Food and Drug Administration
Dockets Management Branch
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857
(301) 827-6860

Dear FDA:

Petition to the FDA to stop LASIK due to the use of research from experiments conducted on human beings without a proper basis to believe it is in the patients' best interests and improper patient informed consent.

Note that the FDA has already set up a working group to address these and other issues I have discussed with the FDA for many months and years (including a Medical Device Report I've already submitted).

The undersigned submits this petition under the enclosed Legal Basis of this Petition (see section 2) and the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs (under 21 CFR, Part 5.10) to request the Commissioner of Food and Drugs to take the enclosed Actions requested for the FDA (see section 3).

It is unethical to conduct experiments on human beings without a proper basis to believe it is in the patients' best interests. It is unethical to Not Follow or avoid IRB and/or research guidelines established by medical review boards, medical Doctors, and/or the government (e.g., the FDA, CDC, etc) to protect research subjects.

These ethics extend to U.S. Doctors regardless of whether the research is conducted in the U.S. or overseas.

LASIK research was used in part to get FDA approval in the US for the lasers (considered Class III, most dangerous, medical devices) used for LASIK (laser-assisted in situ *keratomileusis*) and the microkeratomes used to cut flaps in the cornea. As a result of these research practices and uses, I believe that thousands of patients (consumers) have been permanently injured by bad medical practices, research and marketing practices (including advertisements) that are Not based on reliable scientific evidence.

The scope of this petition involves ALL Microkeratomes that currently have or are in the process of obtaining FDA 510K approvals for use in elective refractive eye surgery.

My hope is that the FDA and CDC, and any other appropriate regulatory authorities investigate and stop harmful patient practices as soon as possible. As many as eight million patients have had LASIK so far.

2006P-0212

CP1

A prior Petition titled "Petition to the Food and Drug Administration regarding Medical Devices used for Elective Refractive Eye Surgery with Premarket Approvals (PMAs)" is hereby incorporated in this petition by reference (All words, information, and/or references, etc.). That Petition was submitted by Dominic Morgan and is hereby incorporated by reference. http://www.lasiksucks4u.com/index.php?option=com_content&task=view&id=21&Itemid=30

A prior petition submitted by Michael Patterson titled "Petition to the Food and Drug Administration to enforce the single-use requirement for all Microkeratomes and their components used for LASIK (in accordance with existing regulations) Or to place a moratorium on their use (a partial or full withdrawal of approval)" is also incorporated herein by reference.

The above petition supports this petition with additional references, examples, bases, reasons and potential actions for the FDA to consider.

If additional information, separate comments or any other modification to this submission is required to comply with the FDA's procedures, please contact the Petitioner as soon as possible. The undersigned hereby petition the FDA to change or cancel a regulation, or to take other action as outlined in the FDA's published procedures (http://www.fda.gov/opacom/backgrounders/voice.html).

Table of Contents

1. Statement of grounds

1.1 Examples of Devices included in the Scope of the Petition

Each of the medical devices used for LASIK are regulated by the FDA as Class I or Class III medical devices. A license for single-use only procedure to perform the procedure may ONLY be obtained from the manufacturers with the purchase of each single-use disposable blade.

Examples of some of the Devices (and their components) included in the Scope of the Petition listed on the FDA website including all lasers currently approved or in review, see http://www.fda.gov/cdrh/LASIK/lasers.htm, and all the microkeratomes with 510Ks or currently under review (including approved substantially equivalent or predicate devices), for instance, see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=103724

HANSATOME MICROKERATOME
CHIRON VISION CORP.
510(k) Number K972808.

1.2 Consistency with FDA's Goals.
The benefits of this petition outweigh the costs by effectively utilizing the limited FDA resources in an area where they are most needed to meet the goals of the FDA, Assuring Medical Product Safety, and protecting the Public Health (http://www.fda.gov/ope/FY03plan/default.htm). The following statements provide the basis for the benefits of this petition. The costs would be based on which agencies and what specific actions are taken based on this petition.

"Consumers spend $326 billion annually in the U.S. on medical products. An estimated 1.3 million people are accidentally injured by medical therapy in the U.S. each year, and as many as 100,000 die as a result of preventable medical errors. FDA must be vigilant in monitoring the production, distribution and use of these products because FDA's presence raises the likelihood that public health and safety problems associated with these products will be addressed and because it is critical to citizen safety."

"To ensure that these products are safe the Agency must oversee their entire life cycle--from production through distribution, and consumption/use. "

"FDA's three primary strategies for ensuring medical product safety are to: a) enhance global vigilance over product manufacturing and distribution; b) strengthen and focus domestic industry monitoring; and, c) expand and automate the systems which report on adverse events associated with the use of medical products. "

The FDA's goals are consistent with preventing injury and protecting the Public Health. Has the FDA ignored or even endorsed another potential Public Health Crisis (e.g., breast implants)?
"A weakened FDA can only move slowly and with uncertainty. Consumer confidence in the Agency suffers, and real health and safety risks may grow."
http://www.fda.gov/ope/fy03plan/goals3.html

* Reduce the risk of medical devices and radiation-emitting products on the market by assuring product quality and correcting problems associated with their production and use."
(http://www.fda.gov/ope/fy03plan/goals.html)

1.3 Legal Basis for this Petition
The Petitioner makes a public demand that the Food and Drug Administration (the leading U.S. public health regulatory agency) assert its authority and supremacy in protecting the Public Health.

There are multiple additional legal bases for this petition because the Microkeratomes are regulated by the FDA as Class I medical devices for use in refractive eye surgery (commonly referred to as LASIK).

1.3.1 In general, **The FDA's guidelines include:**

1.a. "Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries. "
"It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.
The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."
The Purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease. "
I. Basic Principles
II. Medical Research Combined with Professional Care (Clinical Research)
III. Non-Therapeutic Biomedical Research Involving Human Subjects (Non-Clinical Biomedical Research)
http://www.fda.gov/oc/health/helsinki89.html
1.b. The Belmont Report
Ethical Principles and Guidelines for
the Protection of Human Subjects of Research
B. Basic Ethical Principles
C. Applications
Applications of the general principles to the conflict of research leads to consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of subjects of research.
http://www.fda.gov/oc/ohrt/IRBS/belmont.html
1c. The voluntary consent of the human subject is absolutely essential.
The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
http://www.hhs.gov/ohrp/irb/irb_appendices.htm#j5

1.3.2 The FDA does Not regulate the practice of medicine, but the FDA does regulate the research conducted with these FDA approved devices as well as all users and practitioners who use them. Not everything that a medical Doctor does is considered the practice of medicine. Being a licensed medical Doctor does Not allow a person to break Federal or State laws. An off-label use of a device explicitly for the potential benefit of a patient (where the benefit clearly outweighs the risk) would be considered a legitimate practice of medicine. However, when there is no patient benefit and/or the risk outweighs any benefit, then Not following prudent measures to protect patients from physical or mental harm does Not constitute the practice of medicine By definition. Part of the definition of the practice of medicine is to put the patients' best interests ahead of those of the Doctor. Any practitioner or user of these Class I devices (whether or Not he/she happens to be Doctor) who uses them in an unnecessarily risky way (including committing an assault) or who does Not provide informed patient consent would be under the FDA's regulatory authority.

1.3.3 The Petitioner believes that the potential risks versus possible benefits assessment favor the Actions proposed in this petition and are consistent with the FDAs own objectives including Healthy People 2010. "The PHS is committed to achieving the health promotion and disease

prevention objectives of Healthy People 2010, a PHS-led national activity announced in January 2000 to eliminate health disparities and improve years and quality of life." (http://www.fda.gov/OHRMS/DOCKETS/98fr/062502c.pdf).

1.3.4 Section 522(a) states that " In General.--The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class II or class I device the failure of which would be reasonably likely to have serious adverse health consequences" (http://www.fda.gov/cder/guidance/105-115.htm#SEC.%20212).
The FDA authority to protect the Public from injury and the Public Health in general is based on section 522 (21 U.S.C. 360l). The CDRH has recorded that the failure of these devices has caused serious adverse health consequences

1.3.5 Under the FDA's authority with the Federal Food Drug and Cosmetic Act and all rules and regulations promulgated or annexed therein, including, but not limited to section 515(d) (g), 520(e) (q) and (r), 21 CFR 801.109, 21 CFR 803.5, 21 CFR 803.10, 21 CFR 814.82, 21 CFR 814.84, 21 CFR 814.39, and the FOOD AND DRUG ADMINISTRATION MODERIZATION ACT OF 1997, the Petitioner ask the FDA to act and to implement the enclosed Actions.

1.3.6 Title 21 et seq., Title 45 et seq., and the Good Manufacturing Practices act, and other Federal Laws may have been violated by the practitioners who used these devices.

1.3.7 FDA regulations state that the FDA may require the submission of the adverse safety and effectiveness data, as described in the Class I summary or citation under title 21 Parts 800 to 898, Sec. 807.94, Sec. 807.100, section 515, and other Acts
(http://www.fda.gov/cder/present/DIA62002/risk_mgmt/sld019.htm).
(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807). Many adverse events are Not reported.

1.3.8 The FDA is mandated to assure Medical Product Safety. "To ensure that these products are safe the Agency must oversee their entire life cycle--from production through distribution, and consumption/use" (http://www.fda.gov/ope/fy03plan/goals3.html).

The FDA does consider petitions (http://www.fda.gov/opacom/backgrounders/voice.html) and comments for the development of future policy
(http://www.fda.gov/cder/present/DIA62002/risk_mgmt/sld019.htm) and has authority to change that policy under Title 21 Parts 800 to 898, Sec. 807.94, Sec. 807.100, section 515, and other Acts (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=807.100).

1.3.9 The American Academy of Ophthalmology has supported banning a device (bottle rockets) that since 1995 due to it causing eye injuries similar to those caused by elective refractive eye surgery. From July 1990 to December 1994, for instance the total number of serious eye injuries from all causes reported to the United States Eye Injury Registry (USEIR) was 4,575 cases (Serious Eye Injuries Associated With Fireworks- United States, 1990-1994 MMWR Vol. 44/No. 24, June 23, 1995, pp. 449-52; Center for Disease Control MMWR journal). On average over that 4 ½ year time period, that amounts to ~1,017 eye injuries per annum. Based on public information that over a million LASIK operations alone are performed every year and the percentage of those

operations causing serious eye problems, the number of serious eye injuries per annum of elective eye surgery far exceeds all other causes.

1.3.10 The Federal Government CAN enforce Federal law even when licensed Doctors violate it.

2. Reasons for this Petition

2.1 There were warnings sent about potential violations of Federal laws.
For example, a warning letter sent to one researcher, Dr. CaseBeer, noted numerous "deviations" from Title 21 Code of Federal Regulations.

http://www.fda.gov/foi/warning_letters/m2875n.pdf

Emory and Dr. Waring received a warning letter to cease "promoting an investigational device until after the FDA has approved the device for commercial distribution".

http://www.fda.gov/foi/warning_letters/d1908b.pdf

Information was knowingly left out of the labeling and patient informed consent. For instance, patients are Not told about the high risk of dry eye and night vision problems caused by LASIK. Patients were coerced deceptively into paying money for something that was known to permanently damage patients in 100% of cases. The flap never heals after LASIK and there is NO KNOWN physical benefit to the cornea from LASIK. Instead the cornea is permanently injured by LASIK. Patients are required to have true informed consent.

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

2.2. The criteria established for success did Not include guidelines for vision quality and the physical and mental health of the patient. If the Only patient benefit is psychological and there is No physical benefit to the body part that is permanently injured by the surgery (the cornea), then the psychological ramifications to patients who are Not "satisfied" should have been assessed.

Even the benchmark for success is 20/40 which is the barely legal limit for driving and does NOT represent good vision quality. IF you're a high myope your chances of reaching even this low benchmark are just a little better than 50%. Clinical trials are performed on the best screened patients by the top gun surgeons. Why weren't these stats reported to patients in the labeling? Notice how poor the outcomes are for high myopes!
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&...
Outcomes of spherocylinder treatments in the comprehensive refractive surgery LASIK study. Casebeer JC, Kezirian GM. Department of Ophthalmology, University of Utah, Salt Lake City, UT.

"Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act."

http://www.fda.gov/cdrh/pdf/P970053S002a.pdf

In addition, Dr. Waring went overseas to bypass the FDA's procedures and guidelines.

> >Waring directed an excimer laser study at the Yerkes Regional Primate Research Center but had to continue his work in Saudi Arabia during 1993 and 1994 because Food and Drug Administration (FDA) regulations were slowing the pace. "I was becoming frustrated by not being able to take what we had learned in the lab and use it clinically in a way that would really advance the field," he says. "We had lasers to use on people, but we couldn't because the FDA was so restrictive."

http://www.emory.edu/EMORY_MAGAZINE/winter97/inbrief.html
This indicates they did Not have the evidence before introducing the procedures in the US.

> "Because the procedure was ongoing anyway, it was decided to promptly start retrospective and prospective studies. These have now been under way for several years and the results are beginning to come in. Thus, we had the unusual situation in which the statistical basis for the procedure was being developed at the same time that the procedure was actually being introduced into the US."

http://www.slackinc.com/eye/jrs/vol123/edit.htm

Dr. Waring indicated that any new eye surgery procedure should be well studied BEFORE being used on thousands of patients, but then they participated in releasing LASIK before they determined how to reduce the complication rates to a reasonable level. For instance, Dr. Stulting admitted an incidence rate of 10% for epithelial ingrowth was more common, but it is now a more "reasonable" 1%. So why did they continue doing LASIK with 10% rates without first determining how to reduce it by a factor of 10 to 1%?

However, Emory Doctors have admitted the initial complication rates were FAR TOO HIGH.

Even after thousands of patients, five percent complication rates were reported just for problems with the microkeratomes let alone other problems.

> "Although this evidence can be disputed by a study that looked at the rate of complications from both experience and inexperience microkeratome users and found an acceptably safe error rate of five percent. Regardless, a five percent error rate is still high and it is still greatly affected by experience."

("The History and Controversial Future of Refractive Surgery", 1999?, by Michael J. Ward who works at Emory;
http://www.cse.emory.edu/sciencenet/undergrad/SURE/Articles/1999_art_ward.html).

> "The incidence has declined over the years, probably because of improved understanding of the pathology and risk factors. An incidence of 10% was more common years ago. Now, 1% is a more reasonable estimate for the incidence of clinically significant epithelial ingrowth," said Dr. Stulting.
> Although this serious problem occurs less frequently now, surgeons may still need guidance on the risk factors and how to treat ingrowth, said Dr. Stulting.

http://www.eyeworld.org/article.php?sid=3080

Furthermore, these "reduced" rates of complications may Not apply to Doctors they trained who may still be having complication rates 10 times higher. Have they retrained these Doctors how to lower their complication rates up to 10 times using newer techniques? Again, this would Not be ethical and breaches their duty to warn and protect the public health.

Dr. Waring and others continue to state the problems have been dramatically reduced, but they have FAILED to train other Doctors how to ALSO CORRECTLY reduce these problems and the same practices continue. Dr. Meyer's statements about reusing the blades and canulas were made in January and February of 2006. Reuse of these disposable devices leads to an increase in a number of problems including epithelial ingrowth.

"In Atlanta, George O. Waring III heads a refractive surgery center at Emory Vision Correction Center that does LASIK on 600 eyes per month."

"LASIK has been around less than 10 years, but in that time, both the technology and doctors' skills have improved, Waring says. Today, both the microkeratome, the instrument that makes the flap, and the laser, which reshapes the cornea, are getting closer to foolproof, he tells WebMD. "That's why the complications are going down -- but not down to zero yet.""

"the microkeratome, the instrument that makes the flap, and the laser, which reshapes the cornea, are getting closer to foolproof, he tells WebMD."
http://www.webmd.com/content/article/25/1728_57876

2.3. Patients were Not provided proper informed consent including full disclosure of all the risks caused by elective eye surgery including, but not limited to, vision quality loss, and the increased lifetime risks relative to contacts and other refractive eye surgery procedures (e.g., the additional microkeratome risk for LASIK vs. other surgeries like PRK). Further informed consent is also lacking as FDA "approval" implies the safest possible treatment available at the time (that was approved by the FDA as "safe").

Was there "Vigorous investigation and honest disclosure of results coupled with personal restraint and a patient-as-partner philosophy allow us to evaluate new refractive surgery procedures without succumbing to either free market madness or regulatory rigor mortis." as proposed by Dr. Waring?

Do you know anyone who would knowingly consent to Duller Vision, Increased Halos, and Worse Vision in Dim Light? LASIK is Not safe, but the FDA approves something that produces Duller Vision, Increased Halos, and Worse Vision in Dim Light to be AS SAFE as another procedure for the same problem that produces Sharper vision, reduced Halos and better vision in dim light?

Many patients are subjected FDA approved techniques that produce these results. These are Not ethical procedures even with informed consent, but they are ongoing today.

Knowingly Not informing patients is unethical AND illegal in all 50 states.

By common law, I believe this case precedent applies to all 50 states because common law (which is not a tort) is the same everywhere.

Under common law (See Ketchup v. Howard, 2000 WL 174538, Ga. Ct. App. Nov. 29, 2000; http://agg.com/Contents/PublicationDetail.aspx?ID=840), patients are required to receive a higher level of informed consent than they are getting, but the Emory Doctors may Not train other Doctors to understand patients rights to informed consent. For instance, Dr. John Meyer (Emory trained) email me:
"In all of the surgeries I have been involved with, from my time in general surgery to now, consent forms have not listed each individual problem that can occur. If mention is made of the effect of the problem, then there is informed consent. Argument of this point would best be left to the lawyers."

2.4. Patients are Not adequately provided informed consent about the risks or about known problems found from the research that has been conducted before. NO rational person WOULD provide informed consent to the actual risks. Patients are Not told the risks or contraindications for LASIK- many of which apply to a high percentage of patients who actually have LASIK (http://www.fda.gov/cdrh/LASIK/when.htm).

>What We Should Really Tell LASIK Patients
Jack Holladay, MD, MSEE, FACS Houston
"It's important to remember that these patients' pupils did not dilate outside the ablation zone. Patients with pupils that do dilate this much could be expected to have even lower contrast sensitivity. "
"Though contrast sensitivity loss is undesirable, especially in a procedure designed to improve vision, the effects are not debilitating"
http://www.revophth.com/1999/May_articles/RPE9f5LASIK.htm

Patients are told that the LASIK flap is a "protective layer" and has other benefits, but the truth is that the flap WEAKENS the eye permanently and making the eye MORE susceptible to injury than before LASIK- that's Not "protective".
>1995 - The Emory Eye Center is one of a few centers in the country with approval from the Food and Drug Administration to sponsor a study of laser-assisted in situ keratomileusis (LASIK). LASIK corrects nearsightedness by reshaping the cornea's middle layer, leaving the top layer as a protective flap.
http://www.eyecenter.emory.edu/News_Info_History/Our_History/our_history.html

"Combining the flap with the laser provides patients with rapid recovery of vision, minimal discomfort, and the ability to fine-tune or adjust vision in the future, advantages not available with other techniques," said Dr. Waring. He served as principal investigator of the clinical research studies conducted to meet the FDA's strict requirements for examining patients following surgery and for analyzing their outcomes.
http://whsc.emory.edu/_releases/1998june/061898LASIK.html

"**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. "
http://www.fda.gov/cdrh/LASIK/risks.htm

In addition, **Patients are placed in the surgical rotation with surgeons known to have more problems on average (their own research indicates higher complication rates for the first x patients the surgeons do).** The FDA and Emory Doctors have indicated that patient outcomes vary with the experience of the Doctor. The Doctors say the techniques have improved. So why aren't less experienced Doctors better trained on the more recent techniques which are known to be SAFER AND MORE EFFECTIVE?
"So much of the outcome has to do with patient selection ... and physician experience and competence," says FDA's Beers.
"But wavefront-guided LASIK still causes new aberrations, just fewer of them, cautions FDA's Everette Beers."
http://www.cbsnews.com/stories/2003/06/02/health/main556625.shtml
Patients are Not told that the number of complications and the percentage of complications "decrease" steadily during the surgeons "learning curve". Patients are Not informed and they pay the same price for the learning curve surgeries as they do for the experienced surgeons who are ADMITTEDLY SAFER.

Here are the data for the 19 surgeons operating at Emory from the first quarter of our trial out to the seventh quarter of our trial. You can see the number of complications and the percentage of complications during this particular clinical trial over a year and a half time. You'll notice a steady decrease in these complications. In other words, there is a learning curve to LASIK, but the curve can be learned, and we combined the sixth, seventh, and eighth quarters because we had a smaller number of eyes and the complication rate intraoperatively was less than 1 percent.
What did we do to increase our safety? We trained the surgeons. We had a formal credentialing program. We videotaped every case and reviewed the cases that had difficulty, and this led to the fact that three of the 14 surgeons -- I mentioned 19 a minute ago, and that was wrong -- either dropped out or were asked to drop out of the trial because they were not comfortable doing LASIK. So we had strict enforcement criteria for our credentialing, and the increasing safety is quite apparent during this trial in terms of the complications and adverse events.
http://72.14.203.104/search?q=cache:Bl09Ag3wR9gJ:0-www.fda.gov.lilac.une.edu/ohrms/dockets/ac/97/transcpt/3315t2.rtf+diopters+saudi+arabia+waring&hl=en&gl=us&ct=clnk&cd=19
>An estimated 1 million people are expected to have LASIK surgery this year alone, he says. Less than 1% will have complications, "but for that 1%, it's a very important occurrence."
>LASIK has been around less than 10 years, but in that time, both the technology and doctors' skills have improved, Waring says. Today, both the microkeratome, the instrument that makes the flap, and the laser, which reshapes the cornea, are getting closer to foolproof, he tells WebMD. "That's why the complications are going down -- but not down to zero yet."
>Still, people are taking the surgery too casually, Waring says. He encourages those considering LASIK to ask the surgeon questions about the procedure's outcomes and complications, and to shop around. "You need to be critical of discounts, claims of perfect vision," he says.
http://www.webmd.com/content/article/25/1728_57876

>"Since we acquired the ALLEGRETTO WAVE, we are hearing things from patients treated with the Allegretto that we didn't hear with previous technologies. They are returning on the day after surgery saying that their vision is better than they ever had with glasses or contact lenses," said Dr. Doyle Stulting, MD, PhD, Medical Director at Emory Laser Vision.
http://www.highbeam.com/library/docfree.asp?DOCID=1G1:132263641&ctrlInfo=Round18%3AMode18c%3ADocG%3AResult&ao=
http://www.eyecenter.emory.edu/News_Info_History/Publications/InSights_05.pdf

Are patients with large pupils offered a larger treatment zone to reduce glare and halos? Patients are not provided the maximum treatment zone sizes or even given flaps large enough to accommodate the full treatment zone available.
"Ablation zones of 6.0 to 6.5 mm and transition zones of 8.5 to 9.0 mm were used."
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12046881&dopt=Abstract

"LASIK was performed with the Nidek EC-5000 excimer laser; ablation zones 5.5 to 6.0-mm in diameter with transition zones 7.5 to 8-mm in diameter."
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=15307391&dopt=Abstract

Treatment zone size and contours may affect vision quality.

InView	Other Center
Our lasers can be programmed for ablations up to 9.0 mm in diameter. This decreases the risk of glare and halos for patients with large pupils.	

Every Doctor knows to Not do an elective procedure on someone with a pre-existing medical condition that adds risk and restricts them from the likelihood of a positive outcome. Patients cannot provide informed consent for unethical medical procedures. These two patients were treated unethically.

> "The first patient was a patient with penetrating keratoplasty previously. He was the first eye -- he happened to be my patient -- the first eye that we did LASIK over a PK. He had had keratoconus before and we got a buttonhole in the flap because his cornea was steeply curved, and we just didn't realize that at the time. He did get some scarring in the area of the buttonhole, and that gave him a loss of three lines of spectacle corrected visual acuity.
>
> The second patient had had a previous retinal detachment repair, but had a visual acuity of 20/30 preoperatively. We also got a buttonhole in that case and the flap was put back. The healing was rather good, but during the postoperative period he developed an epiretinal membrane. He was being followed on the retina service as well, and his vision fell to 20/50, so it was probably attributed not only to his maculopathy, but possibly to the irregular astigmatism from the buttonhole flap."

http://72.14.203.104/search?q=cache:Bl09Ag3wR9gJ:0-www.fda.gov.lilac.une.edu/ohrms/dockets/ac/97/transcpt/3315t2.rtf+diopters+saudi+arabia+warning&hl=en&gl=us&ct=clnk&cd=19
And this one.

> The third patient was a physician with a refraction of approximately -22.0 **diopters** who had a technically successful LASIK, but had glare after surgery and was placed on pilocarpine, pilocarpine in both eyes to reduce his night glare, and he developed a retinal detachment in the right eye that was not repairable, and his visual acuity was approximately 20/100 at the last visit.

http://72.14.203.104/search?q=cache:Bl09Ag3wR9gJ:0-www.fda.gov.lilac.une.edu/ohrms/dockets/ac/97/transcpt/3315t2.rtf+diopters+saudi+arabia+warning&hl=en&gl=us&ct=clnk&cd=19

Emory sought approval for LASIK with far too little research. Were these research subjects provided true informed consent after the FIRST known SERIOUS PROBLEM with LASIK? If so, then why was LASIK done with an uneffective AND UNSAFE treatment range greater than 15 diopters of nearsightedness (up to a ridiculous 30 diopters)?

> Now, here are the visual acuity results, but you'll see that a substantial number of eyes, around 15 percent, could not see 20/20 or better at baseline. Why not? Because the baseline refraction went up to 22.0 **diopters**, and many of these higher myopes have myopic choreal retinal degeneration that will not allow them to see better. However, only a few eyes could see worse than 20/40, so our 20/40 cutoff here is a very good level to look at visual acuity outcomes.

http://72.14.203.104/search?q=cache:Bl09Ag3wR9gJ:0-www.fda.gov.lilac.une.edu/ohrms/dockets/ac/97/transcpt/3315t2.rtf+diopters+saudi+arabia+warning&hl=en&gl=us&ct=clnk&cd=19

> We'll present two categories of information, safety data -- and the safety data are based on the intent-to-treat paradigm. That is, every patient who entered the operating room, no matter what happened to them, whether they were treated with the laser or not, is entered into the safety data. There are no exclusions.
>
> The efficacy data, however, are based only on patients who actually received the laser ablation, so we can present to you how effective the laser ablation itself was.

http://72.14.203.104/search?q=cache:Bl09Ag3wR9gJ:0-www.fda.gov.lilac.une.edu/ohrms/dockets/ac/97/transcpt/3315t2.rtf+diopters+saudi+arabia+warning&hl=en&gl=us&ct=clnk&cd=19
"If the FDA follows the panel's recommendations, Emory will be the only center in the country to earn approval to perform LASIK."

> "This vote means that Emory has proven through extensive research that its LASIK system is safe and effective for the treatment of nearsightedness up to -15 diopters, which encompasses some 95 percent of all nearsighted patients or approximately 72 million Americans," said Dr. Stulting.

http://whsc.emory.edu/_releases/1998june/061898LASIK.html

> The agency has determined that the indication for this Emory LASIK device will be as follows. The Emory device is indicated for the LASIK treatment of myopia of -1.0 diopter to -15.0 diopters with less than 1.0 diopter of astigmatism. It is therefore important that the panel discuss whether the applicant has provided sufficient valid scientific evidence of the myopic range indicated. However, there is no need to discuss whether the astigmatic correction should be part of the indication.

http://www.fda.gov/ohrms/dockets/ac/97/transcpt/3315t2.pdf

Emory Doctors USED THIS LASER and did LASIK on patients with UP TO 20 diopters of nearsightedness (30 diopters in other studies). Clearly this was NOT SAFE, but they reported "minimal complications". The FDA only approved LASIK up to 14 diopters. Please ask these 20+ diopter patients how they're doing now!

Excimer laser in situ keratomileusis under a corneal flap for myopia of 2 to 20 diopters. CONCLUSION: Excimer laser in situ keratomileusis under a corneal flap can be an effective method of reducing myopia between -2.00 and -20.00 diopters, with minimal complications. Current surgical algorithms need modification to improve predictability of outcome. Stability of refraction after surgery requires further study.

Salah T, **Waring GO 3rd**, **el Maghraby A**, **Moadel K**, **Grimm SB**.
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8623883&dopt=Abstract

2.5. It is Not ethical to tell patients that their vision is going to IMPROVE when in fact even in most cases where the surgery is considered "successful" the patients have "difficulty in night driving". Some patients are "satisfied" with this tradeoff between gaining vision acuity without contacts or glasses and losing vision quality (ghosting and other aberrations, etc.), but EVERYONE should receive proper informed consent that LASIK is a tradeoff in many cases and loss of vision quality (including contrast sensitivity) is frequent. Furthermore, the FDA requires that patients receive the specific information in the Nidek Patient Information Booklet, but these Doctors knowingly do Not provide it to all of their patients.
Knowingly Not telling patients well known problems from the start is unethical. For instance, patients are Not told that the cornea NEVER heals from LASIK and that LASIK permanently weakens the strength of the cornea in 100% of cases. In fact, the flaps cut for LASIK have come up after accidents (airbags, sports, etc.) that would normally result in no injury at all (see http://www.fda.gov/cdrh/LASIK/when.htm).

2.6 They also omitted the true rates of actual complications. For instance, the rates of epithelial ingrowth alone were up to 10% initially.

> "The incidence has declined over the years, probably because of improved understanding of the pathology and risk factors. An incidence of 10% was more common years ago. Now, 1% is a more reasonable estimate for the incidence of clinically significant epithelial ingrowth," said Dr. Stulting.

> Although this serious problem occurs less frequently now, surgeons may still need guidance on the risk factors and how to treat ingrowth, said Dr. Stulting."

http://www.eyeworld.org/article.php?sid=3080

Dr. Waring admitted that the complication rates were high 10 years ago when he conducted the initial research, but it was already being done on thousands of patients.

> LASIK has been around less than 10 years, but in that time, both the technology and doctors' skills have improved, Waring says. Today, both the microkeratome, the instrument that makes the flap, and the laser, which reshapes the cornea, are getting closer to foolproof, he tells WebMD. "That's why the complications are going down -- but not down to zero yet."

http://www.webmd.com/content/article/25/1728_57876

2.7. Dr. Waring stated that the research was done "retrospectively" and patients were treated before prospective studies had even begun. This is contrary to Dr. Waring's statement (in 1995?) that it is "safer for patients and more rational for the profession to proceed in a graduated manner, refining the techniques and improving the results on smaller numbers of patients (or in the laboratory), and saving our mass education for the time when we have worked the bugs out of the technique and have acquired reasonably quantitative descriptions of safety and efficacy?"

> "Because the procedure was ongoing anyway, it was decided to promptly start retrospective and prospective studies. These have now been under way for several years and the results are beginning to come in. Thus, we had the unusual situation in which the statistical basis for the procedure was being developed at the same time that the procedure was actually being introduced into the US." This statement highlights a central problem—we proceed with active teaching of hundreds or thousands of ophthalmologists to use a technique that we are simultaneously figuring out how to do—including the identification of complications and statistical outcomes. Is it not safer for patients and more rational for the profession to proceed in a graduated manner, refining the techniques and improving the results on smaller numbers of patients (or in the laboratory), and saving our mass education for the time when we have worked the bugs out of the technique and have acquired reasonably quantitative descriptions of safety and efficacy?

http://www.slackinc.com/eye/jrs/vol123/edit.htm

2.8. Obtaining informed consent without patients properly understanding how their vision will look afterwards when these complications are PREVENTABLE (even if considered "side effects") is unethical.

These "Emory" Doctors (Dr. Waring, Dr. Thompson, Dr. Song, Dr. Stulting, etc.) used a Nidek laser for years. The consent form given to patients indicated that some vision problems were common, but they did Not include the actual information regarding the true complication rates in their patient consent form. On the Nidek laser, 69.0% of patients reported not just vision problems, but actual difficulty in night driving. I don't know anyone who would knowingly consent to a surgery with a 69% rate of impaired night vision, and only a 31% chance of having no vision problems at all.

2.9 Any surgery with a PREVENTABLE complication rate of MORE THAN 69% is clearly unethical- let alone for a surgery that is Not medically necessary. Patients are used to accepting some risk with surgery, but I do Not personally know anyone who would knowingly take a 69% risk of problems from surgery. Do you?

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 these Emory Doctors URGED the FDA to approve LASIK as safe anyway.

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

Laser in situ keratomileusis for myopia and astigmatism: safety and efficacy: a report by the American Academy of Ophthalmology.
Sugar A, **Rapuano CJ**, **Culbertson WW**, **Huang D**, **Varley GA**, **Agapitos PJ**, **de Luise VP**, **Koch DD**. Ophthalmic Technology Assessment Committee 2000-2001 Refractive Surgery Panel.

They omitted that 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).
Furthermore, they failed to tell their patients that there is a SIGNIFICANT risk of difficulty with vision during the day. For instance, high known rates of monocular diplopia was omitted,
Monocular diplopia related to asymmetric corneal topography after laser in situ keratomileusis. J Refract Surg. 2001 Nov-Dec;17(6):652-7.
Takei K, **Sano Y**, **Achiron LR**, **Carr JD**, **Stulting RD**, **Thompson KP**, **Waring GO 3rd**.
see
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11758983&dopt=Abstract .

> **A subjective assessment of patient symptoms was completed using questionnaires. The following complications were reported from the patient questionnaires used in the study: an increase in fluctuation of vision (40.0% pre-operatively vs. 64.3% post-operatively); glare (35.7% pre-operatively vs. 35.7% post-operatively); and difficulty in night driving (26.2% pre-operatively vs. 69.0% post-operatively).**

P.10 of 31
http://www.fda.gov/cdrh/pdf/P970053S002c.pdf

By Not providing the Patient Information Booklet, they do Not explain to patients that they really have Not determined how much more difficult than usual it will be to see in common very dim light let alone everyday indoor lighting conditions, etc.

- **Although the effects of LASIK on visual performance under poor lighting conditions have not been determined, it is possible that you 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. These effects have been reported as being more common in persons with large pupils (over 6 mm). It is possible that these may be permanent effects.**

p.23 of 31
https://www.fda.gov/cdrh/pdf/P970053S002c.pdf

2.10. The researchers were were Not surprised later when they found problems with prior LASIK techniques they used themselves on thousands of patients.

A Publicly available news article quoted another cofounder of Emory Vision saying that severe vision quality loss from higher order aberrations caused by older LASIK techniques are Not surprising.

"InView ophthalmologist Keith Thompson said the survey did not yield any surprises for doctors. Thompson also said the technology involved in the procedure has improved dramatically since the first trials."

"InView ophthalmologist Keith Thompson said the survey did not yield any surprises for doctors.
"
"Thirty-seven percent of respondents said they experienced minimal to extreme glare after the procedure; 38 percent said they still experienced some type of halo effect from mild to severe; 11 percent said they saw minor to extreme "ghost images" after the procedure."

"Seven percent reported no change and 2 percent said the procedure made their vision worse."
"One of the key issues has always been the safety and long-term assurance that the process won't have untoward effects," Thompson said. "This study gives us further confidence of its [LASIK's] long-term safety."
http://www.11alive.com/news/news_article.aspx?storyid=43304

Emory Vision indicated that better vision quality could be obtained with other LASIK techniques, but they have Not trained other Doctors to use them. The interwave technique results in

"Sharper Vision"
"Reduced Halos"
"Better Vision in Dim Light"
http://www.inviewvision.com/interwave.html

The problems with the Nidek EC-5000 laser they use are WELL KNOWN by these Doctors. "The problem with all excimer lasers on the market today is twofold. First, the engineers assumed that the cornea is spherical rather than prolate. Second, they assumed that their job was to reshape a relatively steep sphere into a relatively flat sphere, rather than to reshape a steep prolate into a flatter prolate. As a result, excimer lasers actually reshape prolate corneas into what is known as oblate...This shape is actually optically worse than a sphere, because now the peripheral rays are bent even more powerfully than in the periphery of a sphere, causing even more pronounced spherical aberration when the pupil dilates...This problem affects every patient who undergoes an excimer laser procedure to some extent." (Dr. Jack Holladay, MD, What We Should Really Tell **LASIK** Patients, Rev. Ophth., 5/99). "We need to think in detail about corneal optics after refractive surgery because the normal cornea is relatively trouble-free. The cornea after refractive surgery is not trouble-free. It frequently has a more aberrated optical performance than its preoperative counterpart. (Dr. Leo J. Maguire, Keratorefractive Surgery, Success, and the Public Health, Am. J. Ophth., Vol. 117, No. 3, 3/94). "We are actually ruining the optics of the eye when we perform **LASIK,"** Holladay said. "That's fine when the pupil is small, but as it gets larger, such as in nighttime conditions, this becomes a problem. For the last five years, I have been preaching that we should not be doing this."
http://jordan.fortwayne.com/ns/proj...asik/LASIK5.php

Standard LASIK induces lots of spherical aberrations.
"I recognized this problem with excimer lasers about 3 years ago"

"Specifically, there is not a single laser on the US market today that delivers the appropriate overall energy for the ablations we perform. The reason is that the lasers are calibrated on a flat surface, so their energy is always delivered perpendicular to the treatment site. Because the cornea is not flat, the lasers today only deliver the appropriate amount of energy to the central point of the treatment site, where it is perpendicular. As the beam moves farther out, regardless of the type of beam it is, it strikes the periphery of the treatment zone obliquely, so its energy diminishes from what is necessary for the proper ablation. Our data show that the lasers are actually undertreating in the periphery—at 6.0 mm, it is about 25% reduced from its designated calculation—and in doing so, they make the cornea more oblate, rather than preserve its natural prolate shape."
http://www.crstodayarchive.com/03_archive/0203/111.html (also
http://surgicaleyes.infopop.cc/eve/ubb.x/a/tpc/f/6541012211/m/5671005311)

This was a study of severe spherical and coma higher order aberrations with "coma mean .96, spherical aberration 1.27"
see slide 16
http://www.opt.uh.edu/research/voi/WavefrontCongress/presentations/Saturday%2003_15_03/56%20Krueger%20WFLTK-WFCONGRESS-RK.pdf

These Emory Doctors had access to a "customized" LASIK system that on average resulted in far less spherical higher order aberrations using the same laser ("Nidek EC-5000 excimer laser").

"Reduction of spherical aberration with the nidek NAVEX customized ablation system." J Refract Surg. 2003 Mar-Apr;19(2 Suppl):S195-201.

"We present a patient with good Snellen acuity but functional impairment by visual aberrations after LASIK. These symptoms resolved after an InterWave-guided LASIK multipass, multistage enhancement treatment to correct spherical aberrations."
Optom Vis Sci. 2003 Feb;80(2):93-6. **"Postoperative LASIK visual aberrations and treatment with InterWave-guided multipass, multistage correction.", Russell GE, Stulting RD, Thompson KP**

A presentation titled by Dr. Thompson:
"Why some patients see poorly after Refractive Surgery".
Why is the quality of my vision poor, but the doctor says that I see 20/20?
Aberrations degrade the quality of vision as the pupil enlarges. On a bright sunny day, patients usually have pupil sizes of 2mm or less; at night, pupils may enlarge to 7-8 mm or more and optical aberrations, if present degrade the quality of vision.
Aberrations Worsen Vision as the Size of the Pupil Increases
Optical aberrations may worsen in some patients following refractive surgery. Aberrations usually result from an irregular corneal shape caused by a non-uniform laser beam, de-centration of the treatment zone, uneven healing of the cornea or unknown factors.
Aberrations cause glare, starbursts or haloes and multiple images.
Patients may be unhappy with the quality of their vision, despite reading the 20/20 line on the chart.
At the Emory Vision Correction Center in Atlanta, we have a new instrument, the DigitalRefractometer or SRR (Spatially Resolved Refractometer), that measures the optical aberrations of the eye. This device provides much more information than the standard test lenses (phoropters) used in most doctor's practices to measure the refraction of the eye.
Patient taking an exam on the SRR
Get with Lisa for Pic
Instead of a single refractive measurement through the entire pupil, the SRR provides dozens of measurements creating a "digital map" of the eye's optical aberrations.

The aberration map helps us understand the exact cause of the patient's visual symptoms. Soon, excimer lasers will be able to create "custom shapes" to correct the irregular shape of the cornea that is the cause of the optical aberrations in many patients." Requests from subjects wishing to volunteer should be sent to Judy Walker, Director of R & D via e:mail--judywalker@emoryvision.com

We welcome all patients
Keith P. Thompson MD
Emory University Medical Director
Emory Vision Correction Center
http://www.surgicaleyes.org/SURGEYE3/tsld001.htm

A document titled
"LASIK Patient Information & Informed Consent Booklet" from Emory Vision Version 5.0 (dated 12/1/2000) and V6.0 (dated 12/2002) indicates:

"Optical aberrations:"
"It is common for patients to notice haloes, ghost images, and a slight distortion of images following LASIK". ". . .Rarely, some patients may have to curtail their night driving."

"Higher-order wavefront aberrations were almost twice as high after RK than after PRK at pupil sizes of 4 and 6 mm. Spherical aberration and coma were slightly higher after PRK than after RK." http://www.journalofrefractivesurge....asp?thing=1885

My conclusion is that this indicates severe vision quality loss from higher order aberrations were commonly caused by the Nidek laser, but these Emory Doctors did it ANYWAY.

2.11. If these acts and/or omissions as set out herein constitute a negligent and/or entire want of care so as to indicate that the acts and/or omissions in question were the result of conscious indifference to the rights, welfare or safety of the patients, or that they constitute malice, as that term is defined by law, then would it be considered malice and reckless endangerment? When viewed objectively from the standpoint of the patients at the time of the occurrence, these acts involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and did these Doctors had actual, subjective awareness of the risk involved but, nevertheless proceeded with conscious indifference to the rights, welfare and safety of others?

These Doctors knowingly engaged in conduct which resulted in NUMEROUS PERMANENT injuries; placed people at elevated risk for serious injuries; and/or were reasonably certain that their conduct would cause serious injuries. Are these acts knowingly committed considered aggravated assault which caused serious bodily injury in violation of any Penal Codes?
This is Not the first time these medical Doctors concluded that eye surgery is safe when in fact it had a LOT of problems. Although Dr. Waring stated that RK is "responsibly safe and effective" based on the PERK study (http://www.emory.edu/EMORY_MAGAZINE/winter97/inbrief.html), he later contradicted himself.
"However, many problems are associated with RK. A group led by Emory University physician, George Waring III, conducted a study on RK entitled "Prospective Evaluation of Radial Keratotomy" or simply "PERK." PERK concluded that as a result of RK, healing is slow, unpredictable and indefinite. Another complication is that corneas could also rupture during blunt trauma (fight, airbag). A study on cadavers which are deceased humans, found that RK caused an eye to rupture significantly easier than other eyes which had different, more commonly used procedures such as LASIK and PRK also mentioned in this paper. This study also found that patients who had RK in the 1980's had an increased need for cataract surgery and corneal transplants. Also, ten years post-surgery, patients still commonly experience visual aberrations such as halos and glare. Despite this, PERK surgeons, National Eye Institute, American Academy of Ophthalmology declared RK "reasonably safe and effective" So far, an estimated one and a half million people have had this procedure. "
"Another side effect of RK can be bacterial infection, which can lead to blindness in that eye. Another more common problem is a disturbance in night vision, which occurs in 45% of patients."
"The necessity of such a surgery is seriously in question. Any surgery is destructive and risks the chance of major complications. In this case, loss of vision and death are entirely possible."

(see "The History and Controversial Future of Refractive Surgery", 1999?, by Michael J. Ward who works at Emory).

Dr. Waring also knows that RK surgery resulted in loss of 2 lines of acuity in 3 % of patients in the study (Waring GO, Lynn MJ, McDonnell PJ, and the PERK Study Group, 1994; http://www.nei.nih.gov/neitrials/viewStudyWeb.aspx?id=28).

2.12. A rate of 3% or higher for a VERY SERIOUS long term complication on formerly healthy patients is TOO HIGH for an elective surgery to be ethical. A "significant decrease in vision with glasses after surgery occurred in 3% of eyes". He also knows that "Two eyes developed delayed bacterial keratitis" (http://jama.ama-assn.org/cgi/content/abstract/263/8/1083), a "shift of the refractive error in the hyperopic direction continued during the 10-year period, and this information is of key import to surgeons and potential refractive surgery candidates", and "the predictability of refractive outcome was less than desired". "Studies by Waring et al 1 looking at PERK Study results 10 years out indicated that 43% of RK patients experienced a 1D. or greater shift toward hyperopia. " (see http://www.opt.indiana.edu/aocle/livlib/post_surgA.htm).
Also "Reported side effects included glare, starbursting, and fluctuating vision."
Authors George O. Waring III, MD, Michael J. Lynn, MS, Peter J. McDonnell, MD and the PERK Study Group http://www.lasersite.com/techinfo.htm
3% of eye had a VERY SERIOUS complication that is Not safe and 43% had long term effectiveness problems, but Dr. Waring states it is "responsibly safe and effective" based on the PERK study. This is Not right for a medical Doctor in my opinion. Note that they now mostly perform LASIK on the same patients they would have performed RK on before. Why couldn't they have waited until safer and more effective solutions were available? Why can't they wait now until safer techniques are available?

2.13. **A financial conflict of interest alone should be cause to consider taking action. This IS a big conflict of interest.** Dr. Waring and other Emory Doctors conducted research and made recommendations to the FDA at the same time that Dr. Stulting (who obviously shared a financial interest in Emory Vision) was head of the FDA's Ophthalmic devices and/or a "consultant" to the panel is an obvious ethical problem.
Receiving money from a manufacturer and serving on the FDA Ophthalmic devices panel creates a conflict of interest and the appearance of a conflict of interest.

The Ophthalmic Devices Panel met on Friday, June 5, 1998, to received updated information on the activities of the Division of Ophthalmic Devices and to consider a premarket approval application (PMA) for a laser system for reducing myopia with astigmatism...

The panel members heard information on the following application for marketing:
PMA P970001 - Emory Vision Correction Center Laser System

Panel recommendation - Approvable with conditions **(unanimous)**

Conditions - recommended labeling changes to reflect panel concerns with issues of safety, post-operative stability, retreatment rates, patient satisfaction and post-operative symptoms, post-operative complications and adverse events

http://www.fda.gov/cdrh/odp.html#4562
Dr. Stulting was chair of the Opthalmic devices panel in 1997 and cofounder of Emory Vision along with Dr. Thompson, and Dr. Waring. Some other members who are now or where at the time LASIK surgeons intended to directly benefit from the FDA approval.
"Dr. Stulting, one of the physicians approved in 1994 to perform LASIK" with the excimer laser"
http://www.eyecenter.emory.edu/News_Info_History/Publications/InSights_05.pdf

"Drs. Ruiz, Soni, and Stulting will remain on as consultants to the Panel. "
"The voting member terms of Drs. Richard Ruiz, Sarita Soni, and the panel Chair, Dr. R. Doyle Stulting will be completed on October 31, 1997. "
http://www.fda.gov/cdrh/odp.html
>Doyle Stulting, M.D., Ph.D., Emory University, Atlanta, GA, presented findings from the U.S. clinical investigation. Dr. Stulting was one of the a medical monitors of the clinical study and is a paid consultant to the sponsor. The clinical study was an open label, non-comparative study in patients with 4.60 to 22.0 D of myopia. The lenses were provided in 1.00 D power increments; the 5 mm lens is available in –5.00 to –20.00 D, and the 6 mm lens is available in –5.00 to –15.00 D. Patients had eight postoperative visits.
http://www.fda.gov/ohrms/dockets/ac/04/minutes/4023m1.pdf
>This is the first time the federal agency, which typically approves devices or drugs for manufacturers, has granted approval directly to a physician team for a surgical system. Full Story

http://www.whsc.emory.edu/_releases/1998june/jun98.html
>Waring's work in refractive surgery has not been limited to radial keratotomy. He is currently the principal investigator of the first noncommercially sponsored study of laser in situ keratomileusis (LASIK). An advance over radial keratotomy, LASIK involves cutting a flap of the cornea, lifting the flap, and using a laser to sculpt the cornea's middle layer. The procedure allows doctors to correct considerably more severe cases of myopia.
>Waring directed an excimer laser study at the Yerkes Regional Primate Research Center but had to continue his work in Saudi Arabia during 1993 and 1994 because Food and Drug Administration (FDA) regulations were slowing the pace. "I was becoming frustrated by not being able to take what we had learned in the lab and use it clinically in a way that would really advance the field," he says. "We had lasers to use on people, but we couldn't because the FDA was so restrictive."
http://www.emory.edu/EMORY_MAGAZINE/winter97/inbrief.html
From the June 26, 1998 print edition
>Since 1980, Emory has been at the forefront of the research and development of refractive surgery (techniques used to reduce or eliminate nearsightedness, farsightedness, and astigmatism), and Waring has helped lead the way. According to Thomas Aaberg, professor and chair of the Department of Ophthalmology, "I think Dr. Waring is really a catalyst in clinical research who brings together insight into corneal problems and then helps to direct the clinical research into ways we can medically and surgically correct those problems."
Waring's interest in refractive surgery began in the late 1970s before it was becoming popular among ophthalmologists. He says he was troubled, though, because many surgeons were more concerned with making money from the surgery than with examining the procedure scientifically. Waring's concerns led him to develop the Prospective Evaluation of Radial Keratotomy (PERK) study, which he directed from 1980 to last year. (Radial keratotomy is a procedure in which a

surgeon uses a diamond knife to cut into the cornea and correct vision problems.) More than thirty papers were published out of the PERK study, and according to Waring, "It's a landmark study in ophthalmology, because it was the first scientific study of refractive surgery. It established radial keratotomy as a responsibly safe and effective method of correcting nearsightedness."
http://www.emory.edu/EMORY_MAGAZINE/winter97/inbrief.html
Emory Doctors also did research on the Summit laser.
Summit sells excimer lasers for use in PRK in the United States and forty other countries. Summit is located in Waltham, Massachusetts. Its laser equipment received FDA approval in 1995.
http://www.ftc.gov/opa/1998/03/eye.htm

no imported Summit lasers may be considered to be covered by those PMAs unless the laser has been remanufactured by Summit to conform to the specifications of the company's approved lasers. Unapproved lasers used outside of an FDA-approved clinical trial violate the Act.
http://www.fda.gov/cdrh/laser797.html

Can quadraplegics provide true informed consent? Can they put the required eye drop medication in their eyes every hour or even every 10 minutes as MANY patients are told to do because of LASIK induced dry eye?

LASIK surgeons know a percentage has severe dry eye and they knowingly don't do tests pre-op and/or do Not know which patients this will occur in (although many risk factors are well known).

So it is OBVIOUSLY brutal and unethical to do this on quadraplegics but they do it anyway. They WILL NOT stop unless someone with some morals and ethics intervenes. The US government is obligated to intervene, but does NOTHING. Obviously it is unethical to do LASIK on quadraplegics because they are in a compromised position, manipulable, and taken advantage of by LASIK.
>Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.
http://www.fda.gov/oc/ohrt/IRBS/belmont.html

Dr. Waring explains:
"The human eye changes its refractive state over time, which is good news for the refractive surgeon. One single refractive surgical correction is not likely to correct ametropia for a lifetime, so surgeons can make a living doing repeated refractive surgery for a lifetime."
***Enhancements Are a Reality of Refractive Surgery*, OPHTH. TIMES, 10/01.**

Emory Doctors have stated that "the necessity of such a surgery is seriously in question" and the real reason for recommending elective eye surgeries in the first place was "that a decrease in reimbursements for cataract surgery by Medicare and other managed care organizations prompted eye doctors to find other revenue generating procedures" rather than the benefit of their patients. If true, then this is Not ethical in my opinion.

"The necessity of such a surgery is seriously in question. Any surgery is destructive and risks the chance of major complications. In this case, loss of vision and death are entirely possible."

"The recent acceptance of refractive surgery is incredibly affected by financial components. An article in Consumer Reports entitled "Surgery Instead of Glasses" (February 1994) suggested that a decrease in reimbursements for cataract surgery by Medicare and other managed care organizations prompted eye doctors to find other revenue generating procedures. Since such procedures are deemed by medical insurance companies to be "unnecessary," patients must pay the bill themselves. In fact, these patients are more motivated to pay for the surgery since it can dramatically enhance one's life."

"However, many problems are associated with RK. A group led by Emory University physician, George Waring III, conducted a study on RK entitled "Prospective Evaluation of Radial Keratotomy" or simply "PERK." PERK concluded that as a result of RK, healing is slow, unpredictable and indefinite. Another complication is that corneas could also rupture during blunt trauma (fight, airbag). A study on cadavers which are deceased humans, found that RK caused an eye to rupture significantly easier than other eyes which had different, more commonly used procedures such as LASIK and PRK also mentioned in this paper. This study also found that patients who had RK in the 1980's had an increased need for cataract surgery and corneal transplants. Also, ten years post-surgery, patients still commonly experience visual aberrations such as halos and glare. Despite this, PERK surgeons, National Eye Institute, American Academy of Ophthalmology declared RK "reasonably safe and effective" So far, an estimated one and a half million people have had this procedure. "

"Another side effect of RK can be bacterial infection, which can lead to blindness in that eye. Another more common problem is a disturbance in night vision, which occurs in 45% of patients."

"But like RK, PRK is characterized by post-operative pain, a need for steroidal treatments to enhance recovery and visual aberrations such as glare and halos can occur. Halos are the rings around lights one often sees when they get a raindrop or other types of solutions in their eyes. " (http://www.cse.emory.edu/sciencenet/undergrad/SURE/Articles/1999_art_ward.html and if the website down, google's cache of the article at http://72.14.203.104/search?q=cache:D6gjRb_110cJ:www.cse.emory.edu/sciencenet/undergrad/SURE/Articles/1999_art_ward.html+&hl=en&gl=us&ct=clnk&cd=1 ; "The History and Controversial Future of Refractive Surgery", 1999?, by Michael J. Ward who works at Emory).

2.14 **During your review, Please consider where Dr. Waring and other Emory Doctors followed Dr. Waring's OWN STATED proposals for ethical research in this field.**

Please do whatever you can to stop these morally reprehensible practices and set an example of medical Doctors who continue to injure THOUSANDS of people every year.

>This is the first time the federal agency, which typically approves devices or drugs for manufacturers, has granted approval directly to a physician team for a surgical system.
http://www.whsc.emory.edu/_releases/1998june/jun98.html

I think this experiment did Not work out well. Emory Doctors promised the FDA they would properly train other Doctors in their 10-step training program, but Emory trained Doctors have admitted to reusing (without ANY sterilization) single-use medical devices used for LASIK (the microkeratome blades and canulas that come into contact with the cornea and blood which are considered highly infectious tissue).

I urge you to take the most stringent possible actions against anyone involved in these horrific reprehensible practices.

Please see attached Exhibits.

Were the interests of surgeons are put before the interests of patients?
Did the Doctors seek to:
"avoid premature teaching of evolving and unproven procedures to hundreds of surgeons who may operate on tens of thousands of patients before discovering important changes or complications."?

"contributed to our knowledge of lamellar refractive surgery and has paved the way for excimer laser in-situ keratomileusis (LASIK)"?
http://www.slackinc.com/eye/jrs/vol115/9ed.htm

What should be done about the use of unethical research?

Emory admitted to Not even DEFINING what an adverse complication was before proceeding with the research.

Let's look now at safety from the point of view of adverse events and complications. Please remember that our study commenced before the agency issued its guidance document on excimer laser surgery, so we did not have benefit of formal definitions of adverse events and complications. Therefore, in our initial document, we defined an adverse event as an unexpected event that threatened visual acuity, and we defined a nonadverse complication as an unexpected event that did not directly threaten visual acuity.
For example, a buttonhole flap is an adverse event, because it creates an irregular flap and irregular astigmatism that threatens acuity, but a free flap, cut all the way through with the loss of the hinge that can be replaced normally during surgery, does not constitute an adverse event because the surface remains unaffected and smooth, but it does constitute a complication.
http://72.14.203.104/search?q=cache:Bl09Ag3wR9gJ:0-www.fda.gov.lilac.une.edu/ohrms/dockets/ac/97/transcpt/3315t2.rtf+diopters+saudi+arabia+warning&hl=en&gl=us&ct=clnk&cd=19

Dr. Waring admitted to BOTH identifying AND PARTICIPING in "THE PATTERN"

PROBLEMS WITH THE AGGRESSIVE MARKET APPROACH

All of the above procedures have increased our knowledge of refractive surgery but I think the clinical morbidity has been too great, as a result of free market madness and its fundamental flaws:

1. The interests of surgeons are put before the interests of patients.
2. Too many procedures are done on too many patients before the risks and benefits are well defined.
3. The surgeon's true belief that each technique is a real advance reduces his or her ability to see and report complications and then to document the reasons that the procedure was stopped or changed.
4. There is inadequate collection and reporting of early clinical data.

Initially, the complications are given little public attention, for fear of lawsuits against the surgeon, to avoid tarnishing the growing reputation of the new procedure, or because of lack of understanding of the complications by practitioners, who sometimes behave like the crowd that extolled the beauty of the emperor's new clothes.

Finally, the procedure quietly disappears, sometimes because publications detail less-than-satisfactory results or a spate of complications, but more commonly because of unsatisfactory personal experience. Seldom do surgeons publish articles that detail their negative experiences and reasons for abandoning the technique.

Many refractive procedures have passed through this pattern. Let's look at three.

http://www.slackinc.com/eye/jrs/vol115/9ed.htm

Dr. Waring identified the adverse, unethical consequences to patients.

Most surgeons have stopped doing hexagonal keratotomy--but only after a few thousand patients had received it, many with poor results.

The procedure fell under the auspices of the FDA; AMO stopped making the lenticules, and most surgeons abandoned it, without publication of the follow-up results and complications.

Automated Lamellar Keratoplasty

it suffers from two fundamental flaws:

Nevertheless, the technique was imported to the United States and propagated widely in courses by Slade and Casebeer with Chiron Vision sponsorship before publication of results.

ALK spawned surgical aberration, capless ALK, propagated by Hollis(17) after he observed that when a cap was lost, the corneal bed reepithelialized and the eye retained a refractive change. He reasoned that this approach was not completely different from excimer laser photorefractive keratectomy. Capless ALK was short-lived because it caused irregular astigmatism and corneal scarring in some eyes.

More Examples

Other procedures have been done in hundreds or thousands of eyes, before problems were detected:

- Connected trapezoidal keratotomy for astigmatism with the complication of poor corneal wound healing.
- High-vaulted Baikoff phakic anterior chamber intraocular lenses for myopia with the complication of endothelial cell damage.

· Deep lamellar keratotomy for hyperopia (hyperopic ALK) with the complication of corneal ectasia when the incision was more than approximately 70% deep.
· Excimer laser photorefractive keratectomy with a 4.5-mm diameter ablation zone for myopia greater than 10.00 D with the complications of corneal scarring and regression of effect.
· Hot needle radial thermokeratoplasty of Fyodorov with the complication of induced irregular astigmatism and regression of effect.
· Radial keratotomy with small diameter clear zones with the complication of irregular astigmatism.

http://www.slackinc.com/eye/jrs/vol115/9ed.htm

Dr. Waring also stated "10 proposals for rational evaluation" of the procedures used.

PROPOSALS FOR MORE RATIONAL EVALUATION

How can refractive surgeons and commercial firms most responsibly introduce and evaluate new refractive surgical procedures, encourage innovation and early adaptors, and at the same time prevent complications in large numbers of patients? Consider 10 idealistic proposals:

1. Strive to maintain an attitude of professional restraint that honestly and compassionately minimizes risks for patients. Bona fide oversight by an institutional review board can help surgeons investigate new ideas.
2. Resist the professional and business pressures that create a mindless rush to be the first doctor with the latest procedure in the most patients for the greatest profit.
3. Evaluate new techniques by uniform international standards. Stating "He has done hundreds of cases and the results are great; he just doesn't publish much" is inadequate.
4. Retain critical discussion of papers presented at meetings to challenge unsupported conclusions and to expose biased claims.
5. Couple a staged evaluation of new techniques with accurate reporting of the results in consecutive series of eyes using a Phase I, II, III paradigm to solve problems and change techniques initially in a small number of eyes.

Phase I

Initial determination of basic effectiveness and safety at one or two locations on a small number of eyes (eg, 10 to 20) with 3 to 6 months follow up.

Phase II

Refinement of techniques and devices at multiple locations (eg, 5 or 6) in a larger number of patients (eg, 100) with approximately 6 months follow up. This is usually done by colleagues or the originator or by surgeons selected by manufacturers.

Phase III

Determination of effectiveness and safety at multiple sites (eg, 10 to 20) on a few hundred patients (eg, 500 to 1000) followed for 1 year or more.

The specific numbers can be altered for each procedure, but this gradual approach with its requisite reporting of results and independent peer review seems appropriately protective of patients, appropriately graded for clinical development by investigators, and appropriately staged for technical development by commercial firms.

6. Establish guidelines for conducting clinical trials in refractive surgery through the International Society of Refractive Surgery (ISRS) and other concerned organizations, as has been done for treatments of lacrimal dysfunction by participants in a National Eye Institute Workshop.(20) Standards for reporting refractive surgical procedures have been published in this Journal.(21) The FDA held hearings to establish outcome standards for laser corneal surgery on July 20, 1995.

7. Disclose the weaknesses and drawbacks of a technique while extolling its virtues and advantages, so that more impressionable colleagues will have a balanced view and a cautious approach. During development, evaluate it; don't sell it.
8. Publish and present papers and developments to actively inform the profession and the patients of new innovation; peer-reviewed journals will publish letters to the editor, brief reports, case studies, preliminary results, in addition to detailed original articles.
9. Avoid premature teaching of evolving and unproven procedures to hundreds of surgeons who may operate on tens of thousands of patients before discovering important changes or complications.
10. Publish negative results and reasons why a technique should be or has been abandoned to minimize repetition of the same problems. This process, similar to postmarket surveillance, may last for years, as occurred with documentation of the hyperopic shift after radial keratotomy.
http://www.slackinc.com/eye/jrs/vol115/9ed.htm
Dr. Waring stated that
We have a responsibility to our patients and our peers to evaluate new procedures gradually, with documentation of the results—both positive and negative—prior to widespread educational dissemination. This is the thrust of my 10 idealistic proposals for a more rational evaluation of new procedures, proposals that both encourage innovation and early adapters and at the same time prevent complications in large numbers of patients.
This cautious approach seems particularly appropriate when the disorder under consideration—refractive errors—can be managed by spectacles or contact lenses or by other elective surgical procedures.
The lust for that power is one of the forces that drives free-market madness. I hope my 10 proposals for rational evaluation of new refractive surgical procedures will stimulate more correspondence and discussion, such as Dr Casebeer has provided, and will reduce somewhat the appetite for personal, institutional, and corporate power in the treatment of our patients.
http://www.slackinc.com/eye/jrs/vol123/edit.htm
Dr. Waring stated that FDA approval was important to him.
This is the first time the FDA ophthalmologic branch has granted premarket approval directly to ophthalmologists. Previous approvals have been granted to manufacturers of ophthalmic devices. Physician-sponsored investigation is one way the FDA is exploring to decrease the time it takes to review and approve for medical technologies in the United States. "This is an extremely important for the FDA and for ophthalmologists, because it puts the practicing physician squarely in the middle of the regulatory process, rather than as a passive bystander waiting for the industry and the government to decide what the physician can and cannot do," says **Waring**.
http://72.14.203.104/search?q=cache:NYi2eTEDI5kJ:www.whsc.emory.edu/_releases/1997august/LASIKfda.html+waring+perk+LASIK&hl=en&gl=us&ct=clnk&cd=16

But research was conducted and FDA approval recommended without enough data collected.

There are many questions and few answers because of the limited data available in the literature. Therefore, I encourage our professional societies to build a forum on the Internet to collect data on cases of iatrogenic keratectsia. With a larger database, we could determine recommendations for a minimal residual stromal thickness, which would benefit us and our patients. "
http://www.ascrs.org/publications/jcrs/gueditoct9.htm

"This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects."
http://www.fda.gov/oc/ohrt/IRBS/belmont.html
Did Dr. Waring, for instance, properly consider the well-being of the subjects?
"When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research, except where the research is directly related to the specific conditions of the class involved."
http://www.fda.gov/oc/ohrt/IRBS/belmont.html

[Dr.] Waring directed an excimer laser study at the Yerkes Regional Primate Research Center but had to continue his work in Saudi Arabia during 1993 and 1994 because Food and Drug Administration (FDA) regulations were slowing the pace. "I was becoming frustrated by not being able to take what we had learned in the lab and use it clinically in a way that would really advance the field," he says. "We had lasers to use on people, but we couldn't because the FDA was so restrictive."
In Saudi Arabia, Waring worked with other surgeons to refine and develop LASIK. He cautions, however, that their research was not random human experimentation. "I was able to set up a clinical research effort in Saudi Arabia to see how these new techniques worked on people," he says. "These were formal clinical trials done in a responsible clinical way, and we have now published a dozen papers from those trials."
When Waring returned to the United States, he applied to the FDA and received the first investigational device exemption to study LASIK in this country. Combining his experience in radial keratotomy with his research in LASIK and other refractive techniques, Waring recently joined with a number of colleagues to create the Emory Vision Correction Center, which is the largest refractive laser center in America.
http://www.emory.edu/EMORY_MAGAZINE/winter97/inbrief.html

As the research has been "published" in the U.S. "from those trials" and used by other researchers and the FDA to indicate that LASIK is "safe", I ask Emory to review whether or Not "These were formal clinical trials done in a responsible clinical way" that FOLLOWED the FDA's established guidelines. Based on Dr. Warings statements above, I believe these guidelines were knowingly Not followed.

For instance, Did Dr. Waring provide true informed consent in these and other clinical trials regarding LASIK, RK and other eye surgery? He has stated numerous times that there are many problems that patients are Not told about. Even now in the US, with LASIK 93% are satisfied and 7% are not http://www.lasereyesurgery.com/article.asp?id=7.

Were patients given a choice between having two procedures or one (they were intentionally left nearsighted with the first procedure)?

We conducted this trial in two steps, in a sense. That is, every patient received a primary procedure and, as I'll discuss in a moment, we undercorrected on purpose to prevent overcorrections, and went back and did enhancement procedures as an integral part of our approach.

http://72.14.203.104/search?q=cache:Bl09Ag3wR9gJ:0-www.fda.gov.lilac.une.edu/ohrms/dockets/ac/97/transcpt/3315t2.rtf+diopters+saudi+arabia+warin g&hl=en&gl=us&ct=clnk&cd=19

Were patients told that even MORE patients lost 2 or more lines of best corrected visual acuity from LASIK than from RK (4 vs 3%)?

Now, here's an example. Here's our Group 1 data, all 1,048 eyes, and here are the number evaluated at each of the follow-up visits, 1,063 in the final acuity, and you will see that there is 8 percent losing two or more lines at three months, but as we go out the follow-up curve we look at the final visual acuity for each eye at its last visit, and that's 4 percent of the eyes losing two or more lines.
http://72.14.203.104/search?q=cache:Bl09Ag3wR9gJ:0-www.fda.gov.lilac.une.edu/ohrms/dockets/ac/97/transcpt/3315t2.rtf+diopters+saudi+arabia+warin g&hl=en&gl=us&ct=clnk&cd=19

Why did they "freeze the database" to only collect exit questionnaires on 140 patients when thousands of patients were in the study?

This is the exit questionnaire, if you please, and we had about 140 people at the time the database was frozen that completed this questionnaire. We asked a lot of questions, but there are two very important questions here that I'll present the results of to you.
http://72.14.203.104/search?q=cache:Bl09Ag3wR9gJ:0-www.fda.gov.lilac.une.edu/ohrms/dockets/ac/97/transcpt/3315t2.rtf+diopters+saudi+arabia+warin g&hl=en&gl=us&ct=clnk&cd=19

Were patients who had more than 15 diopters of nearsightedness (up to 30 diopters) informed that it was known Not to be safe to treat more than 14 (certainly 7) diopters of nearsightedness (LASIK is now known to be unsafe even at 14 diopters)?
The Emory Vision Correction Center is requesting FDA's approval of the medical device which is comprised of the following: an automated microkeratome; Summit Technology Omnimed laser hardware; Summit Technology laser software, single zone, which is currently approved in the United States for PRK for eyes with myopia less than or equal to 7.0 **diopters** at the spectacle plane, and multizone software, Version 2.6.2, not previously approved for marketing in the U.S., for eyes with high refraction; and revised nomogram for LASIK ablation.

The clinical protocol for this study was originally approved for treatment of myopia up to 30.0 **diopters**. In the investigation, myopia was treated for spherical equivalent refraction from -0.25 to 21.25 **diopters**. The data analysis revealed that although LASIK is technically capable of correcting myopia up to 22.0 **diopters**, the corrections greater than 15.0 **diopters** were more likely to have subtle wrinkles in the flap, a less accurate refractive outcome, and glare symptoms under dilated pupil conditions. Therefore, the proposed indication is up to 15.0 **diopters**.

Astigmatism from 1.0 to 4.0 **diopters** was treated in this trial using arcuate transverse keratotomy. The sponsor considers the ARC-T operation a matter of medical practice, and is not requesting this as an indication in this PMA.

http://72.14.203.104/search?q=cache:Bl09Ag3wR9gJ:0-www.fda.gov.lilac.une.edu/ohrms/dockets/ac/97/transcpt/3315t2.rtf+diopters+saudi+arabia+waring&hl=en&gl=us&ct=clnk&cd=19
The baseline refraction indicates that half of the eyes were more than 7.0 **diopters** myopic, up to 22.0 **diopters**, so that half the eyes, if treated in the United States today, could not have been treated by the excimer laser with PRK. This is very important because it emphasizes the expanded range that LASIK can treat.
http://72.14.203.104/search?q=cache:Bl09Ag3wR9gJ:0-www.fda.gov.lilac.une.edu/ohrms/dockets/ac/97/transcpt/3315t2.rtf+diopters+saudi+arabia+waring&hl=en&gl=us&ct=clnk&cd=19

Emory Doctors admitted to Not providing PROPER follow-up for these patients due to lack of funding.
Our resources at Emory were limited. We paid for the trial out of clinical income. We had no extra money for the trial, and we could not hire more personnel to do the follow-up and to bring the patients in for follow-up, so that's why we have a 70 percent follow-up at six months
http://72.14.203.104/search?q=cache:Bl09Ag3wR9gJ:0-www.fda.gov.lilac.une.edu/ohrms/dockets/ac/97/transcpt/3315t2.rtf+diopters+saudi+arabia+waring&hl=en&gl=us&ct=clnk&cd=19

Dr. CaseBeer stated:

> Given the failure of the universities and the ineptitude of the FDA, the private practitioner and industry have joined forces to create an effective operational unit for the introduction of technology.
> When I first saw ALK performed by Dr Ruiz in Bogota in August, 1992, it was apparent to me that he had solved the basic mysteries and problems of keratomileusis. It was also obvious that ALK was coming to the US, with or without statistical backup, and in fact, some 10 or 15 practitioners already had acquired the units and were beginning to do the procedure.
> I will be the first to admit that the introduction was difficult. However, there is no question in my mind that it was the unique combination of the caring private practitioner, with reasonable investigative skills and education, and controlled sale of the instrumentation through education, that led to a successful outcome.
> http://www.slackinc.com/eye/jrs/vol123/edit.htm

Dr. Waring did Not properly assess the risks and benefits of LASIK surgery. I request that Emory do a follow-up of the patients he did the research on in Saudi Arabia to see whether the risks were too high for the benefit to these research subjects. The risks are well KNOWN to be too high for the way Emory trained Doctors to perform LASIK (see information below) so I suspect they were too high for this study as well.

Patients were Not properly informed that their LASIK was KNOWN to be unsafe and uneffective at the time it was performed.

> Now, here are the visual acuity results, but you'll see that a substantial number of eyes, around 15 percent, could not see 20/20 or better at baseline. Why not? Because the baseline refraction went up to 22.0 **diopters**, and many of these higher myopes have

myopic choreal retinal degeneration that will not allow them to see better. However, only a few eyes could see worse than 20/40, so our 20/40 cutoff here is a very good level to look at visual acuity outcomes.

http://72.14.203.104/search?q=cache:Bl09Ag3wR9gJ:0-www.fda.gov.lilac.une.edu/ohrms/dockets/ac/97/transcpt/3315t2.rtf+diopters+saudi+arabia+warin g&hl=en&gl=us&ct=clnk&cd=19

We did a number of trials over there, one published in the AJO, another comparing LASIK in one eye versus PRK in the other eye of the same patients, and my personal conclusion was that LASIK was a preferable procedure to PRK.

However, there was little published data at that time. Our paper was one of the first ones. We didn't know very much about the formal safety and efficacy, and indeed, at the time of PRK approval in the U.S., LASIK was not a labeled indication for the use of the excimer laser.

...

The background objectives that we had were to correct myopia from 2.0 to 30.0 **diopters**. You'll notice in our labeling request we're asking only up to 15, and we'll explain the reason for that as we go.

We had new laser software provided by Summit.

Fourteen surgeons participated in this trial at Emory. Now, this is very important because you are seeing data that's presented as a real world, multiuser -- even though it's one site -- experience. This is not data coming from three skilled surgeons who've had a lot of experience, but many of these surgeons had their first experience as part of this trial, so you are seeing real world data.

Some of you may not be familiar with LASIK, and let us show you just a brief video clip of how LASIK is done. As Dr. Waxler emphasized, the microkeratome and the whole procedure is part of our application. The procedure is done outpatient, topical anesthesia only, lid speculum after a prep and drape, and marking of fiduciary lines on the cornea to line up the flap again when it's created.

http://72.14.203.104/search?q=cache:Bl09Ag3wR9gJ:0-www.fda.gov.lilac.une.edu/ohrms/dockets/ac/97/transcpt/3315t2.rtf+diopters+saudi+arabia+warin g&hl=en&gl=us&ct=clnk&cd=19

3. Actions requested for the FDA

What rule, order, or other administrative action does the petitioner want FDA to issue, amend or revoke?

The Petitioner is willing to work with the FDA and any other Federal agencies in assisting with further development of the implementation of any injury prevention efforts including, but not limited to the following actions.

3.1 ACTION 1. The Petitioner request a moratorium on any further non-medically necessary elective eye surgeries other than for strict humanitarian purposes.

The severity, totality of the risks (and their likelihood) of actual injuries to the public that have occurred from the actual practice (including non-research centers) of non-medically necessary

elective Refractive Eye Surgeries are a larger risk to the public health than identified in previous research and Prudent injury intervention strategies are Not feasible to adequately protect the Public from injury.

There is a precedent for this recommendation: "The Food and Drug Administration today called for a moratorium on the use of silicone gel breast implants until new information on their safety can be thoroughly reviewed by an independent advisory panel and the agency can make a final decision in light of the panel's review." (http://www.fda.gov//bbs/topics/NEWS/NEW00263.html).

ACTION 2. The Petitioner believes that the potential risks versus possible benefits assessment favor a moratorium and/or withdrawal of FDA approval for these devices.

There is a precedent for this recommendation: "The FDA brings together its General and Plastic Surgery Devices Panel to review all of the safety data from the manufacturers' PMA's. The purpose of the panel is to advise FDA as to what they could tell the public about the safety and effectiveness of the silicone breast implants based on the PMA's. The panel is composed of a broad range of experts, including representatives from the fields of plastic surgery, oncology, epidemiology, internal medicine, immunology, radiology, pathology, gynecology, toxicology, sociology, biomaterials and psychology, as well as industry and consumer groups. The panel hearing rejects the data from Dow Corning, Mentor, McGhan, and Bioplasty, concluding there is not sufficient data about the risks and benefits of the devices. The panel recommends the devices stay on the market temporarily and with limited access. The need for more safety data is stressed." (http://www.pbs.org/wgbh/pages/frontline/implants/cron.html)
Review each of these class I devices to assess whether the device is EITHER as safe or substantially equivalent to the legally marketed devices that were or are currently on the U.S. market that the manufacturers used for comparison purposes in their 510(k) submissions for their PMA approvals (http://www.fda.gov/cdrh/dsma/pmaman/front.html; http://www.fda.gov/cdrh/dsma/pmaman/Table%20of%20Contents.html#TopOfPage). As part of this surveillance process, the Petitioner also ask the FDA to consider whether the manufacturers certification that "a reasonable search of all information known or otherwise available about the class I device and other similar legally marketed devices has been conducted (class I certification) (k) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted." Is reasonable based on the available evidence at this time. (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807). See Appendix B and C for further discussion and consideration of this action.

3.3 ACTION 3. Hold an Ophthalmologic advisory panel meeting to consider the research, medical ethics, and any surveillance data to decide whether there is now sufficient data on safety and effectiveness for these class I devices to continue to serve a public health need and whether they should continue to be approved by the FDA. At what point are the risks of certain types of procedures, equipment or procedures significantly higher such that they should banned?

3.4 ACTION 4. Oversee the entire life cycle of these devices--from production through distribution, and consumption/use of these class I devices to assess whether the products are as safe as labeled and safe period as stipulated in their PMA approvals.

The Petitioner challenges you to review suggestive findings regularly to identify how some modifications to the potential "candidates" might be safer for the Public Health. Isn't the first priority to "first do no harm"?
For the Agency to oversee their entire life cycle--from production through distribution, and consumption/use of these class I devices to assess whether the products are as safe as labeled and safe period as stipulated in their PMA approvals. Along with this after market surveillance process, the Petitioner also ask the FDA to reconsider whether the potential risks versus possible benefits assessment favor this action, whether SSED documents provide a reasonable assurance of safety and effectiveness for the device as labeled based on the nonclinical and clinical studies described in the PMA, and whether the SSED accurately summarizes both the positive and negative aspects of the scientific evidence as required for each PMA (http://www.fda.gov/cdrh/dsma/pmaman/sec03.html#P784_26552). The Petitioner also ask the FDA to consider whether the manufacturers certification that "a reasonable search of all information known or otherwise available about the class I device and other similar legally marketed devices has been conducted (class I certification) (k), and whether all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted and was reasonable based on the available evidence at that time" (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807).

3.5 ACTION 5. Conduct a retrospective comprehensive study of the incidence and prevalence of injuries to track ALL the relevant risks. Gather and collect all surveillance and monitoring data to allow proper education and targeting of interventions. Could the Medical Device Surveillance Network, MedSuN program be used for this purpose? The United Sates Eye Injury Registry (USEIR; http://www.useironline.org/Index2.html), a federation of state eye registries, uses a standardized form to obtain voluntarily reported data on eye injuries.
Many public health safety issues have Not been adequately researched.

3.6 ACTION 6. If newer devices become available which have better safety records, then remove the approvals for the older devices. For instance, Intralase lasers have been shown to have a much better safety record (as much as 10 times fewer problems and less serious problems) than mechanical Microkeratome blades for making LASIK flaps. Simply remove the approvals for the older mechanical Microkeratome blades unless they can be shown to be as safe as the newer Intralase lasers.

3.7 ACTION 7. Develop a national agenda for the prevention of injuries from elective refractive eye surgery and implement it through coordination of federal efforts across a variety of private and public agencies including the Department of Health and Human Services. Uniform legislation should be required by law, enacted and enforced in every state to mandate specific minimal safety practices.

The SAFEST possible procedures should be standardized including the best possible equipment preparation and cleaning procedures.

3.8. ACTION 8. Place a moratorium or withdraw approval for any devices already approved as "safe" that are known or shown to be more risky to patients or Not as "safe" as other devices.

4. ENVIRONMENTAL IMPACT STATEMENT

Petitioner claims there is No known environmental impact for any of the actions included in this petition. If applicable, petitioner claims categorical exclusion under 21 CFR 25.30, 25.31, 25.32, 25.33, or 25.34.

5. Certification

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

Michael Patterson 5/11/06

Michael Patterson

[redacted]

exemption 6

[redacted]