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

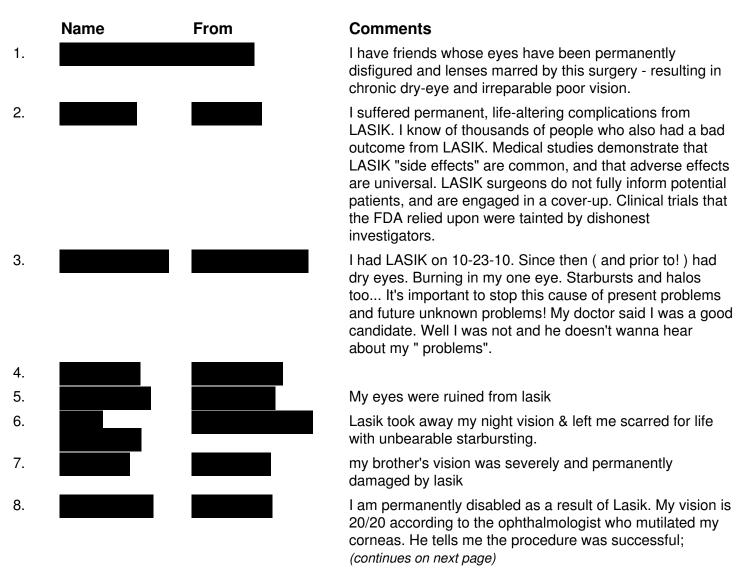
To the Food and Drug Administration Commissioner

We the undersigned support the Citizen Petition to

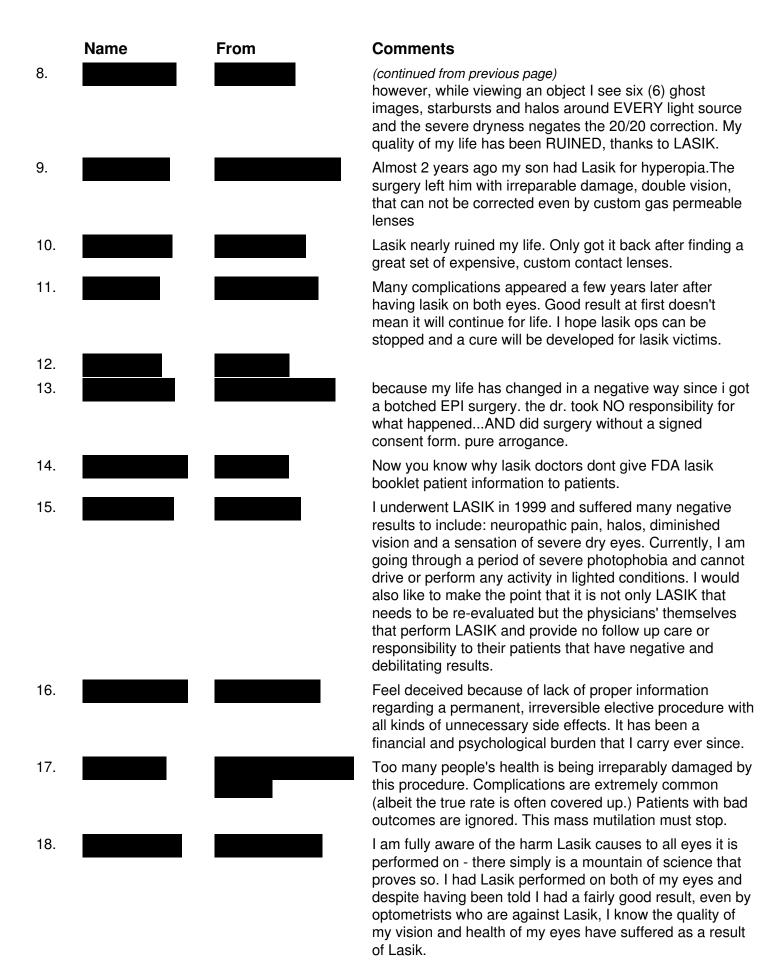
- 1. Withdraw FDA approval (PMA) for all LASIK devices
- 2. Issue a Public Health Advisory with a voluntary recall of LASIK device

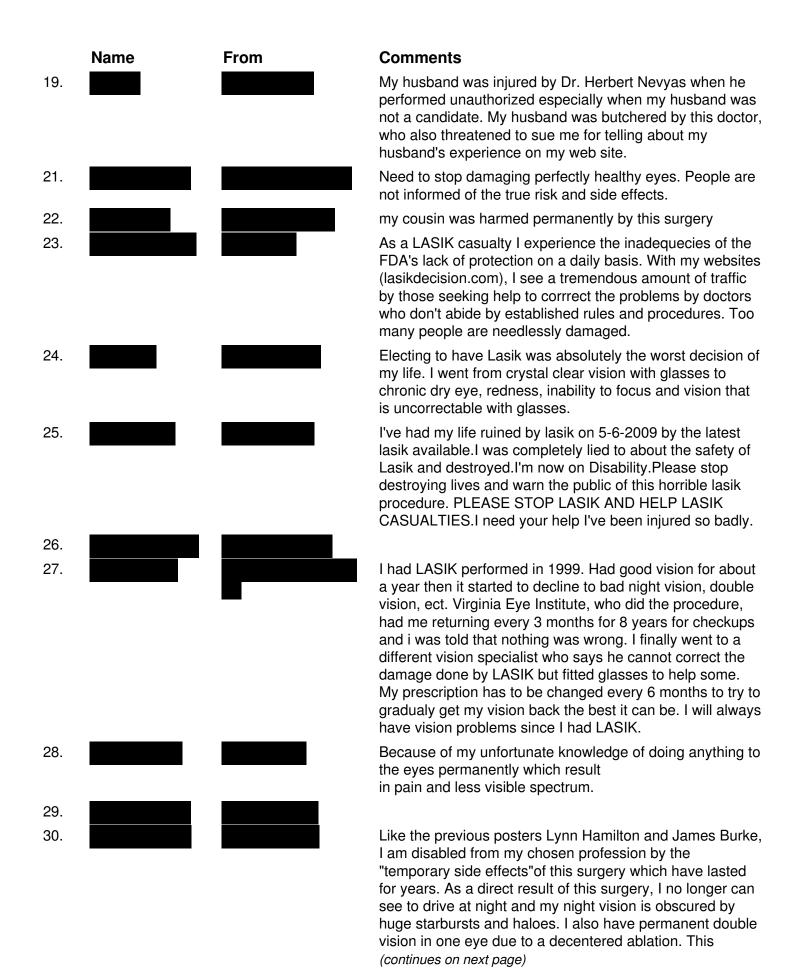
submitted to the FDA, on January 6, 2011, by Waxler Regulary Consultancy, in order "to stop the epidemic of permanent eye injury caused by lasers and microkeratomesused for LASIK eye surgery".

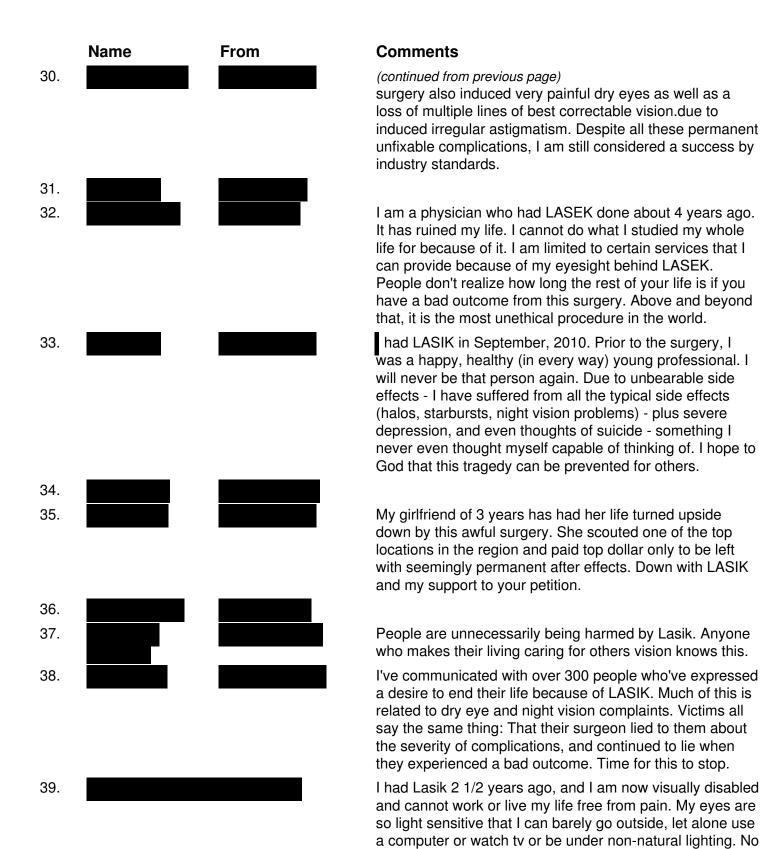
We thank you for taking the time to read this letter.



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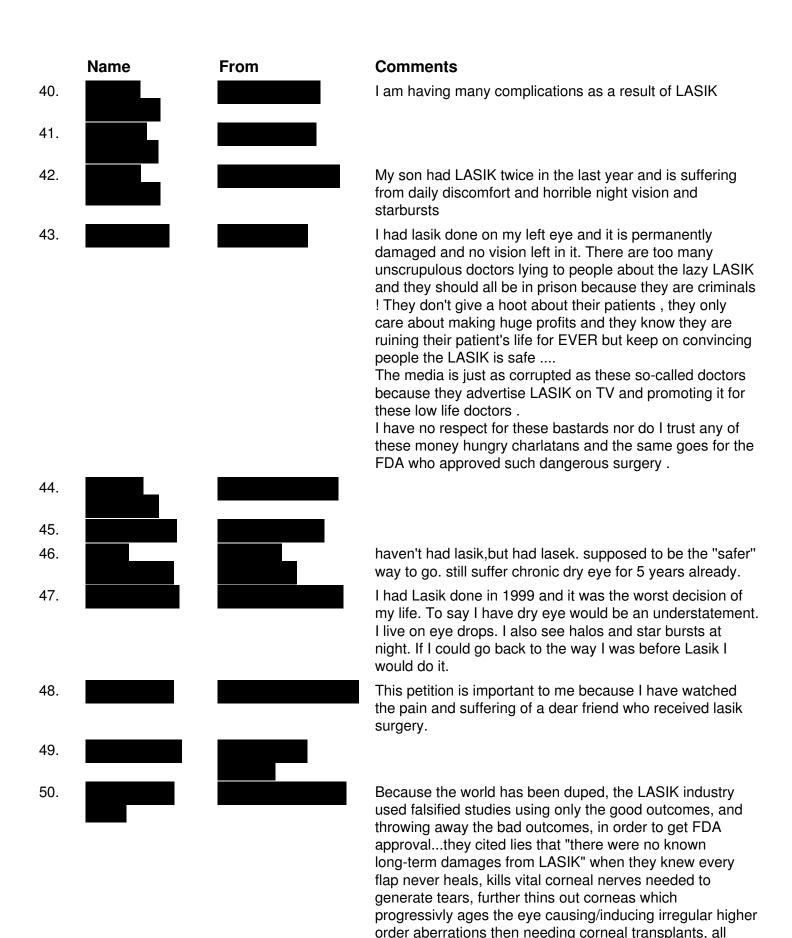






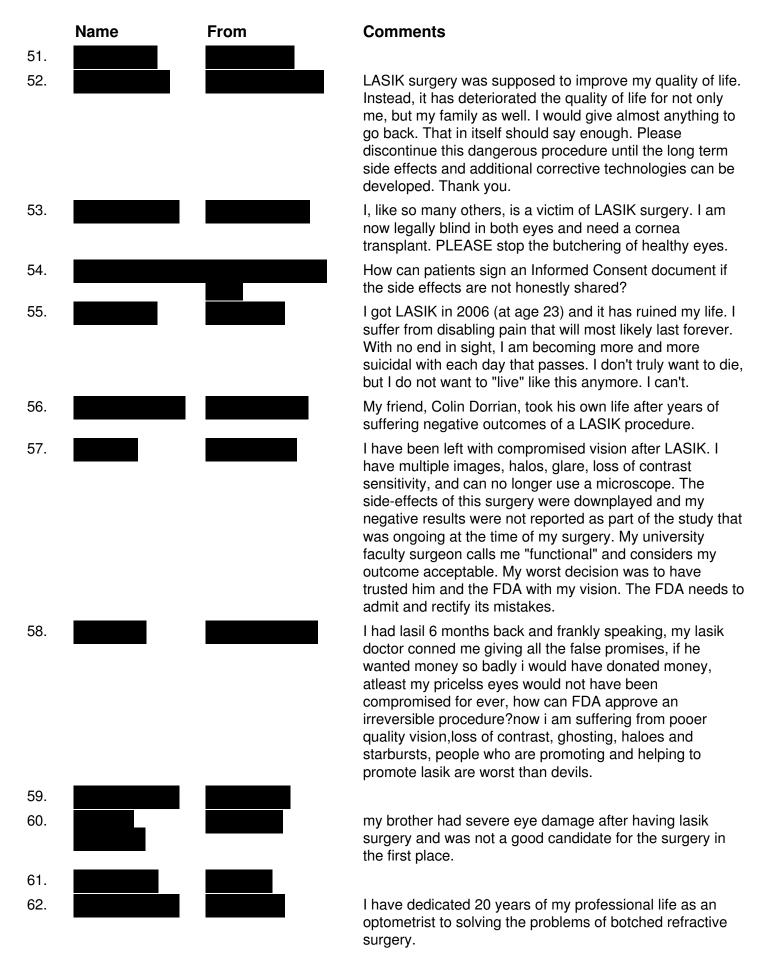
effects don't keep happening.

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

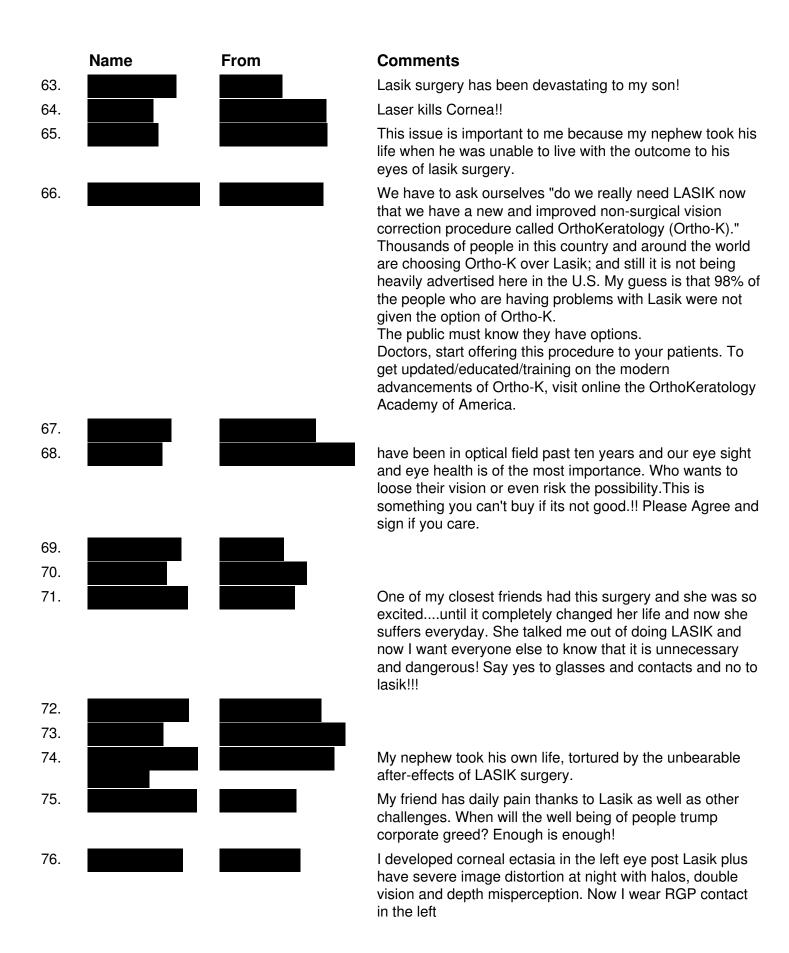


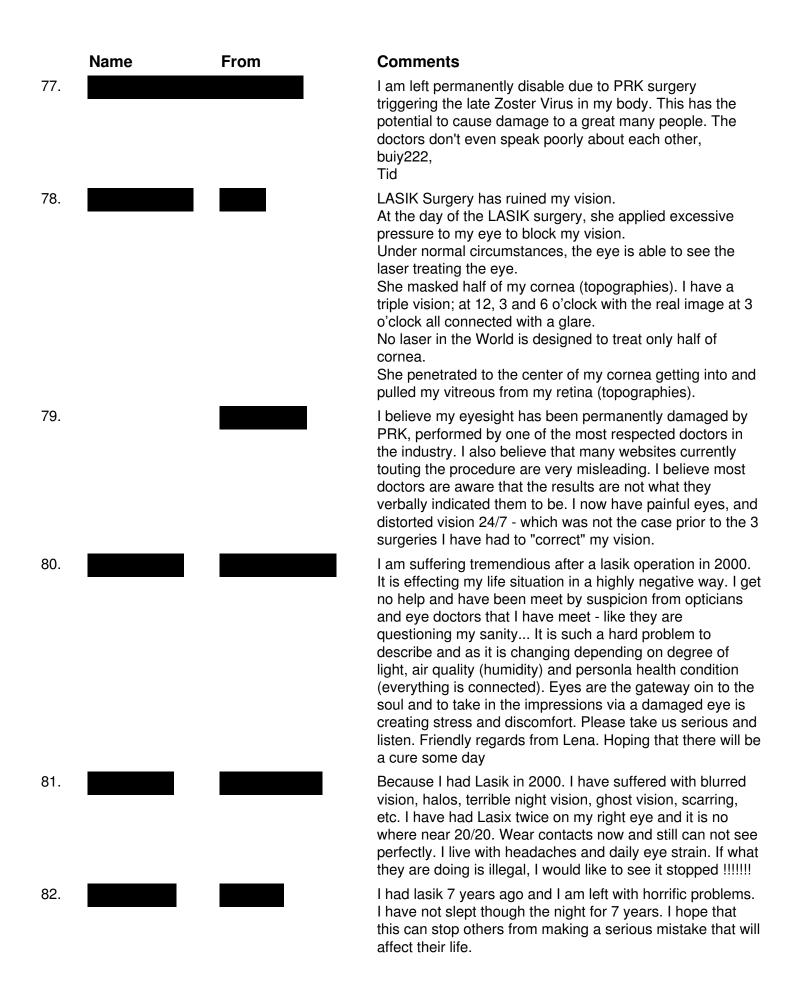
while causing it's victims escalated depression and some

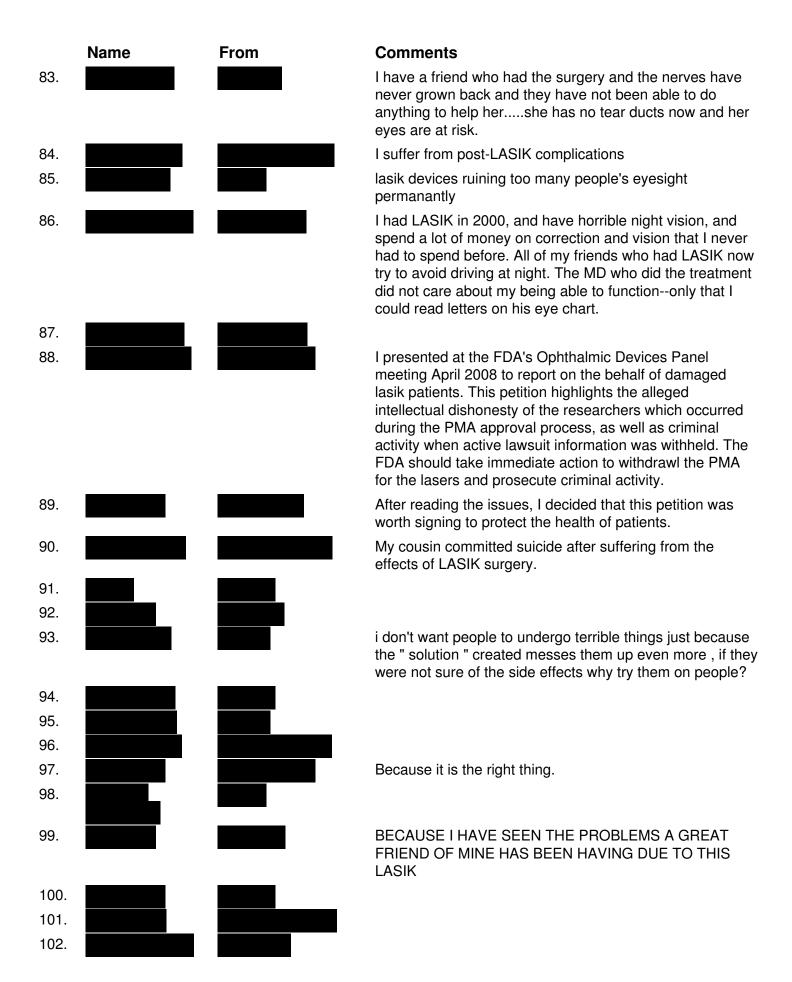
suicidal tendencies because there is no cure.



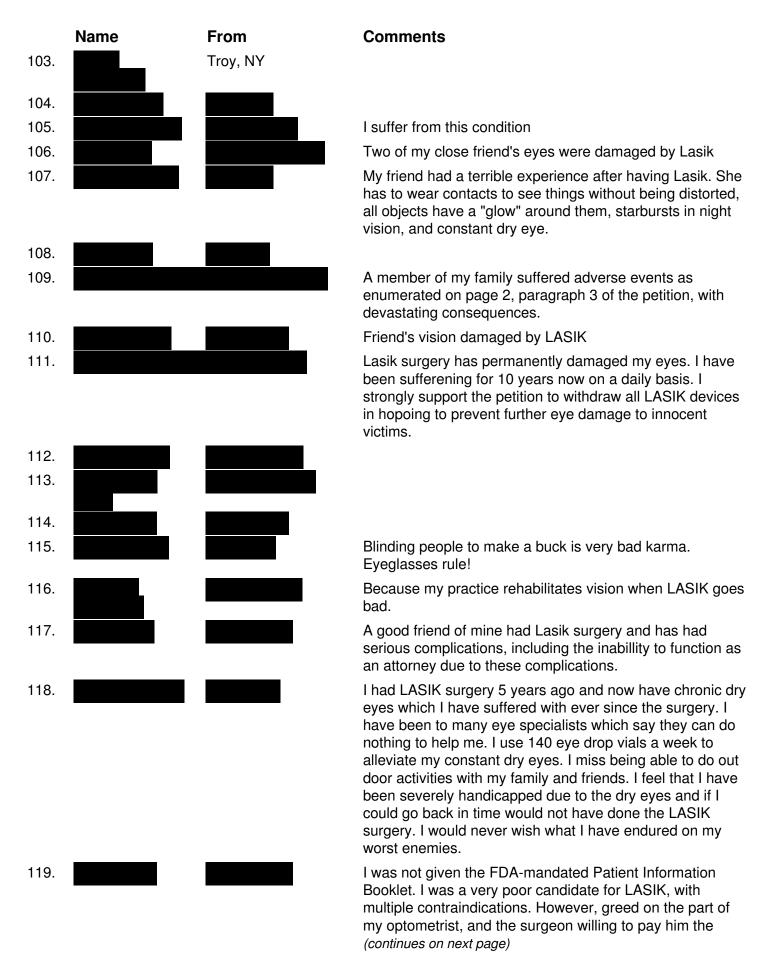
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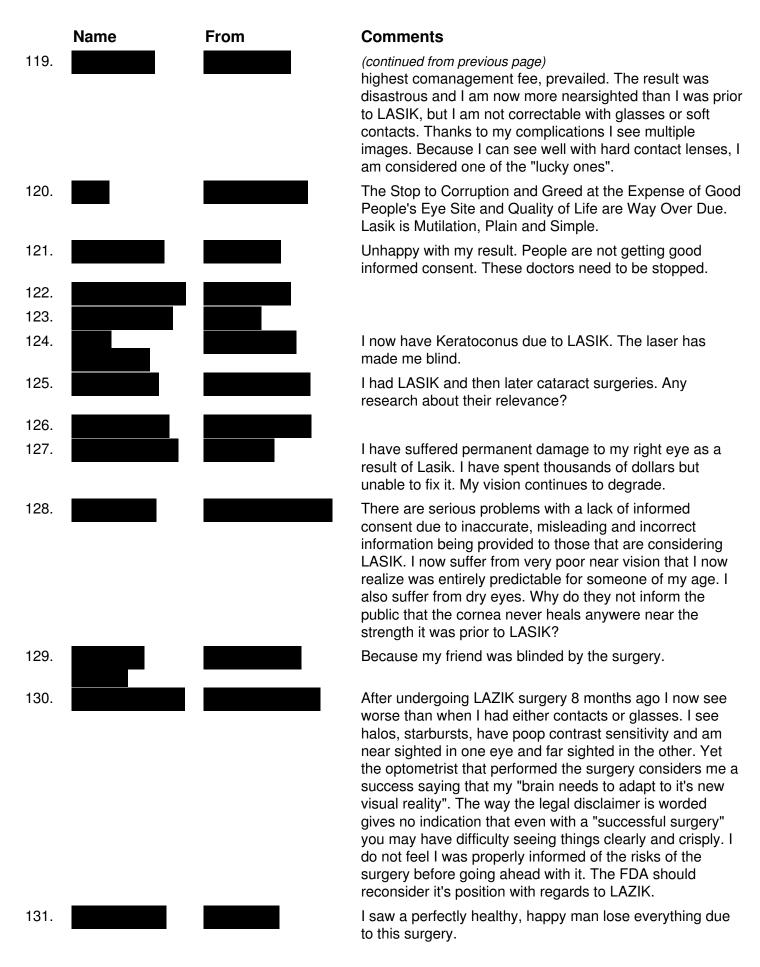




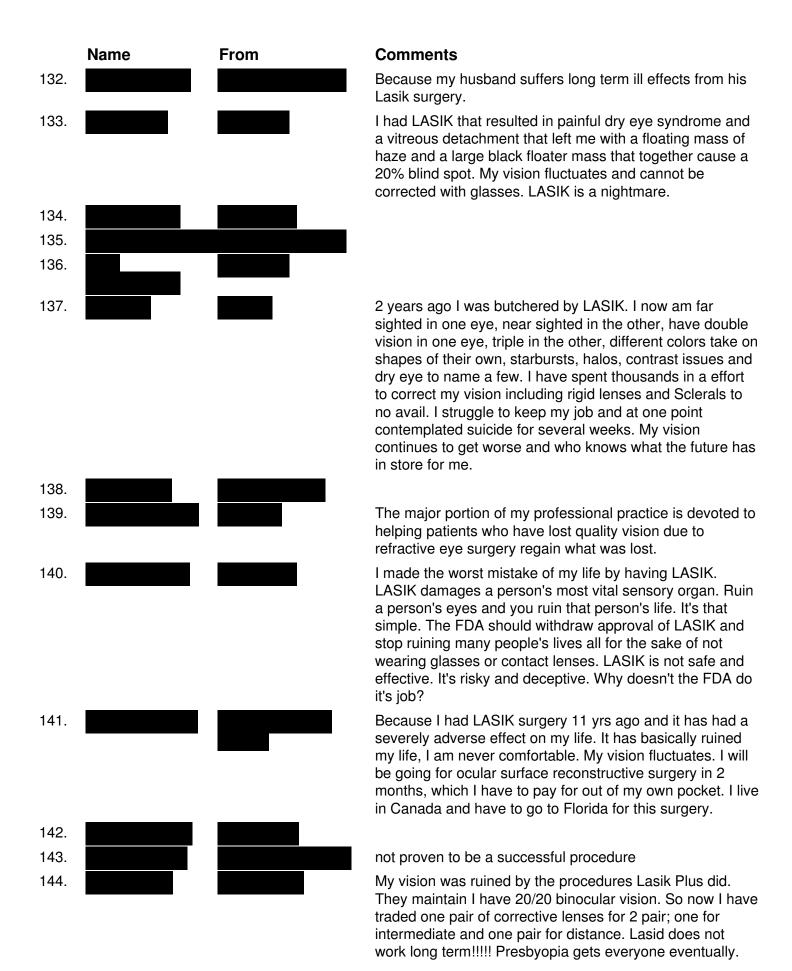
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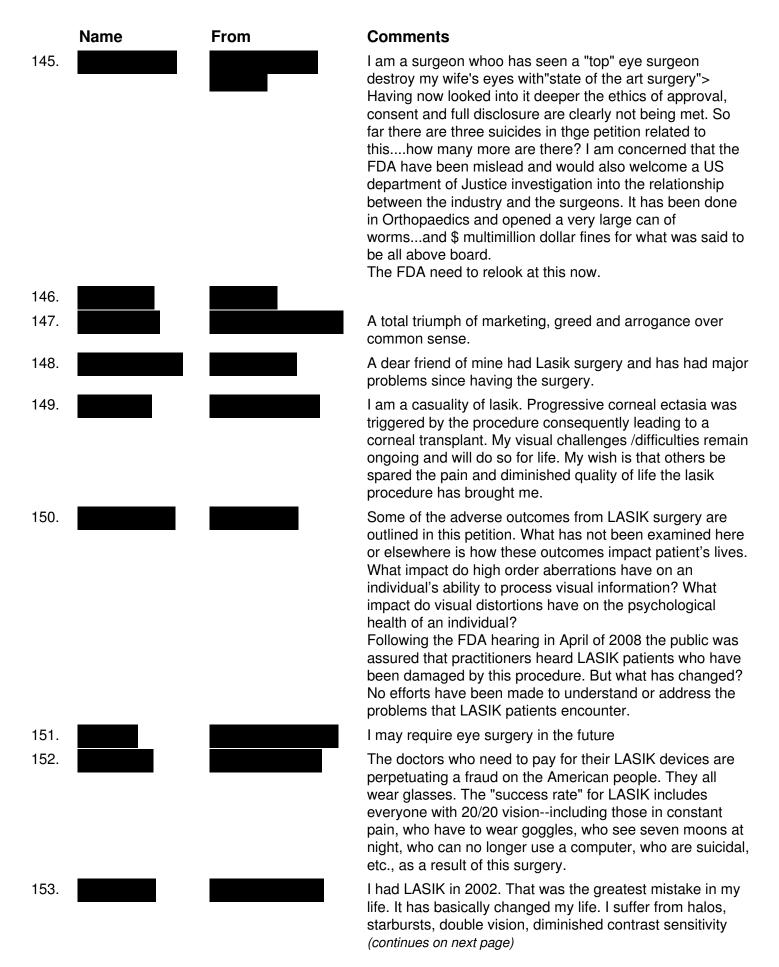
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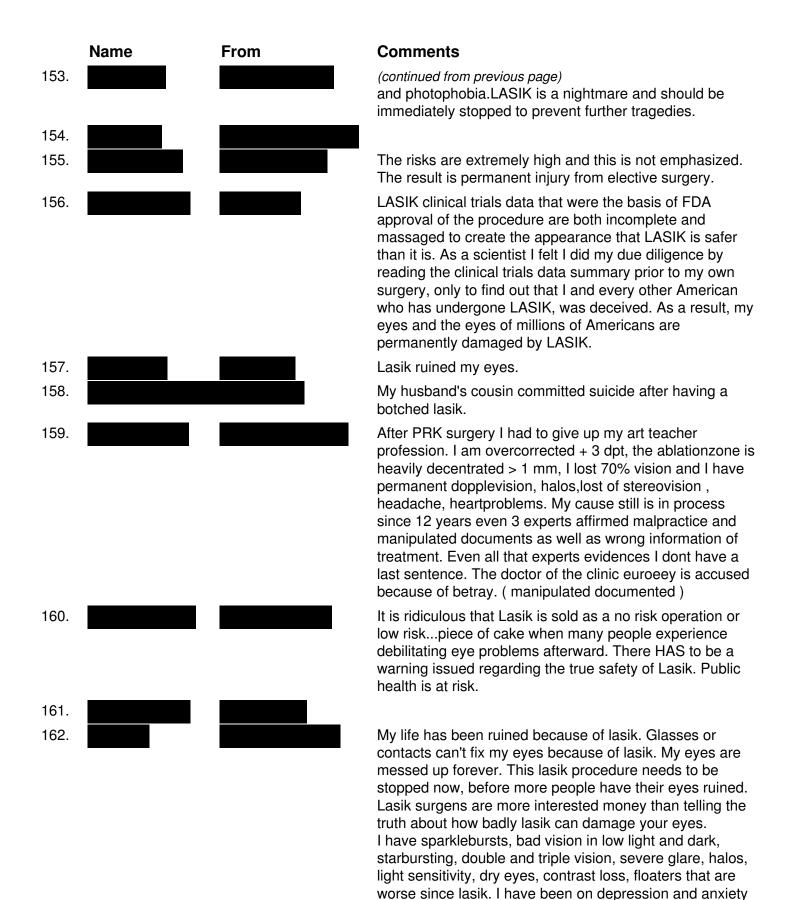
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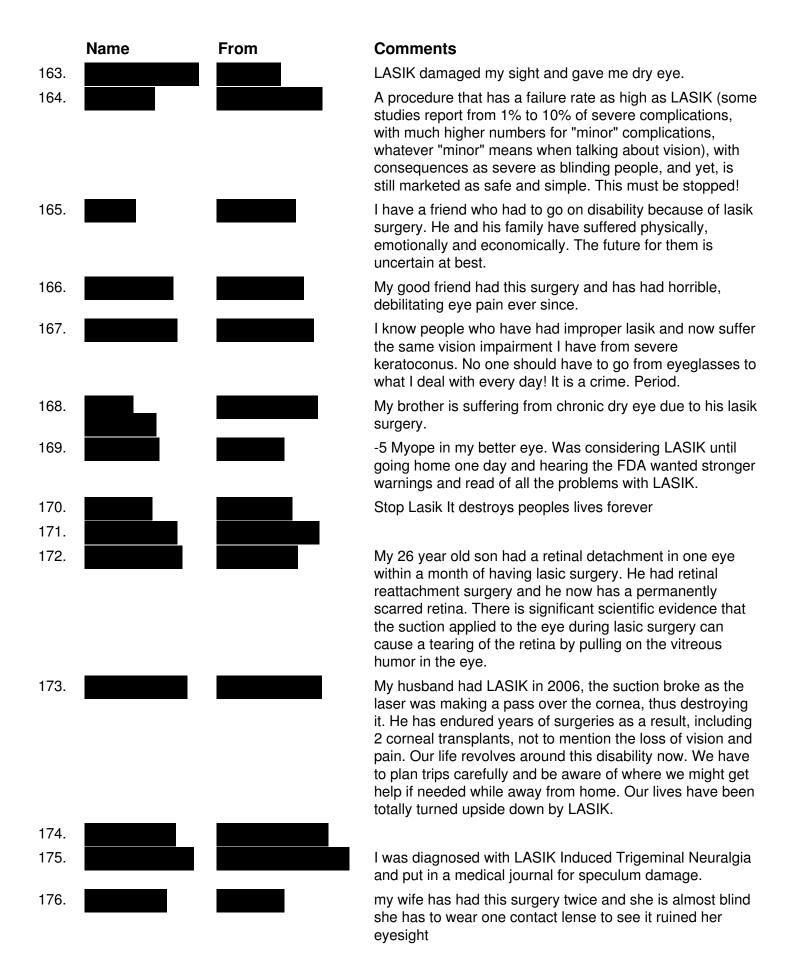


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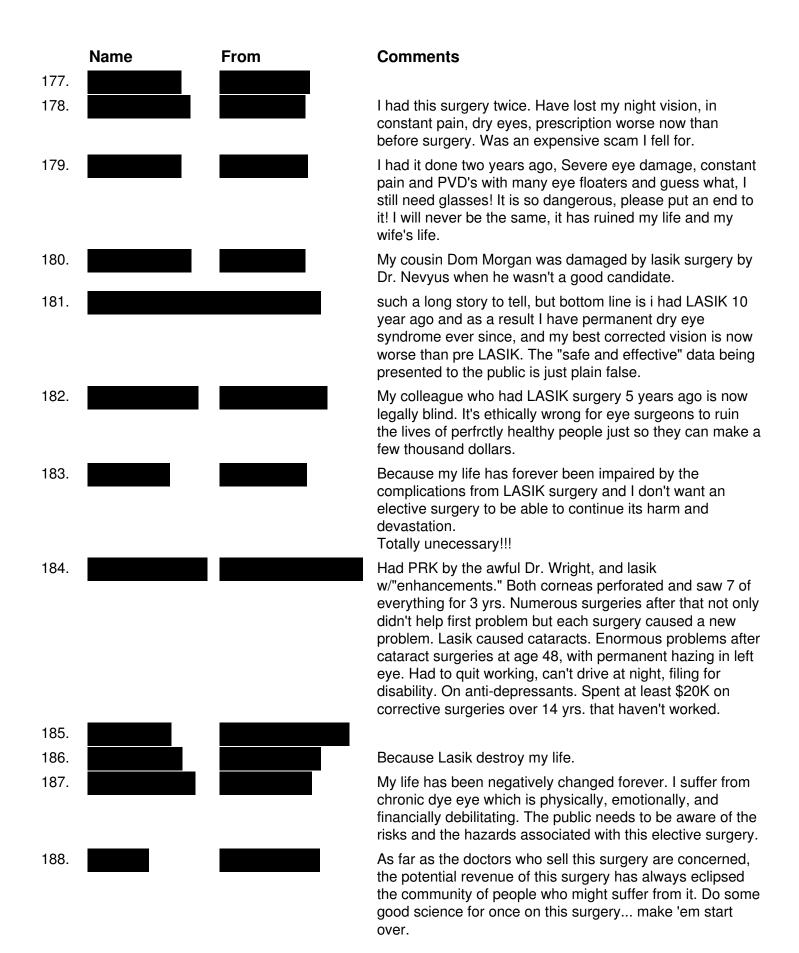


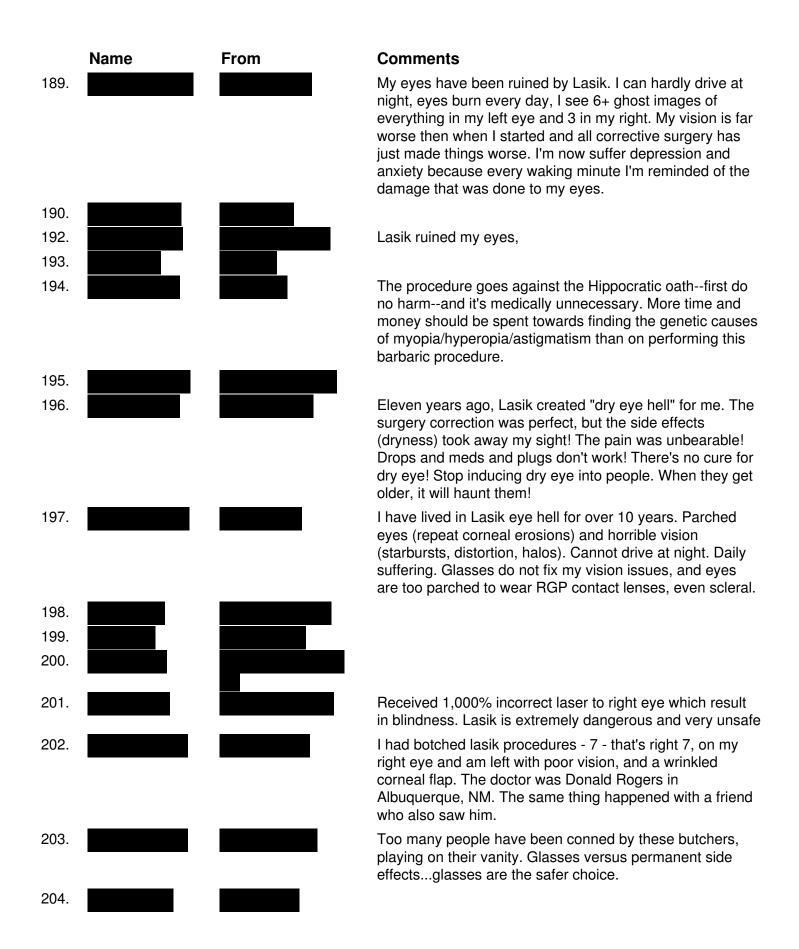
be ruined!

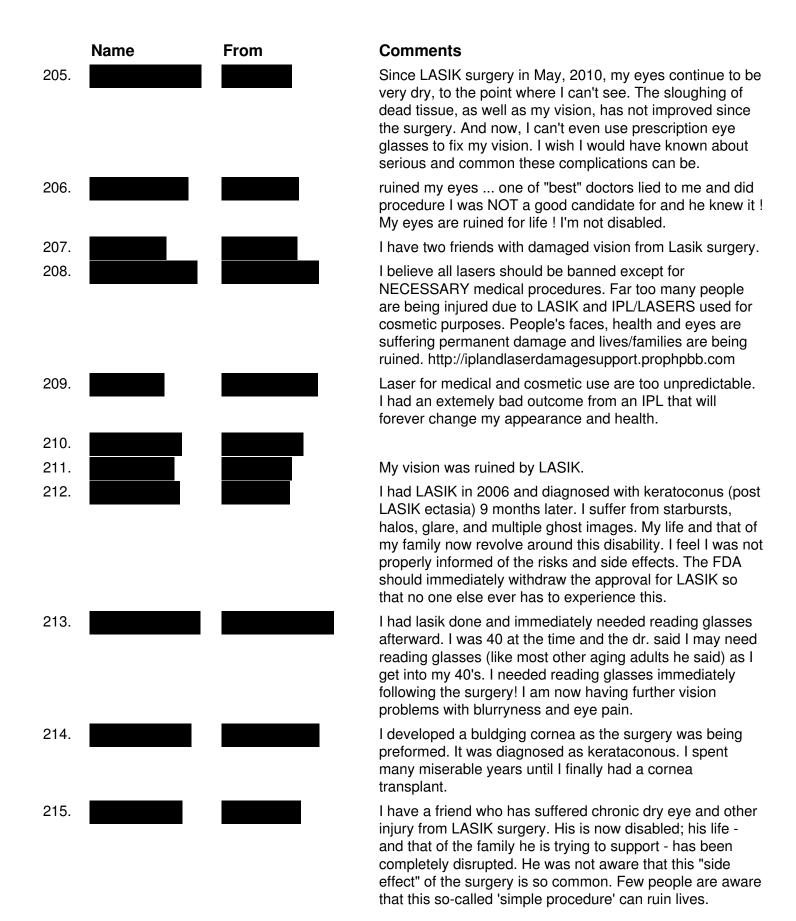
medication since right after having lasik over four years ago. Please stop lasik from causing more people lives to

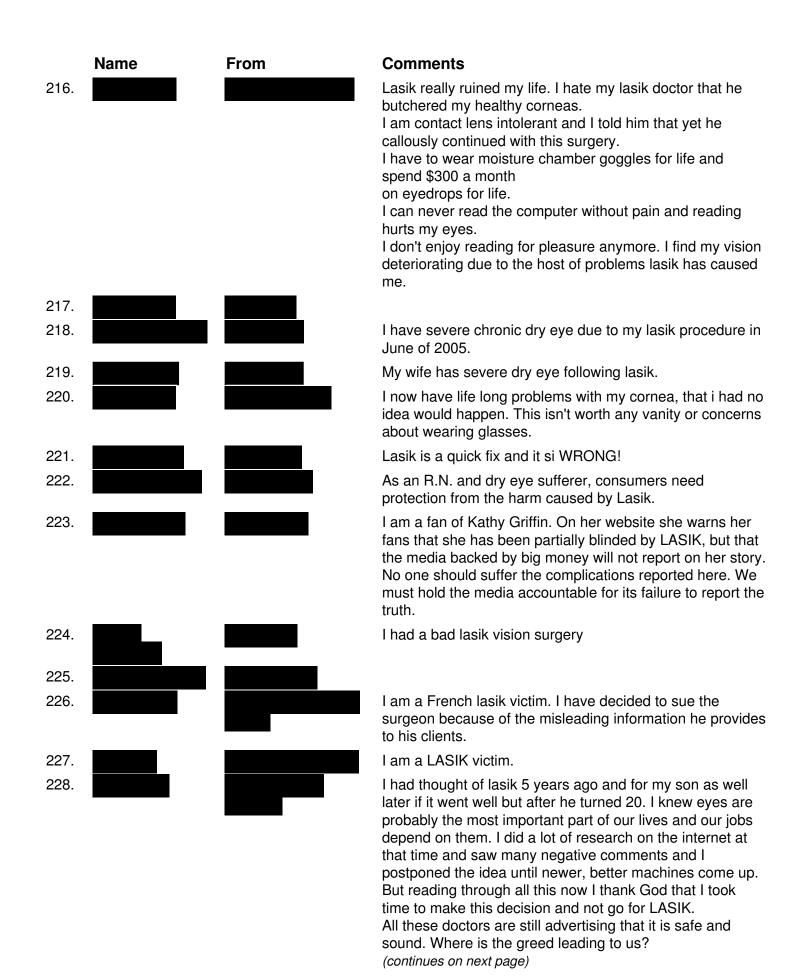


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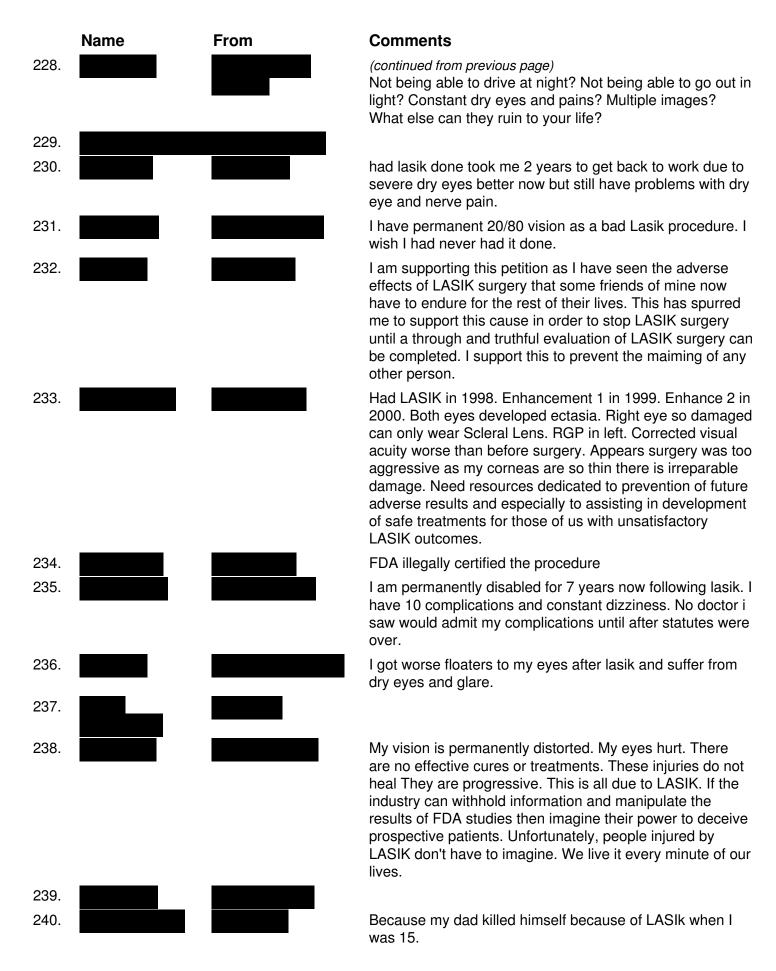




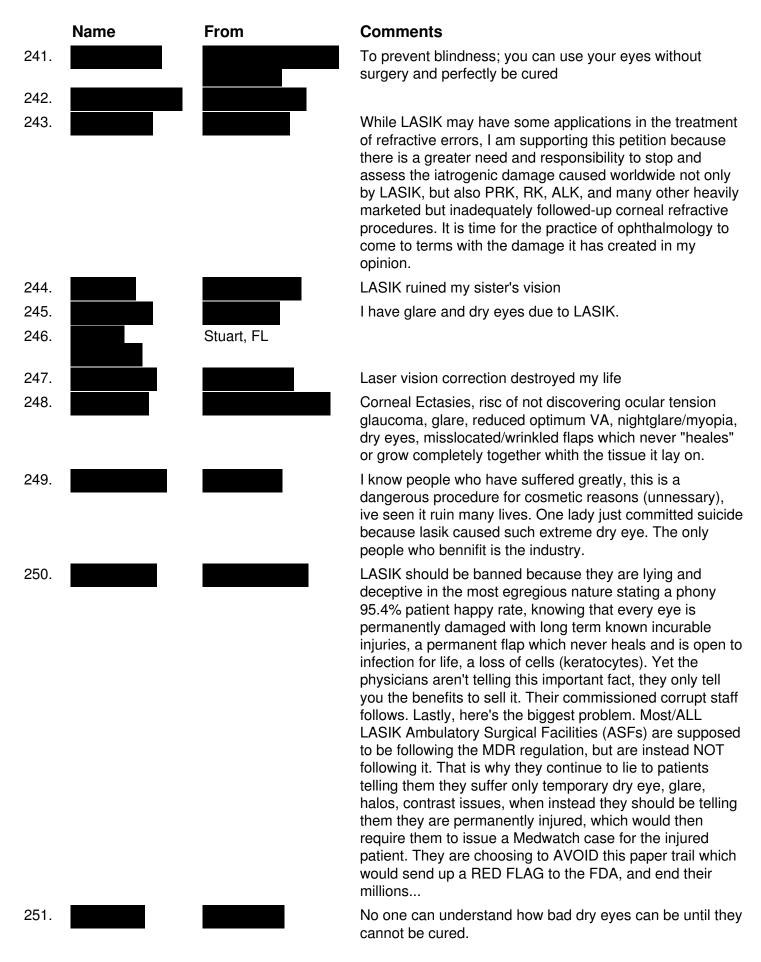




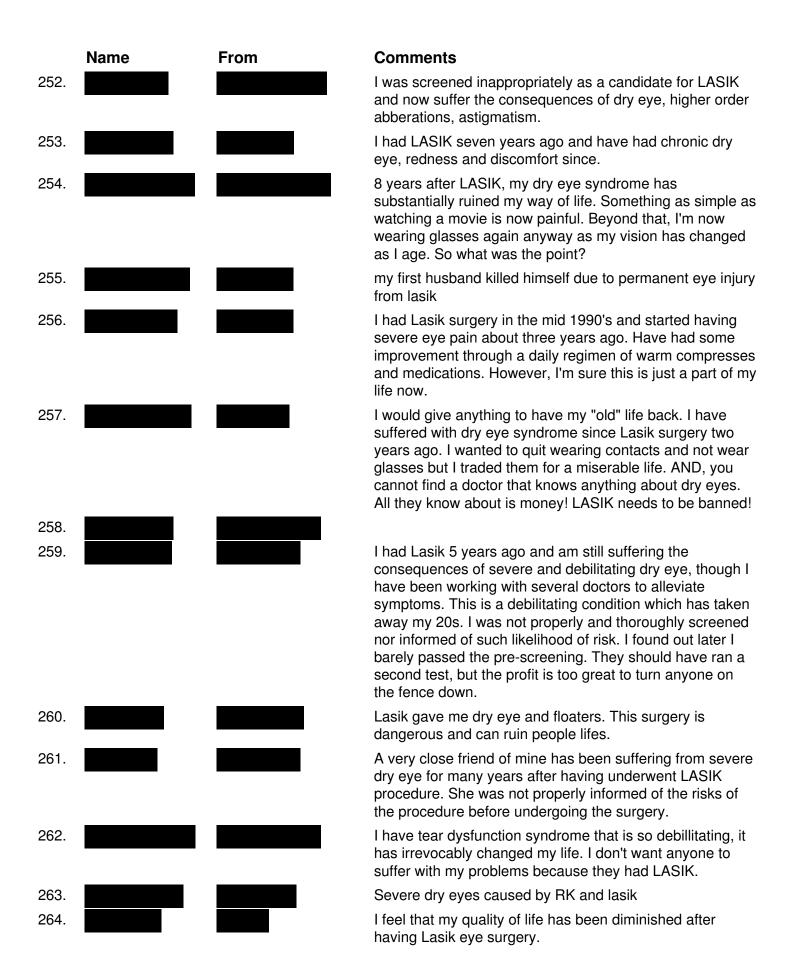
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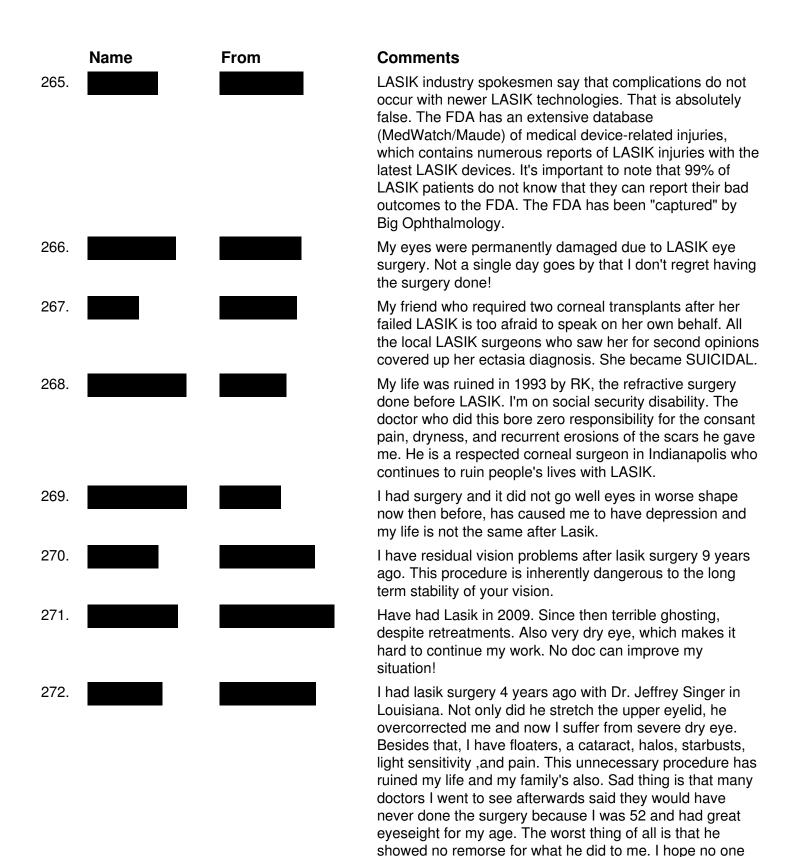


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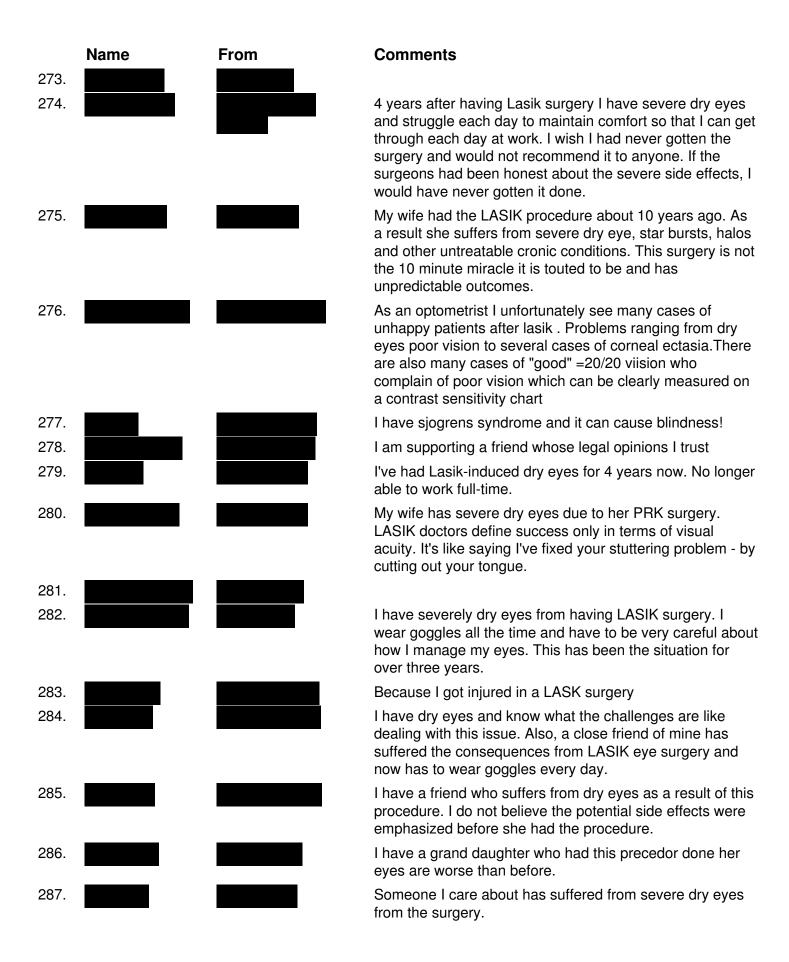


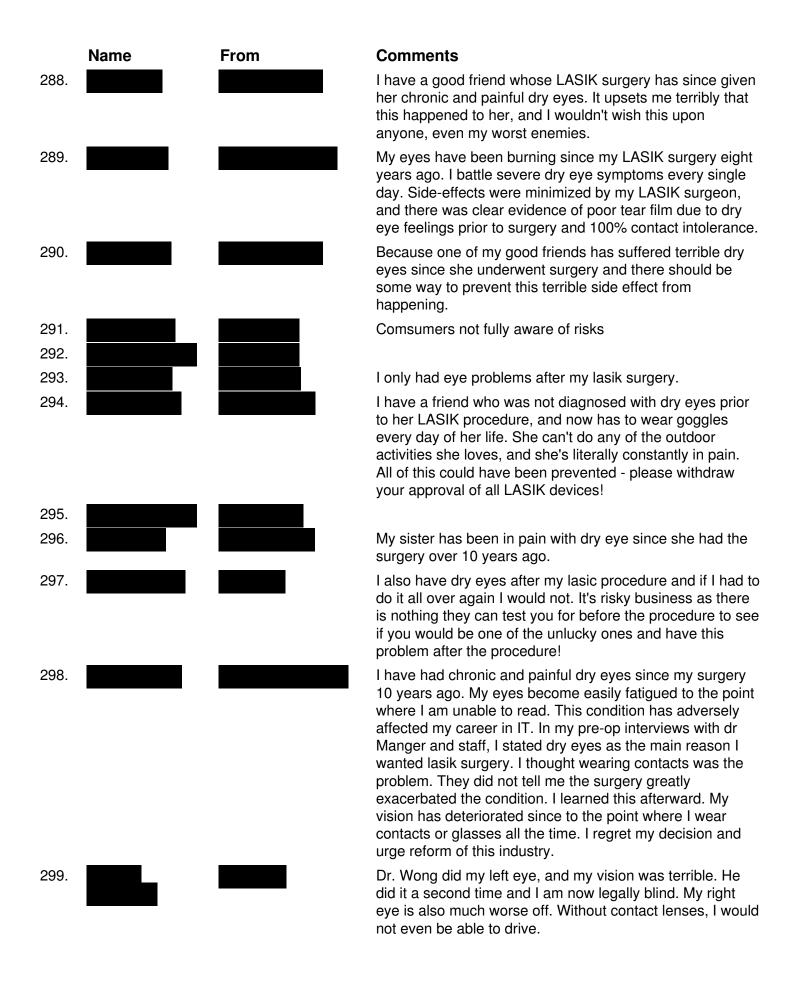
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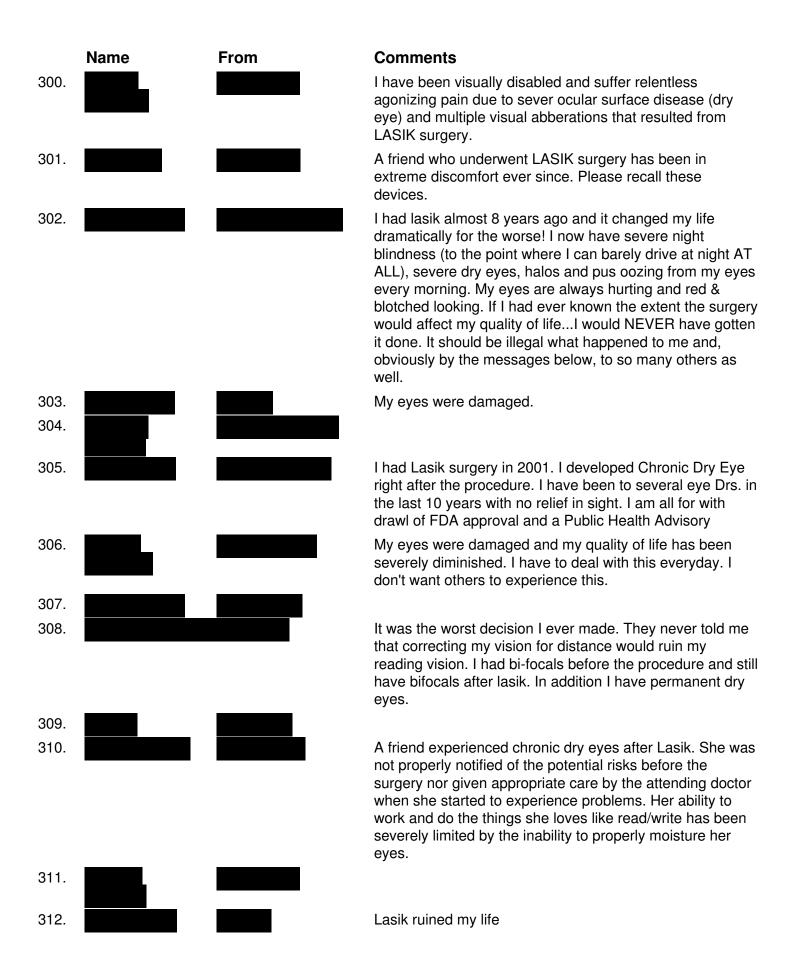


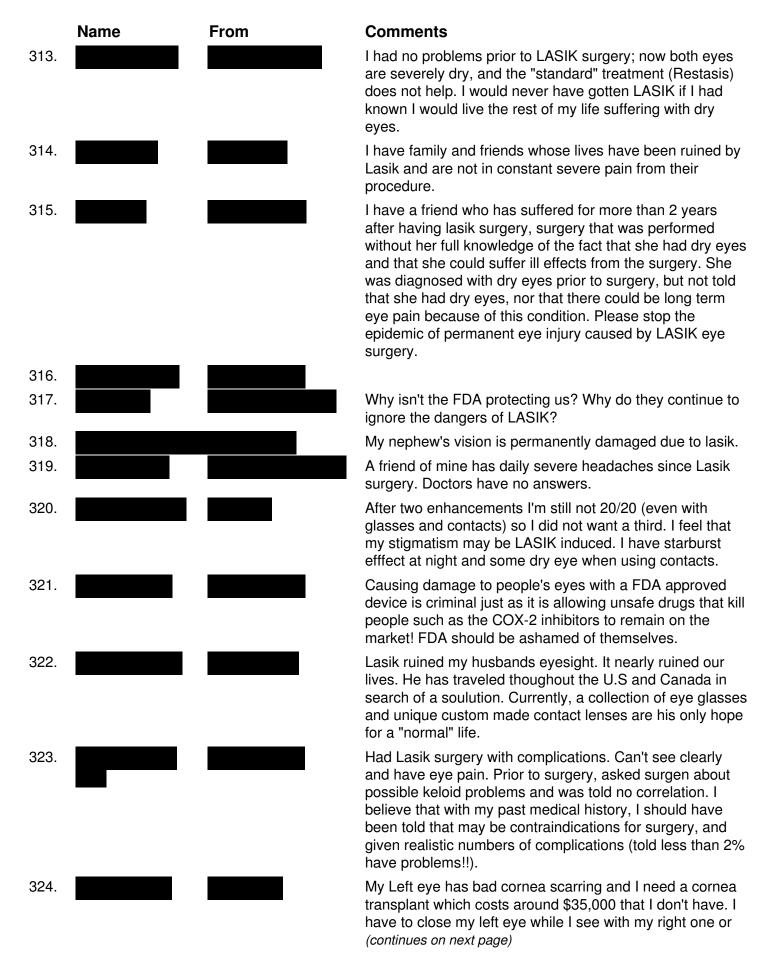


ever hurts his children or other family members in this way. I don't wish this on my worst enemy. It has changed a great life into a miserable one and has taken the best years of my life away. For anyone reading this: NEVER HAVE SURGERY ON YOUR EYES UNLESS IT IS ABSOLUTLEY NECESSARY TO KEEP YOUR VISION!

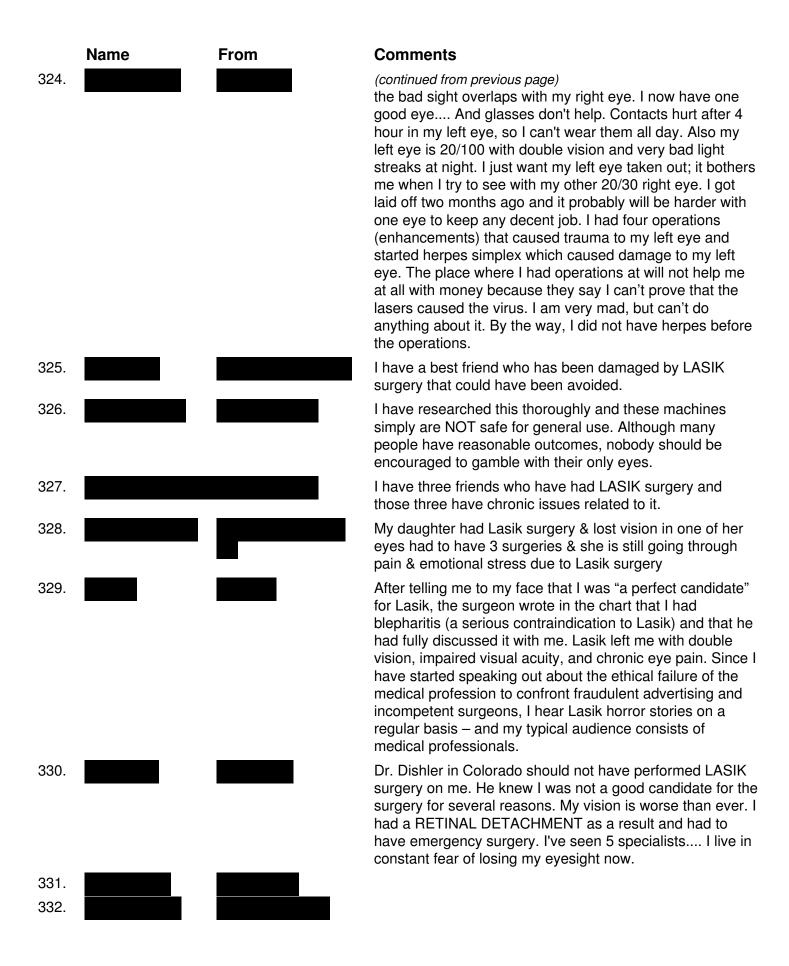


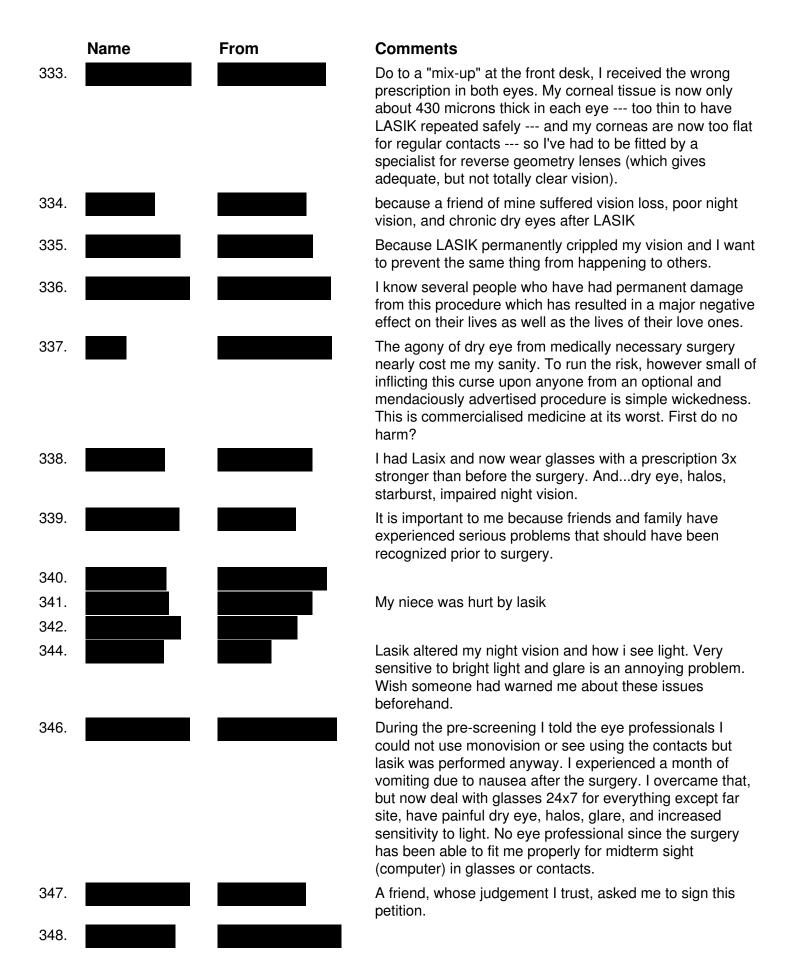


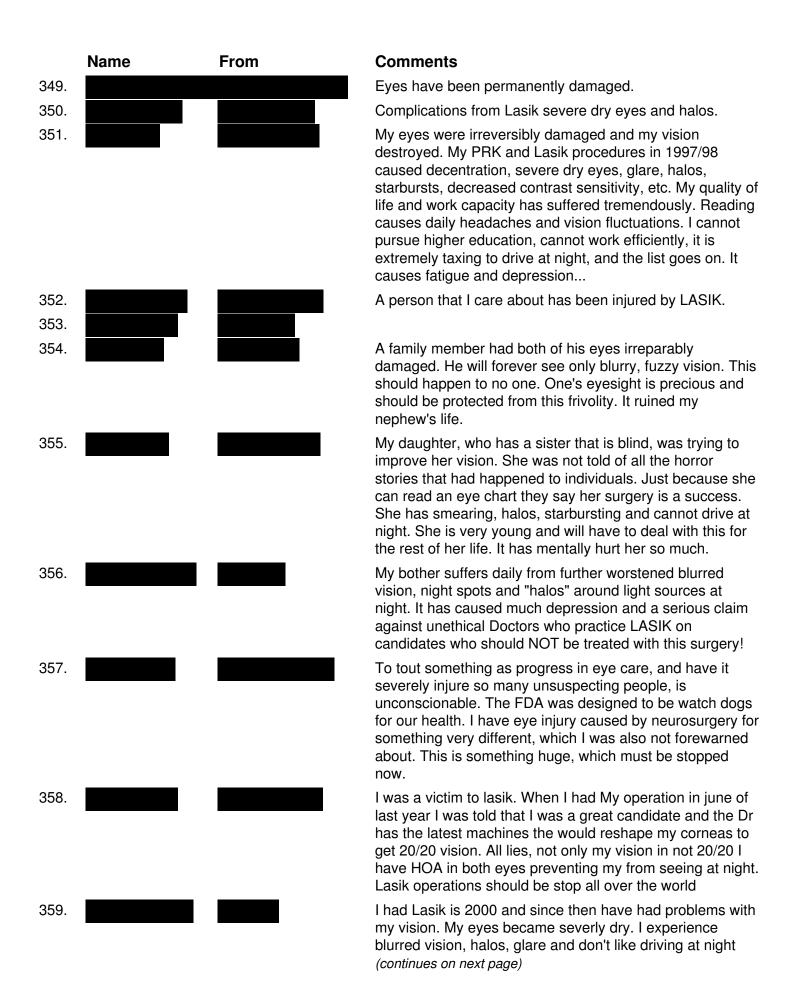




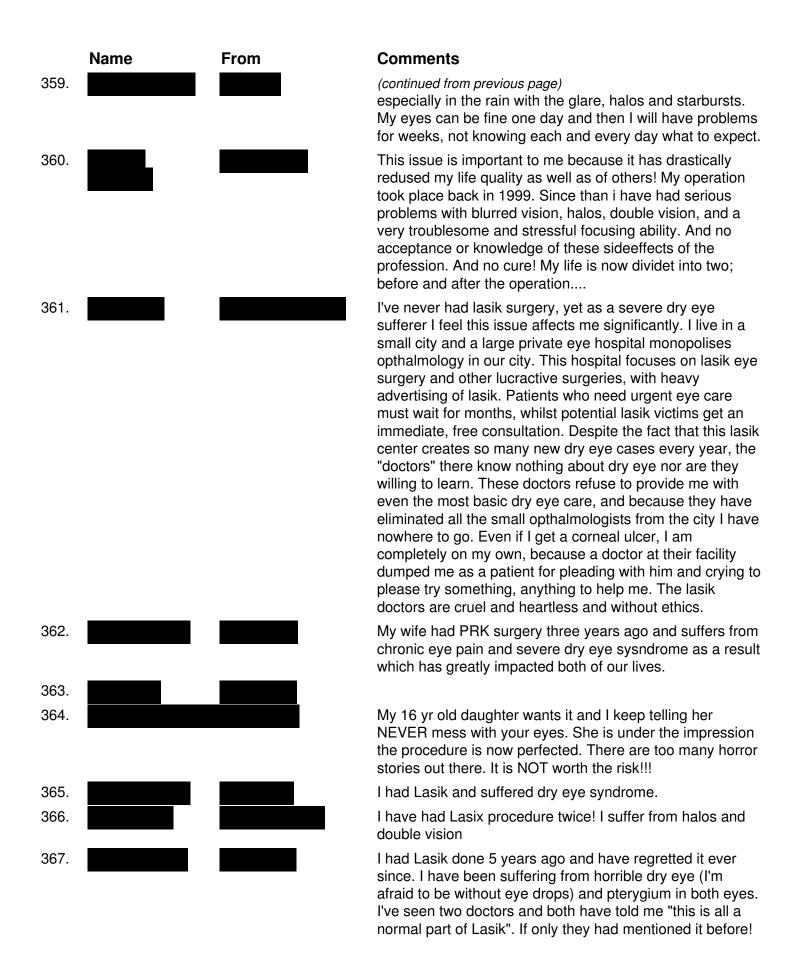
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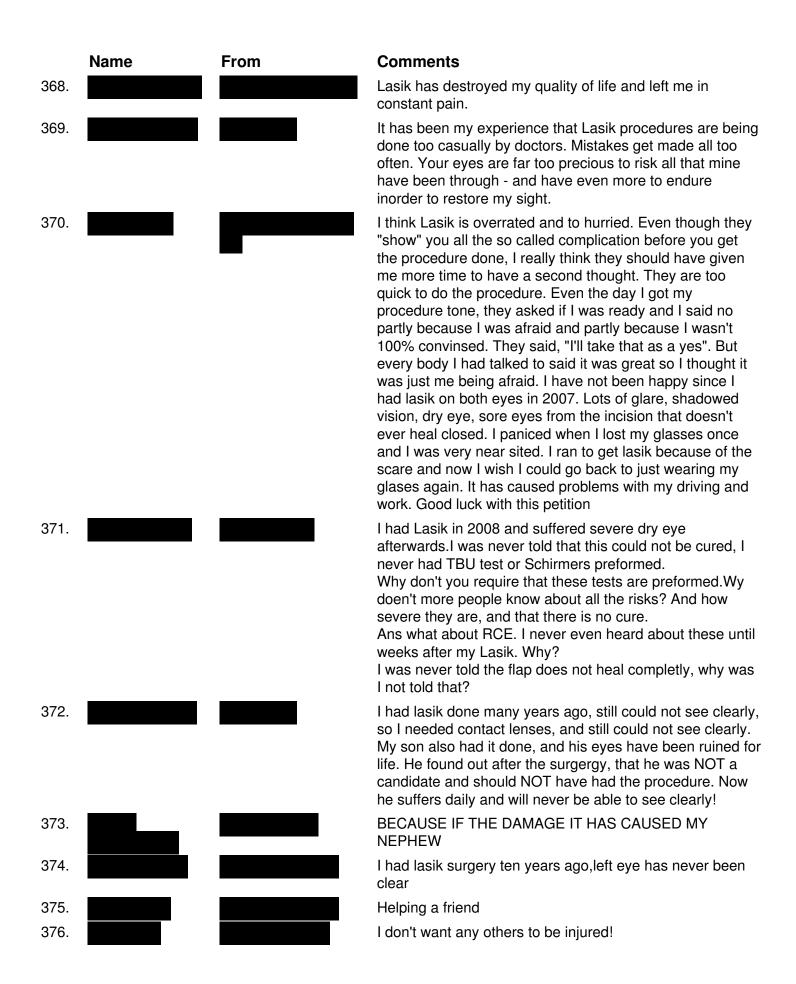






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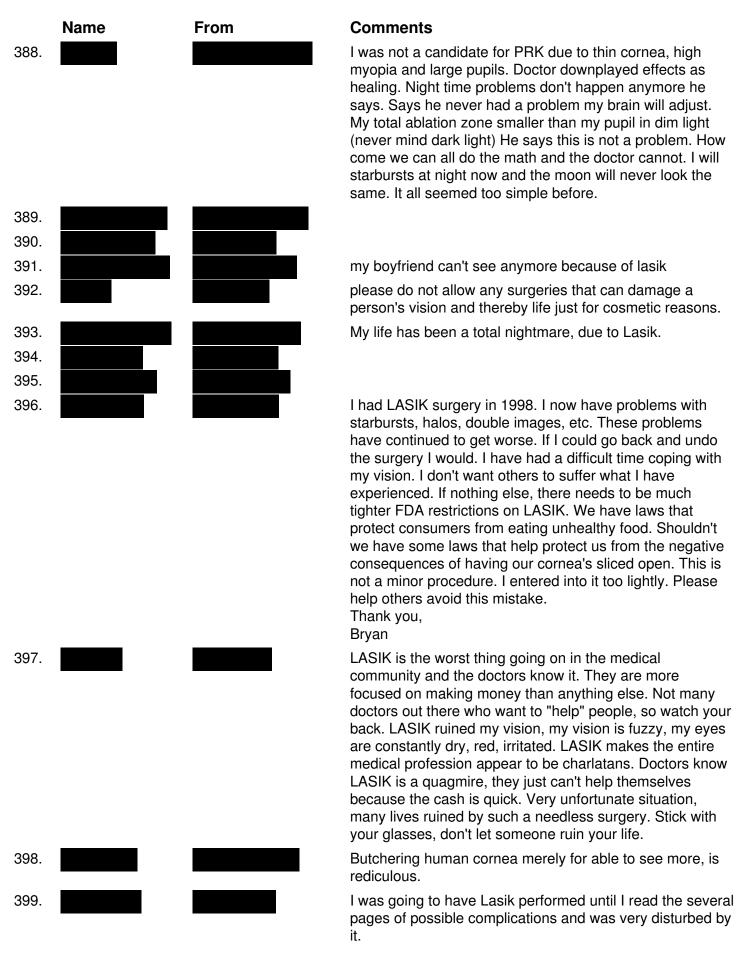




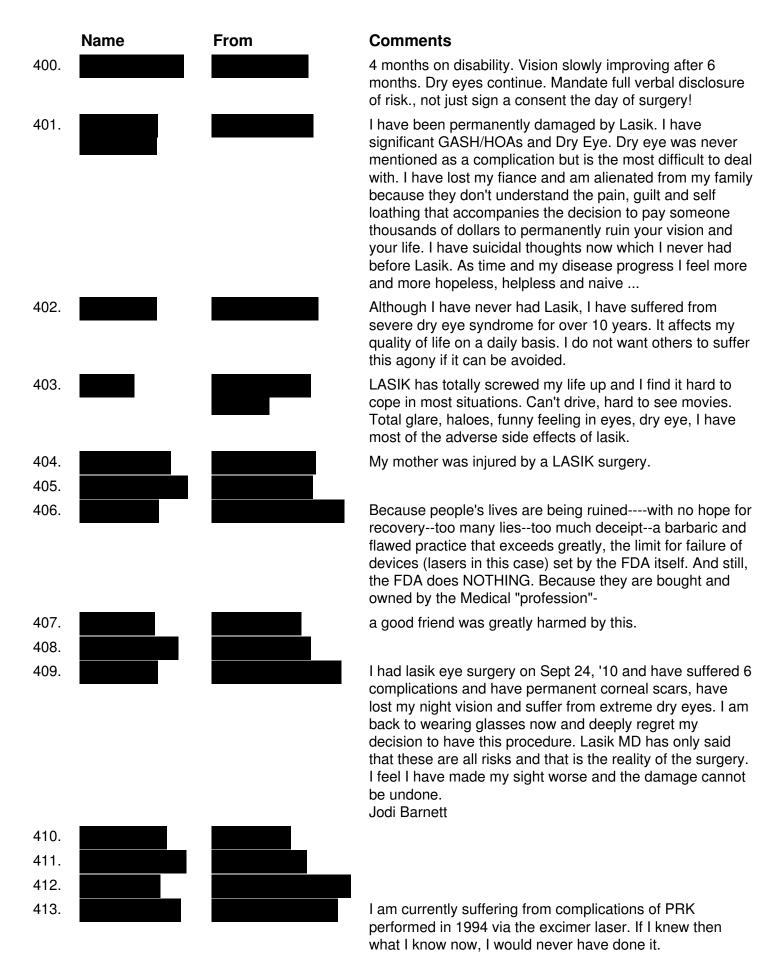
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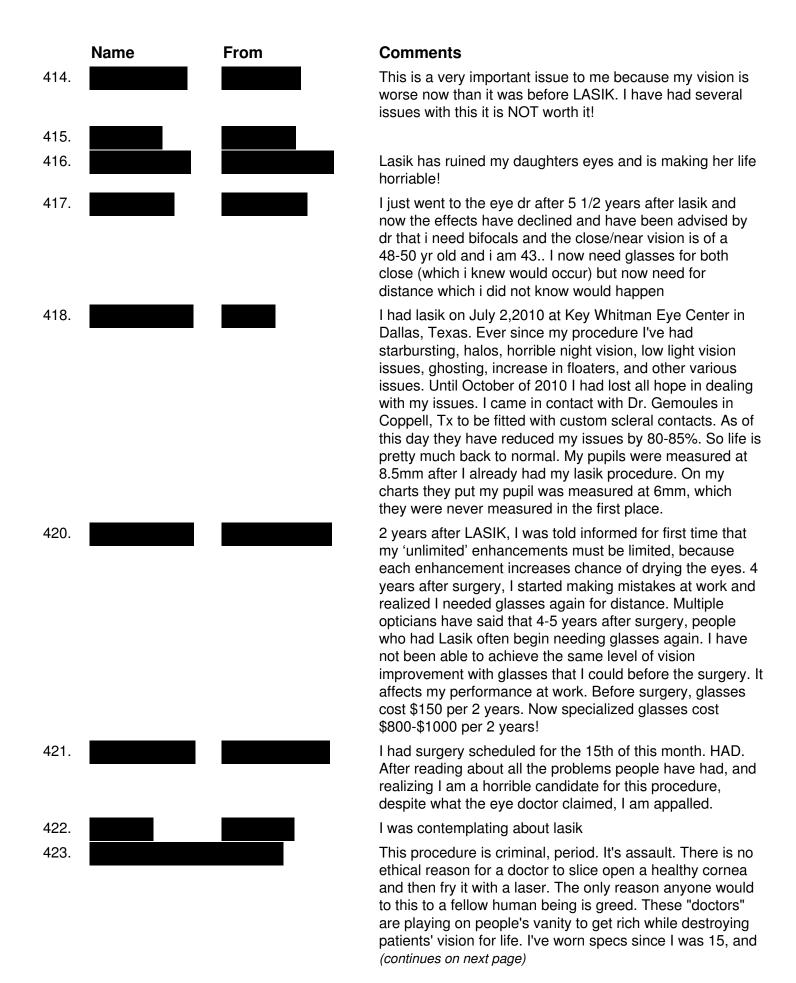
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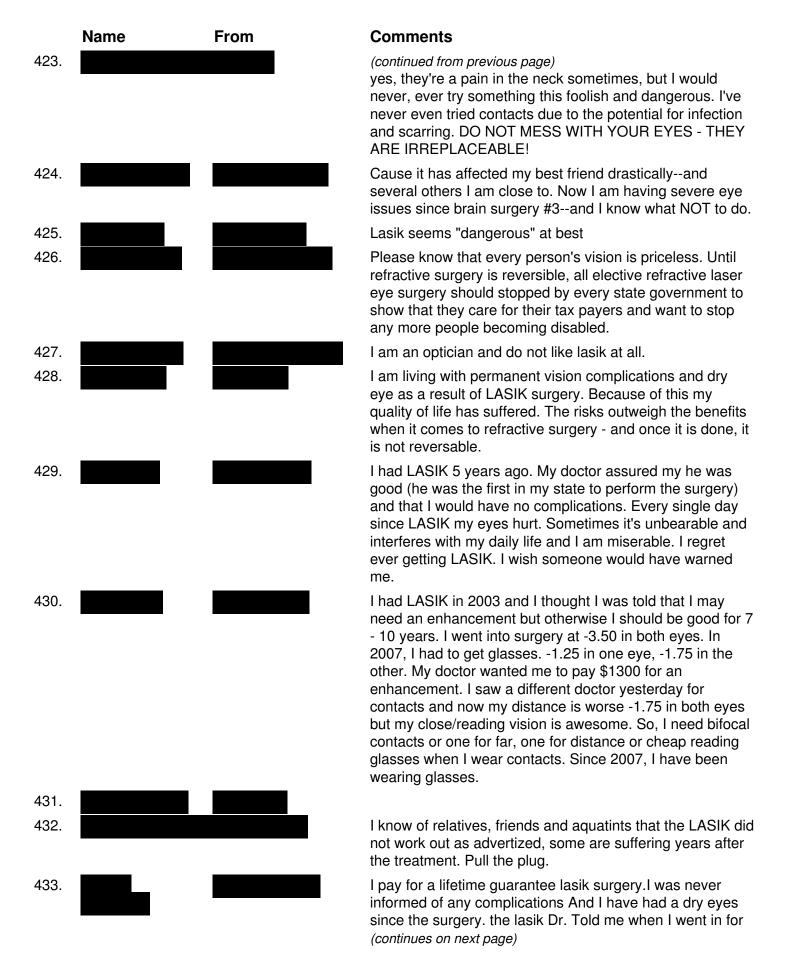
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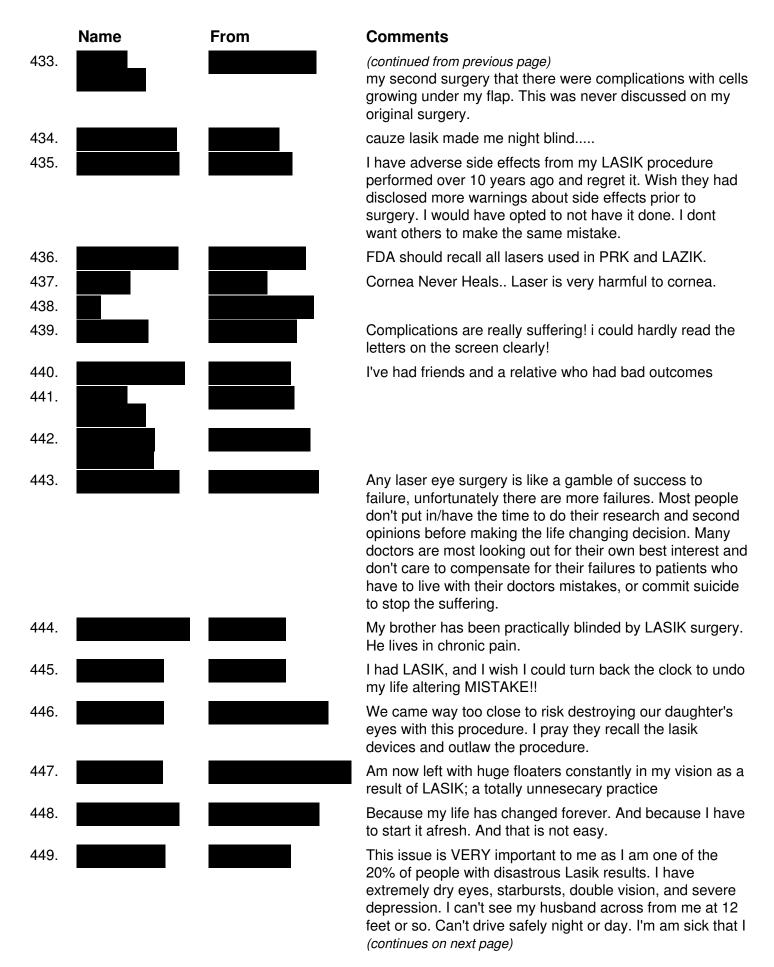
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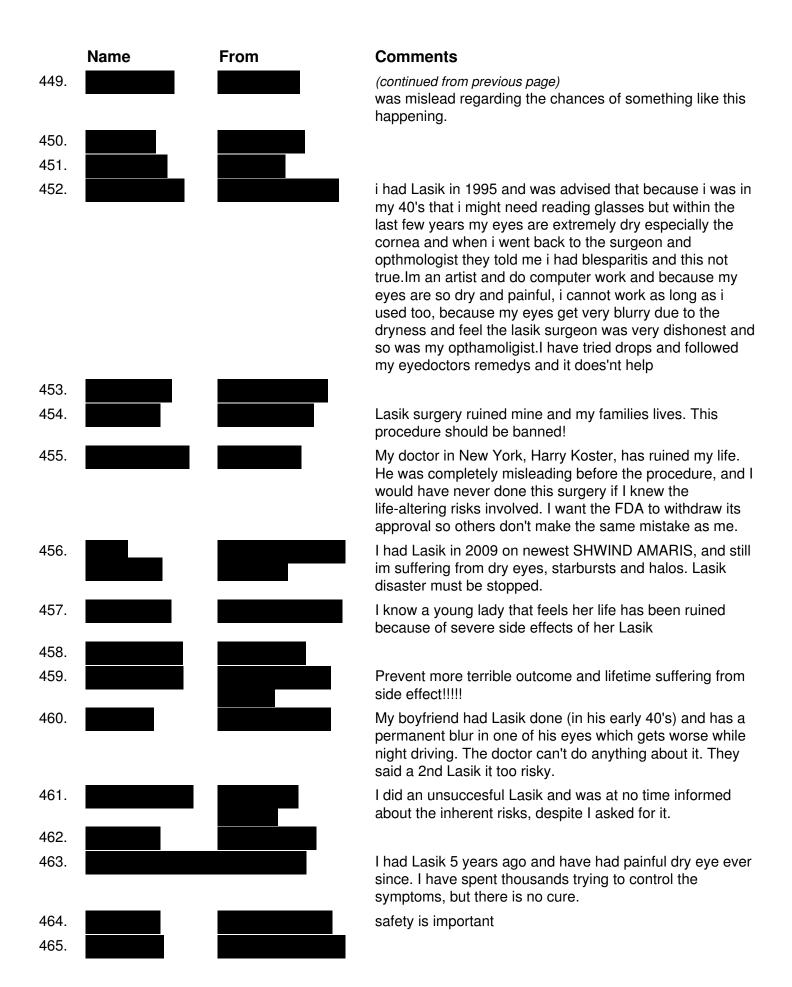
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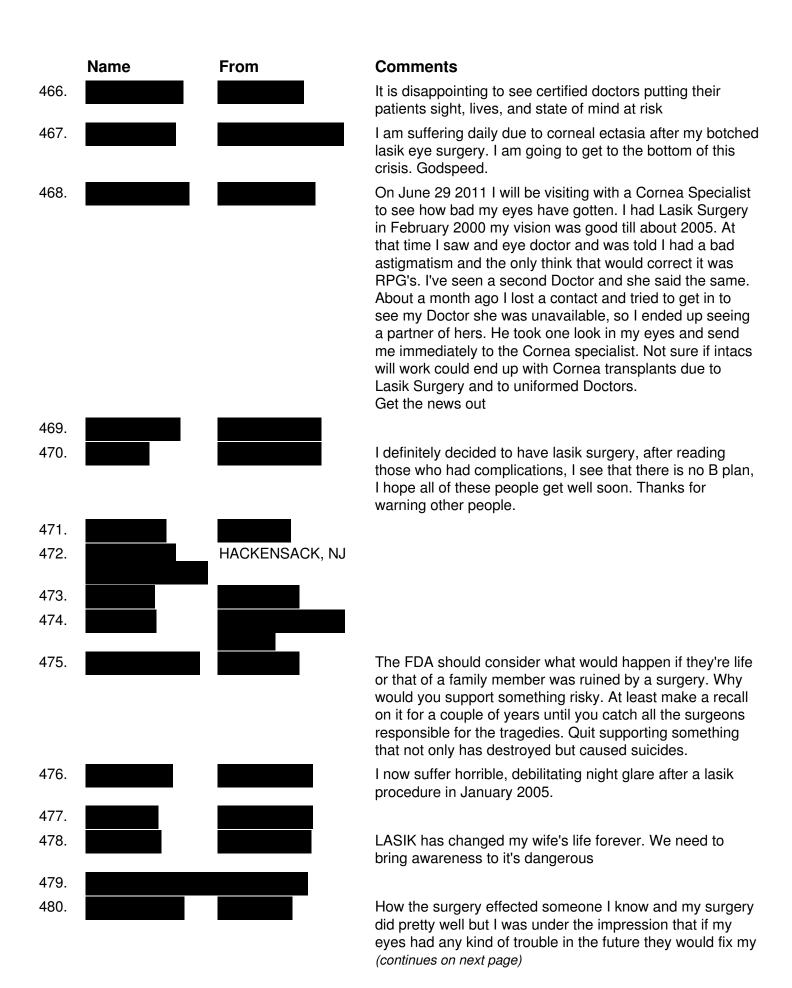
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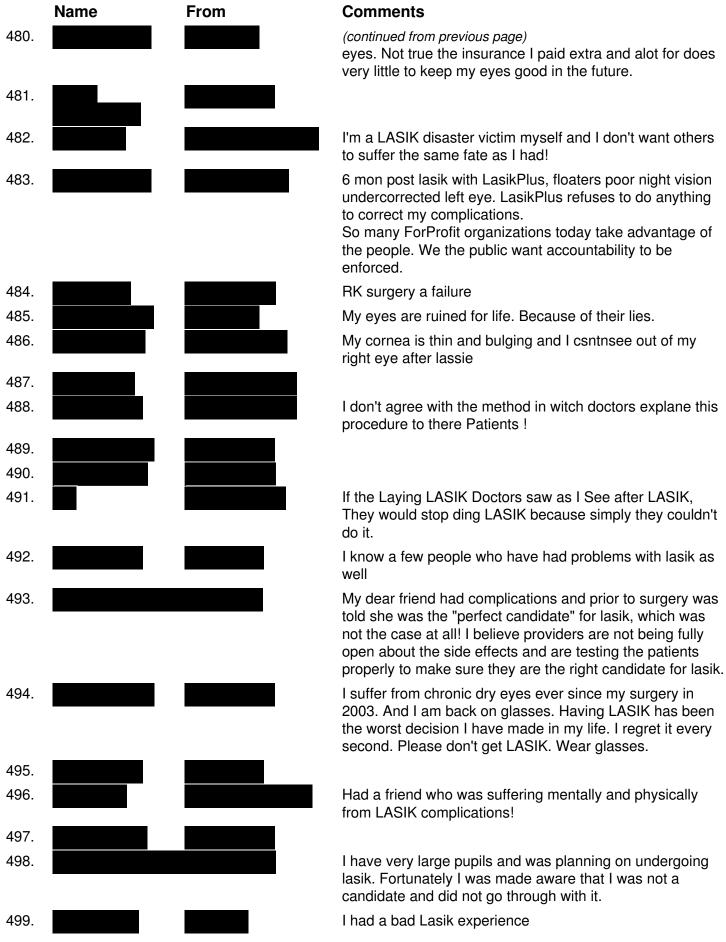
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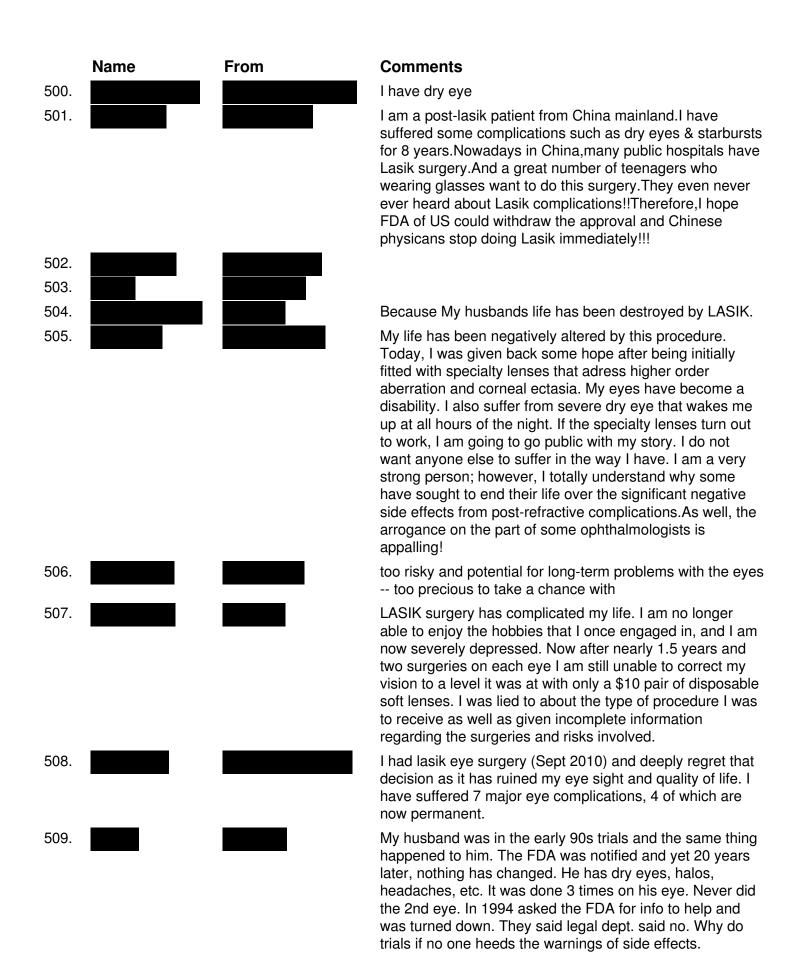
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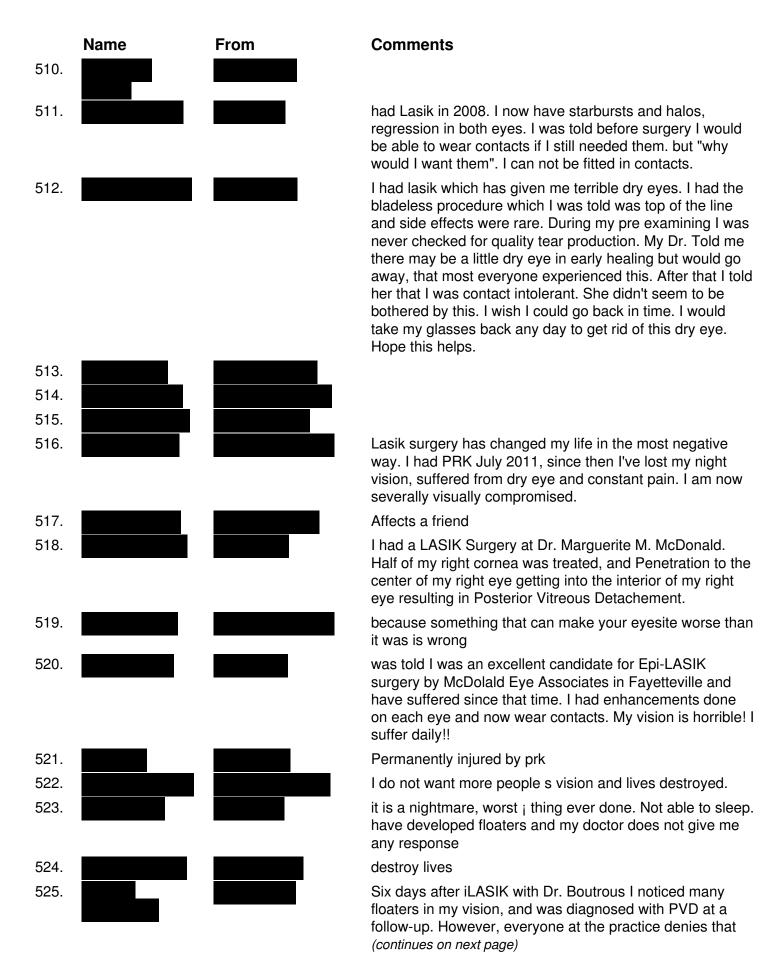


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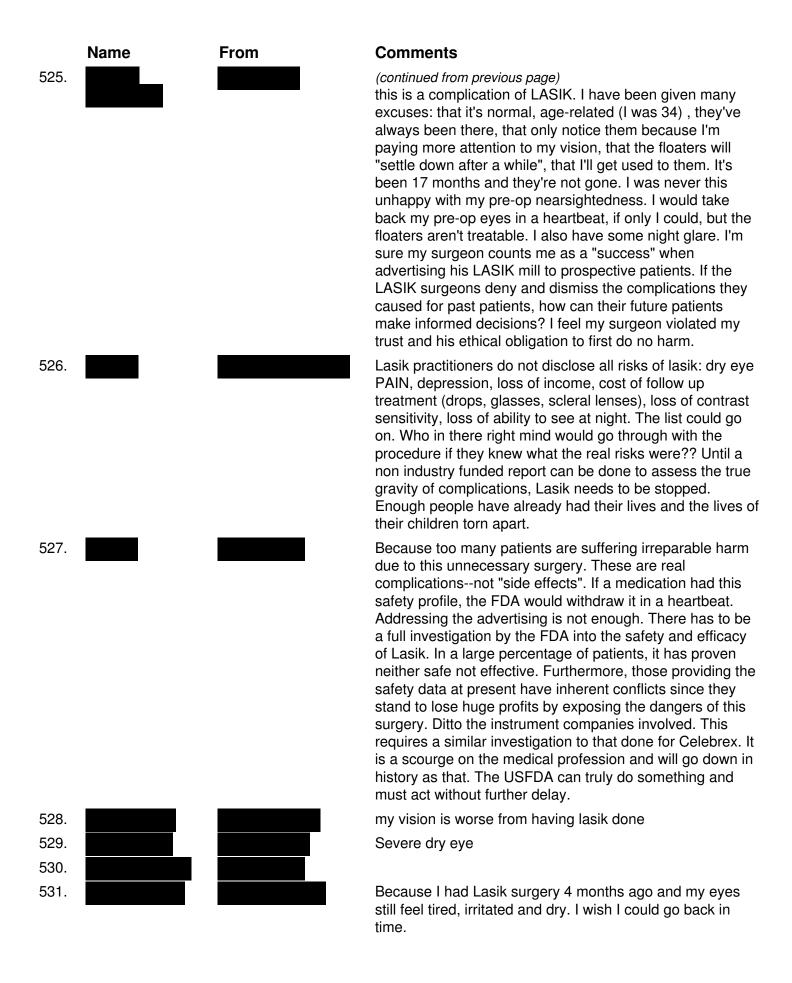


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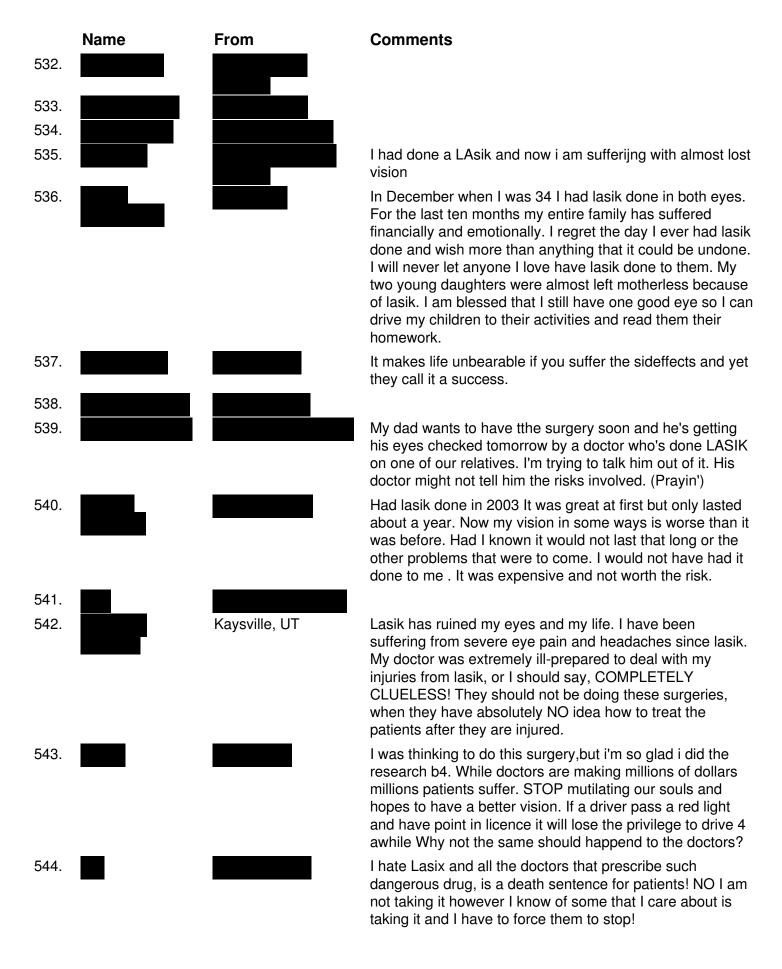




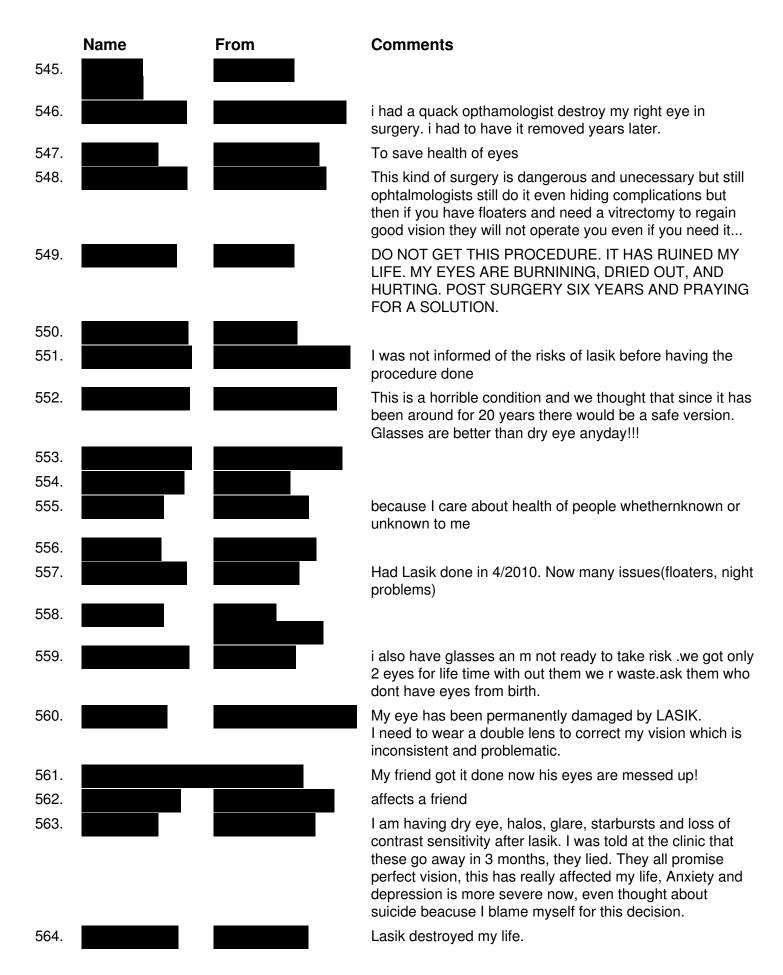
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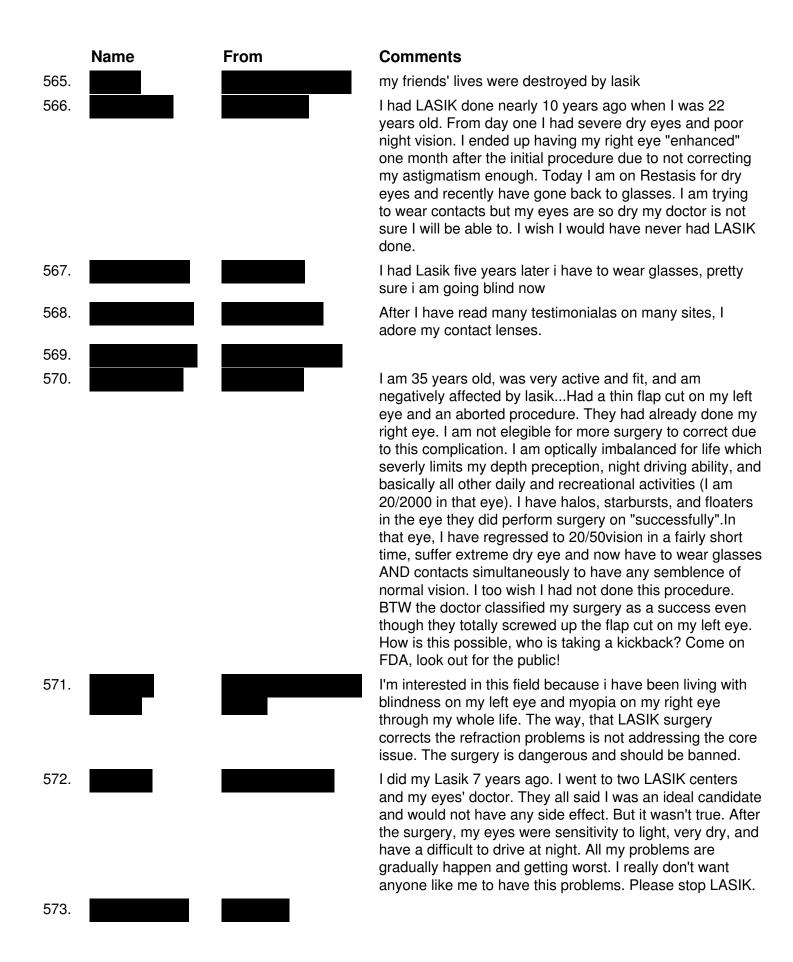
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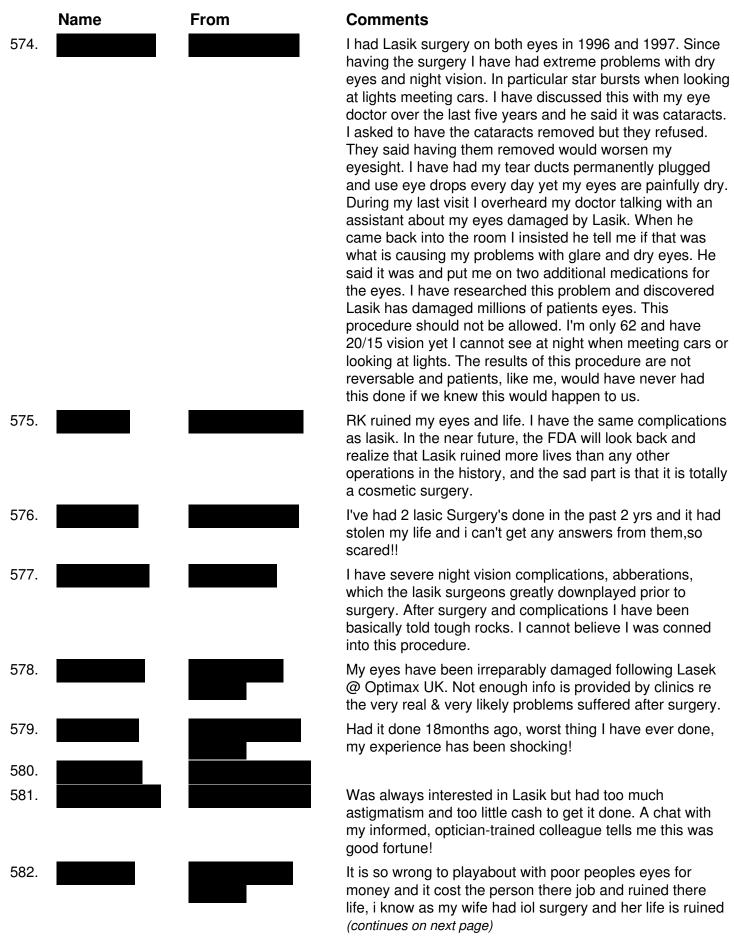


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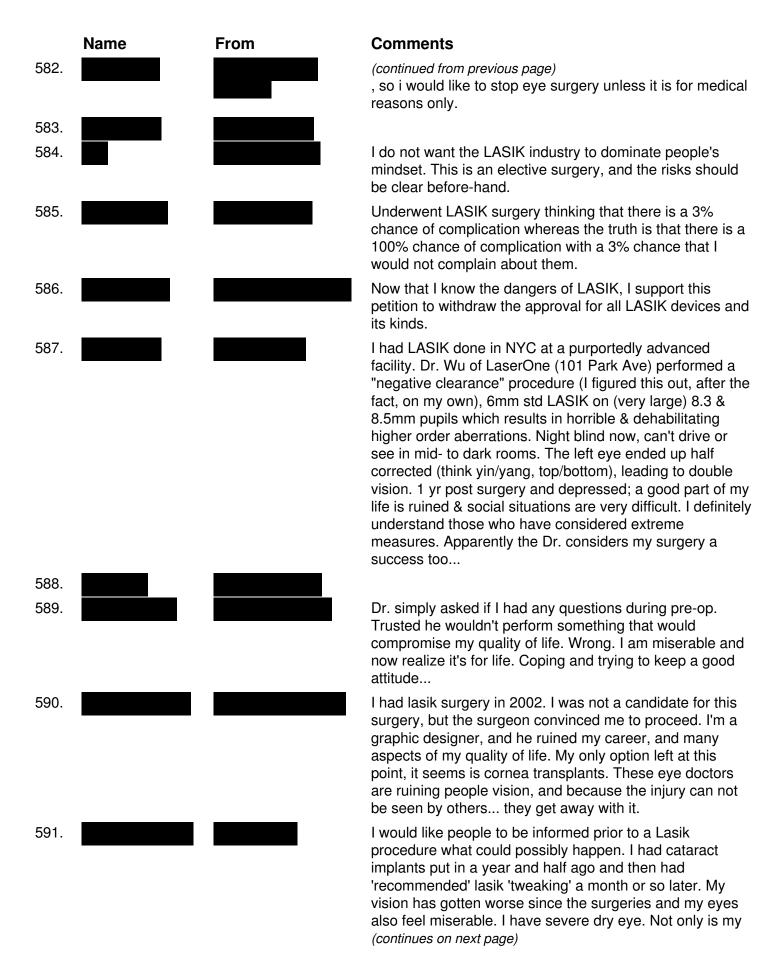


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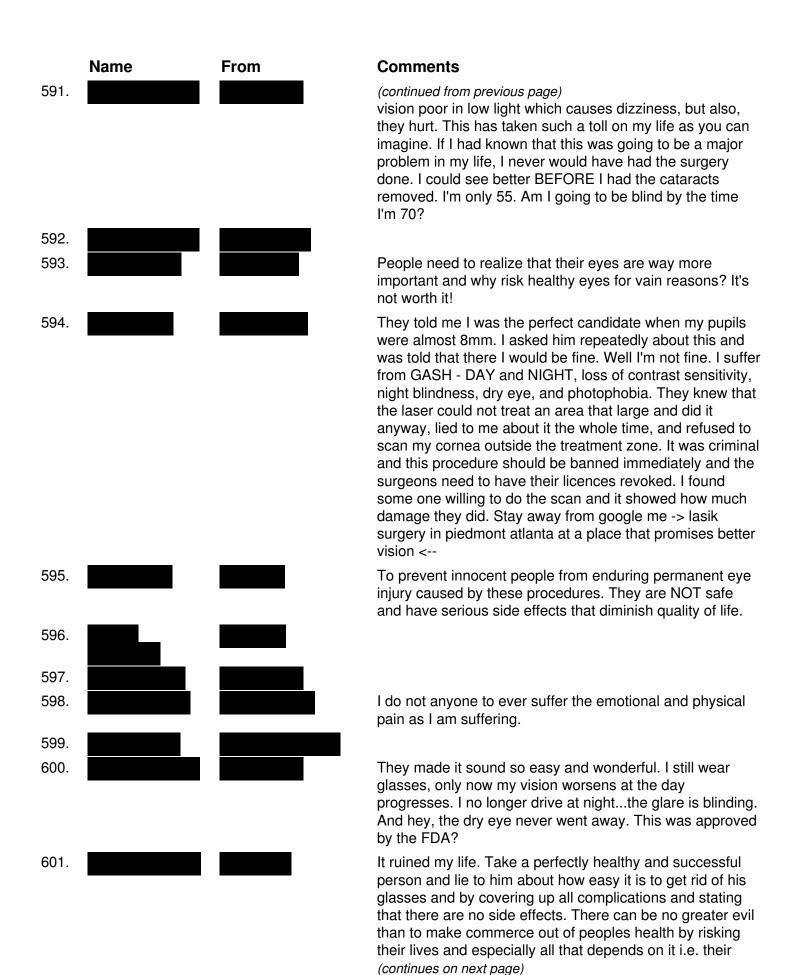




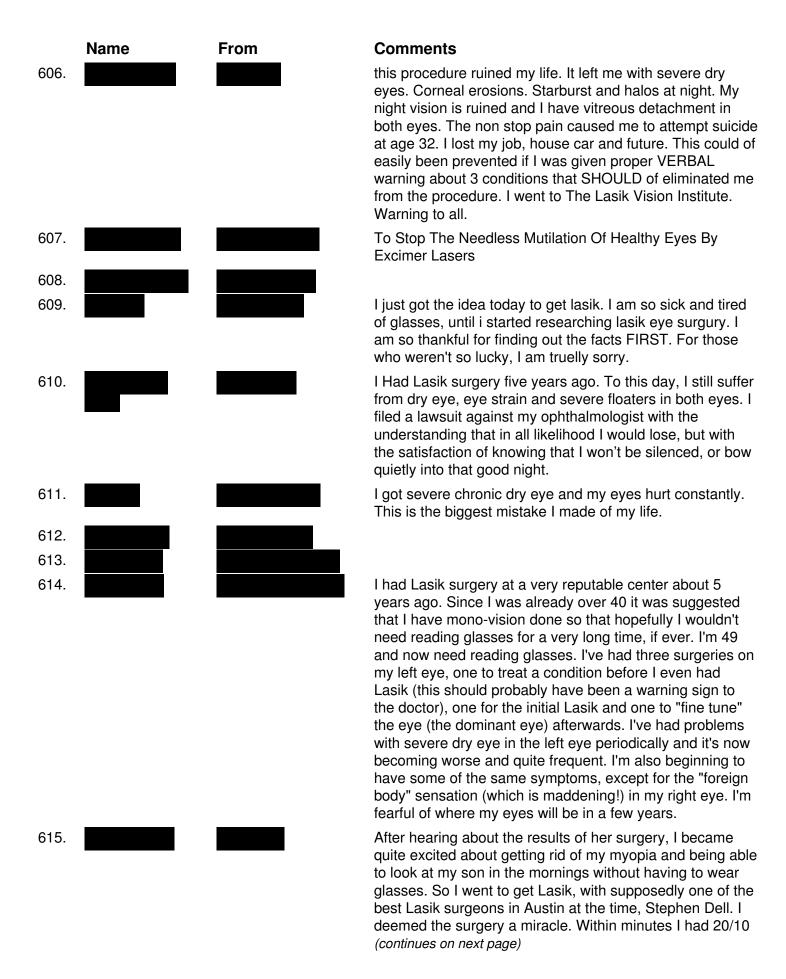
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Page 49 - Signatures 582 - 591



Name Comments From 601. (continued from previous page) 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! 602. I was considering not knowing the risks. 603. 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 604. I have undergone lasik surgery and suffered from ectasia. 605. I've had "rare" complications.



From

Comments

(continued from previous page)

615.

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

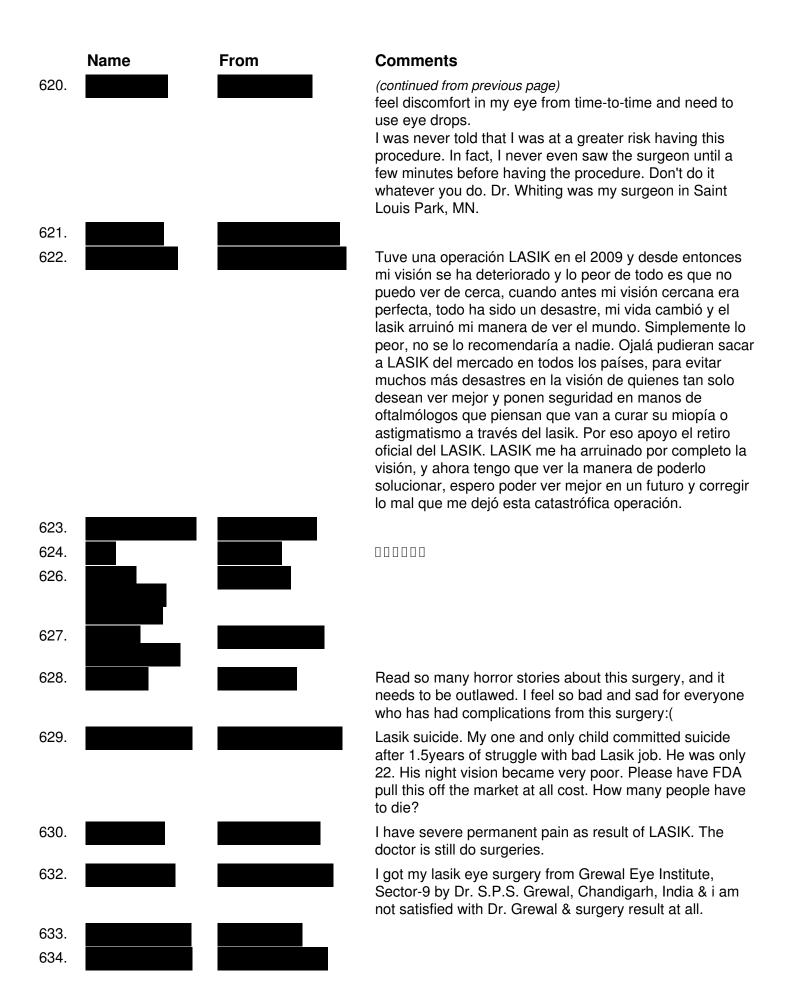


I suffer from serious post lasik complications(2005)

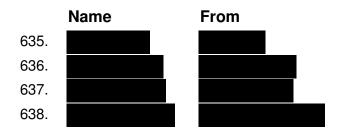
Eye is the most sensitive and important organ in the human body; and under no circumstances experiments with it for the purpose of doing business is tolerable.

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 (continues on next page)

me



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Comments

LASIK ruined my eyes and quality of life.

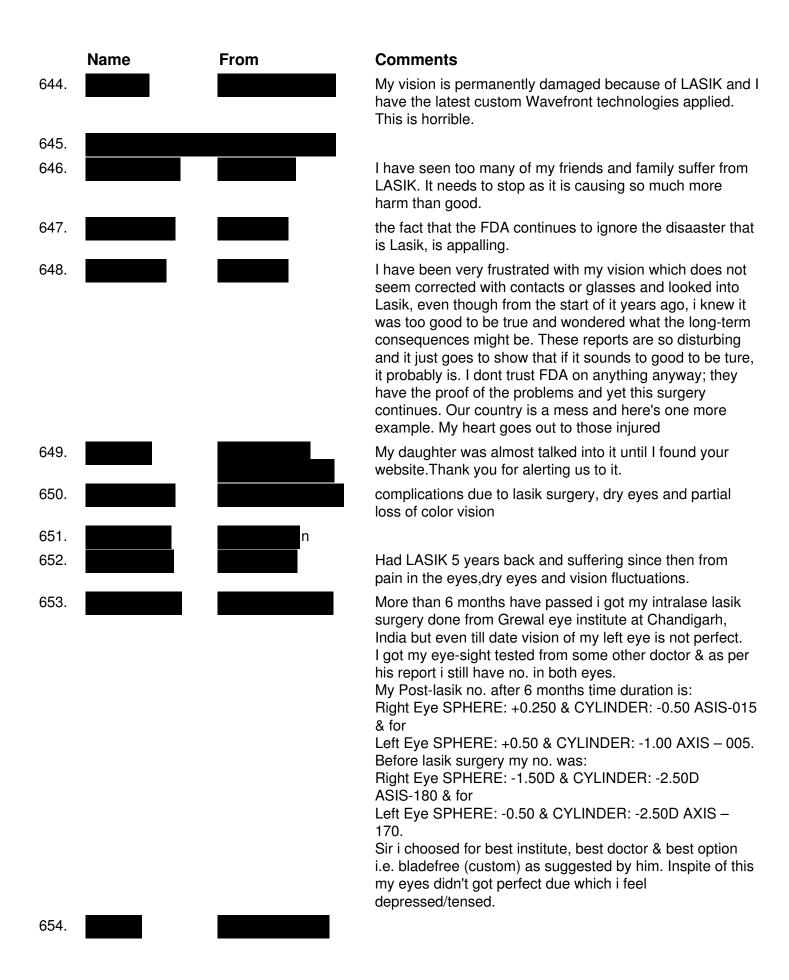
January 12, 2005. A day that I wish I can erase from my life. The day that will hunt me forever until my life has run it's course. This is the day I got "Custom Lasik" which should have been called a Custom Nightmare that will last a life time!! I suffer from bad GASH. I see dayburst, starburst, double 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.

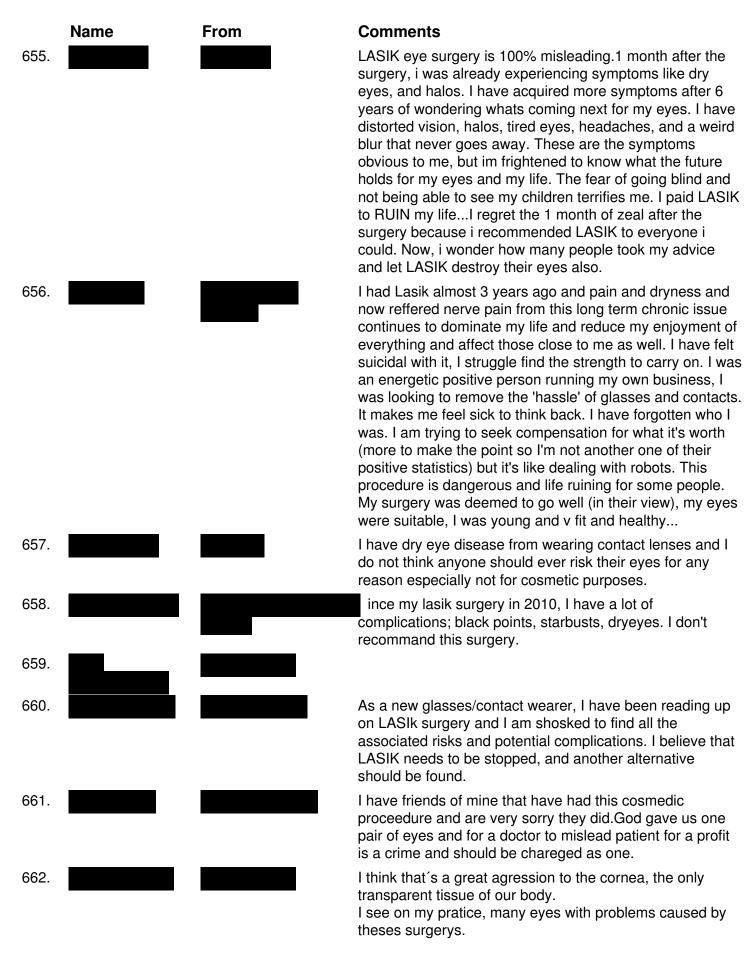


I am an ophthalmologist who is appalled at the unacceptable complications of this cosmetic procedure.

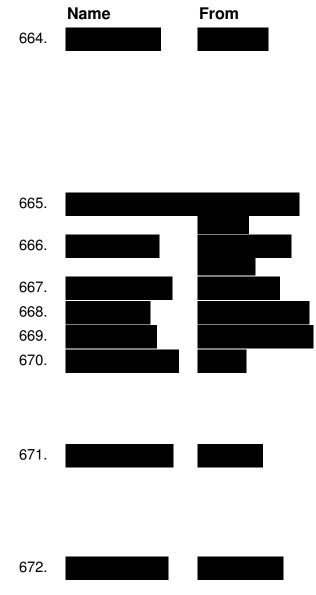
My right eye developed Keratoconus after 3 attempts to improve my vision with Lasik. I've had multiple surgeries on the eye with the last one in 2007, where intacs were inserted in my eye. My next procedure, which will cost \$3,900, is scheduled in June of 2012, and this is called cross-linking to solidify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

My husband sufferred retinal tears x3 followed by a retinal detachment and finally a retinal re-detachment 5 weeks after Lasik





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673.

Comments

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 cylidrical . so i have to completly rely on glasses. i dont know whether this number will go on incresaing

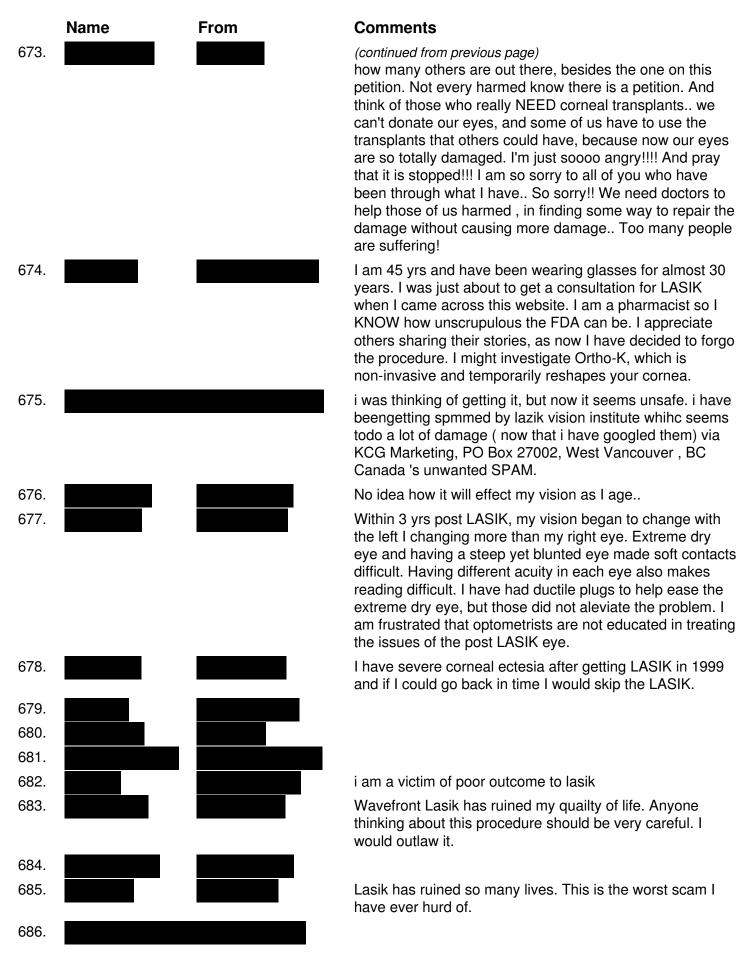
after listening to a story of lasik gne wrong

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

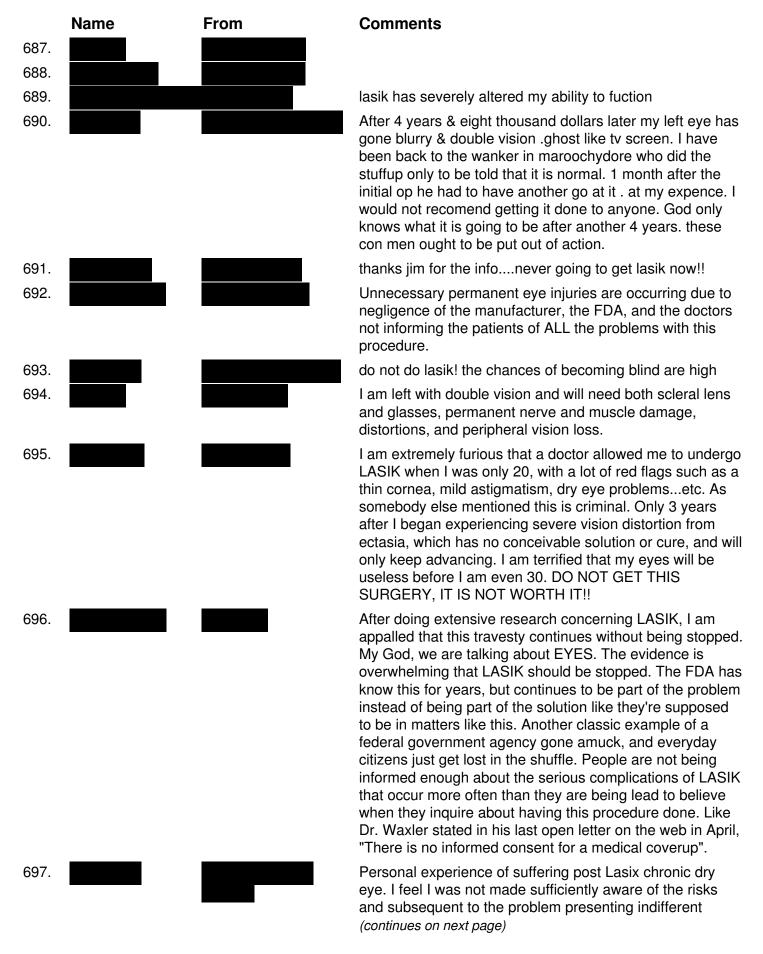
After reading all about this, im glad I have not went throught witht the procedure. Otherwise I would have made the biggest mistake of my life. I think they should outlawed, and should be sued. Patients are putting their trust to a stranger, and risking their lives for better vision. Thats at their own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

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

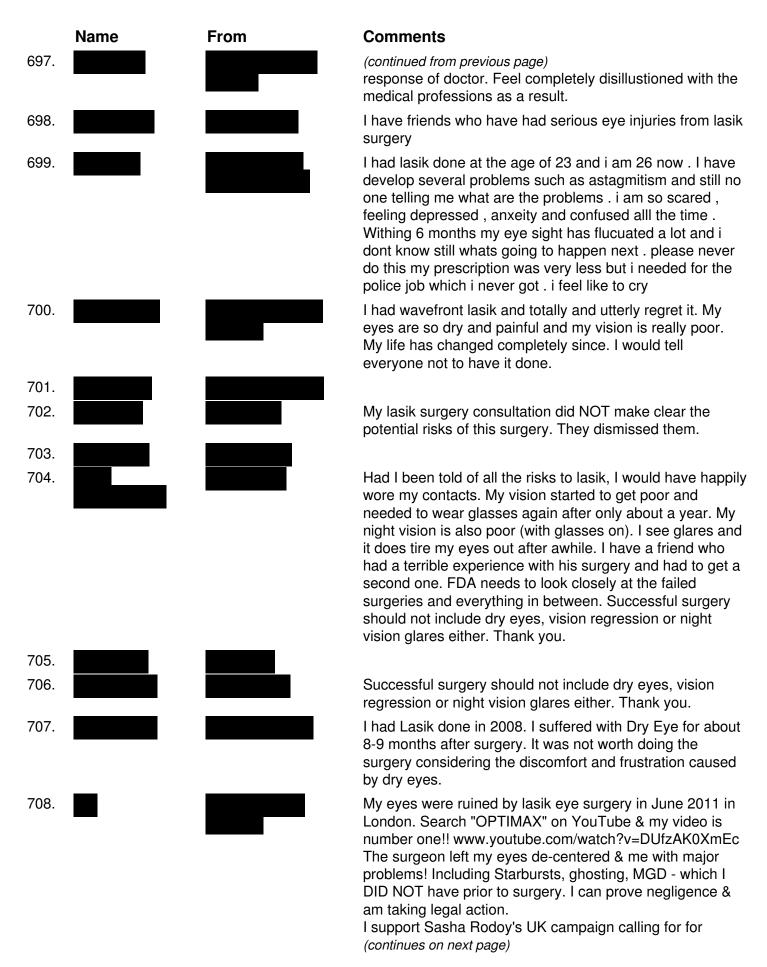
I'm so mad!!! I've been living with such rotten vision since 2006,, I was messed up day one and it just got worse.! No ONE said it could be this bad!!! Swervy world, loss of contrast, ghosty line around people. squares aren't square, circles aren't round,, things aren't clear... and it costs a boatload 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)



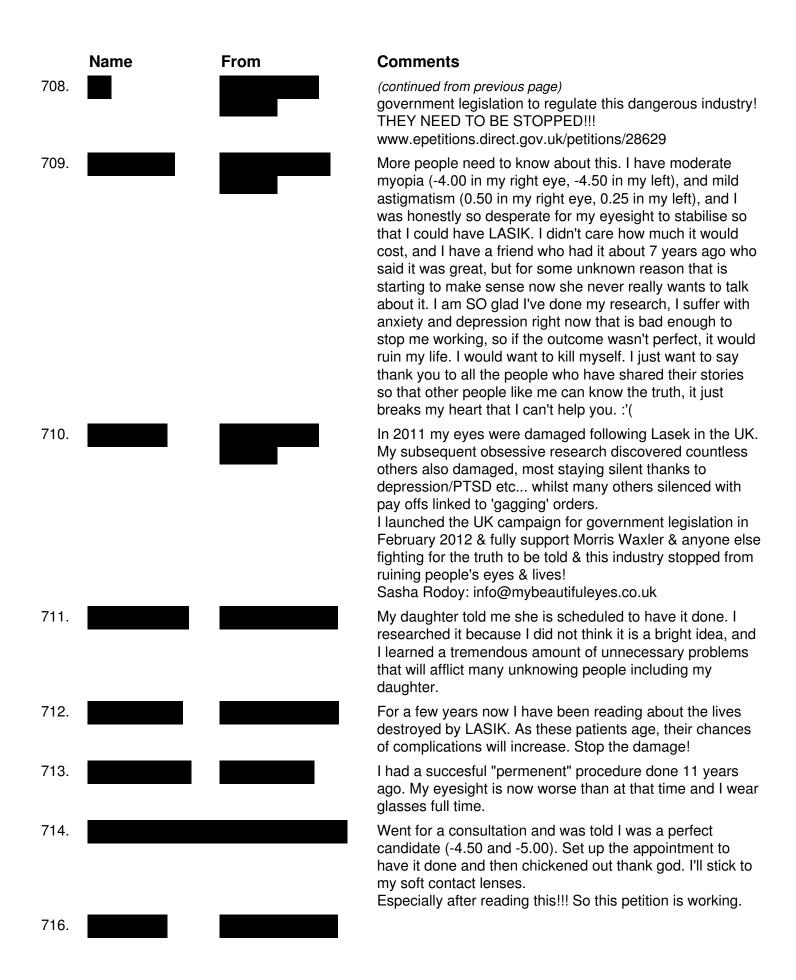
Page 59 - Signatures 673 - 686

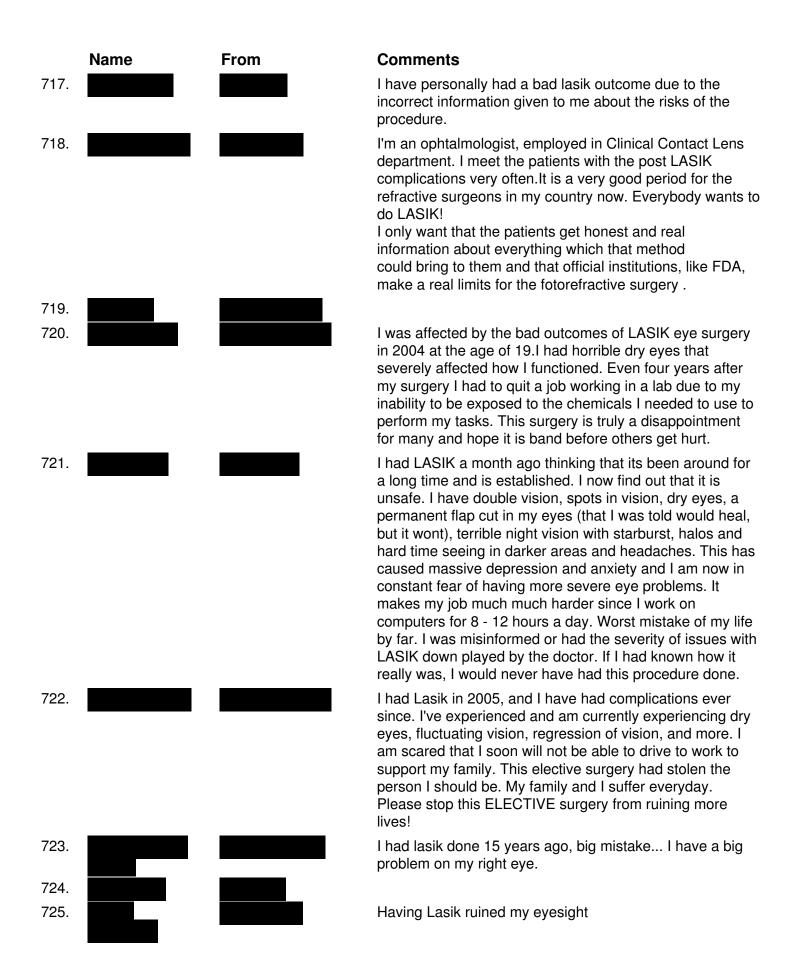


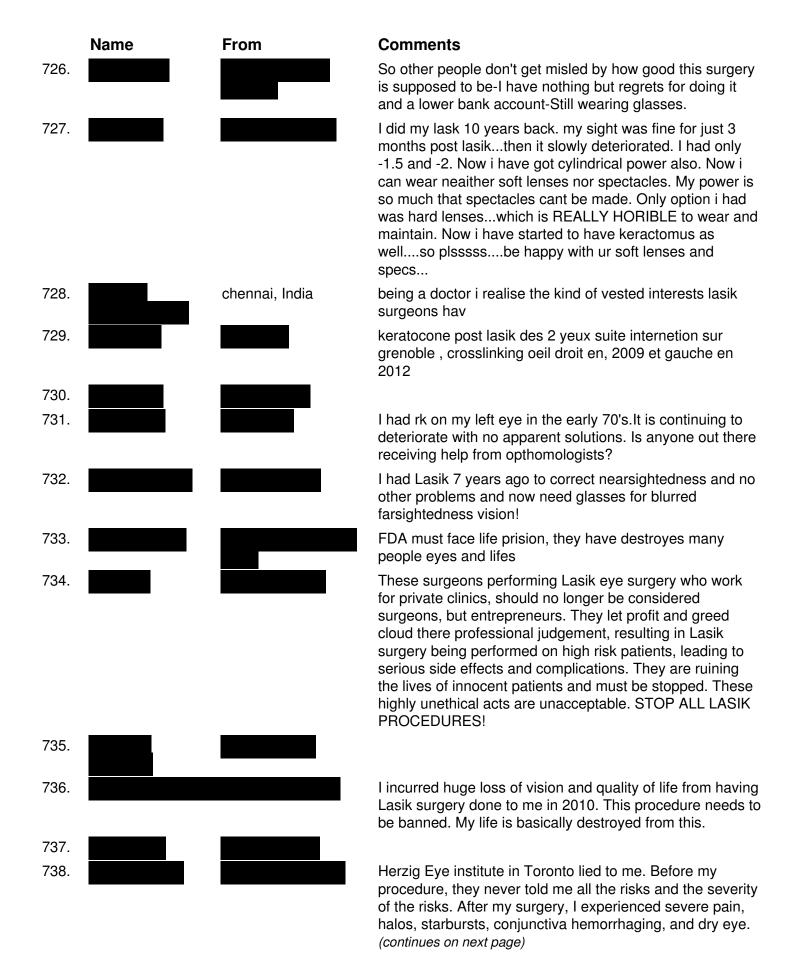
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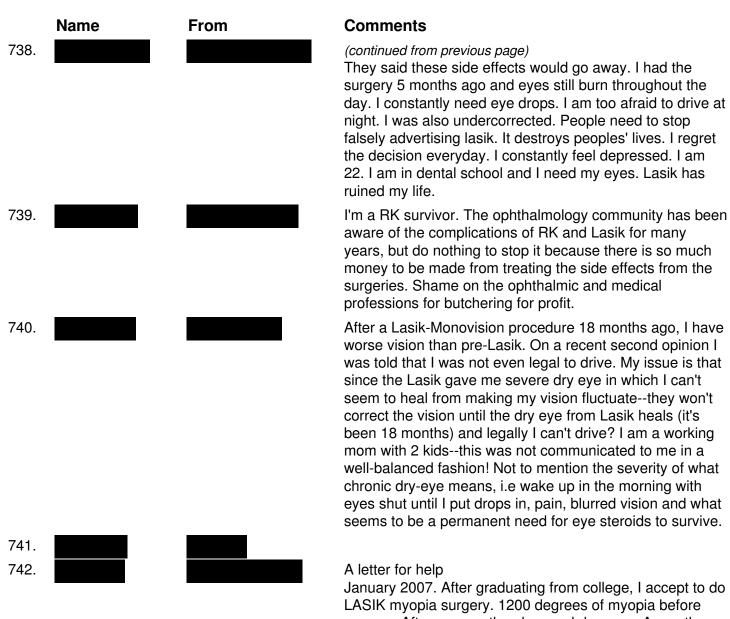
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surgery. After surgery the abnormal dry eyes. A month after the surgery, my left eye began to be uncomfortable together. The left side of the head is not comfortable, that will get better over time, but did not, and it is more and more serious. That 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 (continues on next page)

From

Comments

742.

(continued from previous page) 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

(continues on next page)

From

Comments

742.

(continued from previous page) 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 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)

From

Comments

742.

(continued from previous 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 *(continues on next page)*

From

Comments

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(continued from previous page)

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 dryeye. 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 (continues on next page)

From

Comments

742.

(continued from previous page)

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 *(continues on next page)*

From

Comments

742.

(continued from previous page)

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!

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.

743.

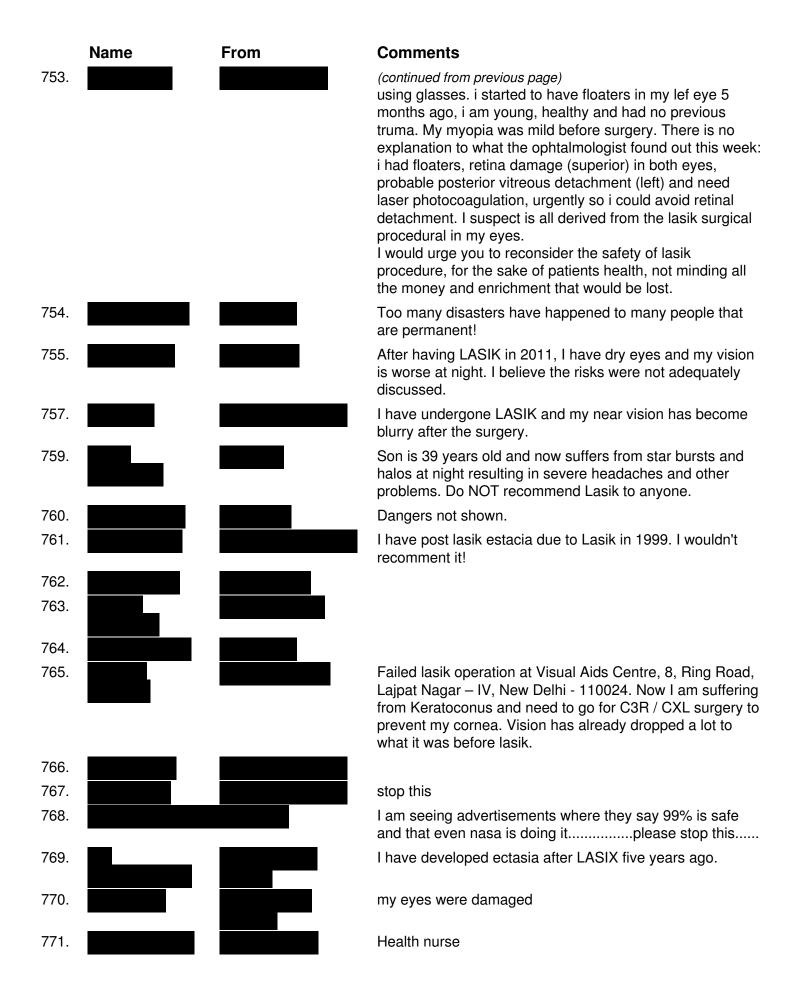
Comments Name From 745. I had IR Customvue Lasik Laser Vision correction on December 15, 2010. On checking i was found to have a refractive error of RE -4.75 DS / -1.50 DC x 40 and the LE was -4.50DS/-2.75DC-140. The corneal topography was normal and the central corneal thickness was 530 microns in the 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 deepakkapoor297@yahoo.com 746. 747. 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. 748. I dont want vulnerable and ignorant people to get hurt. 749. what is side effect of lasik laser 750. I had LASIK and bad outcome 751. My friend had a bad outcome and is now struggling everyday. 752. 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

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 *(continues on next page)*

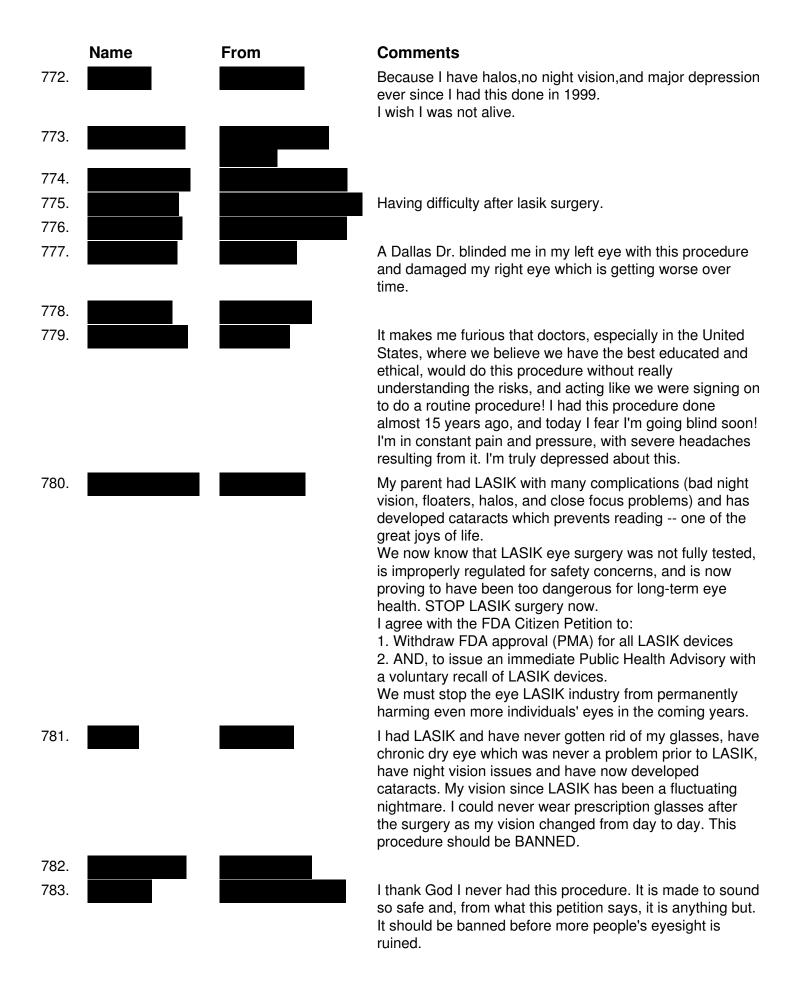
are. This operation is very dangerous and should be banned. Doctors must start saying the truth about this

753.

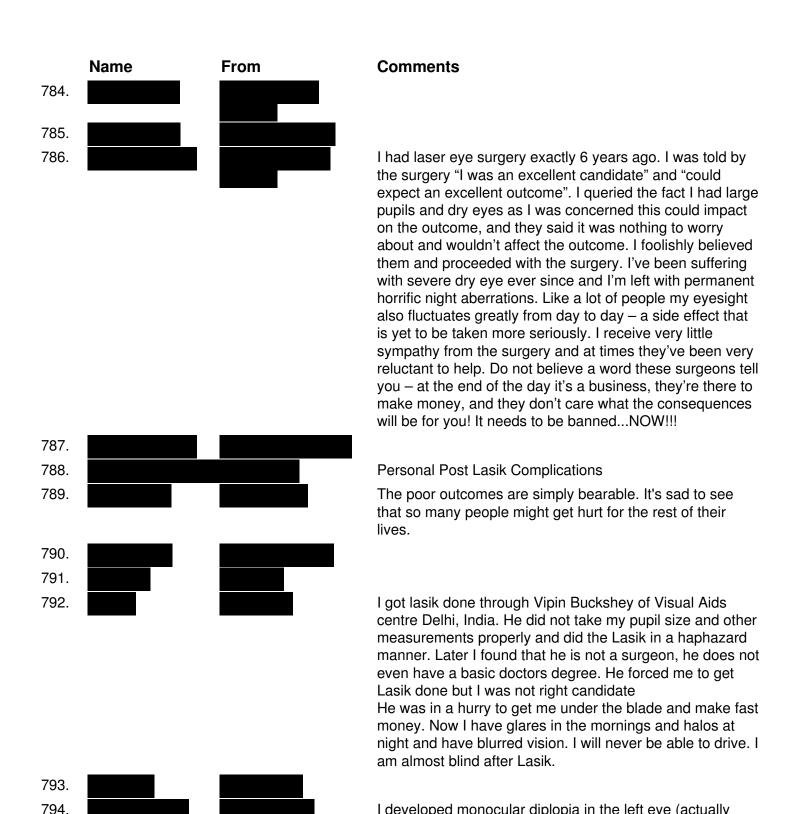
surgery to patients.



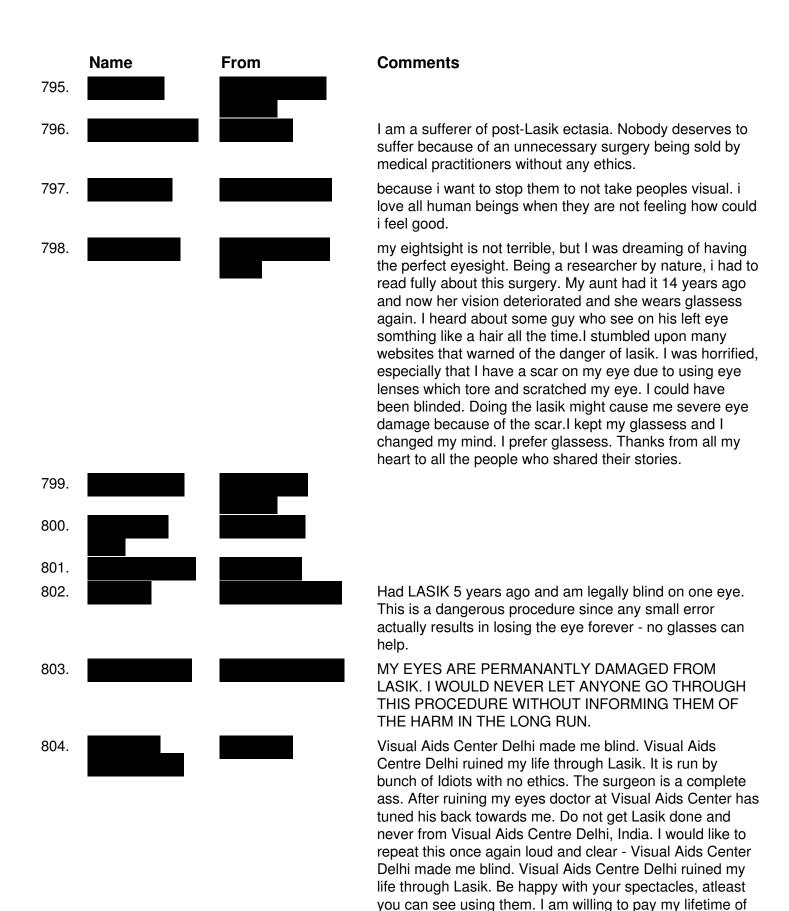
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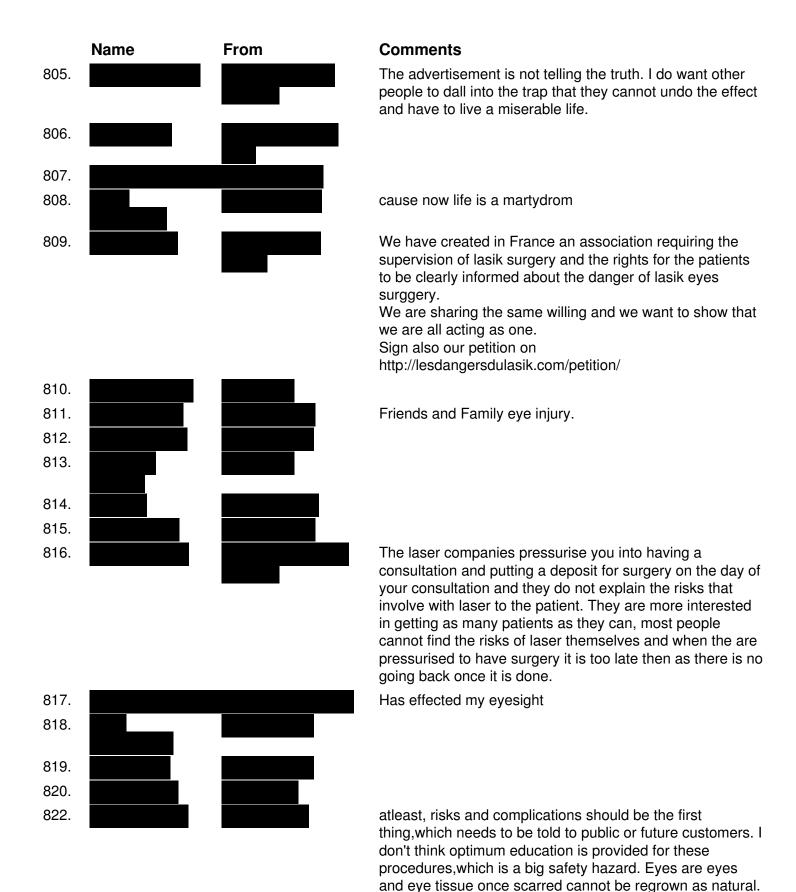
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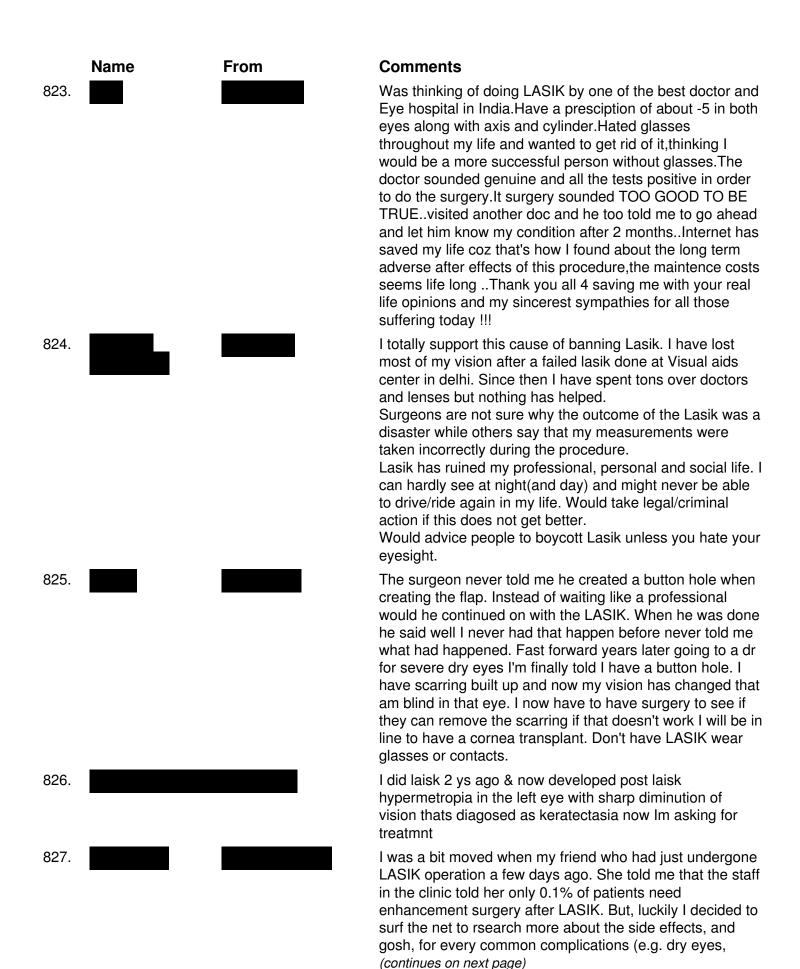


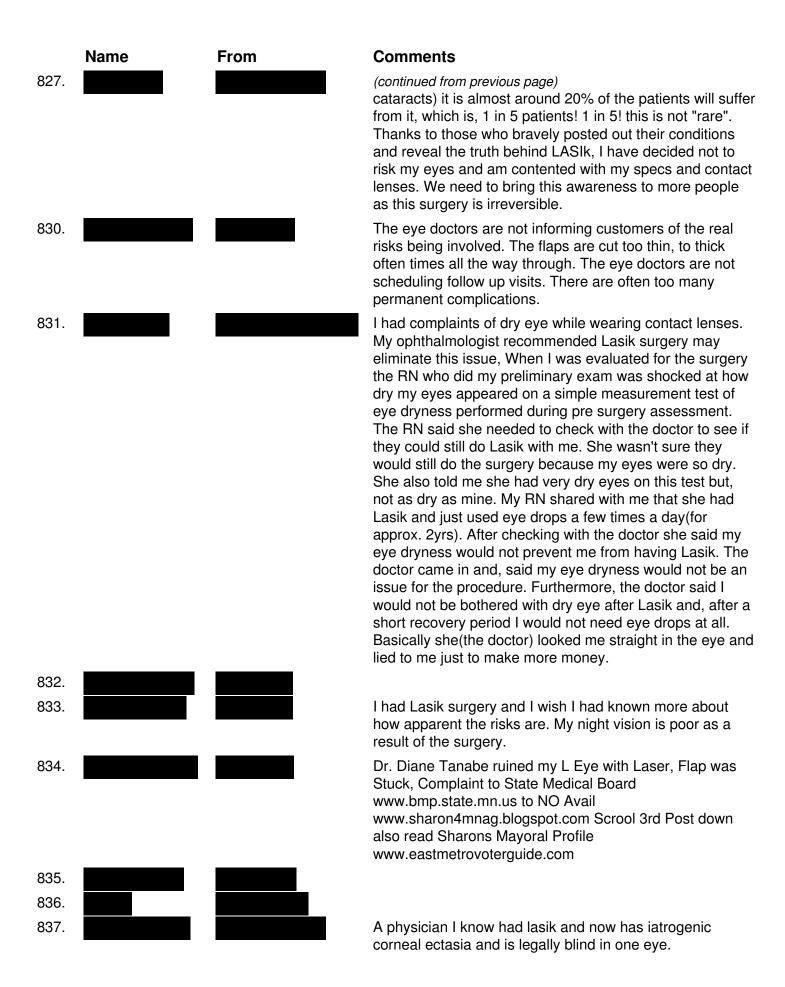
I developed monocular diplopia in the left eye (actually triplopia with visual smearing and blurring) which began within less than three (3) years following the Lasik procedure and worsened until recently. My ophthalmologist examined my eyes in June of 2012 and stated that my vision in the Left eye was 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.



saving to undo my Lasik and get my spectacles back.



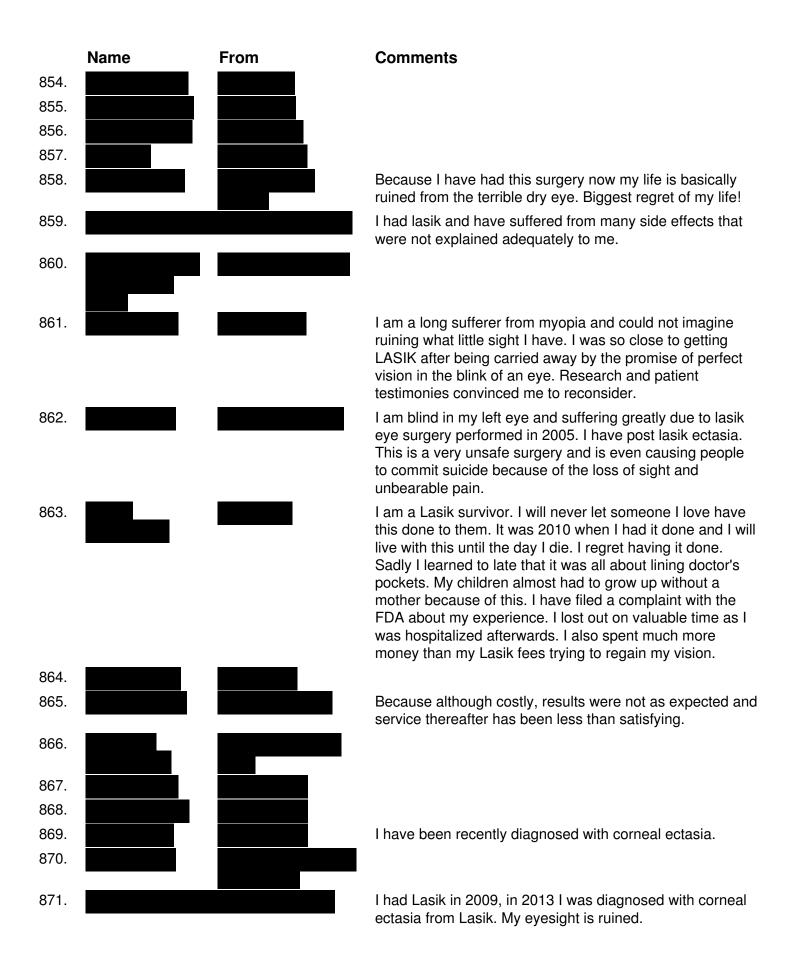




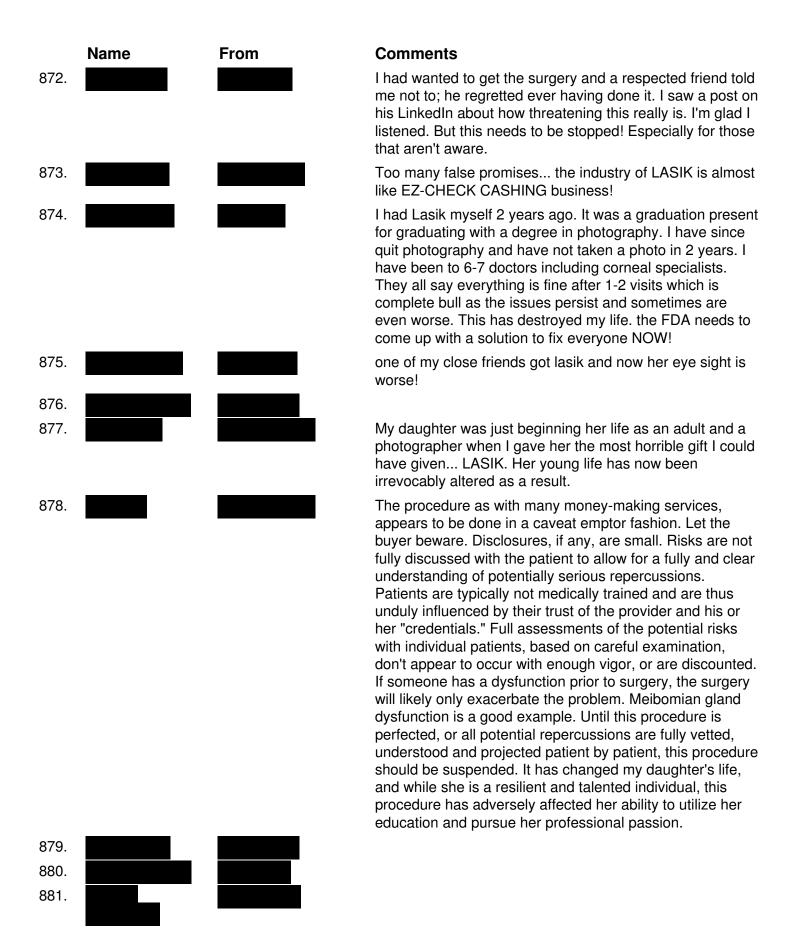
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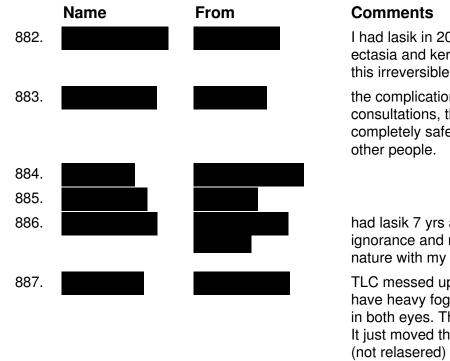


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I had lasik in 2001 and it never worked for me. I developed ectasia and kerotoconous subsequently. Now living with this irreversible damage.

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.

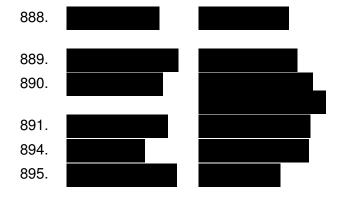
had lasik 7 yrs ago. typical complications. paid for my ignorance and naivity and belief in the integrity of human nature with my eyes

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 greneral is the last thing, that people must do only in cases of emergency.

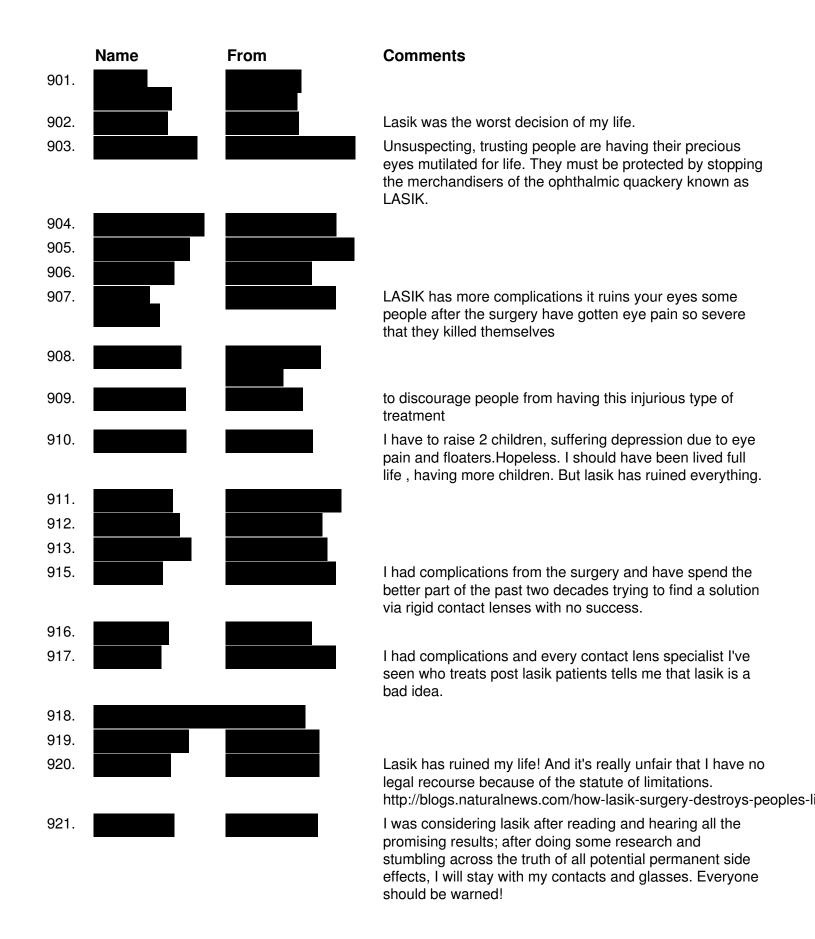
Before lasik, I was such a happy person. I led a normal life and was planning on getting married. I never had a dry eye issue with my glasses before lasik. Now, I am in pain everyday. I can no longer work. I have spent tens of thousands of dollars attempting to correct my chronic dry eye. The money is 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)*

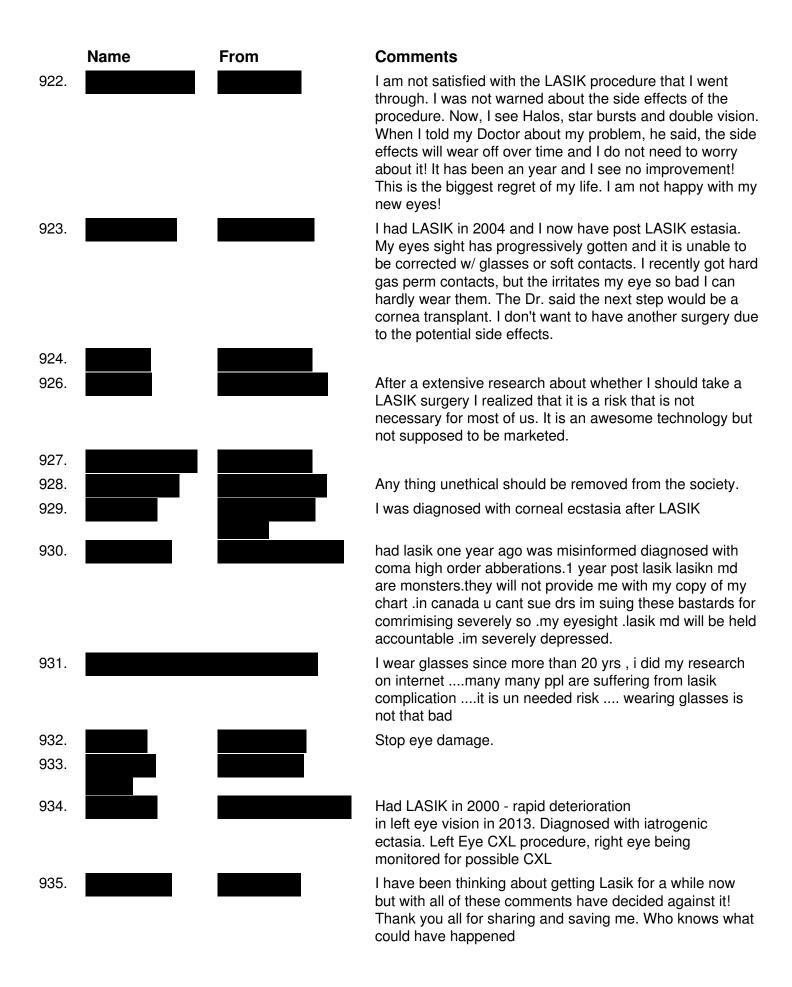


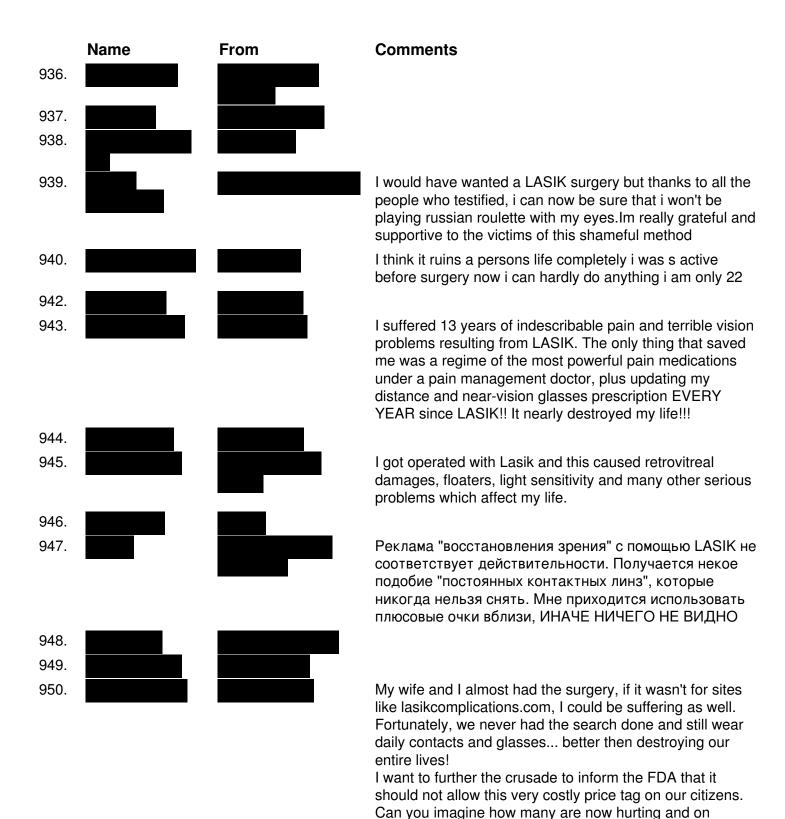
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Name Comments From 895. (continued from previous page) incident cannot cause a person to commit suicide. Here's the thing, lasik was a one day thing, but the burning and the pain is every day. Every single day, almost all day for me. Can that cause 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. 896. 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 inhancement 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 optomoligist 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. 897. because i do not want others to ruin their life 898. 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. 899. http://www.reiser.net/lasik 900.

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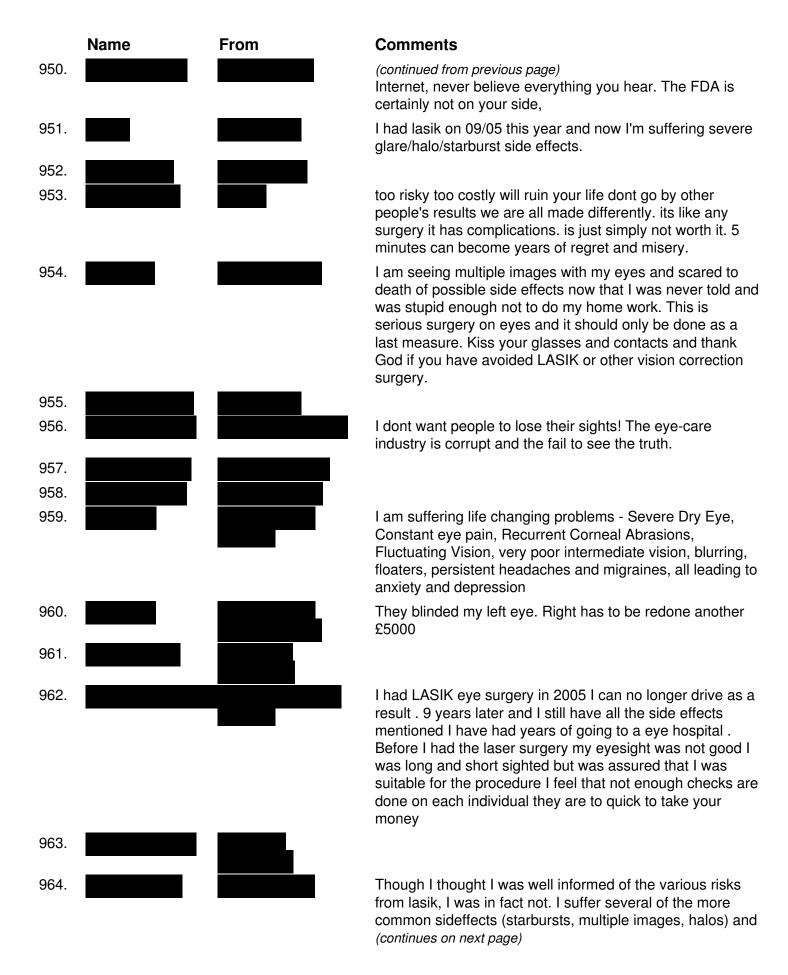




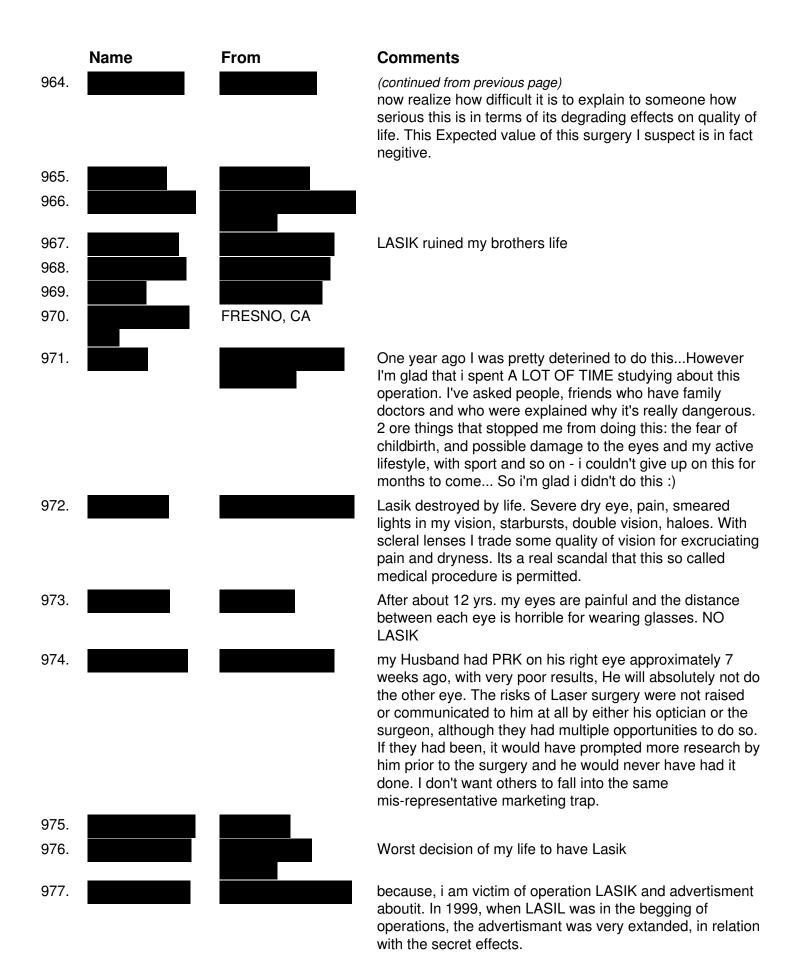
price quick surgeries making surgeons millionaires in only a few years?
Isn't it interesting that so many Doctors doing the surgery never had it done to themselves. I find that very interesting! It's all about the quick money, even if it ruins the lives of those that didn't do their due diligence research. Like the

disability that we all have to pay for because of these high

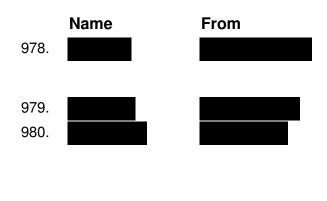
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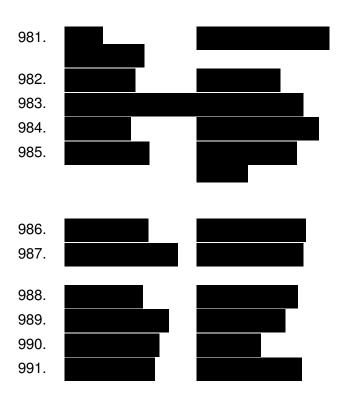


Comments

a Metrpolitan 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



992.

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.

Its 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)*

From

Comments

992.

(continued from previous 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

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.

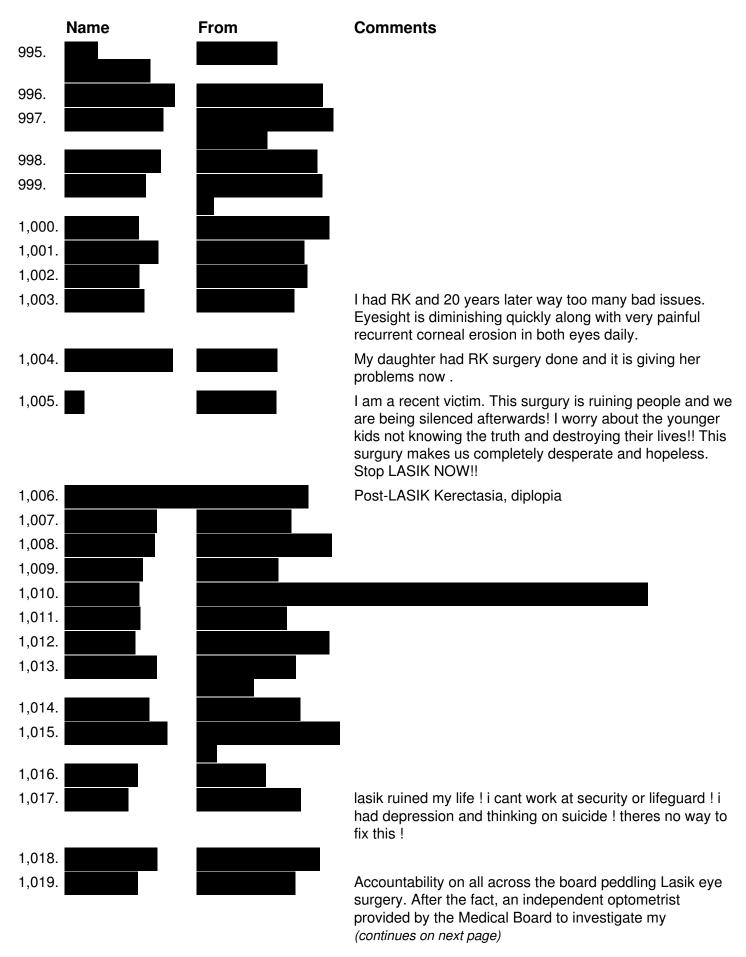
Prior the procedure I was told that the slight dryness will last for 2 months and then back to normal....this was 3 years now and I am nowhere near normal....punctal plugs inserted....let alone the glare, starbursts, lack of contrast, eye fatigue, special ugly glasses that I have to wear to protect the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

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

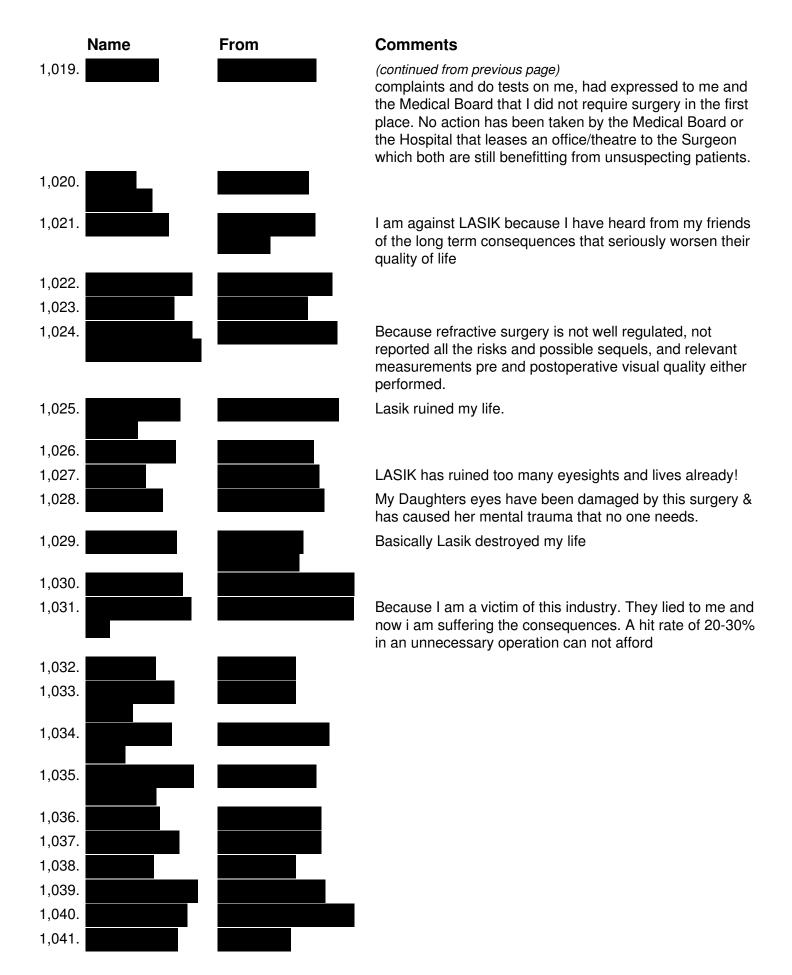
FDA should do its job and stop this crime! Better late than never. "Primum non nocere", right?

993. 994.

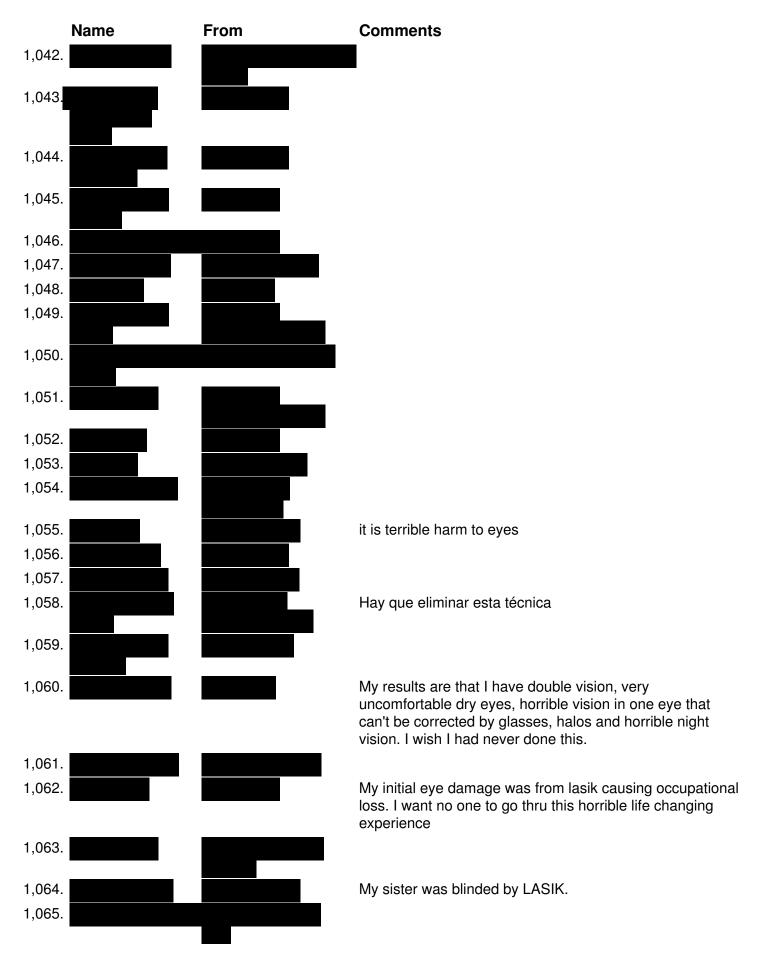




Page 92 - Signatures 995 - 1,019



Page 93 - Signatures 1,019 - 1,041



Page 94 - Signatures 1,042 - 1,065

1,066.	Name	From	Comments Eye Dr and hospitals should honestly inform their patients
ŕ			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.
1,067.			
1,068.			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 this circumstances. please stop immediately this surgeries , please
1,069.			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.
1,070.			
1,071.			
1,072.			Experiencing same situation. Worst decision I ever made and so unnecessary for me. W
1,073.			

Exhibit 1

Waxler Regulatory Consultancy LLC

1920 Arlington Place Madison, WI 53726-4002

608-219-7547 mwaxler@charter.net

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,

Morris Waxler, Ph.D.

Attachment

President

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 eves 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:

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

^{††} Table 1

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

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 State 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.

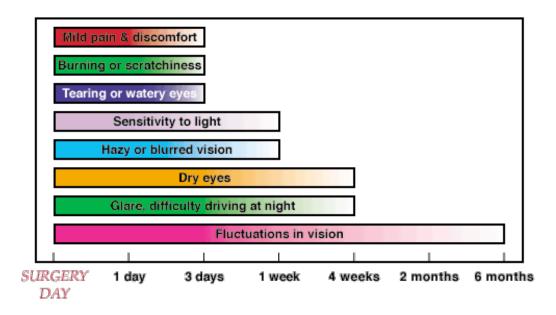
Published scientific data shows LASIK devices induce an average adverse event rate of about 22% that persists beyond six months to five or more years. Moreover, the published data (Section B) shows that LASIK devices transform healthy corneas into sick corneas that:

- 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 graph¹ 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 website³ 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.



What to expect after surgery

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.*

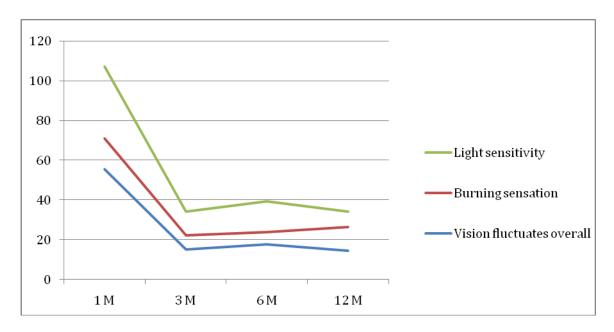


Figure 2 – LASIK Induced Adverse Events

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.

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^{*} The source documents for these data are identified in Table 1A, Appendix.

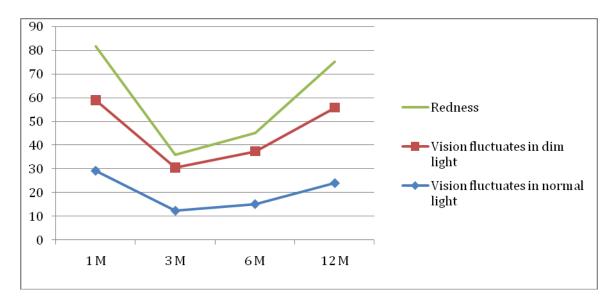


Figure 3 - LASIK Induced Adverse Events

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.

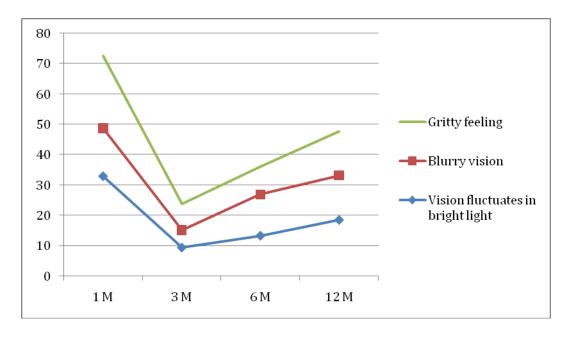


Figure 4 – LASIK Induced Adverse Events

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.

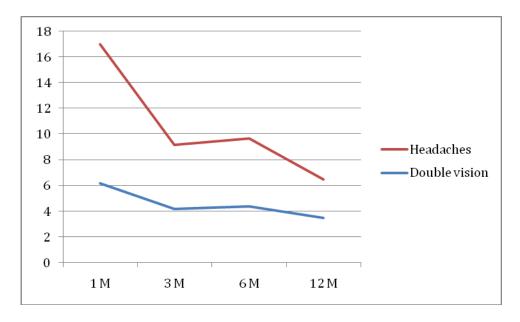


Figure 5 - LASIK Induced Adverse Events

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.

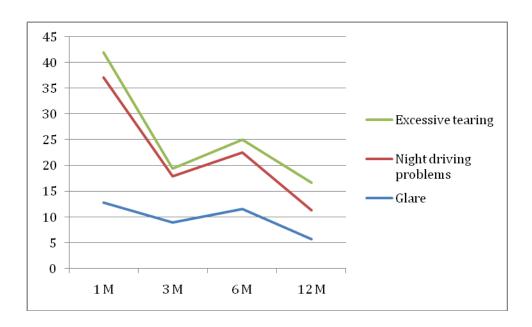


Figure 6 – LASIK Induced Adverse Events

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.

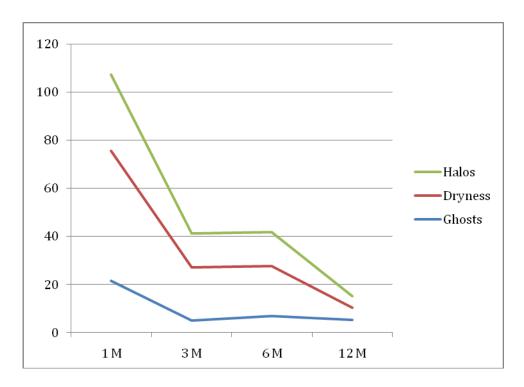


Figure 7 – LASIK Induced Adverse Events

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 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

Manufacturer	Follow-Up (months)	% Data Withheld
Kremer LASIK	12	79.9
Kremer LASIK	12	39.7
VISX LASIK	3	62.1
Nidek EC-5000	12	41.5
LADARVision	6	57.9
VISX Star S2, S3	6	29.4
LaserSight	6	88.2
LaserSight	6	73
VISX	6	4.3
LADARVision 4000	6	68.1
VISX Star S4	6	22.3
Allegretto Wave	3	7.6
Allegretto Wave	6	10.3
LADARVision 4000	3	29.9
VISX Star S4	6	1.1
VISX WaveScan	6	7
VISX Star S4	6	41.8
Allegretto Wave	6	12.3
LADARVision 4000	6	20.2
LADARVision 4000 & 6000	6	0
Allegretto Wave	3	4.2
Allegretto Wave	3	6.4
MEL-80	6	2.2
Nidek EC-5000	12	5.2
VISX Star Wave	12	9.4
		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 \sim 21% (Figure 7, Table 3A), night vision problems at \sim 11% (Figure 6, Table 3A), glare at \sim 12% (Figure 6, Table 3A), and halos at \sim 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

Adverse Event	Published Adverse E	Adverse Event Rate (%) Reported by Manufacturers to FDA	
	Reported %	Mean %	
	46.08		
	9.09		
Dry eyes	35.3 ¹⁰	~22	~20.6
	12.5 ¹¹		
	20.812		
	27.0 ¹³		
	4.0 ¹⁴ 5 years post-LASIK		
	6.1913		
	5.15 ¹⁶		
	10.3 ¹⁷		
Night vision problems	7.118		
	4.7 ¹⁹	~16	~10.9
	29.5^{20}		
	29.0^{21}		
	11.7 ²²		
	33.8^{23}		
	24.0 ²⁴ 5 years post-LASIK		
Glare	12.0^{25}		
	16.3 ²⁶	~20	~11.6
	27.2^{27}		
	24,5 ²⁸		
Halos	24.7 ²⁹		
	30.0^{30}	~19	~14.1
	3.0 ³¹ 5 years post-LASIK		

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 satisfied³² 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

^{*} See Table 3A, Appendix

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 brochures³³). 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 3 – Percent Patients That May Need Spectacles 6-12 Months After LASIK

Manufacturer	FU (mos)	Spectacles May be Needed
Kremer LASIK	12	32.7
Kremer LASIK	12	39.9
VISX Star S2	6	54.1
Nidek EC-5000	12	48.9
LADARVision	9	67.3
LADARVision	9	43.4
VISX Star S2, S3	6	48.1
LaserSight	12	51.8
VISX Star S2,S3	6	61.8
LADARVision 4000	6	17.3
VISX Star S4	12	27.9
Allegretto Wave	12	87.4
Allegretto Wave	12	67.5
LADARVision 4000	6	22.9
VISX Star S4	6	61.8
VISX Star WaveScan	12	27
VISX Star WaveScan	12	28.1
Allegretto Wave	6	69.4
LADARVision 4000	9	9.4
LADARVision 4000 & 6000	9	20.4
Alllegretto Wave	6	40.3
Alllegretto Wave	6	42.9
MEL-80	6	33.4
Nidek EC-5000	12	1.1
MEL-80	6	92.7
VISX Star Wave	12	12.7
		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, seven 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 $\sim 2\%$ 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."

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. 41 Post-LASIK dry eye is a neuropathic

epitheliopathy, ⁴² a medical device induced epidemic. Dry eye is the most common complication of LASIK surgery. ^{43,44} Figure 8 shows how LASIK causes neuropathic dry eye. ⁴⁵

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. 46 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%). 47

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.

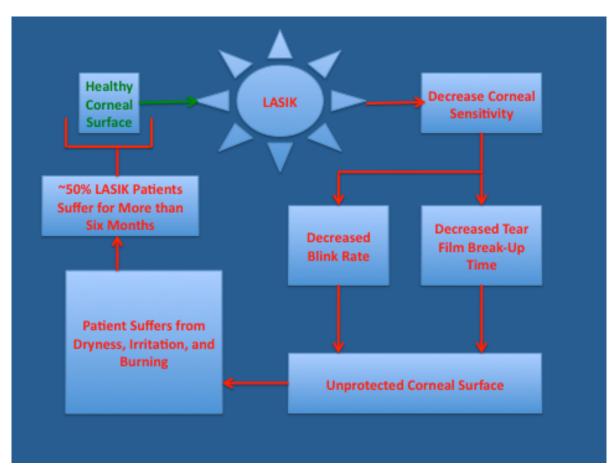


Figure 8 - LASIK Cuts Corneal Nerves, Causing a Dry and Irritated Cornea

Based mostly on: Abelson MB. A Different Animal: Post-LASIK Dry Eye.

Rev. Ophthalmology, Vol. No: 9:08 Issue: 8/15/02

(The statement that "50% LASIK Patients Suffer for More Than Six Months" is based on published data cited in Table 2.)

4. LASIK Devices Induce Progressive Pathology in the Cornea

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.⁵¹ 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.

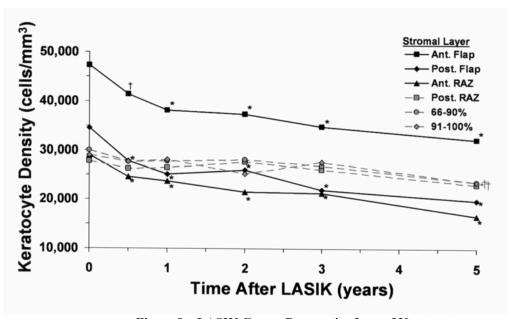


Figure 9 – LASIK Causes Progressive Loss of Keratocytes

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 LASIK⁵⁵

Stromal Layer	Rate of Change (% Per Year)
Anterior flap	-4.3 ± 3.2
Posterior flap	-7.2 ± 4.3
Anterior RAZ (0 to 50 μm)	-8.4 ± 3.7
Posterior RAZ (51 to 100 μm)	-2.6 ± 4.1
Posterior 66% to 90%	-3.5 ± 3.4
Posterior 91% to 100%	-3.1 ± 2.2

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: "TABLE 4. CHANGE IN KERATOCYTE DENSITY BETWEEN 6 MONTHS AND 5 YEARS AFTER LASIK"

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.⁵⁶ Table 5 summarizes some of the reports of keratectasia.⁵⁷ The absence of keratectasia findings in LASIK is likely due to the failure of long-term follow up,⁵⁸ 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, ⁵⁹ 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%.

Binder PS. Analysis of ectasia after laser in situ keratomileusis: risk factors. Journal Cataract Refract Surg. 2007 Sep;33(9):1530-8.

Source	Number	(%)
Reinstein ³ ,*	6/5212	(0.12)
Pallakaris ⁴	19/2873	(0.66)
Rad ⁵	_	(0.2)
Condon ⁶	3/140	(0.8)
Current [†]	3/9283	(0.01)
Kansky [‡]	——————————————————————————————————————	(0.9)
Sergey [‡]	13/23990	(0.05)
Oliviera [‡]	6/2500	(0.24)
Stulting [§]	$\geq 1:5000$	-
ESCRS registry	72	
of ectasia cases (9/2006)		
*Projection		
Myopic errors	Common of the European Con	inter of Colors
	Congress of the European Soci don, England, September 200	
& Retractive Surgeons, Lone		

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-like⁶⁰, often de-centered, warped, chaotic, and rough with stromal microfolds.⁶¹

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

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:⁶⁷

"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. LASIK increases both corneal and total aberrations with changes in the anterior and posterior corneal surfaces contributing to the rise in higher order aberrations. LASIK may correct distortions such as defocus but it induces other distortions. Figure 10 shows the LASIK-induced increase in higher order aberrations.

According to published studies, higher order distortions induced by LASIK are significantly correlated with loss of quality of vision, ⁷² such as loss of contrast sensitivity, ⁷³ and increases in halos and night vision problems. ^{74,75} In addition, LASIK-induced higher order aberrations are more troublesome in binocular than in monocular viewing. ⁷⁶ 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.

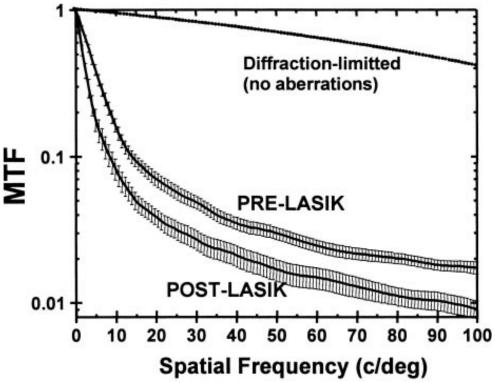


Figure 10 – LASIK-Induced Distortions

From: Moreno-Barriuso E, Lloves JM, Marcos S, et al. Ocular aberrations before and after myopic corneal refractive surgery: LASIK-induced changes measured with laser ray tracing. Invest Ophthalmol Vis Sci 2001; 42:1396-1403: **"Figure 8.** Average MTF (radial profile) before and after LASIK, computed from the wave aberration, and for a 6.5-mm pupil diameter and 543 nm. The *solid lines* are the average across 22 eyes, and the *bars* are the SE for selected frequencies. The diffraction-limited MTF is included for comparison purposes."

Some LASIK manufacturers and allied clinics report waveguided-LASIK devices do not increase higher order aberrations⁷⁷ or cause fewer halos and night vision problems than conventional LASIK devices. R5,79,80 Still others report waveguided-LASIK does increase higher order aberrations or increase aberrations more for one LASIK device than another. Other studies report no significant improvement of waveguide-LASIK compared to conventional LASIK.

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. Most of the decrease in post-LASIK contrast sensitivity found can be explained and computed directly from the physical measurement of the wave aberration. 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. 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.⁸⁷ Also, LASIK causes loss of sensitivity in the midperipheral visual field correlated with refractive error, flap thickness, and optical zone diameter.88

Table 6 – Persistent Loss of Contrast Detection after LASIK

Type of Loss	6 Months (% loss)	12 Months
Low contrast visual acuity	Mean = 20.2	
1.0-2.0D	$20.9^{\dagger\dagger\dagger}$, $11.8^{\ddagger\ddagger}$, $26.2^{\$\$}$, 21.8^{****}	No data
>2D	2.2°	No data
Bright light contrast sensitivity	Mean = 3.8 $0.7^{\dagger\dagger\dagger\dagger}$, $1.7^{\ddagger\ddagger\ddagger}$, 7.5^{f} , $5.5^{\$\$\$\$}$	No data
Dim light contrast sensitivity	Mean = 9.1 5.8^{b} , 7.3^{d} , 12.9^{f} , 10.3^{g}	No data
Contrast Sensitivity	Mean = 6.3	
Bright light without glare	$4.5^{*****}, 3.8^{\dagger\dagger\dagger\dagger}, 10.7^{\ddagger\ddagger\ddagger}$	$1.6^{j}, 14.0^{k},$
Dim light without glare	Mean = 14.2 21.8^{i} , 5.0^{j} , 15.7^{k} ,	4.8 ^j , 15.9 ^k ,
	Mean = 16.4	4.8 ^j , 13.1 ^k ,
Dim light with glare	$27.1^{i}, 5.0^{j}, 22.5^{k},$	
>2 Line Decrease in CS §§§§§§		
Bright without glare	1.0	No data
Dim without glare	8.0	No data
Dim with glare	9.0	No data

^{***} Table 16 - P970043S10b

^{***} Table 19 - P970043S15b

^{§§§} Table 26 − S20b

^{*****} Table 26 – S22b

^{****} Table 19 - P970043S10b

^{****} Table 21 - P970043S15b

^{§§§§} Table 28 – S22b

^{*} Table 11 – S17b

^{*****} Table 11 – S20b

^{*****} Table 22 – S21b

^{§§§§§} 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. Host 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. ⁹⁵ 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. ⁹⁶ 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. ⁹⁷ A review of the literature on wavefront-guided LASIK concludes that evidence does not support claims that wavefront out performs conventional LASIK. ⁹⁸ Femtosecond laser flap creation does not reduce the incidence of most complications. ⁹⁹ 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. ¹⁰⁰ A search of peer-reviewed literature reveals problems associated with the femtosecond laser such as slipped flaps, interface inflammation, flap

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

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)
 - 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
 - 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

Moras Wayler

Appendix – Tables with Additional Details

Table 1A – Percent Adverse Events Data Withheld by Manufacturers

		Approval	withheld by Manula	FU	% Data Withheld (n-N)/N x
Manufacturer	PMA	Date	Data Source	(mos)	100
Kremer LASIK	P970005	2/13/98	Table 9a- Cohort 2	12	79.9
Kremer LASIK	P970005	2/13/98	9b -Cohort 1	12	39.7
VISX LASIK	P990010	7/22/99	TABLE 19	3	62.1
Nidek EC-5000	P970053S2	4/14/00	Table 16	12	41.5
LADARVision	P970043S5	5/9/00	Table 16	6	57.9
VISX Star S2, S3	P900016S12	4/27/01	Table 14	6	29.4
LaserSight	P980008S5	9/28/01	Table 15 - w/o astigmatism	6	88.2
			Table 15 - w		
LaserSight	P980008S5	9/28/01	astigmatism	6	73
VISX	P930016S14	11/6/01	Table 15	6	4.3
LADARVision 4000	P970043S10	10/18/02	Table 18	6	68.1
VISX Star S4	P930016S16b	5/23/03	Table 11b	6	22.3
			Table 26 Study		
Allegretto Wave	P020050	10/7/03	Cohort	3	7.6
Allegretto Wave	P030008	10/10/03	Table 16	6	10.3
LADARVision 4000	P970043S15	6/29/04	Table 22	3	29.9
VISX Star S4	P930016S17c	12/14/04	Table 3-37	6	1.1
VISX WaveScan	P930016S20c	3/17/05	Table 3-26	6	7
VISX Star S4	P930016S21	8/30/05	Table 3-22	6	41.8
Allegretto Wave	P930008S4	4/19/06	Table 15	6	12.3
LADARVision 4000	P970043S20	5/1/06	Table 30	6	20.2
LADARVision 4000 & 6000	P970043S22	5/2/06	Table 30	6	0
			Table 26 Study		
Allegretto Wave	P020050S4	7/26/06	Cohort	3	4.2
			Table 26 Control		
Allegretto Wave	P020050S4	7/26/06	Group	3	6.4
MEL-80	P060004	8/11/06	Table 13	6	2.2
Nidek EC-5000	P970053S9	10/11/06	Table 21	12	5.2
VISX Star Wave	P930016S25	7/11/07	Table 43	12	9.4
				Sum	724
				n	25
				Mean	29.7

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

Manufacturer	PMA	Approval Date	Data Source	FU (mos)	Spectacles May be Needed
Kremer LASIK	P970005	2/13/98	Table 2a –Cohort 1		32.7
Kremer LASIK	P970005	2/13/98	Table 2a –Cohort2	12	39.9
VISX Star S2	P990010	7/22/99	Table 11	6	54.1
Nidek EC-5000	P970053S2	4/14/00	Table 11	12	48.9
LADARVision	P970043S5	5/9/00	Table 10	9	67.3
LADARVision	P970043S5	5/9/00	Table 11	9	43.4
VISX Star S2,S3	P930016S12	4/27/01	Table 5	6	48.1
LaserSight	P980008S5	9/28/01	Table 6	12	51.8
VISX Star S2,S3	P930016S14	11/6/01	Table 5	6	61.8
LADARVision 4000	P970043S10	10/18/02	Table 10	6	17.3
VISX Star S4	P930016S16c	5/23/03	Table 3.5	12	27.9
Allegretto Wave	P020050	10/7/03	Table 5	12	87.4
Allegretto Wave	P030008	10/10/03	Table 5	12	67.5
LADARVision 4000	P970043S15	6/29/04	Table 8	6	22.9
VISX Star S4	P930016S17	12/14/04	Table 7a	6	61.8
VISX Star WaveScan	P930016S20c	3/17/05	Table 3.6	12	27
VISX Star WaveScan	P930016S21c	8/30/05	Table 3-8		28.1
Allegretto Wave	P930008S4	4/19/06	Table 5	6	69.4
LADARVision 4000	P970043S20	5/1/06	Table 13	9	9.4
LADARVision 4000 & 6000	P970043S22	5/2/06	Table 11	9	20.4
Alllegretto Wave	P020050S4	7/26/06	Table 11 *Study Cohort	6	40.3
Alllegretto Wave	P020050S4	7/26/06	Table 11 *Control Cohort	6	42.9
MEL-80	P060004c	8/11/06	Table 14	6	33.4
Nidek EC-5000	P970053S9	10/11/06	Table 12	12	1.1
MEL-80	P060004b	8/11/06	Table 5	6	92.7
VISX Star Wave	P930016S25	7/11/07	Table 15	12	12.7
				Sum	1110.2
				N	26
				Mean	42.7

Table 3A – Mean Percent Vision Adverse Events After LASIK Data From PMA Documents Identified in Table 1A Data Used in Figures 2 - 7

Adverse Events	Months After LASIK			
	1	3	6	12
Vision fluctuates in normal light	29.2	12.4	15.2	24
Vision fluctuates in dim light	29.8	18.1	22.2	31.8
Redness	22.7	5.4	7.6	19.3
Vision fluctuates in bright light	33	9.5	13.4	18.6
Blurry vision	15.8	5.6	13.5	14.6
Gritty feeling	23.7	8.8	9.3	14.4
Vision fluctuates overall	55.6	15.0	17.8	14.4
Burning sensation	15.5	7.3	6.2	12
Light sensitivity	36.2	12.0	15.3	7.8
Glare	12.8	8.9	11.6	5.7
Night driving problems	24.3	9	10.9	5.6
Excessive tearing	4.9	1.6	2.5	5.4
Ghosts	21.4	5.1	7.0	5.3
Dryness	54.2	22.0	20.6	5.0
Halos	31.6	14.0	14.1	4.8
Double vision	6.2	4.2	4.4	3.5
Headaches	10.8	5.0	5.3	3.0
Foreign body sensation	1.4	0.5	2.2	0.8
Pain	2.4	3.0	2.3	0.7

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⁴ CDRH, FDA October 10, 1996. Checklist of Information Usually Submitted in an Investigational Device Exemptions (IDE) Application for Refractive Surgery Lasers

⁵ http://www.lasiknewswire.com/2009/04/fda-update-on-lasik.html

⁶ FDA, OPHTHALMIC DEVICES PANEL Eighty-Seventh Meeting, Tuesday, January 14, 1997. Comments by Marc Odrich, MD (VISX Inc) pp. 89-92.

⁷ Confidential information to be submitted to FDA's Office of Criminal Investigation

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