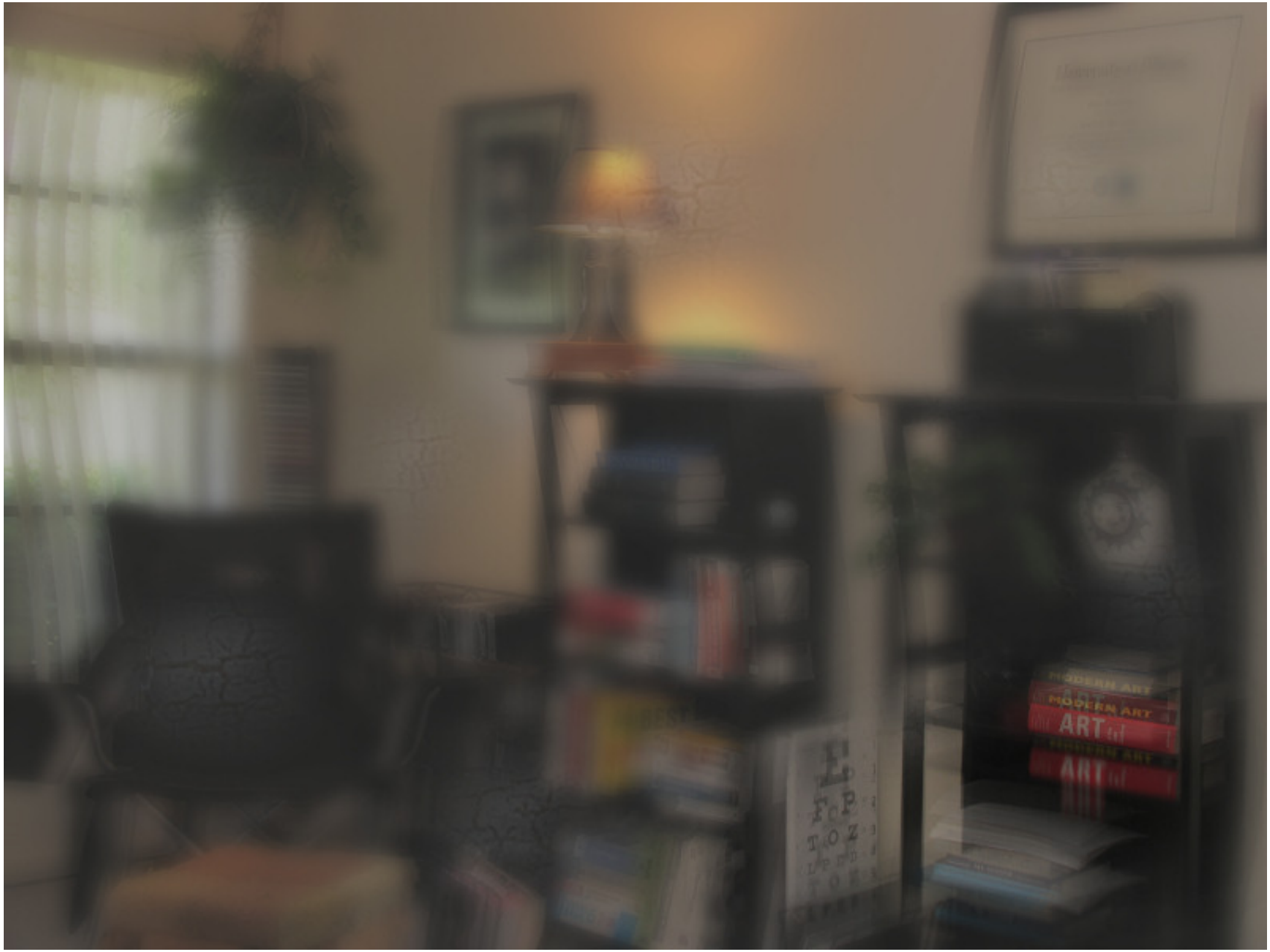
STOP using medical devices for LASIK. This is a simulation of the vision in my left eye. LASIK ruined my vision and my quality of life.



Not All 20/20 Is The Same

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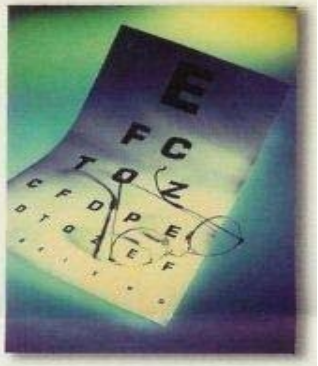
Excimer lasers have been used to correct the nearsightedness, farsightedness and astigmatism of over six million people worldwide. An estimated 98% of these patient are now seeing 20/20 to 20/40 without glasses. With such impressive results, how could you expect laser vision correction to improve?

Quality vs. Quantity of Vision

Since the mid-1800s doctors have measured vision by having patients read letters on a standard Snellen Eye Chart. Doctors consider your vision "normal" if you can identify the small letters on the 20/20 line from a distance of 20 feet. But scoring 20/20 on your vision test doesn't necessarily mean you have excellent vision, especially if the letters you are able to identify are not crisp and clear.



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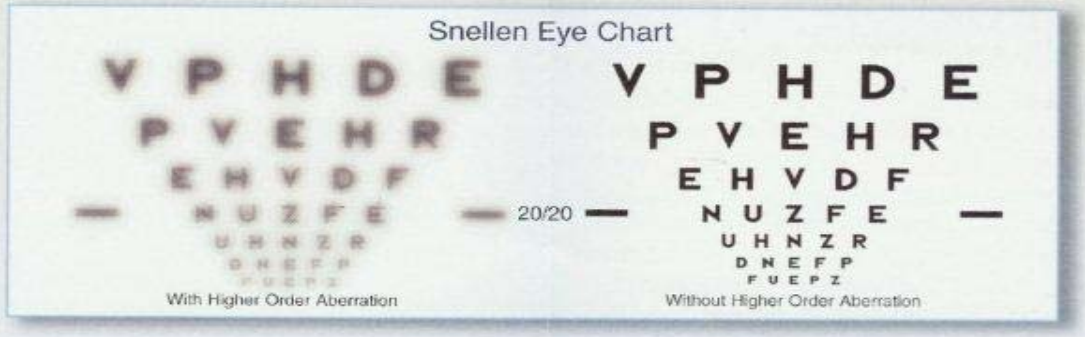

These images show what a Snellen Eye Chart would look like if "higher order aberrations" were present after conventional laser vision correction. Although this person can identify the 20/20 line, the quality of his or her vision would not be ideal

Partial List of my LASIK Complications

- Reuse of the microkeratome blade (stuff is under the flap)
- Microkeratome Failure
- Scar in cornea
- Dry Eye
- Blepharitis
- Striae in cornea
- Ridge in cornea
- Higher Order Aberrations
- Epithelial ingrowth
- Flap Melt
- DLK
- Keratitis

Note: from Different Doctors

Michael Patterson's 5 minute 4 hour FDA Presentation Summary. npatter9@hotmail.com

1. The FDA states Safety was determined with a risk/benefit analysis.

- Where is it? Make the formal risk/benefit analyses public! The risks of cutting a flap for LASIK far outweigh the benefits.
  - Quality of vision and Dry Eye rivggsks were Not evaluated
- I believe no risk/benefit analysis was actually done and the FDA will Not compare the safety of these dangerous devices to any alternative like contacts.
- What value was put on human injury and suffering in the FDA's analysis?
- Clinical trials are Not FDA risk/benefit analyses

Devices approved for LASIK are Not “safe” because cutting a flap for LASIK is Not safe

- A failure rate of 5% or higher is Not safe and the Post-Market Standard of Care for LASIK is Not safe.
- Why aren’t Doctors reporting the truth to the public and the FDA?
- Compared to glasses or contacts, there’s **no way** the benefits of LASIK outweigh the risks of severe permanent injury for life.
  - Contact lenses have the same benefits with far less risks, but Doctors lie about that too.
  - As history already shows, true rates of complications are not reported.
- If the FDA followed Federal Law, Lives can be Saved.

2. Regarding the FDA Not taking any action to regulate LASIK centers under FDA MDR regulations like 21 C.F.R. Part 803

- LASIK Surgery centers meet the Device User Facility definition as an “ambulatory surgical facility” (“ASF”).
- CFR 803 requires the FDA to regulate LASIK centers including their reporting and written procedures
- What has the FDA done
  - To inspect any LASIK facility for written procedures or for Not making reports to the FDA?
  - To assure that each Lasik center follows the ASF procedures like maintaining files and reporting to the FDA!
- Will the FDA explain how they know these Lasik ASFs are complying? Probably Not.
- What FDA "surveillance" program confirmed that LASIK ASFs are reporting adverse events that occur in the ASFs to the FDA?

Disclosing FDA inaction in this public forum is shocking.

- I am skeptical about the ability of the FDA CDRH to explain or defend its performance in public!
  - I would not be surprised to learn that few if any of these ASF "centers" meet the requirements.
- LASIK is a surgery done on millions of people.
- MDR regulation 21 C.F.R. Part 803
  - Defines Device User Facility and includes "ambulatory surgical facility" ("ASF")
  - I believe this encompasses LASIK "centers.“
  - The types of adverse events and serious injuries LASIK victims suffer from must be reported by the ASFs to the FDA.
  - Annual reporting of MDR events submitted on FDR FORM 3419.

Publicize the FDA's lack of action! Please!

- If my suspicion is correct, the FDA has been intentionally **negligent** in the discharge of its responsibility to assure compliance with the MDR regulations.
- Why have there been so few Adverse Event reports to the FDA despite numerous consumer reports?
- By statute, ASFs are required under penalty of law to report device malfunctions.
- This includes a responsibility by physicians where reportable events are observed.
- The reporting requirements apply regardless of clearance and approvals, etc.
- I presented the FDA with evidence of unreported Adverse Events, but the FDA did nothing

3. Regarding bias in the LASIK Quality of Life Study

- The AAO and NEI should be involved, but ASCRS (American Society of Cataract and Refractive Surgery) involvement represents an obvious conflict of interest.
- Researchers Should
  - Not have already drawn a conclusion about Quality of Life and LASIK
  - Not have a financial interest in LASIK or a bias.
- Yet ASCRS has already announced 3 LASIK surgeons for the study.

The FDA knows there is a study showing a connection between LASIK and suicide

- A significant correlation between these two separate events connects them.
- The medical community should know that LASIK patients may be committing suicide at four times the expected rate. That's huge.

LASIK surgeon Dr. Richard Lindstrom

- Has financial interests in the device manufacturer or the procedure.
- Has already drawn his conclusion about quality of life after LASIK
  - He wrote that “no published scientific evidence supports a connection between LASIK and suicide”.
    - I believe this is misleading because I talked to numerous post-LASIK patients with suicidal thoughts, www.lasikmemorial.com and the DSM has diagnoses for Mood disorder due to a General Medical Condition (283.83)
    - From March 5th, 2008 letter titled "LASIK Safety,“
  - He is an Ophthalmologist - not a Psychologist or Psychiatrist.
- Having already stated his bias, I believe he Should Not be allowed to design and conduct a post-LASIK study in connection with the FDA’s post-market review of LASIK.

(Conclusion) After submitting 4 petitions, I ask this Panel and the FDA

- **1. To redo the FDA Risk/Benefit analysis for LASIK**
  - Report the serious nature of the risks from the actual post market standard of care.
  - **Include all the post market risks** like vision quality problems and dry eye!

  We don't do anything to the microkeratome in-between eyes." say the Doctors [emphasis added]
  http://www.fda.gov/OHRMS/DOCKETS/AC/97/transcpt/3315t2.rtf
- **2. For the FDA to regulate LASIK centers as ASFs under existing FDA MDR regulations like 21 C.F.R. Part 803**
  - LASIK surgery centers meet the Device User Facility definition as an ASFs, CFR 803.17
- **3. For the Quality of Life study to use qualified professionals who are completely independent of the LASIK industry.**
  - Do Not allow biased research, but if there is bias then allow equal bias on both sides

- 4. For a moratorium on the devices used for LASIK because LASIK surgery is far too risky and the research was Not ethically done.
- 5. Evaluate Potential LASIK Dry Eye Treatments like Unscented Natural Body Butter from www.mercola.com
- 6. STOP LASIK

LASIK drastically diminishes quality of life far too often!

- 7. I ask for a CRIMINALinvestigation of Doctors knowingly violating FDA labeling and injuring patients- "negligence per se" (e.g., Doctors reusing SUDs like the microkeratome blades), Wanton Endangerment, intentional negligence known to injure patients, failure to warn, etc. HHS OIG, FBI, DOJ, FTC, etc. and State level.

Evidence is in the transcripts from panel meetings.
http://www.fda.gov/OHRMS/DOCKETS/AC/97/transcpt/3315t2.rtf

And in industry publications- e.g.,
http://www.cse.emory.edu/sciencenet/undergrad/SURE/Articles/1999_art_ward.html

http://druganddevicelaw.blogspot.com/2007/01/defenses-to-fdca-based-negligence-per.html

I ask for an investigation by the FDA Office of Criminal Investigations (OCI) of knowingly violating FDA labeling and injuring patients.

- negligence per se (e.g., Doctors reusing SUDs like the microkeratome blades) causing injuries of thousands, Wanton/Reckless Endangerment, intentional negligence known to injure patients, failure to warn, etc.

- Is it criminal to lie to patients and Not publish evidence of an increase in suicide rates? To Not prescreen patients for mental health issues prior to LASIK? Even cause suicides?

- Many Patients considered themselves victims of a medical conspiracy. I have evidence I can provide prosecutors.

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http://lawschool.mikeshecket.com/torts/bartolonevjeckovich.htm

Recently, I discovered a potential LASIK Dry Eye treatment on my own

- Over the last 7+ years, I've tried DOZENS of prescription medications and several other treatments.
  - NONE OF THEM WORKED by themselves!
  - Steroids cause bad problems- cataracts, glaucoma, etc.
- **The skin lotion below is Not a cure for LASIK dry eye.** LASIK permanently cuts the nerves in the cornea and they will Never grow back the same.
- Using Unscented Natural Body Butter on my eyelids seems to help, but my dry eye is still bad enough that my life is still ruined.
- Combined with other treatments that did not work on their own (restasis, xibrom, warm compresses, theratears, etc.)

http://products.mercola.com/natural-body-butter/

- **Unscented Natural Body Butter** is made from:
  - Monolaurin
  - Organic Aloe Vera Juice
  - Organic Virgin Coconut Oil

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- I am reporting a serious vision quality loss, microkeratome failure, scar, epithelial defect, striae, damage to bowman's membrane, blepharitis, and reuse of the microkeratome blade, a Single Use Device.
- The FDA does criminal investigations, but will Not do one regarding LASIK.
  - "A person could defraud or mislead the FDA preventing the agency from conducting its statutorily mandated mission to regulate foods, drugs, cosmetics, devices, etc., and be convicted under the felony provisions of the statute"

  http://www.fdaimports.com/lawyer-attorney-1244596.html
- The FDA Not only did Nothing, the FDA said it was outside any Federal jurisdiction even though the Doctor went from SC to GA and back to injure patients.

I have evidence that I believe shows:

- Widespread corruption and conspiracy to deceive patients and the general public.
- Knowledge of intentional withholding of information about vision quality standards from the FDA risk/benefit analysis both before and after approval.

Risks of LASIK are understated, and LASIK surgeons cannot be trusted to be totally open and honest

- The FDA website lists severe LASIK risks: http://www.fda.gov/cdrh/lasik/risks.htm
  - Although the FDA posts LASIK risks on their website, their list is incomplete and physicians enjoying profits from a multibillion dollar industry cannot be trusted to provide proper informed consent to patients.
- LASIK-induced dry eye is difficult to treat and can be debilitating. **Patients are not adequately warned.**
- Surgeons are not honest to patients about bad outcomes -one Doctor who did several FDA clinical trials said my LASIK problems were caused by “bad luck” and another said I was “doing well”.
- One Doctor who did FDA clinical trials told me they never developed standards for determining acceptable vision quality (his research showed high rates of monocular diplopia that were Not reported to the FDA to my knowledge, see http://www.ncbi.nlm.nih.gov/pubmed/11758983)
  - “Monocular diplopia following LASIK appears to correlate with postoperative corneal refractive power variation inside the pupillary area” http://www.ncbi.nlm.nih.gov/pubmed/11758983

PostMarket Surveillance should focus on the patients who know they are worse off.

- Doctors admit a significant # of patients know they are WORSE after LASIK.
  - “2 percent said the procedure made their vision worse.” http://www.11alive.com/news/news_article.aspx?storyid=43304
  - How many of these are suicidal or depressed?
- “ 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.”

  http://www.11alive.com/news/news_article.aspx?storyid=43304

LASIK-induced Dry Eye Severely Impacts Quality of Life

- **Dry Eye causes** vision problems with reading, working, driving and other aspects of daily living
- **Dry Eye alone caused**
  - Depression, unhappiness for 25.7%
  - A severe interference with activities of daily life for 73%

http://www.ptcommunity.com/ptjournal/fulltext/PTD_dryeye_pt.pdf

(see p.37 of 48)

LASIK complications produce adverse emotional states, including depression and psychological crisis.

- Severe dry eye and loss of vision quality
  - Are common complications of LASIK
  - Are often very severe and even catastrophic
- There is a lot of research on both vision quality problems and depression
  - Like all catastrophic injuries, especially vision injuries, LASIK problems obviously increase the risk of suicide and depression.

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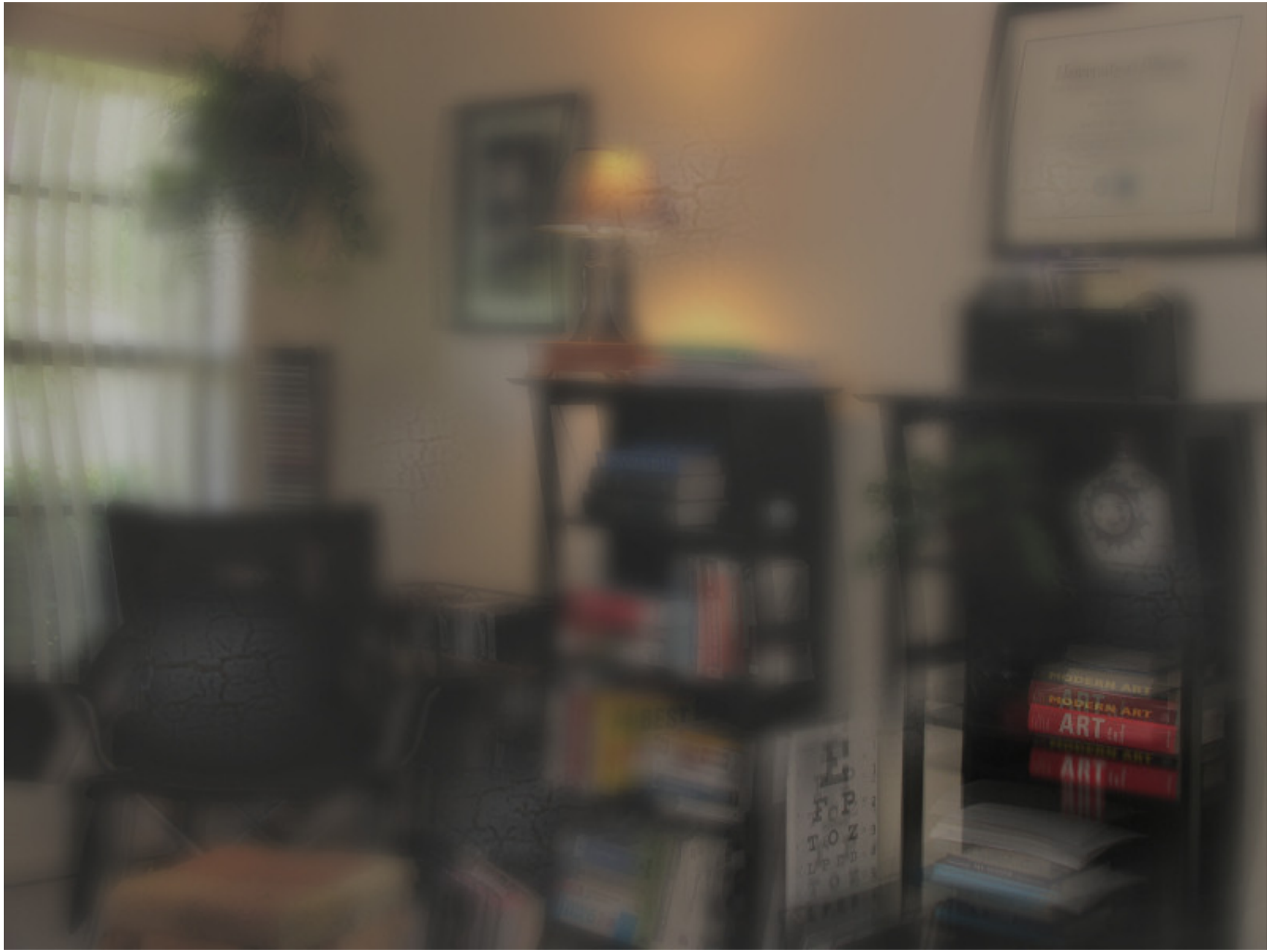

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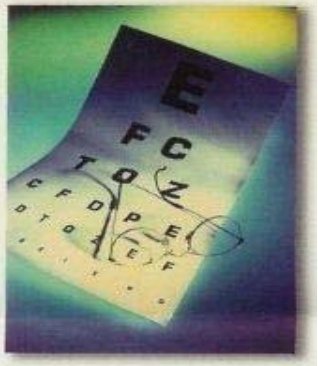

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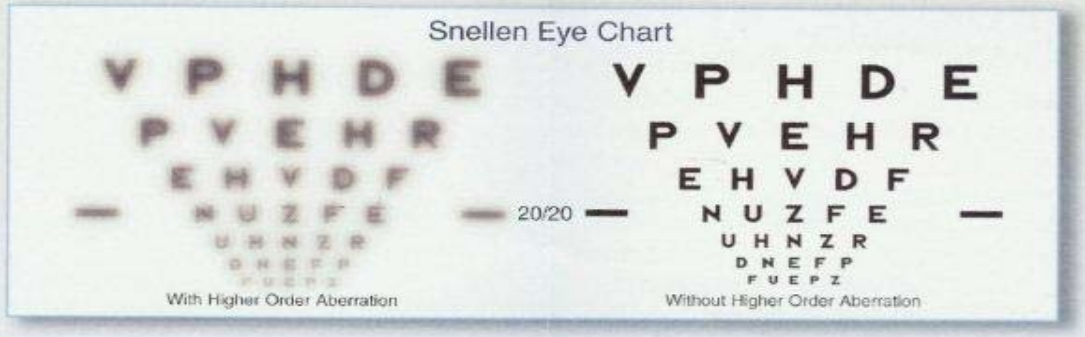

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