

FDA Holds Emergency LASIK Panel Discussion To Interview Hurt LASIK Patients Regarding The Quality of LASIK...

-FDA PANEL DISCUSSION POINTS- April 25th, 2008

Opening Statement: Good morning FDA Panel, registered guests, and fellow hurt LASIK victims. My name is ----- founder of [REDACTED] and I am going on my 9th year of post LASIK visual HELL. Please keep in mind that I have been lied to by my own doctor and 2nd opinion doctors, the same doctor tried to sue me for \$2 million dollars, I have been all over the world having surgeries and looking for cures for 8 years and have spent \$30,000 and am nowhere close to normal. Isn't it ironic that my eyesight had to be ruined by LASIK in order for me to see how corrupt this industry truly is. The name itself says it all: LA....SIK! LA...SIK! Notice, that we are not talking about PRK a surface treatment in reshaping one's cornea. Our efforts are strictly focused on LASIK: "the creation of a permanent FLAP that leaves the cornea scarred for life, never to be returned to it's normal state." For discussion purposes, this submission is outlined detailing the "Problems" believed with LASIK, and then suggestive "Action Steps Needed By The FDA," so that the FDA and the LASIK Community which we are all now a part of, can work together to help to redefine the current standard of care for LASIK, and hopefully fine tune many safety points mentioned and submitted here today.

This will insure that the future of LASIK is either "No LASIK," or a much safer, more patient focused INFORMED version of LASIK. This entire discussion is based on my personal experiences with the FDA, Departments of Regulation, LASIK centers & doctor(s), their staff members, thousands of hurt LASIK Patients I have spoken to over the years, especially the ongoing harassment from the LASIK Industry with "death threats," [REDACTED] & [REDACTED] trying to blackmail hurt LASIK patients like myself, and all of our ongoing efforts to find a cure. At this juncture, I have realized that there is absolutely NO KNOWN CURE for the permanent damages that were done to my only set of eye and others that suffer like me. I preface by saying "this is my opinion throughout," so that this corrupt industry doesn't find a way in which to sue both myself and dozens of others that continue to "cost them hundreds of millions of dollars" which we have estimated from helping 50,000+ patients being "talked out of having LASIK" at an average of \$3,000 a person...You can be assured that this number will exponentially increase after this discussion is broadcasted to the masses. LASIK stocks such as TLC and others will begin to fall even further into the black abyss, while the end consumer will finally be getting "Informed Consent" that such a FDA Panel Discussion is concerned about LASIK and that a congregation of hurt LASIK Patients, many doctors themselves, PHD's, attorneys, and people from all walks of life, come together today, UNITED FOR A SPECIFIC CAUSE, in order to tell their LASIK horror stories in an immediate effort to make things safer for our fellow Americans. Please keep an open mind and hear us today! This is something that effects every single one of you and your family members...

The following 7 discussion points, in my opinion, need to be immediately studied in order to determine whether or not the industry is "misleading" the misinformed public, the consumer, which again is the FDA's mission to protect and serve. The FDA's mission is not to put greedy business first, and the consumer last which appears to be the present state today.

1. The Truth About The FLAP. Can we get the truth? Does it heal or does it NOT heal? : The truth is that the permanent FLAP is more like a screen door in a Florida Hurricane and that "The Flap Never Heals Leaving The Patient With a Permanently Scarred Cornea For Life!!" I want an immediate investigation of "department members acting as patients" who would randomly visit LASIK doctor's offices speaking to their sales clerks, doctors and staff, acting like a consumer asking questions. Ask the LASIK staff and doctors, whether or not LASIK fully heals, leaves a permanent scar, as well as a permanent flap. Listen to the sales pitch you get next. I will promise you that many centers are telling you the following misleading and corrupt answer: Smart Patient asks: "Hey Doc, what happens with the creation of the FLAP, does it ever heal?" Doc Says: "Mr. Patient, the flap heals very similar to a cut on the hand." Smart patient asks: "Hey Doc, what happens if I need an enhancement 1,3,7,13 years later?" Doc Says: "No problem, we can just peel it back and enhance it." Smart Patient asks: "Doc, well then if you are telling me that the flap you will create can be pulled back 1,3,7,13 years later, then how are you determining that the flap heals similar to a cut on one's hand when the cut on one's hand can NOT be pulled back 1,3,7,13 years later?" Doc Says: "You're not a candidate for LASIK, good luck...nurse, please send in the next patient." I want an investigation of the rebuffs that LASIK doctors are telling their patients. Especially the hurt LASIK victims. The Statute of Limitations LASIK doctor's rebuff: Hurt Patient: "Hey Doc, my life is ruined and my vision is seeing all kinds of visual distortions, halos, double vision and dry eye soreness and worst yet I can't go back to contacts since they won't work on me now....in other words Doc, my eyesight can't be fixed through normal means, what happened?" Doc Says: "You are unfortunately in the 5% that LASIK didn't work for. Your eyes healed differently. It may take another 2,3,4,5 years to fully heal and get that last amount of healing needed...In the meantime, try these drops, and these, and these and call me in 6 months and let me know how you are doing..." Do you understand what we are saying today? If you are not willing to investigate this, then you will not uncover the lies.
2. Redefine 'Informed Consent.' Re-Design The FDA pamphlet to include Full Color Pictures & include ALL Known Side Effects Please then distribute to every LASIK Center/Doctor/Staff/Facility and Patients. At the bottom of my presentation, submitted for public record, will include mandatory suggestions needed to really give consumers "Informed Consent" as compared to the minimal and misleading simplicity of data and false "success rates" that are currently being shown to patients via the current FDA website guidelines and FDA pamphlet handed out to patients right before their surgery. Why aren't the

following known risks also included into all "Informed Consent" forms and FDA Guideline Pamphlets/Websites: Loss of normalcy of vision since you have known NORMAL to you since birth, leading to side effects such as loss of 3 dimensional vision now being limited to an appearance of 1 dimensional vision, which could cause severe depression, that may lead to suicide, loss of a life as you once enjoyed, the risk of never being able to wear contacts or glasses again, severe dry eye syndrome, hatred to carry out wrath on one's LASIK doctor, their staff, and their family members even though the patient has had NO previous history of violence, cyclotorsional rotation which isn't being talked about, accelerated aging of the cornea, suction ring creates "yellow cholesterol spots on high cholesterol patients," de-centered flaps, de-centered treatment zones, multiple prescriptions needed but not limited to a patient's outer periphery and inner zone, permanent thinning of the corneal further accelerating ECTASIA, floaters, change of intraocular pressure, EBMD, droopy eyelid and eyelid muscle loss, loss of sport activities, loss of corneal strength being reduced to 2%, being lied to by all follow up LASIK doctors to push you past the Statute of Limitations so that you can't sue the original LASIK doctor, being sued, harassed and defamed by your own LASIK doctor so that they can attempt to quiet your attempts to advertise their mistakes which is a First Amendment Right, loss of a trade, loss of ability to provide income for oneself, loss of clarity of thought, loss of reputation, loss of a retirement, loss of travel, loss of family and friends, and loss of hope and trust for all Medical Doctors and our government to protect.

3. Success Rates Defined By Whom? Redefine "Success Rates" and "The Standard of Care" for Elective LASIK Surgery and then retroactively monitor LASIK Doctors to make sure such a standard of care is being given to the end consumer versus the current status of ongoing violations of the Hippocratic Oath by ALL/MOST LASIK Doctors with no disciplinary action to those same doctors: Success Rates are being falsified by the industry telling patients that they are a "success" when they are a "blunder." 2nd, 3rd, 4th, 5th opinion LASIK doctors are lying to their patients, while being paid substantial diagnosis fees in order to look out for the patient's best interests and NOT the original Lying LASIK doctor. I was told I was a "success" when in reality both eyes were a complete "breach of prequalifying my candidacy for LASIK," as well as a complete and horrific nightmare of a LASIK procedure by [REDACTED] businessman/owner of [REDACTED]. Now others like me have learned the real truth. There is an accepted brotherhood, or secret society of consistent "lying oaths" between all LASIK Doctors to mislead their "botched" unhappy patient that they were a "success" because they can see better without prescription than previously without corrective lenses. That's saying nothing when the patient is telling the Lying LASIK Doctor(s) they are seeing double vision, halos/starbursts, dry eye, and not being able to tolerate nor benefit from ever wearing contact lenses or glasses. The LASIK Doctor then tells the Hurt LASIK Patient to see a psychologist for their "new mental disorder" that they have created in their own minds. This is accepted lying behavior amongst ALL/MOST LASIK Doctors.

4. Redefine the 'Breach of the Standard of Care' so that the FDA can work with the ASCRS, AMA, Departments of Regulation, and other entities to insure 'fair practice' in dealing with the hurt LASIK patient being given FREE medical attention, a financial settlement, and immediate disciplinary action of the LASIK doctor sin fault. Then Immediately Implement 'open communication' with the Hurt LASIK Patient's complaint and the following departments such as ASCRS/Departments of Regulation/AMA Boards to work towards a "Patient Friendly" solution. Create a Complaint Department that specifically handles all complaints from Hurt LASIK Patients and make it mandatory that all staff members, doctors, centers, medical device companies, optometrists, and ophthalmologists all report any cases of patients expressing an "unhappy outcome.

5. Investigate all LASIK Doctors that have had 3 or more LASIK Lawsuits in the past 8 years and immediately implement a "Disciplinary Board" to determine whether or not "Immediate Disciplinary Action" is justified and then take action disciplining each corrupt doctor retroactively speaking. This should include running (6) Billboard advertisements in (6) major cities to start, asking the public's opinion of their LASIK experience: "Hurt From LASIK? The FDA Wants To Know! Call: 1-800-Bad-LASIK. Measure the response over a 6 month period. Run billboard advertising on the major highways and downtown areas of: New York City, Atlanta, Fort Lauderdale, LA, Houston, Dallas, and Chicago. If the response is a few patients, then maybe there is nothing here. If the response is thousands of patients telling you exactly what we today are telling you, then you would have to admit that there is an epidemic and then the FDA's purpose in protecting the "consumer / patient" would be to take immediate action in order to stop cease all LASIK procedures until further studies determine why the outcomes are s----- rt LASIK patient: -----

----- How is it that a LASIK Doctor can continue to buy his way out of jail after having like 50+ lawsuits and all US Departments keep telling me that 'it isn't th----- o discipl-----K Doctors?' I want justice IMMEDIATELY!! Both the----- and the ----- Department of Regulation found "Probable Cause" and it went all th----- to the top where there resides the final decision maker, a "Medical Doctor" to determine the result. All of my complaints have been DECLINED as well as for the 2nd, 3rd, and 4th opinion LASIK doctors whom I paid to tell me honestly what caused the continued visual disturbances. I want an in-depth investigation on my particular case as to why the----- Department of Regulation chooses to NOT INVESTIGATE this sick person. I want my complaints investigated as if this was done to you and you had the power to make this happen now. I want justice and justice is punishing this criminal serial slicer and dicer (my opinion) to be put behind bars in jail so that this behavior doesn't happen to anyone else. My complaints submitted to the ----- on my LASIK Doctor, -----

----- (Destructive in many patient's opinions), their 50+ lawsuits, their frivolous lawsuit on me to the tune of \$2 million dollars, their attempt to get an immediate injunction to shut down www----- SIK.----- exposing their Bloody Dark Secrets, for his children both----- for atte----- and my family ong----- ng with ----- towards my family's detrim----- it, ----- trying to get my wife fired from her Nurse Professorship, for----- contacting the FBI and having the FBI sent to my house because of the ----- wing letter th----- ubmitted to him taking my Lawyer's advice to take the higher road with ----- and he turned it into a "false extortion attempt on my behalf which the FBI agents immediately told me as they left my house in bewilderment as to why they were there in the first place, for Nick threate----- my ex-wife ----- , a Nurse Professor and Honor Student, for ----- being successful in threatening and scaring my ex-wife to force us into a div----- one year ago...To date,----- continues this behavior because he knows that nothing is in place to discipline a Lying LASIK Doctor and that the only thing that can happen is that the FDA can hire a full team of US Marshalls to come in and seize his laser which happened in 2001. He took some of his millions, and simply purchased another laser. Just like a serial killer, he continues to lie, harass, sue, and in many opinions "Rape his patients, while being paid to do so." He is the epitome of the LASIK Industry and he is the Poster LASIK Doctor of what is being created..."Investigate

6. Investigate the LASIK Marketing & Misleading Advertisements that falsely lure the masses. Ask the board of Hurt LASIK Patients if these ads seem fair or misleading. Investigate Glenn Hagele of CRSQA & his LASIK Doctors to see if they are misleading patients and are a "referral network" of hurt LASIK patients being funneled to CRSQA doctors. Also determine if Glenn Hagele is being hired by these same doctors to do "their dirty work for them," defaming Hurt LASIK Patients who operate a website to warn the masses of the dangers not being told.
7. We are here today because we care. Please Work Quickly To Protect The LASIK Doctor's, Their Staff Members, and Their Family's Safety from their very disgruntled Hurt LASIK Patients: I have had thousands of LASIK victims contact me through online references explaining the same hatred they feel towards the LASIK Doctor that took away their eyesight and then lied to them ongoing to prevent having to pay their hurt victim a settlement. Many feel as I do today, that if something does NOT change, that many Hurt LASIK Patients will have made the news one year from today before they take their own lives. The news stations will come in to all departments of the ASCRS, AMA, and the FDA and they will ask the FDA why they didn't head the warning and move quickly enough. I along with others here today, are here to make sure that this does not happen. I present this concern before the panel here today, at my own expense so that LASIK Doctors are NOT going to go home or have to go to work scared for their family's lives, their own lives, their staff member's lives, and so that none

of their Hurt LASIK Patients make the news in a big way which may then have a "snowball effect." We truly care to make things safer across the board. Please hear us today and please then take immediate action further protecting the American consumers you swore to protect! Thank you.



******* Action Steps Immediately Needed By The FDA*******

1. EVERY LASIK PROCEDURE IS FLAWED AND IS DANGEROUS: LASIK doctors need to start telling the entire story. Tell your patients, whom you care so much about, the truth. "THE FLAP IS THE PROBLEM AND IS FLAWED!!" There are both "known problems with the permanent FLAP," as well as "unknown problems with the permanent FLAP. Patients should be informed of both if we live in an honest world of Informed Consent. The FDA needs to quit outsourcing "Medical Device Patient Trials" to the business world which is pretty much, "CORRUPT," and start hiring ethical scientists and researchers to collect the real data so that the public is protected, not money machine industry that truly does NOT care about hurt patients.

The Flap Never Heals: ISN'T THIS SOMETHING IMPORTANT TO KNOW IF YOU WERE A PATIENT CONSIDERING IRREVERSIBLE ELECTIVE LASIK SURGERY? This should be posted on a yellow stickie on every Lasik Staff & Lasik Doctor's forehead! That is why refractive surgeons can "peel" it back and re-shoot, re-shoot, and re-shoot the cornea some more, 2,5,12 years down the road. Patients definitely need to better understand the severity of this, and how they can't open their eyes anymore while swimming, nor engage in any rough sport, nor wipe their eyes without worrying for the rest of their lives if the flap will become "dislodged," and whether not they're going to go blind or need a "corneal transplant."

<http://www.journalofrefrativesurgery.com/showAbst.asp?thing=11320>

CONCLUSIONS

The human corneal stroma typically heals after LASIK in a limited and incomplete fashion; this results in a weak, central and paracentral hypocellular primitive stromal scar that averages 2.4% as strong as normal corneal stroma. Conversely, the LASIK flap wound margin heals by producing a 10-fold stronger, peripheral hypercellular fibrotic stromal scar that averages 28.1% as strong as normal corneal stromal, but displays marked variability. [*J Refract Surg.* 2005;21:433-445.]

*****Action Step Needed By The FDA*****: I challenge you to contact 50 Lasik Centers across American and ask their staff and their Lasik Doctors the following questions and record the response: *"I was thinking about having Lasik, and I am hearing different answers. Does the FLAP heal?"* Listen to their responses and you will then understand the lies being told to every Lasik Patient.

2. THERE NEEDS TO BE A NEW PATIENT FOCUSES "INFORMED CONSENT FORM" IMMEDIATELY ESTABLISHED BY THE FDA, AND REQUIRED BY ALL LASIK DOCTORS TO GIVE TO EVERY ONE OF THEIR POTENTIAL PATIENTS : Currently as the small print describes the symptoms and side effects of Lasik being printed in size 8 font, pushed in front of the patient just seconds before Elective Lasik Eye Surgery, where they don't even have any contacts in for a month prior to the procedure; Thus, the patient really can't sufficiently read the "fine print." This is NOT Informed Consent. It protects the doctor and hurts the patient.

*****Action Step Needed By The FDA*****: The new consent form should explain the following risks in "Large Font Print" with color pictures of all KNOWN and UNKNOWN side effects:

- a. Statute of Limitations & Warning About Lying Lasik Doctor(s) Second Opinions, Patient Defamation/Harassment, & The Importance of "NOT" Signing The Informed Consent Form Which Will Help The Lasik Doctor If There Is A Court Case, While Hurting the Hurt Lasik Patient's Ability To Sue The Lasik Doctor For Damages. What this means to the patient, and in the state of _____, what the timeframe is to sue if they feel there has been a breach of the Standard of Care.
- b. Large Fonts For All Text Throughout FDA Guide: Giving the patient a adequate timeframe, maybe a week, to thoroughly read through this guide NOT like it is currently being used in a "shove in front of the patients just seconds prior to surgery."
- c. Large Pictures Showing The Side Effects: Show the patients the truth. SHOW them. Show them full color pictures of what many, maybe hundreds of thousands of hurt Lasik patients are now seeing like. Show them double vision, ghosted imaging, floaters, detached retinas (in this case a BLACK PICTURES since they are probably now blind), contrast issues, light sensitivity, halos and starbursts, blurred text, and other side effects.

Proper Patient Education Color Test Booklet Handout Made Mandatory:

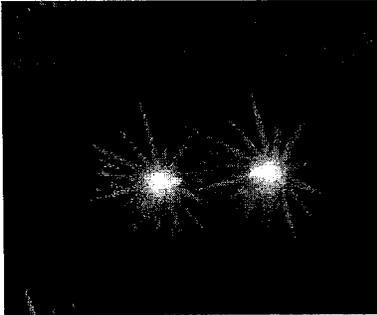
PLEASE NOTE: COMPLETE VERSION IS AT THE VERY BOTTOM OF THIS PRESENTATION).

Refractive surgeons should be required to show potential patients pictures that illustrate "poor Lasik outcomes" and what causes these outcomes. Patients should understand exactly what is going to happen with this procedure and why they are at risk for known and unknown side effects. Then there should be a multiple choice test given to insure that the patient fully understands what Lasik is about...

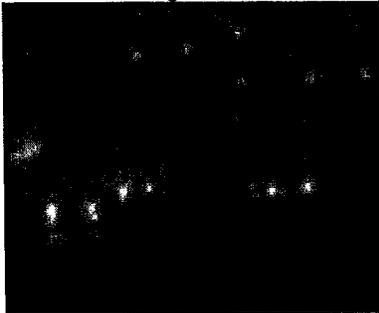
Please see the below pictures to fully understand what patients have to see through for the rest of their lives because these doctors needed to swipe their credit card for \$3,000 to make their

Benz or BMW payment & maintain the "Country Club Lifestyle" so their wives would be happy:

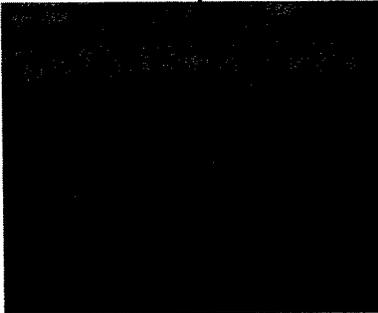
Post Lasik Starburst Disturbances Looks Like This:



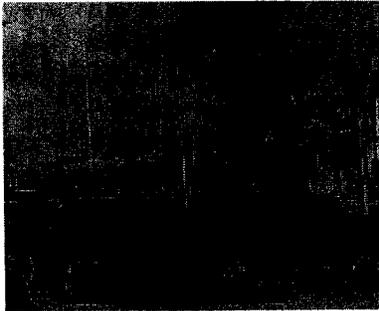
Post Lasik Nighttime Vision Disturbances Look Like This:



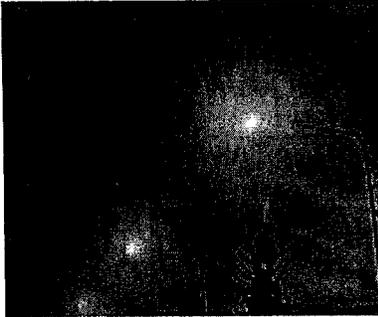
Post Lasik Blurry Vision Disturbances Looks Like This:



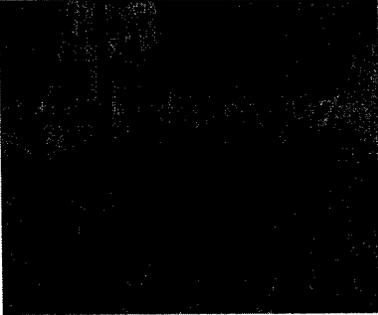
Post Lasik Double Vision / Ghosted Disturbances Look Like This:



Post Lasik Halo Disturbances Look Like This:



Post Lasik Loss of Contrast Color Disturbances Look Like This:



(The above photos courtesy of [REDACTED])

3. LASIK DOCTORS CORRUPTION: "THE EVIL TRUTHS EXPOSED THAT SHOULD BE PUNISHABLE BY IMPRISONMENT, FINES AND LOSS OF MEDICAL LICENSE IMMEDIATELY IMPLEMENTED IN ALL STATES TO PREVENT LOSSES." Lasik Doctors are LYING to cover for other physicians "breach of standards of care" and lying to patients and violating the Hippocratic Oath to "do no harm." (PROOF HERE).

Hippocrates "The Father Of Medicine..."

"I swear by Apollo Physician and Asclepius and Hygieia and Panacea and all the gods and goddesses, making them my witnesses, that I will fulfill according to my ability and judgment this oath and this covenant:

To hold him who has taught me this art as equal to my parents and to live my life in partnership with him, and if he is in need of money to give him a share of mine, and to regard his offspring as equal to my brothers in male lineage and to teach them this art - if they desire to learn it - without fee and covenant; to give a share of precepts and oral instruction and all the other learning to my sons and to the sons of him who has instructed me and to pupils who have signed the covenant and have taken an oath according to the medical law, but no one else. I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice.

I will neither give a deadly drug to anybody who asked for it, nor will I make a suggestion to this effect. Similarly I will not give to a woman an abortive remedy. In purity and holiness I will guard my life and my art. I will not use the knife, not even on sufferers from stone, but will withdraw in favor of such men as are engaged in this work. Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustice, of all mischief and in particular of

sexual relations with both female and male persons, be they free or slaves.

What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself, holding such things shameful to be spoken about. If I fulfill this oath and do not violate it, may it be granted to me to enjoy life and art, being honored with fame among all men for all time to come; if I transgress it and swear falsely, may the opposite of all this be my lot..."

4. THERE NEEDS TO BE A HIGHER "STANDARD OF CARE:." There needs to be a NEW standard of care implemented that is accurate showing----- Blades are still being reused since the FDA isn't monitoring doctors on this. (----- proof here).

"Creating a permanent FLAP that never truly completely heals should be marketed as exactly that."

"Patients are victims and the damages are permanent mostly with no known solutions."

"The Lasik Dr's marketing ways are NOT in the best interests of the patient and are extremely misleading knowingly so, since they know the FDA will NOT get involved..."

Re-Use Of Micro-Keratome Blades: Refractive surgeons should in no way shape or form EVER "reuse a micro keratome" blade on any patient & it should be required by law that the patients take their blades home with them to provide another layer of protection and guarantee, so that the doctor's don't reuse blades...Not only is Lasik unsafe to begin with, but re-using blades is a disgrace on top of that because of the following:

<http://www.opthalmologytimes.com/opthalmologytimes/article/articleDetail.jsp?id=181087&pageID=1>

"Using the confocal scanning microscope,-----and colleagues measured the length of the subbasal nerves per area of field. Betw-----nd six scans of the central cornea, covering slightly different areas of the cornea, will yield distinct samples and allow estimations of the nerve density.

-----described two clinical research studies using these technologies. In the first, a 5-year longitudinal study, he and his colleagues studied the effect of PRK and LASIK on corneal morphology by comparing the corneal nerves preoperatively and postoperatively.

"With PRK," he explained, "the epithelium is removed and Bowman's layer and the anterior stroma are ablated. After the procedure, the epithelium and the nerves heal over the stromal surface. In LASIK, the stroma is ablated behind the flap, leaving Bowman's layer intact. Most of the nerves are cut when the flap is created, and they must eventually return anterior to Bowman's layer," ----- explained.

-----and his colleagues found that after PRK, the nerve densities decrease and gradually increase; by 2 years after PRK there is no significant difference in nerve density from preoperatively. After LASIK, the nerve density also decreases and returns much more slowly; 3 years after surgery, there is still a significant difference from the preoperative density, but by 5

years after surgery there is no significant difference from preoperatively..."

More Research "On Why Lasik Is Unsafe & Why Re-Use of Microkeratome Blades Is Unsafe" Is Compiled For Your Review At:

http://www.lasikliberty.com/index.php?option=com_content&task=view&id=22&Itemid=46

Proper Patient Selection: Refractive surgeons should never perform a refractive procedure, without fully explaining to each and every patient the permanent dangers and possibilities that "could and do happen" to about 30% of total eyes electing to have Lasik. Such permanent side effects include, but aren't only limited to: dry eye syndrome that doesn't go away, nighttime visual disturbances, double vision, halos, starbursts, ghosting, loss of contrast, loss of detail, loss of visual acuity, loss of eye coordination, higher order aberrations, cause of corneal surface and sub-surface irregularities, etc...The following are a list of just some of the patient's website to "spread the word" that Lasik isn't safe.

Pupil Size Does Matter: It is a commonality in the medical world amongst Refractive Surgeons, that pupil size and lack of treatment zone size, does play an important role in the "outcome" for the patient. Unfortunately, many if not hundreds or even into the thousands of doctors performing refractive procedures are not paying attention to the size of the treatment zone/dark room dilated pupil ratios of the patient. They are flat out lying & deceiving patients into thinking that they "are the perfect candidates" and that the procedure "is 100% SAFE."

"----- estimates that 50 percent of patients who have the LASIK procedure done -----d would benefit from large laser treatment zones because they would be less likely to have night vision disturbances. "

What changed between 2003 and 2005/6?

>----- MD, co-author of the study and a faculty member at the -----
----- said, "We know that corneal aberrations - ----- ght
----- ly proportional to the degree of nearsightedness
corrected and the size of the clearance zone – that is, the difference between pupil size and the optical zone treated by the laser. With this study, we now know use of large optical zones is safe and effective in preventing nighttime glare and haloes in patients with large pupils."

"This study shows using ablation zones from six to eight millimeters did not pose a problem in terms of safety. If anything, the larger optical zones had a higher percentage of eyes achieving 20/20 and 20/40 uncorrected visual acuity than the smaller zones," said Academy spokesperson ----- clinical professor of ophthalmology at the -----
----- and attending ophthalmic surgeon at -----
----- ve report on the patients' satisfaction with their night vision outcomes and measuring these treated eyes with wavefront studies to determine the level of postoperative higher order aberrations would be a good follow-up to this study."

"----- estimates that 50 percent of patients who have the LASIK procedure done -----nd would benefit from large laser treatment zones because they would be less likely to have night vision disturbances.

http://www.innovations-report.com/html/reports/medicine_health/report-20154.html

Inferior "Post Lasik" Diagnostic Technologies That Are NOT Accurate For Measuring, Diagnosing And Treating Hurt Lasik Patient Disorders: Totally Removed & Immediately Replaced:

Note: These technologies are NOT accurate for many/most "Hurt Lasik Patients."

Schirmer's Test: This test is a start, but still isn't perfect. There needs to be a test that very accurately detects "dry eye." With the Schirmer's Test, anything that shows dryer than normal results (under 15) should not be a candidate for Refractive Surgery: PRK, LASEK, LASIK.

Snellen Chart: Refractive surgeons are measuring the patient's success if they can read 1 or more letters off of this chart. Doctors are saying it was a "successful outcome" if a patient can read any letters on a specific line: 20/20, 20/40, etc...But what is NOT being factored into the equation, is that many patients are seeing "doubled ghosting vision disturbances," or "loss of detail," or patients are seeing 2 or 3 images of 1 letter. Yet doctors are still reporting "lies" to the patients that "It was a success." All of us "post Lasik casualties of War," know that this test is a joke. You can not tell me that it is okay to let the doctor say "Dean, you are seeing 20/20 perfect vision and are fine." When I'm seeing 2-3 letters per letter, glow, starbursts, halos, & other aberrations. There should also be a test with a "red light" in a dark room to measure the size of the halos, starbursts, aberrations that we all are seeing too!

Slit Lamp Tests: Refractive surgeons all over the country are not properly trained and educated in diagnosing other corneal disorders such as EBMD, "Epithelial Basement Membrane Dystrophy," and other irregularities such as Kerataconus (cone bulging of the cornea) or "thin corneas" such as in the cases of Ectasia, etc...First and foremost, Lasik should never be performed on anyone that has a genetic condition such as EBMD but it is happening. I happened to me. Only 1 doctor in the USA properly diagnosed me with this condition. -----
----- . [REDACTED] ----- agrees that there needs to be some-----
----- in place to make su----- ctor----- --- escreen patients" and practice the "Hippocratic Oath." Even ----- knows that most surgeons can't find and detect these disorders, because they do NOT KNOW WHAT TO LOOK FOR. On myself, he detected EBD in 2 seconds...

5. WHO CAN DISCIPLINE THE LYING LASIK CRIMINAL DOCTORS WHEN THEY KNOW THAT THEY WON'T BE DISCIPLINED BY THE FDA? There needs to be levels of disciplinary action by the FDA and/or by the FDA working with Departments of Government and Medical Boards to make sure that doctors are disciplined properly and their licenses are permanently terminated for "multiple breaches of standards of care." Meaning: They can't continue to take advantage of this system, hurt patients, have no recourse knowing this, and then do it again and "buy their way" out of jail or the courtroom, leaving the injured patient broke with no settlement for loss of medical and loss of wages because of the permanency of post Lasik symptoms and visual handicap created by the doctor. (MY DENIALS proof here).

6. IF THE PROPER DISCIPLINARY DEPARTMENTS DO NOT ACT QUICKLY TO DISCIPLINE A LYING LASIK DOCTOR, WHAT GOVERNMENT BODY IS THERE TO MAKE SURE THERE IS JUSTICE? WHO'S GOING TO PAY TO FIX ALL OF THE HURT LASIK

PATIENTS WHO HAVE BEEN LIED TO BY THEIR LYING LASIK DOCTOR(S)? AND WHO IS GOING TO HELP THEM FIND A CURE? WHO IS GOING TO MAKE SURE THE PATIENT HAS ALL MEDICAL EXPENSES, SUFFERING AND LOST WAGES REIMBURSED? WHO IS GOING TO BE IN CHARGE OF ENFORCING THIS?

7. WHO DETERMINES THE PROPER PATIENT PREQUALIFICATION CANDIDACY FOR LASIK IN WHICH THE LASIK DOCTORS HAVE TO FOLLOW AS THE "STANDARD OF CARE?" What does this mean? The FDA'S website shows the following, but this is not even close to warning the masses about ALL of the KNOWN and UNKNOWN LONG-TERM DAMAGES of Lasik Eye Surgery:

<http://www.fda.gov/cdrh/lasik/risks.htm>

FDA'S WEBSITE WARNING OF THE RISKS SHOWS:

What are the risks and how can I find the right doctor for me?

Most patients are very pleased with the results of their refractive surgery. However, like any other medical procedure, there are risks involved. That's why it is important for you to understand the limitations and possible complications of refractive surgery.

Before undergoing a refractive procedure, you should carefully weigh the risks and benefits based on your own personal value system, and try to avoid being influenced by friends that have had the procedure or doctors encouraging you to do so.

- Some patients lose vision. Some patients lose lines of vision on the vision chart that cannot be corrected with glasses, contact lenses, or surgery as a result of treatment.
- Some patients develop debilitating visual symptoms. Some patients develop glare, halos, and/or double vision that can seriously affect nighttime vision. Even with good vision on the vision chart, some patients do not see as well in situations of low contrast, such as at night or in fog, after treatment as compared to before treatment.
- You may be under treated or over treated. Only a certain percent of patients achieve 20/20 vision without glasses or contacts. You may require additional treatment, but additional treatment may not be possible. You may still need glasses or contact lenses after surgery. This may be true even if you only required a very weak prescription before surgery. If you used reading glasses before surgery, you may still need reading glasses after surgery.
- Some patients may develop severe dry eye syndrome. As a result of surgery, your eye may not be able to produce enough tears to keep the eye moist and comfortable. Dry eye not only causes discomfort, but can reduce visual quality due to intermittent blurring and other visual symptoms. This condition may be permanent. Intensive drop therapy and use of plugs or other procedures may be required.
- Results are generally not as good in patients with very large refractive errors of any type. You should discuss your expectations with your doctor and realize that you may still require glasses or contacts after the surgery.
- For some farsighted patients, results may diminish with age. If you are farsighted, the level of improved vision you experience after surgery may decrease with age. This can occur if your manifest refraction (a vision exam with lenses before dilating drops) is very different from your cycloplegic refraction (a vision exam with lenses after dilating drops).

- Long-term data are not available. LASIK is a relatively new technology. The first laser was approved for LASIK eye surgery in 1998. Therefore, the long-term safety and effectiveness of LASIK surgery is not known.

Additional Risks if you are Considering the Following:

- Monovision

Monovision is one clinical technique used to deal with the correction of presbyopia, the gradual loss of the ability of the eye to change focus for close-up tasks that progresses with age. The intent of monovision is for the presbyopic patient to use one eye for distance viewing and one eye for near viewing. This practice was first applied to fit contact lens wearers and more recently to LASIK and other refractive surgeries. With contact lenses, a presbyopic patient has one eye fit with a contact lens to correct distance vision, and the other eye fit with a contact lens to correct near vision. In the same way, with LASIK, a presbyopic patient has one eye operated on to correct the distance vision, and the other operated on to correct the near vision. In other words, the goal of the surgery is for one eye to have vision worse than 20/20, the commonly referred to goal for LASIK surgical correction of distance vision. Since one eye is corrected for distance viewing and the other eye is corrected for near viewing, the two eyes no longer work together. This results in poorer quality vision and a decrease in depth perception. These effects of monovision are most noticeable in low lighting conditions and when performing tasks requiring very sharp vision. Therefore, you may need to wear glasses or contact lenses to fully correct both eyes for distance or near when performing visually demanding tasks, such as driving at night, operating dangerous equipment, or performing occupational tasks requiring very sharp close vision (e.g., reading small print for long periods of time).

Many patients cannot get used to having one eye blurred at all times. Therefore, if you are considering monovision with LASIK, make sure you go through a trial period with contact lenses to see if you can tolerate monovision, before having the surgery performed on your eyes. Find out if you pass your state's driver's license requirements with monovision.

In addition, you should consider how much your presbyopia is expected to increase in the future. Ask your doctor when you should expect the results of your monovision surgery to no longer be enough for you to see near-by objects clearly without the aid of glasses or contacts, or when a second surgery might be required to further correct your near vision.

- Bilateral Simultaneous Treatment

You may choose to have LASIK surgery on both eyes at the same time or to have surgery on one eye at a time. Although the convenience of having surgery on both eyes on the same day is attractive, this practice is riskier than having two separate surgeries.

If you decide to have one eye done at a time, you and your doctor will decide how long to wait before having surgery on the other eye. If both eyes are treated at the same time or before one eye has a chance to fully heal, you and your doctor do not have the advantage of being able to see how the first eye responds to surgery before the second eye is treated.

Another disadvantage to having surgery on both eyes at the same time is that the vision in both eyes may be blurred after surgery until the initial healing process is over, rather than being able to rely on clear vision in at least one eye at all times.

Finding the Right Doctor

If you are considering refractive surgery, make sure you:

- Compare. The levels of risk and benefit vary slightly not only from procedure to procedure, but from device to device depending on the manufacturer, and from surgeon to surgeon depending on their level of experience with a particular procedure.
- Don't base your decision simply on cost and don't settle for the first eye center, doctor, or procedure you investigate. Remember that the decisions you make about your eyes and refractive surgery will affect you for the rest of your life.
- Be wary of eye centers that advertise, "20/20 vision or your money back" or "package deals." There are never any guarantees in medicine.
- Read. It is important for you to read the patient handbook provided to your doctor by the manufacturer of the device used to perform the refractive procedure. Your doctor should provide you with this handbook and be willing to discuss his/her outcomes (successes as well as complications) compared to the results of studies outlined in the handbook.

Even the best screened patients under the care of most skilled surgeons can experience serious complications.

- During surgery. Malfunction of a device or other error, such as cutting a flap of cornea through and through instead of making a hinge during LASIK surgery, may lead to discontinuation of the procedure or irreversible damage to the eye.
- After surgery. Some complications, such as migration of the flap, inflammation or infection, may require another procedure and/or intensive treatment with drops. Even with aggressive therapy, such complications may lead to temporary loss of vision or even irreversible blindness.

Under the care of an experienced doctor, carefully screened candidates with reasonable expectations and a clear understanding of the risks and alternatives are likely to be happy with the results of their refractive procedure.

Advertising

Be cautious about "slick" advertising and/or deals that sound "too good to be true." Remember, they usually are. There is a lot of competition resulting in a great deal of advertising and bidding for your business. Do your homework.

If you want to know more about advertising ethics, do's and don'ts, or want to report on false advertising, explore the following websites:

- <http://www.ftc.gov/bcp/menu-ads.htm>
- <http://www.ftc.gov/bcp/menu-health.htm>

8. LASIK DOCTORS ARE LYING TO THEIR OWN PATIENTS, INTIMIDATING THEIR OWN HURT LASIK PATIENTS BY HIRING CRSQA/GLENN HAGELE, AND ARE SUING THEIR OWN HURT LASIK PATIENTS FOR HAVING WEBSITES: The hiring - -----

-----of [REDACTED] and [REDACTED] to do their dirty work? What -----ed to the Hippocratic Oath to do "no harm?" What medical and government entity is enforcing this? My submissions which ALL went all the way up to PROBABLE CAUSE on my initial and referring doctors, ALL WERE DENIED by the final top person, which sits a Medical Doctor Coordinator at the top taking care of the doctor, while hurting the patient. Tell me one medical industry that has hundreds of websites from hurt Lasik patients trying to warn the masses about what the FDA should be doing? There are tens of thousands of posts online warning people to stay clear of the "PANDORA'S BOX OF VISUAL HORROR." (SHOW PROOF OF THIS HERE).

WHO IS -----of CRSQA, USAEYES.org, and ComplicatedEyes.org. Is CRSQA An FDA Recognizable Certification Or Are They Misleading Doctors And Patients?: An immediate investigation of a ----- should be issued. ----- is telling innocent patients what many would call "lies" a----- est for them. He is giving medical advice and is NOT a doctor. He charges like \$5,000 per year to give a refractive surgeon a "phony certification," and I guess guarantees those membership fees back many times over. So here is an example of how it works: Example: You type into a search engine (Google): "hurt lasik patient." You will see Glenn's website as #3 (guess), and you will be redirected to his website www.UsaEyes.org thinking that this is an organization looking out for you, the patient, and will then send an email or contact ----- . ----- will seem very knowledgeable about your Lasik problem, and will probably only r----- ou out to a CRSQA stamped surgeon. Unfortunately, this is a conflict of interest. These are "paid referrals." What happened to redirecting and recommending to the patient what's "in the best interests of the patient?" Glenn then went on a rampage to try to financially hurt and threaten any patient that owns and operates a "Anti-Lasik Websites" such as mine.

9. WHY AREN'T THE HURT LASIK PATIENT STORIES MAKING THE HEADLINE NEWS?
THE MEDIA IS CONTROLLED BY (4) MAJOR GROUPS/INDIVIDUALS: It's all part of the gravy train that fuels the "BLOOD MONEY." The media needs money/revenue in order to make a profit. They get this from advertisers. Online, newspaper, radio, tv, cable, direct tv, magazine and other methods. If the media runs a "Documentary On Lasik Being Bad," that would mean that this could be considered a "Conflict of Interest" for the media in publishing any form of "Negative Publicity" to their clients that pay their bills and profits on a multiple media level. It has been known, that Lasik Doctors have sent in legal letters to the media threatening to "sue" if they publish such a story and accuse a doctor of hurting any patients. And thus, the true stories are NOT getting out to the masses. I challenge the FDA to run a full force MEDIA CAMPAIGN on the internet using key words such as: hurt lasik patient, lasik suicide, lasik lawsuits, lasik disaster, lasik nightmare, lasik kills to see how many patients come forth so that the FDA can better tell how many patients have truly been dissatisfied with their results. And don't stop there. What about billboards in 5 metropolitan areas: LA, Houston, Fort Lauderdale, Chicago, and New York? Along with radio and media ads urging anyone who has had a dissatisfying experience with Lasik to come forth and call: 1-800-BAD-LASIK leave their information on a hotline and/or go to: www.FDA.gov/UNHAPPYLASIK.htm so that there is a mechanism in place to determine whether or not the Doctor's success rates are in line with the definition of success that the hurt patients are complaining about. My hypothesis: You will be flabbergasted in the amount of hurt Lasik patients that call and go online, so much, that you will need to immediately stop Lasik for further scrutiny to allow time to protect anyone else from being hurt by the Lying Lasik Industry that has been shown to FALSIFY INFORMATION, SUCCESS RATES, EVEN

LYING TO THEIR OWN DOCTORS/CUSTOMERS in order to keep the "BLOOD MONEY" rolling in.

10. MANY CONCERNS FOR THE LYING LASIK DOCTORS AND FOR THE DAMAGES THAT THEY HAVE DONE TO THEIR INJURED PATIENTS AND THEIR FAMILIES: EPIDEMIC OF HURT LASIK PATIENTS WHO HAVE FIGURED OUT THAT THEIR DOCTOR(S) HAVE LIED TO THEM AND ARE NOW VERY, VERY DISGRUNTLED LASIK PATIENTS: I think from the thousands of hurt Lasik patient calls and emails that have come in, that there is a serious problem on your hands. I have mentioned this for years to the FDA and of course, no response. Dozens of patients have called me and others, and have mentioned that they want to kill themselves, but before they do, they will take wrath out on their doctor, their family and maybe even their staff before doing so. I check the news nightly, surprised myself that this has NOT yet happened. Not yet anyway. Patients are coming from having lost everything, lost their old perfect visual lives, found out that the doctor(s) had lied to them to push them past the Statute of Limitations so they can't sue and fall into a deep state of depression which no one but other hurt Lasik patients seem to understand. They then decide to end it all, because there is no known cure after they have spent thousands and have traveled everywhere trying to find a cure, only to find there are no cures. The Lying Lasik Doctors, I would imagine, are going to work in fear for their lives. IF a patient does this, and it makes the news, then this I would imagine could snowball, and other patients may get on the train and do the same making sure their message gets out. Lying Lasik Doctors have a serious problem, in many people's opinions, of what could happen. We are very concerned about this and are mentioning this at this forum in order to help prevent such an event from happening...Take a look at just a few of the websites warning the MASSES to stay clear of paying a Lying Lasik Doctor \$5,000 to slash a permanent flap in their only corneas and thin out their corneal tissue:

Obviously, there are a lot of people that feel their doctor's didn't properly screen them; Thus, have put the word out in a big way on the world wide web to warn others:

REUTERS Warns Public About Lasik Quality Being Investigated:

<http://www.reuters.com/article/healthNews/idUSN1761471320080317?feedType=RSS&feedName=healthNews>

MSNBC Warns Public About Lasik Quality Being Investigated:

<http://www.msnbc.msn.com/id/23689210/>

YAHOO Warns Public About Lasik Quality Being Investigated:

http://news.yahoo.com/s/nm/20080317/hl_nm/dc_lasik_fda_dc_1

NewYorkTimes Warns Public About Lasik Quality:

http://www.nytimes.com/2008/03/13/fashion/13SKIN.html?_r=1&pagewanted=1&ei=5070&en=01ec95cbca07e3e8&ex=1206158400&emc=eta1&oref=slogin

Chicago Tribune Warns Public That Lasik Failure Rate CAN Be High:

http://www.chicagotribune.com/news/chi-lasik_25feb25,0,7016699.story

The North Carolina Observer Warns Public That Lasik Could Lead To Suicide:

<http://www.newsobserver.com/150/story/920341.html>

March 4th, 2008: Celebrity Germain Dupri goes BLIND after having Lasik:
<http://www.celebrity-mania.com/news/view/00004964.html>

TheGreySheet.com Warns Public About Lasik Quality Being Investigated:
http://www.thegraysheet.com/fdcreports/story/search/submitSearch.do?doClear=true&subsNum=&publications=all&query=lasik+&find_button.x=20&find_button.y=1

Tiger Woods Ex-Girlfriend Ruined From Lasik By Same Doctor? Why Isn't This On Every News Station Across The World Every Time He Wins A Championship?
http://www.lasikfraud.com/tlc_faqs.html

Channel 10: Warns Public About The 10 Things The Lasik Doctor Won't Tell you:
<http://www.local10.com/personalfinance/8037544/detail.html>

Eye Doctor Warning You That Lasik Doctors Are More Interested In Making Money Than In Their Patient's Health or Best Interests:
<http://www.eyeworld.org/article.php?sid=196>

Prominent Medical Doctor Warns The Masses That LASIK Will NEVER BE SAFE!
<http://articles.mercola.com/sites/articles/archive/2006/12/14/lasik-may-ruin-your-sight-as-you-age.aspx>

<http://www.Lasikdisaster.com> (very informative Post Lasik Information)...

<http://www.LasikInfoCenter.net> (very legally informative/has Glare Charts)...

<http://www.foxchicago.com/ezpost/data/16747.shtml> (Fox Chicago news on how bad Lasik really is to inform you)

<http://www.lasikfraud.com/> (very informative A-Z of Lasik & problems with Lasik)

<http://www.fda.gov/cdrh/lasik/contact.htm> (FDA file a LASIK complaint)...

<http://www.visionsimulations.com/> (exactly what to expect to see like after Lasik)

<http://www.doctormyeye.com> (some honest information about Lasik and Post Lasik)

<http://www.lasikmemorial.com> (some honest information about Lasik and Post Lasik)

<http://www.lasermeye.org> (some honest information about Lasik and Post Lasik)

<http://www.flawedlasik.com> (some honest information about Lasik and Post Lasik)

<http://www.surgicaleyes.org> (patient nightmare stories, good Post Lasik Doctors to help you)

<http://www.lasikmemorial.com> (some honest information about Lasik and Post Lasik)

<http://www.lasiksos.com> (some honest information about Lasik and Post Lasik)

<http://www.lasiksucks4u.com> (some honest information about Lasik and Post Lasik)

<http://www.lasikreality.com> (some honest information about Lasik and Post Lasik)

<http://www.refractivessource.com> (some honest information about Lasik and Post Lasik)

<http://www.kcsupport.org> (make sure your doctor correctly evaluates you before Lasik)

<http://www.cleareyeclinic.com/lasik.html> (clinical results of Lasik, 3 questions to ask, but not the right question)

<http://www.anattorneyforyou.com/legal/lasik-litigation.htm> (list of Lasik Litigation Attorneys to help you)

<http://www.opthalmic.hyperguides.com/default.asp?section=body.asp> (pain management & other eye problems/treatments)

http://www.crstoday.com/PDF%20Articles/0105/F3_Daya.html (additional problems Post Lasik)

Submitted FDA Petition by:



So I ask you FDA:

"What are you doing currently to make sure that doctors are not breaching levels of the standard of care patients like you and I should be getting?"

"What disciplinary actions are you willing to enforce and define (if you don't have any in place currently) to move to "ACTION," so that you do what you are supposed to do which is to "look after the safety of the devices to protect Americans, and exterminate / terminate any known medical devices that are lacking safe results, and do this today."

"If you do NOT have anything in place currently, don't you think that the doctor's all talk amongst each other and know this?"

"I would suggest you immediately implement an "ORDER" to massively contact each and every doctor & refractive surgeon across America, & inform them of the "can's" and "can not's," so that you know there is a level of standard for medical care DEFINED..."

"Immediately, call a meeting of the minds, define and dissect the problems that you are informed about, and then answer these by researching "true statistics" and "not skewed data statistics" that the doctor's are lying about..."

"Immediately make every attempt to make the refractive medical devices safest, and seize & destroy all unsatisfactory/inferior technologies that are used on the human eye..."

My story about how -----has ruined hundreds of patients & how I'm working with the Department of Regu-----icago, to close his doors for life. If it were up to me, & hundreds of other patients that he has ruined, we would put him in "jail for life," put 13 locks on his jail cell door, and then destroy all of the keys:

----- then tried to sue me for \$2,000,000.00 after I put all 50 of his lawsuits on my website.

<http://www.lifeafterlasik.com/nickcarolawsuithearing1.htm>

----- lost a lot of money and time trying to "sue and quiet me," & in the end he will be used as an -----ple "of what NOT TO DO / NOR BECOME," by classrooms all over the world. My point is much simpler: "All he had to do was admit that he made a mistake, & then work with me to get the best medical treatment no matter where in the world, & live by the Hippocratic Oath he swore years ago which again is sited below, so that you can see how corrupt the medical community has gotten and how "BIG BUSINESS OWNS & CONTROLS YOU & EVERYTHING REGARDLESS OF THE SAFETY OF THE AMERICANS THEY ARE HURTING DAILY:"

Action Step Needed By The FDA: THERE SHOULD BE A NEW "INFORMED CONSENT PAMPHLET/PACKET" THAT IS TRULY GIVING THE UNEDUCATED AND UNINFORMED PATIENT A TRUE ASSESMENT OF THE RISKS OF LASIK SHOULD COVER THE FOLLOWING:

-FDA PETITION-

"Are We Being Told ALL of the Known Truths About Lasik?"

WHAT IS LASIK SURGERY? Lasik Refractive Surgery Defined:

Laser-Assisted in situ Keratomileusis (LASIK) is a type of refractive laser eye surgery performed by ophthalmologists for correcting myopia, hyperopia, and astigmatism.^[1] The procedure is generally preferred to photorefractive keratectomy, PRK, (also called ASA, Advanced Surface Ablation) because it requires less time for the patient's recovery, and the patient feels less pain, overall; however, there are instances where PRK/ASA is medically indicated as a better alternative to LASIK. Many patients choose LASIK as an alternative to wearing corrective eyeglasses or contact lenses.

Action Step Needed By The FDA: "The Medical Hippocratic Oath:" Every Doctor swears to "DO NO HARM, and to only do what is in the best interest of every patient..."

I swear by Apollo, Asclepius, Hygieia, and Panacea, and I take to witness all the gods, all the goddesses, to keep according to my ability and my judgment, the following Oath.

To consider dear to me, as my parents, him who taught me this art; to live in common with him and, if necessary, to share my goods with him; To look upon his children as my own

brothers, to teach them this art.

I will prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone.

To please no one will I prescribe a deadly drug nor give advice which may cause his death.

Nor will I give a woman a pessary to procure abortion.

But I will preserve the purity of my life and my arts.

I will not cut for stone, even for patients in whom the disease is manifest; I will leave this operation to be performed by practitioners, specialists in this art.

In every house where I come I will enter only for the good of my patients, keeping myself far from all intentional ill-doing and all seduction and especially from the pleasures of love with women or with men, be they free or slaves.

All that may come to my knowledge in the exercise of my profession or in daily commerce with men, which ought not to be spread abroad, I will keep secret and will never reveal.

If I keep this oath faithfully, may I enjoy my life and practice my art, respected by all men and in all times; but if I swerve from it or violate it, may the reverse be my lot.

Action Step Needed By The FDA: Let us compare the sworn Hippocratic Oath, above, to the current practice of medicine as in the "Standard of Care" that is currently being performed.

What is the Standard of Care for Lasik Surgery? In tort law, the standard of care is the degree of prudence and caution required of an individual who is under a duty of care. A breach of the standard is necessary for a successful action in negligence.

The requirements of the standard are closely dependent on circumstances. Whether the standard of care has been breached is determined by the trier of fact, and is usually phrased in terms of the reasonable person. It was famously described in Vaughn v. Menlove (1837) as whether the individual "proceed[ed] with such reasonable caution as a prudent man would have exercised under such circumstances".

What is Medical Negligence? Medical malpractice is an act or omission by a health care provider which deviates from accepted standards of practice in the medical community and which causes injury to the patient. Simply put, medical malpractice is professional negligence (by a healthcare provider) that causes an injury.

Action Step Needed By The FDA: Request For The FDA "Booklet & Website" Pamphlet Outline To Fully Explain The Following Regarding Lasik Surgery & Refractive Surgery "Known Risks" and "Unknown Risks:"

Building a case against the FDA, to prove that the FDA is NOT doing enough to inform the misinformed public about the dangers both "Known" and "Unknown" from having an elective

surgery called: Lasik. How did Lasik every get "Approved" in the first place. The following explanation of the procedure should be given to anyone thinking of having Lasik Surgery:
<http://www.lifeafterlasik.com/exlasikdoc.htm>

First, how/why is it that Wikipedia offers the public a more "fair assessment" of the "Known" and "Unknown" Risks of having Lasik Surgery as shown here below, which completely surpasses the FDA's own website:

Action Step Needed By The FDA: WIKIPEDIA'S WEBSITE:

- Technological development
- 2_Procedure
 - 2.1_Preoperative
 - 2.2_Operation
 - 2.2.1_Flap creation
 - 2.2.2_Laser remodeling
 - 2.2.3_Reposition of flap
 - 2.3_Postoperative
- 3_Higher-order aberrations
 - 3.1_Wavefront-guided LASIK
- 4_Complications
 - 4.1_Intraoperative complications
 - 4.2_Early postoperative complications
 - 4.3_Late postoperative complications
 - 4.4_Other
 - 4.5_Factors affecting surgery
- 5_Patient satisfaction
- 6_Safety and efficacy
- 7_References
- 8_See also
- 9_External links

What is Informed Consent: http://en.wikipedia.org/wiki/Informed_consent

Informed consent is a legal condition whereby a person can be said to have given consent based upon an appreciation and understanding of the facts and implications of an action. The individual needs to be in possession of relevant facts and also of his or her reasoning faculties, such as not being mentally retarded or mentally ill and without an impairment of judgment at the time of consenting. Such impairments might include illness, intoxication, insufficient sleep, and other health problems.

Some acts cannot legally take place because of a lack of informed consent. In cases where an individual is considered unable to give informed consent, another person is generally authorized to give consent on their behalf. Examples of this include the parents or legal guardians of a child and caregivers for the mentally ill. In cases where an individual is provided limited facts, serious ethical issues may arise. Examples of this in a clinical trial in medical research are anticipated and prevented by an ethics committee or Institutional Review Board

Action Step Needed By The FDA: The FDA should explain the following to help insure that every patient considering this elective, "irreversible surgery" fully understands the "Known" and

"Unknown" mental & health risks, possible financial risks from loss of work, and legal exposure from having Lasik such as being sued by your own Lasik doctor. The following should be explained in detail to each and every patient thinking about having Lasik, so that the consumer can make the right choice:

- a. Patient Risks: Known and Unknown.
- b. Statute of Limitations: Differs in each state.
- c. Legal Representation: Very difficult to find a lawyer to sue and build case since the patient signed the "Informed Consent" form.
- d. Doctors & Expert Witnesses: Some/Most Doctors will not testify against another doctor. Please see PDF file attached so that patients are aware that the Medical Community/Insurance Companies are even going to the extent of having "Seminars teaching doctors HOW TO NOT GET SUED" which certainly validates that doctors are NOT practicing the Hippocratic Oath or giving each and every patient "Full Informed Consent."

Lasik still has too many unknowns. Even in 2008, publications, newspapers are STILL WARNING the consumer that even with the most modern lasers and the so called "most experienced doctors," Lasik is still yielding "unpredictability" as mentioned here:

<http://www.nytimes.com/2008/03/13/fashion/13SKIN.html?pagewanted=1&ei=5070&en=01ec95cbca07e3e8&ex=1206158400&emc=eta1>

<http://www.celebrity-mania.com/news/view/00004964.html>

<http://www.newsobserver.com/150/story/920341.html>

<http://www.local10.com/personalfinance/8037544/detail.html>

<http://www.eyeworld.org/article.php?sid=196>

<http://uk.youtube.com/watch?v=lqomPX4ADvE>

<http://uk.youtube.com/watch?v=Pasiq8T3-ZI>

REUTERS Warns Public About Lasik Quality Being Investigated:

<http://www.reuters.com/article/healthNews/idUSN1761471320080317?feedType=RSS&feedName=healthNews>

MSNBC Warns Public About Lasik Quality Being Investigated:

<http://www.msnbc.msn.com/id/23689210/>

YAHOO Warns Public About Lasik Quality Being Investigated:

http://news.yahoo.com/s/nm/20080317/hl_nm/dc_lasik_fda_dc_1

NewYorkTimes Warns Public About Lasik Quality:

http://www.nytimes.com/2008/03/13/fashion/13SKIN.html?_r=1&pagewanted=1&ei=5070&en=01ec95cbca07e3e8&ex=1206158400&emc=eta1&oref=slogin

Chicago Tribune Warns Public That Lasik Failure Rate CAN Be High:
http://www.chicagotribune.com/news/chi-lasik_25feb25,0,7016699.story

The North Carolina Observer Warns Public That Lasik Could Lead To Suicide:
<http://www.newsobserver.com/150/story/920341.html>

March 4th, 2008: Celebrity Germain Dupri goes BLIND after having Lasik:
<http://www.celebrity-mania.com/news/view/00004964.html>

TheGreySheet.com Warns Public About Lasik Quality Being Investigated:
http://www.thegraysheet.com/fdcreports/story/search/submitSearch.do?doClear=true&subsNum=&publications=all&query=lasik+&find_button.x=20&find_button.y=1

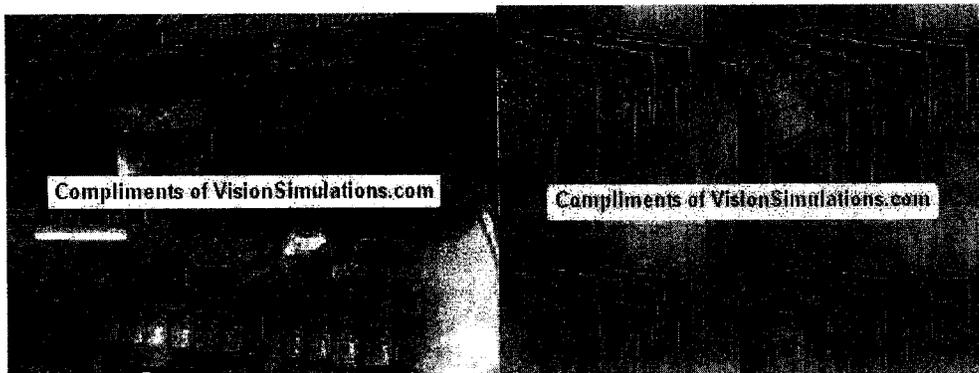
Tiger Woods Ex-Girlfriend Ruined From Lasik By Same Doctor? Why Isn't This On Every News Station
Across The World Every Eime He Wins A Championship?
http://www.lasikfraud.com/tlc_fags.html

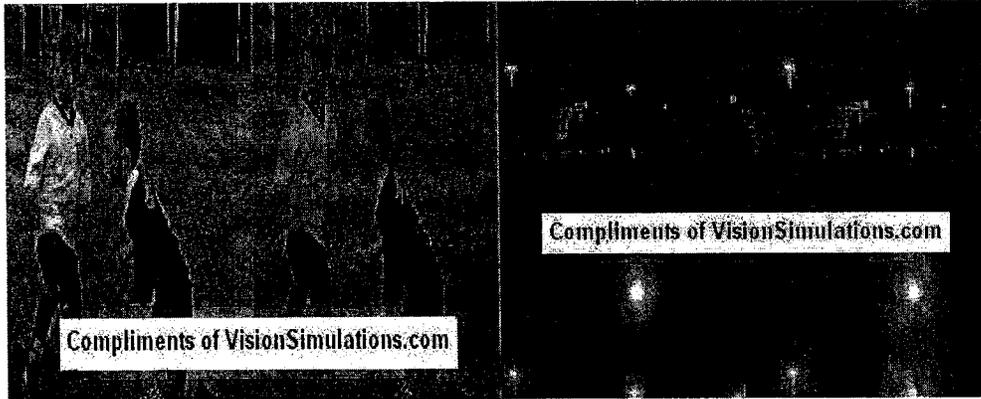
Channel 10: Warns Public About The 10 Things The Lasik Doctor Won't Tell you:
<http://www.local10.com/personalfinance/8037544/detail.html>

Eye Doctor Warning You That Lasik Doctors Are More Interested In Making Money Than In Their Patient's Health or Best Interests:
<http://www.eyeworld.org/article.php?sid=196>

Prominent Medical Doctor Warns The Masses That LASIK Will NEVER BE SAFE!
<http://articles.mercola.com/sites/articles/archive/2006/12/14/lasik-may-ruin-your-sight-as-you-age.aspx>

- a. Pictures of the KNOWN problems should be displayed in FULL COLOR, so that every patient are getting complete, "Informed Consent." Currently, patients are NOT being given enough adequate information of the true risks at hand. Every patient should see what their eyes could see like, by being shown the following pictures:

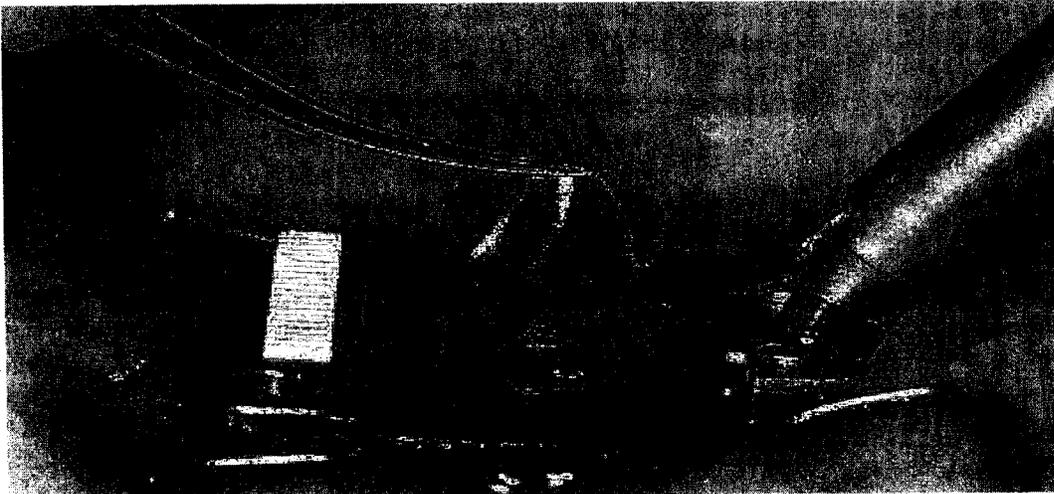




- b. Even the Lasik doctors are complaining about the "skewed success rates" that their Laser Manufacturer is giving them, as well as "unpredictable outcomes" even with the "perfect patient candidates." Watch this news documentary below:

<http://uk.youtube.com/watch?v=lqomPX4ADvE>

Action Step Needed By The FDA: INTRODUCTION OF THE PERMANENT LASIK "FLAP:"
(Mention the truth to every patient and start telling them the truth, *that the FLAP never heals*, and that it leaves the patient's cornea(s) permanently scarred for life with no recourse:)



(A picture depicting the true "FLAP" should be put in every pamphlet and should be mandatory for every doctor to provide to every patient thinking of having Lasik Surgery).

Action Step Needed By The FDA: Lasik Doctor's Marketing Ways: LASIK, or laser in-situ keratomileusis, is a non-reversible procedure in which the surgeon uses a knife called a microkeratome to cut a "FLAP" in the outer layers of the cornea, removing a small amount of the targeted tissue beneath it with the laser, and then replacing the FLAP when finished. LASIK is an invasive elective procedure that penetrates and permanently injures the cornea for life: There is no emergency condition or other reason that requires or demands that you have it performed. LASIK can result in a distorted cornea. This would mean that glasses or contact lenses may not

correct my vision anywhere close to normal. If this distortion in vision is severe, a partial or complete corneal transplant might be necessary to repair the cornea and may make the problems even worse. Shouldn't the Lasik Staff make sure that they represent the positives and all negatives to each and every patient? The FDA needs to work closer with the FTC and the BBB to make sure, and insure, that Lasik Doctors are correctly marketing Lasik.

So, who punishes a Lasik Doctor, if there is a "Breach of Standard of Care By The Physician?" Please see what the FDA spokesperson says about protecting the consumer:

<http://uk.youtube.com/watch?v=Pasjq8T3-ZI>

Please watch at 1:05 into this documentary and then on. At 3:00, you will then hear that the FDA does NOT have the power to discipline a doctor...All they can do is take away the laser which with the Alcon 4000 Ladarvision, they have yet to do just that because so many doctors have it and so much money has been already made. Listen to 2:55 into this documentary to validate that the FDA and Lasik Doctors KNOW, that there is no standard of practice with Lasik and that is the reason we have such a huge epidemic on our hands right now. At 4:15, the FDA's Darlene Bailey admits that things must be "really really bad if the FDA has to go in and physically SEIZE a laser from a Lasik Doctor. The important point, is that even after they seized the laser, the doctor was free to practice and continue "slicing and dicing" more eyes at \$5,000 a pop for a 10 minute procedure...At 5:00 into this, the infamous [REDACTED] (who ruined my eyes and probably thousands of others) was "cleared by the Department of Regulation in Illinios" for any wrongdoing. With further scrutiny, [REDACTED] has over 50+ lawsuits and to date, the Department of Regulation has done nothing to discipline or terminate [REDACTED]'s medical license. Full Informed Consent, should show every single patient how many Lawsuits each doctor has been involved in.

Some patients develop severe dry eye syndrome. No one knows exactly how many develop these problems over time because no "one entity" is taking an interest on this matter to determine how problematic "Dry Eye Syndrome" could be.

This procedure, like all surgery, presents substantial risks, and Not all of them are listed below. You should also understand that there may be other risks known to your doctor that he chooses not to tell you and others not known to your doctor that may become known later. Despite the best of care, complications and side effects may occur; should this happen in your case, the result might be affected even to the extent of making your vision permanently worse for the rest of your life. LASIK does not improve the cornea and there is no cure for the permanent injury in the cornea caused by LASIK.

Over 14 million people in the US alone have had LASIK so a few hundred thousand people with severe problems are considered "rare" or even "very rare". The words very and rare may mean something different to you than the Government and medical Doctors. Question the statistics that the "Lasik Industry" is reporting and compare the "pros" and "cons" with online websites warning you of the true Lasik risks. No one fully is aware of all of the "Known Risks."

Do Not believe that problems with LASIK are "rare" or won't happen to you. The purpose of this pamphlet is to give you "Informed Consent" because such bad results, some life threatening, are happening to tens of thousands of patients from all walks of life.

Action Step Needed By The FDA: What are the "Side Effects" from elective "Lasik Surgery?"
And how do I make sure that the risks are minimized?

"Side effects such as dry eyes, night time starbursts, and reduced contrast sensitivity occur relatively frequently." Ophthalmology. 2002 Jan;109(1):175-87.

-Dr. I Howard Fine, Past President of the American Society of Cataract and Refractive Surgery: "As we all know, LASIK transects the cornea nerves, therefore inducing dry eyes in most patients."

- You may have dry eye after surgery even if you didn't have it before surgery:

<http://www.fda.gov/ohrms/dockets/ac/01/transcripts/3806t1.doc>

www.fda.gov/cdrh/PDF/p990027s006d.pdf

-Most respondents (78.7%) changed the microkeratome blade between patients while 49% in Europe and 36.4% in Oceania preferred to change the microkeratome blade between eyes. These preferences were similar to those in the 2003 survey. The microkeratome blade was changed after 2 or more patients by 11 .1% of Asian respondents and 55.0% of Latin American respondents, which was similar to the pattern in the 2003 survey (17.5% and 50.0%, respectively).

http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_u ids=15721716&query hl=1

-"About a third of complications result from surgeon errors"... "Another third is from technique or equipment problems. The final third comes from unexplainable reasons."

<http://www.gazettearchives.com/health2002/ disc4/000001d3.htm>

Risks Can Be Greatly Minimized If The Lasik Doctors Properly Prequalify Every Patient.

What is considered proper prequalification for every single prospective Lasik Patient:

- a. Full background physical: High blood pressure, high cholesterol, all known eye chart tests & prescriptions, work habits, driving habits, sports habits, genetic diseases?
- b. Three times checking the patients topographies while over the course of 6 – 12 months or longer. NOT rushing a patient through these tests and doing Lasik the same week.
- c. Dry Eye Syndrome: Test, using the Schirmer Test Strips on three separate occasions, should be performed to qualify each and every patient for Dry Eye.
- d. Making sure that both the patient and the Lasik Doctor are defining and agreeing to what "20/20" and "A Lasik Success" means to each. The Lasik Doctor should be asking every patient the following question: "If you depend on your vision for work, sports, clarity of thought, driving

and other important necessities, and your vision is made worse from Lasik, you may never again be able to achieve the BCVA (Best Corrected Visual Acuity) that you were once able to achieve with contacts or glasses...If you do have a bad Lasik Result, and you couldn't live with the possibility of NEVER finding a cure, then I as a medical physician, must practice the Hippocratic Oath and NOT perform this procedure on you."

E. If the Lasik Doctor wants to invest the appropriate time in properly "Prequalifying Each And Every Patient," an assessment and consultation will be held with the surgeon at which time the benefits and risks of an enhancement surgery will be discussed. Some surgeons do surgery on 50 or even 100 patients a day and there's no way they have the time to discuss the risks with you. Regardless, the liability education seminars sponsored by the malpractice insurance companies teach your doctor how to protect his or herself from liability for this by putting in his medical records that he discussed "all" the risks with you even if he didn't. (SEE ATTACHED PDF FILE). He also knows putting "went well" or "doing well" in his records helps protect him even if you are actually seriously injured. The follow-up doctors do Not want their colleagues to stop referring patients or say anything bad about them either (one of their injured patients may go to the your original doctor for help) so they are reluctant to say anything that would let you know the true extent of your injuries.

Action Step Needed By The FDA: THERE ARE KNOWN LONG TERM DAMAGES FROM LASIK!! So, why is the FDA and the Lasik Industry lying to it's citizens it swore to protect?

Known Long-Term Damages That Every Lasik Surgery Yields:

a. Permanently Scars Every Patients Cornea: Every Lasik Doctor should admit, that creating a lifelong flap that never heals is NOT in the best interests of any patient. What is buried under the flap if it does heal? What if the FLAP can't be re-lifted asks an inquisitive patient? Doctor's answer: "The FLAP can be lifted up to several years after the initial surgery..."

b. Creation of a permanent FLAP that never heals: That is why the Lasik Doctors tell every patient that they can lift the flap and perform an "Enhancement" to help tweak the result if it isn't perfect the first time which is now very common to have "Enhancements." Tiger Woods has had Enhancements.

Please Note: that the Flap is permanent and never heals like your skin. The outer layer of the eye called epithelium grows over the edge of the flap forming a scar at the periphery that helps to keep the in place, but the flap is never going to be as strong as your eye was originally. The flap often does get dislodged in the first day after the surgery and takes several days before it heals well enough to stay in place well. Flaps have been dislodged years after surgery by airbags from cars, playing sports, and even everyday activities but within a few months after the surgery the outside of the flap holds it in place fairly well.

c. One Eye At A Time Should Be The Standard: It is SAFER to do one eye at a time. However, every single Lasik Doctor would then have to spend 2x-3x the amount of time to do the second eye, so they urge every patient to do both eyes at the same time. Here is a link showing the FRAUD and CRIME telling patients that it is okay to do 2 eyes simultaneously:

<http://www.refractive.com/patients/faqs.htm>

The problem with this, is that if the procedure didn't work well on one eye and you did the second, then you have no "Safe Zone" or redundant vision to fall back on. If you do 1 eye, wait 1 year to see if you like the result, and then do the 2nd eye, most likely the Lasik Doctor will talk you out of this since it is less profitable to them, fully knowing that this was in the best interests of the patient they swore to protect. The Hippocratic Oath...

d. Permanently Severed Nerves: Every surgery cuts vital nerves that are helping the eye's tear film daily. It has been reported that 98% of the nerves holding the flap down are permanently severed, never to grow back again...leaving only 2% of the nerves around the periphery able to "bond" keeping the flap in place. Don't you think that every patient needs to know this and know how important the eyes ability in producing natural tear film is to the visual quality achievement of every person?

e. Lasik Is Opening Pandora's Box: A box that even the Lasik Manufacturers, Lasik Doctors, and FDA do not fully understand nor are they working to resolve the problems. The problem with this, is that this is "LEGAL RAPE." Patients are paying a trusted doctor to do this to them and at a very expensive \$5,000 a pop! The following eye challenges happen to all of us and the medical community has NOT addressed how the effect of Lasik can actually rapidly accelerate the aging process of the eye.

1. "A minority of people have nearsightedness, farsightedness or astigmatism requiring eyeglasses or contacts for correction that LASIK is even designed to treat. PRESBYOPIC PATIENTS (those requiring a separate prescription for reading) includes everyone. Everyone needs contacts or glasses when they get older because the eye naturally loses its ability to change the focus of the eye to adapt for both far and near vision- Around age 40, the natural lens in the eye starts to lose its ability to accommodate and by age 70 or 80 it is mostly gone. This is called presbyopia and is different from being farsighted (where the best vision is at distances greater than 20 feet away) or nearsighted (where the best vision is less than 20 feet away- the more nearsighted, the closer the best vision is).

2. LASIK only changes the optimal vision distance by reshaping (removing tissue in) the cornea and does Not effect the lens of the eye. After presbyopia, eyeglasses or contacts with multiple prescriptions are used so people can have both near and far vision without changes to their glasses or contacts (changing their correction for different distances). Your doctor may discuss the option of monovision where one eye is nearsighted for near vision and one is targeted for no prescription for distance vision. Many people can never get used to this and you should try this out with contact lenses for several months before hand. Note that if you don't like monovision or want to have more or less nearsighted vision you can just change contact lenses, but after LASIK it is permanent. Some patients after LASIK targeting no prescription will only need to wear correction for near vision tasks (like reading or computer work), but many will end up using correction again later in life just as much as they would have if they had never had LASIK.

3. LASIK was never intended to treat people with other vision conditions (e.g., age related presbyopia, glaucoma, cataracts, etc.). Other vision conditions that commonly occur after people get older may be much more difficult to treat after LASIK and may cause you to continue to need correction like eyeglasses or contacts in the future. For instance, Cataract surgeons frequently offer to change patients' prescriptions by adding a prescription change in the lens they use for replacing the natural lens of the eye which is where cataracts occur. Determining

an accurate prescription for the replacement lens is much more difficult in patients who have had LASIK. LASIK is contraindicated in numerous other eye conditions including common ones like cataracts or glaucoma, and especially when there are problems that injuring the cornea can make worse (like keratoconus).

4. LASIK should Not be done in anyone who has a cataract because LASIK only effects the cornea and does Not fix any problems in the natural lens of the eye where the cataract problems are located. Diagnosing any potential pre-existing eye conditions can be time consuming and it is impossible to know if someone may develop them later in life. In addition, many of the medications used after LASIK are known to cause many of these problems. For example, the steroids used routinely after LASIK and more extensively in those who have LASIK problems (complications) are known to cause cataracts and glaucoma. Many people have been told they were "excellent candidates" for LASIK by one doctor and another doctor told them they had a pre-existing condition that precluded them from having LASIK at all. If these people had listened only to the first doctor they would have been severely damaged by LASIK and in fact many people have been severely damaged, permanently and for life. Many people have been unable to work and have gone on disability.

5. This information is being provided to you so that you can make an informed decision about the use of a device known as a microkeratome, combined with the use of a device known as an excimer laser, to perform LASIK. LASIK is one of a number of alternatives for correcting nearsightedness, farsightedness and astigmatism. In LASIK, the microkeratome is used to shave the cornea to create a flap. The flap then is opened like the page of a book to expose tissue just below the cornea's surface. Next, the excimer laser is used to remove stromal tissue from the cornea to reshape it. Finally, the flap is returned to its original position, without sutures.

6. Patients who have had serious physical problems caused by a medical Doctor have developed psychological and psychiatric problems as well. LASIK causes a lot of different iatrogenic problems. The word iatrogenic means a state of ill health or adverse effect or complication caused by or resulting from medical treatment. However, the term literally means "brought forth by a healer" (*iatros* means healer in Greek); as such, it can refer to good or bad effects.

Action Step Needed By The FDA: Lasik Can Cause Suicide: Why isn't this important risk in the FDA and Lasik Doctor's handbook? Isn't this an important detail to leave out on an \$5,000 elective surgery? Many people have become severely depressed from having LASIK and some have even linked their own suicides (actual suicides, not just attempts) to their LASIK problems. It may be hard to imagine being so depressed over your LASIK result that you would commit suicide, but think about having a severe physical problem that effects you every moment, that is Not treatable and that you went to numerous doctors who try different things and none of them work.. Imagine getting different diagnoses and opinions from different doctors and losing all hope of a cure. Imagine doctors in the US referring you to doctors in foreign countries because they have better equipment there to try to treat your problem. Imagine spending thousands of dollars and a significant portion of your life trying to find a cure and finally realizing that there isn't one and never will be. Imagine total despair, depression, eye pain, bad vision, and no justice. Most patients with problems from LASIK have no recourse against any of the doctors

and many of the follow-up doctors charge much more than for regular eye exams and they will Not take your medical insurance at all. Imagine paying \$250 for a single visit to an eye doctor who cannot cure your problems. Imagine paying thousands for further surgery that only makes your problems worse. Imagine being willing to do anything or pay anything for a treatment.

Action Step Needed By The FDA: THE FDA, SAFETY AND JUSTICE:

The FDA never approved LASIK or any surgery. The FDA only approved the laser used for LASIK. The FDA did review clinical trial data for the lasers, but the microkeratome was approved by the FDA under a separate process called a 510K that only requires it be similar to another already approved device (see <http://www.fda.gov/cdrh/ode/guidance/1376.html>). The FDA did Not review the safety of the microkeratome at all. The FDA states that the lasers are "FDA approved" which means the FDA states they are "safe" and "effective". However, during the approval process for the lasers the FDA intentionally prohibited comparisons of the safety of LASIK to any other refractive surgery procedures or alternatives like contacts or glasses. The FDA does Not use the common definition of the word "safe" when they approve medical devices like the laser. The lasers used for LASIK are NOT safe according to the dictionary definition-free from hurt, injury, danger or risk, careful to avoid danger or controversy, etc. To the contrary, LASIK involves significant risk of mishap, error and substantial harm. The FDA has recalled Lasers after they have permanently damaged hundreds of people.

The FDA states they do a "risk/benefit analysis" to determine whether a medical device (or drug) is "safe". However, they have NEVER published a risk/benefit analysis for LASIK. What value do they put on human injury and suffering in their analysis? They are a government agency so you can Request a copy of their analysis. Please do so before you have LASIK. Without knowing how they compared the benefits to the risks, you cannot have informed consent. They may have a totally different idea of what the benefits are or what the risks are then you do. If you are a US citizen, then you have the right to know.

The FDA will Not allow your doctor to compare the safety or effectiveness of the laser or other medical device he is using on you for LASIK to any other device. The FDA prohibits comparisons even if the FDA knows there are better lasers or techniques already FDA approved and available on the market. I cannot compare them in this informed consent, but I can direct your attention to the FDA information for two specific lasers so you can compare them yourself. Note that some LASIK victims have MOST of these symptoms, not just 1 or 2, but 10 or even 20 different symptoms. Note these problems exist FOR AT LEAST 6 months after surgery so they are probably PERMANENT, and all three of the lasers mentioned below are still FDA approved for use today (2008).

Action Step Needed By The FDA: Before deciding on which doctor or laser you want to permanently injure your eyes from LASIK, I encourage you to review information on the FDA's website about the safety and effectiveness of these three different FDA approved lasers based on the limited information the FDA has published:

1. BAUSCH AND LOMB TECHNOLAS W 217z ZYOPTIX:

FACTS YOU NEED TO KNOW ABOUT WAVEFRONT-GUIDED LASER-ASSISTED IN SITU KERATOMILEUSIS (LASIK) SURGERY FOR THE REDUCTION OR ELIMINATION OF MYOPIC ASTIGMATISM WITH SPHERE UP TO -7.00 DIOPTERS OF NEARSIGHTEDNESS, ASTIGMATISM UP TO -3.00 DIOPTERS AND MRSE < -7.50D) AT THE SPECTACLE PLANE WITH THE BAUSCH AND LOMB TECHNOLAS W 217z ZYOPTIX™ SYSTEM FOR PERSONALIZED VISION CORRECTION

PATIENT INFORMATION BOOKLET

COMPARISON OF SYMPTOMS BEFORE AND AFTER SURGERY

(AT 6 MONTHS, N = 340 EYES TESTED)

Symptom	Worse	Significantly Worse
Dryness	28.8%	2.4%
Fluctuation of Vision*	20.0%	4.2%
Variation in Vision***		
In Dim Light	14.7%	2.7%
In Bright Light	10.3%	0.3%
~ In Normal Light	8.8%	2.4%
Blurring of Vision	14.7%	3.8%
Glare	12.1%	3.2%
Halos	11.8%	2.6%
Redness	9.7%	1.2%
Night Driving Difficulty	9.1%	1.2%
Burning	7.6%	0.3%
Light Sensitivity	7.1%	0.6%
Gritty Feeling	6.2%	0.0%
Headache	4.1%	1.2%
Ghost Images**	3.5%	0.9%
Excessive Tearing	3.2%	0.6%

Pain	2.1%	0.0%
Double Vision	0.9%	2.4%

* Fluctuation in vision only reported on for n= 335 eyes at 6 months

**Ghost images was reported on for n=339 eyes at 6 months

***Variation in vision was reported on for only nr339 eyes at 6 months

From p.17 of 34 pages here, www.fda.gov/cdrh/PDF/p990027s006d.pdf

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Percent corrected to 20/20 or better at 6 months = 92%

Percent corrected to 20/40 or better at 6 months = 99%

From p.10 of 34 pages here, www.fda.gov/cdrh/PDF/p990027s006d.pdf

Based on the above list of problems, do you believe 0% of the patients were dissatisfied at 6 months? From p.21 of 34 pages here, www.fda.gov/cdrh/PDF/p990027s006d.pdf

2. The laser, made by Summit Technology of Waltham, Mass., was approved for treating nearsightedness (0.0 to -14.0 diopters) with or without astigmatism (-0.5 to -5.0 diopters) in people 18 and older whose vision has been stable for the past year:

Approval of the laser was based on a review of clinical studies on safety and effectiveness submitted by Summit and on the recommendation of the Ophthalmic Devices Panel of FDA's Medical Devices Advisory Committee.

In the studies, LASIK was performed on 1,013 eyes at 13 medical centers in the U.S. Patients were followed for six months.

Of the 1,013 eyes treated, 92 percent were corrected to 20/40 or better and 47 percent were corrected to 20/20 or better without glasses or contact lenses.

Short-term side effects included pain (for 24 to 48 hours), corneal swelling, double vision and light sensitivity. In some patients these effects lasted for several weeks.

Side effects experienced by patients six months after treatment included: under-correction (11.9%); over-correction (4.2%); severe halo (3.5%); loss of best

corrected vision with eye glasses (3.0%); severe visual fluctuations (2.6%); and severe glare (1.7%).

Patients with more severe nearsightedness or astigmatism tended to have poorer visual outcomes. Also, glare and haloes tended to be worse in patients with larger haloes tended to be worse in patients with larger pupil size. Some people who have this procedure will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night.

The safety and effectiveness of this procedure have not been established beyond six months.

October 21, 1999 <http://www.fda.gov/bbs/topics/ANSWERS/ANS00981.html>

Please Note: other problems in the first laser above are Not mentioned one way or the other, but compare the effectiveness of this laser from the above quote with the first laser above and the one below.

Percent corrected to 20/20 or better at 6 months = 47%

Percent corrected to 20/40 or better at 6 months = 92%

3. WaveLight ALLEGRETTO WAVE™ Excimer Laser System - P030008:

Table 12 presents a *summary* of adverse events. The benchmark for each adverse event is a rate of less than 1% per event.

Adverse Event

[From 1 to 12 Months] ALL at 0% (no patient injuries at all)

Corneal infiltrate or ulcer requiring treatment Lost, misplaced, or misaligned flap, or any flap/cap problems requiring surgical intervention beyond 1 month

Corneal edema at 1 month or later visible in the slit lamp exam

Any complication leading to intraocular surgery

Melting of the flap of >1 mm sq

Epithelium of > 1mm² in the interface with loss of 2 lines or more of BSCVA Uncontrolled IOP rise with increase of > 5mm Hg or any reading above 25 mm Hg Retinal detachment or retinal vascular accident

Decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction

Table 13:

Complications Summary Table

Complications	6 Months
Corneal edema between 1 week and 1 month after the Procedure	0%
Corneal epithelial defect at 1 month or later	.8%
Any epithelium in the interface	.8%
Foreign body sensations at 1 month or later	0%
Pain at 1 month or later	0%
Ghosting or double images in the operative eye at stability or beyond	0%
Need for lifting and/or reseating of the flap/cap prior to 1 month	0%

Table 14

Change in Patient Symptoms at 6 Months

	Worse	NoChange	Better
Glare from Bright Lights	10.9[%] 29	62.9[%] 163	26.1[%] 68
Halos	13.3[%] 35	68.6[%] 178	18.2[%] 47
Light Sensitivity	12.9[%] 34	67.4[%] 175	19.7[%] 51

Visual Fluctuations 29.5[%] 77 62.5[%] 162 8.0[%] 21

Night Driving Glare 16.0[%] 42 | 61.2[%] 159 22.8[%] 59

See pages 16 and 17 of 21 here, <http://www.fda.gov/cdrh/pdf3/P030008.html>

Percent corrected to 20/20 or better at 6 months = 100%

Percent corrected to 20/40 or better at 6 months = 100%

See p.18 of 21 here, <http://www.fda.gov/cdrh/pdf3/P030008.html>

The Allegretto had a 100% effectiveness rate and lower % adverse events and complications than the other lasers, but doctors are prohibited from even saying anything regarding the relative safety of this device with any other. Decide for yourself.

Why would the FDA intentionally want to restrict you from having informed consent? Will the FDA allow this consent form to even be published? We all still don't even know what the real complication rate is because a Lasik Doctor's definition of success is different than a patient's.

Example: The Snellen Chart. In many people's opinion, isn't even accurate for a post lasik casualty, but this is all the Optometrists and Ophthalmologists have to attempt to define a standard of care and vision, trying to get patients to see 20/20 or better. The problem with this test is that many Post Lasik Patients are seeing 20/20, but they are seeing 2-3 of every letter, along with contrast light sensitivity, halos, starbursts, and other debilitating visual disturbances. The doctors then say, "John Doe...You're a success! Before you had Lasik, you were a -7 Myopia patient who couldn't even function without your contacts or glasses...and now you can." The patient explains: "Yeah, but Doc, I see 2-3 of everything, letters are super imposed, and I can't drive a car at night or hold a job because of this ongoing daily hell you've created..." Doc says, "You knew there were risks, that is why I had you sign away your rights to sue me on the Informed Consent Form..." Doc's assistant says, "Doc, your next patient is waiting..." This might sound comical but this is daily "Standard of Care" or lack of across the board for Lasik Doctors and NO ONE, not ONE US government board is disciplining any of them.

Action Step Needed By The FDA: Steps To Disciplining a Lasik Doctor aren't even working!

- a. File A Complaint with the FDA, AMA, ASCRS, and Dept of Business Regulation.
- b. If Probable Cause: The patient's complaint will be filed and assigned a number.
- c. Probable Cause Investigated:
- d. Decision Is Made: At the top sits a Medical Coordinator who can "ACCEPT" or "DENY" the patient's complaint. In practically if not all cases, they are "DENIED" because a MD/Medical Doctor sits on the throne at the top waiting to "DENY" the claim to protect one of their own

corrupt doctors knowing the patient will finally give up. Why do so many patients not file complaints and give up? Answer: Because they are barely making ends meet daily with ruined vision waiting for a miracle, while they try daily to cope with "ruined optics."

Does The FDA Care? Is the FDA responding to all of the complaints and investigating the current "Standard of Care" and "Disciplinary Actions" (if any) for corrupt and unethical Lying Lasik Doctors that breach the Hippocratic Oath to do "NO HARM?"

As far as the FDA is concerned, once they approve a device as "safe" they never have to review it again. Even if the other device is 1,000 times safer or more effective as far as the FDA is concerned it's just as good to use as any other "approved" device. After reviewing the above information, does it sound to you like the FDA cares about the public health?

The FDA has only approved the laser or the device that was substantially equivalent to the microkeratome (way before 1976 actually without any more recent review) and only for a specific purpose. Other uses are referred to as "off-label" meaning information on that use was never reviewed by the FDA during the approval process. By definition, a legitimate "off-label" use and the practice of medicine involves only doing things that have a known benefit to the patient. However, the FDA continues to refer to things that are known to be harmful and have no benefit to the patient as an "off-label" use.

Example: The FDA knows that "Microkeratome blades are meant to be used only once and then thrown out" (<http://www.fda.gov/cdrh/lasik/expect.htm>) and that reusing the microkeratome blades adds unnecessary risk of further harm with no possible patient benefit (aside from possibly saving a few \$s). Yet the FDA continues to state this is an "off-label" use of this dangerous medical device. The doctor can save about \$50 by reusing the blade on the patients second eye and most of the doctors do reuse these blades. A significant minority of doctors actually reuse the blades on multiple patients (one doctor witnessed each blade being used on 12 patients, 24 eyes per blade) which exposes the patients to any infectious diseases or transmittable eye problems the other patients have. Please Reference:

http://www.lasikliberty.com/index.php?option=com_content&task=view&id=12&Itemid=1)

The FDA knows about this. Even if you ask your doctor not to reuse the blade, he can still reuse the blade without your consent and because you signed this consent form his liability is very limited now. Even if this information was left out of your consent form, most state court systems only require doctors to obtain general consent from patients and will Not approve civil damage awards if there were even vague references in the consent form to any problems that this inhumane act may cause. Just like wakeboarding is not torture in the eyes of the current government, the FDA, other federal government agencies, state and local governments including the courts will not likely uphold your right to informed consent, constitutional rights or your rights as a human being. The Belmont report and Helsinki principles do Not matter. Most court cases are won by the doctors and are very expensive to pursue even if you can find an expert witness willing to tell the truth, which of course we all know you will have to "IMPORT" from outside this country because any Lasik Doctor in America, will be greatly defamed if they go against the Lying Lasik Doctor and the Corrupt Lasik Industry. The average amount won by those few who do get some damages is less than \$100,000. No amount of money can

compensate someone sufficiently for a severe physical injury from LASIK. Justice is a myth and effective propaganda.

Action Step Needed By The FDA:

The FDA puts these risks on their website, but these are not all of the KNOWN risks.

There are risks involved. That's why it is important for you to understand the limitations and possible complications of refractive surgery. Before undergoing a refractive procedure, you should carefully weigh the risks and benefits based on your own personal value system, and try to avoid being influenced by friends that have had the procedure or doctors encouraging you to do so.

- a. Some patients lose vision.
- b. Some patients lose lines of vision on the vision chart that cannot be corrected with glasses, contact lenses, or surgery as a result of treatment.
- c. Some patients develop debilitating visual symptoms.
- d. Some patients develop glare, halos, and/or double vision that can seriously affect nighttime vision. Even with good vision on the vision chart, some patients do not see as well in situations of low contrast, such as at night or in fog, after treatment as compared to before treatment. You may be under treated or over treated.
- e. Only a certain percent of patients achieve 20/20 vision without glasses or contacts.
- f. You may require additional treatment, but additional treatment may not be possible.
- g. You may still need glasses or contact lenses after surgery. This may be true even if you only required a very weak prescription before surgery. If you used reading glasses before surgery, you may still need reading glasses after surgery.
- h. Some patients may develop severe dry eye syndrome. As a result of surgery, your eye may not be able to produce enough tears to keep the eye moist and comfortable. Dry eye not only causes discomfort, but can reduce visual quality due to intermittent blurring and other visual symptoms. This condition may be permanent. Intensive drop therapy and use of plugs or other procedures may be required.
- i. Results are generally not as good in patients with very large refractive errors of any type. You should discuss your expectations with your doctor and realize that you may still require glasses or contacts after the surgery.
- j. For some farsighted patients, results may diminish with age. If you are farsighted, the level of improved vision you experience after surgery may decrease with age. This can occur if your manifest refraction (a vision exam with lenses before dilating drops) is very different from your cycloplegic refraction (a vision exam with lenses after dilating drops).
- k. Long-term data are not available. LASIK is a relatively new technology. The first laser was

approved for LASIK eye surgery in 1998. Therefore, the long-term safety and effectiveness of LASIK surgery is not known: <http://www.fda.gov/cdrh/lasik/risks.htm>

ALTERNATIVES TO LASIK:

If you decide not to have LASIK, there are other methods of correcting your nearsightedness, farsightedness or astigmatism. These alternatives include, among others, eyeglasses, contact lenses and other refractive surgical procedures.

TREATMENT FOR LASIK PROBLEMS (COMPLICATIONS):

Many of the problems listed in this consent form are Not curable. In some cases, the treatments may help reduce the symptoms, but will not eliminate the symptoms or fix the problem. Many patients who can no longer have decent vision with eyeglasses seek expensive contact lenses called rigid gas permeable (RGP) lenses that force the cornea to fit their shape to correct irregularities in the cornea. A lot of new types of contact lenses have been developed in recent years to try to help all the patients who are unable to have their vision corrected even with RGPs. Many patients cannot wear contact lenses for very long after LASIK (due to other problems like dry eye, corneal erosions, etc). Contact lenses are much less comfortable after LASIK than before and the eye can be damaged by contact lenses permanently.

A partial or complete corneal transplant might be necessary to repair the cornea, but even this severe retreatment is unlikely to result in normal vision and may make the problems even worse. Cornea transplants also has problems worse than LASIK and can cause many of the LASIK problems listed below. Many LASIK problems cannot be fixed with transplants (for instance, Ectasia) and there is a shortage of donor tissue partly because of the increased demand caused by LASIK problems.

WHAT THE "PATIENT'S INFORMED CONSENT FORM" SHOULD STATE:

In giving my permission for LASIK, I understand the following: All the long-term risks and effects of LASIK are unknown and may be severe. Note that LASIK has a lot of known short and long-term risks. I have received no guarantee as to the success of my particular case. I understand that the following risks are associated with the procedure and may be permanent (untreatable) for the rest of my life:

Retreatment Risk

Even 90% clarity of vision is still slightly blurry. Enhancement surgeries can be performed when vision is stable UNLESS it is unwise or unsafe. The original flap can usually be lifted with specialized techniques. If the enhancement is performed within the first six months following surgery, there generally is no need to make another cut with the microkeratome and many doctors even relift the flap years after it was made (10 years or longer). If a new LASIK incision

is required, there is greater risk. In order to perform an enhancement surgery, there must be adequate tissue remaining. If there is inadequate tissue, it may not be possible to perform an enhancement. It may be difficult to determine if there is enough issue left or not. If too much tissue is removed and you suffer for the rest of your life, you will have no legal recourse.

LASIK Risk 1: Severe Dry Eye Syndrome

Dry Eye Syndrome - a common condition that occurs when the eyes do not produce enough tears to keep the eye moist and comfortable. Common symptoms of dry eye include pain, stinging, burning, scratchiness, and intermittent blurring of vision.

<http://www.fda.gov/cdrh/LASIK/glossary.htm>

Your eyes can **feel persistently gritty, itchy, burning, and painful**. Take the dry eye test at <http://www.dryeye.org/test.htm> .

Many Dry Eye Syndrome symptoms and challenges may effect hundreds of thousands of people. Notice these end in dysfunction or "itis" meaning "Inflammation or disease of" and "Excessive preoccupation with, indulgence in, reliance on, or possession of the qualities of".

Blepharitis, Mebomian or Lacrimal Gland Dysfunction (mebomianitis), conjunctivitis, and kerato-conjunctivitis sicca. Keratitis (Inflammation of the cornea)- Diffuse Lamelar Keratitis (DLK), Punctate Epithelial Keratitis (PEK) and superficial punctate keratitis (SPK).

It is so difficult to grasp the magnitude of the impact that I asked some others who are suffering greatly after LASIK for their comments on how to explain the degree of suffering and constantness of it better. For additional research and a patient story on the permanent impact on Quality of Life, see http://www.lasikliberty.com/index.php?option=com_content&task=view&id=37&Itemid=57

There are many reasons why LASIK causes dry eye. From reading the literature and talking with patients my estimate is that if a blade is reused for LASIK, then all patients' eyes are drier after LASIK than before, 10 to 50% of eyes are so permanently dry that they use preservative free (if they're properly informed) eye drops for the rest of their life, and that 10 to 20% of patients are so severely effected by dry eye that it dramatically changes their life forever. Even without any eye surgery or LASIK, over 3 million people have dry eyes. Also, most prescription medicaions cause dry eyes which means millions more people have dry eyes even before they have LASIK.

Saying that "significant" vision loss is "rare" or very rare is not enough for a patient to comprehend the full impact that dry eyes can have on their lives. Most people do Not understand that Dry eye effects vision. A relative of mine went through chemo therapy for cancer with all the associated problems (nausea, sickness, etc.). She complained about dry eye as having the biggest negative impact on her quality of life. After the dry eye, she had a lot more understanding about what I was going through- if you haven't experienced it, you have no idea just how severe it is.

Oddly, some people go from doctor to doctor for years asking for help with eye pain or photophobia without receiving a diagnosis of dry eye, much less being offered any treatment options. If this is true for you, request that you be tested for each of the above conditions (<http://www.dryeyepain.com/#DryEye>). Dry eye pain is discussed a lot on the internet too.

There are even prescription manufacturers of products such as *Allergen's "Refresh Plus Lubricant Eye Drops"* that are even going to the extent on the FRONT COVER of their marketing box to say:

"Moisture drops for dry eyes including LASIK dryness..."
NDC 0023-0403-30

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Most people do Not understand that Dry Eye effects your entire vision. A relative of mine went through chemo therapy for cancer with all the associated problems (nausea, sickness, etc.). She complained about dry eye as having the biggest negative impact on her quality of life. After the dry eye, she had a lot more understanding about what I was going through- if you haven't experienced it, you have no idea just how severe it is.

"It's very rare for LASIK to cause permanent, significant vision loss"
Quote is from the websites of many LASIK surgeons.

After LASIK, the cornea may be permanently damaged by using eye drops with preservatives (e.g., visine can no longer be used safely). Extensive use of Expensive non-preservative eye drops and prescription medications (e.g., restasis and antibiotics) may be required for LIFE (as has been prescribed for me by numerous Doctors).

LASIK has a known COMMON adverse event of causing vision quality problems (including night vision problems and problems during the day) and dry eye that very SERIOUSLY (and irreparably in most cases) impairs ones quality of life forever. In the Nidek clinical trials, for instance, there were unreasonably high rates of night vision problems (69%) but the FDA approved LASIK WITH reused blades as safe anyway.

LASIK Risk 2: Severe Loss of Contrast Sensitivity

LASIK Risk 3: General Laser or Microkeratome Failure

I understand that the microkeratome or the excimer laser could malfunction, requiring the procedure to be stopped before completion. Depending on the type of malfunction, this may or may not be accompanied by permanent visual loss. See samples of vision simulations below.

LASIK Risk 4: Reuse of the Microkeratome Blade

There is no patient benefit for reuse of the microkeratome blade, but your doctor may do it anyway to save about \$50.

Risk: The chance of significant increased risk is unknown but in most cases microkeratome blades get duller every time they are reused which causes irregular flaps, less smooth flaps, epithelial in growth, keratitis (inflammation), and other serious problems that can result in permanent visual loss.

Alternatives: A new blade should be used on every eye. IntraLASIK and PRK are alternative surgical treatments that do Not use a blade at all.

LASIK Risk 5: Microkeratome Failure

I understand that, in using the microkeratome, instead of making a flap, an entire portion of the central cornea could be cut off, and could be lost. If preserved, I understand that my doctor would put this tissue back on the eye after the laser treatment, using sutures, according to the ALK procedure method. It is likely that the flap will be rotated from its original position (it is clear tissue so it is hard to realign properly even if your doctor marked it before surgery which they often do not). The flap incision could result in an incomplete flap, or a flap that is too thin. If this happens, the risks from LASIK surgery are increased substantially and no reasonable person would agree to accept these increased risks. If you insist on having LASIK anyway, it is safer if the laser part of the procedure is postponed until the cornea has a chance to heal sufficiently to try to create a second flap in addition to the first flap. There is a substantial risk that the two flaps will intersect and cause a lot of problems in your eye in the future.

Alternatives to creating another LASIK flap: Eyeglasses or contact lenses. PRK are alternative surgical retreatment that does Not create a flap. However, PRK on top of an existing lasik flap is also much more risky than PRK on an eye that has never had surgery.

LASIK Risk 7: Irregular healing of the flap

I understand that irregular healing of the flap could result in a distorted cornea. This would mean that glasses or contact lenses may not correct my vision anywhere close to the level possible before undergoing LASIK. If this distortion in vision is severe, a partial or complete corneal transplant might be necessary to repair the cornea and may make the problems even worse.

LASIK Risk 8: Cornea Perforation

I understand that it is possible a perforation of the cornea could occur, causing devastating complications, including loss of some or all of my vision. This could also be caused by an internal or external eye infection that could not be controlled with antibiotics or other means.

LASIK Risk 9: Severe Infection

I understand that mild or severe infection is possible. Severe infection, even if successfully treated with antibiotics, could lead to permanent scarring and loss of vision that may require corrective laser surgery or, if very severe, corneal transplantation or even loss of the eye. Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss.

LASIK Risk 10: Keratoconus

I understand that I could develop keratoconus. Keratoconus is a degenerative corneal disease affecting vision that occurs in approximately 1/2000 in the general population. While there are several tests that suggest which patients might be at risk, this condition can develop in patients who have normal preoperative topography (a map of the cornea obtained before surgery) and pachymetry (corneal thickness measurement). Since keratoconus may occur on its own, there is no absolute test that will ensure a patient will not develop keratoconus following laser vision correction. Severe keratoconus may need to be treated with a corneal transplant and may make the problems even worse. Mild keratoconus can be corrected by glasses or contact lenses.

LASIK Risk 11: Other miscellaneous cornea problems

Corneal swelling (edema), corneal thinning, appearance of "floaters". Retinal detachment, hemorrhage, venous and arterial blockage, cataract formation, total blindness, and even loss of my eye.

Inflammation of the cornea under the flap (lamellar keratitis) or outer layer of the eye (conjunctivitis), episcleritis, chelazion, bowman's wrinkle, striae, epithelial defect or ingrowth (resulting in flap melt in a significant % of cases), foreign body sensation, allergies, recurrent corneal erosions, etc.

Reported incidence rates vary from less than 1% (www.fda.gov/cdrh/PDF/p990027s006d.pdf) to 5% for each of these problems.

LASIK Risk 12: Vision problems

I understand that there may be increased sensitivity to light, glare, and fluctuations in the sharpness of vision. I understand these conditions may be permanent.

LASIK Risk 13: Prescription problems

I understand that an overcorrection or undercorrection could occur, causing me to become farsighted or nearsighted or increase my astigmatism and that this could be either permanent or treatable. I understand an overcorrection or undercorrection is more likely in people over the age of 40 years and may require the use of glasses for reading or for distance vision some or all of the time.

After refractive surgery, a certain number of patients experience glare, a "starbursting" or halo effect around lights, or other low-light vision problems that may interfere with the ability to drive at night or see well in dim light. The exact cause of these visual problems is not currently known; some ophthalmologists theorize that the risk may be increased in patients with large pupils or high degrees of correction. For most patients, this is a temporary condition that diminishes with time or is correctable by wearing glasses at night or taking eye drops. For some patients, however, these visual problems are permanent. I understand that my vision may not seem as sharp at night as during the day and that I may need to wear glasses at night or take eye drops. I understand that it is not possible to predict whether I will experience these night vision or low light problems, and that I may permanently lose the ability to drive at night or function in dim light because of them. I understand that I should not drive unless my vision is adequate.

I understand that I may not get a full correction from my LASIK procedure and this may require future enhancement procedures, such as more laser treatment or the use of glasses or contact lenses.

I understand that there may be a "balance" problem between my two eyes after LASIK has been performed on one eye, but not the other. This phenomenon is called anisometropia. I understand this would cause eyestrain and make judging distance or depth perception more difficult. I understand that my first eye may take longer to heal than is usual, prolonging the time I could experience anisometropia.

LASIK Risk 3: Ectasia

Risk: Post-LASIK ectasia is reported to occur in approximately one in every 2,500 surgical cases. www.es CRS.org/PUBLICATIONS/EUROTIMES/07May/PostLASIKectasia.pdf

There is a risk of developing ectasia years after the surgery (a life-time risk is Not known) and some cases are never reported so the true incidence rates are unknown. Patients with high

myopia (-8.00 D or higher), thin corneas (less than 500 microns), and keratoconus suspects are at highest risk. Ectasia results in permanent visual loss

Alternatives: Contact lenses or eyeglasses do not have any known risk of causing Ectasia. PRK is an alternative surgical treatment that is far less likely to have this risk because it removes corneal tissue at the surface of the stroma without going as deep in the cornea and without creating a flap in the cornea.

Symptoms:

- Progressive myopia
- Irregular astigmatism
- Ghosting
- Fluctuating vision

- Ocular pain, eye strain, headaches

- Problems with vision- especially scotopic vision (vision in darkness or dim lighting)

- Progression of ectasia leads to severe loss of corrected visual acuity

[Insert samples of vision here]

[Sample Vision simulation #1.]

Description and Treatment

There is no known cure for Ectasia. With Ectasia, your vision cannot be fully corrected by glasses or soft contact lenses. Ordinary daily tasks may become very difficult and cause eye strain. Some patients go on disability. In the most severe cases, patients become legally blind (cannot drive or work). The strongest part of the cornea is in the outer 1/3 (where the collagen that provides the strength is the densest) and cutting a flap permanently weakens this strongest area (research shows the center of the flap has lost 97% of its original strength).

“Iatrogenic keratectasia is a complication after LASIK that is induced inadvertently by the surgeon performing the procedure. The cutting of the flap and the subsequent laser ablation weakens the cornea and causes a bulging in the weakest area. The cornea continues to bulge because it has been destabilized. This bulging results from the cornea being thinned to the point that the internal pressure of the eye affects the structurally weakened cornea. The bulging usually is not even, so the effect is about the same as keratoconus -- a form of irregular astigmatism that is extremely difficult to treat. The process is irreversible once it begins:

Patients with high myopia (-8.00 D or higher), thin corneas (less than 500 microns), and keratoconus suspects are at highest risk. A family history of keratoconus is a warning sign.

There are two known causes of iatrogenic keratectasia after LASIK: 1) the removal of excessive amounts of tissue from the posterior stromal layers, and 2) previous keratoconus (forme fruste keratoconus). It is believed that the progression of ectasia is likely to be hastened by the removal of central corneal tissue. Forme fruste keratoconus is a definite contraindication to LASIK.

According to Amoils(1) , LASIK has certain intrinsic problems, and the combination of incisional surgery and laser ablation has a potential for serious short- and long-term problems.

Keratectasia after LASIK has been reported most frequently when 250 microns of corneal bed are not left remaining after the flap cut and laser ablation. The anterior part of the cornea consists of alternating collagen fibrils and a more complicated interwoven structure. This layer of tissue is about 100-120 microns thick and appears to be the strongest layer of tissue of the cornea. The epithelium (outer skin) is on top of this layer. It is generally about 50 microns thick. This anterior part of the cornea is believed to be the major stress-bearing layer. This layer which is approximately 150 to 170 microns is also the layer used in making the flap. After LASIK, the corneal flap, though apposed to the bed, does not weld to it for years. According to Seiler² , the anterior flap after LASIK does not contribute to the mechanical strength of the cornea. The stress is supported by the residual thickness of the bed alone.

The strongest part of the cornea becomes a chronically "fractured" cornea. The remaining tensile strength is only that of the corneal bed. The fibrils in the corneal bed fit a very regular pattern as compared to the more structurally complicated anterior corneal layer. The deeper stroma appears to have less bio-mechanical strength as compared to the anterior corneal layer according to Park et al³.

The amount of residual stromal bed thickness that is necessary to avoid progressive corneal ectasia after LASIK is unknown. The consensus among most LASIK surgeons is 250 microns."

<http://asklasikdocs.com/forums/showthread.php?t=37>

"One basic assumption is that, if a surgeon removes sufficient corneal stroma, the residual cornea is not strong enough to resist the IOP-related stresses and strains. Some investigators' theoretical calculations suggest that a "safe" residual stromal thickness is between 200 and 250 μm .⁹ Others suggest that removing less than a certain percentage of the preoperative corneal thickness or placing a laser resection at less than 55% of the corneal thickness prevents ectasia.¹⁰"

http://www.crstoday.com/PDF%20Articles/0307/CRST0307_10.php

XXXXXXXXXXXXXXXXXX

I understand that, after LASIK, the eye may be more fragile to trauma from impact. Evidence has shown that, as with any scar, the corneal incision will not be as strong as the cornea originally was at that site. I understand that the treated eye, therefore, is somewhat more vulnerable to all varieties of injuries, at least for the first year following LASIK. I understand it would be advisable for me to wear protective eyewear when engaging in sports or other

activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing object contacting the eye may be high.

I understand that there is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this process.

I understand that there may be pain or a foreign body sensation, particularly during the first 48 hours after surgery.

I understand that temporary glasses either for distance or reading may be necessary while healing occurs and that more than one pair of glasses may be needed.

I understand that the long-term effects of LASIK are unknown and that unforeseen complications or side effects could possibly occur.

I understand that visual acuity I initially gain from LASIK could regress, and that my vision may go partially back to a level that may require glasses or contact lens use to see clearly.

I understand that the correction that I can expect to gain from LASIK may not be perfect. I understand that it is not realistic to expect that this procedure will result in perfect vision, at all times, under all circumstances, for the rest of my life. I understand I may need glasses to refine my vision for some purposes requiring fine detailed vision after some point in my life, and that this might occur soon after surgery or years later.

I understand that I may be given medication in conjunction with the procedure and that my eye may be patched afterward. I therefore, understand that I must not drive the day of surgery and not until I am certain that my vision is adequate for driving.

I understand that if I currently need reading glasses, I will still likely need reading glasses after this treatment. It is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age if I have this surgery.

I understand that, as with all types of surgery, there is a possibility of complications due to anesthesia, drug reactions, or other factors that may involve other parts of my body. I understand that, since it is impossible to state every complication that may occur as a result of any surgery, the list of complications in this form may not be complete.

FOR PRESBYOPIC PATIENTS (those requiring a separate prescription for reading): The option of monovision has been discussed with my ophthalmologist.

W: <http://www.LifeAfterLasik.com>