

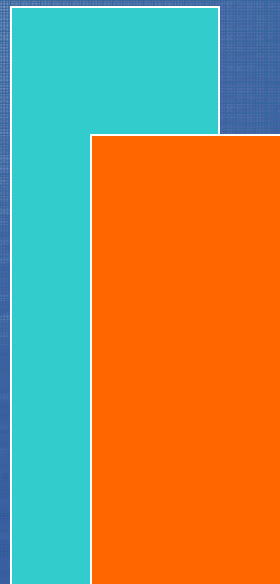
Depression, Suicide, and LASIK Complications Presented by Roger D. Davis, PhD



Abbreviated Version: Presented to the Ophthalmic Devices Panel
of the Food and Drug Administration (FDA)
on April 25th, 2008 in Gaithersburg, Maryland

Studied Suicidal Ideation in the Complications of Refractive Surgery (CORS) Study

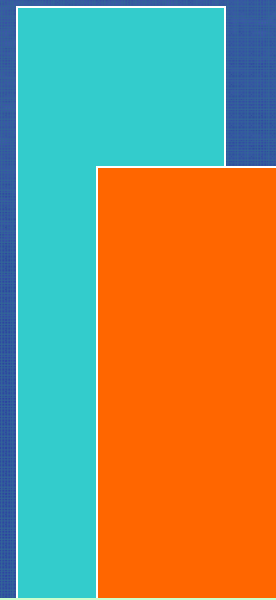
Suicidal Ideation Group



48 of 58
(83%)
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said they
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Suicidality = Success

Depression Group



87 of 115
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- Neither I nor my co-authors regarded the study as especially strong methodologically, since patients were self selected into the study.
- Yet, the conclusions are startling.
 - Dry Eye had the strongest association with Depression and Suicidal Ideation.
 - Higher Order Aberrations were as strongly associated with Suicidal Ideation as Blurry Vision (classically a lower order aberration).



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Suicidal Fantasies of Lasik Complications Patients

- Some patients have travelled widely looking for solutions. Suicidal fantasies express a desire to be done with the journey.
- Some patients powerless to help self or others. Suicidal fantasies express the desire not to be a victim, to return to a world of integrity and compassion.
- Some patients live on the brink, in constant fear their vision is getting worse. No time for conspiracy or anti-LASIK rhetoric. Suicidal fantasies express the desire to escape the anxiety and unpredictability of complications.
- Some patients feel that no one understands what it's like to have their vision. Suicidal fantasies express the desire to have the severity of their problems finally appreciated.
- Some patients feel LASIK is symptomatic of our times. Anxiety is discussed in spiritual or metaphysical terms. Suicidal fantasies express a desire to return to something pure.
- Some patients feel a sense of helpless outrage at the injury of thousands, while the need for action goes unacknowledged by the institutions of the larger society.
- Some patients feel that they paid to have someone destroy their vision. They see themselves as incredibly naive. Suicidal fantasies express the guilt of having wasted one's potential as a human being.

A Moratorium on the Excimer Laser

- Research connecting complications to quality of life provides the ethical basis for informed consent.
- Because this research does not yet exist, refractive surgery cannot be performed ethically, whatever its satisfaction or complication rate.
- Therefore, Refractive Surgery should end.

Full Presentation

Refractive Surgery Shock Syndrome:

Depression, Posttraumatic Stress, Suicidal Ideation
And Complications of Refractive Surgery

Psychological Effects of LASIK Complications

Presented by Roger D. Davis, PhD



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 - RSSS: Emotional and Intrapsychic Effects.
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 - RSSS: Effects of Complications on Intellectual Functioning.
 - RSSS: Effects on the Family.
 - RSSS: Effects on Health and Well-being.
 - RSSS: Contributions of the RS Industry.
 - RSSS: Psychological Aspects of Treatment.
 - RSSS: Role of Internet in Moderating Intensity of RSSS.
 - RSSS: Research Directions.

Part I: My Story

My Story as a Psychological Researcher and Lasik Casualty

Psychological Credentials

- Coauthor of most widely used theoretically based inventory used to assess personality disorders and classic psychiatric disorders for adults and adolescents in United States.
- Coauthor of “Disorders of Personality: DSM-IV and Beyond”, considered the classic text in the field of clinical psychology, for both professionals and graduate students.
- Coauthor of first undergraduate text to introduce personality disorders to college students, “Personality Disorders in Modern Life.”
- Co-editor of the “Oxford Textbook of Psychopathology,” a graduate-level text that has been used at Harvard University, among others.
- Numerous other theoretical and empirical publications, particularly related to the development of psychological tests.

“Lasik Casualty” Credentials

🌐 LASIK in 1998, followed by extreme dry eye and severe ghosting in right eye (supposedly a side-effect), 20/15 acuity.

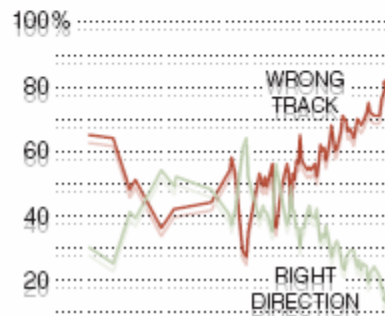
81% in Poll Say Nation Is Headed on the Wrong Track

By [DAVID LEONHARDT](#) and [MARJORIE CONNELLY](#)
Published: April 4, 2008

Americans are more dissatisfied with the country's direction than at any time since the New York Times/CBS News poll began asking about the subject in the early 1990s, according to the latest poll.

On Track?

Do you feel things in this country are generally going in the right direction or do you feel things have pretty seriously gotten off on the wrong track?



In the poll, 81 percent of respondents said they believed “things have pretty seriously gotten off on the wrong track,” up from 69 percent a year ago and 35 percent in early 2002.

Although the public mood has been darkening since the early days of the war in Iraq, it has taken a new turn for the worse in the last few months, as the economy has seemed to slip into recession. There is now nearly a national consensus that the country faces significant problems.

COMMENTS (51)

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ARTICLE TOOLS SPONSORED BY
Young @ Heart

After carefully considering three surgeons, I picked one of the top guys in North America.

According to my surgeon, I was being picky about my vision.

Discovered Surgical Eyes Foundation in January, 2000

- I was being told nothing was wrong with my eyes.
- I was told I was 1 in 10,000.
- I discovered the Surgical Eyes Foundation through an ABC 20/20 piece on LASIK.
- I went to the site and discovered close to 1,000 people with similar complaints, all telling more or less the same story.
- In just a few years, the number of registered users grew to over 9000.

Patients Stories were All More or Less the Same

- That they had no real informed consent for the surgery.
- That their surgeons were telling them there was nothing wrong with their eyes.
- That the LASIK industry was lying to the public about the nature of risk.
- That the industry needed to buy time in order to improve the technology.
- That the industry sought to suppress public awareness of the severity of LASIK injuries in order to maintain public perception of LASIK as safe.
- That the industry needed to “manage” the casualty movement to prevent them from impacting profits.
- Patients considered themselves victims of a medical conspiracy.
- Radial Keratotomy patients who had studied the industry alleged a long history of patient abuse and cover ups.

Became Research Director of Surgical Eyes Foundation

- Served as Research Director for about 1 year.
- During that time, we had an epidemic of Depression and Suicidal Ideation, as well as Posttraumatic Stress.
- New patients were finding the website and its forum every day.
- These patients were in various states of psychological distress, depending mainly on their vision, but also their experiences with their surgeon and the industry.
- To my knowledge these were all telling more or less the same story about how their doctors had treated them.
 - Greed.
 - Medical Corruption.
 - Minimization or Outright Denial of Severity of Complications.

Studied Suicidal Ideation in the Complications of Refractive Surgery Study

Abstract

Purpose: To determine the types and frequency of subjective complaints for patients experiencing complications following refractive surgery.

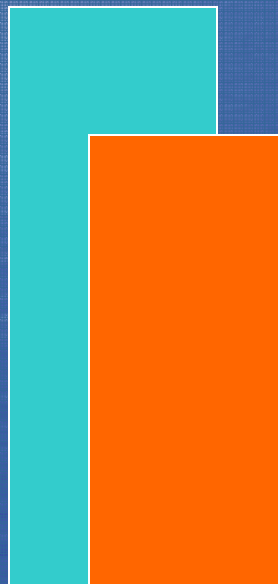
Methods: Participation in the Complications of Refractive Surgery (CORS) survey was voluntary and self-initiated through subject contact with the Surgical Eyes Foundation web site. Patients initially provided an open-ended general complaint, and were later queried about depression, suicidal ideation, and overall success status as judged by their doctor.

Results: A total of 517 responses were submitted. After exclusion criteria, 392 responses were coded resulting in 36 separate subjective complaint categories. 195/392 (50%) responded to the three follow-up questions. 58 subjects reported suicidal ideation as a result of the surgical procedure, and 83% (48/58) of this group were referred to as successes by their surgeon. 115 subjects reported severe depression as a result of the surgical procedure, and 76% (87/115) of this group were referred to as successes by their surgeon.

Conclusions: A multitude of visual complaints and severe psychiatric morbidity may occur after elective refractive surgery. Physicians' and patients' evaluations of quality of life may differ drastically, as evidenced by large numbers of patients experiencing severe depression and suicidal ideation while simultaneously being referred to as a success by their surgeon.

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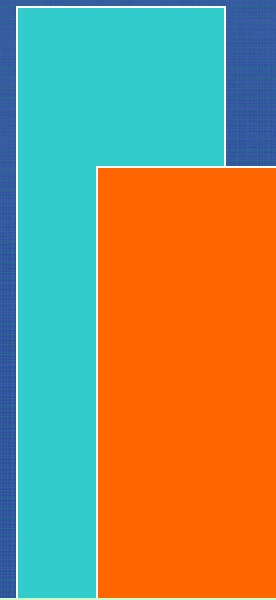
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CORS Converges with Health Utility Studies of Dry Eye

- **Ophthalmology.** 2003 Jul;110(7):1412-9.
- Schiffman RM, Walt JG, Jacobsen G, Doyle JJ, Lebovics G, Sumner W.
- **PURPOSE:** To determine utilities (patient preferences) for dry eye disease. **DESIGN:** Survey study. **PARTICIPANTS:** Fifty-six patients with mild, moderate, or severe dry eye treated by ophthalmologists in the Eye Care Services department of Henry Ford Health Care System. **TESTING:** Patients completed interactive software utility assessment questionnaires by the time trade-off (TTO) method. Utility scores were scaled such that a score of 1.0 = perfect health and 0 = death. Dry eye severity was independently classified using clinical parameters and physician/patient assessments. Global health status, visual functioning, and ocular symptoms were assessed by the Short Form-36 Health Survey, 25-Item National Eye Institute Visual Function Questionnaire (NEI VFQ-25), and Ocular Surface Disease Index survey instruments. **MAIN OUTCOME MEASURES:** Utility scores for a range of dry eye severity states. These utilities were compared with utilities reported for other disease states. Correlations with the general and vision-related health status measures were conducted. **RESULTS:** Fifty-six patients completed the utility assessments with acceptable reliability. Mean utilities for moderate (0.78) and severe dry eye (0.72) by TTO were similar to historical reports for moderate (0.75) and more severe (class III/IV) angina (0.71), respectively. Utility scores correlated with the NEI VFQ-25 composite score ($\rho = 0.32$; $P = 0.037$) and with components of other health measures.
- **CONCLUSIONS: Utilities for the more severe forms of dry eye are in the range of conditions like class III/IV angina (0.71) that are widely recognized as lowering health utilities. Our results underscore how significantly dry eye impacts patients compared with other medical conditions.**

CORS Converges with Health Utility Studies of Visual Impairment

- Ophthalmic Epidemiol. 2000 Sep;7(3):169-85.
- Nease RF, Whitcup SM, Ellwein LB, Fox G, Littenberg B.
- PURPOSE. To quantify and compare the reduction in quality of life due to visual impairment and angina using patient preferences (utilities). METHODS. Using a standard time tradeoff method, we obtained utilities for current vision, monocular and binocular blindness, current angina, and moderate angina in 60 patients with both vision problems and angina pectoris who sought care at the National Eye Institute (NEI), National Naval Medical Center, or Barnes-Jewish Hospital. Patients were characterized clinically based on visual acuity and the Duke Activity Status Index (DASI). Patients also completed a seven-item version of the NEI Visual Functioning Questionnaire and the SF-36 Health Survey Questionnaire. RESULTS. Patients had a median visual acuity of 20/100 in the worst eye, 20/40 in the better eye, and a median DASI of 24.2 (0 = severe functional limitations due to anginal symptoms, 58.2 = no limitations). There was substantial variation in utilities among patients. The average utility for current vision (relative to ideal vision [= 1.0] and death [= 0.0]) was 0.82; the average utility for current angina (relative to no angina symptoms [= 1.0] and death [= 0.0]) was 0.89. Among 26 patients with both visual impairment and recent anginal symptoms, the decrement in utility (on a scale ranging from ideal health [= 1.0] to death [= 0.0]) imposed by current visual impairment was greater than that imposed by current angina symptoms (0.146 versus 0.072, $p=0.08$, Wilcoxon signed rank test). The decrement in utility associated with binocular blindness was greater than the decrement associated with the symptoms of moderate angina (0.477 versus 0.039, $p<0.0001$).
- **CONCLUSIONS. Clinical status is not a surrogate for patient preferences regarding vision impairment or angina. There is substantial variation in utilities within the study population for both experienced and theoretical impairment states which is not explained by variations in clinical status. Some states of visual impairment may pose a greater quality of life burden than anginal symptoms. Because patient preferences for vision vary greatly, individual assessment is warranted for consideration in therapeutic decision making.**

PART II: VISION SIMULATIONS

Vision Simulations are photorealistic re-creations of common aberrations seen by patients with LASIK complications.

www.TheVisionCommunity.com

- Has more vision simulators than anywhere in the world.
- More than the National Eye Institute.
- Used by post-Refractive Surgery patients and Keratoconus patients to explain and simulate their vision for family, friends, physicians, and attorneys.
- Some simulations are focused on eye diseases and conditions (not just LASIK).
- People with all kinds of vision problems experience depression and suicidal ideation...it's not just LASIK complications.

Vision Simulators were Developed to Reduce Suicidal Ideation

- Patients with Aberrations were unable to communicate their vision...to anyone.
- Patients said their doctors didn't care about them.
- Family and Friends only understood "blurry vision," not aberrations like:
 - Ghosting
 - Starbursting
 - Glare
 - Halos
 - Loss of Contrast Sensitivity
- Patients with complications feel very much alone.
- Patients feel Helpless to Communicate their problems, and hopeless to get the industry to do anything to solve them.
- Helplessness and Hopelessness are cardinal features of depression and suicidal ideation.
- Over time, due to the volume of requests, I begin doing vision simulations for patients involved in litigation.

Ghosting

- Does anyone really need research to understand the relationship between Ghosting, Depression, Posttraumatic Stress, and Suicidal Ideation?

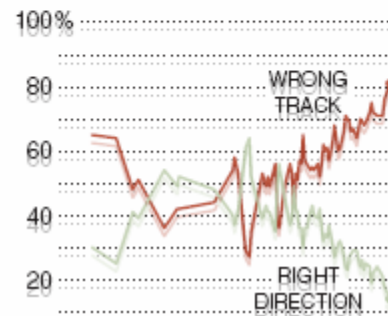
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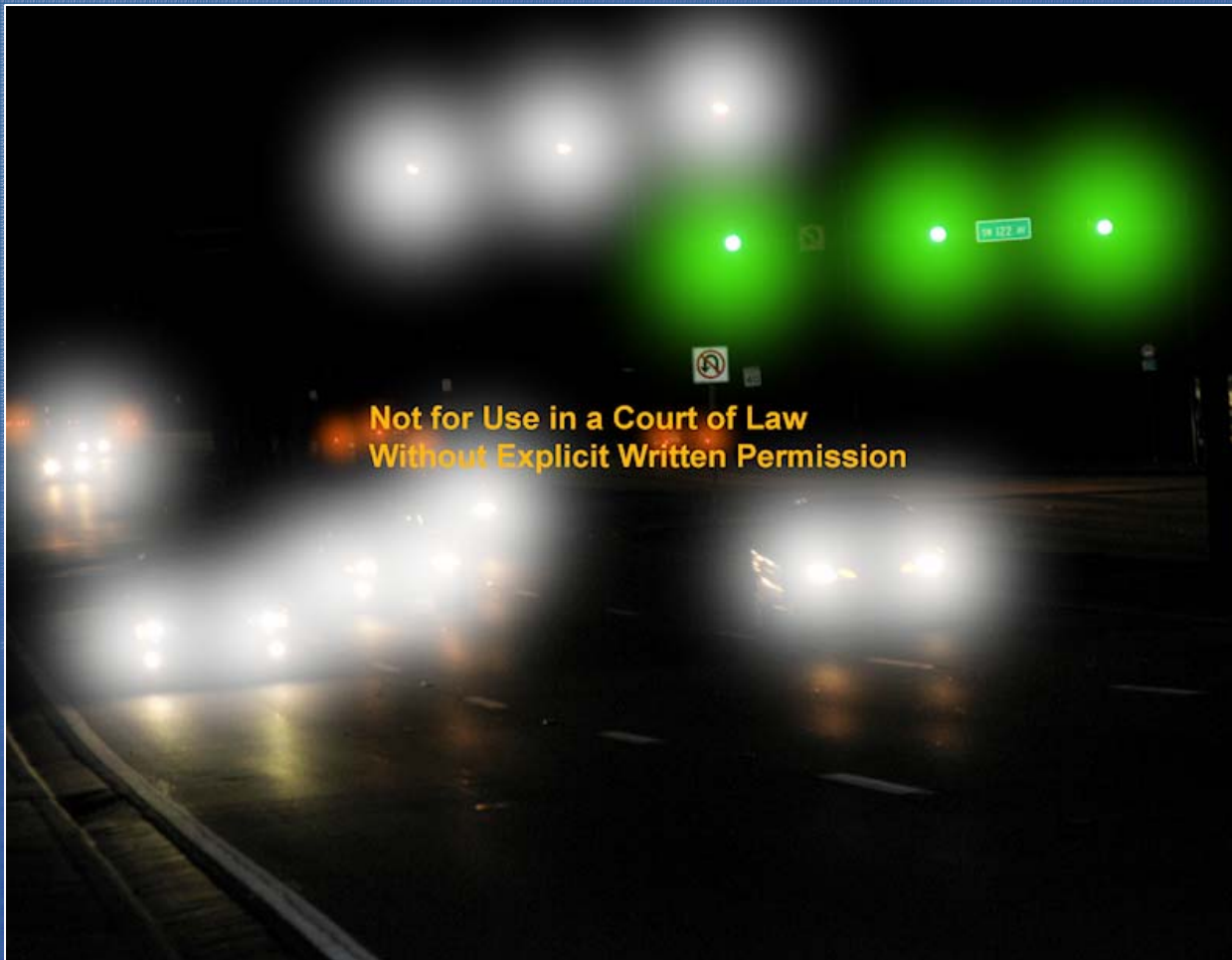
The Quality of Life impact is obvious.

So why was this never studied before LASIK was launched?

People who want to commit suicide continue to ask me this question.

Halos

Who needs research to understand the relationship between Severe Halos and Quality of Life?



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Starbursting: Example from Real Patient with Large Pupils

Who needs research to understand the relationship between Severe Starbursting and Quality of Life?



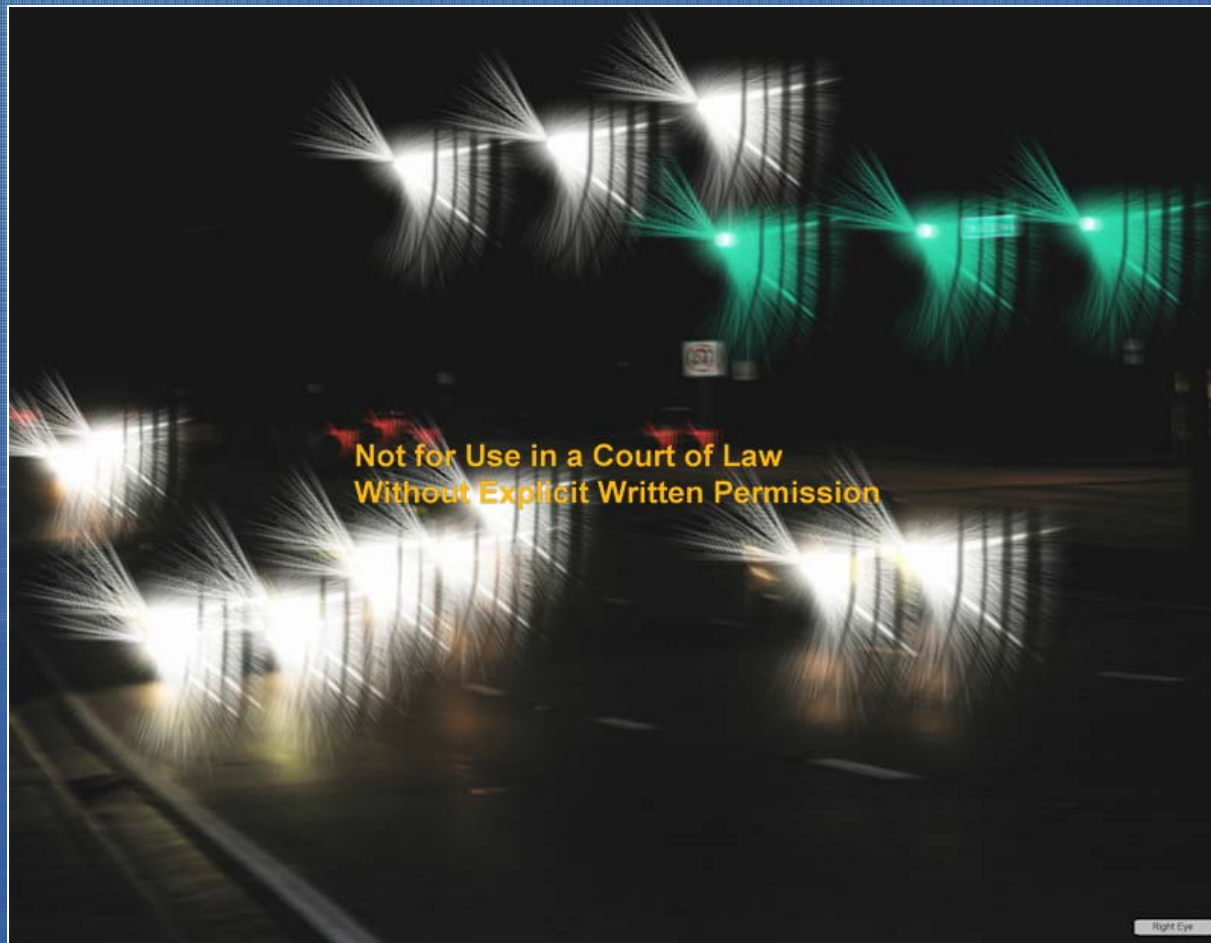
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Starbursting and Suicidality: A Real Patient with Large Pupils

Patient complained of Depression and Suicidal Thoughts. Starburst patterns can be bizarre, simply because many post-LASIK corneal irregularities are bizarre.



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Starbursting Example: A Real Patient with Large Pupils

Another example. Notice that starbursts need not be symmetrical.



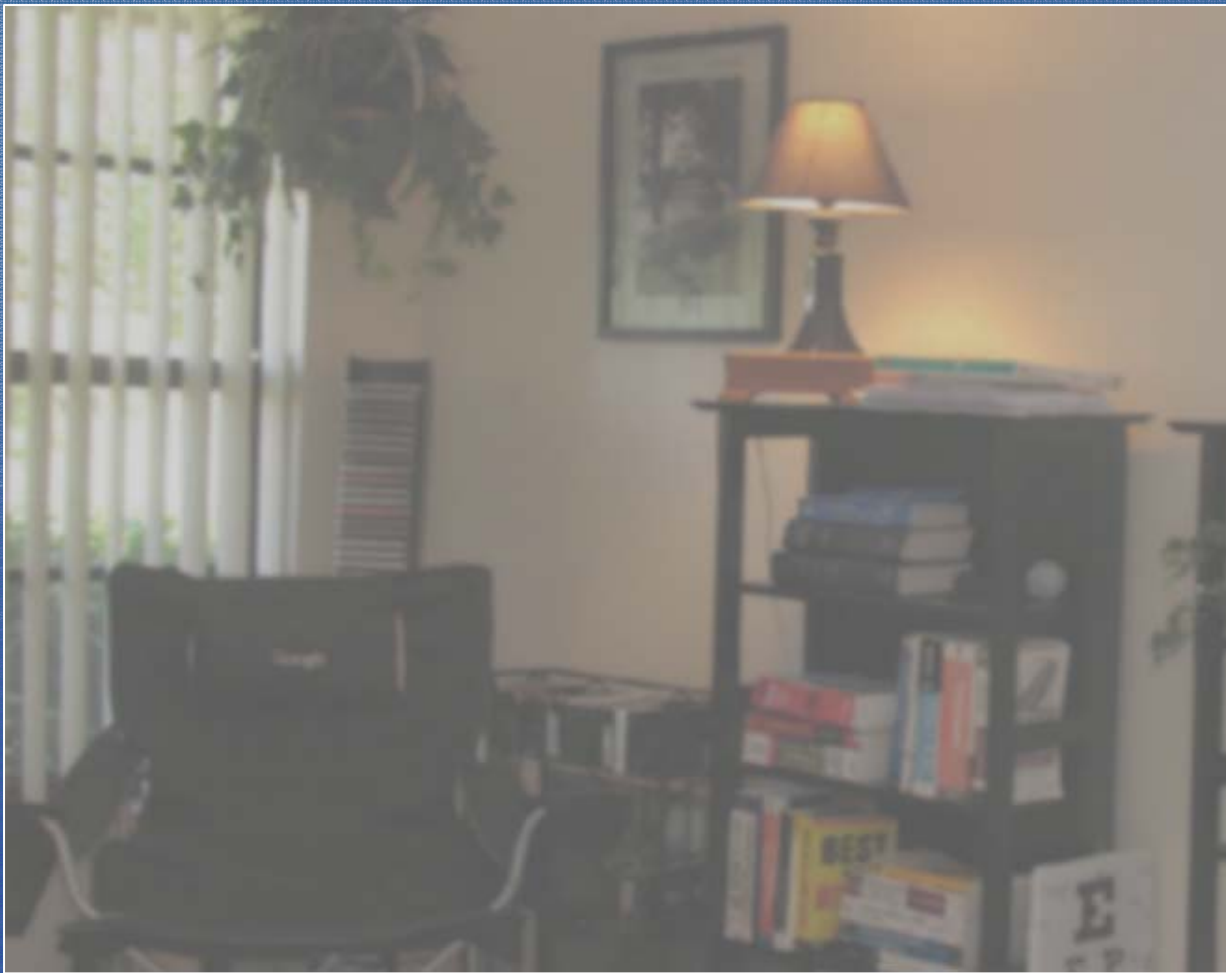
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Loss of Contrast Sensitivity

Does anyone really need research to understand the relationship between Loss of Contrast Sensitivity, Depression, Posttraumatic Stress, and Suicidal Ideation?



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So why was this never studied before LASIK was launched?

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Patients are Struggling to Understand the Relationship Between the FDA and Industry

- In my experience...
 - Patients become depressed and suicidal following LASIK complications not just because of their vision.
 - Many patients are struggling to understand how LASIK could ever be approved by the FDA as “safe” without adequate investigation into the relationship between perceptual aberrations and Quality of Life (why are we millions of patients down the road now?).
 - For these patients, their own perception is proof that LASIK cannot possibly be safe.
 - Some of these patients feel the relationship between the FDA and industry should be subject to criminal investigation.
 - Patients feel that definitions of “safe and effective” are not commonsense definitions, but instead benefit industry at the expense of the public health.

Part III: Refractive Surgery Shock Syndrome

Part III:

Refractive Surgery

Shock Syndrome:

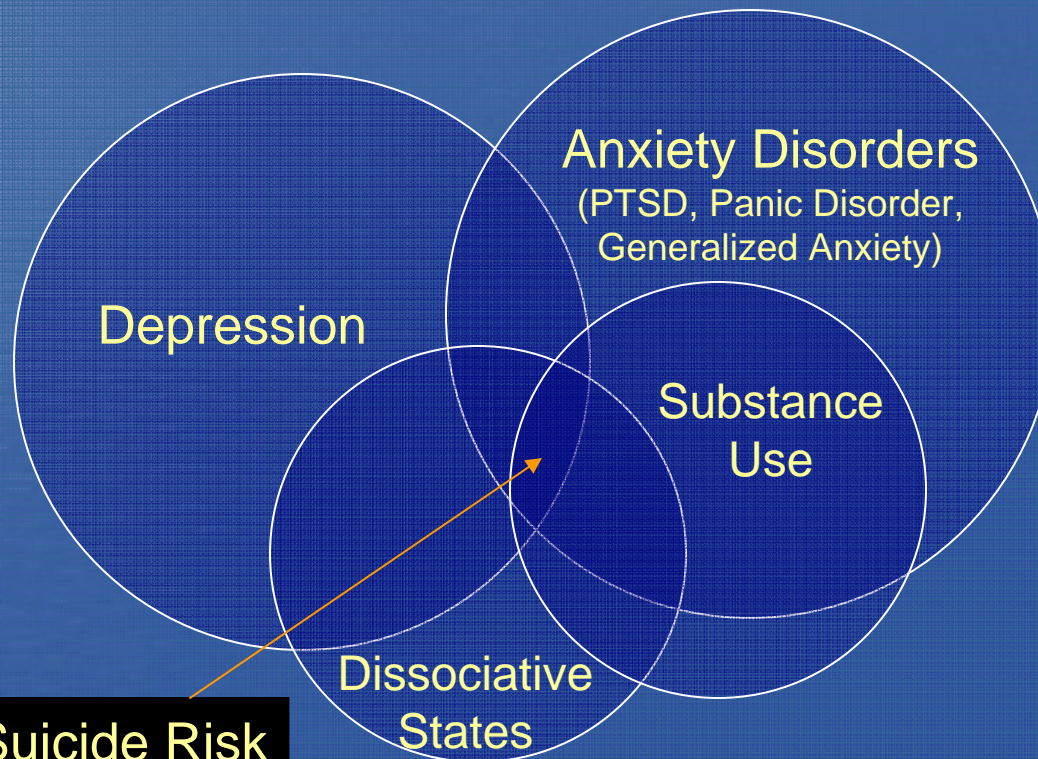
Formal Diagnostic Properties

NOTICE: Limitations

- The contents of the RSSS portion of this presentation are **not** the result of published empirical research.
- Instead, the contents are based upon...
 - My own correspondence with 250-350 LASIK casualties across the United States.
 - An intensive review of the short “Lasik biographies” of over 40 refractive surgery patients, culminating in enough text to fill a novel.
 - Periodic review of postings made by patients at various forums, including SugicalEyes.org (now Vision Surgery Rehab Network), LaserMyEye.org, DryEyeZone.com, and Lasik-Flap.com.
 - My expertise as a psychological researcher, therapist, and designer of psychological tests now in use everyday across the United States.
 - My own experience as a Lasik casualty.
- Because the contents of this presentation are not based upon empirical research, they should be viewed not as fact, but as provisional hypotheses to be sustained, or not, by the scientific method.
- As such, these contents are subject to revision, amplification, or even retraction. Science is never static.
- These limitations do **not** constitute a “fine print legal disclaimer,” but should be taken seriously.

Probably a Highly Heterogeneous Disorder

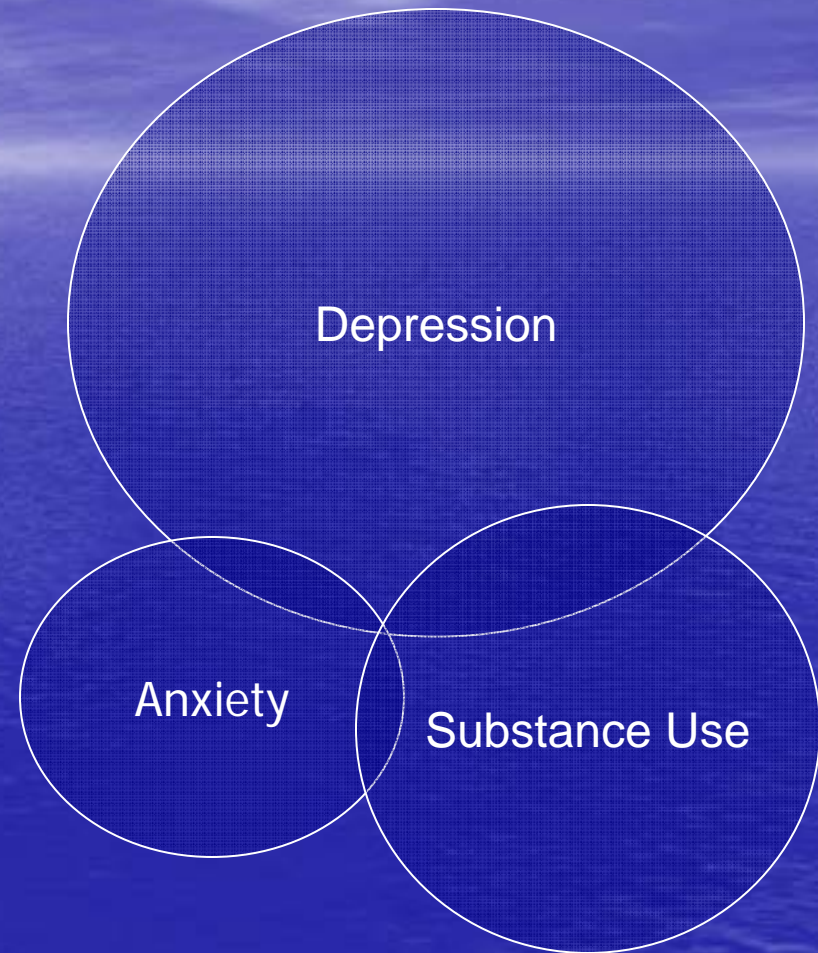
At the level of diagnoses, RSSS is **probably** a highly heterogeneous syndrome which can combine depression, PTSD, other anxiety disorders, substance abuse, and occasionally, certain Dissociative symptoms.



* The name "Refractive Surgery Shock Syndrome" was coined by Gary Vatter in a letter to Ron Link in February, 1999.

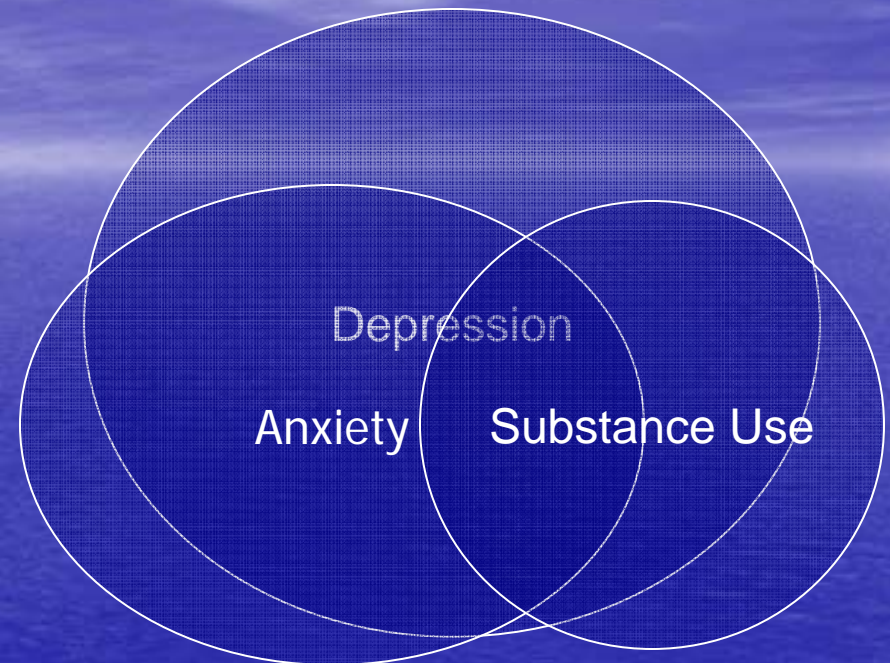
RSSS: A Loose Diagnostic Syndrome?

- As a Loose Syndrome, RSSS patients would present with great diversity.
- Patients would develop DSM-IV disorders more or less independently, including:
 - Depression
 - Adjustment Disorder
 - Acute Stress Disorder and Posttraumatic Stress Disorder
 - Various Anxiety Disorders
 - Various Substance Use Disorders
- Exactly which patient developed which disorder would be determined by:
 - Premorbid characteristics of the patient
 - Current contextual factors (i.e., family, work, doctor-patient relationship).



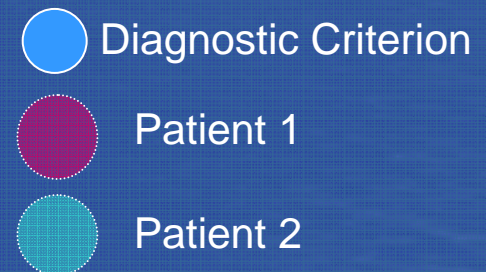
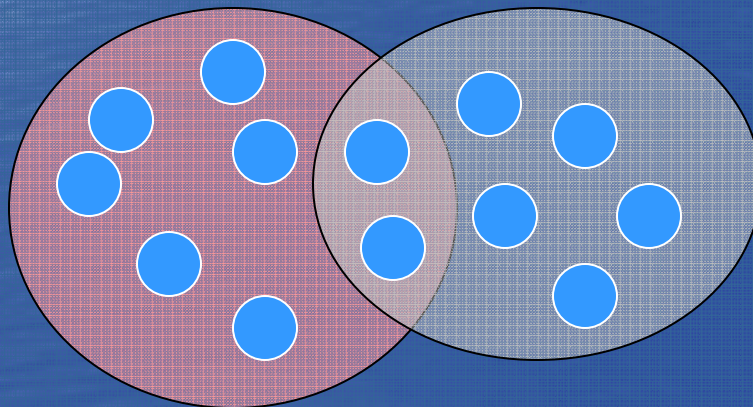
RSSS: A Tight Diagnostic Syndrome?

- As a Tight Syndrome, RSSS patients would present with similar features.
- Patients would develop a similar constellation of DSM-IV symptoms:
 - Depression
 - Adjustment Disorder
 - Acute Stress Disorder and Posttraumatic Stress Disorder
 - Various Anxiety Disorders
 - Various Substance Use Disorders
- The disorder itself determines its symptom picture. Symptom development has its own intrinsic order.
- RSSS patients with similar degrees of damage might develop depression first, then develop symptoms of PTSD and other disorders as level of visual damage increases.



Prototypical Model of DSM is Appropriate for RSSS

- Prototypical model was adopted in DSM-III in 1980 by the American Psychiatric Association.
- Intended to recognize and accommodate the heterogeneity of patients sharing a diagnosis.
 - Patients with the same diagnosis may share few diagnostic symptoms.
 - And therefore, differ greatly in their clinical presentation, sharing a diagnosis, but having few symptoms in common.



As a Heterogenous Disorder...

- Because RSSS is **probably** a highly heterogeneous “loose syndrome”...
 - Few patients will exhibit the full symptom picture.
 - Some patients will exhibit only a single DSM diagnosis (e.g. Depression)
 - Most patients will probably combine symptoms from various DSM diagnoses.
 - Some patients may exhibit diverse symptoms that would not qualify them for any single DSM diagnosis, but nevertheless be “diagnosed” as RSSS.

Part III: Refractive Surgery Shock Syndrome

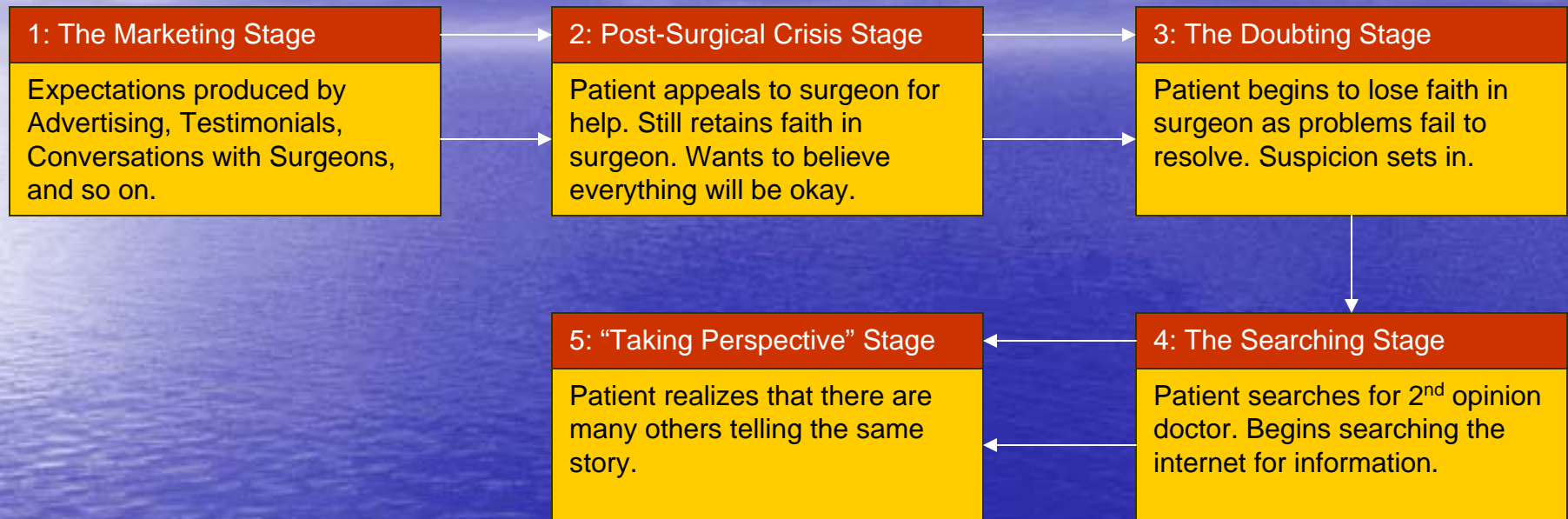
Part III:

Stages in the Development of RSSS Depression and Suicidal Ideation

Five Stages of Coping with RS Complications

- Because refractive surgery is an event that takes place in time, it makes sense to discuss psychological reactions to complications in terms of time.
- Each stage refers to a more or less psychologically coherent state that reflects the individual's attitudes about their vision and about others involved in their refractive surgery.
- Individuals progress through stages of coping as a means of trying to reconcile claims made by their surgeon and the industry with the reality of the vision and their experience meeting other patients with the same stories.
- Not all patients make it to the last stage. Some individuals cope by resignation or avoidance, that is, by refusing to consider the issues.
- No stage has a particular set duration or time limit.

Overview of the Five Stages



The Marketing Stage

- This stage is defined by expectations formed about refractive surgery and the industry based on marketing.
- Candidates form beliefs about refractive surgery based on quality of life claims made in advertising and testimonials.
- Advertising claims include “throw away your glasses and contacts” and “20/20 guarantee or your money back.”
- Marketing establishes unrealistic expectations.
- Patients expect that refractive surgery will completely change their life in a positive way.
- Patients buy LASIK on traditional definition of “doctor as healer.”

The Post-Surgical Crisis Stage

- Patient has Higher Order Aberrations and Ocular Surface Issues.
- Patient is confused because complications were not supposed to happen.
- Patient is disappointed, because a perfect result was promised and expected.
- Patient is anxious because something unknown happened that the patient does not understand.
- Patient may be overwhelmed by Higher Order Aberrations and Ocular Surface issues.
- Doctor-patient relationship is still intact, because the patient may simply believe that more surgery is the answer.
- Patient may actively try to suppress anxiety and continue to trust the doctor.

Patient Emotions

- Confusion.
- Anxiety.
- Disappointment.
- No suicidal ideation at this point.

The Crisis Stage: Questions from Suicidal Patients

- What's going to happen to me?
- How am I going to get my life back?
- Why didn't they tell me this could happen?
- Why didn't my informed consent mention this to me?
- Why didn't they tell me I could have more than one complication?
- Why didn't they tell me it could be this bad?
- Any number of questions about the specifics of the patients ocular condition, topographies, wavefronts, refraction, and so on.

The Doubting Stage

- Confusion passes into bewilderment as patient's problems refuse to resolve or even worsen.
- Anxiety increases: As time presses forward, it becomes clear that resolution is not occurring, or vision is even getting worse.
- Patient may be told nothing is wrong with their eyes.
- Patients told they are still healing, which may or may not be true.
- Doctor-patient relationship is severely strained.
 - Patient may believe that more surgery is the answer.
 - Patient still wants to trust the doctor.
- Nevertheless, the patient can't help but wonder...
 - If everyone comes out perfect, what went wrong with me?
 - Is the doctor telling me the truth about my eyes?
 - Am I really still healing, or am I going to be stuck with this forever?

Patient Emotions

- Bewilderment.
- Panick.
- Depression
- Suicidal Ideation begins as Anxiety peaks. Patients want to escape visual aberrations and ocular surface disease, and fear there is no way back.

The Doubting Stage: Questions from Suicidal Patients

- Why is my surgeon telling me nothing is wrong with my eyes?
- Why is my surgeon denying (or minimizing) that I have any problems?
- Why is my surgeon not recording my complaints in the medical chart?
- Why is the staff being cold to me?
- Why am I being seated away from patients who haven't had the surgery yet?

The Searching Stage: Looking for Help

- In the searching stage, trust between doctor and patient is broken. Patient begins to seek answers elsewhere.
- Patients find 2nd opinion surgeons
 - 2nd opinion surgeons may fear giving patient ammunition for use in litigation.
 - 2nd opinion surgeons may feel the need to protect their colleagues.
 - 2nd opinion surgeons may seek to reinforce original surgeons opinion: Nothing is wrong with your eyes, fail to record problems in medical chart, and so on.
- Patients find others on the internet telling similar stories.
 - You can find as many patients talking about deception as you want.
 - Patients discover an entire community of people whose existence as a group is defined by their collective consciousness as victims of medical deception.
 - I have yet to meet a single patient with complications who speaks about the honesty and integrity of their surgeon.

The Searching Stage: Questions from Depressed and Suicidal Patients

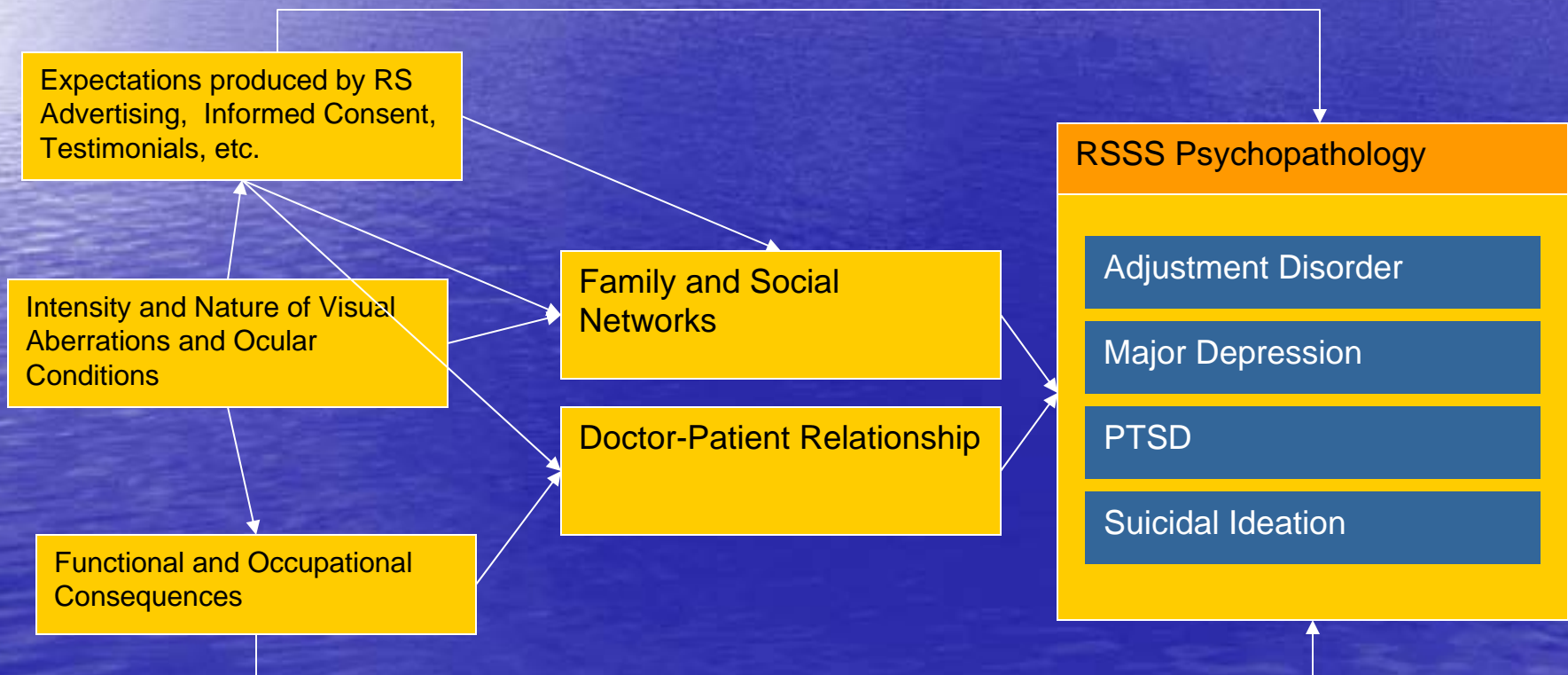
- Why do the doctors I see refuse to tell me the truth about my eyes?
- How long will I have to go on searching for the truth?
- Will the truth about LASIK ever come out?
- How does the little guy fight an industry armed with so many attorneys and so much money?
- Is the white wall of silence proof of medical conspiracy?
- What has happened to our society?
- Why don't good doctors do something?
- How do they get away with this?
- Why doesn't the FDA step in and stop this?

The “Taking Perspective” Stage

- Patients in this stage have been exposed to a variety of information on the internet, from LasikComplications.com to Lasik-Flap.com, as well as multiple 2nd opinion doctors.
 - They’ve had various tests like topographies and aberrometries over and over again. They may be quite sophisticated with regard to interpreting their own medical tests.
-
- Patients at this stage must take stock of their experience and decide whether to
 - 1) Put the experience behind them as best they can. This means going on with life. Finding new sources of happiness and self esteem.
 - 2) Become a “helper” who takes stock of the dynamics of the situation and helps people as much as possible, while not stirring the waters too much.
 - 3) Become an activist who confronts the industry as much as possible within the context of threats of litigation.
 - 4) Remain mired in depression and despair, recycling themes from the previous stages.
 - 5) Commit suicide, either impulsively or rationally.

What CAUSES RSSS?

At the level of psychology, causality is best understood as a complex network of interacting influences.



Refractive Surgery Shock Syndrome:

Observations Relevant to Specific DSM Disorders

Premorbid Psychological Conditions Predispose to the Development of RSSS

- Premorbid psychological conditions predispose to the development of RSSS, but are **not** necessary for the development of RSSS.
- Surgeons should disqualify individuals with any history of depressive disorders or adjustment disorders of any kind, or any individual taking psychiatric medications.
- Individuals with existing psychological conditions more likely to develop full-blown symptom picture of RSSS, featuring multiple comorbid DSM-IV-TR diagnoses.
- Individuals taking SSRI antidepressant medications may not be able to take these medications after refractive surgery, because of dry eye.
- Individuals taking SSRI antidepressant medications may find their vision is worse if the dosage is increased, due to pupillary dilation.

Development of PTSD

- Who is likely to develop PTSD?
- According to the National Center for PTSD:
 - “Those who experience greater stressor magnitude and intensity unpredictability, uncontrollability, sexual (as opposed to nonsexual) victimization, real or perceived responsibility, and betrayal.”
 - **Unpredictability:** Informed consent does not communicate the reality of complications. Pictures are not shown to patients, nor is the comorbidity of complications made real to candidates.
 - **Uncontrollability:** Following surgery, patients have little sense of control over their rehabilitation. Many patients become nomads going from doctor to doctor, looking for solutions that never arrive.
 - **Responsibility:** Patients are blamed by others who do not understand their situation, and eventually many blame themselves, if only for trusting their doctor in a “caveat emptor society.”
 - **Betrayal:** Advertising and marketing provide a baseline for the development of expectations. The reality of visual aberrations and the inadequacy of informed consent create feelings of betrayal and deception.

RSSS PTSD: Dissociative Symptoms

- **Why?** Dissociative symptoms occur because the patient cannot cope emotionally with the reality of what has happened. Simply put, the mind finds it necessary to distort reality, since accepting it would lead to psychological collapse.
- **Decrease in Emotional Responsiveness:** RSSS PTSD patients are “unable to process” what has happened to them, and yet, unable to “get away from their eyes.” They may seem detached, unable to find pleasure in anything, numb.
 - Patients take a long time to response to stimuli (e.g. have difficulty keeping up a conversation).
 - In theory, extreme case might exhibit catatonic states of near complete unresponsiveness.
- **Dissociative Amnesia:** RSSS PTSD patients may be unable to recall facts or events associated with their surgery. These effects are produced primarily by the cognitive effects of the stressor (and need not be produced by tranquilizers given on the day of surgery). Moreover, Dissociative amnesia is not limited to the day of surgery, but can occur with post-op visits or RGP fittings.
- **Feelings of Unreality (Derealization) :** RSSS PTSD patients may feel as if time has slowed down, as if the surrounding world is somehow unreal (“Twilight Zone effect”), or that they are living in a dream.
 - Feelings of unreality are characteristic of DSM-IV Acute Stress Disorder and PTSD.
 - Feelings of unreality are exacerbated by visual aberrations, which distort perception and add to feelings of surrealness.
- **Feelings of Depersonalization.** RSSS PTSD patients may feel that they are looking at the world from outside their bodies, or that they are someone else (“I didn’t believe it could be happening to me”), or that they are functioning like an automaton or machine.

RSSS: Substance Use Disorders

- Substance use is associated with Major Depression and PTSD, which are constituent disorders of RSSS.
- Substance use is an attempt to self-medicate the emotional states associated with RSSS.
 - Substances may be used to “numb out” or to calm anxiety states (e.g. alcohol, marijuana, heroin).
 - Substances may be used to produce fantasy states that distract the RSSS patient from their visual reality (e.g. mushrooms, LSD, mescaline).
 - Substances can be used to induce temporary euphoria (e.g. Ecstasy).
- Substance use can be a deliberate attempt to produce an unconscious state, as a means of escaping the visual aberrations and emotions associated with RSSS.
- Substance use can be a means of medicating sleep disorders induced by dry eye syndrome (“A little alcohol helps me sleep through the night better”)
- RSSS Patients who experience self-blame or self-hatred may state that they do not care whether they develop addictions, since their lives are “already over.”
- Patients with pre-existing substance abuse problems will worsen their abuse.
- Patients with a family history of substance abuse are likely to be especially at risk.
- Patients who have conquered substance abuse problems may return to abuse.
- Substance use can exacerbate relationship and occupational problems encountered by RSSS patients.

RSSS: Self-Destructive Behaviors

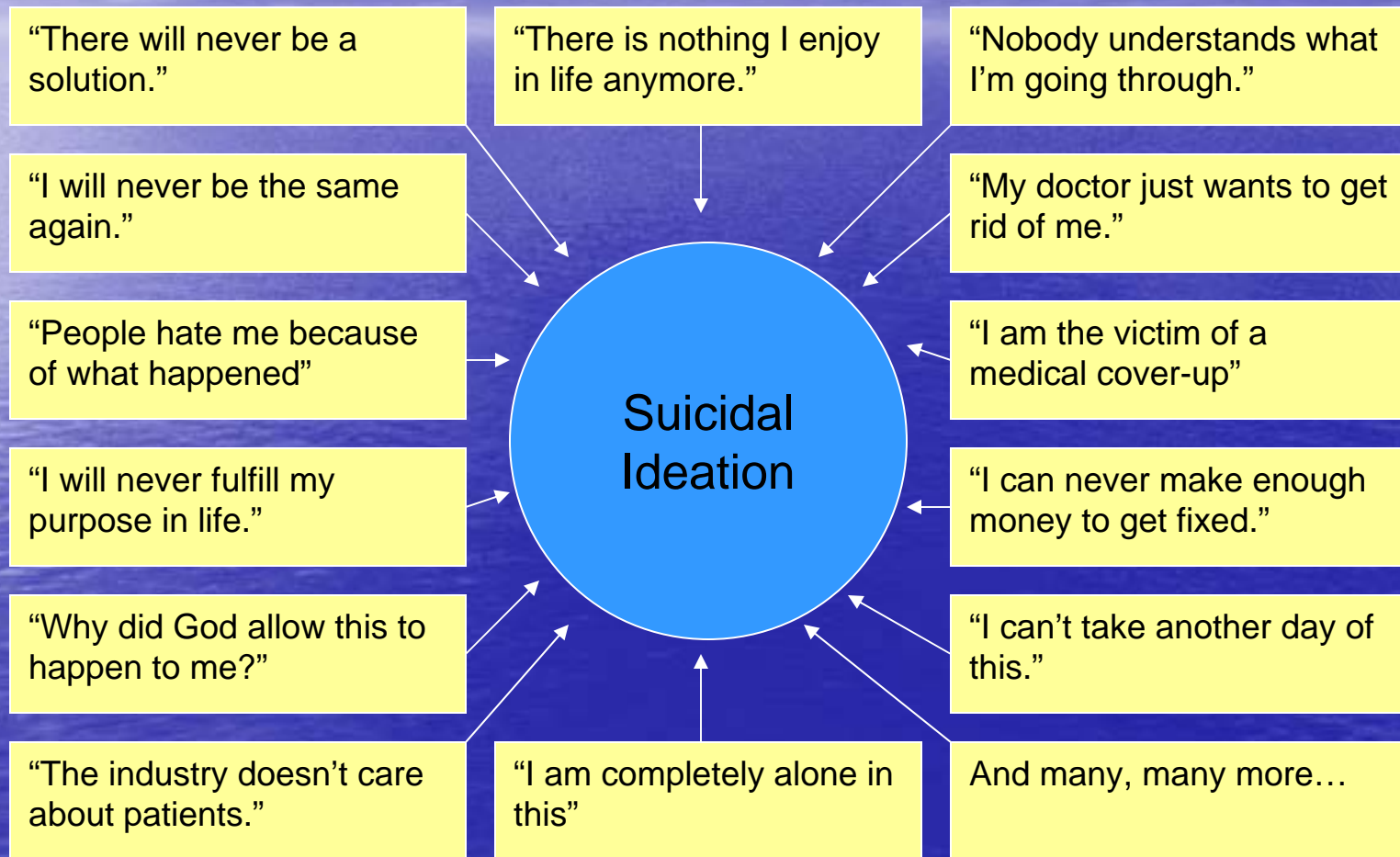
- Self-Destructive behaviors are the result of intense self-blame, or even self-hatred, induced by RS complications.
- Self-blame and self-hatred result from a sense of shame and powerlessness.
- Some self-destructive behaviors also function as a “cry for help.”
- Some self-destructive behaviors are intended to produce a crisis that can distract the patient from the agony caused by their vision.
- Some patients have pre-existing self-destructive traits which are amplified by RS complications (e.g. Borderline personality traits), however, pre-existing self-destructive traits are not necessary for self-destructive behaviors to be produced by complications.
- Receiving hostility or blame from others (i.e., family members or medical professionals) escalates the desire to do harm to oneself.
- Self-destructive behaviors include: Self-mutilation (cutting), eating disorders, sexual promiscuity, and potentially life-threatening activities, such as excessive drug or alcohol use (including the development of addictions) reckless driving (e.g., driving in conditions that are hazardous given the RSSS patient’s visual competency), gambling, buying sprees, suicidal gestures, and possibly domestic violence.
- Self-destructive behaviors may spontaneously appear or exacerbate on the anniversary of the patient’s LASIK.

Suicidal Ideation with 20/20 Vision



- Visual acuity is meaningless as a predictor of psychological adjustment post-Lasik.
- Patients can have 20/20 or better vision, and still experience the desire to end their own life.
- Suicidal ideation expresses a desire for relief.
- In general, patients who are more damaged will have more suicidal ideation.
- Patients who are told that “nothing is wrong with your eyes” experience feelings of helplessness and hopelessness, which escalate suicidal ideation.
- Patients whose visual complaints are validated by medical professionals probably experience less suicidal ideation (“Finally, someone understands!”)
- In general, the less predictable the patient’s vision, the greater the level of suicidal ideation (and of all RSSS symptoms).
- Patients who have fluctuating vision are likely to experience greater levels of suicidal ideation, because they experience greater loss of control over their own lives.
- Patients who receive higher levels of social support at home and at work can be expected to experience lower levels of suicidal ideation.

RSSS: Cognitions Associated with Suicidal Ideations



Refractive Surgery Shock Syndrome:

Emotional and Intrapsychic Effects

(effects internal to the mental functioning of the person)

Common Post-LASIK Emotions

- Shame
- Guilt
- Anger
- Frustration
- Disappointment
- Hopelessness and Helplessness
- Defectiveness or Worthlessness
- Victimization
- Nihilism

Effects on Self-Image and Self-Esteem

- Feelings of Worthlessness
- Feelings of Uselessness
- Feelings of Intense Shame
- Feelings of Nihilism
 - “My life has been for nothing”
- Unable to accomplish personal goals in life.
 - “I am a failure.”
 - “I will never live up to my potential as a human being.”
 - “I will never amount to anything.”
- Feelings of being unwanted by others, or no longer esteemed by them.
 - “I can never make my parents or spouse or children proud of me.”
 - “I am a burden to those who love me.”
 - “I have let my parents or spouse or children down.”
- Feelings of being trapped in a situation no one understands.
 - “No one understand what I’m going through.”
 - “No one cares about me enough to take time to understand.”

Psychological Defense Mechanisms in RSSS: Cognitive Dissonance and 20/Denial

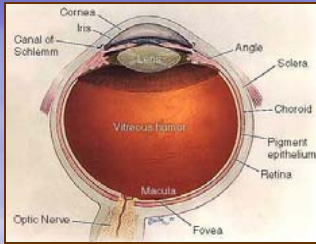
- Cognitive Dissonance (Festinger, 1957) is one of the most widely discussed theories in social psychology.
- CD holds that inconsistency between attitudes and behaviors produces internal psychological conflict, which must be reduced. The intensity of the dissonance is affected by the number of dissonant beliefs and the importance attached to these beliefs.
- Examples of Dissonance:
 - “Yeah, I have to use eye drops all day, but I’m still glad I had LASIK.”
 - “I have double vision, but at least I don’t wear glasses anymore.”
 - Some patients are genuine successes, but an unknown number are in 20/Denial.
 - Those in denial do not contribute to complication rates, and make the surgery appear safer and better than it really is.
- Denial is sometimes an adaptive psychological defense intended to prevent psychological collapse following LASIK complications.
 - Patients who are in denial probably need denial.
 - Confronting patients in denial may lead to anger and increased denial, or increased psychological symptoms.
 - Probably best to leave denial intact and let such patients cope on own timetable.

Suicidal Fantasies

Reactions of Psychologically
Normal Individuals
to the “LASIK Milieu”

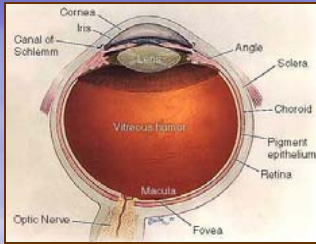
Personality Traits Channel Manifestations of Symptoms of RSSS

- Personality functions as the “immune system” of an individual’s “total psychological matrix,” therefore...
- The personality system is able to “cancel” or “metabolize” environmental stressors of a certain magnitude.
- Beyond this magnitude, the individual begins to manifest frank clinical symptoms, such as anxiety and depression.
- As such, individuals with different personality traits develop sets of concerns about their vision, their future, about themselves, and about the refractive surgery industry.
- These subtypes can be useful in planning psychological interventions for patients, because they allow the therapist to understand the patients subjective world.



Suicidal Fantasies: The Desire to End the Journey

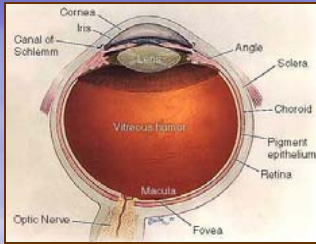
- May have traveled the country searching for solutions to refractive surgery problems.
 - May have seen ten, twenty, or even more ophthalmologists and optometrists in a never-ending search for surgical solutions and contact lenses.
 - May have experienced one or more retreatments that either did nothing or made vision problems worse, or marginally better.
 - May have a dozen or more sets of RGP lenses that can't be worn without discomfort for more than a few hours at a time.
 - Has spent thousands of dollars on possible solutions, without any effective relief.
- Suicidal fantasies express a desire to be done with searching and suffering...to finish the journey.
 - Some patients blame themselves because they are made worse by retreatments.
 - Some patients may exhaust their savings looking for solutions that never arrive.
 - Patients feel they have done everything they could possibly do, so it's reasonable to give up hope.
 - Patients feel that their travels and expenses are rational proof that nothing can be done.
 - To them, helplessness and hopelessness are a reasonable reaction to their situation.
 - Suicide is a rational solution.



Suicidal Fantasies: The Desire to Escape from Anxiety and Unpredictability

- Vacillates between periods of acute psychological crisis and exhaustion.
- Unable to manage pre-Surgery complexities of life due to ocular surface conditions and poor vision.
- Patient is just trying to cope: No time to worry about greedy doctors or “conspiracy theories.”
- Lives in fear that problems are getting worse (ectasia, dry eye).
- If unable to whittle down pre-Lasik responsibilities, lives in fear imminent financial, marital, or career collapse.
- Feels chronically on edge due to fear of what the future might hold.
- Because of internet, patients may know others whose post-LASIK vision has become dramatically worse for unknown reasons.

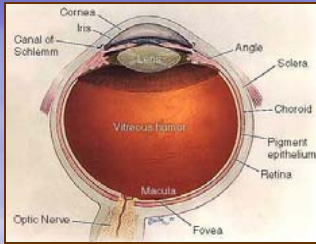
Suicidal fantasies express a desire to be away from conditions of chronic anxiety and stress caused by Lasik complications and their implications for an unpredictable visual future.



Suicidal Fantasies: The Desire to Have Severity of Complications Finally Appreciated

- Feels that nobody understands what it's like for them.
- Feels that doctors don't understand what it's like to see with their aberrations, don't understand their dry eye, or anything else.
- Feels their family doesn't understand what it's like to live with their vision and ocular surface conditions.
- Feels that communicating the significance of these problems is impossible.
- May feel like a freak to have these problems.
- Feels very alone and helpless, because no one can understand.

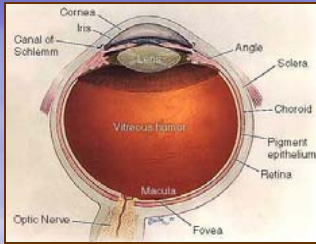
Suicidal fantasies express a wish to have the severity of problems finally appreciated.



Suicidal Fantasies: The Desire to Return to Purity

- Discusses effects of vision issues in metaphysical or spiritual terms.
- Views “Lasik greed” not as an isolated phenomenon, but as symptomatic of the times we live in.
- Cynical about human nature: Sees ophthalmology as having sold its soul to a God called “Money,” thus presaging the future of all medicine.
- Views FDA as having been bought out by the power of money.
- Wants to know “Why would God let this happen?”
- Believes that society will probably never find out what Lasik complications are really like, and may not care if it does find out.
- The existentialist is essentially a disappointed idealist, whose honest faith in the humanism of medicine has been revealed to be unjustified and naïve.

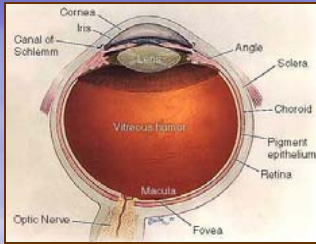
Suicidal fantasies express a desire to be away from temporal greed and evil, as well as a desire to be close to something pure, namely God.



Suicidal Fantasies: The Desire to Withdraw into a Protective Shell

- Numbness expresses a state of extreme withdraw.
- Commonly seen with extreme depression, notably, psychomotor retardation.
- Withdraw can express the “numbing and avoidance” factor of posttraumatic stress.
- Reactions seem delayed, not processed to any depth, devoid of spontaneity, life, or nuance.
- Patient may seem dissociated, or in and out of contact with social reality (lack of eye contact, inability to track conversations at any speed).
- Patient may feel that own thoughts are crawling or disorganized, or may not feel anything at all.

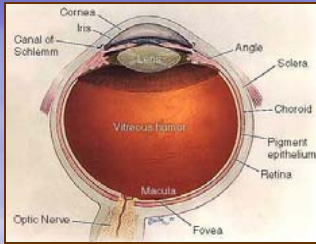
Suicidal fantasies express a desire to retreat into a “protective shell” free from ocular surface trauma, higher order aberrations, the conduct of medical professionals with whom the patient has had contact, the whole industry.



Suicidal Fantasies: The Desire to End the Pretense of Being Okay

- Puts on a face everyday and pretends that everything is okay, or at least not so bad.
- Refuses to acknowledge to others (and to own self) just how bad vision and ocular surface conditions really are.
- Desperately needs to believe that things are okay, and will remain okay.
- Rationalizes refusal to communicate emotional distress by telling self that “if others knew how I really felt, they’d probably think I’m a freak” or “no point in talking about it, they don’t see what I see, so they wouldn’t understand anyway.”
- Denial may also represent refusal to acknowledge that self as damaged or defective.
- May be unable to participate in forum discussions with the larger casualty community, as these tend to put pressure on patient’s denial mechanism.

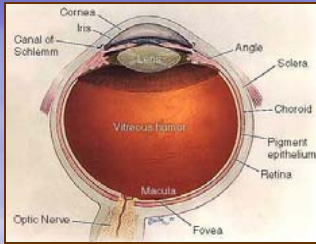
Suicidal crises can occur when denial collapses abruptly under the weight of objective reality: Circumstances develop in which the patient is forced to confront his or her own visual disability and its implications for their life and future. Patient is temporarily overwhelmed, but quickly returns to denial when conditions relent.



Suicidal Fantasies: The Desire to End Self-Blame

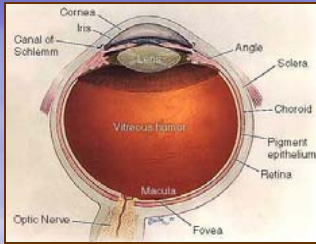
- Feels duped by deceptive and corrupt industry, but blames own self for trusting doctors instead of checking everything out on own.
- Sees self as not only having substantial visual impairment, but as having paid to receive a visual disability.
- Regards LASIK as “stupidest thing I ever did.”
- May assert that “I was never a candidate, and it was right in front of me the whole time, if I’d only checked it out.”
- May regard self as having been incredibly naïve, as available to be taken advantage of.
- Now sees world pragmatically as cruel and exploitive place where people must look out for themselves: Caveat Emptor.

Suicidal fantasies express the desire to be relieved from the guilt of having wasted one’s own life, one’s potential as a human being, and having paid a price to do so. Doesn’t mind making mistakes and learning lessons in life, but views the “LASIK lesson” as simply too hard to swallow, as there is no way back and no way forward (no real recovery).



Perfectionism

- Despite communications with 250-350 patients, I have never observed a patient who I felt was perfectionistic about their vision.
- Such patients typically have multiple “symptoms” as describing in the laser labeling, which singly or collectively contribute to “ocular burden”.
- Assertions of perfectionism seem designed to...
 - Protect the doctor’s ego: The surgeon or surgery can’t be imperfect if the patient is shown to be imperfect.
 - Insulate the doctor from the reality of having tragically damaged another human being.
 - Undermine complaints about dry eye and higher order aberrations on quality of life.
 - Protect the surgeon from possible legal action.
- Assertions of perfectionism rest on a common assumption: That all surgeries produce somewhat imperfect vision, and that patients should be prepared to deal with a certain “normative level” of visual impairment.
- If this is true, then why was it never systematically studied in clinical trials?
- Assertions of perfectionism have no empirical basis. There have been no studies that specifically examine perfectionism among post-LASIK patients.



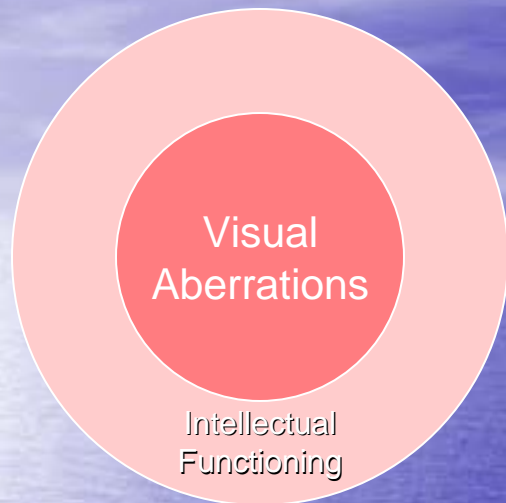
Body Dysmorphic Disorder

- Patients with Body Dysmorphic Disorder are concerned with features felt to be the object of public observation and potential embarrassment or ridicule.
- Vision is not subject to public observation, and therefore, cannot constitute a basis for Body Dysmorphic Disorder
- Diagnoses of Body Dysmorphic Disorder simply reflect ophthalmology's poor understanding of psychology. Refractive surgeons are not psychologists.



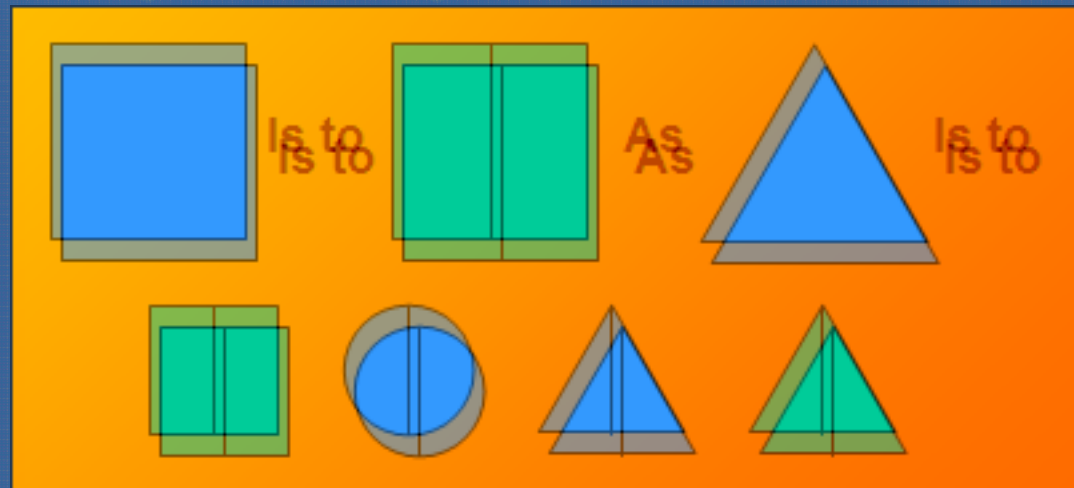
Effects of LASIK complications On Intellectual Functioning

RSSS: Level of Intellectual Functioning: #1



In the Multiaxial Model of the DSM, Axis II is concerned personality and intellectual functioning.

- Effects on Intellectual Function are both Direct and Indirect. Because intellectual functioning rests on the ability to synthesize information accurately across a variety of sensory modalities, RS casualties can be expected to perform lower on IQ tests than before surgery.
- In particular, perceptual speed can be dramatically reduced.
- Test anxiety may be severe, since patient is worried about performing at pre-RS level.
- Patients may seem confused because the visual information they are receiving is confused: Hard to distinguish what is signal and what is noise.



RSSS: Effects on Intellectual Functioning Mediated by DSM Disorders

- Depression:
 - Inability to concentrate is often part of depression.
 - Psychomotor retardation: Feeling that movements and thoughts are crawling. (“I just can’t think anymore.”)
 - Black moods make intellectual activity seem unrewarding, worthless, or pointless (“why should I try...my life is over anywhere...there are no solutions”)
 - Patient refuses to spend effort on cognitive tasks due to fear of failure, or because failure would provide objective confirmation regarding loss of ability.
 - Patients fall back on rote behaviors and lose ability to problem solve creatively, or to follow a complex methodology to its solution.
 - Catastrophic, globalized cognitions tend to soak up short-term memory resources (e.g. “I will never get better”)

RSSS: Effects on Intellectual Functioning also Mediated by DSM Disorders

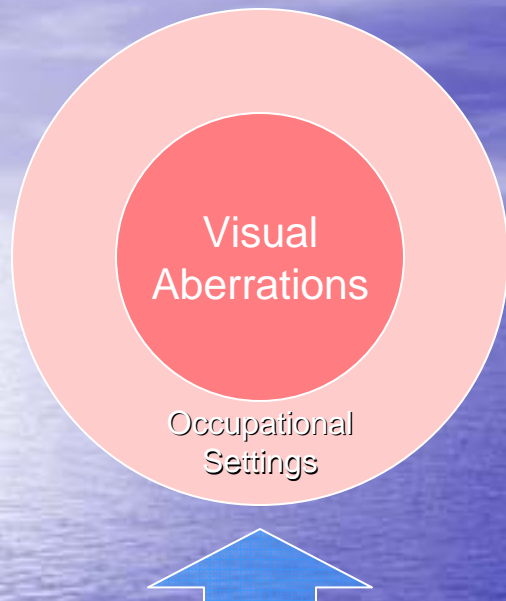
- Post-Traumatic Stress Disorder:
 - Recurrent and intrusive thoughts prevent patient from focusing for extended periods of time.
 - Dissociative states cause patient to lose concentration again and again.
 - Patient “numbs out” and avoids any intense cognitive task.
- Loss of Self Esteem:
 - Patients refuse to problem solve because possibility of failure confirms feelings of shame and worthlessness.
 - Patients lack confidence to produce solutions to complex tasks that are open to public inspection.

Refractive Surgery Shock Syndrome:

Interpersonal and Contextual Effects

- Interpersonal Behavior
- Social Cognition
- Marital and Family Effects
- Effects in Occupational Settings

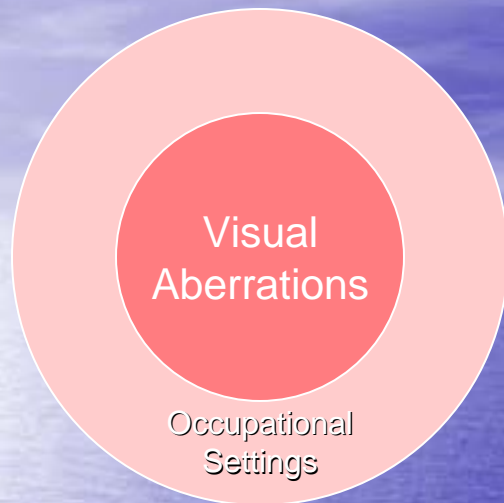
RSSS: Effects at Work



In the Multiaxial Model of the DSM, Axis IV is concerned with the psychosocial environment. Axis IV contextualizes the conditions of Axes I, III, and III, changing their meaning, manifestation, course, and severity. Occupational settings are considered to be part of Axis IV.

- Co-workers do not understand what the patient is going through.
- Patients will receive sympathy at first, but sympathy can turn to anger if patient is perceived as chronically “not pulling your weight.”
- Tactless co-workers exacerbate RSSS by saying, “I had LASIK and mine turned out just fine!”
- Bosses become frustrated because they feel they can no longer count on the employee.
- Patients worry about letting down those they admire.
- Patients feel frustrated by their vision, and worry about falling behind and about increasing pressure to perform at premorbid levels of functioning.
- Patients may spend incredible amounts of psychological energy trying to “put on a happy face,” and eventually collapse under the burden.
- Patients worry they will no longer be able to fulfill their potential in life, but instead must just try to “hang on.”
- Patients worry that bosses will tire of granting them time off to pursue solutions that never seem to work.
- Patients worry that their situation is the object of office conversation behind the scenes, and frequently it is.
- Patients worry that if they lose their job, they will never get another one, or will get a bad recommendation.

RSSS: Effects on Interpersonal and Social Skills



In the Multiaxial Model of the DSM, Axis IV is concerned with the psychosocial environment. Axis IV contextualizes the conditions of Axes I, III, and III, changing their meaning, manifestation, course, and severity. Interpersonal and social skills are, by definition, relevant to Axis IV.

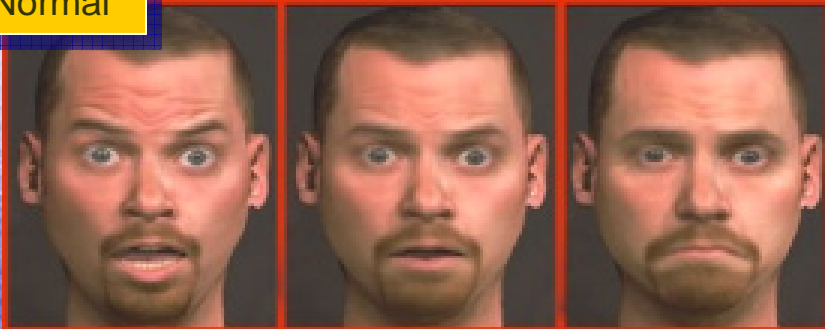
- The DSM disorders which underlie RSSS have broad implications in the interpersonal domain.
 - Research shows that depressed persons eventually elicit anger from others if depression does not abate.
 - Significant others may feel rejected by patients who talk about their suicidal ideations: "You mean, you think our relationship isn't worth sticking around for?"
 - Much, much more.
- Some interpersonal consequences are mediated by cognitive effects of RSSS, so that RSSS patients simply have less sensitivity to subtle interpersonal cues than before refractive surgery.
 - Patients may be unable to discern facial expressions accurately at a conversational distance, or unable to see faces at any distance.
 - Patients are distracted by their visual distortions. These distractions compete for short-term memory resources and prevent patients from responding to subtle social cues.
 - Patients may seem pre-occupied with their visual problems, further distancing them from others.
 - Effective interpersonal behavior requires accurate internal models representing the mind state and motivations of others. Patients may be unable to "finish the processing" of interpersonal events due to intrusive thoughts and imagery.

RSSS: Effects on Social Cognition

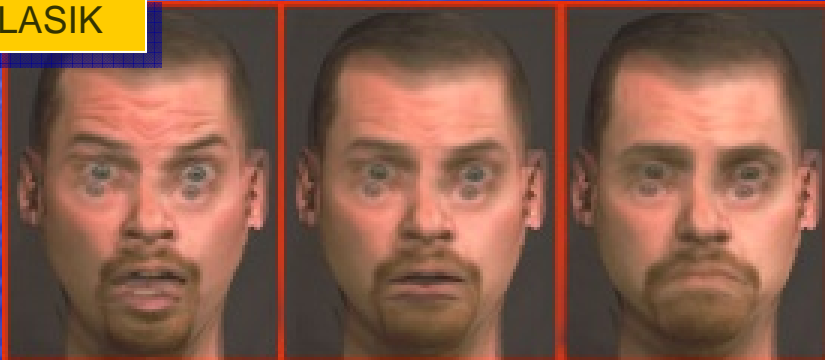
LASIK



Normal



LASIK

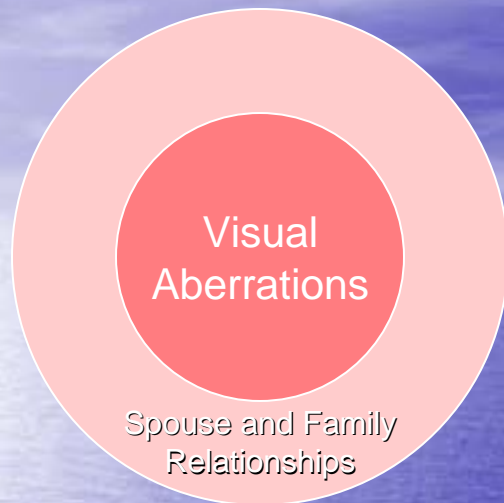


- Social cognition rests upon the ability to create accurate internal representations of the emotional states and agendas of others.
- Patients with RS complications may be unable to correlate facial expressions and emotional states, due to “visual interference.”
- In general, the more subtle the emotional expression, the more visually damaged the patient, and the faster the pace of communication, the more difficult it is for the patient to behave with “social competence.”
- Some patients may chronically “lag behind” when processing nonverbal cues...by the time the patient discovers what is happening, the conversation has moved on.
- RS-Induced deficits of social cognition have broad implications for performance in the workplace and in relationships, where accurate social cognition is paramount.
 - Such deficits affect how the patients responds to others.
 - And affect how others respond to the patient.

Refractive Surgery Shock Syndrome:

Effects on the Family

RSSS: Effects on Family Relationships



In the Multiaxial Model of the DSM, Axis IV is concerned with the psychosocial environment. Axis IV contextualizes the conditions of Axes I, III, and III, changing their meaning, manifestation, course, and severity. Spousal and Family relationships are considered to be part of Axis IV.

- Family members do not understand what the patient is going through.
- Patients will receive sympathy from family members at first, but this sympathy often turns to anger.
- Patients who cannot cope as well as family members would like may receive anger and rejection, leading to escalation of psychological symptoms in the patient, creating a vicious circle.
- Patients may be accused of being obsessed with their eyes.
- Patients may be told to simply “put it behind you.”
- Anger about time and money consumed by search for solutions is manifested in relationships as loss of emotional intimacy and escalation of number and intensity of disagreements.
- Children may feel abandoned by the RSSS parent, and experience reduced educational achievement, or may even act out at home or at school.
- Non-RS spouse wonders “Where did my wife/husband go?” and resents caregiver burden.
- Both RSSS and non-RS spouse “want their old lives back,” but neither knows how to achieve it.
- The RSSS spouse feels intense guilt as an emotional burden and monetary drain on the family.

RSSS: Family and the Suicidal RS Patient

- RSSS family members may become depressed themselves because they cannot understand what has happened to their family, and do not want to “continue living like this.”
- RSSS family members may no longer behave spontaneously around the patient, because they are too self-conscious about saying or doing something that might push the patient over the edge.
- RSSS family members worry about finding the patient dead, or have nightmares about finding the patient dead.
- RSSS family members may secretly try to prepare themselves emotionally for losing the patient.
- RSSS family members may feel extreme guilt for not being able to help the patient, or find help for the patient.
- RSSS family members may feel abandoned by RSSS patients who talk about suicide...they may react with anger and distancing, even though the patient needs unconditional love and support.
- RSSS family members may become highly overprotective of the patient, refuse to allow the patient out of their sight, take total responsibility for the patient’s needs, and otherwise “infantilize” the patient.

RSSS PTSD: Family Exposure to Trauma

- Because the RSSS patient is unable to recover, family may feel that the trauma is always in the present, even though the surgery occurred years ago.
- Family members may accuse RSSS patient of being irritable, easily enraged, unable to relax, distant or distracted, incapable of (or uninterested in) being sensitive to the needs of the family, unable to give love, preoccupied, or demanding.
- Family members may feel confused by, come to avoid, or even isolate the RSSS patient from family life.
- Family members may feel rejected because the RSSS patient wants to avoid talking about his or her feelings while being determined to avoid situations that are visually demanding (e.g. going out at night).
- The RSSS patient may be removed from family planning, because the RSSS patient feels life is over and there is nothing to look forward to.
- Family members may feel guilty and depressed because they are unable to help the RSSS patient, or because they must now manage family financial resources too closely to seek additional help for the RSSS patient (i.e., “enhancement” costs, contact lens fittings).
- Family members may feel betrayed because the RSSS patient is emotionally cold, isolative, and angry.
- If the RSSS patient is a primary financial resource, family members may worry about being helpless or stranded if the RSSS patient is no longer employable.
- Family members may find their own sleep disrupted by the RSSS patients nightmares, or inability to sleep due to dry eye pain (e.g. fumbling for eye drops in the middle of the night).

RSSS Families: Role of Feelings of Deception in Development of Family Trauma

- Just as Feelings of Deception and Betrayal play a role in the development of PTSD, they also play a role in the development of RSSS family trauma.
- Family members may be angry at medical professionals for “taking away my wife/husband,” “destroying the life we had together,” or “destroying our family.”
- Family members may feel extreme outrage due to doctor behaviors that the patient alleges, or behaviors that family members state they have witnessed.
- Anger and outrage vacillate with hopelessness and helplessness.
 - Patients realize they lack the legal resources necessary to confront the RS industry
 - Patients realize that no legal verdict or money award will restore the patient’s vision.
 - And that no legal verdict or money award will restore the family’s life to normal.
- Family members feel bewilderment or anger that informed consent did not give appropriate weight to quality of life impacts (i.e., depression, PTSD, suicidal ideation, anxiety disorders, impact on work, home, and intimacy issues).
- Family members may develop a globalized mistrust of medical professionals in general and vow “never go to a doctor.”

Refractive Surgery Shock Syndrome:

Health Psychology

RSSS and Changes in Health Status

- Patients who develop RSSS are more likely to experience changes in health status than those who do not.
- The greater the intensity of RSSS, the greater the risk for a major change in health status.
- Patients with RSSS have an overall poorer level of health after refractive surgery.
 - Patients tend to exercise less.
 - Patients lose interest in developing or maintaining a healthy diet.
 - Patients exhibit more apathy toward their health.
 - Patients may engage in substance use or risky behaviors that compromise their overall level of health.
 - Patients may fail to comply with drug regimens, particularly where these would be experienced as burdensome or complex before RS.
 - Patients have an overall lower level of immune functioning after RS than before.
 - Patients are simply sick more often than before RS.

Changes in Health Status Mediated by RSSS Symptoms

- Patients who develop RSSS Depression...
 - Develop a sense of apathy toward their own health and “stop taking care of themselves.”
 - Lose the energy and motivation necessary to start or continue an exercise program.
 - Lose the self-discipline necessary to continue a dietary regimen.
 - Feel there is no need to safeguard their health, since their life is essentially over anyway.
 - Sometimes can't remember whether they've taken their medications, even where the motivation exists.
 - May simply wish they were dead, or subconsciously want to punish themselves.
- Patients who develop RSSS PTSD...
 - Feel a sense of “foreshortened future,” such that their overall level of health is irrelevant.
 - Feel “numbed out” and unable to experience any joy or gain from exercising.
 - Avoid exercise if it was previously a strong part of their identity, simply because it constitutes a reminder of what their lives were like before RS.

Origins of Refractive Surgery Shock Syndrome:

Contributions of the RS Industry

- RS Advertising
- Inadequacies of Informed Consent
- Alleged Doctor Behaviors

Feelings of Deception Contribute to RSSS

DSM-IV Quote from PTSD section: “The disorder may be especially severe or long-lasting when the stressor is of human design (e.g. torture, rape). The likelihood of developing the disorder may increase as the intensity of and physical proximity to the stressor increase.”

- Feelings of Deception mediate the development of RSSS symptom expression in many cases.
 - Current Advertising of Refractive Surgery establishes unrealistic expectations which set patients up for severe psychological trauma.
 - Current Informed Consent cloaks real consequences of complication in medical terminology, without addressing quality of life in understandable language.
 - Post-op Discovery that “FDA approval” is almost meaningless, since scientific standards for vision quality are grossly deficient.
 - Post-op Discovery that what surgeons call a complication bears little resemblance to what patients call a complication.
 - Post-op Discovery that so-called “complication rates” are not really scientific, but skewed for marketing purposes.

Contribution of RS Advertising to the Development of RSSS

“10 minutes painless surgery... wake up to perfect vision for the rest of your life.”

“Dr. XXXX was a pioneer in the development of LASIK, and has done over X,XXX procedures.”

RSSS

- Depression
- PTSD
- Other Anxiety Disorders
- Substance Use

Use of “Star Power” to promote trust among the masses.

Use of testimonials establishes trust, while short-circuiting rational thinking about range of outcomes. Testimonials mention only positive effects on quality of life, never the effects of LASIK complications on quality of life.

Contribution of Informed Consent to the Development of RSSS

Patients discover that the purpose of informed consent is legal, not psychological...that it is to protect the doctor, not to inform the patient.

Informed consent focuses on medical terminology, but excludes its quality of life consequences. In contrast, marketing focuses on quality of life, but excludes medical terminology.

RSSS

- Depression
- PTSD
- Other Anxiety Disorders
- Substance Use

Informed consent fails to mention Major Depression, suicidal ideation, PTSD, other anxiety disorders, substance use, and Dissociative conditions, although all of these are medical conditions. Patients are completely unprepared to confront these disorders.

Informed consent fails to prepare patients for co-morbidity of complications, the fact that a single complication makes others much more likely. Patients get 3,4, or 5 complications, without realizing this is even possible. Example: GASH.

Contribution of Alleged “Doctor Behaviors” to the Development of RSSS



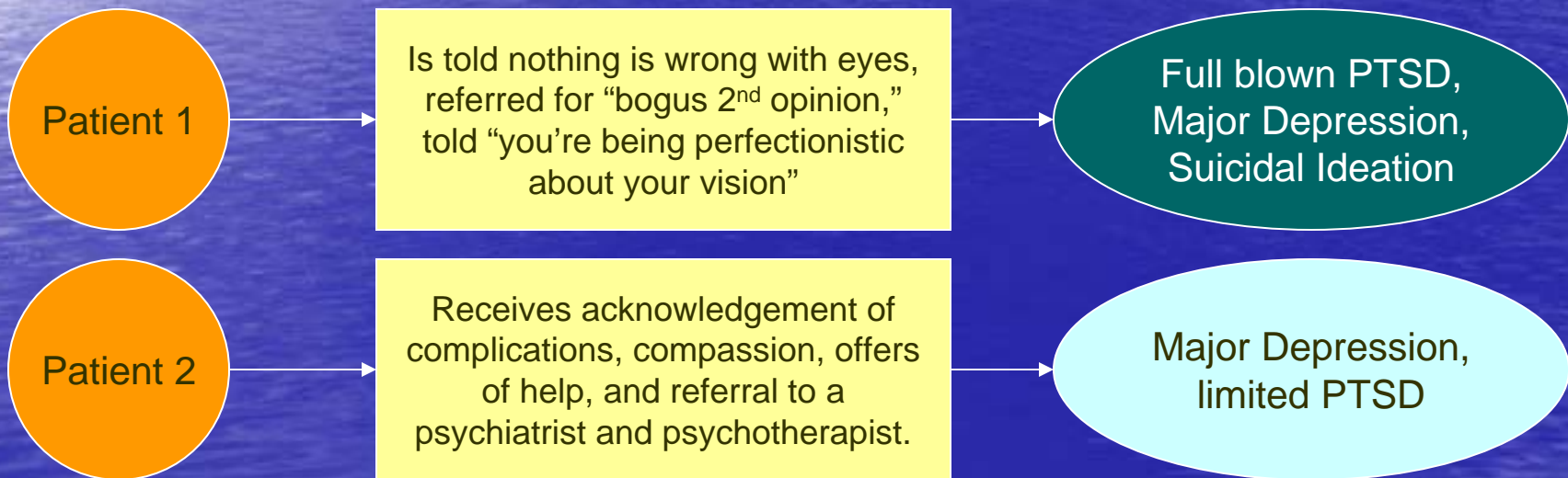
- 9. Hearing similar stories from other patients who have the same surgeon.
- 10. Abandonment of patient.
- 11. Charging patients whose lives have been destroyed even more money for dubious experimental treatments.
- 12. Creating unrealistic hope: “Don’t worry, the technology to fix you is right on the horizon”
- 13. Hearing or seeing the same RS ads to which the patient initially responded.

- 1. Patients told there is nothing wrong with their eyes.
- 2. Patients referred for “bogus 2nd opinion.”
- 3. Patients told they are being perfectionistic about their vision.
- 4. Patients greeted with coldness and hostility when attempting to discuss their complications.
- 5. Patients greeted with an attitude that minimizes the severity of their complications.
- 6. Patients told that their complications can be cured with a contact lens...that never works out.
- 7. Patients subjected to an “enhancement” that makes their vision worse.
- 8. Patients told their complications will abate with time...which may or may not occur.

Identical Complications, Different Outcomes

DSM-IV Quote from PTSD section:

“The disorder may be especially severe or long-lasting when the stressor is of human design (e.g. torture, rape). The likelihood of developing the disorder may increase as the intensity of and physical proximity to the stressor increase.”



Refractive Surgery Shock Syndrome:

Psychological Aspects of Treatment

RS-Induced Disorders are Extremely Difficult to Treat with “Conventional Approaches”

- There is no known psychological treatment which is effective for RSSS, because patients cannot “get away from their eyes.” Accordingly, the immediate cause of the disorder cannot be removed.
- Comorbidity of DSM Disorders makes RSSS much more difficult to treat.
- RSSS PTSD can be expected to be more difficult to treat than “ordinary PTSD,” since in RSSS PTSD, the cause of post-traumatic stress cannot be removed.
- Because RSSS is often at least in part the by-product of broken trust between doctor and patient, patients may find it impossible to establish trust or confidentiality with a psychotherapist, psychiatrist, or other mental health professional.
- Patients with PTSD symptoms will find it especially difficult to pursue solutions that involve visiting a refractive surgeon, and possibly any eye care professional.
- Because psychiatric drugs that might relieve RSSS also affect tear volume and pupil size, the very drugs intended to relieve depression can make patients more suicidal, even where patients have no previous history of psychological disorders.
- Many patients face “money problems” after RS complications, which can greatly narrow the range of psychological treatment options.

Contact Lens Fittings can be Highly Stressful for RSSS Patients

- Contact lens fittings is a high stakes game in which the patient's vision may be completely or partially restored. Because RS complications affect the patient's whole life, patients may feel their whole life is at stake with each fitting.
- Patients who experience RSSS are at risk for exacerbation of depression, suicidal ideation, PTSD, and other symptoms following a "failed fitting."
 - Patients who are known suicide risks should be observed carefully before leaving the clinical setting.
 - Ethically, doctors should inquire about the intensity of suicidal ideation in such patients.
 - Patients who admit to having a suicide plan may need to be hospitalized.
- Patients who are fitted unsuccessfully over and over again may...
 - Develop increased RSSS symptomatology.
 - Protect themselves with "defensive pessimism," and actually expect failure.
- Withdraw from the process of visual rehabilitation, afraid to try again.
 - Because of money spent (most patients have "money problems" after failed RS).
 - Due to hostility from others (spouse, boss) for "wasted" time and resources.
 - Because of fear that another unsuccessful fitting could make symptoms worse.

Restoration of Vision Reduces RSSS severity, But does not eliminate RSSS symptoms

- While Restoration of Vision can be expected to reduce symptoms of RSSS, it is expected that an underlying vulnerability to the disorder may continue for the rest of the patient's life.
 - RSSS is not just about vision...broken trust is core to the disorder.
 - Trust is hard to re-establish once broken.
- Patients who develop RSSS are “psychologically fragile” and may continue to be plagued by symptoms of PTSD, depression, and other RSSS DSM disorders.
 - Patients whose vision has been restored may feel “on edge,” constantly alert to minor fluctuations in their vision that could indicate that something has gone wrong again.
 - Patients know other patients whose eyes have gotten worse over time for reasons unknown, creating massive uncertainty about the future: “Which way is it going to go for me??”
 - Patients who develop PTSD may have a sense of impending doom which does not abate, particularly when restoration of vision is partial rather than complete.
 - Patients whose vision is partially restored live in constant fear of again losing any degree of visual functioning, and can develop exacerbation of RSSS symptoms if they think this might be occurring, even if it really isn't.
 - Patients whose vision is partially or completely restored do not have their lives restored. Patients must start over in rebuilding their lives occupationally and financially. Some have even been divorced by their spouses.
 - Patients face tremendous obstacles that would adversely impact even individuals with perfect vision.

Refractive Surgery Shock Syndrome:

Role of Internet in Creating
Consciousness of Being Part of
a Coverup

Patient Websites Affect the RSSS Response of Patients with Complications

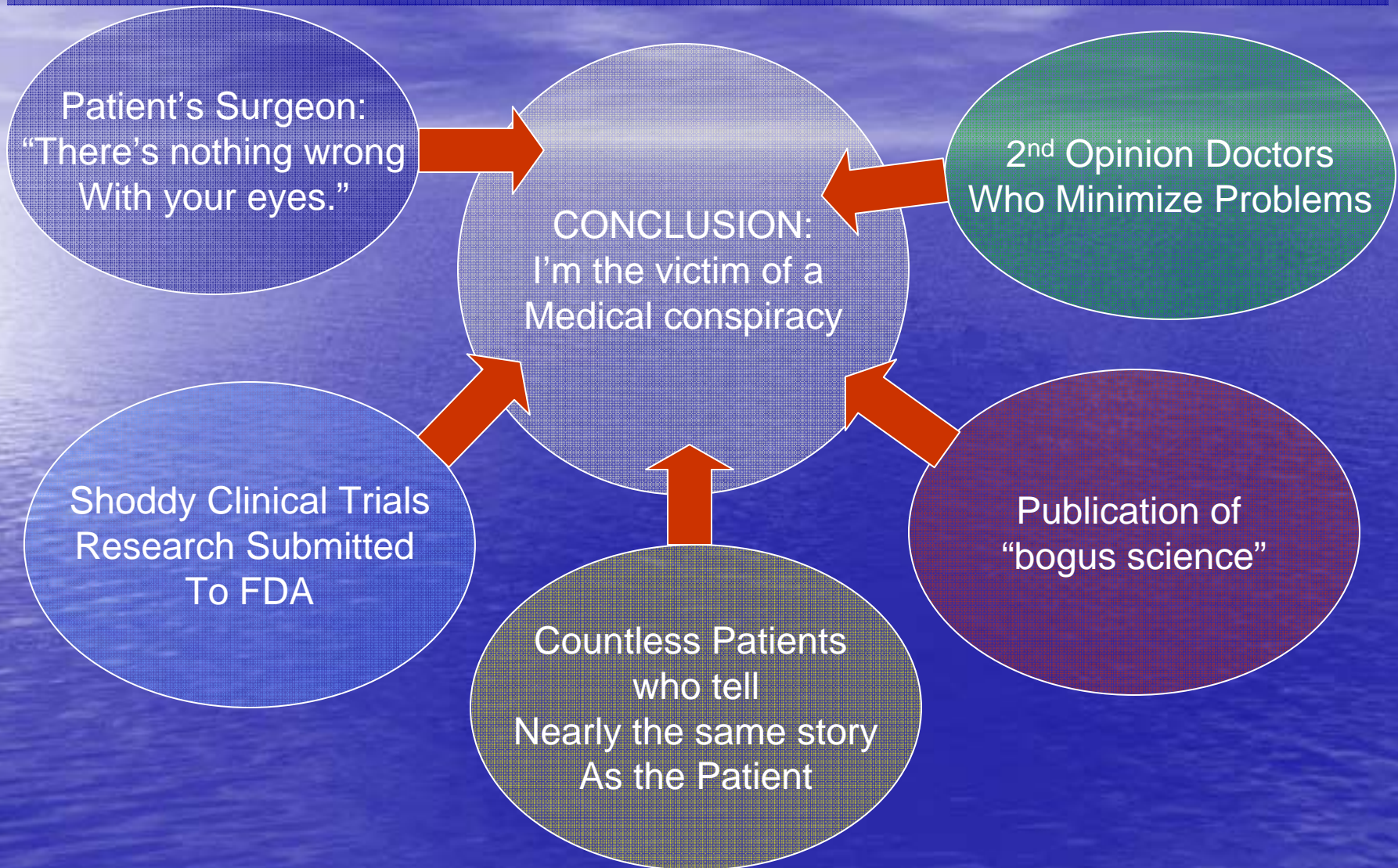


- Patient sites allege that the industry creates its own science, particularly with regard to pupil size, with little regard for scientific integrity.
- Individuals with post-LASIK complications see these websites, examine information offered in support, and may conclude that they victims of a wide-ranging medical conspiracy.
- Are they?

Psychotherapy of RSSS Patients is Complicated by Statements Relevant to Allegations of Medical Conspiracy

- FROM LASIKDISASTER.COM: In July, 1999 this quote was published in EyeWorld:
 - *"We are only starting to ride the enormous growth curve of LASIK in this country. There will be more than enough surgeries for everyone to benefit if we keep our heads by sharing information openly and honestly and by resisting the temptation to criticize the work of our colleagues when we are offering a second opinion to a patient with a suboptimal result. Who was it who said, "When the tide comes in, all the boats in the harbor go up?"*
- Cognitive psychotherapy rests in part on getting patients to challenge false beliefs.
- How do psychotherapists deal with these kinds of statements, published in scientific medical journals, when patients bring this material into therapy?
- This is only one such example. There are many such examples. As a result, psychotherapists have no way to refute the contention that this quote shows "State of Mind."
- Statements such as these exacerbate feelings of distrust between patients and surgeons, and reinforce patient opinion that they are victims of a greedy and dishonest industry.
- Patients want to truth about not only their eyes, but also about their lives. Patients want to know if they are indeed victims of a medical conspiracy. Many have already come to this conclusion.

Patients Allege that Data Supporting Medical Conspiracy Converges from a Variety of Levels



An Example from the FDA's MAUDE Database



The screenshot displays the FDA's MAUDE Database interface. At the top, the FDA logo and "U.S. Food and Drug Administration" are visible, along with the Department of Health and Human Services logo. Below this, the "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH" is identified, with links to the FDA Home Page, CDRH Home Page, Search, CDRH A-Z Index, and Contact CDRH. A navigation menu includes links for 510(k), Registration & Listing, Adverse Events, PMA, Classification, CLIA, CFR Title, Advisory Committees, Assembler, Recalls, Guidance, and Standards. A "CDRH SuperSearch" logo is also present. The main content area is titled "Adverse Event Report" and features a "back to search results" link. The report details a "Patient Outcome" of "Other; Required Intervention Disability" and an "Event Description" where a patient describes a negative LASIK surgery experience, including high astigmatism, large pupils, and complications like microstriae and dry eye.

Adverse Event Report

[back to search results](#)

Patient Outcome Other; Required Intervention Disability

Event Description

I had [redacted] lasik with [redacted] in 2005. I was convinced, by a dr that i had been seeing for more than ten years, to have the surgery during a routine examination. I had been struggling with contact lenses due to my high astigmatism for years so lasik seemed like the perfect solution. I had heard so many good things about the surgery and i never imagined that my dr would mislead me. My mainfest refraction was: od -0. 25 -4. 25 x 95, os -0. 75 - 3. 25 x70. My vavescan refraction was: od +0. 3. 2 -3. 80 x 98, os -0. 52 -3. 25 x 71. My pupils were measured at 8. 3 mm twice before surgery. I was told that i was a good candidate. I do not feel that the procedure should be approved for a pt with very large pupils and such a high prescription. The computer recorded this info before treatment, however, my physician appearently felt that i was an "excellent candiate. " aside from being a bad candidate i also developed micro striae in both of my flaps which may have been caused by inflammation from the [redacted] laser. These folds were kept hidden from me despite my constant complaints of ghost imaging and glare. I eventually got a second opinion and underwent flap suturing with another surgeon which made my striae -and symptoms- much worse. At this point my acuity is correctable to 20/20 with glasses but my vision in low light is terrible. I also have severe dry eye after seven months which causes constant burning and discomfort.

In my experience, the fact that so many patients are telling and hearing the same stories on various patient websites and through email with each other makes their emotional response much worse.

Note that the patient is 20/20.

Refractive Surgery Shock Syndrome:

Research Directions

Famous Philosophers of Science

■ *Karl Popper*

- According to the eminent logician and philosopher of science Karl Popper, the purpose of good scientific research should be to falsify existing scientific theory. Science is a series of successive approximations to objective truth.

■ *Thomas Kuhn*

- Science necessarily takes place in a sociological context, within a community of scientists who articulate a core set of beliefs that describe their subject domain.
- Kuhn states that so-called Normal science “is predicated on the assumption that the scientific community knows what the world is like”
- “Normal science often suppresses fundamental novelties because they are necessarily subversive of its basic commitments.”
- Scientific Research is “a strenuous and devoted attempt to force nature into the conceptual boxes supplied by professional education”

Accordingly, Good Casualty-Driven Science Should...

- In the tradition of Karl Popper...
 - Expose existing assumptions about LASIK to strong threats of falsification via the scientific method.
- In the tradition of Thomas Kuhn...
 - Challenge core assumptions maintained by the RS industry using the scientific method.
 - Establish scientifically that the LASIK industry does not understand “what the world is like” for patients with complications...
 - By elucidating psychological clinical syndromes produced by RS complications.
 - By demonstrating scientifically the inadequacies of informed consent and CAUSAL links of these inadequacies to the development of psychological clinical syndromes.
 - Prevent the subversion of “fundamental novelties” produced by casualty-driven science.

Feelings of Deception must be a Dependent Variable in the Scientific Study of RSSS

- No psychological disorder can be fully understood unless its antecedent causes are elucidated and described for subsequent empirical study.
- Feelings of deception are a legitimate psychological variable reported to affect the severity and course of PTSD, and PTSD is part of RSSS.
- Study of effects of feelings of deception is important for scientific honesty and integrity.
- Feelings of deception are a psychological construct, and do not necessarily entail actual deception.
- A variety of research designs could establish not just a correlational relationship, but a CAUSAL relationship between industry standards of informed consent, alleged doctor behaviors, standards of advertising, and the development and severity of RSSS, if these relationships exist.
- Representative samples are not required to complete these studies (Rasch Model).
- Sample size will not be an issue, since thousands of patients are available.
- Such studies themselves constitute a kind of psychotherapy for patients who feel helpless, hopeless, and alone, because they validate the legitimacy of the patient's own experience in a scientific context.
- Such studies are consistent with the philosophy of science introduced elsewhere in this presentation

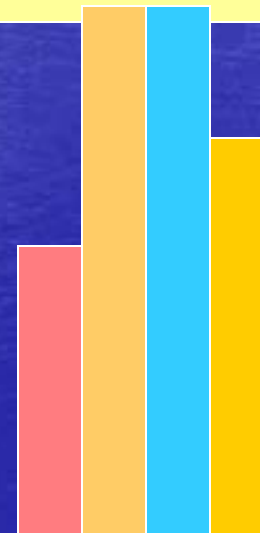
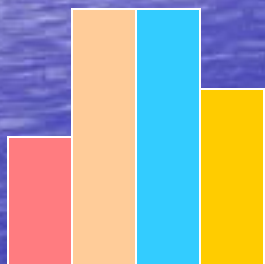
Role of Feelings of Deception in Development of RSSS: Simple Design

Low Feelings of Deception and Betrayal Group

High Feelings of Deception and Betrayal Group

Level of RSSS Symptomatology

- Depression
- PTSD
- Other Anxiety Disorders
- Dissociative Symptoms
- Suicidal Ideation



Groups would be...

- Matched in terms of degree of Visual Damage
- Selected to exclude premorbid psychological symptoms

Satisfaction Surveys are Irrelevant to the Study of Depression and Suicidal Ideation

- To study depression, mental health professional study depression, not joy.
- To study suicidal ideation, mental health professionals study suicidal ideation, not bliss.

Perhaps 5 Percent of All LASIK patients are Dissatisfied, but of this 5%...

What % represent "Simple Dissatisfaction"?
(dissatisfied, but without mental health consequences)

What % are Depressed?

What % have Suicidal Thoughts?

Studies of post-LASIK emotional adjustment must break "Dissatisfaction" into various levels Ranging from simple dissatisfaction to suicidal ideation. Not to do so obfuscates the scientific issues involved.

Research Directions: Medical Ethics Must Become an Empirical Science

- Because there was no empirical research on what candidates for RS would want in their informed consent, psychological variables were uncontrolled.
- Before a consumer-oriented procedure can launch, the FDA should research what patients want to know about risk.
 - “If LASIK could lead to feelings of depression or PTSD, would you want to know?”
 - “If LASIK could lead to feelings of suicide, would you want to know?”
 - “If the relationship between LASIK and depression had never been researched in the FDA approval process, would you want to know?”
- Failure to conduct such research has led to weird doctrines such as “remote risks do not need to be revealed to patients.”
- Such research should be conducted and published immediately, providing a compelling empirical basis on which to revise informed consent nationwide.
- Research on RSSS is important in the development of medical ethics as an empirical science, but requires that patients’ feelings of deception be confronted with scientific honesty and integrity.

Survey Questions: Medical Ethics as an Empirical Science

“If LASIK complications could cause you to want to commit suicide, would you want to know?”

YES NO

Candidates

Y

N

Post-op
Successes

Y

N

Post-op
Casualties

Y

N

Results are fictional, but as you can see, this represents a new and interesting direction for medical ethics, with broad implications for consumer medicine.

Take Home Message for FDA Panel #1: Evidence is Abundant

- The CORS Study presaged what is now becoming public knowledge: Depression and suicidal ideation are common in patients with complications.
- This presentation was originally published in 2004. Most of the content herein was borrowed from that version.
- Depression and Suicidal ideation are widely known in the post-LASIK casualty community.
- Evidence of post-LASIK depression, suicidal ideation, and posttraumatic stress is abundantly available on patient bulletin boards.
- Probably no one who's had severe complications from LASIK doubts the existence of RSSS.
- Patient-led nonprofits (Vision Surgery Rehab Network, LaserMyEye.org) have TONS of experience in dealing with depression, suicidal ideation, post-traumatic stress, and anger.
- LasikMemorial.com has real stories from real people.
- The FDA's MAUDE database (reports adverse outcomes from medical devices) already contains accounts of individuals who are obviously in severe psychological distress.

Take Home Message for FDA Panel #2

- There is an immediate need to study the psychological effects of LASIK in current casualties.
- Current patients may well have a history of experience with the LASIK industry (denial, minimization of suffering) that is unlikely to be duplicated by an industry-led study.
- The industry has a strong conflict of interest in studying depression and suicidal ideation objectively. The public may not understand Higher Order Aberrations, but it does understand depression and suicidal thoughts.
- Patients who already have complications deserve to have their experiences with the LASIK industry recorded dispassionately and scientifically by the Federal Government.
- An industry-led study would probably follow a higher standard of care and have better informed consent, thus reducing feelings of deception and therefore, development of posttraumatic stress.
- Given the number of MDs and PhDs damaged by LASIK, patient-led studies will undoubtedly be done at some point in the future.
- Convergence between patient-led and industry-led national studies will be essential to reducing the psychological burden of patients who believe themselves to be victims of medical conspiracy.

Thank You

- If you are a casualty, my hope is that you found validation and perhaps some relief from your suffering.
- If you are a doctor, my hope is that you learned that LASIK complications affect the entire life of the individual, not just their eyes. Remember, casualties need not only your clinical skills, but also every ounce of compassion in your being if they are to recover from the psychological syndromes that are caused by visual aberrations, ocular conditions, and behaviors they have allegedly experienced with other medical professionals.