least twenty times the 1% rate acceptable to FDA and probably would be much worse if the manufacturers and their agents had not withheld and distorted the safety data. It is highly unlikely, if not impossible, that the FDA would have approved PMAs with a 20% adverse event rate and an effectiveness rate of 57%. Now let us turn to scientific evidence showing that LASIK devices transform healthy corneas into unhealthy ones (Section B).

B. LASIK Creates Sick Corneas From Normal Ones

Published scientific reports demonstrate that LASIK devices make normal corneas sick: the corneal interface never heals completely; is permanently weakened and vulnerable to thinning and bulging (keratectasia), which may require hard contact lenses and corneal transplant. After LASIK a drier often painful and distorted corneal surface compromises night driving.

1. LASIK flap never completely heals

LASIK patients have permanently weak and sick corneas. It is shown that all post-mortem LASIK corneas examined have “permanent pathological changes.” Since the LASIK flap never heals completely it is at a lifetime risk of dislocation. This fragile flap is vulnerable to traumatic eye injury and infection for the remainder of the patient’s life, and numerous reports of dislodged and amputated flaps exist in the literature, even after minor trauma. Diffuse inflammation under the flap (called diffuse lamellar keratitis) is reported to occur as late as 12 years postoperatively. The average incidence of this surgically induced and sight-threatening inflammation is as high with the newer technology of femtosecond laser flap maker as it is with the older mechanical microkeratome.

2. LASIK permanently weakens the cornea

The post-LASIK cornea has a mechanical strength of only ~2% of normal cornea: "Corneal stromal LASIK wounds were found to heal weaker than normal because these structures were not regenerated during the healing response. Moreover, the central and paracentral stromal LASIK wounds were found to heal by producing a hypocellular primitive stromal scar that is very weak in tensile strength, averaging 2.4% of normal, and displays no evidence of remodeling over time in specimens out to 6.5 years after surgery." Diffuse inflammation under the flap (called diffuse lamellar keratitis) is reported to occur as late as 12 years postoperatively. The average incidence of this surgically induced and sight-threatening inflammation is as high with the newer technology of femtosecond laser flap maker as it is with the older mechanical microkeratome.

3. LASIK severs corneal nerves, causing neuropathic dry eyes

The nerves destroyed by LASIK devices are needed for tear production. These nerves never fully recover, often leading to permanent dry eye disease. Post-LASIK dry eye is a neuropathic
epitheliopathy, a medical device induced epidemic. Dry eye is the most common complication of LASIK surgery. Figure 8 shows how LASIK causes neuropathic dry eye.

Patients are not adequately informed of the seriousness and chronic nature of post-LASIK dry eye disease. Moderate chronic dry eye produces a pain level comparable to moderate angina to those who experience it. Six months after LASIK patients with dry eyes (48%) experience soreness of the eye to the touch (6.7%), sharp pains (8.0%), and eyelid sticking to the eyeball (5.6%).

LASIK induces dry eye in 46% of cases performed with mechanical microkeratomes and 9% with the femtosecond laser flap-maker; no subjects had dry eye symptoms preoperatively. Corneal nerves severed and ablated by LASIK never return to their pre-surgical densities and patterns. The LASIK-induced incidence of dry eyes at six months is reported at 12.5% in eyes with nasal hinges and 35.3% in eyes with superior-hinges.

Dry eyes can occur due to contact lens wear but this dry eye is not due to neuropathy. Moreover, removing the contact lenses and treatment with eye drops, are likely to restore the cornea surface to normality. In contrast, LASIK severs corneal nerves in otherwise healthy eyes causing corneal dryness that is essentially permanent since these nerves never completely regenerate.

**Figure 8 – LASIK Cuts Corneal Nerves, Causing a Dry and Irritated Cornea**

(The statement that “50% LASIK Patients Suffer for More Than Six Months” is based on published data cited in Table 2.)
LASIK devices do more damage than cutting corneal nerves; they also cause progressive loss of important corneal cells called keratocytes. LASIK devices change the biomechanical, anatomical, and molecular dynamics of the eye. The cornea is deformed with a rapid rise and fall of intraocular pressure; the flap is cut and brushed back onto a hinge. Then the laser craters the stroma and the flap floated to cover the void.

One of the most striking long-term pathological changes in the post-LASIK cornea is the 5-year progressive decline in the density of corneal stromal keratocytes. Figure 9 shows this decline and Table 4 shows the annual rate of keratocyte loss. Keratocyte density declines in LASIK-induced thinning and bulging of the cornea (keratectasia) but NOT in keratoconic corneas. The density of keratocytes is probably related to corneal stiffness, however, it not yet known if it is linked to keratectasia or some other disease process.

Figure 9 – LASIK Causes Progressive Loss of Keratocytes
From: Erie JC, McLaren JW, Hodge DO, Bourne WM. Long-term corneal keratoctye deficits after photorefractive keratectomy and laser in situ keratomileusis. Trans Am Ophthalmol Soc. 2005;103:56-66; discussion 67-8. 39: “FIGURE 5 Keratocyte density before and after LASIK. In the anterior and posterior stromal flap and the anterior retroablation zone (RAZ), keratocyte density was decreased at all post-LASIK visits from density before LASIK. Cell densities in all remaining stromal layers were first decreased at 5 years after LASIK. *P < .005 and P < .05, when compared with densities before LASIK.”
TABLE 4. CHANGE IN KERATOCYTE DENSITY BETWEEN 6 MONTHS AND 5 YEARS AFTER LASIK

<table>
<thead>
<tr>
<th>Stromal Layer</th>
<th>Rate of Change (% Per Year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior flap</td>
<td>–4.3 ± 3.2</td>
</tr>
<tr>
<td>Posterior flap</td>
<td>–7.2 ± 4.3</td>
</tr>
<tr>
<td>Anterior RAZ (0 to 50 µm)</td>
<td>–8.4 ± 3.7</td>
</tr>
<tr>
<td>Posterior RAZ (51 to 100 µm)</td>
<td>–2.6 ± 4.1</td>
</tr>
<tr>
<td>Posterior 66% to 90%</td>
<td>–3.5 ± 3.4</td>
</tr>
<tr>
<td>Posterior 91% to 100%</td>
<td>–3.1 ± 2.2</td>
</tr>
</tbody>
</table>


5. LASIK Causes Keratectasia, a Sight-Threatening Disorder

The post-LASIK cornea may become thin and bulge weeks, months, or years later to become the potentially blinding condition of keratectasia. The absence of keratectasia findings in LASIK is likely due to the failure of long-term follow up, an interpretation that is consistent with the failure to report adverse events and to follow-up on patients for an extended period of time. Patients may also choose to see a surgeon or eye care practitioner other than the one who performed LASIK and caused the problem they are experiencing.

In a personal communication Dr. Edward Boshnick says that he has at least 75 patients with LASIK-induced keratectasia, strongly suggesting a much higher percentage of LASIK-induced bulging of the cornea than is reported by refractive surgery businesses (user facilities) in the professional journals they control. A worst-case approach would be to select 0.9% as the keratectasia rate. It seems likely that there is a large degree of under reporting of keratectasia so that it is likely that keratectasia rate is at least 0.66%.
Table 5 – Incidence of LASIK Induced Corneal Bulging

Table 1. Reported incidence of post-LASIK ectasia.

<table>
<thead>
<tr>
<th>Source</th>
<th>Number</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reinstein³,*</td>
<td>6/5212</td>
<td>(0.12)</td>
</tr>
<tr>
<td>Pallakaris⁴</td>
<td>19/2873</td>
<td>(0.66)</td>
</tr>
<tr>
<td>Rad⁵</td>
<td>—</td>
<td>(0.2 )</td>
</tr>
<tr>
<td>Condon⁶</td>
<td>3/140</td>
<td>(0.8 )</td>
</tr>
<tr>
<td>Current†</td>
<td>3/9283</td>
<td>(0.01)</td>
</tr>
<tr>
<td>Kansky‡</td>
<td>—</td>
<td>(0.9 )</td>
</tr>
<tr>
<td>Sergey‡</td>
<td>13/23990</td>
<td>(0.05)</td>
</tr>
<tr>
<td>Oliviera‡</td>
<td>6/2500</td>
<td>(0.24)</td>
</tr>
<tr>
<td>Stulting§</td>
<td>≥1:5000</td>
<td>—</td>
</tr>
<tr>
<td>ESCRS registry of ectasia cases (9/2006)</td>
<td>72</td>
<td>—</td>
</tr>
</tbody>
</table>

*Projection
†Myopic errors
§Data presented at the annual meeting of the American Academy of Ophthalmology, Las Vegas, Nevada, USA, November 2006; projection based on literature reports
6. **LASIK Induces Corneal Distortions**

In the attempt to correct defocus (sphere) and astigmatism (cylinder) LASIK devices induce distortions that degrade vision. LASIK devices make corneas more pancake-like\(^6\), often de-centered, warped, chaotic, and rough with stromal microfolds.\(^6\)

Several issues must be resolved in order to prevent double-digit rate of the adverse effects of blur, haloes, glare and night vision losses.\(^6\) These unresolved safety issues include, but are not limited to, laser beam characteristics, alignment issues, corneal tissue thickness, spatial ablation efficiency,\(^6\) large variability in flap thickness, tissue biomechanics and healing response\(^6\) on the alteration of the intended surface structure prescribed for a given treatment.\(^6\)

Dr. Leo Maguire forewarned of the public health threat of LASIK in an editorial published in the March, 1994 edition of American Journal of Ophthalmology:\(^6\)

“I hope the reader will now understand how a patient may have clinically acceptable 20/20 visual acuity in the daytime and still suffer from clinically dangerous visual aberration at night if that patient’s visual system must cope with an altered refractive error, increased glare, poorer contrast discrimination, and preferentially degraded peripheral vision. People die at night in motor vehicle accidents four times as frequently as they do during the day, and these figures are adjusted for miles driven. Night driving presents a hazardous visual experience to adults without aberrations. When we discuss aberration at night we are considering a possible morbid effect of refractive surgery.”

In a normal eye LASIK can only increase corneal aberrations. LASIK-induced aberrations are significant in magnitude, adverse consequences, and frequency. Even the newer wavefront-guided LASIK, that is, LASIK guided by aberration measurements of the client’s healthy cornea, increases higher order aberrations with commensurate losses in contrast sensitivity in myopic eyes greater than or equal to -6D.\(^6\) LASIK increases both corneal and total aberrations with changes in the anterior and posterior corneal surfaces contributing to the rise in higher order aberrations.\(^6\) LASIK may correct distortions such as defocus but it induces other distortions. Figure 10 shows the LASIK-induced increase in higher order aberrations.\(^7\)

According to published studies, higher order distortions induced by LASIK are significantly correlated with loss of quality of vision,\(^7\) such as loss of contrast sensitivity,\(^7\) and increases in halos and night vision problems.\(^7\) In addition, LASIK-induced higher order aberrations are more troublesome in binocular than in monocular viewing.\(^7\) Moreover, binocular vision worsens during post-LASIK recovery because the interocular differences in higher order aberrations increases as each cornea re-models itself to the specific pattern of injuries introduced into each eye.
Some LASIK manufacturers and allied clinics report waveguided-LASIK devices do not increase higher order aberrations or cause fewer halos and night vision problems than conventional LASIK devices.\textsuperscript{77,78,79,80} Still others report waveguided-LASIK does increase higher order aberrations\textsuperscript{81} or increase aberrations more for one LASIK device than another.\textsuperscript{82} Other studies report no significant improvement of waveguide-LASIK compared to conventional LASIK.\textsuperscript{83}

7. **Persistent post-LASIK Loss of Contrast Sensitivity in Dim Light**

There is considerable evidence that LASIK induces corneal aberrations that are linked to losses in contrast sensitivity and critical losses of vision.\textsuperscript{84} Most of the decrease in post-LASIK contrast sensitivity found can be explained and computed directly from the physical measurement of the wave aberration.\textsuperscript{85} LASIK increases higher order aberrations and decreases contrast sensitivity at 6 and 12 months. There are no data after 12 months but it can be assumed from the high percentage of contrast sensitivity loss and night vision disturbances that have been reported remain as long as the cornea is unstable, which appears to be many years.

LASIK manufacturers and their collaborators successfully lobbied FDA to use a 6 mm pupil diameter for measuring safety and effectiveness instead of a larger one. Also, they successfully lobbied FDA not to require LASIK manufacturers to measure contrast sensitivity in dim light before and after LASIK.\textsuperscript{86} Since the induction of visual aberrations are directly related to pupil size, this practice effectively "clip off" aberrations outside the 6 mm central zone and ignore the aberrations that patients see in dim light through a large pupil. The consequences of these decisions are seen below.
Table 6 shows contrast sensitivity losses for the VISX LASIK device. At 6 months LASIK reduces low contrast visual acuity one to two diopters for 20.2% of the subjects while 2.2% of patients lose more than 2 diopters. Also, predictably contrast sensitivity losses in dim light are worse (9.1%) than losses in bright light (3.8%). Contrast sensitivity in dim light with a glare source is worse (16.4%) than in dim light without glare (14.2%) which in turn is worse than in bright light without glare (6.3%). These losses in contrast sensitivity persist 12 months after LASIK.

LASIK induces dim light contrast sensitivity losses by light scatter (haze) at high spatial frequencies and by defocus (optical aberrations) at medium and high spatial frequencies.\textsuperscript{87} Also, LASIK causes loss of sensitivity in the midperipheral visual field correlated with refractive error, flap thickness, and optical zone diameter.\textsuperscript{88}

### Table 6 – Persistent Loss of Contrast Detection after LASIK

<table>
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<tr>
<th>Type of Loss</th>
<th>6 Months (% loss)</th>
<th>12 Months</th>
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<td>Low contrast visual acuity</td>
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<td>&gt;2D</td>
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<td>20.9\textsuperscript{††††}, 11.8\textsuperscript{††††}, 26.2\textsuperscript{§§§§}, 21.8\textsuperscript{****}</td>
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</tr>
<tr>
<td></td>
<td>2.2\textsuperscript{c}</td>
<td></td>
</tr>
<tr>
<td>Bright light contrast sensitivity</td>
<td>Mean = 3.8</td>
<td>No data</td>
</tr>
<tr>
<td></td>
<td>0.7\textsuperscript{†††††}, 1.7\textsuperscript{†††††}, 7.5\textsuperscript{f}, 5.5\textsuperscript{§§§§§}</td>
<td></td>
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<tr>
<td>Dim light contrast sensitivity</td>
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<tr>
<td></td>
<td>5.8\textsuperscript{b}, 7.3\textsuperscript{e}, 12.9\textsuperscript{f}, 10.3\textsuperscript{g}</td>
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<tr>
<td>Contrast Sensitivity</td>
<td>Mean = 6.3</td>
<td></td>
</tr>
<tr>
<td>Bright light without glare</td>
<td>Mean = 4.5\textsuperscript{*****}, 3.8\textsuperscript{††††††}, 10.7\textsuperscript{††††††††}</td>
<td>1.6\textsuperscript{i}, 14.0\textsuperscript{k}</td>
</tr>
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<td>Dim light with glare</td>
<td>Mean = 16.4</td>
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<td>27.1\textsuperscript{i}, 5.0\textsuperscript{i}, 22.5\textsuperscript{k}</td>
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<tr>
<td>&gt;2 Line Decrease in CS\textsuperscript{§§§§§}</td>
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<tr>
<td>Bright without glare</td>
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<tr>
<td>Dim without glare</td>
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</tr>
<tr>
<td>Dim with glare</td>
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\textsuperscript{†††} Table 16 - P970043S10b
\textsuperscript{††††} Table 19 - P970043S15b
\textsuperscript{§§§} Table 26 – S20b
\textsuperscript{****} Table 26 – S22b
\textsuperscript{†††††} Table 19 - P970043S10b
\textsuperscript{†††††} Table 21 - P970043S15b
\textsuperscript{§§§§} Table 28 – S22b
\textsuperscript{****} Table 11 – S17b
\textsuperscript{†††††} Table 11 – S20b
\textsuperscript{§§§§} Table 22 – S21b
\textsuperscript{§§§§} Table 36 – S25b
8. **LASIK is Unstable and Regresses**

Multiple studies have determined that the effects of LASIK are unstable and regress. Seven years after LASIK fifty-five percent are unhappy with their vision and the number of eyes that lost 2 or more lines of visual acuity has doubled. Another study found similar results at 8 years with only 39% of highly myopic eyes with a visual acuity of 20/20 uncorrected, along with a significant increase in higher order aberrations, and decrease in contrast sensitivity; deterioration in vision occurred even after wavefront-guided LASIK. Similar vision deterioration over time has been found after corneal surgery with other LASIK devices.

9. **LASIK Creates the Need for Additional Eye Care**

A catalogue of the additional medical care that LASIK patients require is beyond the scope of this petition. However, this care is considerable, costly, and often accompanied by additional risk. LASIK patients often need treatment for LASIK-induced adverse events including but not limited to dry eyes, night vision impairment, diffuse lamellar keratitis, and keratectasia. Two additional problems are particularly thorny.

a. **LASIK Increases Risk of Undiagnosed Glaucoma**

Having LASIK increases the lifetime risk of undiagnosed glaucoma because the post-LASIK cornea produces falsely low intraocular pressure (IOP) readings. IOP measurements are performed during routine eye exams to screen for glaucoma. Therefore, vision-threatening glaucoma may go undiagnosed and untreated in patients who have had LASIK surgery. Glaucoma is a leading cause of blindness.

b. **LASIK Increases risk of Poor Outcome Following Cataract Surgery**

Also, because LASIK devices change corneal shape, the risk of a poor outcome from cataract surgery is increased. Most people who have LASIK will require cataract surgery later in life and the surgeon’s measurements of post-LASIK corneas to calculate the appropriate intraocular lens (IOL) power will likely be inaccurate.

10. **Newer LASIK Devices Cause the Same Permanent Corneal Damage as Older Models.**

Newer technologies have not resolved problems inherent in the LASIK procedure, such as induction of aberrations that impair night vision and nerve damage that causes post-LASIK dry eye. In fact, studies show that wavefront-guided and wavefront-optimized LASIK actually increase, not decrease, higher order aberrations, reducing visual quality in previously untreated eyes. This study demonstrates that wavefront guided LASIK induces a 1.9 fold increase in total aberrations at 6 months, a 5-fold increase in vertical distortions and a large increase in spherical aberrations. A review of the literature on wavefront-guided LASIK concludes that evidence does not support claims that wavefront out performs conventional LASIK. Femtosecond laser flap creation does not reduce the incidence of most complications. Furthermore, femtosecond-created laser flaps are more difficult to lift than flaps created with a blade, which may result in a higher incidence of torn flaps. The femtosecond laser keratome currently requires longer suction on the eye than blade microkeratomes to create the LASIK flap. The incidence of suction ring-induced posterior vitreous detachment with blade microkeratomes is high at 13% overall, and 24% for patients with high myopia in one study. A search of peer-reviewed literature reveals problems associated with the femtosecond laser such as slipped flaps, interface inflammation, flap

**** Highly myopic defined as equal to or greater than -6 D.

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folds, infectious keratitis, corneal stromal inflammation, delayed wound healing, macular hemorrhage, and gas bubbles in the anterior chamber after surgery.101

II. Public Health Alert - Key Warnings

The following outline summarizes LASIK risks that must be conveyed to the public.

❖ Safety problems (risks)
  o Adverse event percentages
    ▪ Persistent adverse events, including dry eyes and night vision difficulties: >20%
    ▪ Other problems: >1%
    ▪ Sight threatening thinning and bulging of the cornea (keratectasia): at least 0.66%
  o Permanent pathology in cornea
    ▪ LASIK flap
      • Never heals
      • May be accidentally dislodged for the rest of a patient's lifetime
    ▪ Mechanical strength of post-LASIK cornea only ~2% strength of normal cornea
    ▪ Progressive loss of corneal cells for years after LASIK
    ▪ Corneal nerve damage never fully recovers
  o Types of adverse events to expect
    ▪ Glare, halos, dry eye and compromised night driving
    ▪ Permanent loss of contrast sensitivity
    ▪ Unstable vision
    ▪ Permanent corneal haze
    ▪ Permanent dry eye
    ▪ Night time vision permanently impaired
    ▪ Vision improvements from LASIK will likely decline with age
    ▪ May require corneal transplant, expensive special hard contact lenses, or cross-linking treatment due to thinning and bulging of the cornea
    ▪ Extreme light sensitivity
  o Potential future eye problems
    ▪ Undiagnosed glaucoma
    ▪ Poor outcome from cataract surgery
❖ Benefits (effectiveness) – about 43% of LASIK cases may have temporary freedom from wearing spectacles or contact lenses

I. ENVIRONMENTAL IMPACT

The actions requested in this Petition will have no environmental impact. Also, the petitioner claims categorical exclusion under 21 CFR 25.34(a) so that the preparation of an environmental impact statement is not necessary.

III. ECONOMIC IMPACT

Waxler Regulatory Consultancy believes that the petitioner’s proposed FDA actions (Section I) will minimize iatrogenic injuries from LASIK, thus leading to less morbidity and to better utilization of health care dollars.

IV. CERTIFICATION
The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

I declare under penalty of perjury that the forgoing is true and correct.

Sincerely,

Morris Waxler
## Appendix – Tables with Additional Details

### Table 1A – Percent Adverse Events Data Withheld by Manufacturers

<table>
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<tr>
<th>Manufacturer</th>
<th>PMA</th>
<th>Approval Date</th>
<th>Data Source</th>
<th>FU (mos)</th>
<th>% Data Withheld (n-N)/N x 100</th>
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| Sum          | 724       | n         | 25         | Mean   | 29.7  |

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Table 2A – Percent Patients That May Need Spectacles 6-12 Months After LASIK

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<th>Manufacturer</th>
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<th>Approval Date</th>
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<td>Sum</td>
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<tr>
<td>Mean</td>
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Table 3A – Mean Percent Vision Adverse Events After LASIK
Data From PMA Documents Identified in Table 1A
Data Used in Figures 2 - 7

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Months After LASIK</th>
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<tr>
<td>Vision fluctuates in normal light</td>
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<tr>
<td>Vision fluctuates in dim light</td>
<td>29.8</td>
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<tr>
<td>Redness</td>
<td>22.7</td>
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<tr>
<td>Vision fluctuates in bright light</td>
<td>33</td>
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<tr>
<td>Blurry vision</td>
<td>15.8</td>
</tr>
<tr>
<td>Gritty feeling</td>
<td>23.7</td>
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<tr>
<td>Vision fluctuates overall</td>
<td>55.6</td>
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<tr>
<td>Burning sensation</td>
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<tr>
<td>Light sensitivity</td>
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<tr>
<td>Glare</td>
<td>12.8</td>
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<tr>
<td>Night driving problems</td>
<td>24.3</td>
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<tr>
<td>Excessive tearing</td>
<td>4.9</td>
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<tr>
<td>Ghosts</td>
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<td>Dryness</td>
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<td>Halos</td>
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<td>Double vision</td>
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<td>Headaches</td>
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<td>Foreign body sensation</td>
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<td>Pain</td>
<td>2.4</td>
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Citations

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Waxler Regulatory Consultancy LLC
1/6/11
ultrasound corneal analysis identifies anatomic correlation with scanning spot laser systems.


Personal communication Ed Boshnick, December 15, 2010 9:43:28 PM CST


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