



June 28–30, 2013
The Breakers
Palm Beach, Florida

SYLLABUS

www.ophmasters.com

*Jointly sponsored by
AKH, Inc., Advancing Knowledge in Healthcare, Inc.
and the Florida Society of Ophthalmology.*

SCHEDULE OF EVENTS

Please note: *All general educational sessions will held in Ponce de Leon I-III.*

Friday, June 28

- 7:00 AM–5:00 PM ATTENDEE REGISTRATION
- 3:00–4:00 PM **STATE MANDATED COURSES**
Recognizing Patients at Risk for Domestic Violence
Teresa Drake, Esq.
- 4:00–6:00 PM **Prevention of Medical Errors**
Sandra Strickland, RN, MSN, LHRM, CPHRM
- 6:15–7:45 PM WELCOME RECEPTION WITH EXHIBITORS
Ponce de Leon IV-VI

Saturday, June 29

- 7:00–7:50 AM ATTENDEE REGISTRATION/BREAKFAST
- 7:55–8:00 AM WELCOME AND INTRODUCTIONS
- 8:00–8:40 AM **What about Femtosecond Laser Cataract Surgery: Is It Really Worth It?**
Karl G. Stonecipher, MD
- 8:40–9:20 AM **Landmark Glaucoma Trials: What We Have and Have Not Learned (I&II)**
Kuldev Singh, MD, MPH
- 9:20–10:10 AM MELVIN L. RUBIN, MD AWARD LECTURER
Central Serous Retinopathy: What's New?
Lee M. Jampol, MD
- 10:10–10:40 AM BREAK WITH EXHIBITORS
Ponce de Leon IV-VI
- 10:40–11:20 AM **The Toric IOL: Strategies for Success**
Warren E. Hill, MD
- 11:20–11:40 AM **What Went Wrong?**
Warren E. Hill, MD
- 11:40 AM –12:00 PM **IOL Power Calculations: Following Keratorefractive Surgery**
Warren E. Hill, MD
- 12:00–12:40 PM **Disruptive Innovation: Predicting the Future of Medicine (and Ophthalmology)**
Edward Buckley, MD
- 12:50–2:05 PM LEADERSHIP LUNCHEON
Mediterranean Ballroom
(The luncheon is included in FSO member registration. Non-Member and guest tickets are available for purchase at the registration desk. Tickets are \$100/person)

2:15–3:00 PM DESSERT RECEPTION WITH EXHIBITORS
Ponce de Leon IV-VI

3:00–5:00 PM **SUBSPECIALTY SYMPOSIA**

- **NEURO-OPHTHALMOLOGY**
Chair: Joshua Pasol, MD
Location: Ponce de Leon I-III
- **PEDIATRIC OPTHALMOLOGY**
Chair: Arysol Soltero-Niffenegger, MD
Location: South Mezzanine 2
- **REFRACTIVE SURGERY**
Chair: Clifford L. Salinger, MD
Location: South Mezzanine 3–4
- **RETINA-VITREOUS**
Chair: Stephen G. Schwartz, MD, MBA
Location: South Mezzanine 9–10

7:00–10:00 PM FOUNDATION EVENT—*A NIGHT IN LITTLE ITALY*
Mediterranean Ballroom

7:00–10:00 PM CHILDREN'S PARTY
Gulfstream 4

Sunday, June 30

7:00 AM ATTENDEE REGISTRATION/BREAKFAST

7:30–8:30 AM **Closed Claims Study***
Steven I. Rosenfeld, MD
**Attendance required at this lecture to qualify for the OMIC discount*

8:35–9:05 AM **Neuro-op Diagnoses Not to Miss**
Steven A. Newman, MD

9:05–9:15 AM RESIDENT LECTURE (NON-CME)
Quantitative Proteomics of Vitreous Humor to Identify Markers in the Induction of Posterior Vitreous Detachment
Ravi Keshavamurthy, MD

9:15–9:45 AM **Glaucoma Surgery with and without Cataract Surgery: Evolution vs. Revolution**
Kuldev Singh, MD, MPH

9:45–9:55 AM RESIDENT LECTURE (NON-CME)
Standardized Training Examination among Ophthalmology Residents
Andrew Carey, MD

9:55–10:25 AM **Diabetic Retinopathy: What's New in the DRCR Study?**
Lee M. Jampol, MD

10:25–10:45 AM	BREAK <i>West Ballroom Foyer</i>
10:45–10:55 AM	RESIDENT LECTURE (NON-CME) Treatment of Macular Edema in Genetic Retinal Dystrophies Daniel T. Kasuga, MD
10:55–11:25 AM	Imaging in Ophthalmology Steven A. Newman, MD
11:25–11:35 AM	RESIDENT LECTURE (NON-CME) An 18-Year Review of Microbial Keratitis: Isolate Trends and Susceptibilities Basil K. Williams, MD
11:35 AM–12:05 PM	Orbital Lesions in Children Edward Buckley, MD
12:05–12:35 PM	Presbyopia: The Final Frontier Karl G. Stonecipher, MD
12:35 PM	ADJOURN

LEARNING OBJECTIVES

Target Audience

This program has been designed to meet the educational needs of physicians and nurses who have a specialized interest in the field of ophthalmology.

Learning Objectives

Upon completion of the educational activity, participants should be able to:

- Systematically evaluate a child with proptosis;
- Determine what to image and the importance of tailoring the imaging studies to the suspected lesion;
- Discuss the importance of visual field testing and assessment of afferent visual pathways;
- Recognize the relationship between intraocular pressure and glaucoma;
- Understand the limitations of randomized clinical trials;
- Differentiate between objectives for patients with mild vs. severe glaucoma;
- Recognize the evolving role of new technology (OCT) in predicting and assessing patients with pituitary lesions;
- Describe the results of the collaborative normal tension glaucoma study;
- Review how to image and the critical importance of interacting with your radiologist;
- Review the importance of excluding restrictive strabismus as a cause of double vision;
- Recognize what is required for measurement, marking, placement and the calculation of surgically induced astigmatism;
- Understand how to handle IOL power calculations following refractive surgery;
- Demonstrate risk management measures designed to prevent high-risk medical errors;
- Conduct efficient and effective screenings for domestic violence.

ACCREDITATION



CME/CE provided by AKH Inc., Advancing Knowledge in Healthcare

Physicians

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of AKH Inc. and the Florida Society of Ophthalmology. AKH Inc. is accredited by the ACCME to provide continuing medical education for physicians. AKH Inc. designates this live for a maximum of 18.5 *AMA PRA Category 1 Credits™*. Physicians should claim only credit commensurate with the extent of their participation in the activity.

The maximum allocation for participants attending the following courses: 2 PRA Category 1 Credits™ for Prevention of Medical Errors course and 1 PRA Category 1 Credit™ for Recognizing Patients at Risk for Domestic Violence.

Coding-Of the 18.5 *AMA PRA Category 1 Credits™*, 5.25 *PRA Category 1 Credits™* are available for the Coding Course.

Physician Assistants

NCCPA accepts *AMA PRA Category 1 Credit™* from organizations accredited by ACCME.

Nursing

AKH Inc. is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's COA.

AKH Inc. designates this educational activity for 18.3 contact hours. Accreditation applies solely to educational activities and does not imply approval or endorsement of any commercial product by the ANCC-COA.

FL Nursing

AKH Inc. is an approved provider for nursing continuing education by the Florida Board of Nursing #50-2560. AKH Inc. designates this educational activity for 18.3 contact hours (1.83 CEU).

The maximum allocation for participants attending the following courses: 2 contact hours for Prevention of Medical Errors course, 1 contact hour for Recognizing Patients at Risk for Domestic Violence and 5.25 contact hours for the Coding Course.

Criteria for Success

Statements of credit will be awarded based on the participant's attendance and submission of the activity evaluation form. A statement of credit will be available upon completion of an online evaluation/claimed credit form at www.ophmasters.com/cme. You may claim credit online for this meeting until **August 9, 2013**. If you have questions about this CME/CE activity, please contact AKH Inc. at akhcustomerservice@akhealthcare.com.

Disclaimer

This course is designed solely to provide the healthcare professional with information to assist in his/her practice and professional development and is not to be considered a diagnostic tool to replace professional advice or treatment. The course serves as a general guide to the healthcare professional, and therefore, cannot be considered as giving legal, nursing, medical, or other professional advice in specific cases. AKH Inc. specifically disclaims responsibility for any adverse consequences resulting directly or indirectly from information in the course, for undetected error, or through reader's misunderstanding of the content.

Commercial Support

This activity has been supported by unrestricted educational grants from the following companies: Alcon Laboratories, Allergan, Inc., Bausch + Lomb, Medicus, a division of Valeant Pharmaceuticals, Ophthalmic Mutual Insurance Company, Regeneron Pharmaceuticals and The Doctors Company.

FACULTY

Featured Faculty

Pediatric Ophthalmology

Edward Buckley, MD

Banks Anderson, Sr. Professor of Ophthalmology
Professor of Pediatrics
Vice Dean for Medical Education
Duke University Medical School
Durham, NC

Cataract/IOL/Anterior Segment

Warren E. Hill, MD, FACS

Medical Director
East Valley Ophthalmology
Mesa, AZ

Melvin L. Rubin, MD Award Lecturer

Retina-Vitreous

Lee M. Jampol, MD

Louis Feinberg Professor of Ophthalmology
Feinberg School of Medicine
Northwestern University
Chicago IL

Neuro-Ophthalmology

Steven A. Newman, MD

Professor of Ophthalmology
University of Virginia School of Medicine
Charlottesville, VA

Glaucoma

Kuldev Singh, MD, MPH

Byers Eye Institute
Stanford University
Palo Alto, CA

Refractive Surgery/Anterior Segment

Karl G. Stonecipher, MD

Southeastern Eye Center
Greensboro, NC

Adjunct Faculty

Teresa Drake, Esq.

Director
University of Florida
Levin College of Law
Intimate Partner Violence Assistance Clinic
Gainesville, FL

Sandra Strickland, RN, MSN, LHRM, CPHRM

Director of Patient Safety-SE Region
The Doctors Company
Jacksonville, FL

Steven I. Rosenfeld, MD, FACS

Voluntary Professor
University of Miami
Miller School of Medicine
Bascom Palmer Eye Institute
Delray Eye Associates
Delray Beach, FL

SUBSPECIALTY FACULTY

Frank W. Bowden, III, MD

Bowden Eye & Associates
Jacksonville, FL

Hilda Capo, MD

Bascom Palmer Eye Institute
Miami, FL

Kara M. Cavuoto, MD

Bascom Palmer Eye Institute
Miami, FL

William W. Culbertson, MD

Bascom Palmer Eye Institute
Miami, FL

Janet L. Davis, MD

Bascom Palmer Eye Institute
Miami, FL

Harry W. Flynn, Jr., MD

Bascom Palmer Eye Institute
Miami, FL

Jorge A. Fortun, MD

Bascom Palmer Eye Institute
Palm Beach, FL

Michael H. Goldstein, MD, MM

Tufts Medical Center
Boston, MA

J. William Harbour, MD

Bascom Palmer Eye Institute
Miami, FL

Stacey J. Kruger, MD

Stacey J. Kruger, MD & Associates
Miami, FL

Marc H. Levy, MD

Sarasota Retina Institute
Sarasota, FL

Craig A. McKeown, MD

Bascom Palmer Eye Institute
Miami, FL

Jaime H. Membreno, MD

Retina Macula Specialists
Kissimmee, FL

Timothy G. Murray, MD

Bascom Palmer Eye Institute
Miami, FL

Joshua Pasol, MD*

Bascom Palmer Eye Institute
Miami, FL

Peter J. Polack, MD

Ocala Eye
Ocala, FL

Clifford L. Salinger, MD*

VIP Laser Center
Palm Beach, FL

Stephen G. Schwartz, MD, MBA*

Bascom Palmer Eye Institute
Naples, FL

Arysol Soltero-Niffenegger, MD*

Sarasota, FL

**Subspecialty Symposia Program Chairs*

FACULTY/PLANNERS/STAFF DISCLOSURES

DISCLOSURE DECLARATION

It is the policy of AKH Inc. to ensure independence, balance, objectivity, scientific rigor, and integrity in all of its continuing education activities. The faculty must disclose to the participants any significant relationships with commercial interests whose products or devices may be mentioned in the activity or with the commercial supporter of this continuing education activity. Identified conflict of interest is resolved by AKH prior to accreditation of the activity. AKH planners and reviewers have no relevant financial relationships to disclose.

DISCLOSURE OF UNLABELED USE AND INVESTIGATIONAL PRODUCT

This educational activity may include discussion of uses of agents that are investigational and/or unapproved by the FDA. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications, and warnings.

FACULTY DISCLOSURES			
NAME	RELATIONSHIP	COMPANY	
Frank W. Bowden, III, MD	N/A	Nothing to disclose	
Edward Buckley, MD	N/A	Nothing to disclose	
Hilda Capo, MD	N/A	Nothing to disclose	
Kara Cavuoto, MD	N/A	Nothing to disclose	
William W. Culbertson, MD	Consultant	OptiMedica Corporation (4)	
Janet L. Davis, MD	N/A	Nothing to disclose	
Teresa Drake, Esq.	N/A	Nothing to disclose	
Harry W. Flynn, Jr., MD	Consultant	Santen Pharmaceutical Co., Ltd. (1)	
	Speakers Bureau	Vindico Medical Education (1)	
Jorge A. Fortun, MD	Consultant	Thromhogenics (2)	
Michael H. Goldstein, MD, MM	Consultant	Eleven Biotherapeutics (4); Inanovate (1);	
	Stockholder	Eleven Biotherapeutics; Hemera Biosciences Inc.; Inanovate	
J. William Harbour, MD	Consultant	Castle Biosciences Incorporated	
Warren E. Hill, MD, FACS	Consultant	Alcon Laboratories, Inc.; Clarity Medical Systems, Inc.; Haag-Streit AG (4)	
	Contracted Research	Alcon Laboratories, Inc.; Haag-Streit AG (4)	
	Speakers Bureau	Alcon Laboratories, Inc.; Haag-Streit AG; Oculus, Inc. (4)	
	Stockholder	Bausch & Lomb, Incorporated; Clarity Medical Systems, Inc.; Haag-Streit AG (3)	
Lee M. Jampol, MD	N/A	Nothing to disclose	
Krishna S. Kishor, MD	N/A	Nothing to disclose	
Stacey J. Kruger, MD	N/A	Nothing to disclose	
Mark H. Levy, MD	Contracted Research	Eli Lilly and Company (2); The EMMES Corporation/National Institutes of Health (NIH)(4); Jaeb Center for Health Research (3); Lovelace Scientific Resources (2); Notal Vision™ Quark Pharmaceuticals, Inc. USA. (2); (4); Roskamp Institute (2); XOMA Ltd. (2)	
Craig A. McKeown, MD	N/A	Nothing to disclose	
Jaime H. Membreno, MD	N/A	Nothing to disclose	
Timothy G. Murray	N/A	Nothing to disclose	
Arysol Soltero Niffenegger, MD	N/A	Nothing to disclose	
Steven A. Newman, MD	N/A	Nothing to disclose	
Joshua Pasol, MD	N/A	Nothing to disclose	
Peter J. Polack, MD	N/A	Nothing to disclose	
Steven I. Rosenfeld, MD	N/A	Nothing to disclose	
Clifford L. Salinger, MD	Speakers Bureau	Bausch & Lomb, Incorporated; ScienceBased Health; TearLab; TearScience®	
Stephen G. Schwartz, MD, MBA	Consultant	Alimera Sciences; Bausch & Lomb, Incorporated (2)	
	Speakers Bureau	Regeneron Pharmaceuticals, Inc. (2)	
Kuldev Singh, MD, MPH	Consultant	Alcon Laboratories, Inc.; Allergan, Inc.; Bausch & Lomb, Incorporated; Ivantis, Inc.; Transcend Medical, Inc.	
Karl G. Stonecipher, MD	Advisory Board	Alcon Surgical; LaserACE	
	Consultant	Alcon Laboratories, Inc.; Alcon Surgical; Allergan, Inc.; Bausch & Lomb, Incorporated; NIDEK CO., LTD.; Refocus Group, Inc.	
	Contracted Research	Alcon Laboratories, Inc.; Allergan, Inc.; Bausch & Lomb, Incorporated; NIDEK CO., LTD.; PresbiTech, Inc.; Refocus Group, Inc.	
Sandra Strickland, RN, MSN, LHRM, CPHRM	N/A	Nothing to disclose	
PLANNER DISCLOSURES			
AKH & FSO Staff/Planners		N/A	Nothing to disclose
Compensation Range	1= \$0-\$1,000	2= \$1,001-\$10,000	3= \$10,001-\$50,000
			4=≥\$50,001

Friday, June 28, 2013

Teresa Drake, Esq.

Teresa Drake is currently the Director of the Intimate Partner Violence Assistance Clinic (IPVAC) at the University of Florida Levin College of Law. This first-of-its-kind domestic violence clinic is collaboration between the U.F.'s College of Law, College of Medicine, Shands Teaching Hospital and the local non-profit Peaceful Paths Domestic Abuse Network. The multidisciplinary IPVAC team consists of law students, a licensed clinical social worker and an outreach counselor who provide wrap-around holistic legal, medical, mental health and case management services to low income survivors of domestic violence. In addition to teaching 5 hours per week in the clinic, Teresa has also instructs all first year law students and second year medical students about the dynamics of domestic violence and how to screen and refer client/patients.

Prior to IPVAC, Teresa worked for Florida's Eight Judicial Circuit Office of the State Attorney for 13 years: first as a Child Welfare Attorney; then as a domestic violence prosecutor; and finally as the Division Chief of County Court. Teresa had the distinction of trying the largest child abuse case in the history of Florida.

Teresa is a nationally recognized expert in intimate partner violence. As such she has provided training for the National District Attorneys Association, the Battered Women's Justice Project, US Department of Justice Office on Violence Against Women and Aequitas. Teresa received the Ellen Foster Award in 2000 for outstanding commitment to the betterment of children. In 2010, she received the Community Advocate Award from Peaceful Paths and in 2011 the Woman of Distinction Award from Santa Fe College.

Teresa began working in domestic violence over 25 years ago as a victim advocate with the Network of Victim Assistance in Bucks County, Pa. She received her Juris Doctorate with honors in 1994 from the University of Florida. Her Bachelor of Science is in Design and Marketing from Drexel University College of Media and Design in Philadelphia, PA.

Intimate Partner Violence and the Medical Community

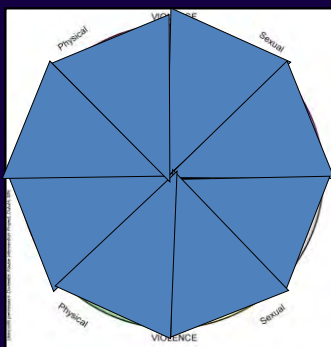
Teresa Drake, J.D.,
Director, *The Source Program*,
University of Florida
Levin College of Law;
drake@law.ufl.edu



Definitions of IPV?

- "Intimate Partner Violence" (IPV) has become interchangeable with "domestic violence" in most literature. It includes dating violence and sexual violence
- IPV is a pattern of coercive, controlling behaviors designed to exert power and control over a person in an intimate relationship through the use of intimidation, threat, physical or psychological harm, or harassment
- IPV is a learned behavior found in every socioeconomic, racial, ethnic, cultural group in society and among heterosexuals, lesbians, gays, bisexuals and transsexuals.

Power & Control Wheel



Context Determines Type of Perpetrator

- Batterer /IPV (95% of cases)
- Self Defender, or response to battering/reactive violence: one-time response, usually women
- One time assailant, not a batterer
- Generally violent fighter (hothead)
- Severe mental health issues.

IPV Numbers and Facts

- U.S. Surgeon General declared that attacks by male partners are the #1 cause of injury to women ages 15 – 45
- AMA and CDC says 1 in 3 women will be the survivor of IPV at some point in her life (rape, physical violence and/or stalking)
- CDC says 1 in 4 women have experienced severe physical violence by an intimate partner.



IPV Numbers and Facts



- 85% - 95% of those battered in U.S. are women
- A woman is battered every 15 seconds
- Over 50% of homeless women and children were victims of IPV.

IPV Numbers and Facts

- 17% of adult pregnant women are battered
- 21% of pregnant teens are battered
- According to a 2001 study published in the JAMA, approximately 20% of women who died during pregnancy were murdered. IPV is the leading cause of traumatic death among pregnant women in the US.



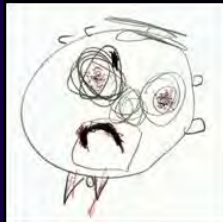
IPV Numbers and Facts

- Emotional effects of IPV play a factor in ¼ of female suicides and are the leading cause of substance abuse among women
- 40 -60% of men who abuse women also abuse children.



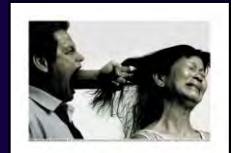
IPV Numbers and Facts

- Abused women divorce their abusive husbands at a much higher divorce rate than the general public
- Less than 1/3 of d/v incidents are reported to law enforcement
- Those women that do report, usually wait until the 7-8 incident to do so.



Why Doesn't She Just Leave

- Being Beaten by a "loved" one sets up a conflict between two instincts:
 - The instinct to stay in a secure environment (family)
 - And the instinct to flee a dangerous environment
- There are many barriers to leaving besides fear of the batterer and lack of resources...



Barriers to Leaving

- SAFETY
- SHAME
- Lack of financial resources
- Fear that she will lose her children (custody or DCF)
- Belief that criminal justice system /social services will not protect
- Fear that no one will believe her
- Fear of deportation
- Fear of blackmail for wrongdoing by the victim
- Fear of "outing"
- Fear of repercussions from culture/religion
- Fear of losing support systems such as family & friends
- Lack of language skills
- Fear of what will happen to her partner.

The Most Dangerous Time

- The most dangerous time for a battered woman is when she finally decides on separation
- As many as 75% of IPV calls made to police and 73% of the emergency room IPV visits occur after separation
- Of women killed by their abusers, 70% are killed during the process of trying to leave.



Why Should the Medical Community Care?



- U.S. DOJ reported that 37% of all women in the EDs for violence-related injuries were injured by a current or former intimate partner
- 44-47% of woman killed by their intimate partners were seen in the healthcare system for physical injuries within one year of their murder
 - 29% called law enforcement, usually after the 7-8 incident
 - 4% called or went to a shelter.

Why Should the Medical Community Care?



- 92% of women who were physically abused by their partners did not discuss these incidents with their physicians
- 57% did not discuss the incidents with anyone
- 70% - 81% of the patients reported they would like their healthcare providers to ask them privately about IPV.

Largest Study Ever Done

- The Relationship of Adverse Childhood Experiences to Adult Health Status (ACE)
- A collaborative effort of Kaiser Permanente and the Center for Disease Control
- 18,000 people interviewed in California
- www.CDC.gov. (search Adverse Childhood Experiences)



ACE Study

- Demographics of study group:
 - Mostly middle class
 - 54% Female, 46% Male
 - 74% Caucasian, 11% Hispanic/Latino
 - Age: 46% over 60, 20% 50-59, 18% 40-49
 - Education:
 - 39% college grad or higher
 - 36% some college
 - 17% HS grad
 - 7% not HS grad.

ACE Study

- 10 ACE's studied:

➤ Physical abuse	28.3%
➤ Household substance abuse	26.9
➤ Divorce or separation	23.3
➤ Sexual abuse	20.7
➤ Household mental illness	19.4
➤ Emotional neglect	14.8
➤ Household domestic violence	12.7
➤ Emotional abuse	10.6
➤ Physical neglect	9.9
➤ Incarcerated household member.	4.7

ACE Study

- Results: More than half participants have at least once ACE
- ACE's are strong predictors of later health risk and disease.

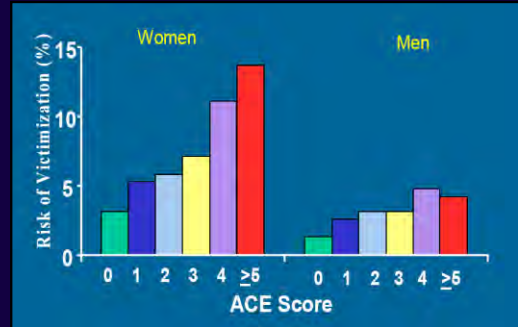


ACE Study & Domestic Violence

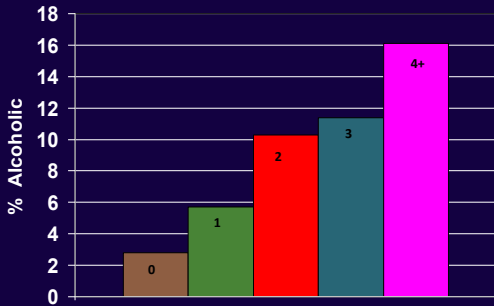
- 95% of the participants who reported domestic violence also reported at least one other type of ACE
- 80% reported at least two other ACE's
- 60% reported at least three ACE's
- 48% reported four or more ACE's.



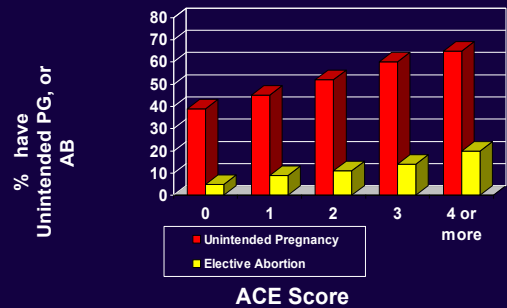
ACE Score and the Risk of Being a Victim of Domestic Violence



ACE Score and the Risk of Adult Alcoholism



ACE Score and the Risk of Unintended Pregnancy or Elective Abortion



Could Build A Similar Bar Graph For:



- Smoking, Chronic lung disease
- Depression, Suicide attempts
- Illicit drug use, Liver disease
- Multiple sex partners, STD's
- Ischemic heart disease.

Screening Patients for IPV

SCREEN ALL PATIENTS

Not just the ones you have a "feeling" about!



Screening Patients for IPV

Always talk to the patient **ALONE**



Screening Patients for IPV

➤ Begin by letting patients know that IPV has become so common, you ask all patients about it

➤ Tell your patient that everything she says will be confidential, unless she discloses that her children are being harmed by her partner.



Relationship History

Patient Name: _____ Date: _____
 Patient Name: _____ Patient ID#: _____

Any DV answers checked result in a referral to the Support Program

Screening Question	Response	Comments
1. Do you or anyone else in your household have been physically harmed (e.g., punched, kicked, pushed, pulled, shaken, or thrown) by a partner or someone you know well? If you are unsure, please check this box.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2. Have you or anyone else in your household been sexually abused (e.g., forced to have sex, forced to perform sexual acts, or forced to watch someone else perform sexual acts) by a partner or someone you know well?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3. In the past 12 months, have you or anyone else in your household been threatened with physical or sexual harm by a partner or someone you know well? If you are unsure, please check this box.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Domestic Violence Screening Form 6/12

Screening Patients for IPV

➤ If the patient discloses IPV



➤ Tell her she does not deserve to be battered,
 ➤ Give her the number of the local certified domestic violence center. See www.fcadv.org.

Screening Patients for IPV

➤ If the patient denies IPV, offer her the number of the local domestic violence center and tell her to give it to someone who needs it

➤ Let her know that you are always someone she can talk to about IPV.



Screening Patients for IPV



If your patient has come with a partner that you suspect may be someone she is afraid of, ask if she is safe to leave the clinic

Screening Patients for IPV

Validate your patient's feelings, which may be confusion, worry, anger, or rage. She needs to know:

- You will listen to her and believe her without judgment
- She does not deserve to be battered
- She has done nothing wrong
- She is not alone, abuse is common problem affecting millions of women
- Help is available through the local domestic violence center
- ...and, that if she is not yet ready to disclose, you are a source she can come to later.

Results of Screen

Remember, the goal of screening is to place resources in the hands of women who need them, not to get women to leave a bad situation.

Call Law Enforcement

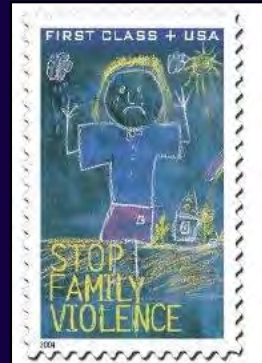
Fla. Stat. 790.24 Report of medical treatment of certain wounds

Any physician, nurse, or employee thereof knowingly treating or asked to treat any person suffering from a gunshot wound or life threatening injury indicating an act or violence shall report the same immediately to the sheriff's department. This does not affect child abuse or elder abuse reporting requirements.

Thank You

Teresa Drake, J.D.
Director
The Source Program
U.F. Levin College of Law
drake@law.ufl.edu

This project was supported by Grant No. 2009-WI-AV-0006 awarded by the Office on Violence Against Women, U.S. Department of Justice. The opinions, findings, conclusions, and recommendations expressed in this publication (program/evaluation) are those of the author(s) and do not necessarily reflect the views of the Department of Justice, Office on Violence Against Women.



Intimate-Partner Violence — What Physicians Can Do

Jane M. Liebschutz, M.D., M.P.H., and Emily F. Rothman, Sc.D.

The U.S. Centers for Disease Control and Prevention (CDC) recently released a comprehensive report on the prevalence of sexual violence, stalking, and intimate-partner violence (IPV) in the United States.¹ The report relays the alarming findings that 35.6% of women in this country are raped, assaulted, or stalked by intimate partners at some point during their lives, and approximately 6% experience these events in any given year. Men are also at risk for IPV victimization: 28.5% report having been victimized at some time during their lifetime, and 5% report victimization within the past year. But the forms and consequences of IPV experienced by women and men are not the same. Women are more than twice as likely as men to experience sexual coercion in their intimate relationships (17% vs. 8%) and are twice as likely to experience severe forms of physical assault by an intimate partner, such as being choked, hit with a fist, or kicked (24.3% vs. 13.8%). The most striking differences relate to the consequences: very few men (5.2%) report ever being fearful of their intimate partners, in contrast to 28.8% of women, and

women are almost four times as likely as men to be injured by a partner (14.8% vs. 4.0%).

The costs of IPV are burdensome, for the health care system and for society. A decade ago, the CDC estimated the cost of IPV to the United States to be \$5.8 billion per year (\$10.4 billion in 2012 dollars), and it's been estimated that the cost of providing health care to adult survivors of IPV ranges from \$2.3 billion to \$7.0 billion in the first year after the assault. The annual health care costs for women who are experiencing ongoing IPV are 42% higher than those for nonabused women. This finding is unsurprising, given the evidence that IPV victimization of women increases the risks of injury, gastrointestinal disorders, chronic pain, central nervous system symptoms (including fainting and seizures), hypertension, and gynecologic problems.²

What can physicians do about IPV? All health care providers should be alert to aspects of patients' histories or symptoms that could suggest IPV and then should follow up with specific questions. According to the U.S. Preventive Services Task Force, screening

asymptomatic female patients for IPV victimization may provide benefits, with minimal adverse effects.³ As of August 2012, new guidelines under the Affordable Care Act require insurance coverage to include IPV screening and counseling as part of eight essential health services for women at no additional cost to the patient.⁴ Therefore, at a minimum, all primary care physicians should now be screening female patients 12 years of age or older for IPV. Specialty professional organizations recommend that obstetricians and pediatricians also consider performing regular IPV screening. Numerous IPV screening instruments may be used to begin a dialogue with the patient; one of them (known as HITS) is shown in the table.⁵ Another question that may be used to start a discussion about safety at home is simply, "Are you afraid of your partner or anyone else?"

There are several steps doctors should take when patients report potential IPV. First, clinicians should acknowledge the patient's admission of abuse: we advise thanking the patient for trusting the provider with the information and expressing concern about the patient's safety. Second, we suggest asking the patient if he or she would like to be connected to IPV advocacy services. If patients do want legal assistance, counseling, shelter, or other services, local domestic violence agencies affiliated with the state coalition are likely to be the most reliable resources (see box). Third, clinicians should offer the patient the National Domestic Vio-

The HITS Screening Tool for Domestic Violence.*

How Often Does Your Partner	Never	Rarely	Sometimes	Fairly Often	Frequently
Physically hurt you	1	2	3	4	5
Insult or talk down to you	1	2	3	4	5
Threaten you with harm	1	2	3	4	5
Scream or curse at you	1	2	3	4	5

* A total score of more than 10 is suggestive of intimate partner violence. This information, called R3, is available as a free Android or iPhone app. From Sherin et al.⁵

Key Resources

National Domestic Violence Hotline, www.thehotline.org/, 1-800-799-SAFE (7233). Provides crisis intervention, information, and referrals for victims of domestic violence.

Futures without Violence, www.futureswithoutviolence.org, a national organization dedicated to improving the health care response to violence; offers resources and information for providers and health care organizations.

Virtual Lecture Hall, www.vlh.com/domesticviolenceCME. Evidence-based online IPV training, free access for 30 days, \$25/credit hour for CME certificate.

National Network to End Domestic Violence, www.nnedv.org. National organization of state domestic violence coalitions.

Child Welfare Information Gateway, Children's Bureau, Administration for Children and Families, U.S. Department of Health and Human Services, www.childwelfare.gov. Information and resources on child abuse and neglect.

lence hotline number (see box); the hotline makes printed, pocket-size handouts (palm cards) available to providers who wish to distribute them to patients. Fourth, clinicians should consider whether child protective services are required. In many states, the abuse of one parent by another does not necessitate a report to child protective services, so it's up to the clinician to determine whether a report is warranted. Clinicians should consider inviting the patient to make the report directly in order to increase the likelihood that staff members at child protective services agencies will view the patient as able to maintain a safe household for the children. Fifth, they should screen the patient for coexisting depression, anxiety, and substance abuse. And they should use caution when prescribing sedatives, since the sedating action may diminish patients' physical or mental ability to defend themselves or deescalate tensions.

When patients screen negative for IPV but the provider nevertheless suspects that they're experiencing abuse, it's important that the provider not force disclosure. It's not critical that the patient acknowledge IPV victimization in

order to benefit from the screening. Asking IPV-related questions signals to the patient that the provider is caring and concerned, trustworthy, and willing to discuss the topic during a future visit. Moreover, simply being asked the questions may prompt the patient to reconsider privately whether his or her relationship is healthy. And of course providers need not receive a positive screening response in order to provide universal education about IPV. Even if a patient screens negative, we would encourage the provider to state that many patients do experience IPV at some point and that there are many resources to help people who feel unsafe in their relationships. Handing palm cards with the national hotline number to all patients and encouraging them to take one for a friend if they wish, for example, may be an effective way of providing help to victims who don't feel comfortable disclosing their situations.

There are several ways in which providers can do unintentional harm to patients who are experiencing IPV. Asking no questions about IPV may signal that the provider is not a potential resource for the patient. But the

manner in which IPV victimization is documented in patient records can have ramifications for child custody cases. Detailed information about best practices for IPV documentation is available from the national organization Futures without Violence (see box). In addition, providers should refrain from telling patients who are experiencing IPV what they must do (e.g., "you need to leave"). Only trained experts in IPV advocacy are qualified to help victims determine their own best course to safety. There is a potential for lethal and injurious harm, particularly when one partner attempts to leave the relationship. For this reason, actively ensuring that the link between the patient and an IPV advocacy agency is made successfully is the best practice. Finally, it's critically important that providers respect the confidentiality of patients who are experiencing IPV. Not only do victims face stigma and prejudice, but employers and insurers could potentially discriminate against them if their status became known.

IPV is now recognized as a substantial public health problem. Health care providers can play a critical role in helping to reduce and prevent IPV by screening and referring patients to appropriate resources, familiarizing themselves with best practices related to IPV documentation and victim response, and presenting themselves as caring and trustworthy allies for their patients who are experiencing abuse. Research has established that health care-based screenings and interventions for IPV can benefit patients,³ and the Affordable Care Act ensures that preventive care will include these screenings for women and ado-

lescents. There is thus some cause for hope that we may curb the violence and play a role in creating safer homes and safer families nationwide.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From Boston University School of Medicine (J.M.L.) and the Boston University School of Public Health (E.F.R.) — both in Boston.

1. Black M, Basile K, Breiding M, et al. The National Intimate Partner and Sexual Violence Survey: 2010 summary report. Atlanta: National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 2011.
 2. Campbell JC. Health consequences of intimate partner violence. *Lancet* 2002;359:1331-6.
 3. Nelson HD, Bougatsos C, Blazina I. Screening women for intimate partner violence: a systematic review to update the U.S. Preventive Services Task Force Recommendation. *Ann Intern Med* 2012;156:796-808.
 4. James L, Shaeffer S. Interpersonal and domestic violence screening and counseling: understanding new federal rules and providing resources for health providers. *Futures without violence*. May 2012 (http://www.futureswithoutviolence.org/userfiles/file/HealthCare/FWV-screening_memo_Final.pdf).
 5. Sherin KM, Sinacore JM, Li XQ, Zitter RE, Shakil A. HITS: a short domestic violence screening tool for use in a family practice setting. *Fam Med* 1998;30:508-12.
- DOI: 10.1056/NEJMp1204278
Copyright © 2012 Massachusetts Medical Society.

Sandra C. Strickland, RN, MSN, LHRM, CPHRM

Sandra Strickland is the Director of Risk Management Services for The Doctors Company. She earned a Master in Nursing degree from Medical University of South Carolina and her Bachelor of Nursing degree from Barton College in Wilson, North Carolina. Mrs. Strickland is a Licensed Health Care Risk Manager, Certified Professional Healthcare Risk Manager, and a Registered Nurse with over twenty years of experience in the healthcare and over fifteen years in healthcare risk management. She is a member of the American Society of Health Care Risk Managers and the Florida Society of Health Care Risk Managers.


...reward physicians who advance the practice of good medicine.

Prevention of Medical Errors

FS 456.013(7)

Florida Society of Ophthalmology
 June 28, 2013

Presented by
 Sandra C. Strickland, RN, MSN, CPHRM, LHRM
 Director of Patient Safety - SE Region

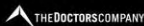


Course Objectives

At the conclusion of this presentation, participants will be able to:

- Recognize medical error reduction and prevention strategies
- Describe a root-cause analysis
- Identify patient safety goals
- Recite the most "misdiagnosed" conditions

Prevention of Medical Errors / 2

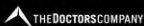


How Often Do Medical Errors Occur?

- If death from medical errors was a disease— it would be the third leading cause of death in the U.S. (cancer, heart disease)
- During the two hours of this presentation, 22 people in the U.S. will die as a result of medical errors
- **One in every 11 – 12 Ophthalmologists will experience a negligence claim during their career**

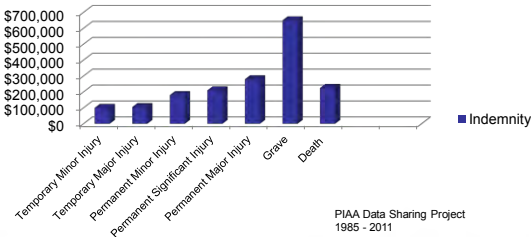
U.S. Department of Health and Human Services,
 National Center for Health Statistics,
Health, United States, 2002, Table 33, p. 132

Prevention of Medical Errors / 3



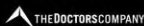
Ophthalmology Claims

Average Indemnity by Injury



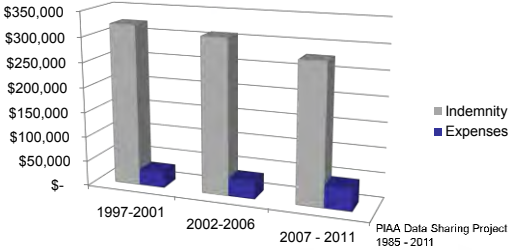
PIAA Data Sharing Project 1985 - 2011

Prevention of Medical Errors / 4




Ophthalmology Claims

Average Payment by Close Year



PIAA Data Sharing Project 1985 - 2011

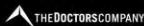
Prevention of Medical Errors / 5



Ophthalmology Error

Improper performance of surgery	54%
Diagnostic error	13%
Improper performance of treatment	10%

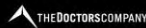
Prevention of Medical Errors / 6



Ophthalmology Procedures

Cataract surgery	36%
Lasik surgery	10%
Vitreous operations	5%

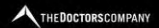
Prevention of Medical Errors / 7



Contributing Factors

Known risks	32%
Patient non-compliance	10%
Procedure selection and management	8%

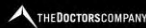
Prevention of Medical Errors / 8



Injury

Partial or total loss of vision	32%
Worsening condition after treatment	23%
Hemorrhage	8%

Prevention of Medical Errors / 9

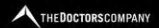


Words From a Wise Patient Safety Expert

"Errors must be accepted as system flaws, not character flaws."
"Make it easy to do right and difficult to do wrong."

-Lucien Leape, MD

Prevention of Medical Errors / 10

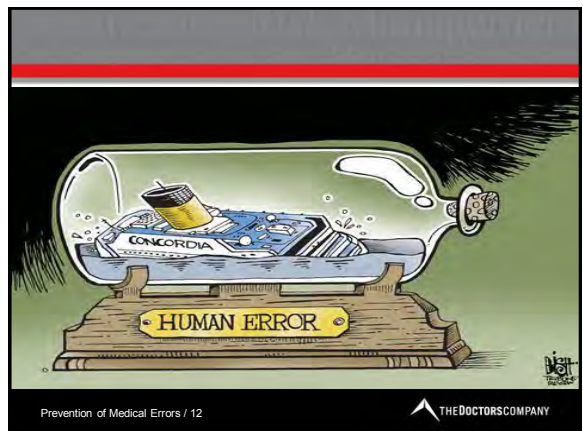
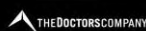


Root Cause Analysis

- Structured and process-focused framework
- Credible and thorough
- Active and latent—what, how, and why
 - Specific underlying causes
 - Reasonably identifiable
 - Controlled or influenced
- Generate specific recommendations

Primary aim: Avoid culture of individual blame

Prevention of Medical Errors / 11

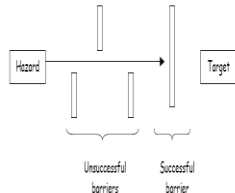


Prevention of Medical Errors / 12



Root Causes—Medical Errors

- Communication factors
- Unclear lines of authority
- Highly variable settings
- Varied health care processes
- Time pressured environment
- System deficiencies
- Vulnerable defense barriers
- Human fallibility



National Patient Safety Foundation

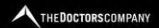
Prevention of Medical Errors / 13



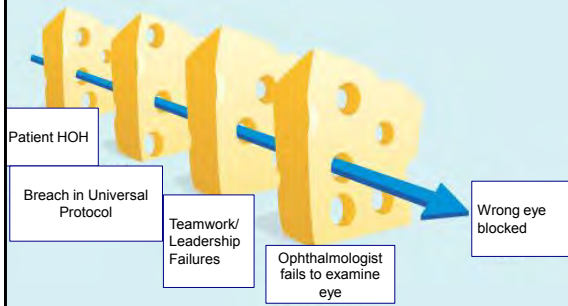
System Design



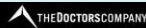
Prevention of Medical Errors / 14



Swiss Cheese Model



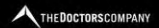
Prevention of Medical Errors / 15



The most prevalent root cause of medical errors is...

Communication

Prevention of Medical Errors / 16



YOU DON'T KNOW WHAT P.Q.T. IS? HOW AM I SUPPOSED TO HELP YOU, IF YOU HAVEN'T LEARNED ALL OF OUR ACRONYMS?

Prevention of Medical Errors / 17



RCA Communication Errors

- Language barriers
- Knowledge deficits
- Limited health literacy skills
- Internal communication failures
- Personal bias
- Haste

Prevention of Medical Errors / 18

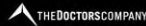


Focus on the Patient

If left to tell their story, how long would a patient actually talk?

How Doctors Think, by Dr. Jerome Groopman, JAMA 1999

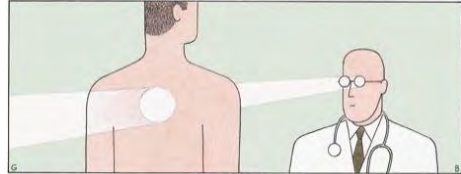
Prevention of Medical Errors / 19



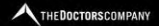
What's The Trouble?

How doctors think.
by Jerome Groopman, January 29, 2007

Most physicians already have in mind two or three possible diagnoses within minutes of meeting a patient.



Prevention of Medical Errors / 20



GP's Communication Study

"What can I do for you today?"

Average time by patients: **28.6 seconds**.

Older age group spent longer.

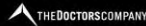
No gender differences.

Conclusions: Patients are able to explain calmly and without interruptions the reason for their visit.

Interruptions by the doctor are probably unnecessary and do not save time

ncbi.nlm.nih.gov/pubmed/8467052 Instituto de Medicina Social de la Universidad de Lubliana, Eslovenia

Prevention of Medical Errors / 21



Low Health Literacy

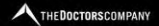
90 million people have literacy related health risks

1 out of 5 read at _____ grade level

50%—Understand directions for taking medications correctly

www.npsf.org

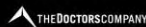
Prevention of Medical Errors / 22



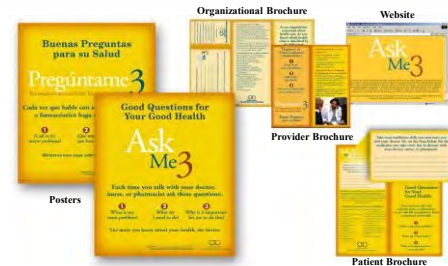
"Doctors are beginning to accept that stomach ulcers are infectious. They are caused by a bug called Helicobacter."
[Helicobacter pylori.]

Ocean Spray
AOB
once

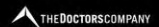
Prevention of Medical Errors / 23



Ask Me 3— Program Materials Available in English and Spanish



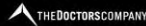
Prevention of Medical Errors / 24



Communication Risk Assessment

- ___ Visual or hearing impairment
- ___ Speech ability/language articulation
- ___ Foreign language spoken
- ___ Dysphonia, (laryngeal/oral/dental)
- ___ Patient or physician time constraints
- ___ Unavailability of face-to-face conversation
- ___ Illness
- ___ Altered mental state or wakefulness
- ___ Medication effects
- ___ CVA or brain injury
- ___ Psychological or emotional stress
- ___ Gender differences
- ___ Racial/Cultural differences

Prevention of Medical Errors / 25



Smart phones

"I'M PHONING TO LET YOU KNOW I'VE FAXED YOU TO SAY I'VE SENT AN EMAIL ASKING YOU TO CALL ME"

Prevention of Medical Errors / 26

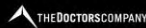


Preventing eCommunication Errors

- Sensitive test results
- Requests for narcotics
- Facetime or photo diagnosis
- Getting information from family members

J Gen Intern Med. 2005 October; 20(10): 959-963 Preventing Communication Errors in Telephone Medicine—A Case-Based Approach. Anna B. Reisman, MD and Karen E. Brown, MD

Prevention of Medical Errors / 27



Case Study

E-mail on Friday afternoon:

CC: Poor vision. "Spots."

Response: Follow up with optometrist on Monday.

Outcome: Retinal Detachment. Vision loss.

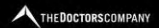
What would have prevented this?

Handoff communication

Triage training

Auto-reply

Prevention of Medical Errors / 28



Clinician—Clinician Communications

- Referrals
- Surgical clearance
- Site to Site
- Handoff: SBAR Report
 - Situation
 - Background
 - Assessment
 - Response

Prevention of Medical Errors / 29



Communications Error Prevention

- Patientcentric culture
- Awareness
- Team building
- Training
- Protocols—checklists
- Eye contact
- Slow down
- Listen
- Language
- Visual aids
- Limit and repeat
- Ask Me 3
- Verify with teach back



Prevention of Medical Errors / 30



System Errors

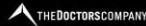
Increase with medical complexity and number of practitioners involved

Prevalent Root Causes:

- Failure to define parameters
- Inadequate documentation
- System failure and faulty communication of clinical concerns

OUTCOME: Wrong procedure or diagnostic error

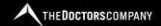
Prevention of Medical Errors / 31



Problematic Conditions: MD & DO

- Wrong site/wrong procedure surgery
- Cancer
- Cardiac conditions
- Inappropriate opioid prescribing
- Neurological conditions
- Acute abdomen related conditions
- Timely diagnosis of surgical complications
- Pregnancy complications

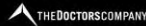
Prevention of Medical Errors / 32



Preventing System Failures

- Appropriate history
- Adequate examination
- Evaluation and pursuit
- Bias alert
- Referral
- Clarify roles
- Tracking systems
- Manage noncompliance
- Root cause analysis
- Define parameters

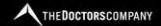
Prevention of Medical Errors / 33



Case Study

- 65 y/o male. Reduced vision. Age related cataracts OU.
- OS cataract extraction in May.
- Pre-op CXR: Abnormal – Nodular density L hilum...not reviewed by ophthalmologist.
- 4 months later - OD cataract extraction
- 2nd pre-op CXR: enlarging hilum with significantly enlarged lobulated mass. Ophthalmologist notified after induction.
- CT confirmed lung mass. L thoracotomy & pneumonectomy. Poorly differentiated adenocarcinoma w/ 4 of 8 hilar lymph nodes positive for metastasis.

Prevention of Medical Errors / 34



Wrong-Site/Wrong Procedure Surgery

Ambulatory settings

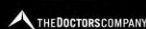
Wrong body part or site

Most prevalent root causes:

- Communication
- Orientation and training

Joint Commission on Accreditation of Healthcare Organizations

Prevention of Medical Errors / 35



Case Study

- 59 y/o female – c/o glare, decreased visual acuity – OS
- Corrected VA 20/20 OD and 20/25 OS.
- Glare testing VA 20/80 OD and 20/100 OS.
- Uncomplicated cataract surgery OS
- PO day 1: VA w/ pinhole 20/150 OS. Anterior chamber 2+ cells. Tobradex gtts 4x/day. Return 1 wk.
- Informed by OR nurse of wrong IOL = 17.0 diopter vs. 20.5
- Patient informed. Lens exchange planned.
- Mishap during lens exchange – VA remained 20/150 after 2 months. Referred to corneal specialist for corneal transplant.
- Post transplant – VA w/ refraction of 20/25 OS, with continued c/o residual cloudiness d/t posterior capsule haze

Prevention of Medical Errors / 36



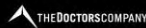
Pre-Procedure Verification Process

Address missing information or discrepancies before starting the procedure

- Verify patient, procedure, side, lens, equipment
- Involve the patient
- Prepare and plan
- Checklists

Gleaned from The Joint Commission Universal Protocols

Prevention of Medical Errors / 37



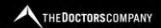
Mark the Procedure Site...

- Consistent, Unambiguous marking
- At or near the procedure site
- Permanent and visible after prep and drape
- Adhesive marker not ideal
- Before the procedure
- Involve the patient
- By the performing practitioner

Ultimately, the performing practitioner is accountable

Gleaned from The Joint Commission Universal Protocols

Prevention of Medical Errors / 38



Pre-Procedure Verification Process

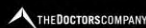
Document everything relevant:

- History and physical, signed consent form, pre-anesthesia assessment
- Diagnostic and radiology test results
 - Images and scans, pathology reports, biopsy reports
- Any required implants, devices, special equipment

Match the items that are to be available in the procedure area to the patient

Gleaned from The Joint Commission Universal Protocols

Prevention of Medical Errors / 39



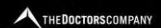
World Health Organization **SURGICAL SAFETY CHECKLIST (FIRST EDITION)**

Before induction of anaesthesia Before skin incision Before patient leaves operating room

SIGN IN	TIME OUT	SIGN OUT
<input type="checkbox"/> PATIENT HAS CONFIRMED: <ul style="list-style-type: none"> • IDENTITY • SITE • PROCEDURE • CONSENT 	<input type="checkbox"/> CRITICAL ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE	<input type="checkbox"/> NURSE VERBALLY CONFIRMS WITH THE TEAM
<input type="checkbox"/> SITE MARKED (NOT APPLICABLE)	<input type="checkbox"/> SURGICAL, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM: <ul style="list-style-type: none"> • PATIENT • SITE • PROCEDURE 	<input type="checkbox"/> THE NAME OF THE PROCEDURE ACCORDS
<input type="checkbox"/> ANAESTHESIA SAFETY CHECK COMPLETED	<input type="checkbox"/> ANTICIPATED CRITICAL EVENTS	<input type="checkbox"/> THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (IF NOT APPLICABLE)
<input type="checkbox"/> PLEASE COMMENT ON PATIENT AND FUNCTIONING	<input type="checkbox"/> SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?	<input type="checkbox"/> HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME)
<input type="checkbox"/> DOES PATIENT HAVE A: <ul style="list-style-type: none"> KNOWN ALLERGY? <ul style="list-style-type: none"> NO YES DIFFICULT AIRWAY/ASPIRATION RISK? <ul style="list-style-type: none"> NO YES, AND EQUIPMENT/ASSISTANCE AVAILABLE RISK OF ~500ML BLOOD LOSS (SPECIAL IN CHILDREN)? <ul style="list-style-type: none"> NO YES, AND ADEQUATE VASCULAR ACCESS AND FLUIDS PLANNED 	<input type="checkbox"/> ANAESTHESIA TEAM REVIEWS: ARE THERE ANY REGION-SPECIFIC CONCERNS?	<input type="checkbox"/> WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED
	<input type="checkbox"/> NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?	<input type="checkbox"/> SURGICAL, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS REVIEW
	<input type="checkbox"/> HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES? <ul style="list-style-type: none"> YES NOT APPLICABLE IS ESSENTIAL IMAGING DISPLAYED? <ul style="list-style-type: none"> YES NOT APPLICABLE 	

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

Prevention of Medical Errors / 40



Preventing Wrong-Site/Wrong Procedure Surgery

FAC 64B8-9.007 (MD) and 64B15-14.006 (DO)
Standards of Practice

- “...requiring the team and physician to pause prior to initiation of the surgery/procedure to verbally confirm the side, site, patient identity, and surgery/procedure.”
- “...the medical record shall specifically reflect when this confirmation procedure was completed and which personnel on the surgical team confirmed each item.”
- “The provisions ...shall be applicable to anesthesia providers prior to administering anesthesia or anesthetic agents or performing regional blocks at any time both within or outside a surgery setting.”

1/29/2013

Prevention of Medical Errors / 41



Department of Health and Board of Medicine Sanctions

Examples of first offense sanctions:

- Letter of concern
- \$5,000
- Costs of investigation and processing (@\$2,500)
- 5 CME's Risk Management
- 1 hour lecture—develop and deliver

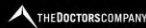
Prevention of Medical Errors / 42



FTD/DID Surgical Complications

- Most claims entail acceptable medical complications
- Failure to supervise/monitor post-op is the most prevalent root cause of medical error
- Prevalent post-op complications
 - Infection
 - Perforation
 - Suture failure
 - Bleeding
- Foreign body retention—*res ipsa loquitur* case

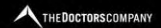
Prevention of Medical Errors / 43



Management of Surgical Complications

- Re-evaluate prior to discharge
- Review all labs and diagnostic studies
- Document the absence of clinical indications of complications
- Prompt follow-up appointments and document no-shows
- Document your medical rationale
- Increase communication
- Seek legal or risk management guidance

Prevention of Medical Errors / 44



Text of Duke's Letter to UNOS Explaining Transplant Mistakes

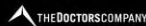
Posted: Feb 21, 2003

Durham, NC—The following letter was sent Friday to the United Network for Organ Sharing (UNOS).

Duke University Hospital has completed the initial phase review of the events related to the heart/lung transplant from donor _____. We provide the following to promote our joint efforts in the peer review of this incident and for the purpose of performance improvement.

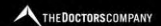
We have concluded that human error occurred at several points in the organ placement process that had no structured redundancy.

Prevention of Medical Errors / 45



West Boca High cheerleader got fraction of drug needed, lawyer charges

Prevention of Medical Errors / 46



Medication Errors

- 40%—Administering
- 21%—Improper Documentation
- 17%—Dispensing
- 11%—Faulty Prescribing
- 10%—Other
 - Inadequate communication
 - Inappropriate formularies
- 1%—Inadequate Monitoring

41% of ophthalmology patient visits = medication rx

U.S. Pharmacopeia, Database of Hospital Medication Errors

Prevention of Medical Errors / 47



Top Products Involving Medication Error

- Insulin
- Albuterol
- Morphine
- KCl
- Heparin
- Cefazolin
- Warfarin
- Furosemide
- Levofloxacin
- Vancomycin

MEDMARX/USP Drug Safety Review

Prevention of Medical Errors / 48

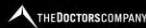


Medication Error Root Causes

- Illegibility
- V.O and T.O
- Abbreviations
- Multiple medications
- Multiple prescribers
- Multiple "handoffs"
- Concentrations
- LASA medications
- Patient understanding
- Monitoring
- Unfamiliar medication



Prevention of Medical Errors / 49

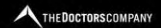


Health Care Notification Network (HCNN)

www.hcnn.net

- Secure online service
- Delivers urgent patient safety alerts
- Replaces paper-based alerts
- Medication recalls, warnings, and national public health emergencies
- Fulfills FDA guidance for e-communication of patient safety notification
- Protects healthcare provider privacy

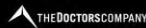
Prevention of Medical Errors / 50



Official JCAHO "Do Not Use" List

Do Not Use	Potential Problem	Use Instead
U (unit)	Mistaken for "0" (zero)	Write "unit"
IU (International Unit)	Mistaken for IV (intravenous) or the number 10 (ten)	Write "International Unit"
O.D., OD, q.d., qd (daily) O.O.D., OOD, q.o.d, qod (every other day), q.i.d. (four times daily)	Mistaken for each other Period after the O mistaken for "I" and the "O" mistaken for "I"	Write "daily" Write "every other day" Write "four times daily"
Trailing zero (X.0 mg)* Lack of leading zero (.X mg)	Decimal point is missed 2.0 → 20 mg .2 → 2 mg	Write "X mg" Write "0.X mg"

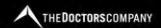
Prevention of Medical Errors / 51



Abbreviations, Acronyms and Symbols

Do Not Use	Potential Problem	Use Instead
> (greater than) < (less than)	Misinterpreted as the number "7" (seven) or the letter "L" Confused for one another	Write "greater than" Write "less than"
Abbreviations for drug names	Misinterpreted due to similar abbreviations for multiple drugs	Write drug names in full
Apothecary units	Unfamiliar to many practitioners. Confused with metric units.	Use metric units

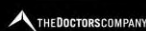
Prevention of Medical Errors / 52



LASA Medications



Prevention of Medical Errors / 53



- Hospital Accused of Overdosing Quaid's Twin Babies
- Cedars Allegedly Gave Infants 1,000 Times More Heparin Than Needed
- Posted: 8:40 am EST November 21, 2007
- Updated: 11:23 am EST November 21, 2007

Prevention of Medical Errors / 54



Case Study

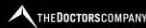
37 y/o male with c/o L lower lid swelling x 3 days. PCN allergy – currently on no medications.

DX: Hordelum Rx: Ampicillin 250 mg tid X 5 days. Warm compress to L lid,

After 2 doses, patient called office with c/o skin rash and itching. Ampicillin d/c'd. Tetracycline 500 mg tid x 5 days rx'd. Treated with Benadryl and Medrol Dose-Pak.

Three days later patient admitted w/ confluent, erythematous rash over entire trunk and extremities. Treated with IV steroids, H1 & H2 blockers and topical steroids. Discharged after 3 days to continue oral and topical steroids and Benadryl.

Prevention of Medical Errors / 55



Inappropriate Opioid Prescribing

- Pain management claims most difficult to defend
- Indemnity payment - approximately 50%
- Undiagnosed psychiatric conditions, addiction and/or diversion
- FS 456.44(c) Controlled substance prescribers
 - Practitioner profile
 - Prescription pads
 - Management
 - Monitoring

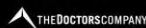
PIAA Research Notes
Florida Statutes and Administrative Codes

Prevention of Medical Errors / 56

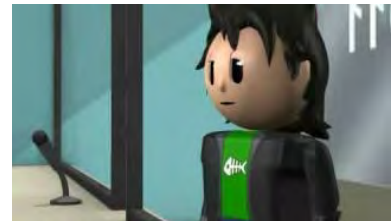
Inappropriate Opioid Prescribing (continued)

- Failure to evaluate
 - Inadequate history, physical exam
- FTD prior to initiation of txt
 - Inadequate medical rationale
- Failure to obtain medical records or verification
 - No documentation
- Failure to establish treatment goals
 - Pain reduction–improvement
- FTD abuse
 - No screening/monitoring of addictive potential
- Deviation from the “Contract”
 - No documentation

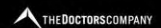
Prevention of Medical Errors / 57



[Medication](#)



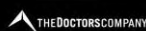
Prevention of Medical Errors / 58



Medication Error Prevention

- Electronic ordering or fax
- Pre-printed scripts
- Brand and generic names
- Medication's purpose
- Limit v.o. and t.o.
- Refill protocols
- Medication history and current profile
- Medication/Allergy alerts

Prevention of Medical Errors / 59



Medication Error Prevention

- Review chart
- Caution with symbols, abbreviations, and decimals (e.g., 0. and .0)
- Storage and Labeling–LASA
- Limit concentrations
- Written information
- Warnings
- Delegation
- Competency evaluation

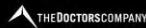
Prevention of Medical Errors / 60



Disclosing Medical Error

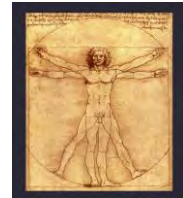
- Seek legal/risk management guidance
- Communicate
- Express concern/empathy
- Do not blame
- Present a plan
- Confirm patient/parent understanding
- Document
- www.sorryworks.net

Prevention of Medical Errors / 61



2013 National Patient Safety Goals

- Patient ID
- Medication safety
 - Reconciliation
- Prevent infection
- Prevent surgical mistakes
- Communication
- Patient risks
 - Recognition and response



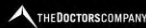
Prevention of Medical Errors / 62



Their Trust Is In You



Prevention of Medical Errors / 63



“The pessimist complains about the wind; the optimist expects it to change; the realist adjusts the sails.”

—William Arthur Ward

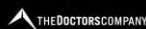
Prevention of Medical Errors / 64

Your Role in Reducing Medical Error

- Establish culture
- Promote effective team functioning
- Anticipate the unexpected
- Create an environment of trust and cooperation

PRIMUM NON NOCERE

Prevention of Medical Errors / 65



Mission Statement

sstrickland@thedoctors.com
(800) 421-2368, ext. 3016

**Our Mission Is to Advance,
Protect, and Reward the
Practice of Good Medicine**

For further Patient Safety information,
please visit our Web site at:
www.thedoctors.com

Prevention of Medical Errors / 66



Saturday, June 29, 2013

Karl G. Stonecipher, MD

Karl G. Stonecipher, MD is a cornea and refractive trained surgical specialist and the Director of The Laser Center in Greensboro, North Carolina, which he joined in 2005. Prior to that appointment he had been the director of the Southeastern Laser and Refractive Center in Greensboro, North Carolina from 1991-2005. He is a Clinical Assistant Professor at the University of North Carolina and assists in the refractive surgery training of the residents in the department of Ophthalmology.

Dr. Stonecipher received his undergraduate degrees in Biology and Chemistry from Southern Methodist University. His medical degree was obtained from the University of Oklahoma Health Sciences Center and his residency in Ophthalmology was at Tulane University from 1987 through 1990. He spent 18 months in a cornea and refractive surgery fellowship with Dr. J. James Rowsey at the McGee Eye Institute. Dr. Stonecipher has additional basic science education from Stanford University prior to starting in practice at Southeastern Eye Center. He has performed over 65,000 refractive surgical procedures and over 25,000 cataract surgical procedures.

With more than 100 book chapters, abstracts and articles published, Dr. Stonecipher speaks both nationally and internationally on refractive, cataract, presbyopic and corneal surgery.

Dr. Stonecipher has been certified by the American Board of Ophthalmology since 1992. His memberships include the American Academy of Ophthalmology, the International Society for Refractive Surgeons, and the American Society of Cataract and Refractive Surgery. He is currently involved in FDA trials for the Study of Cornea, Cataract, Presbyopic and Refractive Surgery. He recently received the Achievement Award from the American Academy of Ophthalmology and is listed as one of the Top Fifty Ophthalmologist by Cataract and Refractive Surgery Today, registered with Who's Who in Ophthalmology, and picked as one of Americas Top Ophthalmologists.

Born and raised in Oklahoma City, Oklahoma, Dr. Stonecipher and his wife, Lynne, have two children, Megan and Kody, and live in Greensboro, North Carolina.

Cataract Surgery

Is there any way to make it better?

*Karl Stonecipher, MD
Clinical Assistant Professor of Ophthalmology,
University of North Carolina
Medical Director, TLC Greensboro*

Does the femtosecond laser help?



But I want to start out positive....



Postoperative Day 1 and Month 1
Visual Outcomes between CE/IOL
and FS/CE/IOL



METHODS

- 2 GROUPS (N-103)
- LENSX
- CE IOL

OUR CENTER HAS DONE OVER 1300 CASES (3 SURGEONS)

THIS SERIES IS CONSECUTIVE PATIENTS FROM ONE SURGEON (KGS)

PATIENTS TARGETED FOR PLANO

2.7 MM INCISION LENGTH

PREMIUM IOL CHANNEL PATIENTS

NO RETINAL OR SYSTEMIC PATHOLOGY

NO COMPLICATIONS INTROPERATIVELY OR POSTOPERATIVELY

AXIAL LENGTH

LENSX

- AVERAGE 24.2+/-1.3 MM
- RANGE 20.97 TO 28.46

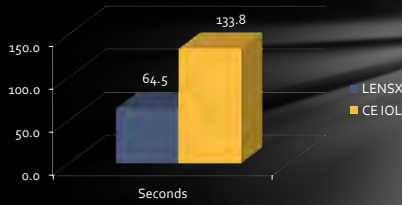
CE IOL

- AVERAGE 23.3+/- .5 MM
- RANGE 21.25 TO 27.67

Video Clip

A 64% REDUCION IN PHACO TIME

PHACO TIMES

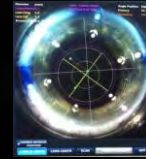


"Compared to control porcine eyes, femtosecond laser phacoemulsification resulted in a 43% reduction in phacoemulsification power and a 51% decrease in phacoemulsification time."
 Nagy Z, Takacs A, Filkorn T, Sarayba M. Initial clinical evaluation of an intraocular femtosecond laser in cataract surgery. J Refract Surg. 2009 Dec;25(12):1053-60.

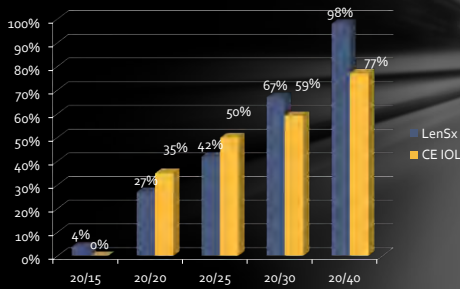
POD 1 AVERAGE UCVA

LENSX
 Day 1 Average
 0.74+/-0.21

CE IOL
 Day 1 Average
 0.69+/-0.1



POD 1 UCVA



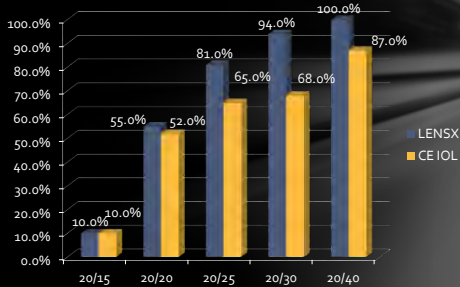
MONTH 1 AVERAGE UCVA

LENSX
 Month 1 Average
 0.9+/-0.19
 SE -0.23+/-0.47 D

CE IOL
 Month 1 Average
 0.82+/-0.29
 SE -0.44+/-0.41 D



MONTH 1 UCVA



WHAT ABOUT LASIK VS FS VS MANUAL?

Overall 81% of the FS laser group saw 20/30 or better at 1 month compared to 65% of the manual group.

In a comparative set of LASIK patients, overall 98% of the LASIK group saw 20/20 or better at 1 month and 89% of the group saw 20/20 at POD 1.

SUMMARY

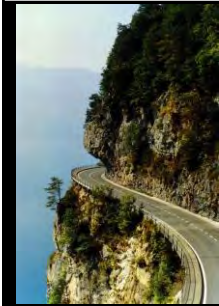
64% REDUCTION IN PHACO TIME
POD 1 100% $\leq 20/40$ LENSX vs 77% CE IOL
POD 1 67% $\leq 20/30$ vs 59% CE IOL
MONTH 1 100% $\leq 20/40$ LENSX vs 87% CE IOL
MONTH 1 94% $\leq 20/30$ LENSX vs 68% CE IOL

What about the tough cases?

Video Clip

Video Clip

Does intraoperative aberrometry matter?



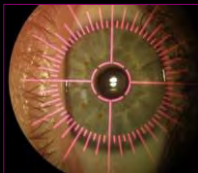
Improvement in Refractive Outcomes with Femtosecond Toric IOL's with the use of Intraoperative Wavefront Aberrometry

Karl Stonecipher, MD

Michael Woodcock, MD



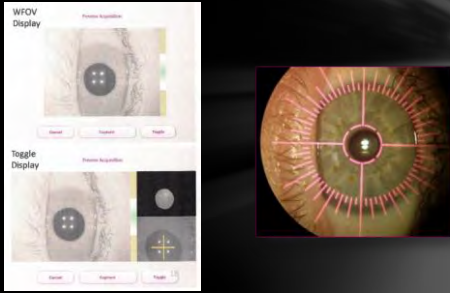
ORA ANALYSIS



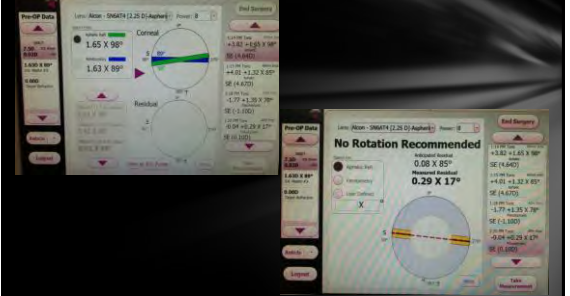
CASE STUDY



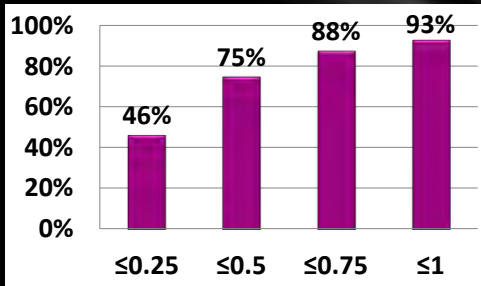
CASE STUDY



CASE STUDY



Standard Toric Cases Absolute Prediction Error



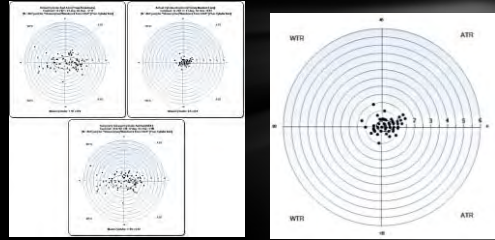
N=56, Mean 0.39 ± 0.37

*Dr Stonecipher & Dr Woodcock Toric Data

Standard Toric Cases Cylinder Reduction

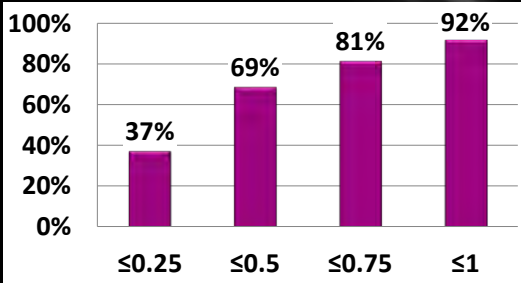
Pre-op Keratometric Astigmatism
N= 86, Mean Cyl 1.91 ± 0.90

Post-op Refractive Cylinder
N= 86, Mean Cyl 0.50 ± 0.40



*Dr Stonecipher & Dr Woodcock Toric Data

Standard Toric Cases Post Op Cylinder Distribution



N=86

*Dr Stonecipher & Dr Woodcock Toric Data

CONCLUSIONS

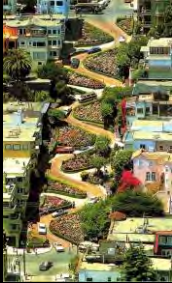
Prediction Error

- 75% OF CASES WERE +/-0.5 D
- 46% OF CASES WERE +/-0.25D

Postop Cylinder distribution

- 69% OF CASES WERE LEFT WITH LESS THAN 0.5D OF CYLINDER
- 37% OF CASES WERE LEFT WITH LESS THAN 0.25 D OF CYLINDER

What about surface disease detection?



Keys to Success

Preop Evaluation:

- Preop evaluation for dry eye/blepharitis
- Can impact corneal topography/keratometry
- Preop Topography
- Preop OCT of Macula

26

How common is Blepharitis in patients scheduled for cataract surgery?

Study of 100 Patients (200 Eyes) Scheduled for Cataract Surgery at 2 Centers

- 59% of patients were diagnosed with Blepharitis



Photo compliments of Hank Perry, MD

TBUT < 7 seconds:
- 61% of patients with blepharitis

Incidence of Blepharitis in Patients Scheduled for Phacoemulsification
Jodi Luchs, MD, Carlos Buznego, MD, William Trattler, MD: ASCRS, Boston, April 2010

27

Dry Eye Study

■ Prospective, multi-center study (9 sites)

- Mark Packer, MD
- Damien Goldberg, MD
- Parag Majmudar, MD
- Eric Donnenfeld, MD
- Marguerite McDonald, MD
- Karl Stonecipher, MD
- Jon Vukich, MD
- Chaz Reilly, MD
- Gregg Berdy, MD
- Ranjan Malhotra, MD
- William Trattler, MD



■ 136 patients (272 eyes) scheduled for cataract surgery

- Avg Age: 70 yrs old (range: 54 to 87)

28

Are Cataract Surgery Patients Symptomatic for Dry Eye?

Foreign body sensation complaints:

- 59%: Never
- 28%: Some of the time
- 87%

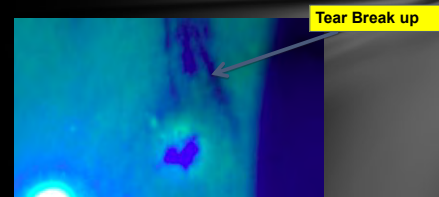
FBS: Half, most or all of the time:
Only 13% of patients

29

Tear Break up Time

What time is considered abnormal?

- 5 seconds?
- 7 seconds?
- 10 seconds?



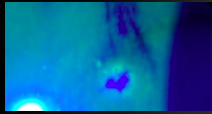
30

Results: Tear Break up Time

N = 136 patients (272 eyes) from 9 Centers

Average TBUT: **4.95 seconds**

of eyes with TBUT \leq 5 seconds: 171 eyes (**62.9%**)



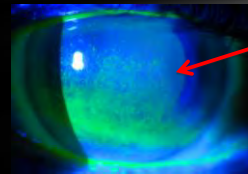
31

Corneal Staining

N = 136 patients (272 eyes)

Positive Corneal Staining: 209 eyes (76.8%)

Central Corneal Staining: 136 eyes (**50%**)



Central Corneal Staining

32

Schirmer's Scores

N = 136 patients (272 eyes)

Eyes with Schirmer's score \leq 5: 58 eyes (21.3%)

Eyes with Schirmer's score \leq 10: 132 eyes (48.5%)



33

Summary

(Patients scheduled for cataract surgery)

Patients are often asymptomatic

Dry eye signs are very common in patients scheduled for cataract surgery

- TBUT:
 - More than **60%** with very abnormal TBUT (\leq 5 seconds)
- Corneal Staining
 - **50%** with Central staining
- Schirmer's score
 - **21.3%** with very low Schirmer's (\leq 5mm)

34

Why is it important to identify and treat Dry eye and Blepharitis Preop

Answer:

- Because these conditions can impact:
 - **IOL calculations**
 - Inaccurate **keratometry** can lead to wrong IOL power
 - LRI or Toric IOL **axis and/or magnitude**
 - Inaccurate **keratometry**
 - Inaccurate **topography**

2011.02.17-MM3003

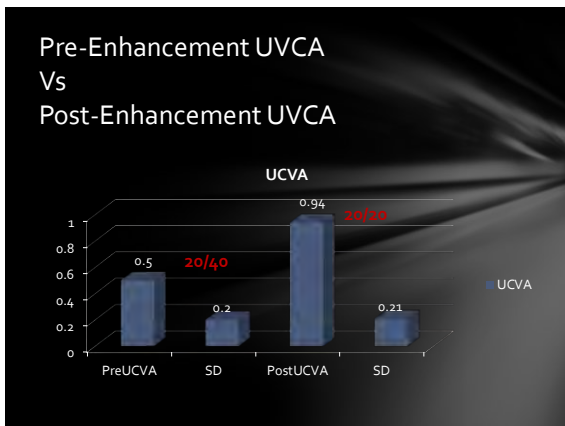
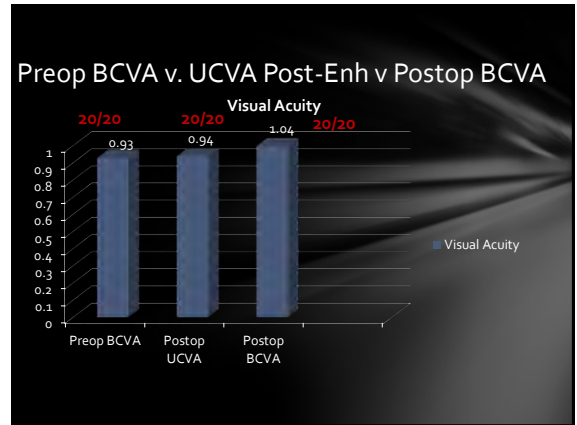
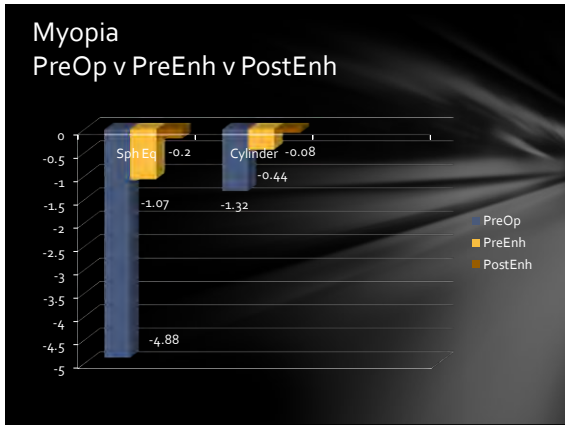
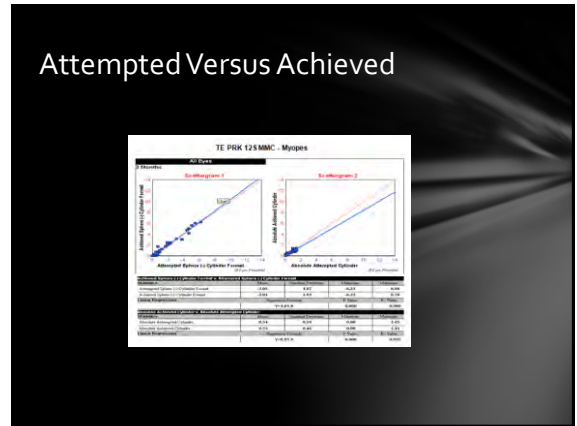
35

The go second workup....

1. OSDI
2. Fluorescein
Corneal Staining
TBUT
3. Lissamine green

www.hubpharmaceuticals.com





Complications

- No intraoperative or postoperative complications
- No Haze or Scarring Postoperatively
- No infections

WHY?

CONCLUSIONS



Transepithelial PRK is a safe and effective method to correct residual refractive error. At the present time you can only correct the refractive error but in most cases that will resolve the patients subjective complaints

COMMENTS

If you need to do a Custom Treatment you can remove the epithelium with alcohol
I use a cut off of 0.35 RMSH
Lower levels of Myopia show coupling and nomogram adjustments must be made otherwise the Manifest Refraction is the guideline for treatment

Myopic/Myopic Astigmatic

Treatment zones of 6.0 to 9.0 mm based on conventional, wavefront optimized or customized treatment.

Transepithelial an option

PTK diameter 6.5 mm/ 0.5 mm Transition Zone

Spherical Adjustment
0.66 D

Standard PRK 6.0 mm

±2S MMC if indicated

Frozen BSS Irrigation

Medications + BCL

Video Clip

Hyperopic/Hyperopic Astigmatic

Need a treatment zone of 9.0 mm

Transepithelial not an option with the current technology available.

Video Clip

Mixed Astigmatism

Need optical zone of 9.0 mm

Transepithelial not an option

Can use IPS or LenSX for Laser

Relaxing Incisions or IAK's



New technology?



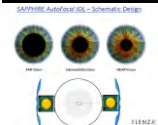
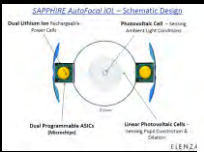
To Potentially Restore 'Dynamic' Accommodation



Real Footage



Rapid response – ideally no need for intervention by patient.
No restrictions in viewing direction for objects at any distance



Continuously variable addition up to perhaps 3 or 4 D
No loss in image contrast at any distance

How do I deal with the unhappy patient?

1. Mental
2. Examination
3. Treatment

THANK YOU

Kuldev Singh, MD, MPH

Kuldev Singh, MD, MPH is Professor of Ophthalmology and Director, Glaucoma Service at the Stanford University School of Medicine. Dr. Singh received his MD and MPH degrees from the Johns Hopkins University School of Medicine and was an Eleanor Naylor Dana Charitable Trust Fellow at the Wilmer Eye Institute.

He completed his ophthalmology residency at the Casey Eye Institute, Oregon Health and Science University followed by a Heed Foundation Fellowship focusing on glaucoma at the Bascom Palmer Eye Institute in Miami. Dr. Singh has published over 100 peer-reviewed articles and has delivered over 200 invited lectures on six continents. He has edited two textbooks and served on the editorial board of nine ophthalmic publications.

Dr. Singh's current research interests focus on glaucoma surgical trials, glaucoma genetics, the epidemiology of glaucomatous disease and health care delivery in developing countries. His clinical practice focuses on the medical, laser and surgical management of glaucoma, and the surgical management of cataract in patients with glaucoma.

Dr. Singh is Vice President of the American Glaucoma Society and will begin a two year term as President in January, 2013. He serves on the Board of Governors of the World Glaucoma Association and has previously served as Executive Vice President. Dr. Singh has served as Chair and Methodologist for the glaucoma section of the Ophthalmic Technology Assessment Panel of the American Academy of Ophthalmology (AAO) and was Glaucoma Subspecialty Day Co-Chair at the 2002 and 2003 AAO Meetings. He is the chair of the Program Committee for Glaucoma Subspecialty Day 2012.

Dr. Singh received the Senior Achievement Award from AAO in 2005 and Secretariat Awards in 2006 and 2009. He was a member of the team that won first prize in the Cataract Surgery section of the American Society of Cataract and Refractive Surgery Challenge Cup in 2006. Dr. Singh served as an Academic Advising Dean at the Stanford University School of Medicine from 2002-2005 and two three year terms as an elected member of the Faculty Senate. He was the sole recipient of the Franklin G. Ebaugh Jr. Award presented at the 2006 Stanford commencement ceremonies. Dr. Singh was one of two recipients of the 2012 Stanford University Asian American Faculty Award.

The Landmark Glaucoma Trials: What We Have and Have Not Learned

Kuldev Singh, MD, MPH
 Professor of Ophthalmology
 Director, Glaucoma Service
 Stanford University School of Medicine

The Randomized Clinical Trial: Beware of Limitations.
 Journal of Glaucoma 13(2); 87-89. April, 2004.

Hierarchy of Evidence



- Prospective, randomized, controlled
- Controlled
- Cohort
- Cross sectional
- Case control
- Case series and case reports

Evolution of Clinical Trials

- Concurrent controls without randomization:
 - Lind, Scurvy – 1747
 - Semmelweis, Puerperal fever – 1848
 - Goldberger, Pellagra – 1914
- With randomization:
 - Diehl, Cold vaccine – 1938
 - Medical Research Council, Streptomycin, tuberculosis - 1947

Joseph Lind's Treatise on Scurvy (HMS Salisbury, 1754)

12 scurvy patients selected; course of study 6 days

<u>Group</u>	<u>n</u>	<u>Treatment (Exposure)</u>
1	2	Cider (1 qt/day)
2	2	Oil of vitriol (sulfate of Cu; Zn, Fe)
3	2	Vinegar
4	2	Seawater
5	2	Garlic, radish, balsam (pitch) & myrrh (perfume/incense)
6	2	Oranges & lemons

Patients in group 6 fit for duty (Outcome); others remained sick

Hypothesis

- Is the right question being asked?
- Has the question been formulated correctly?

Timing

- Is the question being asked likely to be relevant when the study is completed?

Design

- Masking: single, double or triple
- Sample size and power
- Randomization

Conduct

- Study population
- Selection bias
- Ascertainment bias

Interpretation

- Preconceived notions
- Data mining

“advice on diet is insecurely based, even that which recommends a reduction in saturated fats including dairy products” while “the evidence for an association between moderate alcohol intake and reduced risk is consistent, yet advocacy of drinking remarkable by its absence.”

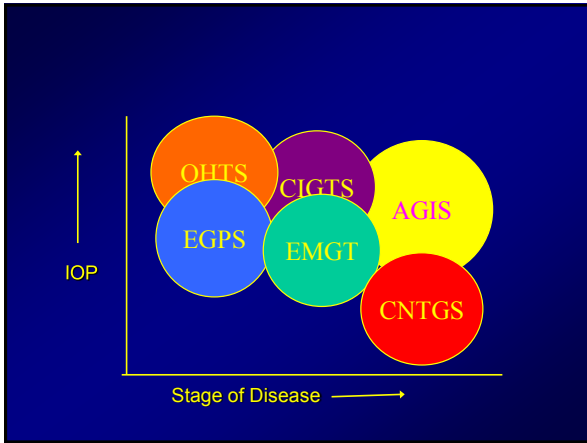
McCormick J. The Multifactorial Aetiology of Coronary Heart Disease: A Dangerous Delusion. *Perspectives in Biology and Medicine*, 1988; 32(1): 103-108.

Eddy and Billings Report

The Purist Perspective

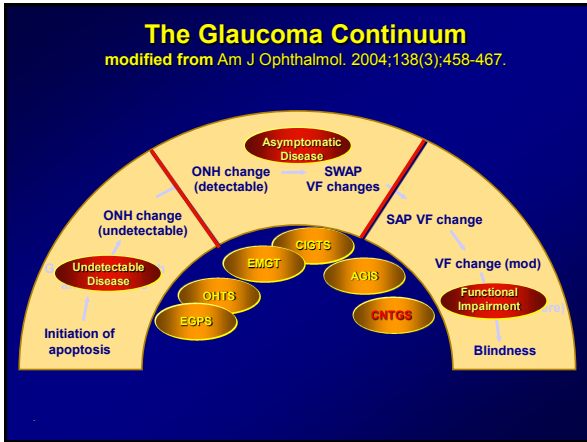
“No randomized controlled studies proving the efficacy of therapy for primary open angle glaucoma”

Eddy DM, Billings J. The quality of medical evidence: implications for quality of care. *Health Aff (Millwood)*. 1988;7:19-32



Studies and Goals

Study	Disease State	IOP Endpoint
OHTS	High IOP	20% reduction
EMGTS/EGPS	Early	None
CIGTS	Non-Advanced	VF & IOP dependent
CNTGS	Advanced Progressive NTG	30% reduction
AGIS	Advanced	< 18 mm Hg



Collaborative Normal Tension Glaucoma Study (CNTGS)

Initiated by Glaucoma Research Foundation
San Francisco, CA

Question: Is IOP lowering therapy appropriate in patients with normal tension glaucoma?

CNTGS

One eye of 145 subjects randomized to observation or treatment

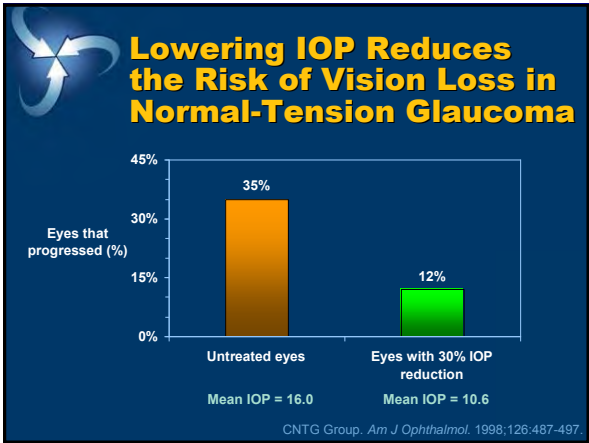
Documented progression of visual field defects, new disc hemorrhage or field defects that threatened fixation

IOP up to 24 mm Hg

All eyes treated if progression or fixation threatened

30% IOP reduction- medicines, laser and surgery

No beta blocker and other adrenergic agent use



CNTGS

- 30% IOP lowering was achieved in 57% of patients on medical therapy with or without laser trabeculoplasty
- Approximately half of eyes with no prior history of progression did not progress without treatment over 7 years
- Confirmatory visual fields were found to be essential in eyes suspected to have progressed

CNTGS: Risk Factors for Progression

- Prior progression
- Disc hemorrhage
- Migraine headache
- Female gender
- Non-Asian race

What We Learned from CNTGS

- Treatment is effective in lowering IOP with NTG
- IOP lowering is effective in reducing risk of visual field progression in NTG
- Surgical therapy is associated with cataract progression

Advanced Glaucoma Intervention Study (AGIS)

- Sponsored by the National Eye Institute
- \$ 17 million
- Question: In patients with advanced glaucoma uncontrolled on maximal medical therapy, should the next step be laser trabeculoplasty or trabeculectomy?

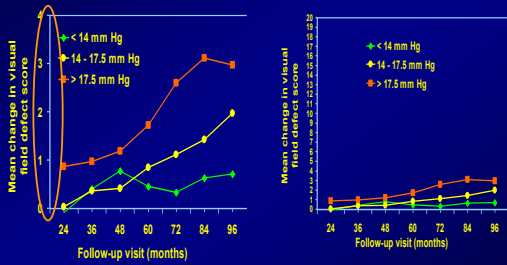
AGIS

- 789 eyes of 591 patients
- IOP 18-21 mm Hg with deterioration of fields or IOP 21 mm Hg or greater with sufficient field loss
- 8 years of follow-up
- Treatment protocol
 - A-T-T
 - T-A-T
 - Supplemented by medication, goal <18 mm Hg

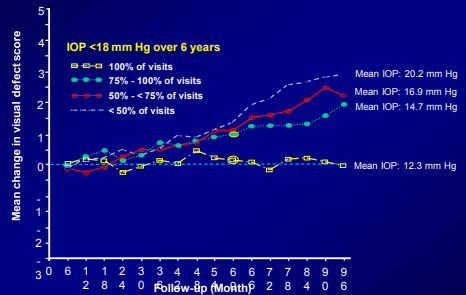
AGIS: Answer to Initial Question

- Greater reduction in IOP with TAT sequence
 - Both blacks and whites
- Preservation of vision
 - Whites: TAT
 - Blacks: ATT

AGIS: Predictive Analysis*

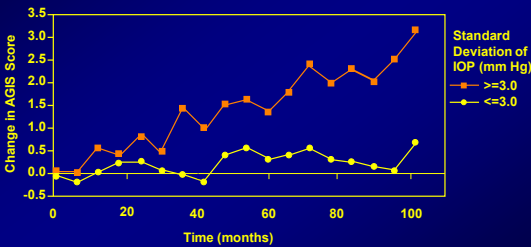


AGIS: Associative Analysis*



*Mean change in visual field defect score by percent of visits over 6 years with IOP < 18 mm Hg AGIS Investigators. *Am J Ophthalmol.* 2000;130:429-440.

IOP Fluctuation and Visual Field Progression



Nouri-Mahdavi et al. *Ophthalmology* 2004; 111(9):1627-1635

What We Learned From AGIS

- Trabeculectomy lowers IOP better than laser trabeculoplasty
- ? Maintaining IOP below a threshold is beneficial

Ocular Hypertension Treatment Study (OHTS)

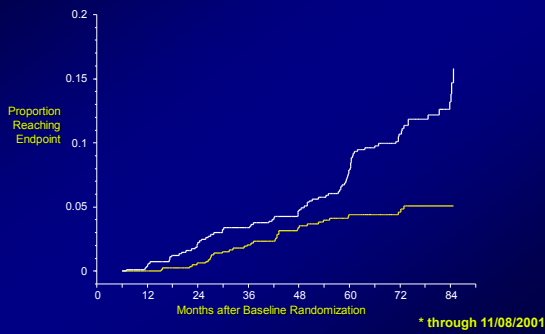
- Sponsored by the National Eye Institute
- \$ 29 million and counting
- Question: Does lowering IOP in ocular hypertensive patients decrease the likelihood of conversion to glaucoma ?

OHTS

- Entrance criteria:
 - IOP between 24 and 32 mm Hg in one eye and at least 21 mm Hg in fellow eye
 - normal optic nerves
 - normal visual fields
- 1,636 subjects at 23 clinical centers
- 20% lowering of IOP or no treatment

OHTS: Primary POAG Endpoints*

Log Rank P-value < 0.001
Hazard ratio 0.40, 95% CI (0.27, 0.59)



OHTS Reduction in Risk

- Relative risk reduction: 50%
- Reduction in absolute risk: 5%
- Number needed to treat: 20

Risk Factors for Progression: Univariate and Multivariate Analyses

- Age
- CCT
- Certain visual field parameters
- Optic nerve cupping

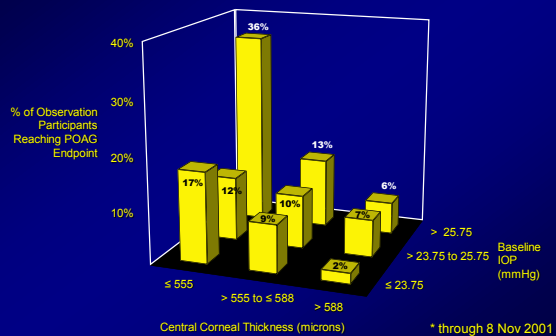
Risk Factors for Progression: Univariate Analysis Only

- Race
- Male gender
- Heart disease

Previously Hypothesized Risk Factors Not Found to Be Predictive

- Family history
- Diabetes (protective)

Observation Participants at POAG Endpoint* Central Corneal Thickness vs. Baseline IOP (mmHg)



What We learned from OHTS

- Central corneal thickness measurement is a must in all patients with ocular hypertension and perhaps in all patients in a glaucoma practice
- Lowering IOP reduces the risk of glaucomatous optic nerve and visual field progression
- A calculator is available to assess the risk of developing glaucoma in patients with ocular hypertension

What We Didn't Learn From OHTS

- Risk reduction with IOP lowering is proportionately equal for all patients with ocular hypertension
- Treatment of ocular hypertension reduces the risk of ultimate functional vision loss from glaucoma

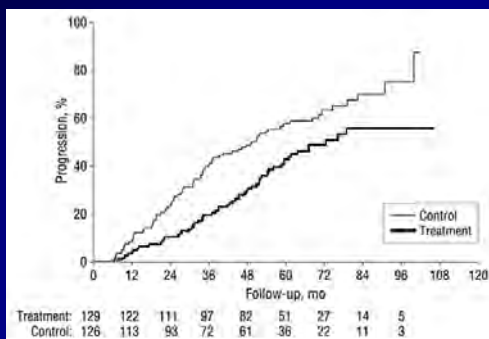
Early Manifest Glaucoma Trial (EMGT)

- Sponsored by the National Eye Institute, conducted in Sweden
- Question: Should patients newly diagnosed with glaucoma be treated with IOP lowering therapy?

EMGT

- 44,243 screened to identify 255 new patients with open angle glaucoma who were randomized to:
 - Argon laser trabeculoplasty and betaxolol
 - No treatment
- No target IOP
- Treated and untreated groups had 45% and 62% rates of progression respectively

EMGT



EMGT: Risk Factors for Progression

- Higher baseline IOP
- Higher treated IOP
- Exfoliation syndrome
- Frequent disc hemorrhages
- Older age
- Bilateral disease

Fluctuation of IOP and Glaucoma Progression in EMGT

Bengtsson et al Ophthalmology 114(2), 2007

- Mean IOP HR(1.11) p<.0001
- IOP Fluctuation HR(1.00) p<.999

Ocular Perfusion Pressure in EMGT

Leske MC et al. Ophthalmology 2007, 114(11): 1965-72.

- In patients with higher baseline IOP:
 - Lower systolic BP increased risk
- In patients with lower baseline IOP:
 - Higher systolic BP decreased risk

EMGT: Conclusions

- IOP lowering therapy was beneficial in patients newly identified as having open angle glaucoma
- Every mm Hg of IOP lowering resulted in a 10% reduction in risk of progression
- Mean IOP is a more important risk factor than IOP fluctuation

Collaborative Initial Glaucoma Treatment Study: CIGTS

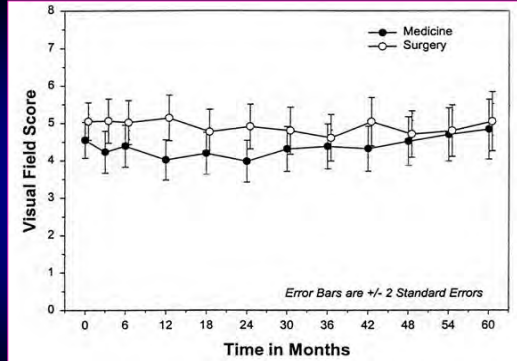
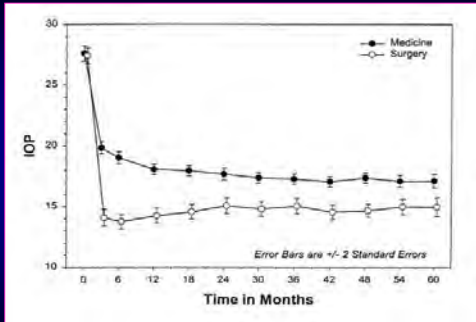
- Sponsored by the National Eye Institute
- \$ 17 million
- Question: In patients with newly diagnosed glaucoma, is initial surgical therapy preferable to medical therapy?

CIGTS

- 607 patients, at 14 centers, newly diagnosed with open angle glaucoma, randomized to initial medical therapy or trabeculectomy
- M-A-T vs T-A-M
- Primary outcome variable: visual field
- Secondary outcome variables: IOP, visual acuity, quality of life, cataract formation

CIGTS: Target IOP

$[1-(\text{reference IOP} + \text{VF Score})/100]^* \text{reference IOP}$



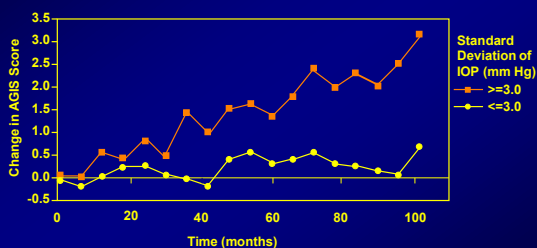
CIGTS: Conclusions

- Greater IOP reduction in initial trabeculectomy group at all time points, average over 5 years: 46% versus 38% (approx. 2-3 mm difference).
- No difference in visual field preservation between groups
- Greater visual acuity loss in the surgery group, largely due to cataract
- Greater ocular symptoms in initial surgical therapy group

What We Learned From CIGTS

- Initial medical therapy is generally preferable to initial surgical therapy
- Every mm Hg does not matter once you substantially reduce IOP

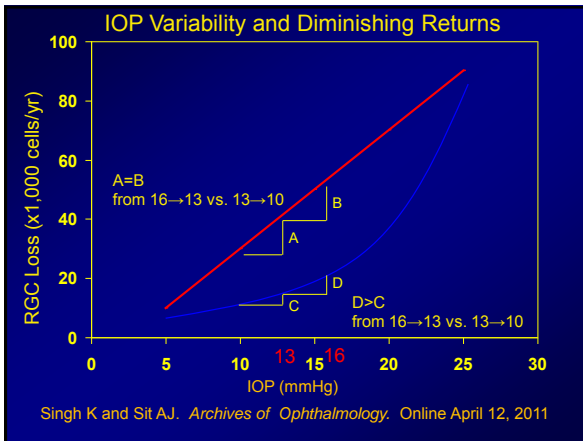
IOP Fluctuation and Visual Field Progression



Nouri-Mahdavi et al. Ophthalmology 2004;111(9):1627-1635

IOP Fluctuation: Two Hypothetical IOP Scenarios

- Patient 1: 13 mm Hg on each of 16 AGIS visits over 8 years
- Patient 2: 10 mm Hg on half of the visits and 16 mm Hg on the other half



Summary: IOP Fluctuation

- Short term (24 hour) IOP fluctuation and long term IOP variability have been hypothesized to be independent risk factors for glaucoma progression
- Short term IOP fluctuation is difficult to study
- The assessment of long term IOP variability as a risk factor for glaucoma progression may be confounded by a non linear IOP-glaucoma progression relationship

European Glaucoma Prevention Study: EGPS

Does IOP lowering therapy in ocular hypertensive patients decrease the likelihood of conversion to glaucoma relative to placebo therapy?

EGPS

- 1081 subjects
- 4 European countries
- Age 30-80
- IOP between 22 and 29 mm Hg in one eye
- Visual acuity 20/40 or better
- 2 normal reliable visual fields
- Normal optic nerves- stereo disc photos
- Treated group received Dorzolamide TID
- Placebo group received vehicle for Dorzolamide

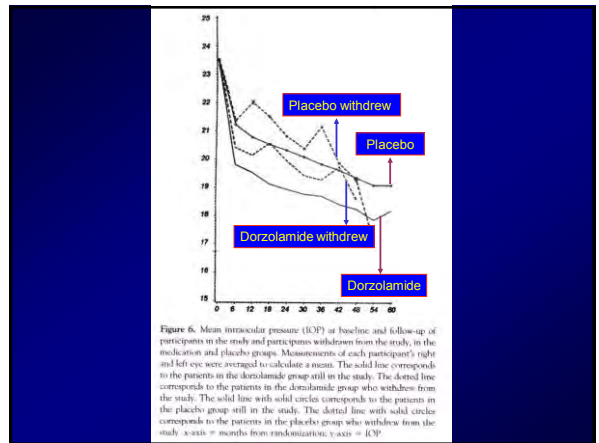
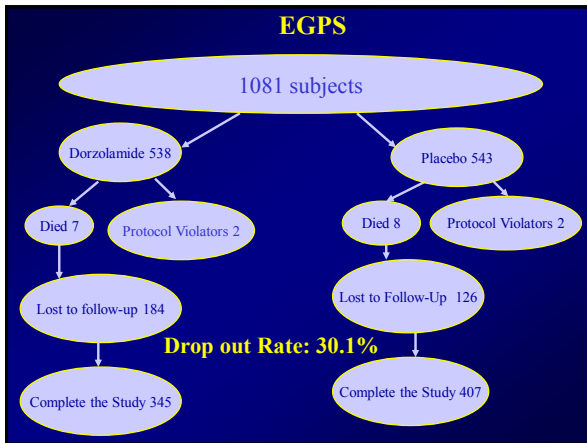
EGPS: Study End Points

Efficacy end point: worsening of visual field, optic nerve or both

Safety end point: IOP greater than 34 mm Hg on 2 different visits within one week

EGPS: Major Findings

- Large placebo effect with vehicle
- Small but significant difference in IOP lowering between medication and placebo treated groups
- No difference in proportion of eyes developing POAG between medication and placebo groups



	Dorzolamide	Placebo
Mean IOP Reduction 6 months	14.5%	9.3%
Mean IOP Reduction 60 months	22.1%	18.7%
		$P < 0.0001$
Conversion to Efficacy Endpoint 60 months	13.4%	14.1%
		Hazard ratio, 0.86; 95% CI, 0.58-1.26; $P = 0.1$
Conversion to Efficacy or Safety End Point - 60 months	13.7%	16.4%
		Hazard ratio, 0.73; 95% CI, 0.51-1.06; $P = 0.1$

EGPS:

Mean Central Corneal Thickness

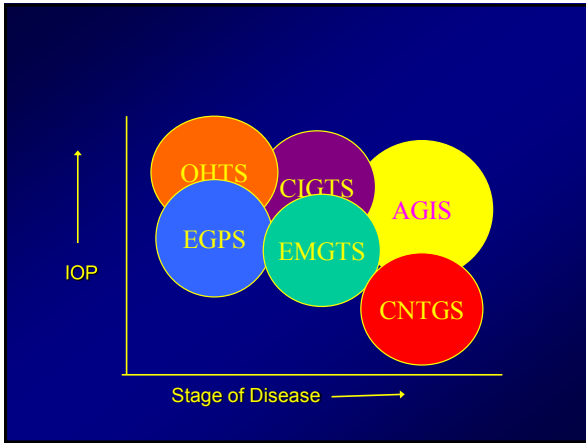
- Dorzolamide group: $574\mu\text{m} \pm 39.0\mu\text{m}$
- Placebo group: $570\mu\text{m} \pm 37.8\mu\text{m}$

EGPS: Potential Limitations

- ? Regression to the mean
- Mean entry IOP of 23.5 mm Hg
- Thicker than average central corneas
- Large dropout rate: approx 30%

What We Learned from EGPS

Don't forget the placebo effect



Summary

- Randomized clinical trials are not perfect
- The potential for bias in design, conduct and interpretation should be addressed prior to, during and after the study period

Lee M. Jampol, MD

Dr. Jampol is Professor of Ophthalmology at Northwestern University. His career has focused on clinical trials, inflammatory diseases (white spots) of the retina, cystoid macular edema, pharmacology of the retina and central serous chorioretinopathy. He also worked on diabetic retinopathy and age related macular degeneration. Since 1985, when he became a member of the Data Monitoring Committee of the Macular Photocoagulation Study, he has been extensively involved in data monitoring and planning of clinical trials. He has been on the data monitoring committees of the MPS, SST, SCORE and the DRCR, as well as corporate studies, and has served on the external advisory committees of the Latino Eye Study and the Beaver Dam Study.

Administratively, he has been President of the American Ophthalmological Society, Trustee and Vice President of ARVO, President of the Macula Society, and Chairman of the Department of Ophthalmology at Northwestern University from 1983-2010.

Presently, Dr. Jampol is the Chair of the Diabetic Retinopathy Clinical Research Network (DRCR.net), a U-10 from the NIH supporting research on diabetic retinopathy.

Central Serous Chorioretinopathy

Lee M. Jampol, MD
Northwestern University
Chicago, IL



Treatments for CSC

Standard of Care: PDT, Laser

- Micropulse diode laser
- Spironolactone
- Finasteride
- Methotrexate
- Acetazolamide
- Ketaconazole
- RU486 (Mifepristone)
- Valproic acid
- Beta-blockers
- Alpha-blockers
- Ranabizumab
- Bevacizumab
- Aspirin
- Placebo

- Carbachol
- Anti-inflammatories
- H. pylori eradication
- Corticosteroids!!!**
- ACTH
- Anti-syphilitic drugs
- Anti-TB drugs
- Insulin-free pancreatic extract
- Thyroid extract
- TTT
- Tranquilizer
- Psychotherapy
- Retrolubar tolazoline
- Subconjunctival salt solutions
- Subconjunctival albumin
- Subconjunctival milk!!!!???**

Central Serous Chorioretinopathy

- Very common cause of visual loss- all ages, male and female
- Outcome usually good but there are many exceptions
- Photodynamic Therapy improves the outcome of persistent cases

CSC

- Unilateral or bilateral
- Young or elderly
- Males or females



Serous Detachments

- Lupus
- Organ transplant
- Crohn's disease
- Many others



Central Serous Choroidopathy

Optical Coherence Tomography (OCT)



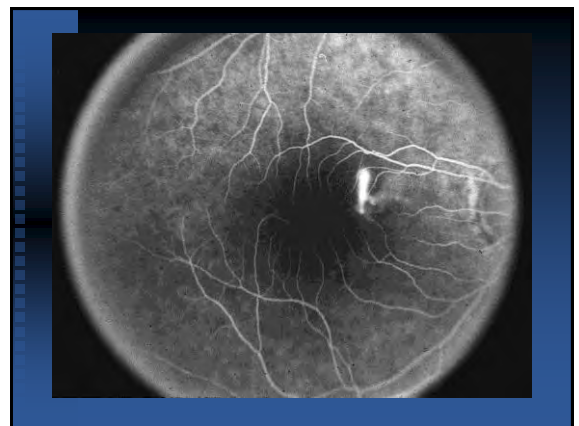
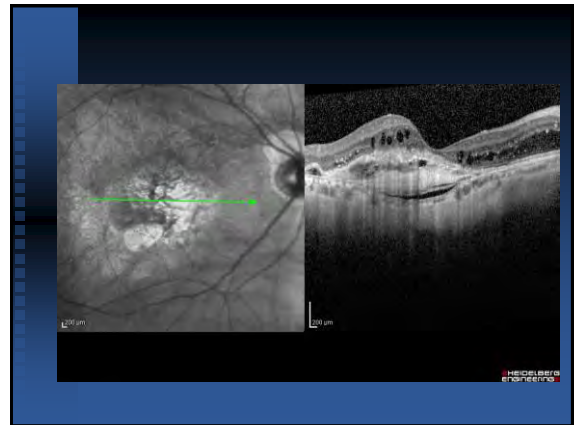
Retina elevated without cystic edema overlying NSD. Photoreceptor outer segments continue to grow.

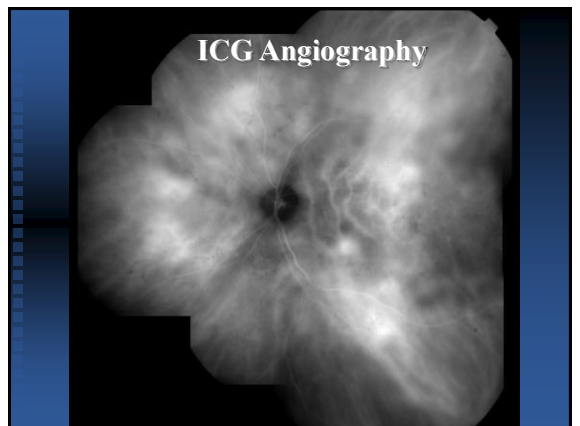
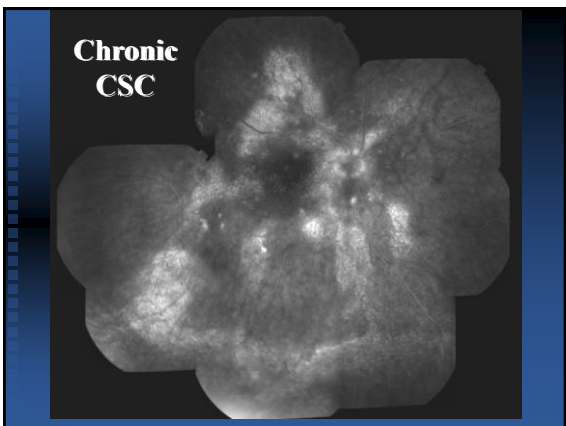
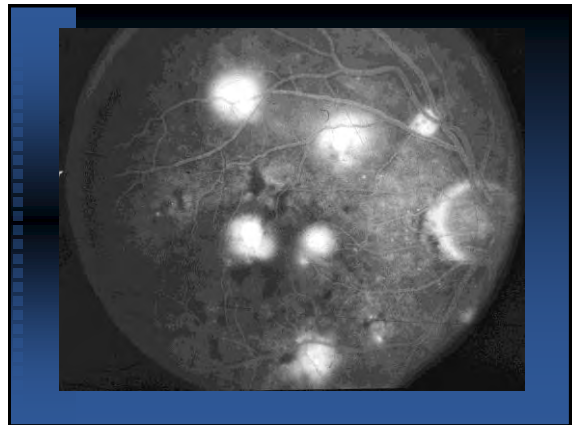
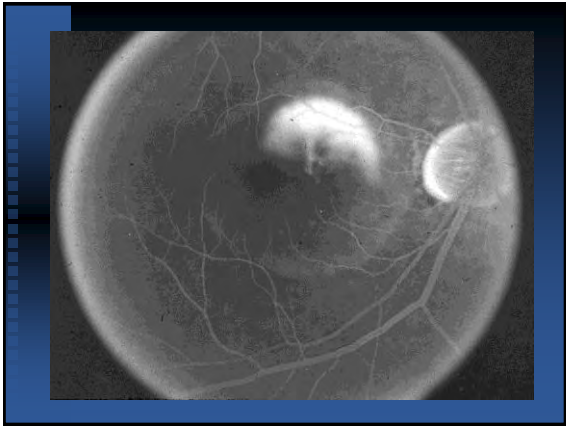


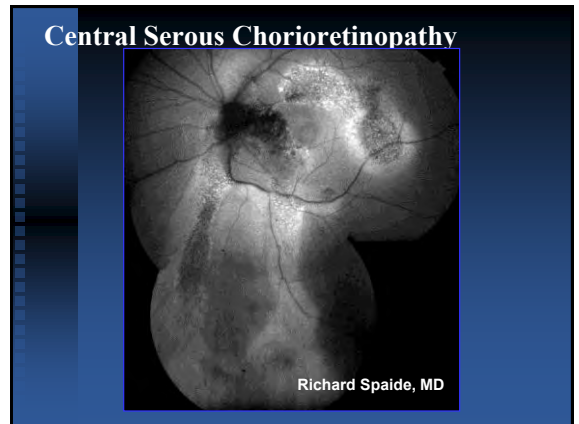
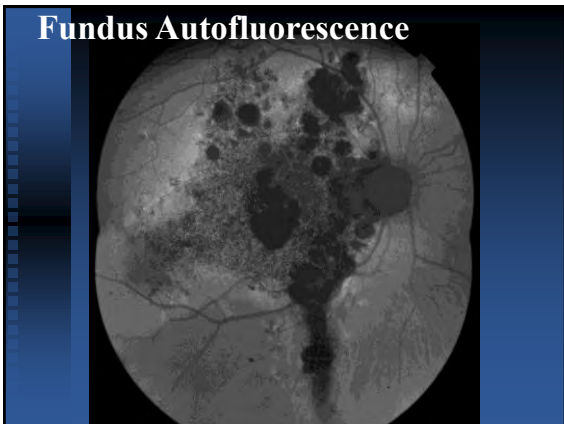
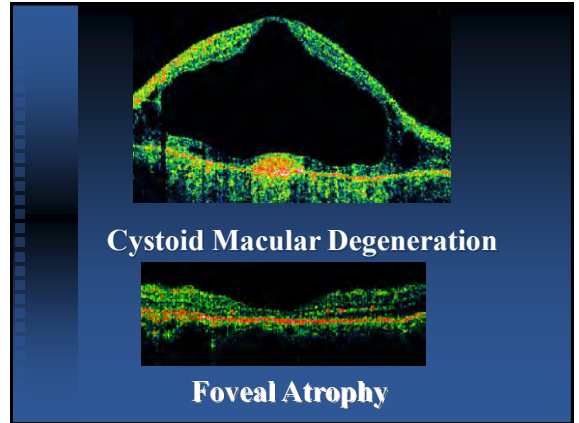
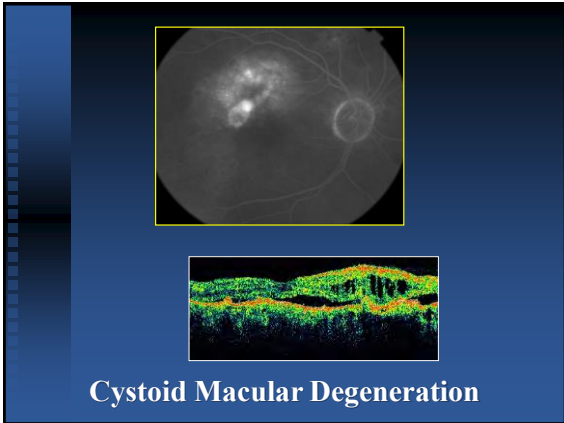
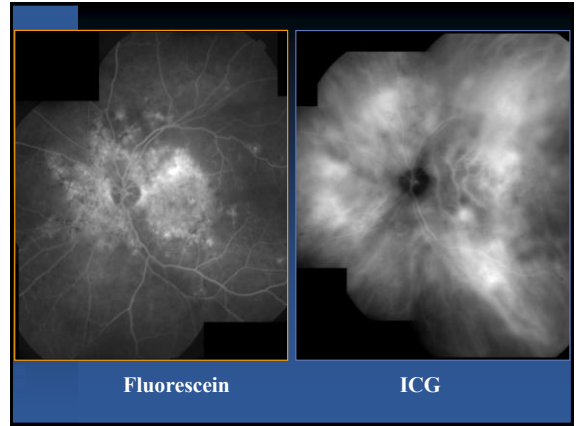
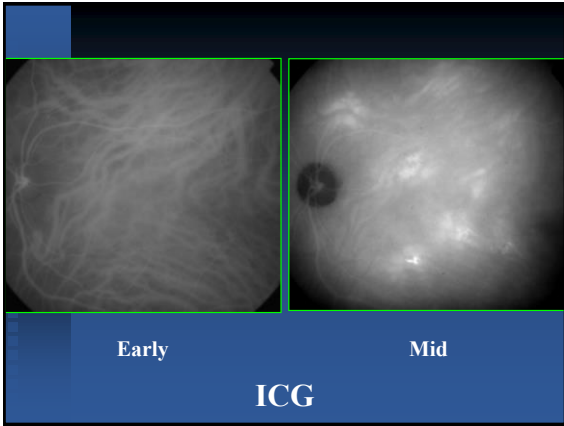
Central Serous Choroidopathy

Optical Coherence Tomography (OCT) Variations

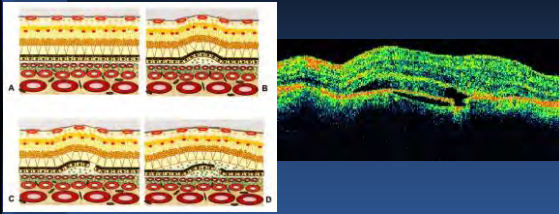
<p>Neurosensory retinal detachment with increased reflection at RPE leak</p>	<p>Neurosensory retinal detachment with small RPE detachment</p>
<p>NSD with small RPE detachment and collection of subretinal fibrin</p>	<p>No subretinal fluid, but only a small RPE detachment</p>



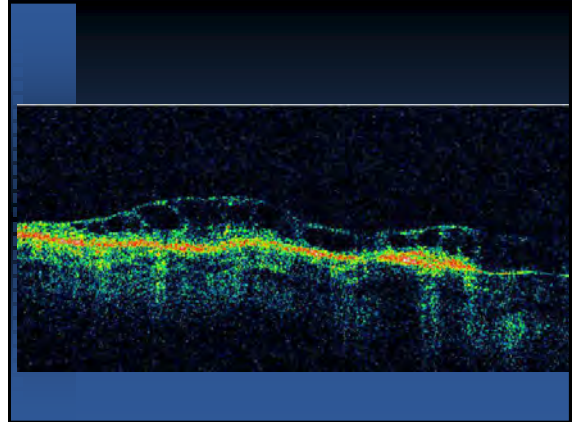




Pathogenesis of CSC



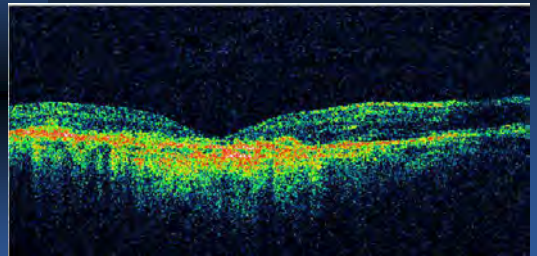
RPE Leak



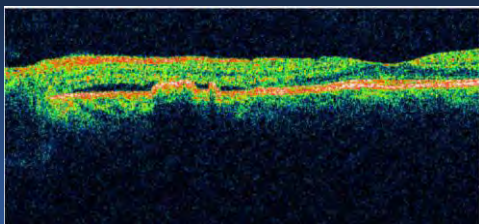
VALUE OF OCT

- Presence of subretinal fluid
- Presence of RPE detachment
- Fovea thickness (thinning a poor sign)
- Presence of scar tissue under retina CNV vs. IPCV
- Presence of scarring in retina
- RPE degeneration (chronic)
- Choroidal thickness and response to treatment

Thinned Fovea



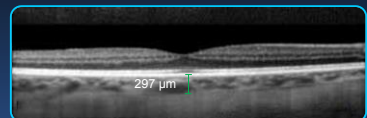
CSCR Nasal to Fovea



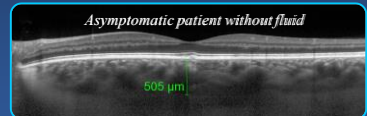
Central Serous Choroidopathy

Enhanced Depth Optical Coherence Tomography (ED-OCT)

NORMAL
Typical ED-OCT
Choroidal thickness
297 μm



CSC Patient
Typical ED-OCT
Choroidal thickness
500 μm

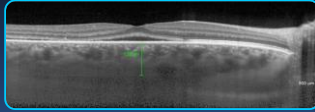


Central Serous Choroidopathy

Enhanced Depth Optical Coherence Tomography (ED-OCT)

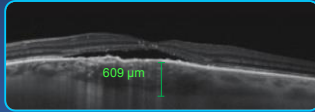
CSC Pt. #1 with NSD

ED-OCT
Choroidal thickness
539 μm



CSC Pt. #2 with NSD

ED-OCT
Choroidal thickness
609 μm



Treatments for CSC

Standard of Care: PDT, Laser

- Micropulse diode laser
- Spiroinolactone
- Finasteride
- Methotrexate
- Acetazolamide
- Ketaconazole
- RU486 (Mifepristone)
- Valproic acid
- Beta-blockers
- Alpha-blockers
- Ranabizumab
- Bevacizumab
- Aspirin
- Placebo

- Carbachol
- Anti-inflammatories
- H. pylori eradication
- Corticosteroids!!!**
- ACTH
- Anti-syphilitic drugs
- Anti-TB drugs
- Insulin-free pancreatic extract
- Thyroid extract
- TTT
- Tranquilizer
- Psychotherapy
- Retrolubar tolazoline
- Subconjunctival salt solutions
- Subconjunctival albumin
- Subconjunctival milk!!!!???**

Corticosteroids and CSC

- ◆ Exogenous – systemic
 - ◆ Depot
 - ◆ Periocular
 - ◆ Topical (skin and ? Eye)
- ◆ Endogenous steroid imbalance

CSC and Exogenous Steroid Use

Central serous chorioretinopathy complicating systemic corticosteroid treatment

MASATO WAKAKURA AND SATOSHI ISHIKAWA
From the Department of Ophthalmology, Kitasato University, School of Medicine, 1-15-1 Kitasato, Sagamihara, Kanagawa 228, Japan

Br J of Ophthalmol 68, 329-331, 1984



- **Landmark Article** – First association of exogenous steroid use and CSC
- Two case reports of patients who developed CSC after receiving betamethasone for retrobulbar neuritis
- CSC recurred each time with 3 successive treatments

CSC and Exogenous Steroid Use

Corticosteroids and Central Serous Chorioretinopathy

Cynthia A. Carvalho-Reccia, MD, Lawrence A. Yannuzzi, MD, Shuma Negido, MD, Richard F. Spaide, MD, K. Bailey Freund, MD, Hanna Rodriguez-Coleman, MD, Marcio Leshano, MD, Tomohiro Iida, MD

Ophthalmology 109:1834-1837, Oct 2002 USA

- 50 patients with CSC compared to 15 age matched controls

Group	Exogenous Steroids Hx	Cushing's Disease
Central Serous	52%	1%
Control	16%	0%

P < 0.0001

CSC and Exogenous Steroid Use

Carvalho-Reccia, CA, et al. Ophthalmology 109:1834-1837, Oct 2002

Steroid Type	Incidence
Inhaled & intranasal steroids	16 (62%)
Oral steroids	6 (23%)
Intra-articular steroid injection	3 (11%)
Intravenous steroid injection	1 (4%)

Reported elsewhere: Periocular injection, Intravitreal injection, Epidural, External steroid cream and shampoo
Never reported: Topical steroid drops

CSC and Medications

- **Glucocorticoids** – in all forms:
 - ✓ Oral, intravenous, intramuscular steroids
 - ✓ Topical steroid cream and shampoos
 - ✓ Pulmonary steroid inhaler & nasal spray
 - ✓ Intra-articular steroid injection
 - ✓ Periocular & intravitreal steroid injection



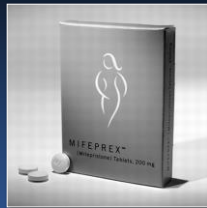
CSC and Medications

- **Glucocorticoids** – in all forms:
 - ✓ Oral, intravenous, intramuscular steroids
 - ✓ Topical steroid cream and shampoos
 - ✓ Pulmonary steroid inhaler & nasal spray
 - ✓ Intra-articular steroid injection
 - ✓ Periocular & intravitreal steroid injection
- **Sildenafil** (Viagra®) – and related phosphodiesterase (PDE5) inhibitors



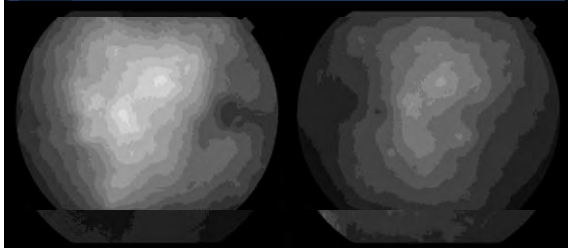
Mifepristone (RU-486)

- Potent glucocorticoid receptor antagonist
- FDA approved as an abortifacient
- Orally bioavailable
- Minimal side effects
 - ◆ skin rash
 - ◆ reversible liver enzyme elevation
- Investigated for:
 - ◆ Cushing's disease
 - ◆ meningioma,
 - ◆ uterine leiomyomata
 - ◆ Depression

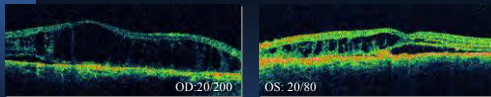


Patient A3/B3

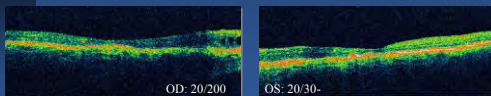
- 63 year-old white male
- POH: CSC x 7 years
- deterioration of vision
- Va: 20/200; 20/80 OD-OS



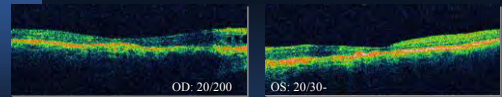
Mifepristone Challenge



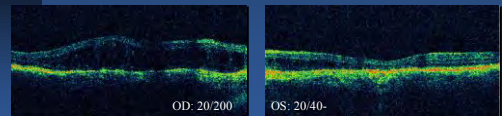
Mifepristone 200mg daily x 12 weeks



Mifepristone Discontinued

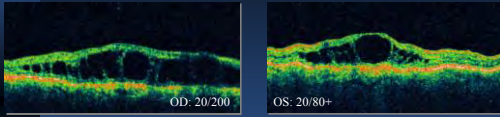


4 months later....



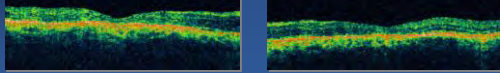
2 Years Later...

- Decreased vision in both eyes
- PDT with no response



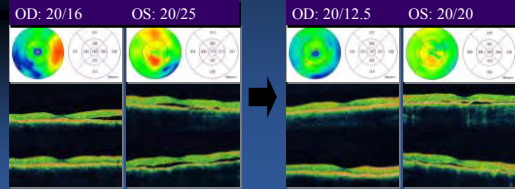
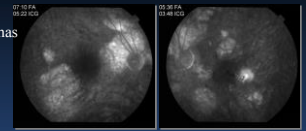
Rechallenged with Mifepristone 200mg x 4 weeks...

After 12 weeks vision improves to 20/180+ OD, and 20/50+ OS



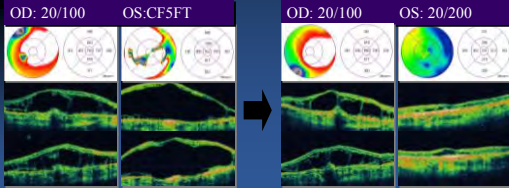
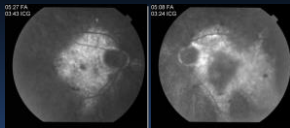
Patient B9

- 38 Year-old white female
- Persistent and enlarging scotomas OD>OS
- CSC x 4 years
- History of systemic steroids

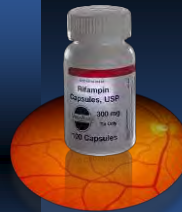


Patient B10

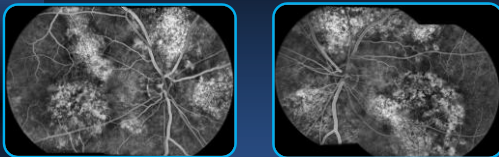
- 58 Year-old white male
- Worsening vision OU
- CSC x 10 years
- PDT x 4, thermal laser



*Rifampin for
Central Serous
Choroidopathy*



Index Case: P.S.



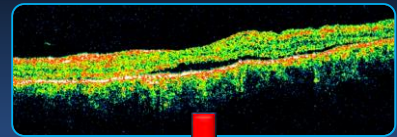
Impression:

- Central serous choroidopathy
- versus
- Tuberculous related maculopathy

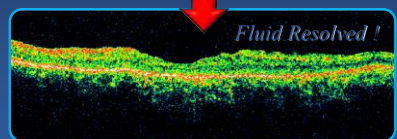
Index Case: P.S. ~ 1 mo later



OD
20/70
Pre-
Therapy



OD
20/80
1 mo Later





Index Case: P.S. ~ 1 mo later

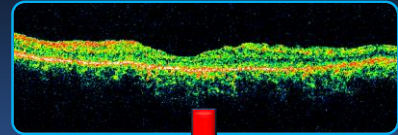


- Anti-tuberculosis therapy for **9 months**
- Vision stable
- No leakage/recurrent sub-retinal fluid - **OCT remains dry**
- *Therapy discontinued*

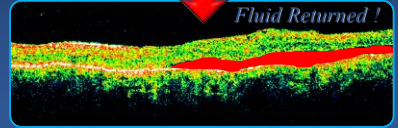


Index Case: P.S. ~ 2 mo later

OD
20/80
At end of TB therapy



OD
20/80
2 mo after stopping TB meds



Index Case: *Publication*

CHRONIC CENTRAL SEROUS CHORIORETINOPATHY RESPONSIVE TO RIFAMPIN

Zac B. Ravage, MD,¹ Kirk H. Packo, MD,² Catherine M. Creticos, MD,³ Pauline T. Merrill, MD⁴

Retinal Cases & Brief Reports Ahead of Print:1-4, 2011 

- **First Report** of Rifampin for central serous
- Single case report



Rifampin – The Down Side



- Headache
- Nausea
- Urine/fluids turns orange
- Back pain
- Allergy – rash (*2 patients stopped*)
- **Increases metabolism of some medications** (coumadin, Viagra)

Aldosterone Theory of Central Serous

Francine Behar-Cohen Paris.

Prednisone and other steroids can stimulate
Glucocorticoid receptor (RU486 blocks)
Aldosterone receptor (MR-mineralocorticoid)
Perhaps latter causes CSC

Rat

Intravitreal corticosterone-choroidal enlargement
Aldosterone-same
Upregulate endothelial vasodilatory K channel

Block this receptor
Oral eplerenone
Works in rat

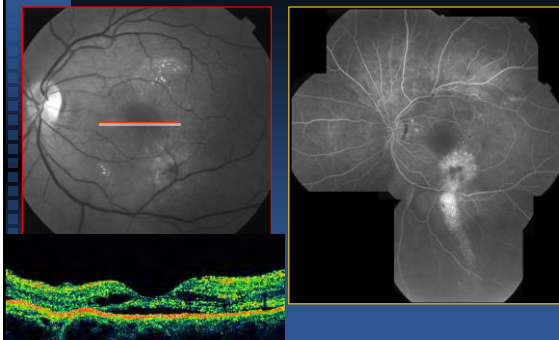
Human

2 drugs
-Eplerenone
-Spironolactone

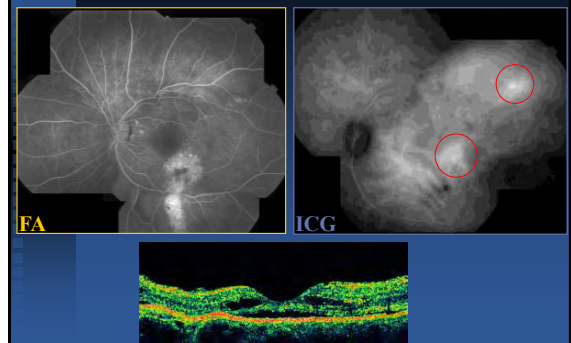
2 patients- benefit with eplerenone (?)
Randomized trial with spironolactone

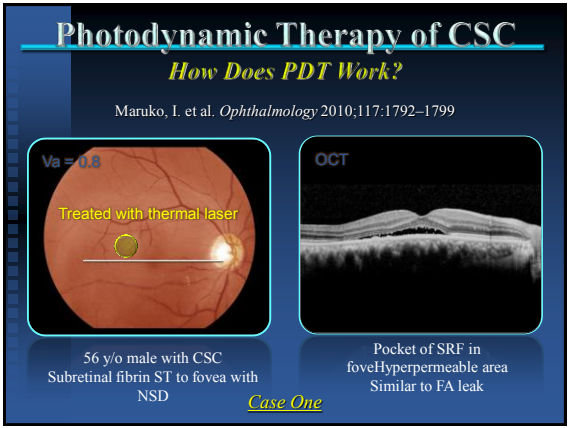
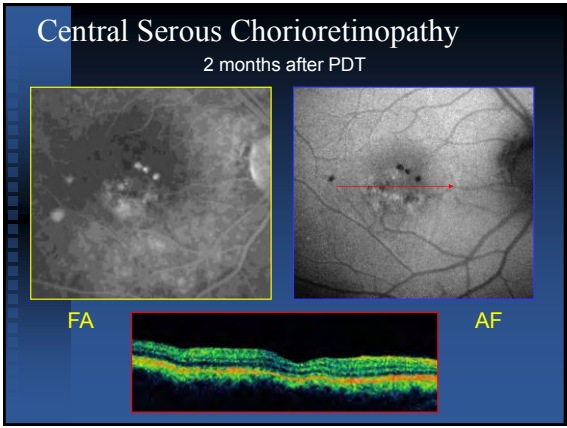
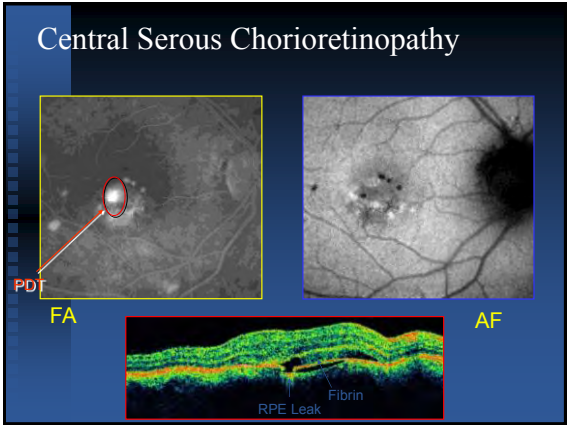
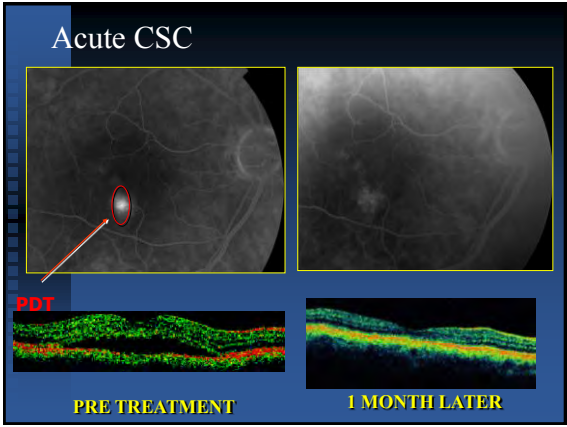
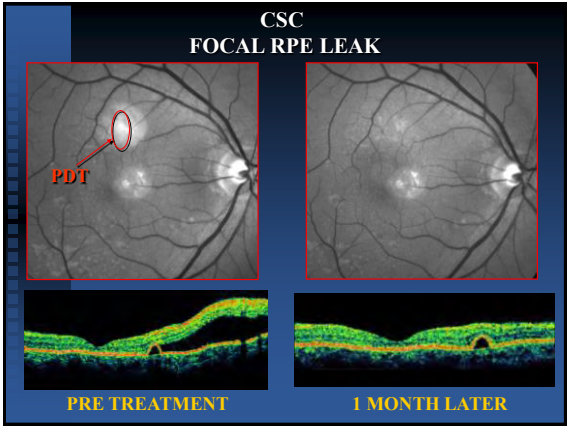
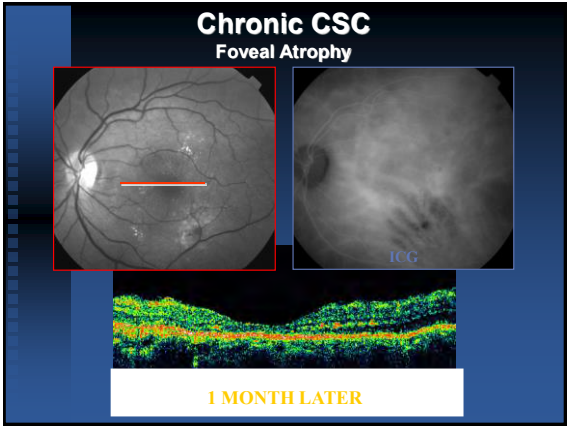
With these drugs, need to use with caution
in patients with renal disease. Can be problems
with elevated potassium.

Chronic CSC



Chronic CSC



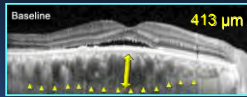


Photodynamic Therapy of CSC

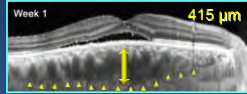
How Does PDT Work?

Maruko, I. et al. *Ophthalmology* 2010;117:1792-1799

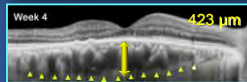
Pre-Laser
Enhanced depth OCT shows severely thickened choroid



Choroidal thickness unchanged with focal laser



4 Weeks Post-Laser
Choroidal thickness unchanged
- SRF resolved

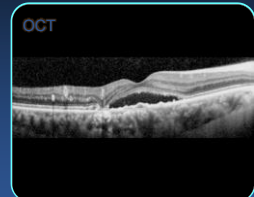
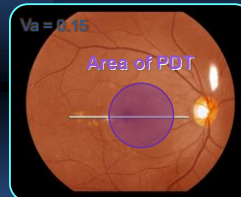


Case One

Photodynamic Therapy of CSC

How Does PDT Work?

Maruko, I. et al. *Ophthalmology* 2010;117:1792-1799



59 y/o male with CSC & NSD
Scar temporal to fovea from prior laser

Pocket of SRF in fovea, Irregular RPE, disruption of outer retina prior laser scar

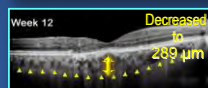
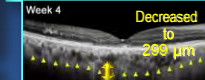
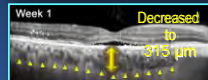
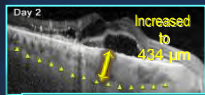
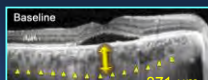
Case Two

Photodynamic Therapy of CSC

How Does PDT Work?

Maruko, I. et al. *Ophthalmology* 2010;117:1792-1799

PDT causes decreased choroidal thickness

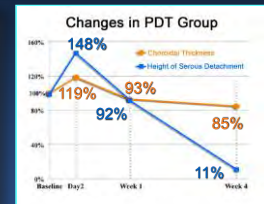
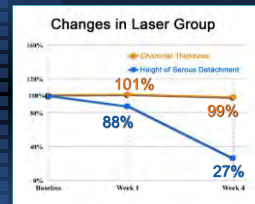


Case Two

Photodynamic Therapy of CSC

How Does PDT Work?

Maruko, I. et al. *Ophthalmology* 2010;117:1792-1799



- Steady decrease in SRF
- NO change in choroidal thickness

- Steady decrease in SRF
- Initial increase in choroidal thickness, then decrease with time



PDT is thus currently the top therapy for CSC but there are still problems:

- Even with modifications (reduced dose, time or fluence), it may still cause decreased sensitivity, fixation loss, increased SRF
- Leakage points may be too diffuse to allow treatment
- Insurance may not cover it, and patient can't afford the drug
- Thus, systemic therapy may be desirable

Warren E. Hill, MD

Dr. Hill has been the Medical Director of East Valley Ophthalmology in Mesa, Arizona for the past 27 years. He received his medical degree from the University of Arizona and his ophthalmology training at the University of Rochester, in Rochester, New York. He has devoted the majority of his professional activities to performing challenging anterior segment surgery for other ophthalmologists and the mathematics of intraocular lens power calculations. He has delivered more than 500 papers and 11 named lectureships to ophthalmic societies both in the United States and internationally in 34 countries and on six continents.

In 2007 Dr. Hill was appointed the Cataract and Anterior Segment Subspecialty Editor for the American Academy of Ophthalmology's Ophthalmic News and Education (O.N.E.) Network, a position he held until 2010. He has also received the American Academy of Ophthalmology's Achievement and Secretariat Awards.

Aside from the practice of ophthalmology, Dr. Hill enjoys flying his military airplane in air show close formation demonstrations and is licensed as a multi-engine commercial pilot.

Toric IOL Calculations

What you need to know

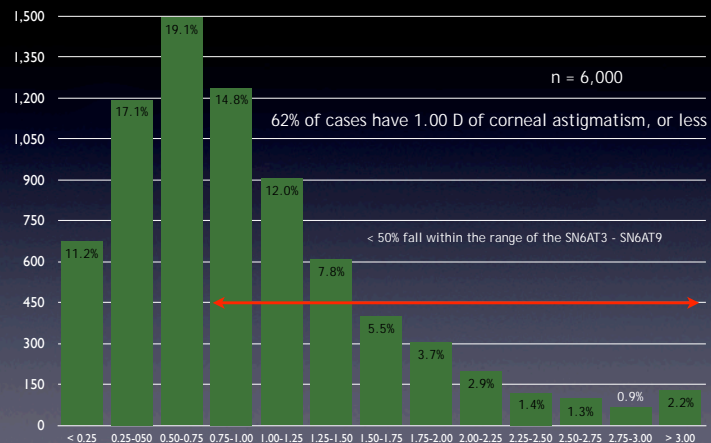
2013 Masters in Ophthalmology

Florida Society of Ophthalmology

June 29, 2013

Warren E. Hill, MD
East Valley Ophthalmology
Mesa, Arizona

Prevalence of Corneal Astigmatism Prior to Cataract Surgery



Astigmatic solutions

Why correct corneal astigmatism?

3 mm simulated pupil.
3 meter sign height.
25 meter viewing distance.



No astigmatism



0.50 D @ 090 degrees
Simulated Vision

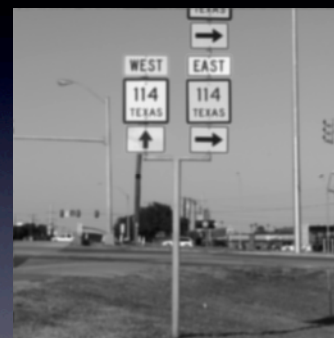
Astigmatic solutions

Why correct corneal astigmatism?

3 mm simulated pupil.
3 meter sign height.
25 meter viewing distance.



No astigmatism



1.00 D @ 090 degrees
Simulated Vision

Astigmatic solutions

Why correct corneal astigmatism?

3 mm simulated pupil.
3 meter sign height.
25 meter viewing distance.



No astigmatism



1.50 D @ 090 degrees
Simulated Vision

TOR124725K

20

Warren E. Hill, MD, FACS

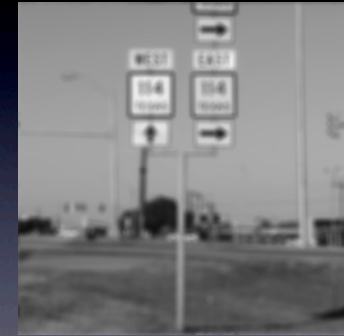
Astigmatic solutions

Why correct corneal astigmatism?

3 mm simulated pupil.
3 meter sign height.
25 meter viewing distance.



No astigmatism



2.00 D @ 090 degrees
Simulated Vision

TOR124725K

21

Warren E. Hill, MD, FACS

Astigmatic solutions

Why correct corneal astigmatism?

WARREN E. HILL, MD, FACS
DIPLOMATE, AMERICAN BOARD OF OPHTHALMOLOGY
5620 E. BROADWAY ROAD
MESA, ARIZONA 85206

EAST VALLEY OPHTHALMOLOGY, LTD. TELEPHONE: (480) 981-6111

NAME: John Smithfield DATE: 9/10/2012

ADDRESS: 123 Baseline Dr. Mesa, AZ AGE: 59

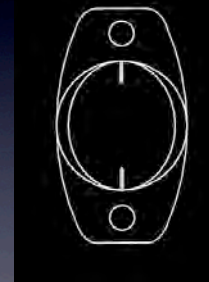
	Spherical	1st Ord Cyl & Axis	Trefoil & Axis	Coma & Axis	2nd Ord Cyl & Axis	Tetrafoil & Axis	Spherical Aberration	
Distance	OD	-1.25	+1.25 x 123	0.25 x 045	0.01 x 180	0.23 x 030	0.23 x 022	0.17
	OS	-1.25	+2.25 x 180	0.02 x 045	0.09 x 180	0.29 x 030	0.27 x 022	0.31
Reading	OD	+2.25	OPTICIAN PLUMMER NOTE: HIGHER ORDER ABERRATIONS ARE IN RMS MICRONS. BIFOCAL PROGRESSIVE TRIFOCAL EXECUTIVE					
	OS	+2.25						

Warren E. Hill, M.D.

Warren E. Hill, MD, FACS

Astigmatic solutions - historical perspective

Plate haptic silicone toric intraocular lens



First generation toric IOL

Challenges

- Limited cylindrical power selection.
- Only Ks used for determining toric IOL alignment.
- Problems with rotational instability.
- Older design, spherical optic.

Result

Inability to accurately predict the correct postoperative astigmatic alignment and consistently achieve the required cylindrical power.

8

Warren E. Hill, MD, FACS

Astigmatic solutions - historical perspective

Single piece acrylic toric intraocular lens



Single piece aspheric toric IOL

Improvements

Small step cylindrical power selection.

Sophisticated vector analysis companion software to refine toric IOL power and alignment.

Excellent rotational stability. The acrylic material quickly interacts with the posterior lens capsule.¹

Advanced design, aspheric optic.

Result

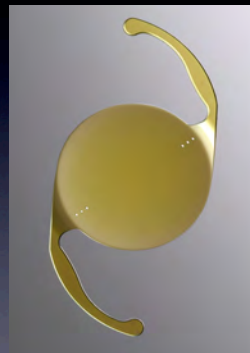
Compared to LRIs, and first generation toric IOLs, there is a greater ability to predict the correct post-operative astigmatic alignment and required toric power. The result is a more precise correction of post-operative corneal astigmatism.

1. Linnola RJ, Sund M, Ylänen R, Pihlajaniemi T. Adhesion of soluble fibronectin, laminin, and collagen type IV to intraocular lens materials. J Cataract Refract Surg. 1999;25:1486-1491.

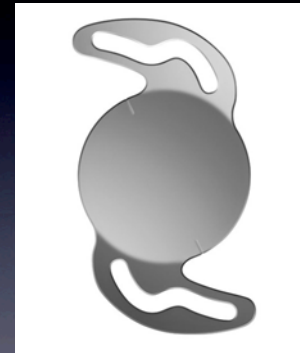
Warren E. Hill, MD, FACS

Toric IOL solutions

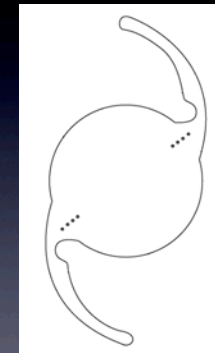
A variety of toric intraocular lens are available in Canada* and currently only one toric is available in the United States **



Alcon AcrySof toric **



Rayner T-flex toric *



AMO Tecnis toric *

Warren E. Hill, MD, FACS

Measuring pre-operative corneal astigmatism

What is the best way to go about this?

Step 1 - Determine the orientation of the steep and the flat meridians.

Step 2 - Measure the power difference between these two meridians.

Avoid the mindset that for the toric IOL you are "getting a set of Ks."

The corneal measurements for calculating the spherical power of the IOL and the measurements for the toric IOL may be obtained differently.

Warren E. Hill, MD, FACS

Steep meridian and astigmatism power

Getting it right

Multiple methods may be useful for confirmatory purposes, but resist the temptation to average multiple measurement methods.

Manual Ks ≠ Auto Ks ≠ Sim Ks ≠ Scheimpflug Ks ≠ Slit Scan Ks

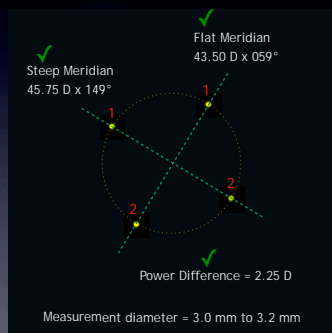
Different measurement areas, different algorithms, different methods.

Do not expect these measurements to always correspond.

Warren E. Hill, MD, FACS

Manual keratometry for the toric IOL

B&L style keratometer: variable image size, fixed object size



Manual Ophthalmometry / Keratometry

- Operator manually identifies principal meridians where measurements are taken at a total of 4 points.

Advantages

- Operator can take as much time as needed in order to carefully locate the principal meridians and determine the power at each.
- Calibration is not required for the determination of the power difference between meridians.

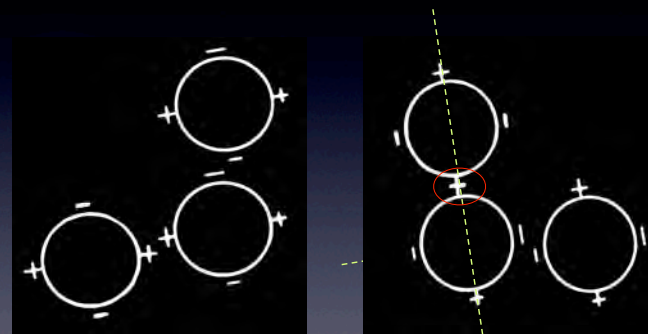
Disadvantages

- Highly operator dependent (low skill = poor outcomes).
- Exact meridian identification difficult for low astigmats.

Warren E. Hill, MD, FACS

Measuring pre-operative corneal astigmatism

What is the best way to go about this?

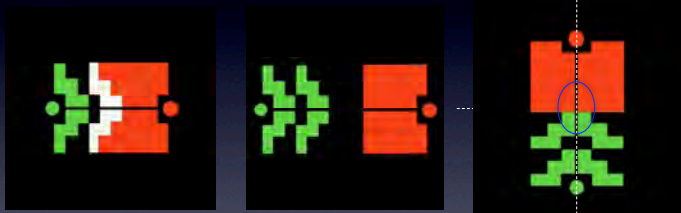


Step 12: Align meridian & power with horizontal (flat) & vertical (steep) meridian.

Warren E. Hill, MD, FACS

Measuring pre-operative corneal astigmatism

Javal-Schiötz ophthalmometry - an accurate and reliable form of manual keratometry



Power & axis values for the horizontal and vertical meridians are entered into the corresponding flat and steep fields of the toric calculator.

Haag-Streit OM 900[®]
Rodenstock C-MES[®]
Topcon OMTE-1[®]

Warren E. Hill, MD, FACS

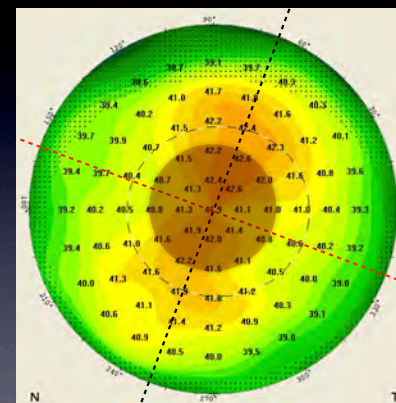
Measuring pre-operative corneal astigmatism

What is the best way to go about this?

Steep meridian = 067°

Flat meridian = 157°

Central 3.0 mm to 3.5 mm

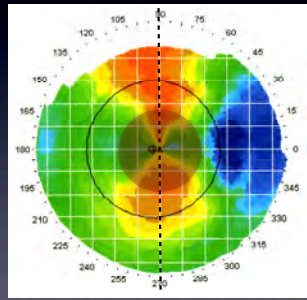
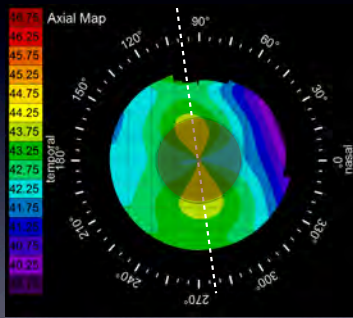


Low anterior corneal astigmatism

Warren E. Hill, MD, FACS

Ideal toric IOL candidates

Most effective for patients with regular astigmatism



Warren E. Hill, MD, FACS

Ideal toric IOL candidates

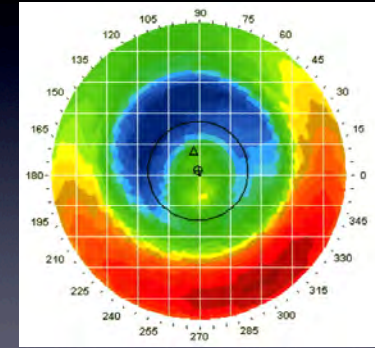
Most effective for patients with regular astigmatism

Avoid ...

- Keratoconus.
- Pellucid marginal degeneration.
- Prior radial keratotomy.
- Unusual corneas after LASIK & PRK.

Remember ...

- You are creating "pseudophakic lenticular astigmatism."
- If corneal astigmatism changes significantly in the future, contact lens correction may be difficult.



Warren E. Hill, MD, FACS

Low density autokeratometry for toric IOL

2.5 mm single zone autokeratometer

OD (right)		
K1: 46.42 D @ 57°	7.27 mm	
K2: 47.14 D @ 147°	7.16 mm	
$\Delta D: +0.72 D @ 147^\circ$		
K1: 46.42 D @ 53°	7.27 mm	
K2: 47.14 D @ 143°	7.16 mm	
$\Delta D: +0.72 D @ 143^\circ$		
K1: 46.42 D @ 42°	7.27 mm	
K2: 47.14 D @ 132°	7.16 mm	
$\Delta D: +0.72 D @ 132^\circ$		
n: 1.3375		

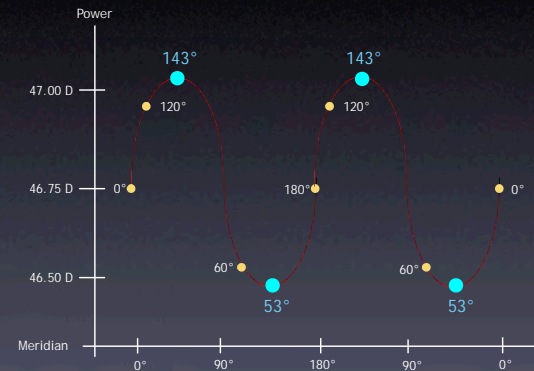


6 locations sampled over 360 degrees.
Measurement points separated by 60 degrees.
Widest spacing at 30°, 90° and 150°.
Intended to calculate the spherical power.

Warren E. Hill, MD, FACS

Low density autokeratometry for toric IOL

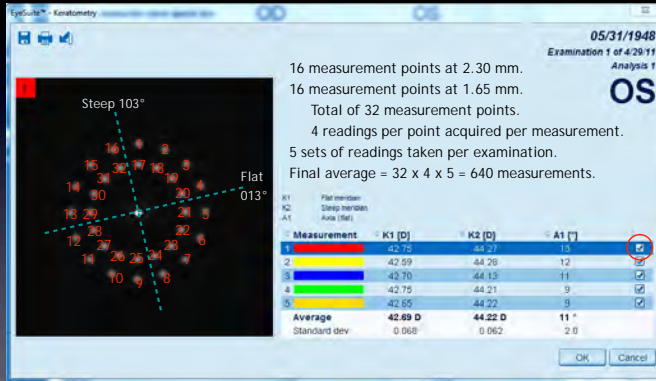
2.5 mm single zone autokeratometer



Warren E. Hill, MD, FACS

High density autokeratometry for toric IOL

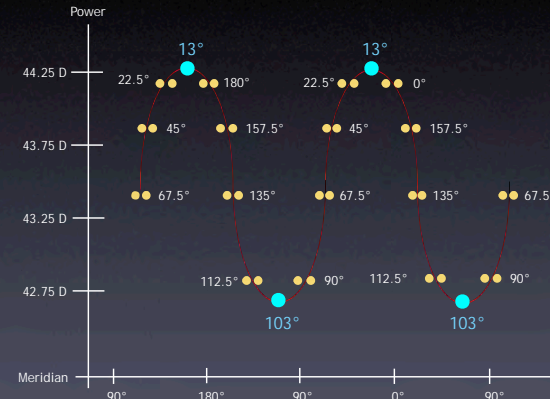
1.65 mm and 2.3 mm dual zone autokeratometer



Warren E. Hill, MD, FACS

High density autokeratometry for toric IOL

1.65 mm and 2.3 mm dual zone autokeratometer



Warren E. Hill, MD

Real World Example

Warren E. Hill, MD, FACS

High density vs. low density autokeratometry

The numbers are the same... aren't they?

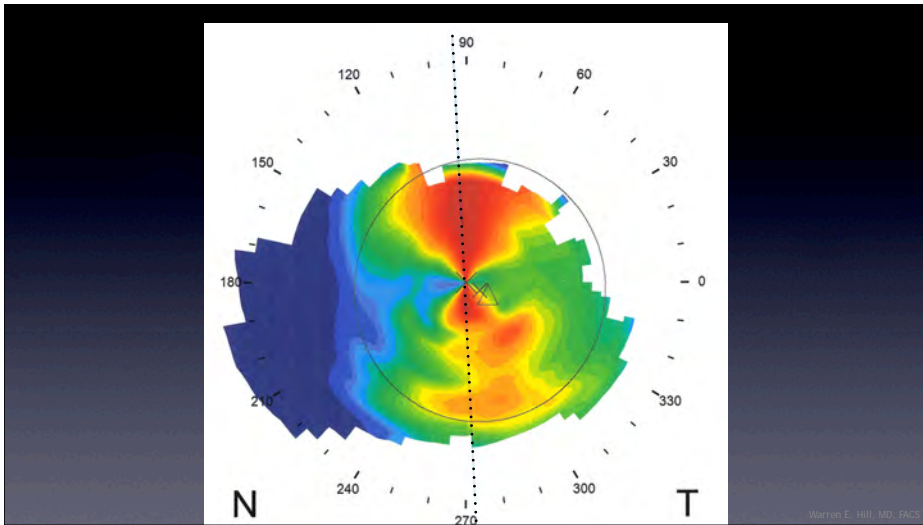
Avg: 40.86/44.06 D	
K1: 40.81 D @ 15°	
K2: 43.89 D @ 105°	
ΔD: +3.08 D @ 105°	
K1: 40.81 D @ 18°	
K2: 44.18 D @ 108°	
ΔD: +3.37 D @ 108°	
K1: 40.91 D @ 16°	
K2: 44.18 D @ 106°	
ΔD: +3.27 D @ 106°	

Low density 2.5 mm autokeratometry

40.92 D @ 3°	±0.123 D
44.46 D @ 93°	±0.128 D
3.54 D @ 93°	±1.9°
1.3375	

High density 1.65 mm and 2.30 mm autokeratometry

Warren E. Hill, MD, FACS

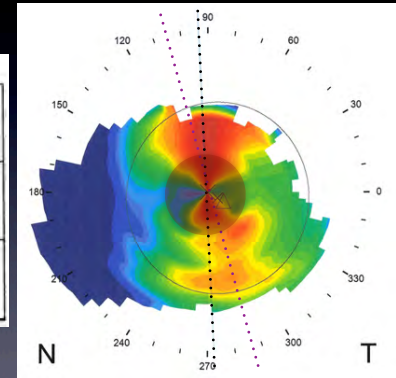


High density vs. low density autokeratometry

The numbers are the same... aren't they?

Avg: 40.86/44.06 D	
K1: 40.81 D @ 15°	
K2: 43.89 D @ 105°	
ΔD: +3.08 D @ 105°	
K1: 40.81 D @ 18°	
K2: 44.18 D @ 108°	
ΔD: +3.37 D @ 108°	
K1: 40.91 D @ 16°	
K2: 44.18 D @ 106°	
ΔD: +3.27 D @ 106°	

Low density autokeratometry

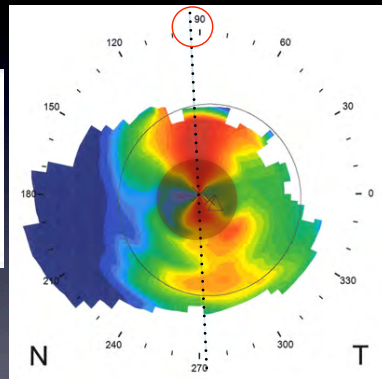


High density vs. low density autokeratometry

The numbers are the same... aren't they?

40.92 D @ 3°	±0.123 D
44.46 D @ 93°	±0.128 D
3.54 D @ 93°	±1.9°
1.3375	

High density autokeratometry



High density vs. low density autokeratometry

The numbers are the same... aren't they?

Lens Recommendation		Lens Recommendation	
<p>OS (Left)</p>		<p>OS (Left)</p>	
<p>AcrySof IQ Toric IOL: SNGAT6</p> <p>IOL Spherical Equivalent (SE): 21.5 D</p> <p>Axis of Placement: 106°</p> <p>Cylinder Power (IOL Plane): 3.75 D</p> <p>Cylinder Power (Corneal Plane): 2.57 D</p>		<p>AcrySof IQ Toric IOL: SNGAT7</p> <p>IOL Spherical Equivalent (SE): 21.5 D</p> <p>Axis of Placement: 90°</p> <p>Cylinder Power (IOL Plane): 4.50 D</p> <p>Cylinder Power (Corneal Plane): 3.08 D</p>	
<p>Calculation Details</p> <p>Pre-Op Corneal Astigmatism: 3.27 D x 106°</p> <p>Surgeonically Induced Astigmatism: 0.55 D x 15°</p> <p>Crossed-Cylinder Result (corneal plane): 3.72 D x 164°</p> <p>Anticipated Residual Astigmatism: 0.15 D x 164°</p>		<p>Calculation Details</p> <p>Pre-Op Corneal Astigmatism: 3.54 D x 93°</p> <p>Surgeonically Induced Astigmatism: 0.55 D x 15°</p> <p>Crossed-Cylinder Result (corneal plane): 3.09 D x 99°</p> <p>Anticipated Residual Astigmatism: 0.61 D x 99°</p>	
<p>Patient Data</p> <p>Flat K: 40.81 D</p> <p>θ Flat Axis: 18°</p> <p>Steep K: 44.18 D</p> <p>θ Steep Axis: 108°</p> <p>IOL Spherical Power (P-IOL): 21.5 D</p> <p>Surgeonically Induced Astigmatism (SIA): 0.55 D</p> <p>Incision Location (IL): 106°</p>		<p>Patient Data</p> <p>Flat K: 40.92 D</p> <p>θ Flat Axis: 3°</p> <p>Steep K: 44.46 D</p> <p>θ Steep Axis: 93°</p> <p>IOL Spherical Power (P-IOL): 21.5 D</p> <p>Surgeonically Induced Astigmatism (SIA): 0.55 D</p> <p>Incision Location (IL): 109°</p>	

Low density autokeratometry

High density autokeratometry

High density vs. low density autokeratometry

The numbers are the same... aren't they?

High density Ks SN6AT7

Post-op Day #1 MR = -0.25 +0.25 x 090

Low density Ks SN6AT6

Angular Error $16^\circ \times 3.3\% \times 3.08 \text{ D} = 1.63 \text{ D}$

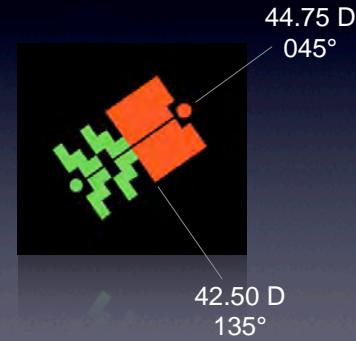
Toric IOL Power Error $0.75 \text{ D} \times 0.70 = 0.53 \text{ D}$

Predicted Astigmatism Under-correction $1.63 \text{ D} + 0.53 \text{ D} = 2.16 \text{ D}$

Warren E. Hill, MD, FACS

Impact of surgically induced astigmatism

A change in the magnitude and direction of pre-operative corneal astigmatism



The other accuracy problem

Q: Why is it that the astigmatic power correction and location of the steep meridian are often different than expected following toric IOL implantation?

A: We have not been taking into account a second important influencing factor.

Warren E. Hill, MD, FACS

Impact of surgically induced astigmatism

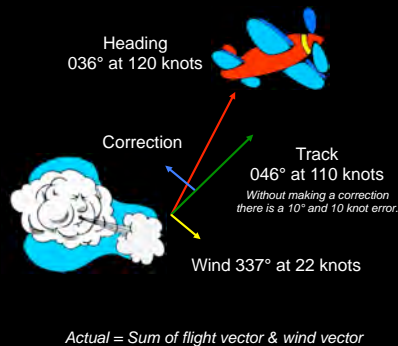
Corneal astigmatism is a vector quantity

Small airplane flying to Gotham City
120 knots to the Northeast (036°)

Wind
22 knots out of the Northwest (337°)

No wind 120 knots at 036°
With wind 110 knots at 046°

The sum of the two vectors results in the need for a change in direction combined with an increase in power to maintain same direction & speed.



Warren E. Hill, MD, FACS

Effect of surgically induced astigmatism

Calculating the new meridian and power of post-op corneal astigmatism

Pre-op keratometry

Steep K 44.75 x 135°
Flat K 43.25 x 045°

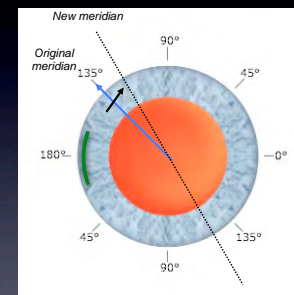
Incision

2.4 mm @ 180°

Post-op keratometry

Steep K 44.75 x 123°
Flat K 43.25 x 033°

Meridian shift = 12°
Arithmetic power change = 0.0 D
Corneal vector power change = 0.62 D
Capsular bag vector power change = 0.92 D



Right Eye

Warren E. Hill, MD, FACS

Effect of surgically induced astigmatism

Calculating the new meridian and power of post-op corneal astigmatism

Pre-op keratometry

Steep K 44.75 x 135°
Flat K 43.25 x 045°

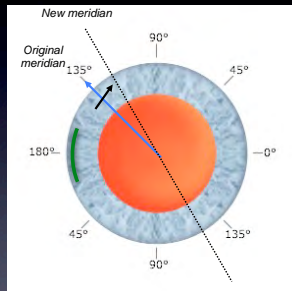
Incision

2.4 mm @ 180°

Post-op keratometry

Steep K 44.25 x 123°
Flat K 43.50 x 033°

Meridian shift = 12°
Arithmetic power change = 0.50 D
Corneal vector power change = 0.87 D
Capsular bag vector power change = 1.28 D



Right Eye

Warren E. Hill, MD, FACS

Effect of surgically induced astigmatism

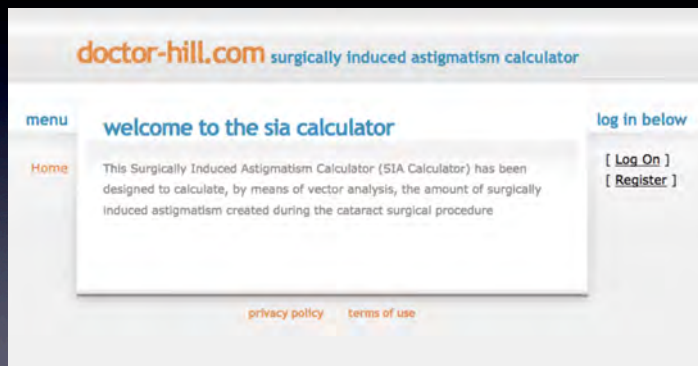
Newest generation on-line toric SIA calculator

www.SIA-calculator.com

Warren E. Hill, MD, FACS

www.SIA-calculator.com

Newest generation surgically induced astigmatism calculator



Impact of surgically induced astigmatism

Why are my results not consistent from one patient to another?

Items that influence surgically induced astigmatism

Location (*superior > temporal*)

Incision architecture (*3-plane vs. 2-plane vs. single plane*)

Corneal radius (*smaller > larger*)

Corneal thickness (*thinner > thicker*)

Corneal rigidity (*less rigid > more rigid*)

Folded diameter of IOL passing through the incision. (*incision stretching*)

Variations in all of the above.

It should not be expected that the amount of surgically induced astigmatism will be exactly the same for all patients.

Warren E. Hill, MD, FACS

Effect of surgically induced astigmatism

First version of the AcrySof® Toric IOL calculator - 2002



Warren E. Hill, MD, FACS

Effect of surgically induced astigmatism

First version of the AcrySof® Toric IOL calculator - 2002

PreOp K Cyl: 1.25 @ 105°

K1:	44.50	A1:	105	1	2	3
K2:	43.25	A2:	15	4	5	6
SurgCyl:	0.50	7	8	9		
PhacoAxis:	temporal	B	0	.		
IOL:	20.50	CALC	clr			

21.0 + 2.25 X 101

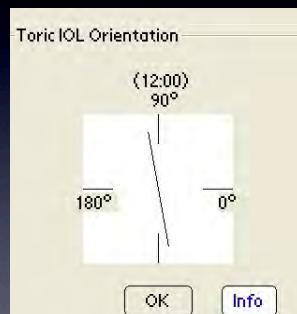
> use Alcon SA60T4 <

See Graphic Details

Warren E. Hill, MD, FACS

Effect of surgically induced astigmatism

First version of the AcrySof® Toric IOL calculator - 2002



Warren E. Hill, MD, FACS

ACRYSOFT TORIC ASTIGMATISM IOL Alcon CE

Please enter the pre-op information for the patient.

Surgeon Name	Dr. Smith	Patient Information
Patient Name	Mr. Jones	
Additional Patient Information (I.D., Case, etc.)	#1223	
Eye Selection	<input type="radio"/> OD (Right) <input checked="" type="radio"/> OS (Left)	<p>Manual or Lenstar Keratometry (K₁ & meridian and K₂ & meridian)</p>
K Notation	<input checked="" type="radio"/> Diopter <input type="radio"/> Millimeter	
Flat K	41.6 35.00D ~ 50.00D	
@ Flat Axis	120 0° ~ 180°	
Steep K	43.8 35.00D ~ 50.00D	IOL Spherical Power
@ Steep Axis	30 0° ~ 180°	
IOL Spherical Power (P-IOL)	21.0 D 6.0 D ~ 30.0 D	
Surgically Induced Astigmatism (SIA)	0.5 0.00D ~ 2.00D	Surgically Induced Astigmatism and Incision Location
Incision Location (IL)	0 0° ~ 360°	
Continue		

V: 3.2.0

Tutorial | Help | Country | Privacy Policy & Legal Terms

Surgeon & Patient Information

Surgeon Name: Dr. Smith
 Patient Name: Mr. Jones
 Additional Patient Information (I.D., Case, etc.): #1333

Lens Details

AcrySof® IQ Toric IOL: SN6AT4
 IOL Spherical Equivalent (SE): 21.0 D
 Axis of Placement: 36°
 Cylinder Power (IOL Plane): 2.25 D
 Cylinder Power (Corneal Plane): 1.55 D

Calculation Details

Pre-Op Corneal Astigmatism: 2.20 D X 36°
 Surgically Induced Astigmatism: 0.50 D X 90°
 Crossed-Cylinder Result (Corneal plane): 2.00 D X 36°
 Anticipated Residual Astigmatism: 0.45 D X 36°

Pre-Op Information

Patient Data: Flat K: 41.60 D, D Flat Axis: 120°, Steep K: 43.80 D, D Steep Axis: 30°, IOL Spherical Power (P-IOL): 21.0 D, Surgically Induced Astigmatism (SIA): 0.50 D, Incision Location (IL): 9°

Notes:

42

Warren E. Hill, MD, FACS

Surgeon: Hill, Warren (Lenstar) PreOp Exam date: 06/21/2011 **OS**

Ref: -0.75 +0.00 X 0 VTX: 12.50 Target Rx: -0.75
 BCVA: 20/25 UCVA: 20/30 Target Axis: 0.00
 K1: 41.99 @ 6 HWTW: 12.80 mm Avg. K: 43.37 rc: 1.3375
 K2: 44.75 @ 96 ACD: 3.01 mm Adj. K: 43.37
 AL (Optical): 24.83 mm Lens Thick: 5.23 mm Adj. AL:

Formula: Holladay II

Alcon SN6ATx Procedure: Std Phaco SRG Endd ACD(Opt): 5.63
 IOL Ref. IOL Ref.
 17.50 -0.12 17.50 -0.19
 18.00 -0.44 18.00 -0.52
 18.46 -0.75 18.46 -0.75
 18.50 -0.77 18.50 -0.85
 19.00 -1.11 19.00 -1.19

Alcon SN609P Procedure: Std Phaco SRG Endd ACD(Opt): 5.56
 IOL Ref. IOL Ref.
 17.50 -0.12 17.50 -0.19
 18.00 -0.44 18.00 -0.52
 18.46 -0.75 18.46 -0.75
 18.50 -0.85 18.50 -0.85
 19.00 -1.19 19.00 -1.19

Staar CQ-2015 Procedure: Std Phaco SRG Endd ACD(Opt): 5.23
 IOL Ref. IOL Ref.
 17.00 -0.23 17.50 -0.10
 17.50 -0.57 18.00 -0.43
 17.76 -0.75 18.48 -0.75
 18.00 -0.92 18.50 -0.76
 18.50 -1.27 19.00 -1.09

Alcon MA50BM Procedure: Std Phaco SRG Endd ACD(Opt): 5.64
 IOL Ref. IOL Ref.
 17.50 -0.12 17.50 -0.10
 18.00 -0.43 18.00 -0.43
 18.48 -0.75 18.48 -0.75
 18.50 -0.76 18.50 -0.76
 19.00 -1.09 19.00 -1.09

Notes:

The probability of the HWTW occurring in the population is < 2.3%.
 Probability for the AXIAL LENGTH binocular difference occurring in the population is < 0.1%.
 Probability for this LT binocular difference occurring in the population is < 3.5%.

Print <- PreOp. Toric Calc. Surgery ->

43

Warren E. Hill, MD, FACS

Surgeon: Hill, Warren (Lenstar) PreOp Date: 06/21/2011 **OS**

Ref: -0.75 +0.00 X 0 VTX: 12.50 Target Rx: -0.75
 BCVA: 20/25 UCVA: 20/30 Target Axis: 0.00
 K1: 41.99 @ 6 Steep K: 44.75 @ 96 rc: 1.3375
 Avg. K: 43.37 Adj. K: 43.37

Surgically Induced Astigmatism: 0.42 D
 Incision Location: 0°

Toric Lens from Active Lens List: SN6ATx (Std Phaco)

Formula: Holladay II

Alcon SN6ATx Procedure: Std Phaco SRG Endd ACD(Opt): 5.63
 IOL Ref. IOL Ref.
 17.50 -0.12 17.50 -0.19
 18.00 -0.44 18.00 -0.52
 18.46 -0.75 18.46 -0.75
 18.50 -0.77 18.50 -0.85
 19.00 -1.11 19.00 -1.19

Res. Astom.

SN6AT7 +2.51 D x 85°
 SN6AT3 +2.17 D x 95°
 SN6AT4 +1.67 D x 95°
 SN6AT5 +1.17 D x 95°
 SN6AT6 +0.67 D x 95°
 SN6AT7 +0.17 D x 95°
 SN6AT8 +0.31 D x 5°
 SN6AT9 +0.83 D x 5°

IOL Placement Axis: 95°
 IOL Ideal Toricity: 4.800 @ IOL
 Residual Ref.: -0.86 +0.17 D x 95°

Incision @ 0° IOL @ 95°

44

Warren E. Hill, MD, FACS

Toric Incision Optimizer

Residual Astigmatism

LEFT EYE:
 0° & 360° = Temporal
 180° = Nasal

Incision at:
 0°
 120°
 252°
 300°

OK Cancel

45

Warren E. Hill, MD, FACS

Surgeon: Hill, Warren (Lenstar) PreOp Date: 06/21/2011 OS

Ref: -0.75 +0.00 X 0 VTX: 12.50 Target Rx: -0.75
 BCVA: 20/25 UCVA: 20/30 Adj. At: _____
 Flat K: 41.99 @ 6 Steep K: 44.75 @ 96 m: 1.3375
 Avg. K: 43.37 Adj. K: 43.37

Surgically Induced Astigmatism: 0.42 D

Incision Location: 72° Optimize...

Toric Lens from Active Lens List: SMIATx (Std Phaco)

Formula: Holladay II

Alcon SMIATx Procedure: Std Phaco
 SRIG Entrod ACD(Std): 5.63

IOL	Ball
17.50	-0.12
18.00	-0.44
18.46	-0.75
18.50	-0.77
19.00	-1.11

Incision @ 72° IOL @ 100°

IOL Placement Axis: 100°
 IOL Ideal Toricity: 3.78D @ 10L
 Residual Ref.: -0.77 +0.00 D x 100°

Surgeon Positioned at Patient's Head

Warren E. Hill, MD, FACS

Baylor toric nomogram

Douglas Koch, MD

- Assume the following posterior corneal astigmatism:
 WTR corneas = 0.50 D
 ATR corneas = 0.30 D
- Measure posterior corneal astigmatism when feasible.
- Target 0.25 D to 0.50 D of post-op WTR astigmatism.
 This anticipates an ATR astigmatism shift with increasing age.
- Use the Holladay 2 formula for spherical power calculation.

Warren E. Hill, MD, FACS

Baylor toric
Douglas Koch

Baylor Toric IOL Nomogram

WTR Astigmatism
(Target range 0.25 - 0.50 D WTR)

Astigmatism (D)	Toric IOL
≤ 1.69	0 (PCRI if >1.00)
1.70 - 2.19	T3
2.20 - 2.69	T4
2.70 - 3.19	T5

0.7 D shift: UP

CULLEN EYE INSTITUTE BCM Baylor College of Medicine

Warren E. Hill, MD, FACS

Baylor toric
Douglas Koch

Baylor Toric IOL Nomogram

ATR Astigmatism
(Target range 0.25 - 0.50 D WTR)

Astigmatism (D)	Toric IOL
≤ 0.39	0
0.40* - 0.79	T3
0.80 - 1.29	T4
1.30 - 1.79	T5

*Especially if specs have more ATR

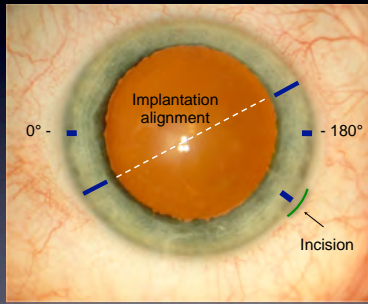
0.7 D shift: DOWN

CULLEN EYE INSTITUTE BCM Baylor College of Medicine

Warren E. Hill, MD, FACS

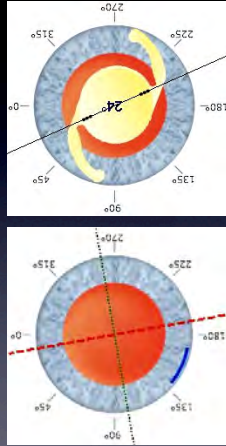
Astigmatic solutions

Patient marking technique



Reference marks, implantation & incision.

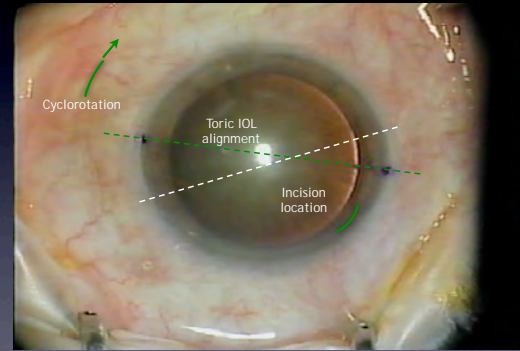
Take care to avoid position-associated cyclorotation



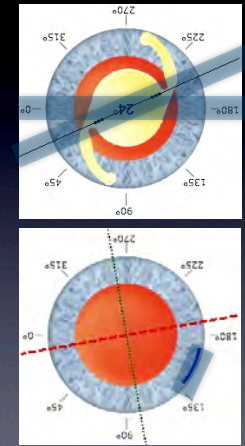
Warren E. Hill, MD, FACS

Astigmatic solutions

Patient marking technique



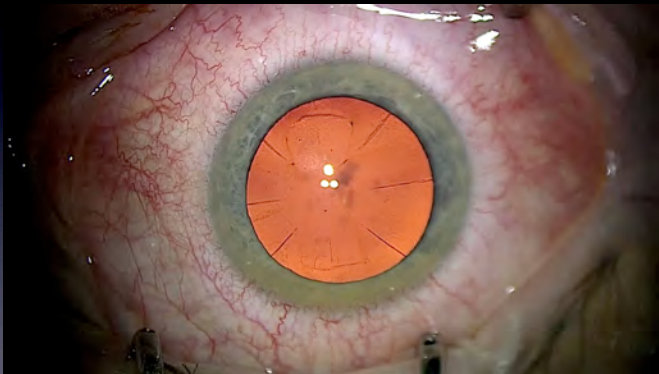
Inverted copy of toric calculator print-out showing implantation & incision locations.



Warren E. Hill, MD, FACS

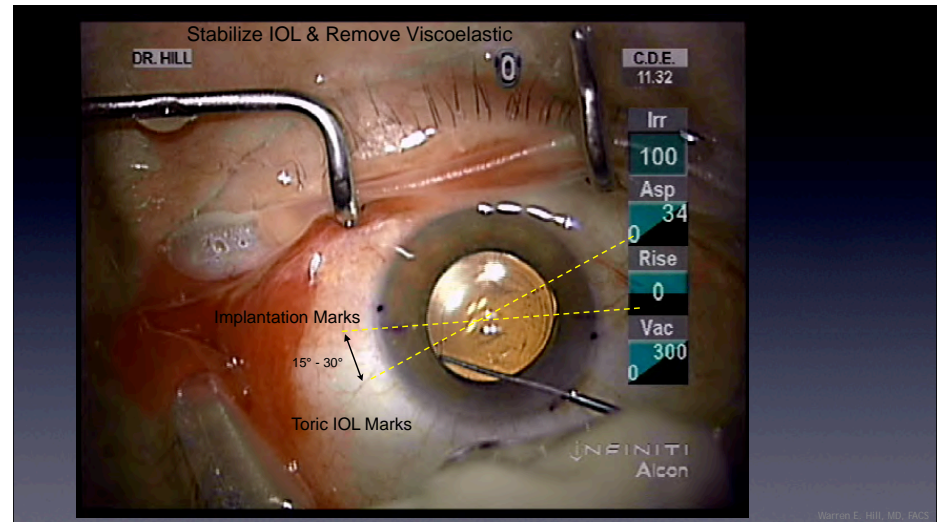
The capsulorrhexis

Defining portion of cataract surgery for accurate refractive outcomes

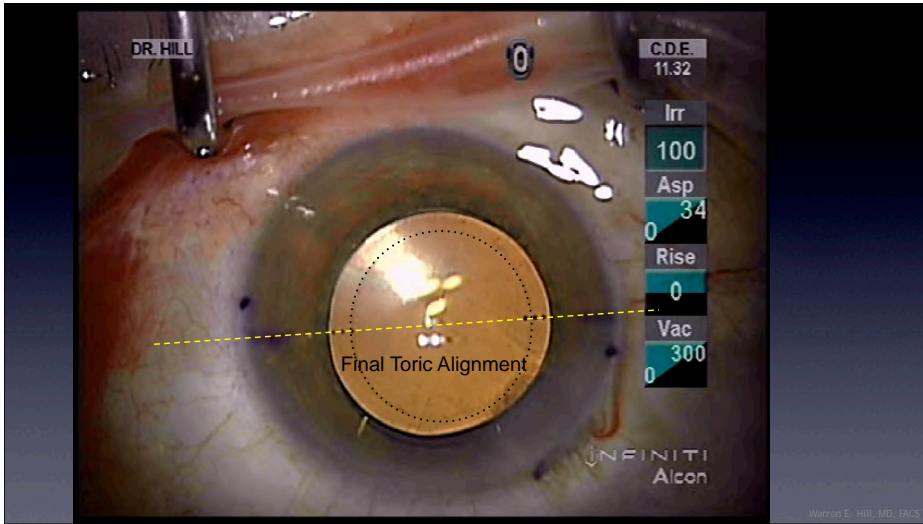


Mastel Precision 5.75 mm capsulorrhexis marker for 5.25 mm rhexis.

Warren E. Hill, MD, FACS

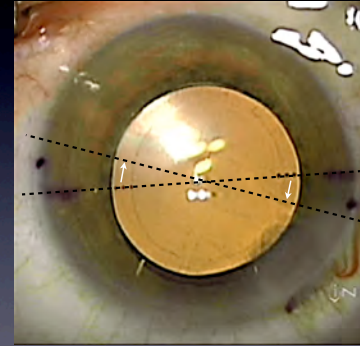


Warren E. Hill, MD, FACS



IOL aligned on the wrong meridian?

On-line reverse vector solution calculator



Calculated steep meridian = 015°
 T6 Toric IOL placement = 015°
 Post-op MR = -0.75 + 1.75 x 140 !!!
 Reverse vector solution...
 Rotate the toric to 175°
 New MR will be -0.13 + 0.01 x 040
 How do I calculate this?

Warren E. Hill, MD, FACS

Warren E. Hill, MD, FACS

IOL aligned on the wrong meridian?

On-line reverse vector solution calculator

- On line resource, provided free of charge
- Created by John Berdahl, MD and David Hardten, MD
- Designed to determine if a previously placed Toric IOL is ideally aligned.

www.astigmatismfix.com

Warren E. Hill, MD, FACS



Summary: Toric IOLs

Best practices

- ✓ Topography to confirm *regular astigmatism*.
- ✓ Optical biometry AL & Ks for *spherical IOL power*.
- ✓ Independently determine the *power difference between meridians*.
- ✓ Independently determine the *steep meridian*.
- ✓ Ideally, use a higher measurement density keratometer.
- ✓ Calculate your surgically induced astigmatism.
- ✓ Include posterior corneal astigmatism in toric planning.

Warren E. Hill, MD, FACS



Warren E. Hill, MD

Dr. Hill has been the Medical Director of East Valley Ophthalmology in Mesa, Arizona for the past 27 years. He received his medical degree from the University of Arizona and his ophthalmology training at the University of Rochester, in Rochester, New York. He has devoted the majority of his professional activities to performing challenging anterior segment surgery for other ophthalmologists and the mathematics of intraocular lens power calculations. He has delivered more than 500 papers and 11 named lectureships to ophthalmic societies both in the United States and internationally in 34 countries and on six continents.

In 2007 Dr. Hill was appointed the Cataract and Anterior Segment Subspecialty Editor for the American Academy of Ophthalmology's Ophthalmic News and Education (O.N.E.) Network, a position he held until 2010. He has also received the American Academy of Ophthalmology's Achievement and Secretariat Awards.

Aside from the practice of ophthalmology, Dr. Hill enjoys flying his military airplane in air show close formation demonstrations and is licensed as a multi-engine commercial pilot.

What Went Wrong?

Biometry & IOL Selection Misadventures

2013 Masters in Ophthalmology

Florida Society of Ophthalmology

June 29, 2013

Warren E. Hill, MD
East Valley Ophthalmology
Mesa, Arizona

Disclosure statement

Warren E. Hill, MD

The author has no proprietary interest in any products, or methods mentioned in this presentation.
Current industry relationships are with:

Alcon Laboratories
Consultant, Speaker, Research

Bausch & Lomb
Consultant, Research

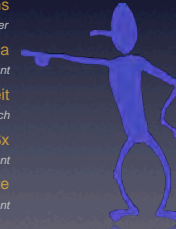
Clarity Medical Systems
Consultant, Stockholder

Elezena
Consultant

Haag-Streit
Consultant, Speaker, Research

LenSx
Consultant

Oculus Optikgeräte
Consultant



*"It ain't what you don't know that gets you into trouble;
it's what you know for sure that just ain't so."*

- Mark Twain

Warren E. Hill, MD, FACS

Biometry & IOL selection misadventures

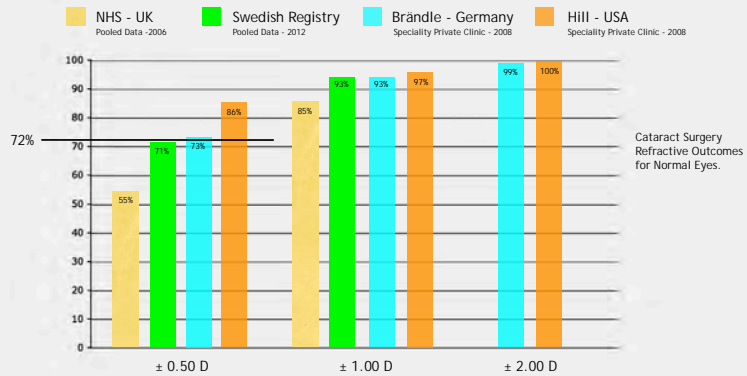
Real world results.

History: Normal axial length, normal Ks.

Procedures: Optical biometry with IOLMaster.
Standard phacoemulsification.
+21.0 D SN60WF IOL.

Outcome: -1.00 +0.25 x 180
Measurements repeated, the same!
Why are my outcomes not better?

Warren E. Hill, MD, FACS



Behndig et al. Aiming for emmetropia after cataract surgery. Swedish National Cataract Register study. J Cataract Refract Surg 2012; 38: 1181-1186.
 Proposed benchmark for normal eyes: Gale RP, et al. Benchmark standards for refractive outcomes after NHS cataract surgery. Presented at the Royal College of Ophthalmologists Congress, 2006. Eye Advance: 08/24/07.
 Brändle J. in Haigis W: IOL calculation in long and short eyes. In Mastering the technique of IOL power calculations. Garg A, Hoyos JE, Dementiev D (eds) Jaypee Brothers Medical Publishers (P) Ltd., New Delhi, pp. 75-5, 2005.

Achieving optimal refractive outcomes

> 1 % of surgical practices of 1,021 Haigis formula optimization databases (>200,000 cases)

Refraction Analysis						
	Mean Rx error	Mean Abs Rx Err	St. Dev Rx Err	Max Ref error	% +/- 0.5 D	% +/- 1.0 D
SRK/T	0.00	0.25	0.31	0.85	91.1%	100.0%
Hoffer Q	0.00	0.27	0.34	0.98	85.3%	100.0%
Holladay 1	0.00	0.24	0.29	0.76	91.1%	100.0%
Haigis	-0.01	0.23	0.29	0.87	90.2%	100.0%
SRK-II	-0.01	0.45	0.62	3.00	67.4%	92.0%

Achieving optimal refractive outcomes

6% of surgical practices of 1,021 Haigis formula optimization databases (>200,000 cases)

Refraction Analysis						
	Mean Rx error	Mean Abs Rx Err	St. Dev Rx Err	Max Ref error	% +/- 0.5 D	% +/- 1.0 D
SRK/T	0.00	0.29	0.37	1.39	83.4%	99.3%
Hoffer Q	0.00	0.28	0.35	0.99	84.1%	100.0%
Holladay 1	0.00	0.27	0.33	1.01	85.5%	99.6%
Haigis	0.00	0.26	0.33	1.00	88.0%	99.6%
SRK-II	0.00	0.44	0.57	2.33	66.4%	92.6%

Achieving optimal refractive outcomes

The overwhelming majority of surgical practices are around this level of accuracy

Refraction Analysis						
	Mean Rx error	Mean Abs Rx Err	St. Dev Rx Err	Max Ref error	% +/- 0.5 D	% +/- 1.0 D
SRK/T	0.00	0.32	0.41	1.25	78.2%	97.8%
Hoffer Q	0.00	0.36	0.46	1.76	74.2%	97.3%
Holladay 1	0.00	0.32	0.41	1.20	78.7%	99.6%
Haigis	0.00	0.32	0.41	1.39	77.8%	97.8%
SRK-II	0.00	0.50	0.66	2.22	59.1%	89.8%

Historical perspective

Refractive accuracy doubles every five to ten years.

Era	Accuracy Limit	Accepted IOL Power Calculation Standard	Advanced Technology Basis For Each Era
1967	N/A	Fyodorov & Kolinko	Axial length & ACD based on schematic eyes.
1972	± 5.00 D	18.00 D + (1.25 x Ref)	IOL formulas still not widely used.
1974	± 3.00 D	Colenbrander & Hoffer	Ultrasound-based IOL calculations.
1975	± 3.00 D	Binkhorst	Further refinement of 1st generation formulas.
1980	± 2.00 D	SRK & Lloyd	Regression equations (AL, Ks & outcomes).
1986	± 1.00 D	Hoffer & SRK 2	Applanation A-scan & 2-variable formulas.
1996	± 0.50 D	H1, SRK/T & Hoffer Q	Immersion A-scan & 3 rd generation formulas.
2005	± 0.37 D	Haigis & Holladay 2	IOLMaster [®] , & 4 th & 5 th generation formulas.
2009	± 0.25 D	Olsen & Improved RT	Lenstar LS900 [®] & 6 th generation methodologies.
2014	± 0.18 D	NN, RBF & other methods	Engineering-based statistical models.

Warren E. Hill, MD, FACS

Biometry & IOL selection misadventures

Real world results.

Mean Absolute Error	Calculation Component
Δa	Biometry
Δb	Keratometry
Δc	Configuration of the rhexis
Δd	IOL power formula (ELP _o)
Δe	Retinal thickness around fovea
Δf	IOL manufacturing tolerance

For a series of patients ...

$$\text{Absolute Error} = \sqrt{(\Delta a)^2 + (\Delta b)^2 + (\Delta c)^2 + (\Delta d)^2 \dots (\Delta n)^2}$$

Warren E. Hill, MD, FACS

Biometry & IOL selection misadventures

Q: What are the differences between theoretical formulas? A: Estimation of the ELP.

Axial Length Vergence Formula

$$IOL_e = \frac{1336}{AL_o - ELP_o} - \frac{1336}{\frac{1336}{\frac{1000}{1000 + K_o} - V} - ELP_o}$$

↑
Each theoretical formula estimates the ELP_o differently.

Warren E. Hill, MD, FACS

Achieving optimal refractive outcomes

What happened?

History: Axial myope of 34.25 mm.

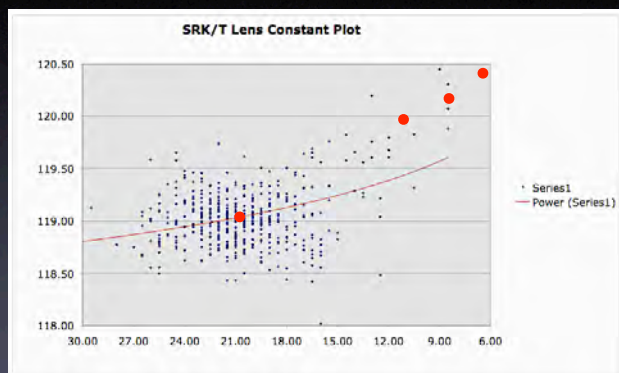
Procedures: Optical biometry with IOLMaster.
Standard phacoemulsification.
MN60MA extended range IOL.

Outcome: +1.50 D

Warren E. Hill, MD, FACS

High to extreme axial myopia

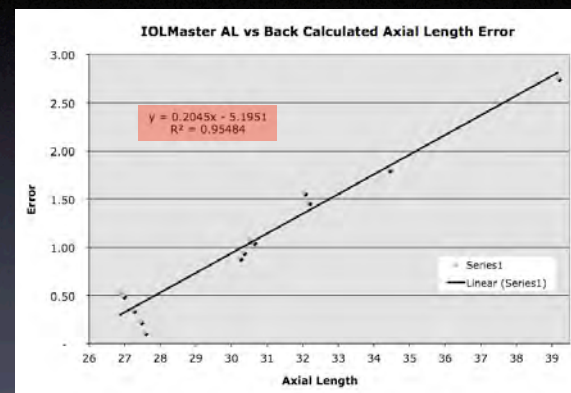
Why are we getting hyperopic errors?



SN60WF, March, 2006

High to extreme axial myopia

Why are we getting hyperopic errors?



MA60MA, June, 2008

High to extreme axial myopia

Why are we getting hyperopic errors?

LABORATORY SCIENCE

Intraocular lens calculation in extreme myopia

Wolfgang Haigis, MS, PhD

PURPOSE: To study from a theoretical viewpoint the effects in cases of extreme myopia of the different axial length (AL) behavior of current intraocular lens (IOL) calculation formulas and the problems caused by changes in lens geometry in the transition from plus to minus lenses.

SETTING: University Eye Hospital, Wuerzburg, Germany.

METHODS: A comparison of the thick-lens and thin-lens approach was made with allowance for the role of IOL constants and exemplified in model calculations based on design data of the MA60MA IOL in the power range from +5.0 to -5.0 diopters. Ray tracing was used to define model eyes for the MA60MA IOL, and the IOL constants producing the correct lens powers with the Haigis formula were determined.

RESULTS: An equation was derived linking lens geometry represented by the positions of the principal planes with the effective thin-lens position and thus with the respective IOL constants. Because IOL geometry changes considerably at the transition from plus to minus powers, a corresponding change is obtained in the necessary IOL constants. If no allowance is made for this effect, refractive errors increasing with AL will be associated with minus-power IOLs.

CONCLUSION: Plus IOLs and minus IOLs have to be characterized by different sets of IOL constants.

J Cataract Refract Surg 2009; 35:906-911 © 2009 ASCRS and ESCRS

High to extreme axial myopia

Why are we getting hyperopic errors?

MA60MA & MN60MA optical biometry lens constants

Optimized lens constants

	+5.00 to plano	-1.00 to -5.00
Holladay 1	10.35	-6.82

SRK/T	126.70	103.80
-------	--------	--------

Haigis (+) power: a0 = 5.92 a1 = 0.40 a2 = 0.10

Haigis (-) power: a0 = -4.00 a1 = 0.40 a2 = 0.10

Manufacturer's listed lens constant = 118.9



ARTICLE

Optimizing intraocular lens power calculations in eyes with axial lengths above 25.0 mm

Li Wang, MD, PhD, Mariko Shirayama, MD, Xingxuan Jack Ma, Thomas Kohren, MD, PhD, FEBO, Douglas D. Koch, MD

PURPOSE: To evaluate the accuracy of refractive prediction of 4 intraocular lens (IOL) power calculation formulas in eyes with axial length (AL) greater than 25.0 mm and to propose a method of optimizing AL to improve the accuracy.

SETTING: Guleen Eye Institute, Baylor College of Medicine, Houston, Texas, USA, and Department of Ophthalmology, Goethe University, Frankfurt am Main, Germany.

DESIGN: Case series.

METHODS: Refractive prediction errors with the Holladay 1, Haigis, SRK/T, and Hoffer D formulas were evaluated in consecutive cases. Eyes were randomized to a group used to develop the method of optimizing AL by back-calculation or a group used for validation. Further validation was performed in 2 additional data sets.

RESULTS: The optimized AL values were highly correlated with the IOLMaster AL (R^2 from 0.990 to 0.976). In the validating group, the method of optimizing AL significantly reduced the mean numerical errors for IOLs greater than 5.00 diopters (D) from +0.27 to +0.68 D to -0.19 to -0.02 D and for IOLs of 5.00 D or less from +1.13 to +1.87 D to -0.21 to +0.01 D, respectively (all $P < .05$). In 2 additional validation data sets, this method significantly reduced the percentage of eyes that would be left hyperopic.

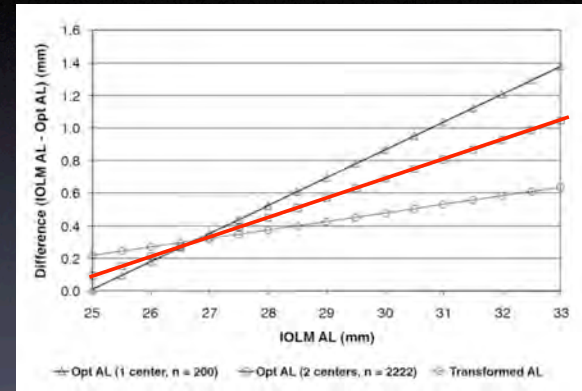
CONCLUSIONS: The proposed method of optimizing AL significantly reduced the percentage of long eyes with a hyperopic outcome. Updated optimizing AL formulas by combining all eyes from the 2 study centers are proposed.

Financial Disclosure: No author has a financial or proprietary interest in any material or method mentioned.

J Cataract Refract Surg 2011; 37:2018-2027 © 2011 ASCRS and ESCRS

High to extreme axial myopia

Why are we getting hyperopic errors?



Wang & Koch, MA60MA - JCRS November, 2011

High to extreme axial myopia

Why are we getting hyperopic errors?

Optical biometry axial length adjustment beyond 25 mm

$$\text{New AL} = 0.8829 \times \text{AL} + 2.825$$

Plug this back into the IOLMaster, use Holladay 1 and select the IOL that gives the least amount of minus.

Standard optical biometry Holladay 1 lens constants

$$\text{MN60MA} = 1.87$$

$$\text{SN60WF} = 1.80$$

Biomerty & IOL Selection Misadventures

High to extreme axial myopia

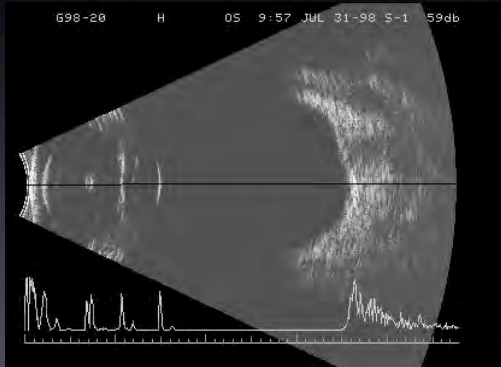
History: Axial myope of 31.38 mm.

Procedures: Routine immersion biometry. Axial length adjusted & Holladay 1 used. Standard phacoemulsification. MN60MA extended range IOL.

Outcome: +1.50 D

Biomerty & IOL Selection Misadventures

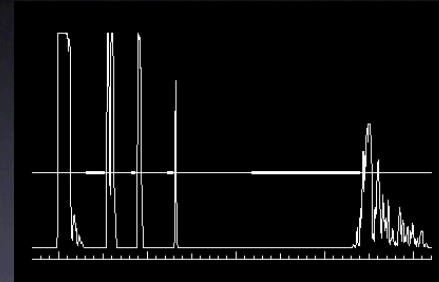
High to extreme axial myopia



Warren E. Hill, MD, FACS

Biomerty & IOL Selection Misadventures

High to extreme axial myopia



Immersion A-scan in a patient with high myopia and a staphyloma.

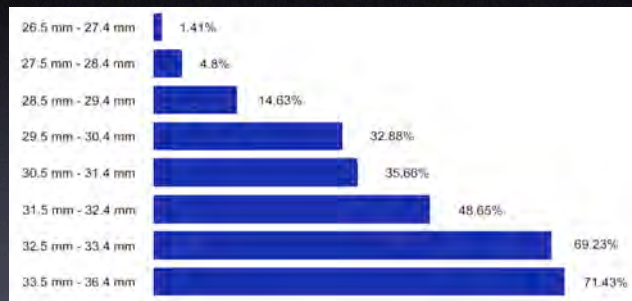
Staphyloma

- Normal anterior segment ultrasound pattern.
- Low amplitude, poorly defined retinal spike.
- Measurements that are widely variable.
- Axial length typically greater than 26.0 mm.
- There may be a history of progressive myopia.

Warren E. Hill, MD, FACS

Biomerty & IOL Selection Misadventures

High to extreme axial myopia

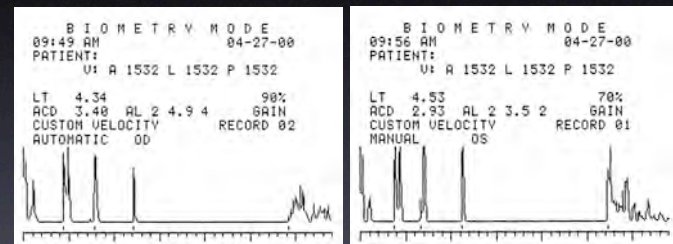


Am J Ophthalmol. 1971; 71:42

Warren E. Hill, MD, FACS

Biomerty & IOL Selection Misadventures

High to extreme axial myopia



Right eye: type 1 peripapillary posterior staphyloma.

MR = -3.75 +1.00 x 170

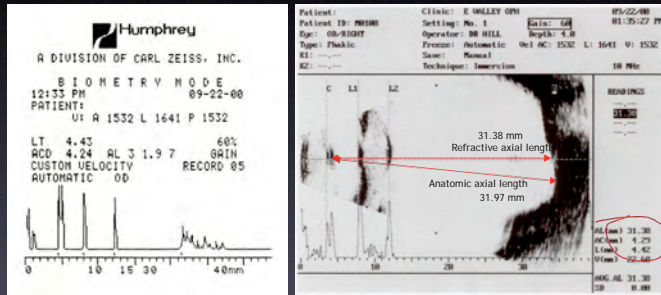
Left eye: normal posterior segment.

MR = Plano +0.50 x 165

Warren E. Hill, MD, FACS

Biomerty & IOL Selection Misadventures

High to extreme axial myopia



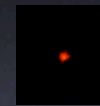
Standard Immersion A-scan.

Simultaneous vector A & B-scan with the Alcon UltraScan.

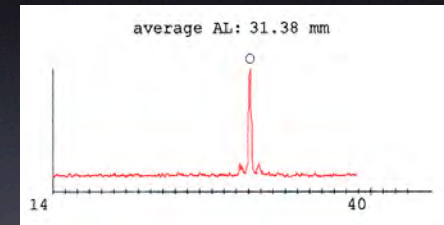
Warren E. Hill, MD, FACS

Biomerty & IOL Selection Misadventures

High to extreme axial myopia



IOLMaster fixation light.
Take measurements without removing the patient's glasses.



Partial coherence interferometry gives the refractive axial length.

Warren E. Hill, MD, FACS

Biomerty & IOL Selection Misadventures

High to extreme axial myopia

History: Axial myope of 31.38 mm.

Procedures: Routine immersion biometry.
Axial length adjusted & Holladay 1 used.
Standard phacoemulsification.
MN60MA extended range IOL.

Outcome: +1.50 D

Warren E. Hill, MD, FACS

Biomerty & IOL Selection Misadventures

High to extreme axial myopia

Management options

- Observation and / or spectacles.
- Contact lens.
- LASIK or PRK.
- Secondary piggyback IOL.
- IOL exchange.

Warren E. Hill, MD, FACS

Biomerty & IOL Selection Misadventures

High to extreme axial myopia

Requirements for successful piggyback IOL

- Primary IOL is completely within the capsular bag.
- There is satisfactory room for a secondary piggyback.
- The primary IOL does not have a strongly positive shape factor with a steep anterior radius.

Warren E. Hill, MD, FACS

Biomerty & IOL Selection Misadventures

High to extreme axial myopia

How do I calculate the piggyback IOL power?

- Careful manifest refraction. No auto-refractions!
- For hyperopic errors, multiply SE by 1.5 up to +7.00 D.
- For myopic errors, multiply the SE by 1.3, down to -7.00 D.
- For increased accuracy, or a SE greater than ± 7.00 D, use the Holladay R formula, or the refractive vergence formula.

www.docholladay.com

Holladay R formula

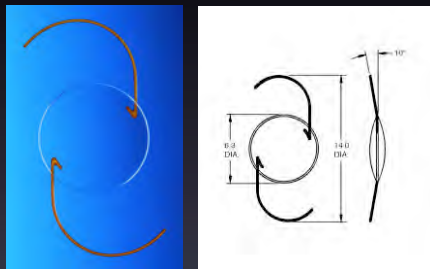
www.doctor-hill.com

Refractive vergence formula Excel spreadsheet

Warren E. Hill, MD, FACS

Biomerty & IOL Selection Misadventures

High to extreme axial myopia



Staar AQ-5010V & AQ-2010V 3-piece silicone IOL

Warren E. Hill, MD, FACS

Biomerty & IOL Selection Misadventures

High to extreme axial myopia

How do I calculate the piggyback IOL power?

IOL Power Calculations From Refractive Data - Refractive Vergence Formula for Pseudophakic and Aphakic Eyes v. 02.8							
Warren E. Hill, MD, FACS East Valley Ophthalmology, Ltd. Mesa, Arizona USA							
Patient: Mary Jones				IOL: Staar AQ-5010V			
Date: 1-Nov-08				Referring Physician: John Smith, MD			
Position: Piggyback IOL in sulcus							
Note: Do not enter data into the tan colored boxes							
ELPo	Vtx	Kk1	Kk2	Ko - avg	Pre Op Seq	Post Op Rx	IOL Power
4.80	12.0	42.25	43.00	42.10	2.75	0.00	4.00

Warren E. Hill, MD, FACS

Biomerty & IOL Selection Misadventures

High to extreme axial myopia

How do I calculate the piggyback IOL power?

Manifest refraction.

Current Ks.

Target post-op refraction.

Select IOL to be implanted.

Power to be added or subtracted at the plane of the sulcus using a piggyback IOL.

Surgeon: Hill, Warren (IOLMaster) 07/31/2007		OD
Refraction: +2.75 +0.00 X 15	AL(DCLM): 23.49	
Vertex: 12.50	Alt. AL:	
BCVA: 20/20	Ref WAVA: 12.00	
UCVA: 20/80	Plastic ACD: 0.00	
K1: 42.25 @ 15	Plastic Lens Th: 0.00	
K2: 43.00 @ 105	Target Iref: 0.00	
Average K: 42.63	Tot. Axial: 0.00	
Absorb K: 42.63		
Additive		
Eye Status: Pseudophakic	PreOp Pathology: No	
New PC Lens: in sulcus	Prev. IOL: No	
	Retrobulbar: No	
Secondary Piggy-Back IOL	Scleral Excise: No	
	Silicone in Vitreous Cavity: No	
Formula: Holladay R		
Lens #1 Spher AQ-5010V		
Procedure: SNI Phaco		
SRG Entered ACD: 5.55		
IOL	Pred. Ref.	
3.00	-0.71	
3.50	-0.26	
4.00	0.00	
4.50	-0.00	
Lens Power NA		

Warren E. Hill, MD, FACS

Biomerty & IOL Selection Misadventures

High to extreme axial myopia

Important caveat !!!

Unless there is a large amount of space between the iris and the primary IOL, avoid using 3-piece acrylics as the secondary piggyback. The square, truncated edges and semi-tacky nature of the acrylic material may interact with the posterior iris and lead to:

- Iris transillumination defects.
- Pigment dispersion.
- Secondary glaucoma.
- Intermittent uveitis.

Warren E. Hill, MD, FACS

Achieving optimal refractive outcomes

What happened?

History: 21.95 mm axial hyperope

Procedures: Routine optical biometry.
Holladay 2 formula used
Standard phacoemulsification.
+32.50 D SN60AT IOL perfectly placed
Measurements repeated... the same

Outcome: +3.25 D unanticipated hyperopia

Warren E. Hill, MD, FACS

Historical perspective

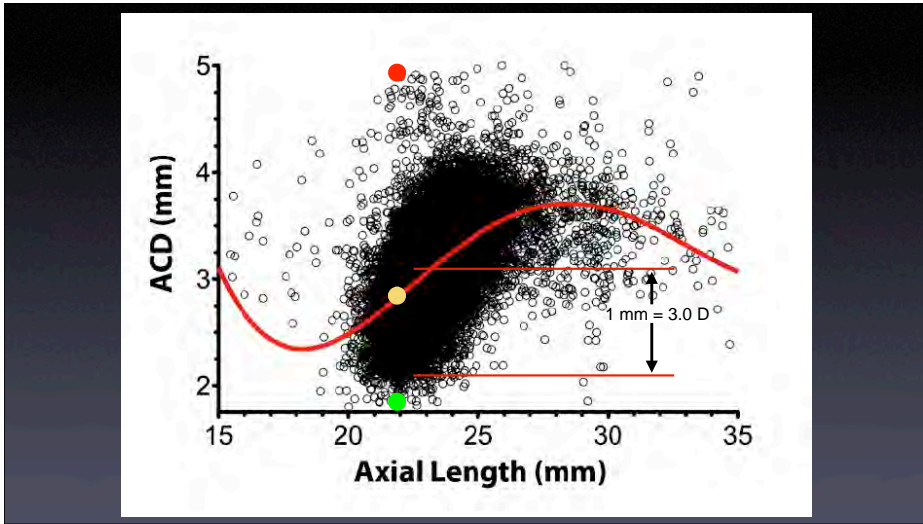
Q: What are the differences between theoretical formulas? A: Estimation of the ELP.

Axial Length Vergence Formula

$$IOL_e = \frac{1336}{AL_o - ELP_o} - \frac{1336}{\frac{1336}{\frac{1000}{DPostRx} + K_o} - ELP_o}$$

↑
Each theoretical formula estimates the ELP_o differently.

Warren E. Hill, MD, FACS



Older IOL power calculation formulas

Sources of errors in IOL power calculations

Incorrect assumptions

FALSE: The anterior and posterior segments of the eye are mostly proportional.

Short eyes may be assumed to have more shallow anterior chambers.
 Long eyes may be assumed to have deeper anterior chambers.

FALSE: Keratometry and ACD are always related.

Steep Ks area assumed to have deeper anterior chambers.
 Flat Ks area assumed to have more shallow anterior chambers.

Holladay JT, Gills JP, Leidelin J, Cherchio M. Achieving emmetropia in extremely short eyes with two piggyback posterior chamber intraocular lenses. *Ophthalmology*. 1996;103:1118-1123.

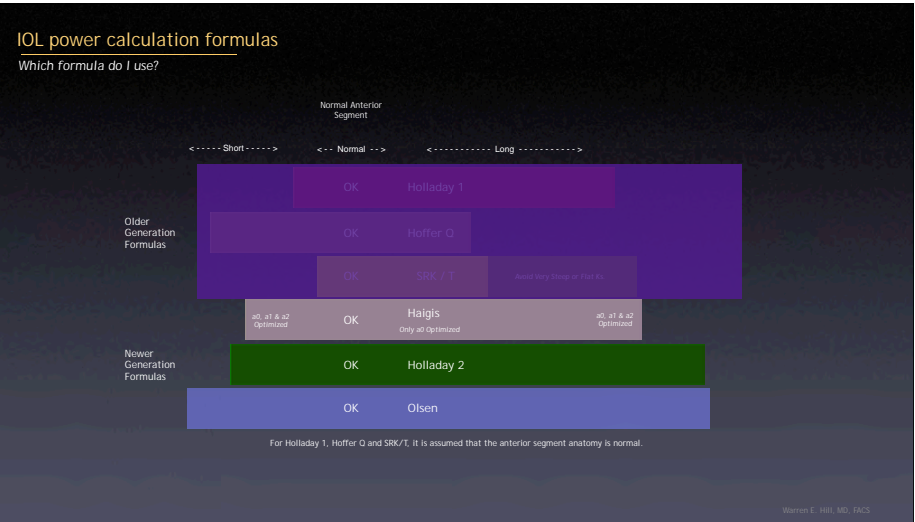
IOL power calculation formulas

Sources of errors in IOL power calculations

		Axial Length		
		Short	Normal	Long
Anterior Segment Size	Small	Small eye Nanophthalmia 0%	Microcornea 2%	Microcornea 0% & Axial myopia
	Normal	Axial hyperopia 80%	Normal 96%	Axial myopia 90%
	Large	Megalocornea 20% & Axial hyperopia	Megalocornea 2%	Large eye & Axial myopia 10% Buphthalmos

Holladay JT. Standardizing constants for ultrasonic biometry, keratometry, and intraocular lens power calculations. *JCRS* 1997;23:1356-1370.

Warren E. Hill, MD, FACS



Trends

Keep up with a rapid evolution

IOL power calculation methodologies are evolving.

Advanced Theoretical Holladay 2 (Holladay, USA) - 1998.

OKULIX* Ray Tracing (Preussner, Germany) - 2002.

Improved Theoretical ELP₀ (Olsen, Denmark) - 2009.

Improved Ray Tracing Algorithm (Aramberri, Spain) - 2010.

Statical Engineering Model (Hill-Koch-Wang-Lam-Gayton, USA) - 2014.

Physicians should think in terms of a 5 to 8 year horizon.
Additional, precise information will be required for better accuracy.

Warren E. Hill, MD, FACS

Biomerty & IOL Selection Misadventures

High to extreme axial hyperopia

Management options

- Observation and / or spectacles.
- Contact lens.
- LASIK or PRK.
- Secondary piggyback IOL.
- IOL exchange.

Warren E. Hill, MD, FACS

Biomerty & IOL Selection Misadventures

High to extreme axial hyperopia

Indications for a change in IOL power.

- Intolerable anisometropia.
- Unsatisfactory refractive outcome.
- Prior keratorefractive surgery - *consistent outcomes remain elusive*.
- Legal issues surrounding measurements and calculations.

Warren E. Hill, MD, FACS

Biomerty & IOL Selection Misadventures

High to extreme axial hyperopia

Sources of IOL power calculation error

- **Axial length** - becoming less of an issue with immersion A-scan & OCB.
- **Keratometry** - now a more common cause. *Ophthalmology*, 2007; 114:417-424.
- **Formula inaccuracy** - newer formulas required to meet patient expectations.
- **Difficult clinical situations** - prior LASIK, keratoconus, staphyloma, etc.
- **Wrong IOL implanted** - develop a multi-step process for IOL verification.

Warren E. Hill, MD, FACS

Post-cataract surgery refractive surprise

What should I do?

When is a lens exchange a better option?

- Early in the post-op course.
- There is no doubt as to the reason for the refractive surprise.
- Where a piggyback IOL may not be a workable option.

Warren E. Hill, MD, FACS

Post-cataract surgery refractive surprise

What should I do?

How do I calculate the exchange IOL power?

- Careful manifest refraction and Ks.
- Use the Holladay R formula, or the refractive vergence formula with the effective lens position of the current IOL.

www.dochoolladay.com

Holladay R formula

www.doctor-hill.com

Refractive vergence formula Excel spreadsheet

Warren E. Hill, MD, FACS

Post-cataract surgery refractive surprise

The refractive vergence formula - axial length independent calculation

How do I calculate the exchange IOL power?

IOL Power Calculations From Refractive Data - Refractive Vergence Formula
for Pseudophakic and Aphakic Eyes v. 02.8

Warren E. Hill, MD, FACS East Valley Ophthalmology, Ltd. Mesa, Arizona USA

Patient: Mary Jones IOL: Alcon SN60WF
Date: 1-Nov-08 Referring Physician: John Smith, MD
Position: Lens exchange in capsular bag

Note: Do not enter data into the tan colored boxes

ELPo	Vtx	Kk1	Kk2	Ko - avg	Pre Op Seq	Post Op Rx	IOL Power
5.50	12.0	41.00	43.00	41.48	3.25	0.00	5.00

Warren E. Hill, MD, FACS

Post-cataract surgery refractive surprise

The Holladay R formula
Axial length independent calculation

How do I calculate the exchange IOL power?

Manifest refraction.

Current Ks.

Target post-op refraction.

IOL currently in place.

Power to be added or subtracted at the plane of the capsular bag.

Surgeon: Hill, Warren (IOLMaster) 07/31/2007

Refraction: +3.25 +0.00 X 15 AL(IOL): 23.49

Wkrc: 12.50 Adj AL:

SCUR: 2070 Hor Wkrc: 11.00

UCUR: 2080 Phakic ACD: 0.00

K1: 41.00 @15 Phakic Lens Th: 0.00

K2: 43.00 @165 Target Ref: 0.00

Average K: 42.00 Tgt Adj: 0.00

Adjusted K: 42.00

OD

Formula: Holladay R

Lens #1 Alcon SN60WF
Procedure: Sio Phaco
SRG Entered ACD: 5.55

EL	Prod. Ref.
4.50	0.34
5.00	0.00
5.50	0.68
6.00	-0.35
6.50	-0.70

Warren E. Hill, MD, FACS



Warren E. Hill, MD

Dr. Hill has been the Medical Director of East Valley Ophthalmology in Mesa, Arizona for the past 27 years. He received his medical degree from the University of Arizona and his ophthalmology training at the University of Rochester, in Rochester, New York. He has devoted the majority of his professional activities to performing challenging anterior segment surgery for other ophthalmologists and the mathematics of intraocular lens power calculations. He has delivered more than 500 papers and 11 named lectureships to ophthalmic societies both in the United States and internationally in 34 countries and on six continents.

In 2007 Dr. Hill was appointed the Cataract and Anterior Segment Subspecialty Editor for the American Academy of Ophthalmology's Ophthalmic News and Education (O.N.E.) Network, a position he held until 2010. He has also received the American Academy of Ophthalmology's Achievement and Secretariat Awards.

Aside from the practice of ophthalmology, Dr. Hill enjoys flying his military airplane in air show close formation demonstrations and is licensed as a multi-engine commercial pilot.

Post-Refractive IOL Power Calculations

Help!

2013 Masters in Ophthalmology

Florida Society of Ophthalmology

June 29, 2013

Warren E. Hill, MD
East Valley Ophthalmology
Mesa, Arizona

Disclosure statement

Warren E. Hill, MD

The author has no proprietary interest in any products, or methods mentioned in this presentation. Current industry relationships are with:

Alcon Laboratories
Consultant, Speaker, Research

Bausch & Lomb
Consultant, Research

Clarity Medical Systems
Consultant, Stockholder

Elezena
Consultant

Haag-Streit
Consultant, Speaker, Research

LenSx
Consultant

Oculus Optikgeräte
Consultant

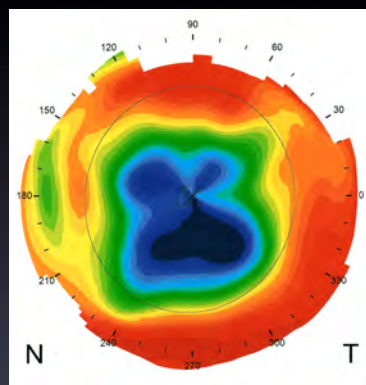


Prior keratorefractive surgery

The next major challenge for ophthalmology!

How do you handle an IOL power calculation for patients with prior LASIK, PRK and RK?

1. Send to a willing colleague.
2. Do it, but ask a colleague for help.
3. Do the calculation completely on your own.
4. Enter a state of general despair.
5. Use special web-based software.



Prior 8-incision RK Front Surface Power Map.

Warren E. Hill, MD, FACS

Prior keratorefractive surgery

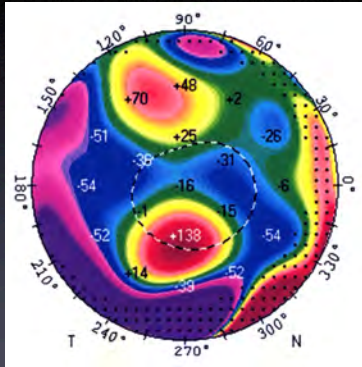
What are the special skills required?



Warren E. Hill, MD, FACS

Prior keratorefractive surgery

The next major challenge for ophthalmology!



It's not really as bad as you might imagine.

IOL power calculations after prior RK, myopic LASIK & PRK.

Why is this all so difficult?

Keratometry and topography will incorrectly read the central corneal power following all forms of keratorefractive surgery.

Most theoretical formulas will make incorrect assumptions regarding the estimation of the effective lens position following LASIK, PRK, or RK.

SRK/T > Holladay 1 > Hoffer Q

A "double K" method is usually required.

Haigis is immune to the LASIK, PRK and RK central corneal power change artifact.

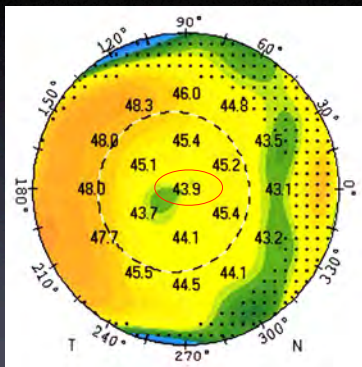
Prior laser refractive surgery

Source: David Harman of MarketScope

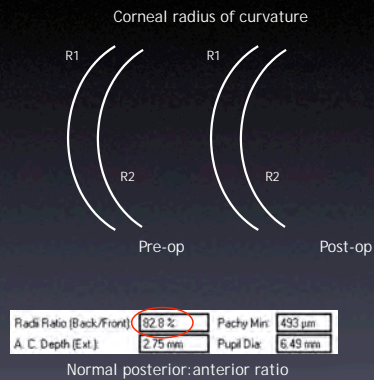
Year	USA Only	Outside USA	Global
1996	86,700	223,000	309,700
1997	198,950	402,900	601,850
1998	443,100	634,200	1,067,300
1999	919,400	892,500	1,811,900
2000	1,370,750	1,142,450	2,513,200
2001	1,310,000	1,260,400	2,570,400
2002	1,146,900	1,684,300	2,831,200
2003	1,122,100	1,807,900	2,930,000
2004	1,309,900	1,907,000	3,216,900
2005	1,335,300	2,026,000	3,362,100
2006	1,307,474	2,166,650	3,474,124
2007	1,328,948	2,338,990	3,667,939
2008	984,555	2,118,100	3,102,655
2009	730,847	2,539,476	3,270,323
TOTALS	13,594,924	21,143,866	34,729,591

Prior keratorefractive surgery

Normal cornea

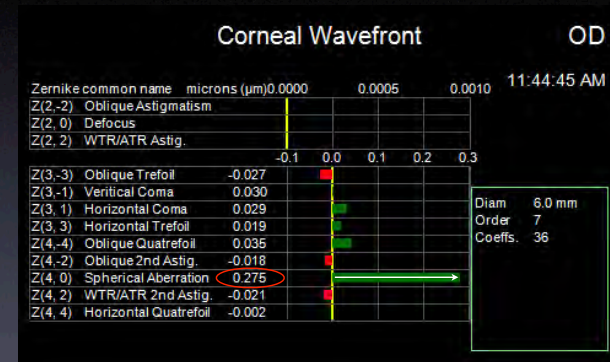


Normal cornea after front refractive power map.



Prior keratorefractive surgery

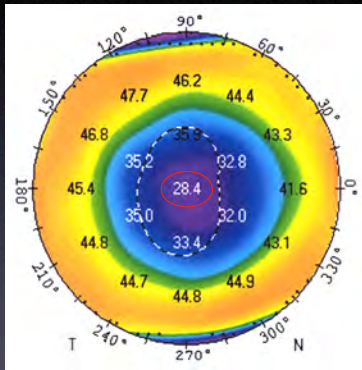
Normal cornea



Anterior corneal spherical aberration is the only Zernike coefficient with a large non-zero mean value.

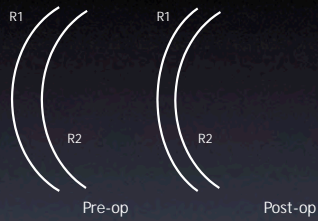
Prior keratorefractive surgery for myopia

Prior radial keratotomy - Corneal changes



Prior RK front power refractive map.

Corneal radius of curvature



Radi Ratio (Back/Front)	82.8%	Pachy Min	493 μm
A. C. Depth (Ext.)	2.75 mm	Pupil Dia	6.49 mm

Normal posterior:anterior ratio

Radi Ratio (Back/Front)	105.6%	Pachy Min	547 μm
A. C. Depth (Ext.)	4.23 mm	Pupil Dia	5.32 mm

Increased Post-RK posterior:anterior ratio

Warren E. Hill, MD, FACS

Prior keratorefractive surgery for myopia

Other changes following RK

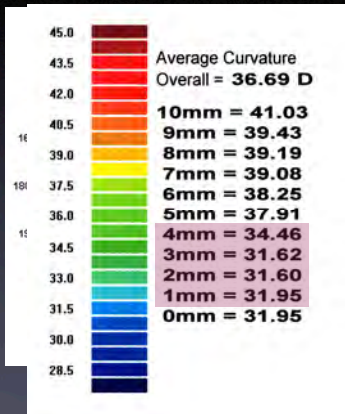
Corneal Wavefront		OD
ANSI Z80.28		7/25/2008
Zernike common name		3:17:44 PM
Z(2,-2) Oblique Astigmatism	-1.539	
Z(2,0) Defocus	0.000	
Z(2,2) WTR/ATR Astig.	-3.009	
Z(3,-3) Oblique Trefoil	-0.219	Diam 6.0 mm
Z(3,-1) Vertical Coma	1.842	Order 6
Z(3,1) Horizontal Coma	-2.413	Coeffs. 28
Z(3,3) Horizontal Trefoil	0.498	
Z(4,-4) Oblique Quatrefoil	-0.124	
Z(4,-2) Oblique 2nd Astig.	-0.010	
Z(4,0) Spherical Aberration	1.599	
Z(4,2) WTR/ATR 2nd Astig.	1.210	
Z(4,4) Horizontal Quatrefoil	-0.526	

Warren E. Hill, M.D.

Warren E. Hill, MD, FACS

Prior radial keratotomy

Example - estimation of central corneal power following RK



4mm = 34.46
3mm = 31.62
2mm = 31.60
1mm = 31.95

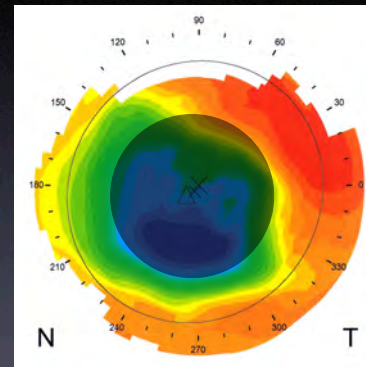
Atlas 1 - 4 mm Numerical View 32.41 D
 Back Calculated 32.28 D
 Difference +0.11 D

Refractive Target: -0.50 D to -0.75 D

Warren E. Hill, MD, FACS

Prior radial keratotomy

Example - estimation of central corneal power following RK



Zeiss Atlas 9000 topographer: 1 - 4 mm ring power average.

1 mm ring	38.94 D
2 mm ring	38.79 D
3 mm ring	39.09 D
4 mm ring	39.96 D

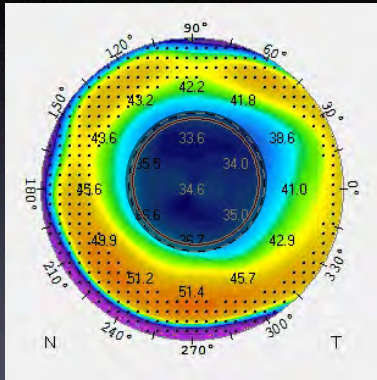
Atlas 1 - 4 mm ring power 39.20 D
 Back Calculated 39.09 D
 Difference +0.11 D

Refractive Target: -0.50 D to -0.75 D

Warren E. Hill, MD, FACS

Prior radial keratotomy

Example - estimation of central corneal power following RK



Pentacam HD 50-scan 4.0 mm Power Distribution Zone Sagittal Power (Front) - Centered on the Pupil.

Power Calculations in Actual Zone:

K1:	34.2 (89°)
K2:	35.2 (179°)
Km:	34.7 D
Peak:	33.7 D
65% Mean:	34.3 D

Pentacam 4.0 mm Zone **34.70 D**
 Back Calculated **34.61 D**
 Difference **+0.09 D**
 Refractive Target: **-0.50 D**

Warren E. Hill, MD, FACS

Prior radial keratotomy

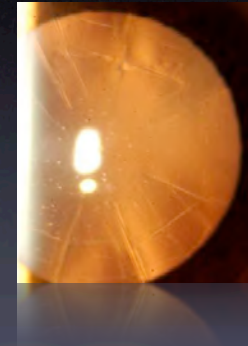
What to look for following cataract surgery

Transient post-op hyperopia - "Rule of 2s"

Patients with previous RK often show variable amounts of transient hyperopia following cataract surgery in the immediate post-op period.

If the refractive target remains elusive, plans for an IOL exchange, or a piggyback IOL, should not be made until there are two stable refractions, on two consecutive visits, two months after surgery, at the same time of the day.

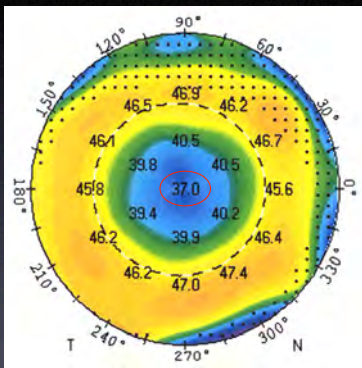
IOL power calculations should be targeted for $-0.50 D$ to $-0.75 D$. The refractive goal should be to have the operative eye mildly myopic so that five to ten years later, the refractive error does not drift into hyperopia.



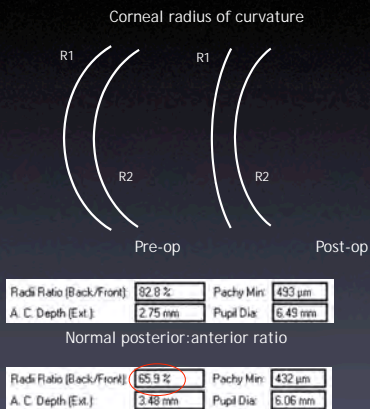
Warren E. Hill, MD, FACS

Prior keratorefractive surgery for myopia

Myopic LASIK - Corneal changes



Prior myopic LASIK front power refractive map.

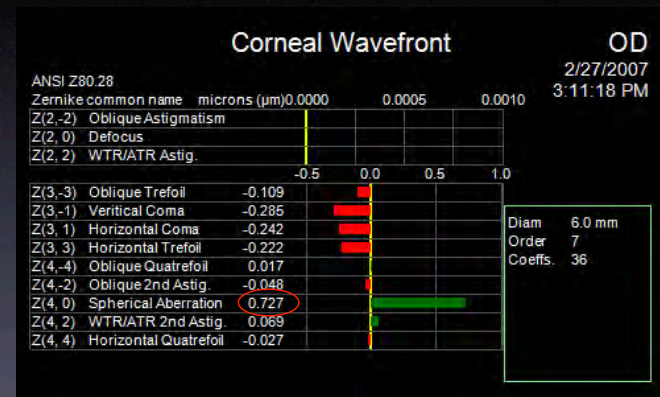


Decreased post-myopic LASIK posterior:anterior ratio

Warren E. Hill, MD, FACS

Prior keratorefractive surgery for myopia

Other changes following myopic LASIK and PRK



Warren E. Hill, MD, FACS

Prior keratorefractive surgery for myopia

IOL power calculations - the Holladay 2 formula

PreOp Pathology: **No**
 Prev. RK...: **Yes** ← Double K method activation.
 Keratoconus: **No** ← Actual pre-LASIK Ks or Population Mean Value
 Scleral Buckle: **No**

Refraction: **-0.25 +0.00 X 131** Axial Len: **26.32**
 Vertex: **12.00** Adj. AL:
 BCVA: **20/60** Hor W4-W: **12.60**
 UCVA: **20/300** Phakic ACD: **4.11**
 K1: **41.21 @2** Phakic Lens Th.: **3.42**
 K2: **41.77 @92** Target Ref: **0.00**
 Average K: **41.49** Tgt Add: **0.00**
 Adjusted K: **40.50** ← Estimated central corneal power

Formula: **Holladay II**
 Lens #1 Alcon SN60WF
 Procedure: **Std Phaco**
 SRG Entered ACD: **5.50**

IOL	Pred. Ref.
16.00	0.63
16.50	0.31
16.99	0.00
17.00	-0.01
17.50	-0.34

For post-RK & LASIK IOL power calculations, the "double K" option of the Holladay 2 formula increases overall accuracy.

Prior keratorefractive surgery for myopia

3rd generation, 2-variable formula power adjustment

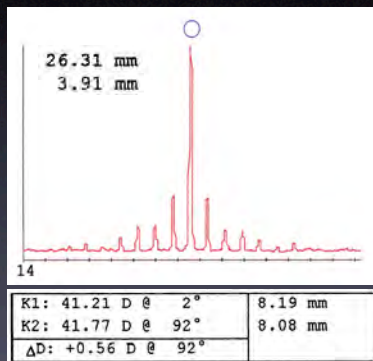
Aramberri "double K method" IOL power adjustment table for Holladay 1

Myopic Tx	AL 23	24	25	26	27	28	29
- 2	+0.5	+0.5	+0.5	+0.4	+0.4	+0.3	+0.3
- 4	+1.0	+1.0	+1.1	+0.9	+0.8	+0.6	+0.6
- 6	+1.5	+1.6	+1.6	+1.5	+1.2	+1.0	+1.0
- 8	+2.0	+2.1	+2.2	+2.0	+1.7	+1.5	+1.5
- 10	+2.6	+2.7	+2.8	+2.6	+2.2	+2.0	+1.9

Koch, D, Wang, L. Calculating IOL power in eyes that have had refractive surgery. JCRS 2003 29(11) 2039-2042.

Prior keratorefractive surgery for myopia

First reliable calculation method - the Haigis-L formula



Haigis-L Formula

Measured in mm by Zeiss IOLMaster

- Axial length
- Anterior chamber depth
- R₁ & R₂ corneal radii

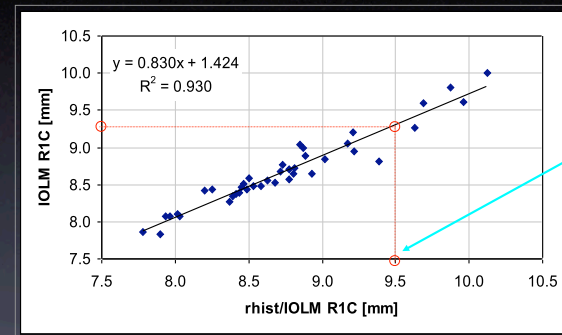
No historical data required.

General accuracy 0.50 D to 0.75 D.

Feature of IOLMaster software versions 4.0 and higher.

Prior keratorefractive surgery for myopia

First reliable calculation method - the Haigis-L formula



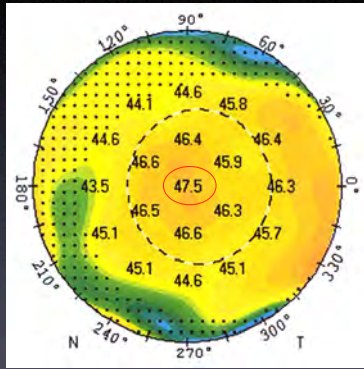
Effective (actual) radius is flatter than what is measured.

Haigis W, Janklich R, Wessely D, Loge B, Grein H-J. Messung von Hornhautradien bei normalen Augen und Augen nach LASIK. 18. Kongress der Deutschen Ophthalmochirurgen, Nürnberg, 08.-11.05.2002. Abstracts, p.143, 2003.

Haigis W, Langerbecher A, Seitz B. Zur IOL-Berechnung nach hornhautrefraktiven Eingriffen. Der Ophthalmologe 100, Suppl. 1, S18, 2003

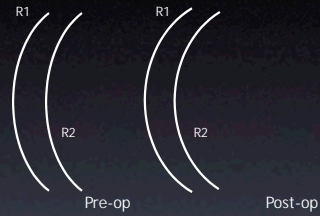
Prior keratorefractive surgery for hyperopia

Hyperopic LASIK - Corneal changes



Hyperopic LASIK front refractive power map.

Corneal radius of curvature



Radii Ratio (Back/Front)	82.8%	Pachy Min	493 μm
A. C. Depth (Ext.)	2.75 mm	Pupil Dia	6.49 mm

Normal posterior:anterior ratio

Radii Ratio (Back/Front)	97.9%	Pachy Min	543 μm
A. C. Depth (Ext.)	2.82 mm	Pupil Dia	6.26 mm

Increased post-hyperopic LASIK posterior:anterior ratio

Warren E. Hill, MD, FACS

Prior keratorefractive surgery for hyperopia

Estimation of central corneal power following hyperopic LASIK

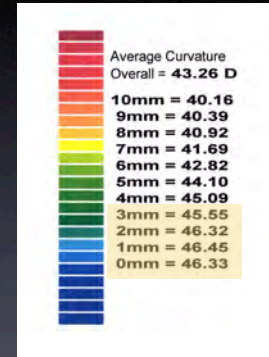
Directly Measured Central Corneal Power Value

Method #1

Average the 0, 1, 2 & 3 mm annular power values of the Numerical View or the same ring powers of the Zeiss Atlas topographer.

Method #2

Effective refractive power (EffR_{adj}) from the Holladay Diagnostic Summary of the EyeSys Corneal Analysis System.



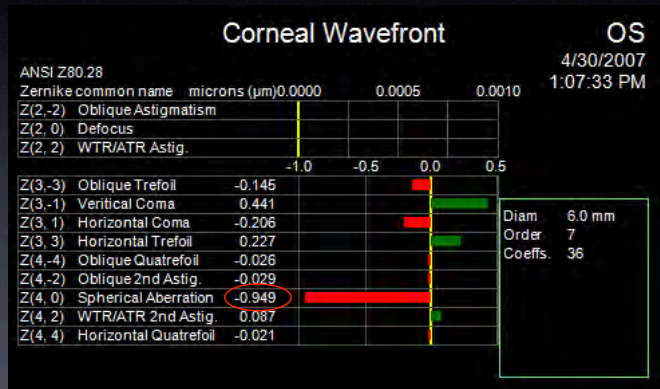
Numerical View of the Zeiss Atlas topographer. Ring power values.

Wang J, Jackson DW, Koch DD. Methods of estimating corneal refractive power after hyperopic laser in situ keratomileusis. J Cataract Refract Surg. 2002;28:954-961.

Warren E. Hill, MD, FACS

Prior keratorefractive surgery for hyperopia

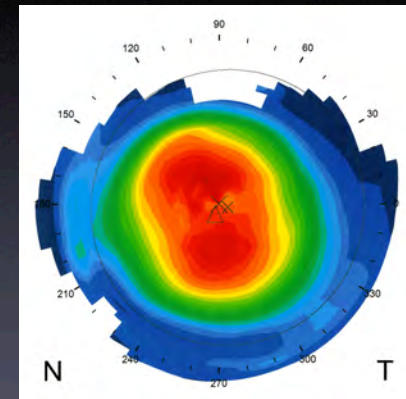
Other changes following hyperopic LASIK and PRK



Warren E. Hill, MD, FACS

Prior keratorefractive surgery for hyperopia

Central corneal steepening of hyperopic LASIK and PRK

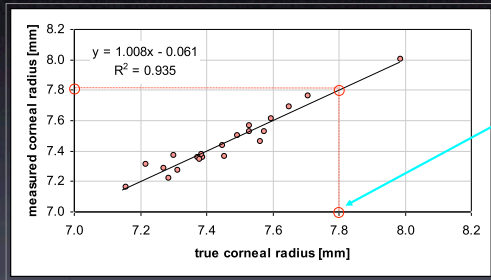


Warren E. Hill, MD, FACS

Prior keratorefractive surgery for hyperopia

Following hyperopic LASIK, the IOLMaster measured corneal radius is very close to being correct

Refractive laser surgery for hyperopia - Haigis-L



Effective (actual) radius is very close to the measured radius.

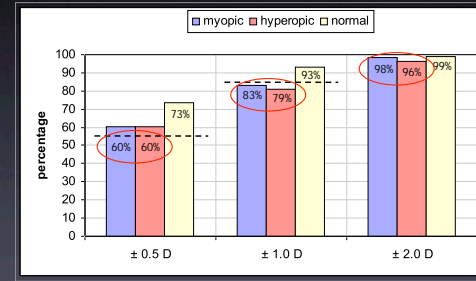
Haigis W, Lege BAM, Neuhann TF: Bestimmung wirksamer Hornhautradien nach hyperoper LASIK. Fortschritte der Ophthalmochirurgie (A.Schamer, A.Reuscher, Th. Neuhann (Hrsg)), 15. Kongress der Deutschen Ophthalmochirurgen. Diomed-Verlag, Ebelbach, p.95, 2005

Warren E. Hill, MD, FACS

Prior keratorefractive surgery for hyperopia

Clinical results for the Haigis and Haigis-L formula

Percentage of correct post-op refractive predictions using Haigis-L following refractive surgery is very close to the UK NHS criteria for post-op refractive outcomes for normal eyes.



Proposed benchmark for normal eyes: Gale RP, Saldana M, Johnston RL, Zuberhuhler B, McKibbin: Benchmark standards for refractive outcomes after NHS cataract surgery. Eye advance online publication. 24 August 2007.

Haigis W. The Haigis-L Formula. Presented at the ESCRS meeting, September, 2008. Berlin, Germany.

Warren E. Hill, MD, FACS

Prior keratorefractive surgery for myopia

Methods of estimating the central corneal power, IOL power, or both

Corneal power estimation

1. Clinical history
2. Topographic adjustment
3. EyeSys adj-EffRP
4. Wang-Koch-Maloney
5. Atlas 4 mm zone
6. Galilei
7. Adjusted Atlas 0-3
8. Potvin-Hill
9. Choy-Lee-Park
10. Hamed-Wang-Koch
11. Contact lens
12. Savini-Barboni-Zanini
13. Ronje
14. Camellin
15. Jarade
16. Ferrara
17. Rosa
18. Spicher
19. Contact lens method
20. Salvini IR

IOL power estimation

1. Aramberrri double K modification
2. Feiz & Mannis
3. Masket regression
4. Modified Masket
5. Haigis-L myopic
6. Haigis-L hyperopic
7. Holladay 2
8. Shammas no history
9. Wake Forrest
10. Ianchulev
11. Mackool
12. BESST
13. Corneal bypass
14. Ladas
15. Latkany flat K
16. HHK
17. Waddy

Warren E. Hill, MD, FACS

Prior keratorefractive surgery for myopia

Typical post-myopic LASIK IOL power calculation using the Holladay 2 formula

Calculation Method	Calculated IOL Power Using Holladay 2	
Feiz & Mannis	+24.50	<- Typical upper limit if > 8.00 D of correction
Clinical history	+22.50	
Topographic power adjustment	+22.50	
Wang-Koch-Maloney	+23.50	
Masket	+22.00	Correct IOL power usually falls somewhere in this middle range area.
Shammas	+22.50	
Modified Masket	+21.50	
Haigis-L	+22.50	
Average manual Ks	+20.00	<- Always below lower limit

Correct IOL power is probably somewhere between +23.5 D and +22.00 D

Mean IOL power = +22.42
+22.50 D IOL selected

Warren E. Hill, MD, FACS

Prior keratorefractive surgery

ASCRS post-keratorefractive surgery on-line calculator

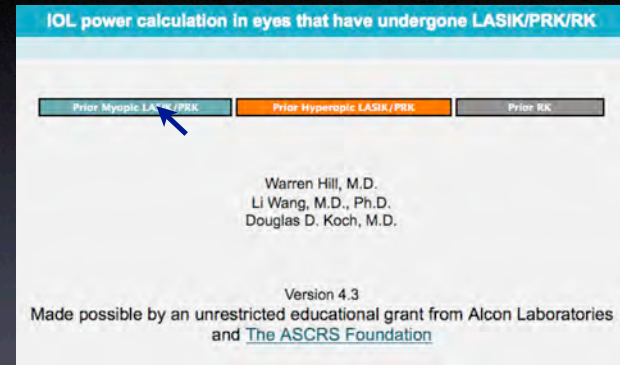


#1 Go to the ASCRS web site at www.ascrs.org

Warren E. Hill, MD, FACS

Prior myopic LASIK / PRK

ASCRS post-keratorefractive surgery on-line calculator



#2 Select "Prior Myopic LASIK / PRK"

Warren E. Hill, MD, FACS

IOL Calculator for Eyes with Prior Myopic LASIK/PRK
(Your data will not be saved. Please print a copy for your record.)

Please enter all data available and press "Calculate"

Doctor Name: Warren E. Hill, MD | Patient Name: Mary A. Jones | Eye: Right | IOL Model: S609WF

Pre-LASIK/PRK Data:
 Refraction*: Sph(D) -7.25 | Cyl(D)* 1.00 | Vertex (if empty, 12.5 mm will be used) 12.5
 Keratometry: K1(D) 44.75 | K2(D) 43.75

Post-LASIK/PRK Data:
 Refraction*: Sph(D) -0.25 | Cyl(D)* 0.50 | Vertex(mm) 12.5
 Topography: EyeSys 39.07 | Atlas 38.88 | Tomey ACCP 38.75 | Galilei 36.50 | V5.2.1 or later | V5.2 or earlier

Optical (IOLMaster/Lenstar)/Ultrasound Biometric Data:
 Ks: K1(D) 38.71 | K2(D) 39.07 | Keratometric Index (n)** 1.3375 | 1.332 | Other
 AL(mm) 27.13 | ACD(mm) 3.25 | Target Ref (D) 0.00
 Lens Constants****: A-const(SRK/T) 119.02 | SF(Holladay1) 1.82 | Haigis a1 -0.782 | Haigis a2 0.206 | Haigis a3 0.221

Buttons: Calculate, Reset Form

#3 Fill in as much data as you have.

Warren E. Hill, MD, FACS

IOL calculation formulas used: Double-K Holladay 1¹, Shammas-PL², & Haigis-L³

Using Pre-LASIK/PRK Ks + ΔMR

History ~~18.12~~
 Feiz-Mannis ~~18.74~~
 Corneal Bypass ~~18.26~~

¹Adju

Average IOL Power (ΔMR on)

Average IOL Power (All Available Formulas): 18.31
Min: 17.84
Max: 18.62

Haigis W (2008). Intraocular lens calculation after refractive surgery for myopia: Haigis-L formula. JCRS 34: 1658-1663.

Using a corneal radius in mm as measured by the IOLMaster (r meas), the Haigis-L algorithm generates a corrected corneal radius (r corr) which is then used by the regular Haigis formula to calculate IOL power following myopic laser vision correction. The corrected radius to be entered into the regular Haigis formula is calculated as follows:

$$r_{corr} = 331.5 / (-5.1625 \times r_{meas} + 82.2603 - 0.35)$$

18.37
18.62
18.52
18.30

#4 As many calculations are carried out for which data has been entered.

Warren E. Hill, MD, FACS

Prior myopic LASIK / PRK

ASCRS post-myopic LASIK on-line calculator - Calculation accuracy Wang, et al. J Cataract Refract Surg 2010; 36:1466-1473

Methods	% within ± 0.50 D	% within ± 1.00 D
Using Pre-LASIK/PRK Ks + ΔMR		
Clinical History	44	69
Feiz-Mannis	57	60
Corneal Bypass	37	68
Using ΔMR*		
Adjusted EfIRP	62	86
Adjusted Atlas0-3	64	90
Masket	57	91
Modified-Masket	67	90
Using No Prior Data*		
Wang-Koch-Maloney	58	96
Shammas	60	90
Hatgis-L	60	94
Using Average IOL Power*	72	93

Warren E. Hill, MD, FACS

Prior radial keratometry

ASCRS post-keratorefractive surgery on-line calculator

IOL power calculation in eyes that have undergone LASIK/PRK/RK

Prior Myopic LASIK/PRK
 Prior Hyperopic LASIK/PRK
 Prior RK

Warren Hill, M.D.
Li Wang, M.D., Ph.D.
Douglas D. Koch, M.D.

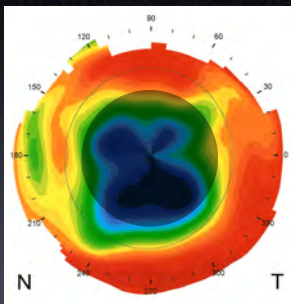
Version 4.3
Made possible by an unrestricted educational grant from Alcon Laboratories and [The ASCRS Foundation](#)

#2 Select "Prior RK."

Warren E. Hill, MD, FACS

Prior radial keratometry

Atlas topographer - ASCRS post-keratorefractive surgery on-line calculator



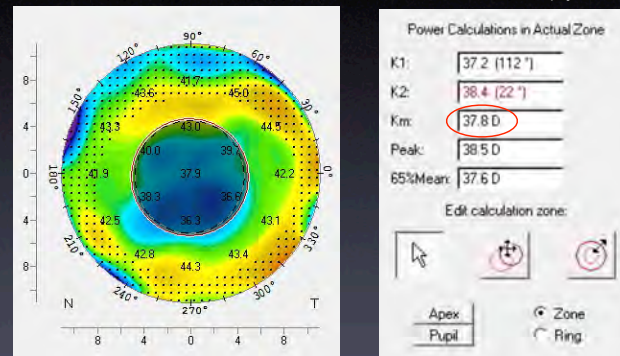
Steep K	40.49 D @ 17°
Flat K	39.67 D @ 107°
Astigmatism	0.81 D
1 mm ring	36.93 D
2 mm ring	36.95 D
3 mm ring	37.75 D
4 mm ring	39.63 D

$$(36.93 + 36.95 + 37.75 + 39.63) / 4 = 37.82 \text{ D}$$

Warren E. Hill, MD, FACS

Prior radial keratometry

Pentacam - ASCRS post-keratorefractive surgery on-line calculator



Pentacam HD 50-scan 4.0 mm Power Distribution Zone
Km Value - Sagittal Power (Front) - Centered on the Pupil.

Warren E. Hill, MD, FACS

IOL Calculator for Eyes with Prior RK
(Your data will not be saved. Please print a copy for your record.)

Power Calculations in Actual Zone

K1: 41.0 (116°)
K2: 41.7 (26°)
Kav: 41.4 D
Peak: 41.7 D
65% Mean: 41.8 D

Edit calculation zone:

Apex: Zone
Pupil: Ring

X: 0.02 mm
Y: 0.29 mm
Zone Dia: 4.0 mm

Ultrasound lens constants.

Calculate Reset Form

#3 Fill in as much data as you have.

Warren E. Hill, MD, FACS

IOL Powers

Packer M, Brown LK, Hoffman RS, Fine IH (2004), Intraocular lens power calculation after incisional and thermal keratorefractive surgery. J Cataract Refract Surg. 30:1430-4.

Fang JP, Hill WE, Wang L, Chang V, Koch DD. Advanced Intraocular Lens Power Calculations. Kohnen and Koch (ed), In: Essentials in Ophthalmology - Cataract and Refractive Surgery. Springer-Verlag, Berlin, 2007.

The Effective Refractive Power (EffRP), which is displayed in the Holladay Diagnostic Summary of the EyeSys Corneal Analysis System, samples all points within the central 3 mm and takes into account the Stiles-Crawford effect. In this method, the EffRP is used as central corneal power for IOL power calculation.

#4 As many calculations are carried out for which you have data.

Warren E. Hill, MD, FACS

Prior keratorefractive surgery
The next major challenge for ophthalmology!

www.doctor-hill.com

- Corneal power estimation after keratorefractive surgery.
 - Radial keratotomy.
 - RK + hyperopic LASIK enhancement.
 - Myopic LASIK.
 - Hyperopic LASIK.
- IOL power calculation after keratorefractive surgery.
 - Holladay 2 formula.
 - Aramberri double K method correction.
 - SRK/T, Hoffer Q, Holladay 1.
 - Haigis-L.
 - ASCRS Post-keratorefractive calculator.

Warren E. Hill, MD, FACS

Prior radial keratotomy

IOL selection based on anterior corneal spherical aberration

Ideally, the anterior corneal spherical aberration should be measured prior to cataract surgery. If it is not possible to do so, select an aspheric IOL that does not worsen the anterior corneal spherical aberration profile.

AMO Tecnis (-0.275 μm) Alcon IQ Lens (-0.200 μm) Bausch & Lomb Li61A0 (0.00 μm) Alcon SN60AT (+0.198 μm)

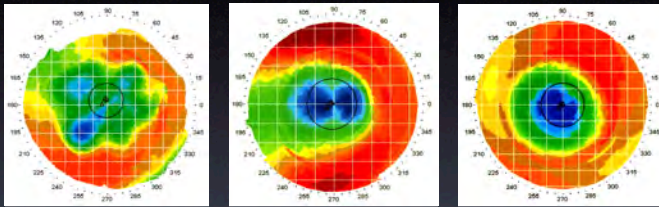
RK & Myopic LASIK Better option... aspheric IOL with negative spherical aberration.

Hyperopic LASIK Aberration neutral IOL, or spherical IOL (depends on amount of treatment)

Warren E. Hill, MD, FACS

Prior keratorefractive surgery for myopia

Gather more information and re-run calculations, if...



Validation guidelines

- * IOL power difference between eyes > 2.00 D. (Monovision was not the intended goal.)
- * IOL power > 23.00 D or < +17.00 D. (Exception: old RK & prior PTK IOL powers may be very high.)

Warren E. Hill, MD, FACS

Prior keratorefractive surgery

Refractive IOLs (multifocal, accommodating and toric)

Toric IOLs

It's best to demonstrate regular astigmatism, with an identifiable steep meridian.

RK = Multiple steep & multiple flat meridians.

Myopic LASIK = Irregular astigmatism.

Hyperopic LASIK = Generally has a steep central zone and lacks of an identifiable steep meridian.

Intraoperative aberrometry = Net solution; may allow for expanded use of toric IOLs.

Multifocal IOLs

Only with relatively low amounts of treatment to limit spherical aberration.

Ablation must be centered, or coma will be elevated (must be < 0.32 microns).

Multifocal IOL + multifocal cornea = Significant visual compromise.

Accommodating IOLs

Adds an additional element of refractive uncertainty, with a variable ELP.

Crystalens AO is aspheric, but does not add negative spherical aberration.

Warren E. Hill, MD, FACS

Prior keratorefractive surgery

Summary

Put together an overall plan based on what is known to give good results.

Be prepared to be the adult in the conversation when discussing costly refractive options, such as toric, diffractive and accommodating IOLs.

Be comfortable explaining the current limitations of technology and performing an IOL exchange. Expectations may exceed what is possible!

Have access to the appropriate tools for the job:

Optical biometer: (IOLMaster or Lenstar)

Topographer: Ideally, one that has been validated for LASIK & RK calculations & gives a solid corneal aberration profile.

ASCRS on-line post-keratorefractive calculator: Updated on a regular basis.

After RK be patient. Wait for the post-op refraction to stabilize. (6-16 weeks!)

Be realistic... there can be no expectation of a specific refractive outcome. Everyone needs to understand that cataract surgery after LASIK & RK is mostly rehabilitative rather than than refractive.

Warren E. Hill, MD, FACS



Warren E. Hill, MD, FACS

Edward Buckley, MD

Dr. Buckley is a native of Cincinnati, Ohio. He graduated from Duke University in 1972 with a BSE in Electrical Engineering. He received his MD degree from Duke in 1977 followed by a residency in ophthalmology. He then completed two fellowships, one in pediatric ophthalmology and the other in neuro-ophthalmology, both at the University of Miami Bascom Palmer Eye Institute returning to the faculty at Duke in 1983. He is currently the Banks Anderson, Sr. Distinguished Professor of Ophthalmology and Pediatrics. He was the Chief of both the Pediatric and Neuro-ophthalmology services for many years and is now the Vice Dean for Education for the School of Medicine, overseeing all of the student education programs including the PA, DPT, Path Assistant and Masters of Clinical Research, Biostatistics, and Clinical Leadership. He has been involved with the development of the Duke-National University of Singapore Medical School (Duke-NUS) education program since 2001 and currently Co-Chairs the Duke-NUS Academic Committee. He is the director of the pediatric ophthalmology fellowship program at Duke and has trained over 45 clinical and 10 research fellows.

Dr. Buckley has served as President of the American Association of Pediatric Ophthalmology (AAPOS) and Strabismus, Chair of the American Board of Ophthalmology, Chair of the Section of Ophthalmology of the American Academy of Pediatrics, President of the American Orthoptic Society, and is the current Editor-in-Chief of the Journal of AAPOS. He has received the Life Time Achievement Award from the American Academy of Ophthalmology (AAO) and AAPOS. He has published/edited eight books, 40 book chapters, and over 120 peer-reviewed articles. He has given many prestigious named lectures including the Marshall Parks Lecture at the AAO, the Costenbader lecture at AAPOS and the Richard Scobee Memorial Lecture for the AACO. Although he is considered an expert in multiple aspects of pediatric ophthalmology, Dr. Buckley, is perhaps best known for his research and clinical innovations involving the treatment of complicated strabismus and congenital cataracts.

Disruptive Innovation

Predicting the Future of Medicine

Edward G. Buckley, MD

Professor of Ophthalmology and Pediatrics
Associate Dean for Medical Education
Duke University Medical School

A Glimpse into the Future of Health Care

- Complains to friend – my right elbow is sore
- Friend suggests “NEW” machine at Drug Store. Just need urine sample
- Goes to store – pours in urine sample
- Computer diagnoses “tennis elbow”
- Advises using warm compresses and rest for 2 weeks

The Future of Health Care

Decides to Test this “new” Technology

Mixes:

- Tap water
- Stool from dog
- Daughter/wife urine
- Smashes walnuts with a hammer
- Takes mixture to drug store

The Future of Health Care

Computer analyzes mixture

Advises:

Your water is hard – use softener

Dog’s got worms – needs treatment

Daughter is using Cocaine – needs rehab

Wife’s pregnant – twins – not yours –get lawyer

And if you don’t stop hammering –

your elbow will never get better

What happens to organizations ?

Of the organizations that existed in the Western World in 1530, only 66 have survived:

The parliament of Iceland
The parliament of the Isle of Mann
2 Churches
62 Universities

Educational institutions have an extraordinary ability to adapt

Why do organizations Fail?

Store Brands
Credit cards
Catalog retailing
Supply

Sears
Xerox
Digital Equipment
General Motors
RCA

?

Wal-Mart
Cannon
Dell, Compaq
Toyota
Sony

Bad management? Bureaucracy? Poor planning?
Inadequate skills? No resources?
Talented managers, strong products,
first rate technical know how, deep pockets

What Happened ?

Why could they not respond to change?

Either.....

1) The companies were *never* well managed

or

2) **Good management** was the reason they failed!

Was there is something about the way they were run that sowed the seeds for eventual failure ?

Best Business Practices

All these companies:

- Listened to their customers
- Invested in improvement technology
- Maximized return on investment
- Allocated resources for best returns

Why did these companies fail ???

Technology / Innovation

Labor
Materials
Capital
Energy
Information

Process

Outputs
of
Higher
Value

Innovations

Sustaining

Desktop computers

- Maintain rate of improvement
- Something more or better in the attributes they already have
- Make product or service better in ways which are already valued

Disruptive

Laptop computers

- Different attributes, cheaper, simpler
- Perform worse along one or two dimensions
- Doesn't address next needs of current users

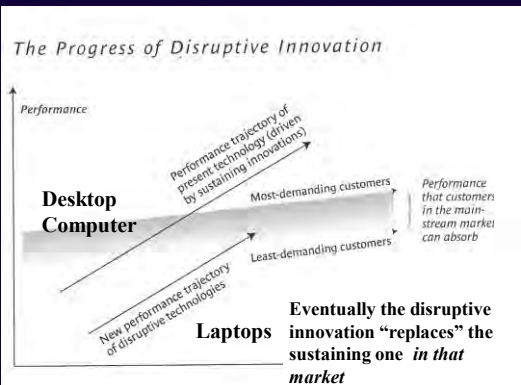
Disruptive Innovations

Enables...

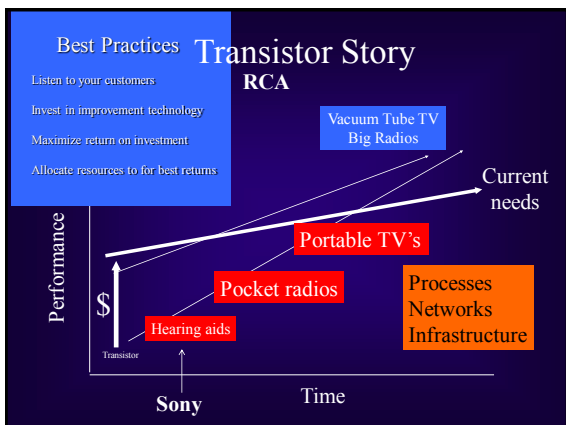
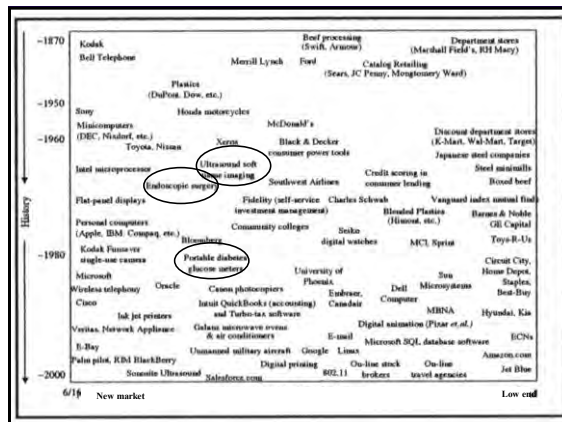
less skilled people
to do more conveniently,
in less expensive settings.....

Things that historically required....

expensive specialists
in centralized
inconvenient locations



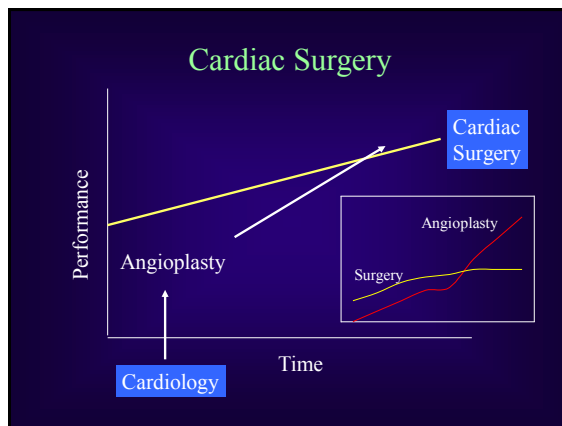
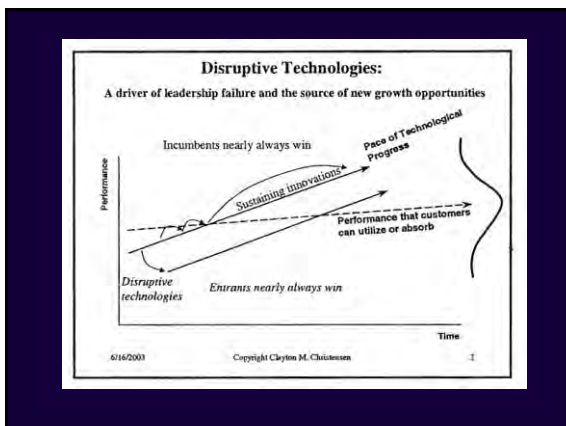
Examples: ??????

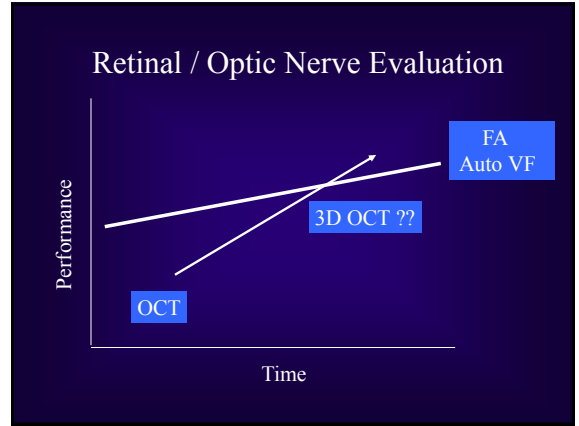
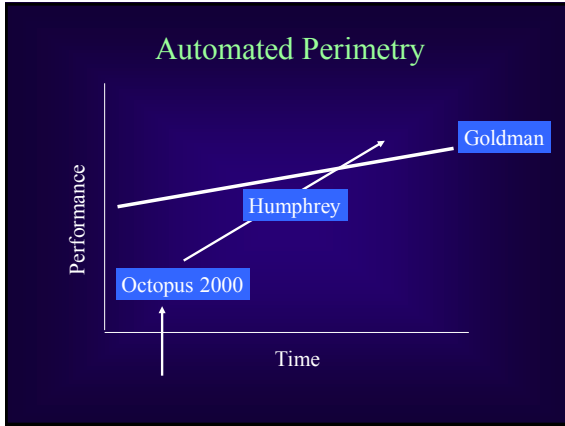


Disruptive Innovation

Why good companies fail

- Organizational impediments
- Lack of capabilities (radical change)
- Value Networks (resource allocation)



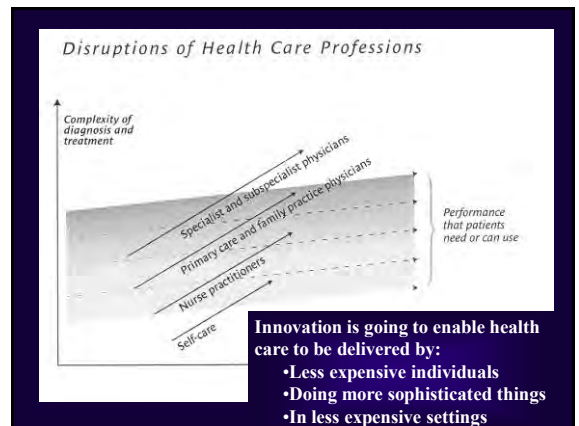
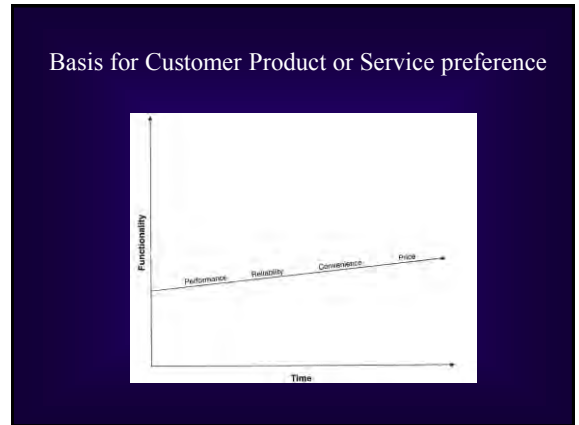


Basis for Customer Product or Service preference

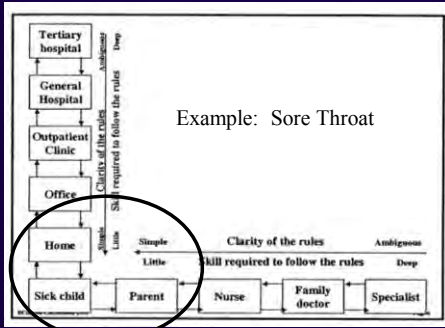
1. Functionality
2. Reliability
3. Convenience
4. Price

Performance oversupply

Academic vs Private Practice

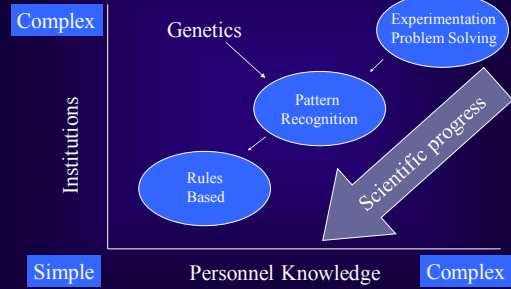


Treatment paradigm

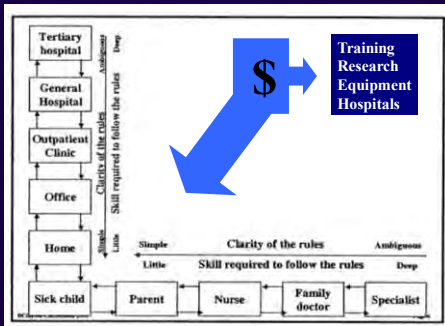


Scientific and Technological Disruptions

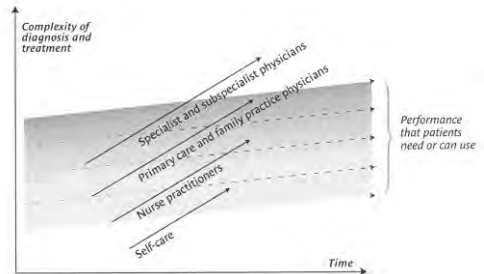
Leukemia



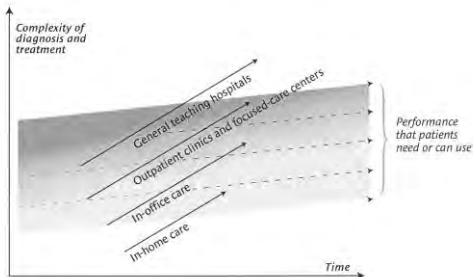
Business as usual in health care



Disruptions of Health Care Professions



Disruptions of Health Care Institutions



Disruptive innovations have.....

- Made health care more efficient
- Reduced costs
- Increased access
- Maintained quality

Diagnosis and treatment

Rule based - Nurse practitioners and PA's
Infectious diseases, hypertension, arthritis

Ophthalmic techs refracting

"the Medical Board of California published a legal opinion in April 2004 that, in its present form, prohibits ophthalmic and optometric allied health personnel from performing "subjective refraction" [refractometry] for California ophthalmologists and optometrists".

Christensen HBR 2000

Disruptive Innovation



3:00–5:00 PM

Subspecialty Symposia

Neuro-Ophthalmology 2013

Chair: Joshua Pasol, MD

Location: Ponce de Leon I-III

Saturday, June 29

3:00 PM	WELCOME AND INTRODUCTIONS Joshua Pasol, MD
3:00–3:45 PM	Pituitary Tumor and the Ophthalmologist Steven A. Newman, MD
3:45–4:00 PM	QUESTIONS AND ANSWERS
4:00–4:45 PM	Normal Tension Glaucoma Kuldev Singh, MD, MPH
4:45–5:00 PM	QUESTIONS AND ANSWERS
5:00 PM	ADJOURN

Pediatric Ophthalmology 2013

Chair: Arysol Soltero-Niffenegger, MD

Location: South Mezzanine 2

Saturday, June 29

- | | |
|--------------|--|
| 3:00 PM | WELCOME AND INTRODUCTIONS
Arysol Soltero-Niffenegger, MD |
| 3:00–3:30 PM | Where the Wild Things Are: When Neuro and Strabismus Collide
Edward Buckley, MD |
| 3:30–4:00 PM | The Closer to South Beach, the Bigger the Muscles
Hilda Capo MD and Kara M. Cavuoto, MD |
| 4:00–4:30 PM | The Infant Aphakia Treatment Study and Optimal Infant Cataract Management:
What Have We Learned So Far?
Stacey J. Kruger, MD |
| 4:30–5:00 PM | Visual Disability From Transient Diplopia
Craig A. McKeown, MD |
| 5:00 PM | ADJOURN |

Refractive Surgery 2013

Chair: Clifford L. Salinger, MD

Location: South Mezzanine 3–4

Saturday, June 29

- | | |
|--------------|---|
| 3:00 PM | WELCOME AND INTRODUCTIONS
Clifford L. Salinger, MD |
| 3:00–3:20 PM | Higher Order Aberrations Following Lasik & RK
Warren E. Hill, MD |
| 3:20–3:40 PM | How Can We Get 20/15 by 2015 in All of Our Patients?
Karl G. Stonecipher, MD |
| 3:40–4:00 PM | Lenticular Refractive Surgery Options in Clinical Practice
Frank W. Bowden, III, MD |
| 4:00–4:20 PM | The Role of Ocular Surface Disease in Refractive Surgery
Peter J. Polack, MD |
| 4:20–4:40 PM | Use of a Novel Topically Applied IL-1 Receptor Antagonist in Patients with Moderate to Severe Dry Eye Disease
Michael H. Goldstein, MD, MM |
| 4:40–5:00 PM | IntraStromal Astigmatic Keratotomy (ISAK) with a Femtosecond Cataract Laser for the Intraoperative Reduction of Corneal Astigmatism During Routine Cataract Surgery
William W. Culbertson, MD |
| 5:00 PM | ADJOURN |

Retina-Vitreous 2013

Chair: Stephen G. Schwartz, MD, MBA

Location: South Mezzanine 9–10

Saturday, June 29

3:00 PM	WELCOME AND INTRODUCTIONS Stephen G. Schwartz, MD, MBA
3:00–3:20 PM	SD OCT of White Spot Syndromes Lee M. Jampol, MD
3:20–3:30 PM	Posterior Segment Tumors: An Update J. William Harbour, MD
3:30–3:40 PM	Viral Infection of the Posterior Segment Janet L. Davis, MD
3:40–3:50 PM	The Clinical Course of Vitreomacular Adhesion Managed by Initial Observation Harry W. Flynn, Jr., MD
3:50–4:00 PM	Surgical Approaches to Molecular Genomic Profiling in Uveal Melanoma Timothy G. Murray, MD
4:00–4:10 PM	Current Status of the Implantable Miniature Telescope (IMT) in Florida Marc H. Levy, MD
4:10–4:20 PM	Ocriplasmin in the Treatment of Symptomatic Vitreomacular Adhesion and Macular Hole Jorge A. Fortun, MD
4:20–4:30 PM	Masquerade Syndrome Jaime H. Membreno, MD
4:30–4:40 PM	Floater Scotoma Stephen G. Schwartz, MD, MBA
4:40–5:00 PM	QUESTIONS AND ANSWERS
5:00 PM	ADJOURN

Sunday, June 30, 2013


Steven I. Rosenfeld, MD, FACS

Dr. Rosenfeld is a board-certified, fellowship-trained ophthalmologist who specializes in medical and surgical treatments of corneal conditions, infectious and inflammatory eye diseases, refractive surgery, and cataract surgery. Dr. Rosenfeld has been in private practice with Delray Eye Associates, PA since 1985. He is a fellow of the American College of Surgeons and the American Academy of Ophthalmology, and an Associate Examiner for the American Board of Ophthalmology. Dr. Rosenfeld currently serves as a Voluntary Professor on the clinical faculty at the Bascom Palmer Eye Institute, University of Miami Miller School of Medicine, where he has been on the faculty since completing his fellowship. Dr. Rosenfeld has been a Committee Member on the Board of OMIC since 2010.

Dr. Rosenfeld has authored dozens of textbook chapters and scientific articles on the topics of cataract surgery, PRK and LASIK surgery, corneal transplant surgery, and ocular infections. He has co-authored two recent textbooks — one on Lens and Cataract Surgery and one on Refractive Surgery — under the auspices of the American Academy of Ophthalmology. He is on the editorial review boards of *EyeNet* magazine and Focal Points Clinical Modules and is a reviewer for *Ophthalmology* and the *American Journal of Ophthalmology*. Dr. Rosenfeld has been honored with numerous awards from the American Academy of Ophthalmology, including the Achievement Award, Senior Achievement Award, and Secretariat for Education Award and Lifelong Education for the Ophthalmologist Award. He is also a recipient of the Physician's Recognition Award from the American Medical Association and is listed as one of the best doctors in *Best Doctors in America*, *Who's Who in America*, *Who's Who in the World*, *Top Doctors*, and Florida Super Doctors, just to name a few. Dr. Rosenfeld frequently lectures at ophthalmic meetings nationwide.

Dr. Rosenfeld earned his undergraduate degree with honors at the Johns Hopkins University and was elected Phi Beta Kappa. He obtained his medical degree at the Yale University School of Medicine, where he was elected into the Alpha Omega Alpha Honor Medical Society. He completed his medical internship at Yale/New Haven Hospital and his ophthalmology residency at Barnes Jewish Hospital at Washington University School of Medicine in St. Louis. Dr. Rosenfeld continued his extensive training with a Heed Foundation Fellowship in Cornea and External Diseases at the Bascom Palmer Eye Institute in Miami.

Dr. Rosenfeld is a member of numerous professional associations, including the American Academy of Ophthalmology, the American Society for Cataract and Refractive Surgery, the Association for Research in Vision and Ophthalmology, the Ocular Microbiology and Immunology Group, the Cornea Society, the Society of Heed Fellows, the Eye Bank Association of America, the Paton Society, the International Society of Refractive Surgery, the Florida Medical Association, the Florida Society of Ophthalmology, the Palm Beach County Ophthalmology Society and the Palm Beach County Medical Society.




OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

Closed Claims Study and Areas Where Medical Malpractice Occurs

Steven I Rosenfeld MD

Florida Society of Ophthalmology
June 30, 2013
Palm Beach, FL

Sponsored by the
American Academy of Ophthalmology




OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

Legal Elements of Medical Malpractice "The Four D's"

- **D**uty of MD to treat patient
- **D**eviation from standard of care (requires expert testimony)
 - What would a reasonably prudent physician do in the same or similar circumstances?
- **D**irect causal relationship between deviation and the alleged injury/damages (ie. proximate cause)
- **D**amages: actual economic and non-economic
 - If paid = "indemnity" payment

Sponsored by the
American Academy of Ophthalmology

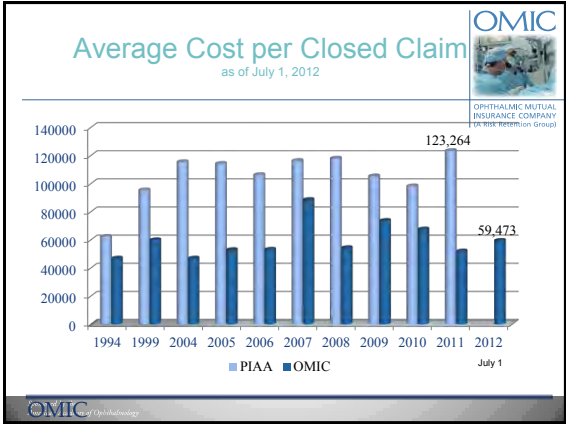
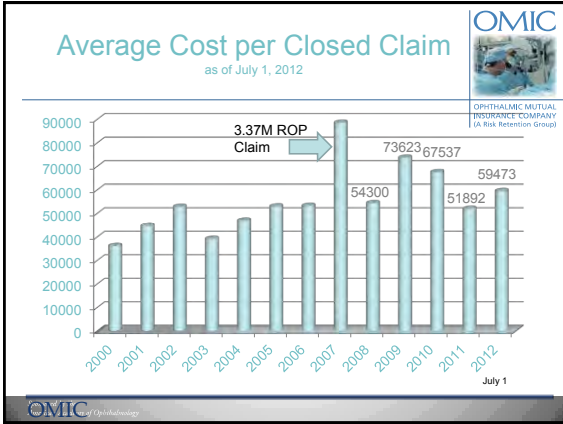
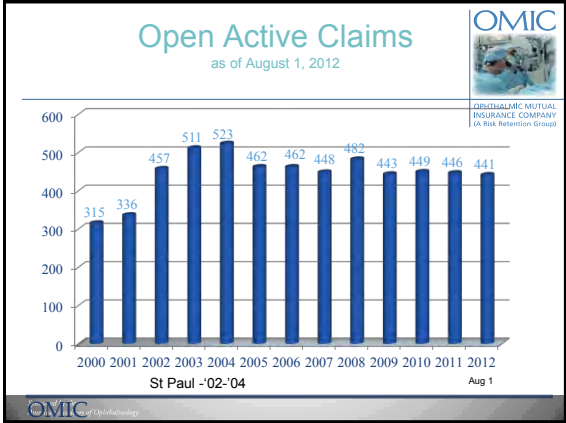



OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

OMIC Claims Experience

Where are claims happening?

Sponsored by the
American Academy of Ophthalmology






OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

By Specialty

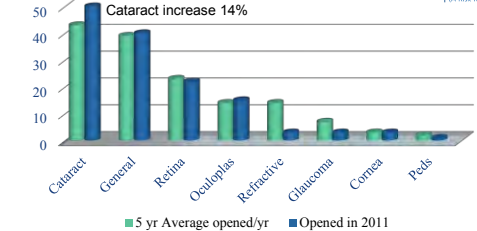
Sponsored by the
American Academy of Ophthalmology



OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)


Frequency by Specialty

Claims Opened per year
as of December 31, 2011



■ 5 yr Average opened/yr ■ Opened in 2011

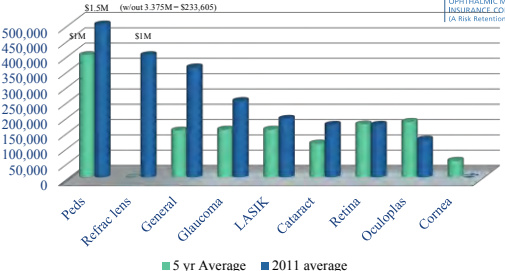
OMIC of Ophthalmology



OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)


Severity by Specialty

Average Settlements per year
as of December 31, 2011



■ 5 yr Average ■ 2011 average

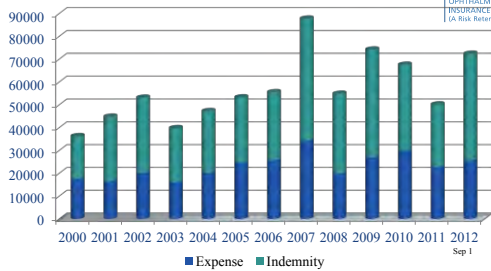
OMIC of Ophthalmology



OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

Average Cost per Closed Claim


as of September 1, 2012



■ Expense ■ Indemnity

Sep 1

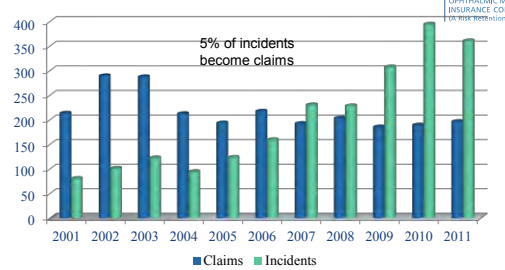
OMIC of Ophthalmology



OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

Opened Claims vs. Incidents


January 1 to December 31, 2011



■ Claims ■ Incidents

5% of incidents become claims

OMIC of Ophthalmology



OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

OMIC's Top Ten Settlements 2011

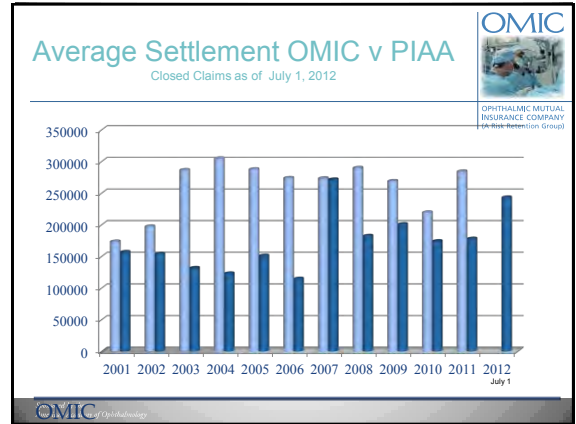
Amount	Description	Specialty	Date
\$1,500,000	ROP	Peds	12/14/11
\$1,000,000	Phakic implant & record errors Plaintiff verdict	Refractive	8/2/2011
\$1,000,000	Failure Dx Foreign body-enucleation	General	12/21/2011
\$ 883,416	Code during Cataract Surgery	Surgicenter	9/19/2011
\$ 800,000	Severe Corneal burn	Entity	10/19/2011
\$ 755,204	Vitrectomy for RD	Retina	12/6/2011
\$ 588,443	Corneal Rupture	General	6/20/2011
\$ 475,000	Failure Dx RD	General	12/7/2011
\$ 450,000	Delayed Dx/referral Glaucoma	General	12/13/2011
\$ 450,000	Steroids post LASIK= Glaucoma	Refractive	11/14/2011

OMIC of Ophthalmology

OMIC's Largest Settlements

Amount	Description	Specialty	Year
\$3,375,000	ROP	Retina	2007
\$2,000,000	Gloma in 10 mo old baby	Pediatric	2009
\$1,800,000	Glaucoma in 8 yr old	Pediatric	2001
\$1,500,000	ROP	Peds	2011
\$1,000,000	Rx of corneal ulcer in 2yr old	General	1999
\$1,000,000	MisDx sarcoid/Pred overdose	General	2002
\$1,000,000	ROP	Pediatric	2009
\$1,000,000	ROP	Pediatric	2010
\$1,000,000	Phakic implant & record errors Plaintiff verdict	General	2011
\$999,999	Stroke S/P strabismus surgery	General	1999
\$983,771	LASIK ectasia	Refractive	2006

9-1-2012



Case Study 1- Group Liability

Negligent Retinal Surgery and Mgmt. of Pt.

Elderly female patient with retina problems, seen by multiple physicians in a group practice over a long period of time.

- 11/04- Physician #1, Retinal specialist-
 - Pars plana vitrectomy OS for vitreous hemorrhage.
 - Marked sheathing of the vasculature, possible CRVO.
- 2/05- Postop Pt developed cataract and RD OS.
 - Scleral buckle, vitrectomy and silicone oil OS.
 - CF vision but stable.
- 4/05- IOP in 50s, refer to physician #2, Glaucoma specialist in group.
 - Timolol and Diamox Rx.
 - IOP down to 33 OD and 8 OS.
 - Uveitis was felt to contributing to increased IOP OU

Negligent Retinal Surgery and Mgmt. of Pt.

- 10/07- Cat surgery OD by Physician #3 in group,
 - no red reflex present
 - Post capsule not well defined so IOL not placed
 - At FU/- whitish red reflex present
 - VA OD=HM
 - Refer back to Physician #1, retinal specialist
- 10/23/07- Retinal specialist –Pars plana vitrectomy w endolaser OD due to non clearing vitreous hemorrhage.
- 12/19/07- Found RD OD w/ no retinal break.
 - Suspect exudative RD, recommended surgery OD
- 3/4/08- Retinal specialist found recurrent RD OD
- 3/18/08 RD repair OD, removed silicone oil.
 - Optic nerve appeared pale and vessels attenuated.

Negligent Retinal Surgery and Mgmt. of Pt.

- 4/29/08- Retinal specialist referred Pt to University physician because subretinal fluid re-accumulating and new retinal hemorrhage OD.
- 5/07/08- Retinal specialist spoke w/ Pt and family, was told that Pt was going to have corneal transplant. University physician said optic nerve OD had been severed. Our insured retinal specialist advised they misunderstood because that would have resulted in NLP.
- DAMAGES: OD- 20/30 to HM. OS- CF but stable
- Allegation: Care OD negligent and caused her to lose her on good eye. Now blind OU.

Negligent Retinal Surgery and Mgmt. of Pt.



OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

Defense-

- Iritis did not cause problem and glaucoma did not cause problem. Glaucoma physician did not do VF or put a numerical value on cup to disc. (claimed he was managing an emergent situation).
- SOL defense for OS care but not OD.
 - Physician #1 saw Pt 2004 to 2005. F/U 4-6 mos. No appt set, 26 mos till next appt.
 - Physician #2 saw Pt 2006, and Pt filed claim two years later.
- GROUP saw Pt during the entire time so liable for entire course of care.

OMIC Ophthalmology

Negligent Retinal Surgery and Mgmt of Pt.



OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

•Physician #1 (Retinal specialist) and entity settled, other physicians dismissed:

- \$500,000 physician #1
- \$225,000 entity
- Risk Management Issues:
 - Documentation
 - Follow Up
 - Group Liability

OMIC Ophthalmology

Case #2- Vicarious Liability Risk of Surgical Facility



OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

OMIC Ophthalmology

Wrong IOL inserted Cataract Surgery



OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

- 7/16/07- Physician performed Cat Surg OD. Ordered correct lens. Hospital pulled lenses, and handed wrong IOL to physician (intended for later case).
- Physician discussed with Pt. More myopic than planned.
- Offered lens exchange
- 8/20/07- Lens exchange OD. Postop 20/20. Pt went to University to confirm done correctly.

Liability
15-20% chance of defense verdict. Verdict range: \$150-\$250K. Settlement range: \$50K-\$100K

Physician settled for \$75,000
Hospital settled for \$75,000

OMIC Ophthalmology

Wrong IOL inserted Cataract Surgery



OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

Claim settled for \$75,000
Expenses to defend claim \$87,000

OMIC Ophthalmology

Wrong IOL inserted Cataract Surgery




OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)


- Risk Management Issues
 - Inability to find supportive defense experts
 - Stuck on "Captain-of-the-ship" theory.
 - Documentation clear that physician ordered correct lens and hospital ordered correct lens
 - Physician needs to verify power of the lens prior to insertion**

OMIC Ophthalmology


Case #3- Timely Referral



OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)




Failure to properly refer patient resulted in stroke




OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

- 2/14/07- 53 yo male presented to ophthalmologist with c/o 8-9 episodes of acute LOV right eye, associated with bending over or straining. Reported vision became very gray except for small area at the top. Episodes lasted 4-5 minutes with slight pain at times.
- Uneventful eye exam except for PSC cataract OD
- Assessment: Transient retinal arterial occlusion OD
- Bending the neck caused a plaque to break off and float to the ophthalmic artery or transient vascular compression.
- Instructed Pt to see his PCP w/in 2 weeks, and call ophthalmologist if increase in pain, redness or decreased vision




Failure to properly refer patient resulted in stroke




OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

- 2/21/07 – Pt taken by ambulance to ER after suddenly collapsing at work. Arrived within 40 minutes of incident.
 - Speech slurred, left side weakness.
 - CT showed hyperdense clot in the right cerebral artery consistent with acute vascular occlusion (CVA).
 - Pt. received thrombolytics and admitted to ICU to monitor.
- 2/26/07- CT of head due to c/o increased weakness. Showed high attenuation of the right basal ganglia w/ some adjacent low attenuation changes.
 - Indicative of subacute intracranial hemorrhage, location consistent w/ hypertensive bleed.




Failure to properly refer patient resulted in stroke




OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

- 2/28/07- Pt. underwent carotid endarterectomy and angioplasty
- 3/2/07 - CT showed resolving hemorrhage
- 3/3/07 – Pt. discharged from the hospital w/ left side weakness. Rehab needed.
- 4/07- Pt. suffered myocardial infarction and underwent coronary balloon angioplasty
- 6/07- Pt underwent CABG.




Failure to properly refer patient resulted in stroke




OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

Liability:

- OMIC review found care was below SOC:
 - Earlier referral to PCP.
 - Differential Dx of CVA would have helped defense but not documented.
 - No sed rate obtained.
 - Pt negligence also noted by one of OMIC reviewers.
- Defense Experts (3) supported ophthalmologist. However; likely that a plaintiff expert would be found to support immediate referral to PCP.



Failure to properly refer patient resulted in stroke





OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

Damages

- Loss of earnings, loss of earning capacity, permanent neurological impairment, and continuing medical expenses.
- OMIC retained Neurology expert believed slight dexterity problems in left hand – not enough to prevent work. No cognitive deficits.
- Verdict potential: \$1-2 million. Settlement range: \$500K – 750K


Settled for \$500K
\$300 physician and \$200K practice entity






OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

Case #4: Negligent Injection of Kenalog







OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

Negligent Injection of Kenalog

- 56 yo male pt
- 5/5/09- Pt given Kenalog injection OD for proliferative diabetic retinopathy (PDR) and subsequently developed uveitis.
- 5/7/09- Pt c/o of decrease in vision after injection. Will call for an appt.
- 5/8/09- VA CF 6 feet OD. Dx Pseudoendophthalmitis OD, Rx Vigamox drops
- 5/9/09- DDX of endophthalmitis versus allergic reaction OD. Physician recommended Rx for infection but Pt wanted to observe.
- 5/12/09- Uveitis decreased OD. Laser recommended for PDR OS. Pt. wanted only OD Rx'd.
- 5/19/09- VA 20/200 OD, 20/25 OS with uveitis OD.
- 6/1/09 and 6/2/09- VA HM OD. Acute rise in IOP. Anterior Chamber paracentesis.
- 6/3 and 6/4/09 No show for F/U appts. Referred to Glaucoma specialist with appt. for 6/8 arranged.







OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

Negligent Injection of Kenalog

- 6/6/09- Condition worsens. c/o of nausea. Pt checked for acute glaucoma. Exam revealed severe PDR and macular edema. Vision: LP OD, IOP 52 OD. Pt was offered but declined another anterior chamber paracentesis. Pt to see Glaucoma consultant on June 8th.
- 6/17/09- Glaucoma consultant reported Pt underwent an uncomplicated MMC Trabeculectomy OD.
- 6/23/09- Conversation between ophthalmologist and Glaucoma specialist, discussed diagnostic vitrectomy to clear vitreous debris and photocoagulation for extensive diabetic retinopathy and to rule out infection.







OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

Negligent Injection of Kenalog

Damages

- Vision decreased from 20/40 to CF 2 feet.
- Liability: Questionable
 - Unfortunate case wherein two possible complications, sterile uveitis and increased IOP both occurred.
- Settlement Value: Under \$350K
- % Chance for Defense Verdict: 60-70%
 - Some non compliance but minor.







OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

Negligent Injection of Kenalog

- Went to Trial
 - Plaintiff Expert was not a retinal specialist.
 - Defense attorney skillful at cross examination of plaintiff expert
 - Consent documentation good.
 - Employees of practice testimony on non-compliant behavior of Pt
 - Defense expert very qualified and supported treatment.
 - Including off label use of Kenalog (testified 60% of injections were off label).
 - Pt's other health issues: hypertension, diabetes, stroke, coronary artery disease with heart attack

After 2 ½ hours of deliberation: Defense Verdict
(Note: Case had a potential value of \$350,000)






OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

Thank You!

FSO Members insured by OMIC: Turn in the sign-in sheet so you can receive your 10% premium discount!



Steven A. Newman, MD

After obtaining his undergraduate degree in physics from Princeton University, Dr. Newman attended the Albert Einstein School of Medicine, and was inducted into Alpha Omega Alpha. He did his internship, medical and ophthalmology residencies at the Washington School of Medicine in St. Louis, and was a staff fellow at the National Health Institute. Dr. Newman completed a fellowship in neuro-ophthalmology at the Wilmer Eye Institute in Baltimore. He held professorships in ophthalmology and neurology at the University of Virginia and currently serves as Professor of Ophthalmology at UVA. He has lectured and published extensively.

Dr. Newman has been recognized with an Honor Award, a Senior Honor Award, and Lifetime Achievement Award from the American Academy of Ophthalmology as well as three Secretariat Awards and received a Faculty Award from Joint Commission on Allied Health Personnel in Ophthalmology. He is a member of International Neuro-Ophthalmology Society, the North American Neuro-Ophthalmology Society, the Association for Research in Vision and Ophthalmology and the Pan-American Society of Ophthalmology. He is a fellow of the American Academy of Ophthalmology and the North American Neuro-Ophthalmology Society. He has also served as the NANOS Representative to the Council of the American Academy of Ophthalmology, chairman of the Neuro-Ophthalmology Section V of the BCSC, and member of the POC/MOC committees, as well as past Chairman of the Compass Committee. He is past Vice President of the North American Neuro-Ophthalmology Society, past President of the North American Skull Base Society, and past President of the Cogan Ophthalmic History Society. He is the orbital consultant at Walter Reed Army Medical Center. His international missions include work with ORBIS in Bangladesh and Virginia Children's Connection in India.

Neuro-ophthalmic Diagnoses Not to Miss



Steven A. Newman, MD
Charlottesville, VA

Importance of Neuro-ophthalmic Diagnoses

- Severe consequences
 - Irreversible damage to the patient (potentially treatable; things that can kill the patient)
 - Medicolegal implications
- Unusual unexpected pattern
 - Delay in diagnosis: expense
 - Consequence for patient
 - Do you have to call me every day?

Severe Consequences

- Keep you out of trouble
- “First we’ll kill all the lawyers”
- This is what you came to this lecture for

BAW 81yo female

9/10: ↓Va

Va 20/200, 2/200

N 20/400 OD

VF:

Ext: w/q

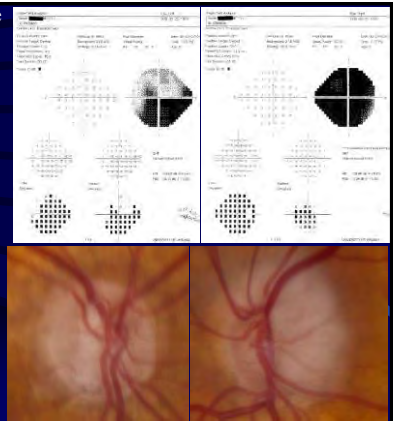
P: 1.2log RAPD

EOM: full

SLE: PC-IOL

Ta: 10 OU

Fundus:



BAW – POH

Glaucoma X 20yrs

2000: Phaco OD

2007: Phaco OS

9/10 (2wks before): check up glaucoma

Va 20/30 OU

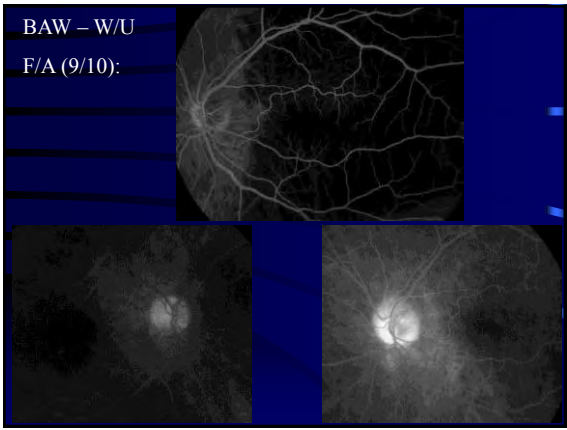
Ta: 16 OU

9/10 (10d before): light sensitivity

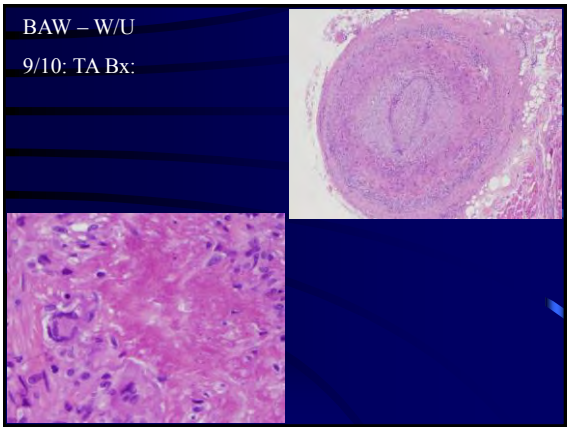
Rx: “Wear sunglasses”

BAW – PMH

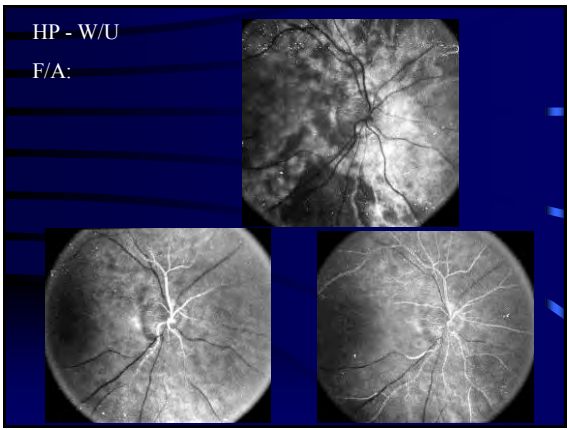
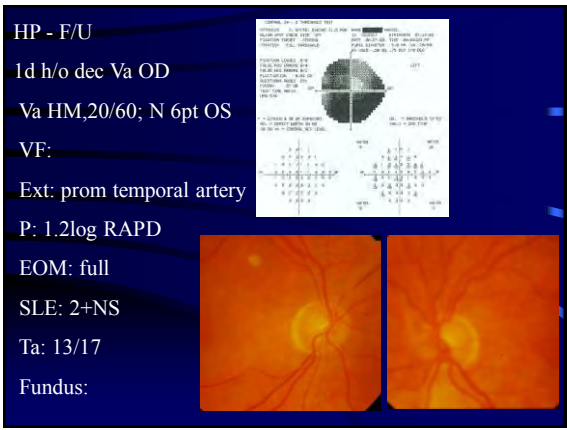
9/10 (9d before): “Pain in head & jaw, sometimes
shoulder + sore throat”



BAW – W/U
9/10: ESR: 74
Platelets: 554k
CRP: 77.9



HP 78yo male
PMH: AODM
POH: POAG on Timoptic
6/88: 3mo h/o temporal & occipital HA, jaw claudication
4d h/o blue vision
Evaluation: Va 20/50,20/60
Ext: tender temporal artery
ESR: 75



HP - W/U

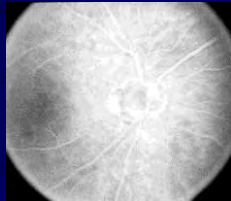
Ta Bx: GCA

Rx: 2gm IV methylprednisolone

Va 20/200,20/60

F/A:

80mg prednisone



CWA 86yo male

10/05: 1yr h/o dec Va OS

2d transient dec Va OD

Va 20/50,CF 1'

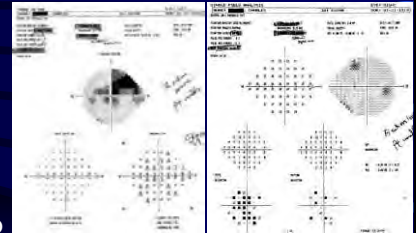
N J7,20/800

VF:

P: LAPD

SLE: 3+NS

Fundus: ARMD



CWA - Rx

11/05: Phaco OS

CWA - F/U

12/05: episodic visual loss OD

Va CF 5',HM; N J10 OD

VF: severe constriction

Ext: w/q

P: LAPD

SLE: 1+ C/F OS

Ta: 16/10

Fundus: disc edema OD

ESR: 24

CWA - F/U

1/06: ER w/ "vesicular" eruption

Dx: zoster

Rx: Valtrex

Residual tenderness over scalp

Trouble w/ swallowing

CWA

3/06: Referral

Va 20/50,LP

N 8pt OD

VF:

Ext:

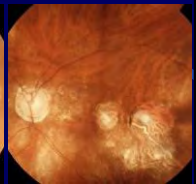
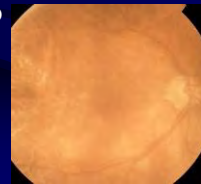
P: >1.8log LAPD

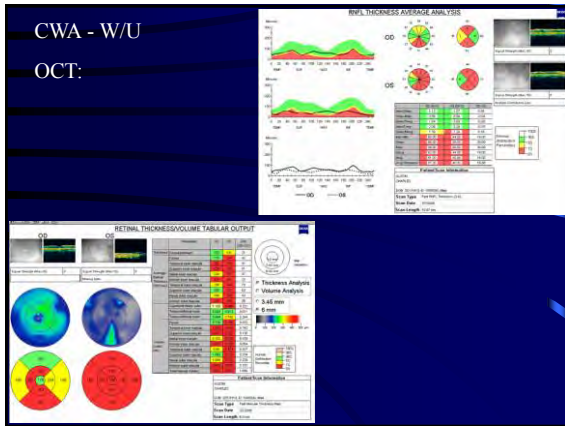
EOM: full

SLE: 3+NS OD

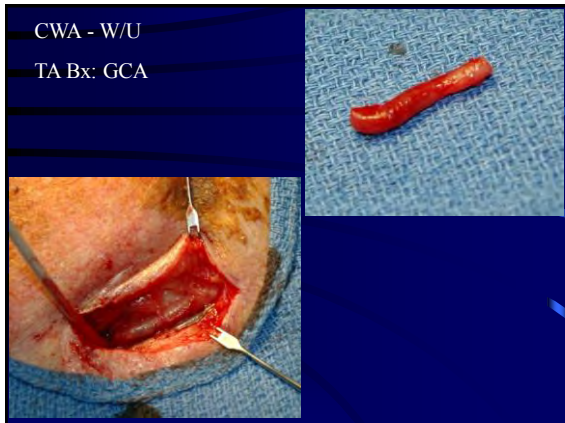
Ta: 13 OU

Fundus:





CWA - W/U
ESR: 17
CRP: 1.1



CWA - Rx
IV pulse steroids
Prednisone


Severe Consequences

- Giant cell arteritis


Giant Cell Arteritis

- Only 5% of AION
- ESR not always elevated
- Preceding amaurosis
- Diplopia possible
- Jaw claudication very suggestive
- Rx first (IV steroids); bx later
- Incidence dramatically inc w/ age

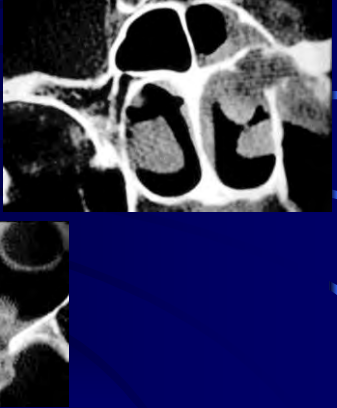
EL 82yo woman
 7/85: 6wk h/o L brow ache
 5wk h/o L ptosis + diplopia
 4wk h/o sudden visual loss OS
 Dx: "GCA"
 Bx TA: negative
 Rx: prednisone



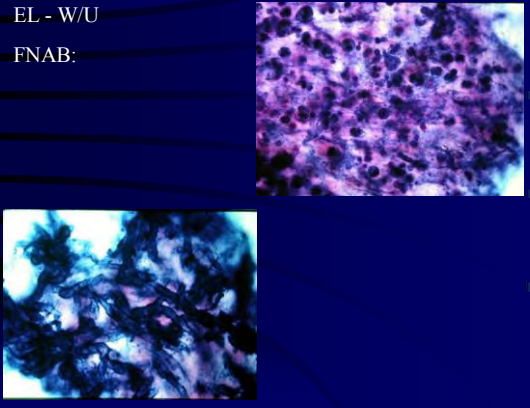
EL- PE
 Va 20/30, NLP
 VF: slight constriction OD
 Ext: 8mm L ptosis, H 19/22
 P: 4+ LAPD
 EOM: absent abd OS, limit vertical
 SLE: 2+ NS
 Fundus: early OA OS





EL - W/U
 Review CT:



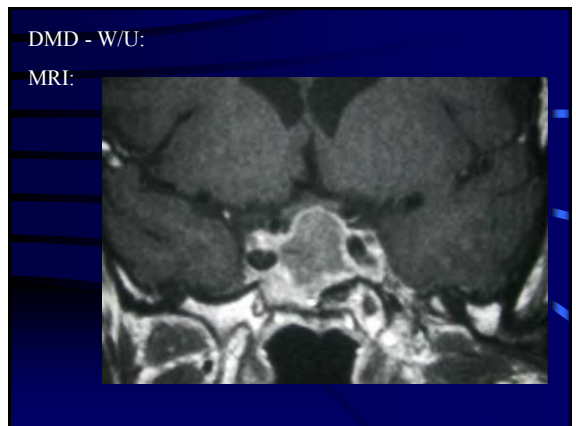
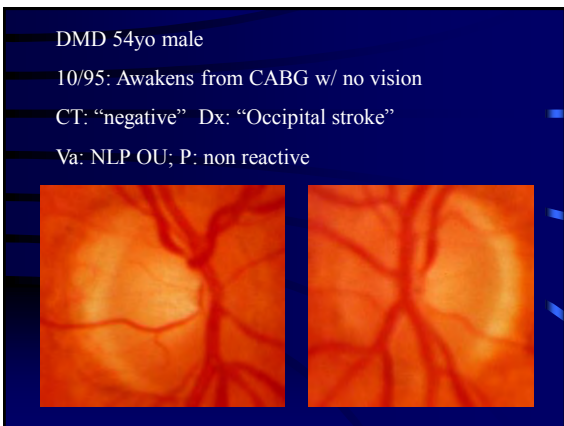
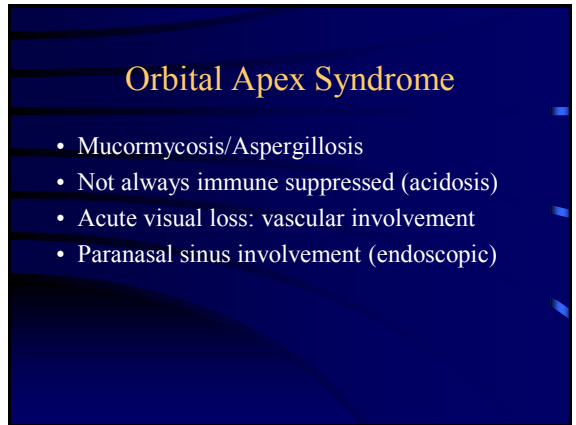
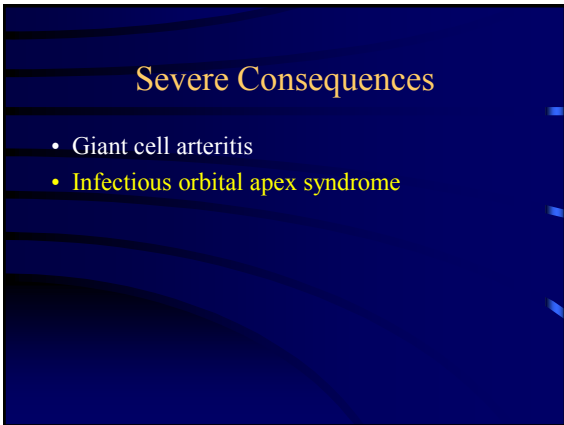
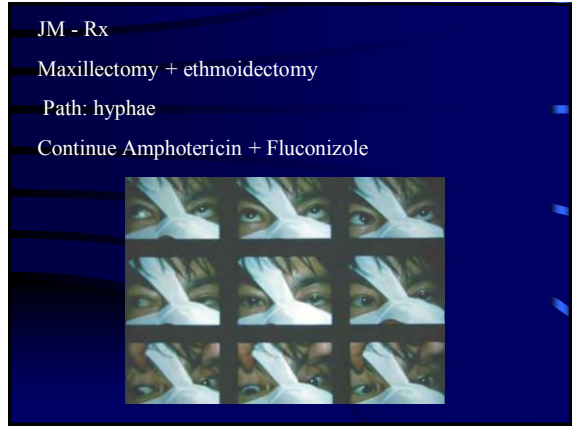
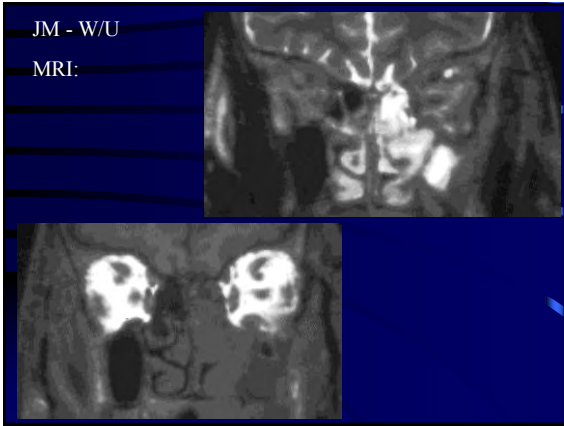
EL - W/U
 FNAB:



JM 35yo male
 10/96: 20d h/o redness L face
 4d h/o dec sensation L face
 2d h/o double vision
 N 3pt,5pt
 VF: CF all quad
 Ext: no corneal OS, H 15/16
 P: 5/3 w/o APD
 EOM: dec abd OS
 Fundus: nl DMV

JM - PMH
 Dx: DM
 Ketoacidosis before transfer
 Rx:
 Timentin
 Vancomycin
 Acyclovir
 Cipro
 Amphotericin



Severe Consequences

- Giant cell arteritis
- Infectious orbital apex syndrome
- Pituitary apoplexy

Pituitary Apoplexy

- Acute onset
 - Decrease vision
 - Ophthalmoplegia
 - Mental status changes
- Pituitary tumor not always known before hand
- Surgery may precipitate a bleed

PE 45yo female

9/08: 1wk HA + diplopia

N 6pt, 3pt

VF: full

Ext: R ptosis

P: 4.5/3 w/o APD

EOM:

PLE: wnl

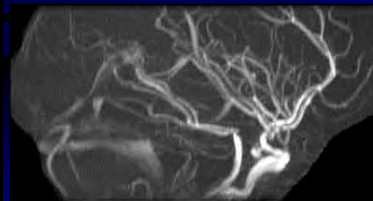
Tt: soft OU

Fundus: nl DMV



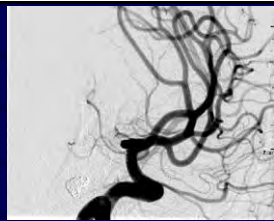
PE – W/U

MRA (9/08):



PE – Rx

9/08: Coil P-com aneurysm



PE – F/U

12/08: Double gone

Va 20/20 OU

VF: full

Ext: Palp 7/9

P: 3/3.5 w/o APD

EOM:

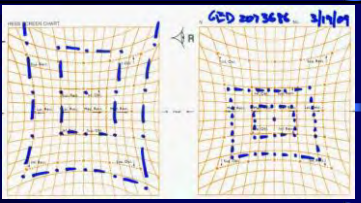
SLE: wnl

Tt: soft OU

Fundus: nl DMV



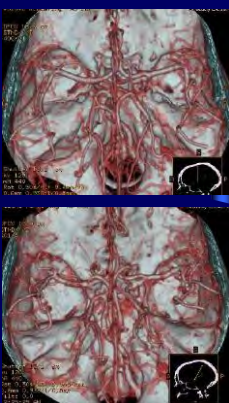
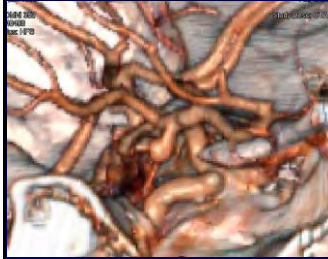
GED 54yo female
 3/09: Double vision
 Va 20/20 OU
 N 4pt,3pt
 VF:
 Ext: palp 8/10
 P: 3-2 w/o APD
 EOM:
 SLE: wnl
 Ta: 20/16
 Fundus: nl DMV



GED – W/U
 Pneumotonometry



GED – PMH
 CTA:



Severe Consequences

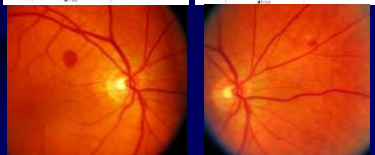
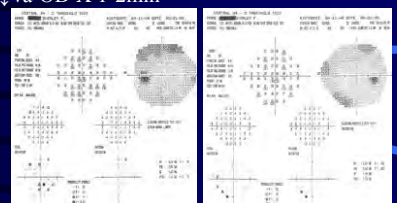
- Giant cell arteritis
- Infectious orbital apex syndrome
- Pituitary apoplexy
- Aneurysmal IIIrd nerve palsy

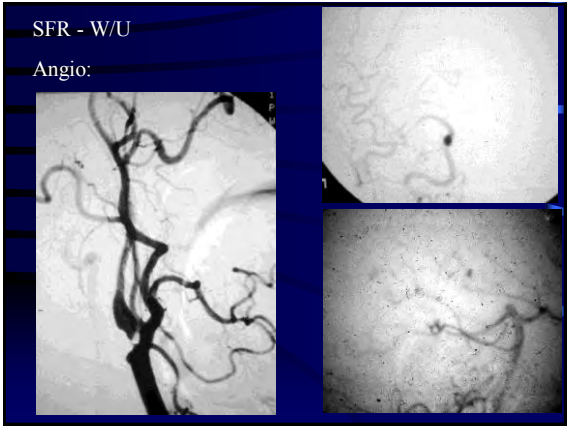
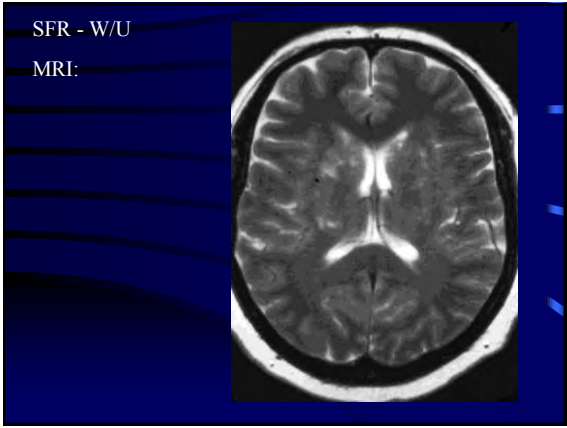
Aneurysmal IIIrd

- Pupil sparing not present (for acute p-com)
 - Pupil sparing not rare w/ cavernous mass
- Potential for missing w/ MRA/CTA
- Sentinel bleeds

SFR 59yo female
 9/99: 2-3mo h/o ↓Va OD X 1-2min

Va 20/20 OU
 N 3pt OU
 VF:
 Ext: w/q
 P: w/o APD
 EOM: full
 SLE: trace NS
 Ta: 18/17
 Fundus:





SFR - Rx
10/99: R carotid endarterectomy

- ### Severe Consequences
- Giant cell arteritis
 - Infectious orbital apex syndrome
 - Pituitary apoplexy
 - Aneurysmal IIIrd nerve palsy
 - Amaurosis fugax

- ### Amaurosis Fugax
- Carotid artery disease (17% proximal vessels)
 - Retinal emboli
 - Risk of hemispheric stroke
 - Age >75
 - Male
 - Hx of hemispheric TIA
 - >80% carotid stenosis
 - Lack collateral circulation
 - Non invasive carotid study
 - Death from cardiovascular disease

NFL 43yo male
4/08: Transient ↓Va OD
Va 20/20 OU
N 3pt OU
VF:
Ext: w/q
P: w/o APD
EOM: full
SLE: wnl
Ta: 15 OU
Fundus:

NFL – PMH

Very active: hang gliding, running

4/08: Dull R HA at time of visual loss (while hiking)
persistent

NFL – W/U



NFL – W/

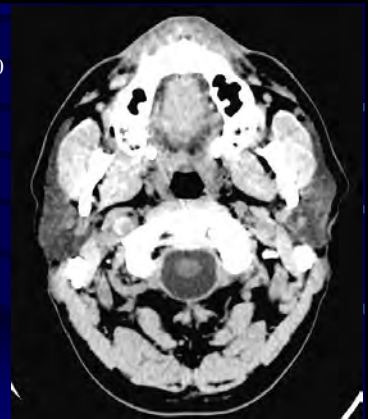
Cocaine test:



NFL – W/U

ODM: 90/45; 105/50

CT (4/08):



NFL – Rx

Heparin

Coumadin

6mo later switch to ASA

Severe Consequences

- Giant cell arteritis
- Infectious orbital apex syndrome
- Pituitary apoplexy
- Aneurysmal IIIrd nerve palsy
- Amaurosis fugax
- **Carotid dissection**

Carotid Dissection

- Traumatic (chiropractic) vs spontaneous
- Risk: fibromuscular dysplasia, Ehlers-Danlos IV
- Symptoms:
 - Facial pain
 - Horner's syndrome (58%)
 - Dysgeusia
- Consequence
 - Hemispheric stroke
 - CRAO/BRAO

Commonly Missed Diagnoses

- Afferent system: decreased vision
- Efferent system: double vision
- Orbital findings

CMB 65yo female

2/10: ↓Va

Va 2/200,20/30

N 20/800,3pt

VF:

Ext: w/q

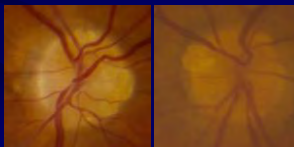
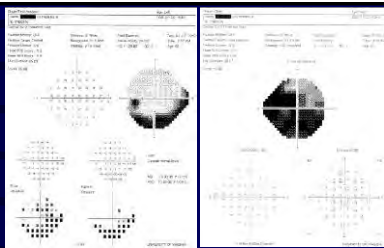
P: >1.8log RAPD

EOM: full

SLE: PC-IOL OD,2+NS OS

Ta: 14 OU

Fundus:



CMB – PMH

Breast cancer

s/p mastectomy

Diverticulitis

2007: Lymphoma

CMB – POH

2005: Cataract

10/05: Phaco OD

11/05: Va 20/25 OU

2/08: YAG OD

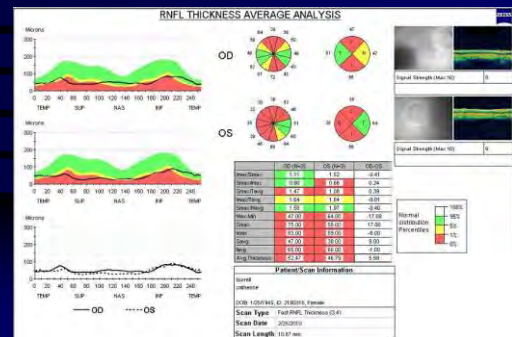
10/08: Va 20/25- OU

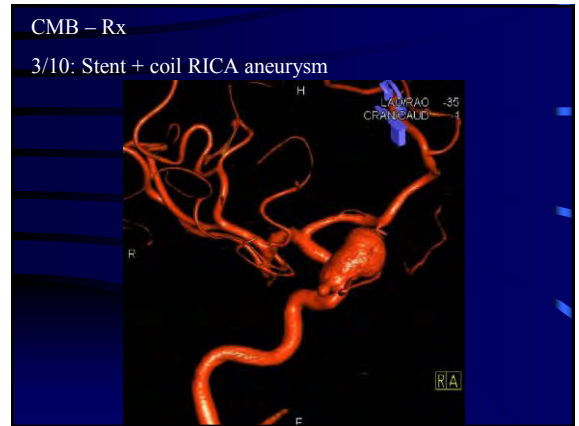
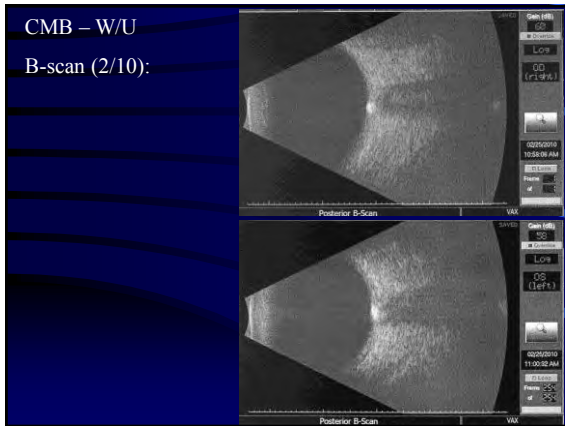
1/10: 1yr h/o ↓Va OD

Va CF,20/25

CMB – W/U

OCT NFL (2/10):





Commonly Missed Diagnoses

- Compressive optic neuropathy

Compressive Optic Neuropathy

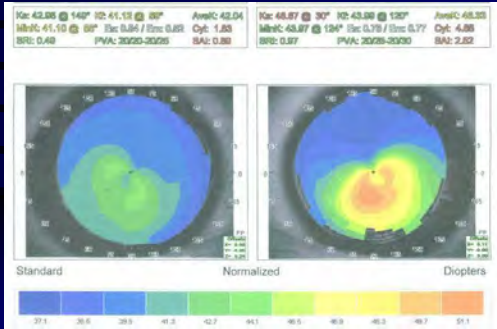
- Usually slowly progressive
- Get the old records:
 - Amblyopia
 - Previous tumor
- “Chronic optic neuritis”
- Importance of visual fields
- Importance of an afferent pupillary defect
- Avoid attributing to other diseases

SEY 25yo male
8/07: ↓Va
Va 20/20,20/40
N 3pt OU (5cm OS)
VF:
Ext: w/q
P: w/o APD
EOM: full
SLE: wnl
Fundus: nl DMV

SEY – POH
Glasses X 2yrs
2005: LASIK

SEY – W/U

Corneal topography:



Commonly Missed Diagnoses

- Compressive optic neuropathy
- Oil droplet cataracts
- Corneal pathology

Anterior Segment Pathology

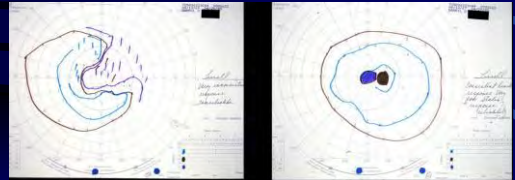
- Absence of an afferent pupillary defect
- Oil droplet cataract: double density (SLE)
- Corneal warpage (keratoconus): corneoscope
- Corneal topography or Pentacam
- Retinoscope



DOM 25yo male

4/93: Bilateral visual loss while in jail

Va: 3/200 OU; no APD; Disc: normal



DOM – W/U

ERG: wnl

Serology:

VDRL: neg

ESR: nl

ANA: negative

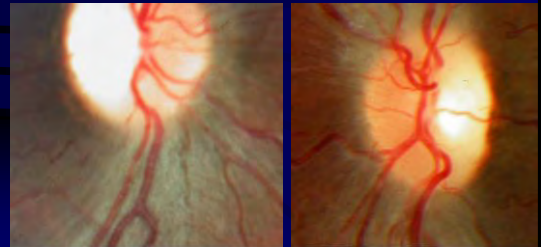
CBC: nl

DOM - W/U

Leber's genetic screen: + mutation at 3460

F/U (7mo): "Worse"

Va: 3/200 OU; N: 20/400 equiv OU



NFM 42yo female

11/92: 10mo h/o "blurred Va & trouble w/ colors"

Va: 20/70,20/200; N: 6pt,26pt; 3/10 HRR plates OU

VF:

Ext: w/q

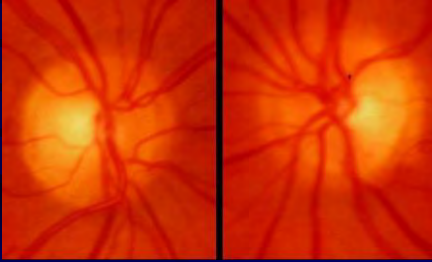
P: w/o APD

EOM: full

SLE: wnl

Ta: 19/16

Fundus:



NFM – PMH

4 laparotomies w/ small bowel resection 1973-7

Rx: Parenteral multivitamins + hydroxycobalamin

NFM – F/U

12/92(1mo): "Better"

Va: 20/25 OU

N: 3pt,4pt

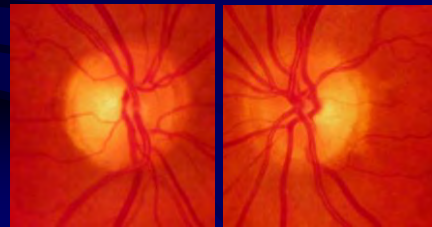
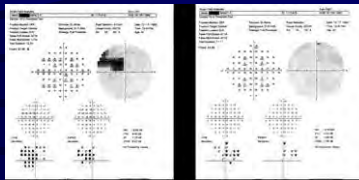
VF:

Ext: w/q

P: w/o APD

SLE: wnl

Fundus:



NFM - F/U

7/93 (8mo): "Marked improvement"

Va: 20/20 OU

N: 3pt OU

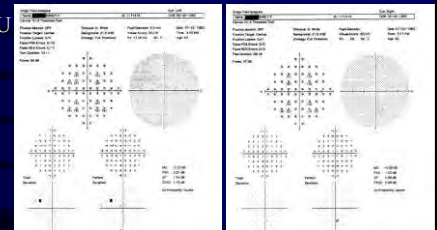
VF:

Ext: w/q

P: w/o APD

SLE: wnl

Fundus: PM dropout



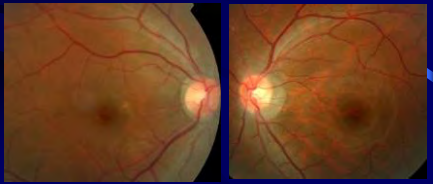
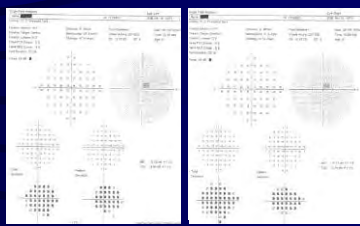
Commonly Missed Diagnoses

- Compressive optic neuropathy
- Oil droplet cataracts
- Corneal pathology
- Hereditary/Metabolic optic neuropathies

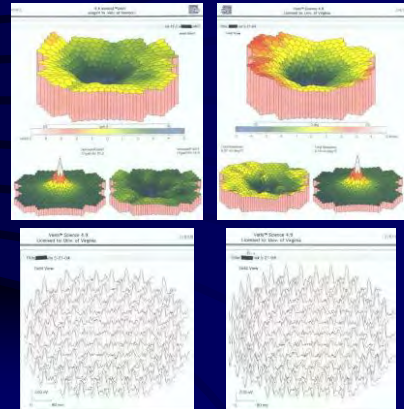
Hereditary/Metabolic Optic Neuropathy

- Central scotoma
- Discs may be normal early
- Ask for family history: maternal
- Previous GI surgery

BL 31yo male
 5/04: Decrease vision
 Va 20/100,20/200
 VF:
 Ext: w/q
 P: w/o APD
 EOM: full
 SLE: wnl
 Ta: 15/14
 Fundus:



BL – W/U
 mERG:



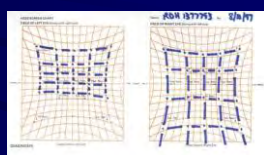
Commonly Missed Diagnoses

- Compressive optic neuropathy
- Oil droplet cataracts
- Corneal pathology
- Hereditary/Metabolic optic neuropathies
- **Maculopathy**

Occult Maculopathies

- Metamorphopsia (Amsler grid)
- Lack of afferent pupillary defect (APD)
- Central scotoma w/o breakout
- OCT
- F/A, ICG
- mERG

RDH 36yo male
 8/97: 2mo h/o vertical diplopia
 Va: 20/15 OU; N: 3pt OU; no APD
 Ext: no proptosis



AChR Ab +

Commonly Missed Diagnoses

- Compressive optic neuropathy
- Oil droplet cataracts
- Corneal pathology
- Hereditary/Metabolic optic neuropathies
- Maculopathy
- **Myasthenia gravis**

Myasthenia Gravis

- When pattern doesn't fit cranial nerve (even when it does)
- When variable (worse when tired)
- Not associated with pain or pupillary changes

LAD 77yo female

5/96: Double vision "after cataract"

Va 20/20, 20/25; N 3pt, 4pt

VF: full

Ext: palp 9 OU, H 16 OU

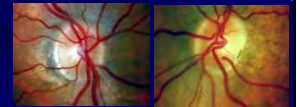
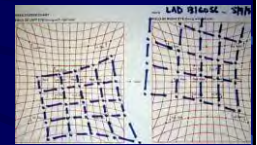
P: w/o APD

EOM: RHT inc up gaze

SLE: PC-IOL

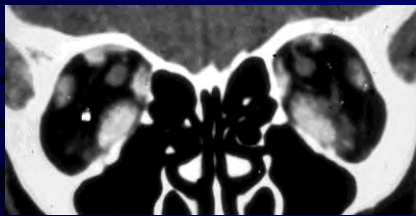
Ta: 20/19

Fundus: nl DMV



LAD - W/U

CT:



Commonly Missed Diagnoses

- Compressive optic neuropathy
- Oil droplet cataracts
- Corneal pathology
- Hereditary/Metabolic optic neuropathies
- Maculopathy
- Myasthenia gravis
- **Thyroid orbitopathy**

Thyroid Orbitopathy

- Not easy if no proptosis or prior hx thyroid disease
- Most common cause orbital pathology (50%)
- Imaging (enlarged EOM)
- Evidence of restriction (elevated IOP)
- Thyrotropin inhibitor binding assay
- Optic neuropathy only 5-8%

PAC 19yo male

4/84: MVA w/ "double vision"

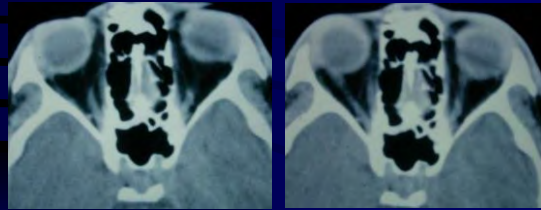
CT: "normal"

Va: 20/15 OU; N: 3pt OU; VF: full

EOM: limitation adduction & abduction OS



PAC - Review of negative CT:

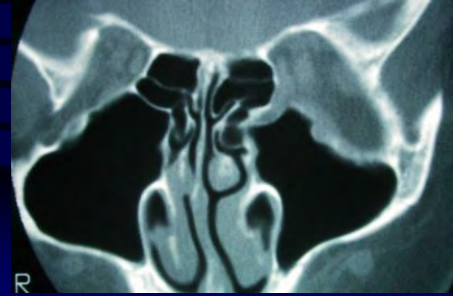


Look straight

Look left

PAC - W/U: IOP OS \uparrow 17 \rightarrow 30 w/ attempt abduction

Repeat CT:



Commonly Missed Diagnoses

- Compressive optic neuropathy
- Oil droplet cataracts
- Corneal pathology
- Hereditary/Metabolic optic neuropathies
- Maculopathy
- Myasthenia gravis
- Thyroid orbitopathy
- **Other restrictive strabismus**

Orbital Restriction

- Previous history of trauma
- Previous history of neoplastic disease
- Proptosis or other orbital signs
- Positive forced ductions or elevated IOP
- Imaging (CT) with coronals

HDM 61yo female

10/95: Acute blurred vision

“Nothing on eye exam”

Symptoms resolved in 4 days

Some associated headache

11/95: Double vision

CT: “normal”

MRI: “normal”

Dx: IVth nerve palsy

HDM - F/U

11/95: Pulsatile tinnitus

ENT: hearing normal

Rx: nortriptyline + Atenolol

HDM - F/U

1/96: Recurrent double vision


“Redness”

Dx: “infection”

Rx: Cipro

Progressive conjunctival prolapse

Refer to UVA



HDM - PE

Va 20/25,20/400; N 3pt,26pt

VF:

Ext: 3+ chemosis, H 22/24

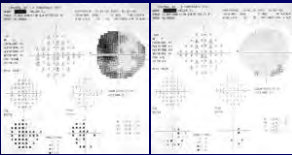

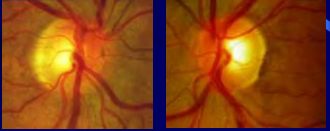
P: .9-1.2log LAPD

EOM: Absent abd OS, limit OD, 45ΔLET

SLE: wnl

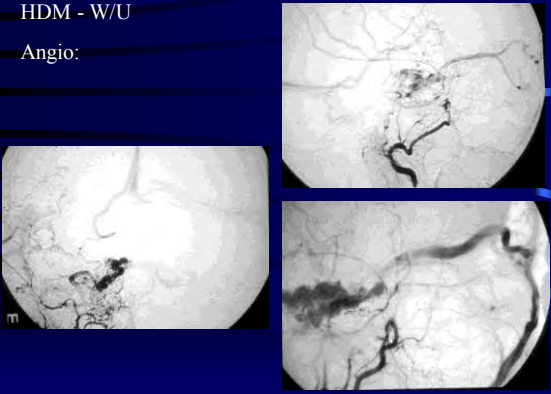
Ta: 21/23

Fundus:

HDM - W/U

Angio:



Commonly Missed Diagnoses

- Compressive optic neuropathy
- Oil droplet cataracts
- Corneal pathology
- Hereditary/Metabolic optic neuropathies
- Maculopathy
- Myasthenia gravis
- Thyroid orbitopathy
- Other restrictive strabismus
- **Carotid cavernous fistula**

Carotid-Cavernous Fistula

- Episcleral venous engorgement not conjunctivitis
- Direct (high flow following trauma)
- Low flow (dural)
- Ask about bruit
- Look for increased pulse pressure

LGS 79yo male

4/03: Diplopia

Va 20/20,20/80

N 3pt,10pt

VF:

Ext: ptosis OS, H 16/20, ↓sens V1,2

P: .9log LAPD

EOM: complete ophthalmoplegia

SLE: 1+NS

Ta: 26/21

Fundus: nl DMV

LGS – PMH

2001: “Red spot” L temple

6/02: “Numbness L face”

8/02: Pain L face

Dental consult

Neurology: Neurontin

12/02: Worsen pain

MRI (1/03): “Periventricular white spots”

2/03: Neurosurgery consult for trigeminal neuralgia

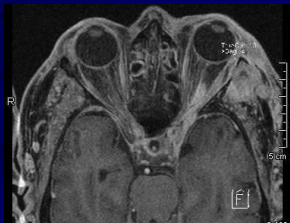
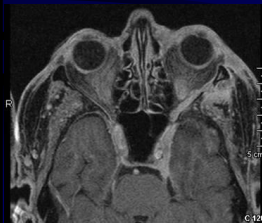
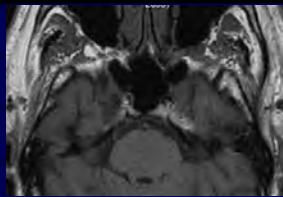
LGS – POH

12/02: Oblique double vision

2/03: L ptosis

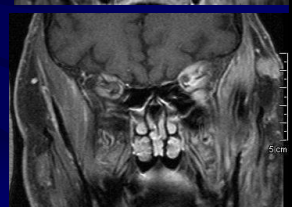
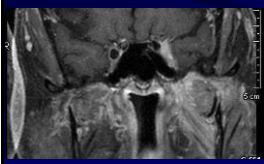
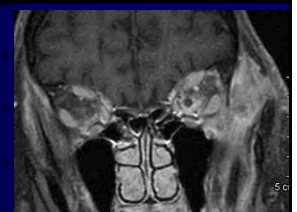
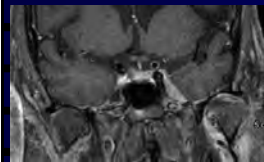
LGS – W/U

MRI:



LGS – W/U

MRI:



LGS – Rx

60Gy RT

Commonly Missed Diagnoses

- Compressive optic neuropathy
- Oil droplet cataracts
- Corneal pathology
- Hereditary/Metabolic optic neuropathies
- Maculopathy
- Myasthenia gravis
- Thyroid orbitopathy
- Other restrictive strabismus
- Carotid cavernous fistula
- **Neurotrophic spread of cancer**

Neurotrophic Spread

- Previous history of facial tumor (squamous)
- NUMBNESS – BAD
- When the imaging studies don't fit the clinical finding recheck imaging

Anxiety Level

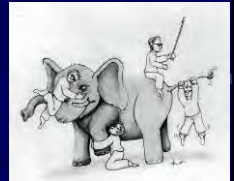
- Acute visual loss (especially normal disc)
- Visual field defects (especially if respect vertical)
- Acute painful ophthalmoplegia (especially if pupil involved)
- Numbness (with or without pain)
- Painful anisocoria

Mnemonics for All

- 5 A's on a CD
 - Arteritis
 - Apex syndrome
 - Apoplexy
 - Aneurysm
 - Amaurosis
- Don't forget C/D
 - Compression
 - Dissection

Conclusions

- Ocular malalignment (diplopia)
 - Restrictive
 - Paretic (not all CN): MG/skew
- All decreased vision not optic neuropathy
 - Anterior segment (lens; cornea)
 - Retina (maculopathy)
 - Importance of visual fields
- Orbital signs demand imaging
- Follow-up critical



Kuldev Singh, MD, MPH

Kuldev Singh, MD, MPH is Professor of Ophthalmology and Director, Glaucoma Service at the Stanford University School of Medicine. Dr. Singh received his MD and MPH degrees from the Johns Hopkins University School of Medicine and was an Eleanor Naylor Dana Charitable Trust Fellow at the Wilmer Eye Institute.

He completed his ophthalmology residency at the Casey Eye Institute, Oregon Health and Science University followed by a Heed Foundation Fellowship focusing on glaucoma at the Bascom Palmer Eye Institute in Miami. Dr. Singh has published over 100 peer-reviewed articles and has delivered over 200 invited lectures on six continents. He has edited two textbooks and served on the editorial board of nine ophthalmic publications.

Dr. Singh's current research interests focus on glaucoma surgical trials, glaucoma genetics, the epidemiology of glaucomatous disease and health care delivery in developing countries. His clinical practice focuses on the medical, laser and surgical management of glaucoma, and the surgical management of cataract in patients with glaucoma.

Dr. Singh is Vice President of the American Glaucoma Society and will begin a two year term as President in January, 2013. He serves on the Board of Governors of the World Glaucoma Association and has previously served as Executive Vice President. Dr. Singh has served as Chair and Methodologist for the glaucoma section of the Ophthalmic Technology Assessment Panel of the American Academy of Ophthalmology (AAO) and was Glaucoma Subspecialty Day Co-Chair at the 2002 and 2003 AAO Meetings. He is the chair of the Program Committee for Glaucoma Subspecialty Day 2012.

Dr. Singh received the Senior Achievement Award from AAO in 2005 and Secretariat Awards in 2006 and 2009. He was a member of the team that won first prize in the Cataract Surgery section of the American Society of Cataract and Refractive Surgery Challenge Cup in 2006. Dr. Singh served as an Academic Advising Dean at the Stanford University School of Medicine from 2002-2005 and two three year terms as an elected member of the Faculty Senate. He was the sole recipient of the Franklin G. Ebaugh Jr. Award presented at the 2006 Stanford commencement ceremonies. Dr. Singh was one of two recipients of the 2012 Stanford University Asian American Faculty Award.

Glaucoma Surgery With and Without Cataract Surgery: Evolution vs. Revolution

Kuldev Singh, MD, MPH
Professor of Ophthalmology
Director, Glaucoma Service
Stanford University School of Medicine

GUEST EDITORIAL

Glaucoma surgery with and without cataract surgery: Revolution or evolution?

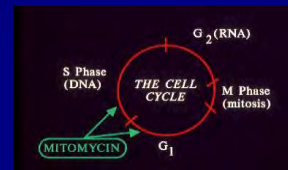
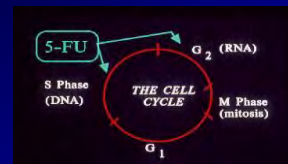
Daniel Choi, MD
Pitipong Suramethakul, MD
Richard L. Lindstrom, MD
Kuldev Singh, MD, MPH

Journal of Cataract and Refractive Surgery July, 2012.

- Traditional glaucoma surgery: Evolution
- Combined glaucoma and cataract surgery: Revolution

Trabeculectomy Controversies

- Limbus vs Fornix based flap
- Antifibrotic choice
- Modification with adjunctive implant





Trabeculectomy with Intraoperative Mitomycin C versus 5-Fluorouracil Prospective Randomized Clinical Trial

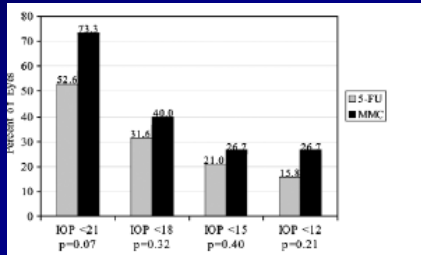
Kuldev Singh, MD,¹ Kala Mehta, DSc,² Naaghi M. Shaikh, MD,¹ James C. Tsou, MD,³ Marlene R. Moser, MD,⁴ Donald L. Budenz, MD,⁵ David S. Greenfield, MD,^{5,6} Philip P. Chen, MD,⁷ John S. Cohen, MD,⁸ George S. Baerveldt, MD,^{9,10} Saad Shaikh, MD,¹ the Primary Trabeculectomy Antimetabolite Study Group

Ophthalmology Volume 107, Number 12, December 2000

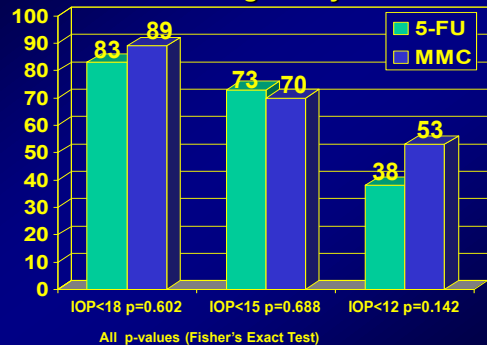
Long-term Comparison of Primary Trabeculectomy With 5-Fluorouracil Versus Mitomycin C in West Africa

Hanna Y. Kim, BS, Peter R. Egbert, MD, and Kuldev Singh, MD, MPH

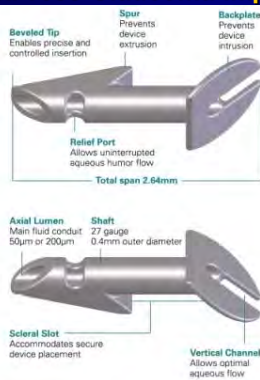
J. Glaucoma • Volume 17, Number 7, October/November 2008



PTAS: Intermediate Term Results Percentage of Eyes



Express Glaucoma Implant



Trabeculectomy: Pro

- Excellent IOP lowering when it works
- IOP lowering can be titrated
- Does not preclude later drainage device implantation

Trabeculectomy: Con

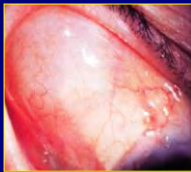
- Bleb related complications including infection
- Hypotony
- Failure over time

5 Predictions for Trabeculectomy in 5 Years

- Decrease in numbers
- Most common stand-alone procedure
- Less than 50% of combined cataract and glaucoma procedures
- First operation of choice for severe and high risk glaucoma
- Increased standardization of procedure

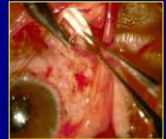
TVT Study: Purpose

To compare the safety and efficacy of tube shunt surgery to trabeculectomy with MMC in patients with previous ocular surgery

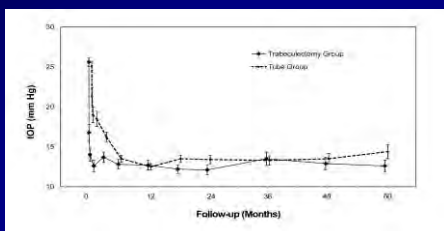


Treatment Groups

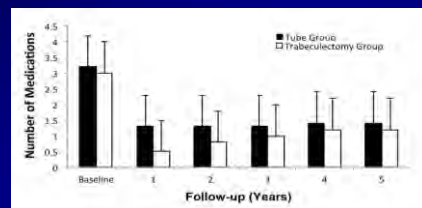
- Tube group
 - 350-mm² Baerveldt glaucoma implant
 - Superotemporal quadrant
 - Flow restriction
- Trabeculectomy group
 - Superior trabeculectomy
 - MMC 0.4 mg/ml for 4 minutes



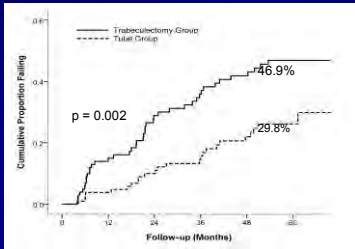
Intraocular Pressure



Medications

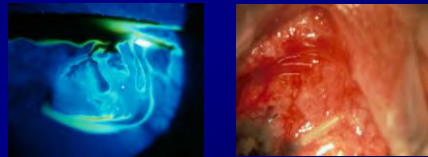


Probability of Failure



Complications

Early postoperative complications occurred more frequently after trabeculectomy with MMC compared with tube shunt surgery, but both procedures were associated with similar rates of late postoperative and serious complications



TVT Major Findings

- Greater rate of success in the tube group
- Comparable postoperative meds in two groups
- Similar rates of serious postoperative complications

Choice of Tube vs Trab

Singh K, Gedde SJ and the TVT Study Group.
IOC 51(3): 141-54, 2011.

- Conjunctival scarring
- Prior use of mitomycin C
- Risk Factors for Failure
- Disease severity/risk
- IOP goal
- Ease of follow-up
- ? Next procedure

Combined Cataract and Glaucoma Surgery: Revolution

IOP Lowering With Cataract Surgery

- IOP reduction with phacoemulsification in POAG patients
Matsumura M et al. Nippon Ganka Gakkai Zasshi. 1996; November: 100(11): 885-889.
- Effect also seen in eyes without glaucoma
Tennen DG and Masket S J Cataract Refractive Surg; 1996; 22: 568-570.
- Greater effect in eyes with Exfoliation Syndrome
Damji KF Br J Ophthalmol 2006 Aug;90(8):1014-1018.
Mierzejewski A Klin Oczna. 2008;110(1-3):11-17.
Cimetta DJ and Cimetta AC Eur J Ophthalmology. 2008 Jan-Feb;18(1): 77-81.

IOP Lowering With Cataract Surgery

- **Greater effect in eyes with higher preoperative IOP**
Poley et al J Cataract Refractive Surg; 2008; May;34(5):724-742.
Shingleton BJ J Cataract Refractive Surg; 2008; Nov;34(11):1834-1841.
- **No impact on diurnal IOP fluctuation**
Kim KS et al. Journal of Glaucoma 2009; Jun-Jul;18(5): 399-402.
- **IOP lowering predicted by preoperative IOP and anterior chamber depth**
Issa, SA Br J Ophthalmology. 2005 May;89(5): 543-546.

IOP Lowering With Cataract Surgery

- **Benefit of phacoemulsification following acute angle closure**
Lam DS Ophthalmology. 2008 Jul;115(7):1134-40.

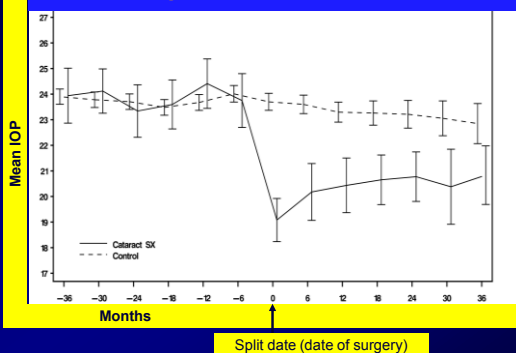
Mechanism?

- Fluid “cleans” trabecular meshwork?
- Opening of trabecular meshwork?
- Inflammatory?

Friedman D. et al.
Surgical Strategies for Coexisting Glaucoma and Caratact: An Evidence-based Update
Ophthalmology 2002; Vol 109(10):1902-1913.

- Weak but consistent evidence that cataract surgery with phacoemulsification lowers IOP: 2-4 mm Hg

Ocular Hypertensive Treatment Study-OHTS Mansberger et al. presented at AGS, 2011



Glaucoma Surgery: The Numbers

- Fewer than 100,000 glaucoma surgery procedures a year in the U.S.
- 3.4 million cataract operations/year
- 15-20% of cataract surgery patients are receiving IOP lowering medications at the time of surgery

QUEST EDITORIAL

Timely cataract surgery for improved glaucoma management

Robert T. Chang, MD
Bradford J. Shingleton, MD
Kuldev Singh, MD, MPH

J CATARACT REFRACT SURG - VOL 38, OCTOBER 2012

Cataract Plus Options

Other novel approaches

- Ab interno trabecular stents
- Ab interno suprachoroidal shunts

Summary and Predictions

- Modern cataract surgery is the most commonly performed IOP lowering procedure
- Cataract surgery may improve glaucoma management
- Novel glaucoma procedures will reduce the threshold for performing combined cataract and glaucoma surgery

Lee M. Jampol, MD

Dr. Jampol is Professor of Ophthalmology at Northwestern University. His career has focused on clinical trials, inflammatory diseases (white spots) of the retina, cystoid macular edema, pharmacology of the retina and central serous chorioretinopathy. He also worked on diabetic retinopathy and age related macular degeneration. Since 1985, when he became a member of the Data Monitoring Committee of the Macular Photocoagulation Study, he has been extensively involved in data monitoring and planning of clinical trials. He has been on the data monitoring committees of the MPS, SST, SCORE and the DRCR, as well as corporate studies, and has served on the external advisory committees of the Latino Eye Study and the Beaver Dam Study.

Administratively, he has been President of the American Ophthalmological Society, Trustee and Vice President of ARVO, President of the Macula Society, and Chairman of the Department of Ophthalmology at Northwestern University from 1983-2010.

Presently, Dr. Jampol is the Chair of the Diabetic Retinopathy Clinical Research Network (DRCR.net), a U-10 from the NIH supporting research on diabetic retinopathy.

The Diabetic Retinopathy Clinical Research Network

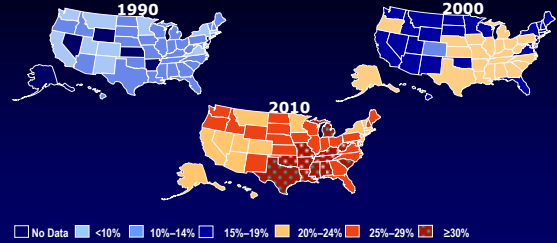
Dedicated to multicenter clinical research of diabetic retinopathy, macular edema and associated conditions

Supported through a cooperative agreement from the National Eye Institute and the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Department of Health and Human Services EY14231, EY018817



Obesity Trends* Among U.S. Adults BRFSS, 1990, 2000, 2010

(*BMI ≥30, or about 30 lbs. overweight for 5'4" person)



DRCR.net Overview

- Objective:
 - The development of a collaborative network to facilitate multicenter clinical research on diabetic retinopathy, DME and associated conditions.
- Funding:
 - National Eye Institute (NEI) and The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)-sponsored cooperative agreement initiated September 2002.
 - Current award 2009-2013

3

DRCR.net Overview

- **Network Chair:**
Lee M. Jampol, M.D.
Northwestern University Medical School, Department of Ophthalmology, Chicago, IL
- **Past Chair:** Neil M. Bressler, M.D.
Wilmer Ophthalmological Institute at Johns Hopkins, Baltimore, MD
- **Director of the Coordinating Center:**
Adam R. Glassman, M.S. (Jaeb Center for Health Research)
- **National Eye Institute Project Officer:** Eleanor B. Schron, Ph.D., R.N.
- **Vice-Chairs (2013):**
Carl W. Baker, M.D., Paducah Retinal Center;
Scott M. Friedman, M.D., Florida Retina Consultants
Jennifer K. Sun, M.D., M.P.H., Joslin Diabetes Center

4

Priority Initiatives

- Involvement of community-based practices, as well as “academic” or university-based centers.
- *Collaborate with industry* to facilitate investigations and pursue opportunities otherwise not possible and to do so in a manner consistent with the Network’s dedication to academic integrity and optimal clinical trial performance.

5

Organization: Clinical Sites of the Network

- Overall Network Participation (as of 9/30/12)
 - 266 sites submitted application for Network
 - 950 total Investigators; 3018 additional personnel
- Network is open and continually solicits participation of new sites and investigators

6

Current Network Participation

- 119 active sites (81 community, 38 academic)
 - 385 Investigators
 - 1,163 additional personnel



7

What Has Been Learned? Diabetic Macular Edema Treatment

- Protocol B: Over 2 years, focal/grid photocoagulation is more effective and has fewer side effects than 1 mg or 4 mg doses of preservative-free intravitreal triamcinolone.
- Protocol E: In cases of DME with good visual acuity, peribulbar triamcinolone, with or without focal photocoagulation, is unlikely to be of substantial benefit.
- Protocol H: The results demonstrated that intravitreal bevacizumab can reduce DME in some eyes, but the study was not designed to determine whether the treatment was beneficial.

8

What Has Been Learned? Optical Coherence Tomography

- Protocol G: CSF thickness on Stratus OCT™ in people with diabetes and minimal or no retinopathy are similar to a normative database of people without diabetes. CSF thickness is greater in men than in women.
- Protocol O: Mean CSF thickness is ~70 μm thicker when measured with Heidelberg Spectralis OCT as compared with Stratus OCT among individuals with diabetes in the absence of retinopathy or with minimal non-proliferative retinopathy and a normal macular architecture. CSF thickness values ≥320 μm for men and 305 μm for women are proposed as gender-specific thickness levels.

9



Image: National Eye Institute, National Institutes of Health

10

Protocol I: Intravitreal Ranibizumab or Triamcinolone Acetonide in Combination with Laser Photocoagulation for DME

Objective

To evaluate the safety and efficacy of intravitreal anti-VEGF treatment in combination with immediate or deferred focal/grid laser photocoagulation and intravitreal corticosteroids in combination with focal/grid laser compared with focal/grid laser alone in eyes with center-involved DME

Major Eligibility Criteria

• CME involving the center of the macula (OCT CSF ≥ 250 μm) responsible for visual acuity of 20/32 or worse

Protocol Status

• Total enrolled (3/07-12/08): 691 subjects/854 eyes at 52 sites
• Final 5 year visit anticipated December 2013

Protocol M: Effect of Diabetes Education during Ophthalmology Visits on Diabetes Control

Objective

- To assess whether glycemic control (assessed with HbA1c measurement) in individuals with type 1 or type 2 diabetes can be improved with a point-of-care measurement of HbA1c in the ophthalmologist's office combined with a personalized risk assessment for diabetic retinopathy and other complications of diabetes

12

Protocol M: Effect of Diabetes Education during Ophthalmology Visits on Diabetes Control

- Major Eligibility Criteria
 - Diagnosis of diabetes mellitus (type 1 or type 2)
 - Patient is not eligible if patient has a known HbA1c <7.5% within prior 6 months
- Enrollment (completed)
 - Total enrolled: 1900+

Protocol N: An Evaluation of Intravitreal Ranibizumab for Vitreous Hemorrhage Due to Proliferative Diabetic Retinopathy

- Objective
 - To determine if intravitreal injections of ranibizumab decrease the proportion of eyes in which vitrectomy is performed compared with saline injections in eyes presenting with vitreous hemorrhage from proliferative diabetic retinopathy

Protocol N: An Evaluation of Intravitreal Ranibizumab for Vitreous Hemorrhage Due to PDR

- Major Eligibility Criteria
 - Study eye with
 - Vitreous hemorrhage causing vision impairment, presumed to be from PDR, and precluding completion of PRP
 - Immediate vitrectomy not required
- Protocol Status
 - Total enrolled (6/10-10/11): 261 subjects at 61 sites

Results

- A single intravitreal injection of anti-vegf did not decrease the necessity for vitrectomy compared to saline. However the anti-vegf group did show less recurrent vitreous hemorrhages, more complete PRP's and slightly better vision.

Protocol R: A Phase II Evaluation of Topical NSAIDs in Eyes with Non Central Involved DME

- Objective
 - To assess the effects of topical NSAIDs on macular retina volume compared with placebo in eyes with non-central DME
 - To assess the effects of topical NSAIDs on central subfield thickness and to compare the progression of non-central DME to central DME as determined by OCT and stereoscopic fundus photographs

Protocol R continued

- Major Eligibility Criteria
 - Best corrected E-ETDRS VA letter score ≥ 74 (20/25 or better)
 - Definite retinal thickening due to DME within 3000 μm of the center of the macula but not involving the central subfield
 - No focal/grid laser within the last 6 months or other treatment for DME within the last 4 months
- Enrollment
 - Fully enrolled: over 120 subjects randomized at more than 61 sites (as of 9/30/12)

Protocol S: Prompt PRP versus Intravitreal Ranibizumab with Deferred PRP for PDR

> Objective

- To determine if visual acuity outcomes at 2 years in eyes with PDR that receive anti-VEGF therapy with deferred PRP are non-inferior to those in eyes that receive standard prompt PRP therapy.

19

Protocol S: Prompt PRP versus Intravitreal Ranibizumab with Deferred PRP for PDR

> Major Eligibility Criteria

- Study eye with
 - PDR for which PRP can be safely deferred for at least 4 weeks in the investigator's judgment.
 - No prior PRP
 - Visual acuity letter score in the study eye ≥ 24 (~ Snellen equivalent of 20/320 or better)
- > Enrollment (ongoing)
 - Goal: 380 study eyes fully enrolled

20

Protocol T: A Comparative Effectiveness Study of Intravitreal Aflibercept, Bevacizumab and Ranibizumab for DME

> Objective

- To compare the efficacy and safety of intravitreal (1) aflibercept, (2) bevacizumab, and (3) ranibizumab when given to treat central-involved DME
 - Specifically, the primary outcome is to assess if either of these three anti-VEGF products is superior to the other with respect to mean changes in visual acuity.

21

Protocol T: A Comparative Effectiveness Study of Intravitreal Aflibercept, Bevacizumab and Ranibizumab for DME

> Major Eligibility Criteria

- Study eye with
 - Central-involved DME (OCT CSF $\geq 250 \mu\text{m}$ on Zeiss Stratus or equivalent on spectral domain OCT).
 - Visual acuity letter score ≤ 78 and > 24 (~ Snellen 20/32 to 20/320) within eight days of randomization.
 - No prior intravitreal anti-VEG within prior 12 months
- > Enrollment (ongoing)
 - Total enrolled: more than 490 of more than 660 eyes enrolled

22

Genes in Diabetic Retinopathy Project

> Objective

- To create a repository of genetic material and clinical phenotype information as a resource for the research community
- The database may provide the opportunity to assess genetic susceptibility and resistance to DR and also variants impacting visually-important biomarkers for ME and neovascularization.

> Enrollment (Ongoing)

- Total enrolled: 500 subjects

23

Protocols In Development

- > Treatment of Center Involved DME in Eyes with Incomplete Response to Anti-VEGF Therapy
- > Focal/Grid Macular Laser versus Prompt or Deferred Anti-VEGF Treatment for Center Involved DME in Eyes with Excellent Visual Acuity



Many slides adapted from The Diabetic Retinopathy Clinical Research Network* available at www.drcr.net

Diabetic Macular Edema

Lee M. Jampol, MD
Neil Bressler, MD

Principles of DRCR.net DME Treatment: Intravitreal Anti-VEGF

- Improving on OCT or VA → **Inject**
 - Improving = OCT central subfield thickness decreased by $\geq 10\%$ or VA letter score improved by ≥ 5
- Worsening on OCT or VA → **Inject**
 - Worsening = OCT central subfield thickness increased by $\geq 10\%$ or visual acuity letter score decreased by ≥ 5
- Stable: not improving or worsening on OCT or VA →

Principles of DRCR.net DME Treatment: Intravitreal Anti-VEGF:

What to Consider When Stable:

- Only stable since the last injection → **Inject**
- Stable for at least 2 consecutive injections:
 - OCT CSF $< 250 \mu\text{m}$ and VA 20/20 or better → **Defer injection**, return in 4 weeks; if stable or improve, double follow-up to 8 weeks; if worsen, inject

Principles of DRCR.net DME Treatment: Intravitreal Anti-VEGF:

What to Consider When Stable:

- Only stable since the last injection → **Inject**
- Stable for at least 2 consecutive injections
 - OCT CSF $< 250 \mu\text{m}$ and VA 20/20 or better → **Defer injection**; return in 4 weeks; if stable or improve, double follow-up to 8 weeks; if worsen, inject
- Stable for at least 2 consecutive injections
 - OCT CSF $\geq 250 \mu\text{m}$ or VA worse than 20/20:
 - Less than 6 months of injections → **Inject**
 - ≥ 24 -week visit → **Defer injection, consider laser**; return in 4 weeks; if stable or improve, double follow-up to 8 weeks; if worsen, inject

Injections Prior to 3 Year*

	Ranibizumab + Prompt Laser N=144	Ranibizumab + Deferred Laser N=147
<i>Theoretic maximal</i> number of injections prior to 3- year visit	39	39

Injections Prior to 3 Year*

	Ranibizumab + Prompt Laser N=144	Ranibizumab + Deferred Laser N=147
<i>Theoretic maximal</i> number of injections prior to 3- year visit	39	39
Median number of injections in year one (1 st , 2 nd 6 months)	8 (6, 3)	9 (6,3)

Injections Prior to 3 Year*

	Ranibizumab + Prompt Laser N=144	Ranibizumab + Deferred Laser N=147
<i>Theoretic maximal</i> number of injections prior to 3- year visit	39	39
Median number of injections in year one (1 st , 2 nd 6 months)	8 (6, 3)	9 (6,3)
Median number of injections in year two	2	3

Injections Prior to 3 Year*

	Ranibizumab + Prompt Laser N=144	Ranibizumab + Deferred Laser N=147
<i>Theoretic maximal</i> number of injections prior to 3- year visit	39	39
Median number of injections in year one (1 st , 2 nd 6 months)	8 (6, 3)	9 (6,3)
Median number of injections in year two	2	3
Median number of injections in year three	1	2

Injections Prior to 3 Year*

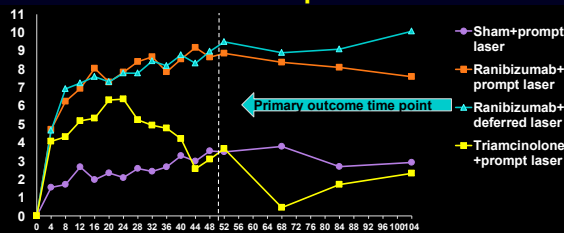
	Ranibizumab + Prompt Laser N=144	Ranibizumab + Deferred Laser N=147
<i>Theoretic maximal</i> number of injections prior to 3- year visit	39	39
Median number of injections in year one (1 st , 2 nd 6 months)	8 (6, 3)	9 (6,3)
Median number of injections in year two	2	3
Median number of injections in year three	1	2
Median number of injections prior to 3 year visit	12	15

What About Focal/Grid Laser

- Focal/grid laser can be added when thickening remains and there no longer is improvement after a number of injections
 - Injections may be withheld, but resumed if the edema worsens following laser

34

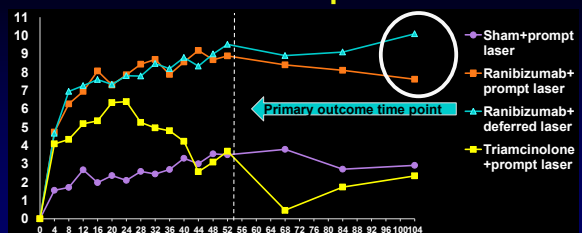
Mean Change in Visual Acuity (Letters)* at Follow-up Visits



*Values that were ≤ 30 letters were assigned a value of 30.
 †P-values for difference in mean change in visual acuity from sham+prompt laser at the 52-week visit: ranibizumab+prompt laser <0.001; ranibizumab+deferred laser <0.001; and triamcinolone+prompt laser=0.31.

35

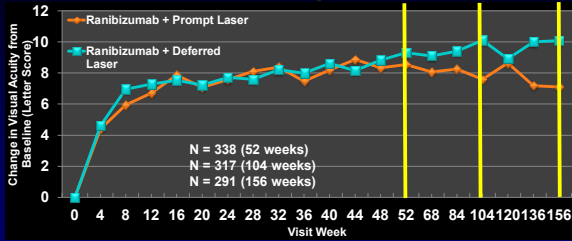
Mean Change in Visual Acuity (Letters)* at Follow-up Visits



*Values that were ≤ 30 letters were assigned a value of 30.
 †P-values for difference in mean change in visual acuity from sham+prompt laser at the 52-week visit: ranibizumab+prompt laser <0.001; ranibizumab+deferred laser <0.001; and triamcinolone+prompt laser=0.31.

36

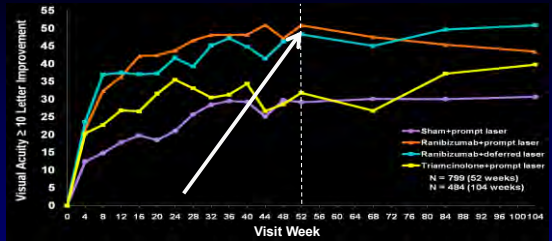
Mean Change in Visual Acuity* at Follow-up Visits



*Truncated to ± 30 letters

37

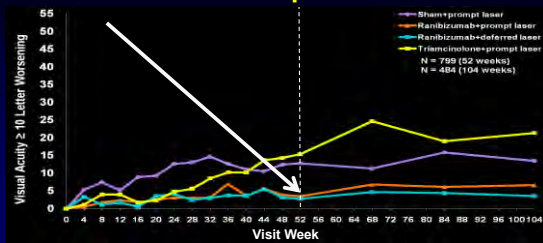
≥ 10 Letter Improvement in Visual Acuity at Follow-up Visits



P values for the difference in proportion of 10 letter improvement in visual acuity from sham+prompt laser at the 52-week visit: ranibizumab+prompt laser <math>< 0.001</math>; ranibizumab+deferred laser <math>< 0.001</math>; triamcinolone+prompt laser = 0.16

38

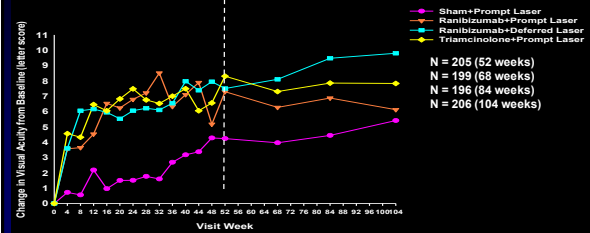
≥ 10 Letter Worsening in Visual Acuity at Follow-up Visits



P values for the difference in proportion of 10 letter worsening in visual acuity from sham+prompt laser at the 52-week visit: ranibizumab+prompt laser = 0.001; ranibizumab+deferred laser = 0.001; triamcinolone+prompt laser = 0.72

39

Mean Change in Visual Acuity* at Follow-up Visits: Pseudophakic Eyes at Baseline



*Truncated ± 30 letters

Elevated Intraocular Pressure/Glaucoma During 2-Years of Follow-up

Elevated Intraocular Pressure/Glaucoma	Sham + Prompt Laser N = 293	Ranibizumab + Prompt Laser N = 187	Ranibizumab + Deferred Laser N = 188	Triamcinolone + Prompt Laser N = 186
Increase ≥ 10 mmHg from baseline	8%	9%	6%	42%
IOP ≥ 30 mmHg	3%	2%	3%	27%
Initiation of IOP-lowering meds at any visit [†]	5%	5%	3%	28%
Number of eyes meeting ≥ 1 of the above	11%	11%	7%	50%
Glaucoma surgery [†]	<1%	1%	0	1%

[†]Excludes eyes with IOP lowering medications at baseline.

[†]Includes 2 filter and 2 ciliary body destruction.

IOP = intraocular pressure.

Conclusions

- Focal/grid laser performed at the initiation of intravitreal ranibizumab is no better, and possibly worse, than deferring laser for at least 24 weeks in eyes with DME involving the fovea and vision impairment.
- Fewer injections were needed in years 2 and 3 to sustain VA gains observed in year 1. However, more were needed in the ranibizumab+deferred laser group.

42

“ . . . intravitreal ranibizumab with prompt or deferred laser was more effective through at least 2 years compared with prompt laser alone or corticosteroids with laser for the treatment of DME involving the central macula, although uncommonly associated with endophthalmitis . . . “

“ . . . Ranibizumab should be considered for patients with DME and characteristics similar to those of the cohort in this clinical trial, including vision impairment with DME involving the center of the macula. . . “

43

Steven A. Newman, MD

After obtaining his undergraduate degree in physics from Princeton University, Dr. Newman attended the Albert Einstein School of Medicine, and was inducted into Alpha Omega Alpha. He did his internship, medical and ophthalmology residencies at the Washington School of Medicine in St. Louis, and was a staff fellow at the National Health Institute. Dr. Newman completed a fellowship in neuro-ophthalmology at the Wilmer Eye Institute in Baltimore. He held professorships in ophthalmology and neurology at the University of Virginia and currently serves as Professor of Ophthalmology at UVA. He has lectured and published extensively.

Dr. Newman has been recognized with an Honor Award, a Senior Honor Award, and Lifetime Achievement Award from the American Academy of Ophthalmology as well as three Secretariat Awards and received a Faculty Award from Joint Commission on Allied Health Personnel in Ophthalmology. He is a member of International Neuro-Ophthalmology Society, the North American Neuro-Ophthalmology Society, the Association for Research in Vision and Ophthalmology and the Pan-American Society of Ophthalmology. He is a fellow of the American Academy of Ophthalmology and the North American Neuro-Ophthalmology Society. He has also served as the NANOS Representative to the Council of the American Academy of Ophthalmology, chairman of the Neuro-Ophthalmology Section V of the BCSC, and member of the POC/MOC committees, as well as past Chairman of the Compass Committee. He is past Vice President of the North American Neuro-Ophthalmology Society, past President of the North American Skull Base Society, and past President of the Cogan Ophthalmic History Society. He is the orbital consultant at Walter Reed Army Medical Center. His international missions include work with ORBIS in Bangladesh and Virginia Children's Connection in India.

Imaging in Ophthalmology



Steven A. Newman, MD
Charlottesville, VA

Disclosure

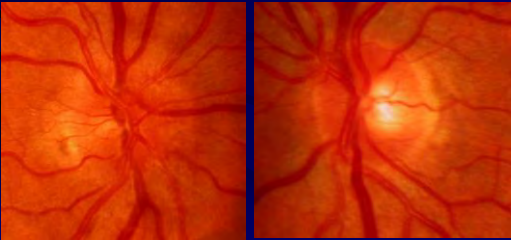
- Are you kidding? This is Neuro-ophthalmology
- No I'm not a radiologist (? Want to be)

HJH 63yo male

3/97: 1 day h/o sudden visual loss OD

Va: NLP, 20/20; N: 3pt OS; >3log RAPD

EOM: ↓elevation/depression OS



HJH - PMH:

12/96: 1 day h/o pain OS + diplopia

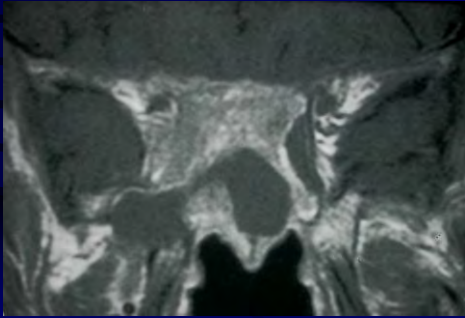
Ptosis + ↓adduction → Dx: "diabetic IIIrd" OS

1/97: Diplopia better

2/97: Abduction deficit → Dx: "diabetic R VI"

HJH - W/U:

MRI:

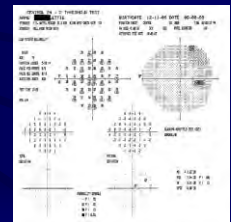
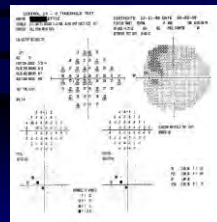


LFH 84yo female

2/94: "Second opinion"

1983: Ta: 26 → Dx: glaucoma; Rx: Timoptic

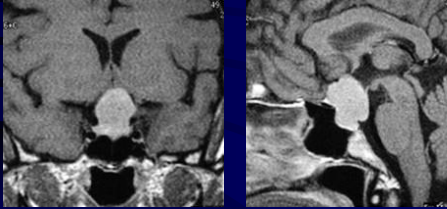
1987: "Arcuate VF defect" 1988: "No progression"



LFH - F/U: 2/94: No visual complaints

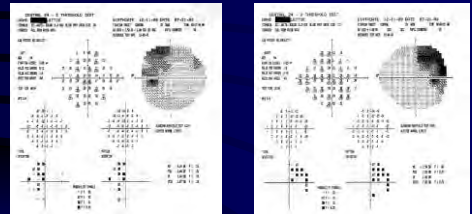
Va: 20/25,20/50; N: 3pt,4pt; 7.5/10 HRR plates OD, 5 OS

No APD; SLE: 1-2+NS; Ta: 16/20



LFH - Review previous VF:

7/93:



Introduction

- There is no “Orbitobrainogram”
- Imaging is expensive (limited resources)
- Newer imaging techniques may take longer
 - Only certain sequences are possible
 - Only certain areas can be imaged

History

- Roentgen and discovery of x-rays (1895)
- First use of x-ray ophthalmology (1896)
- Pneumoencephalography (1918)
- Angiography (Moniz 1927)
- CT scan (early 1970's)
- MRI (late 1970's)

Introduction

- When to order
- What to order
- How to order

When Not to Order

- When you won't look at the results
- When previous studies done and not reviewed
- When it won't change what you are doing
- When the chance of a mass lesion is remote

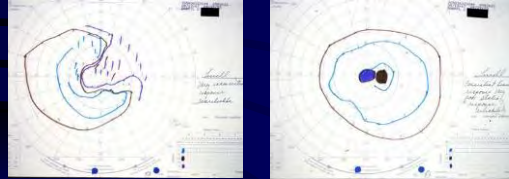
When Not to Order

- Acute Va loss, disc edema in older patient
- Arcuate VF loss, preserved Va, inc CDR
- Isolated ocular motor palsy in vasculopath
 - IVth nerve palsy w/ or w/o CHI
 - VIth nerve palsy
 - Pupil sparing IIIrd nerve palsy
- Pain without numbness

DOM 25yo male

4/93: Bilateral visual loss while in jail

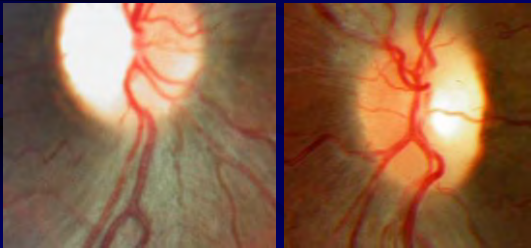
Va: 3/200 OU; no APD; Disc: normal



DOM - W/U: Leber's genetic screen: + mutation at 3460

F/U (7mo): "Worse"

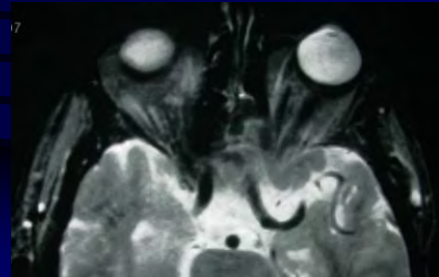
Va: 3/200 OU; N: 20/400 equiv OU



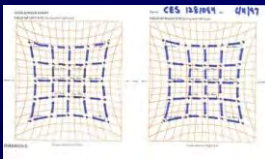
CES 72yo male

6/97: 6wk h/o intermittent diplopia; 3wk L ptosis

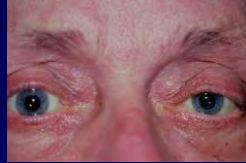
Va: 20/25 OU; N: 3pt,4pt; VF: full



CES - EOM:



Tensilon test:



When to Image Afferent System

- Evidence of an optic neuropathy
 - Acuity loss + VF changes
 - Progression
- Bitemporal visual field (presume chiasm)
- Homonymous hemianopsia
 - Tract/radiation/cortex
 - Ischemic/neoplastic/inflammatory

MKE 51yo female
 1/01: 2wk blur OD
 Va 20/20 OU
 N 5pt,3pt
 VF:
 Ext: H 14/12
 P: dilated
 EOM: full
 SLE: tr NS
 Fundus:

The image displays visual field plots for both eyes, showing normal results. Below the plots are two fundus photographs showing the optic disc and retinal vessels.

MKE – W/U
 F/A (1/01):

Two fundus photographs showing the optic disc and retinal vessels.

MKE – W/U
 Dx: AION

Two fundus photographs showing the optic disc and retinal vessels.

MKE – F/U
 3/01: “No Δ”
 Va 20/20 OU
 N 5pt,4pt
 VF:
 Ext: w/q
 P: .3log RAPD
 EOM: full
 SLE: tr NS
 Ta: 14/16
 Fundus:

The image displays visual field plots for both eyes, showing normal results. Below the plots are two fundus photographs showing the optic disc and retinal vessels.

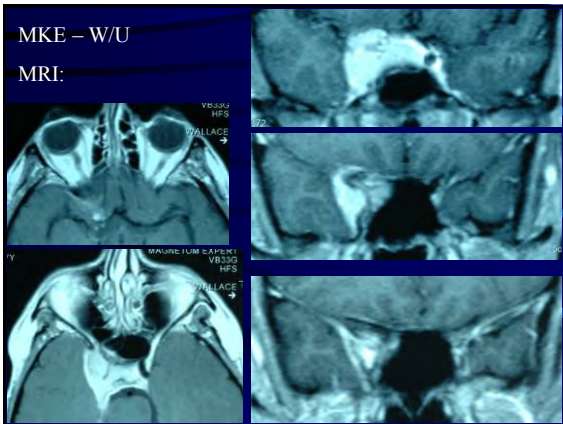
MKE – F/U
 2/07: Gradual ↓Va
 Va 20/60,20/20
 N 26pt,3pt
 VF:
 Ext: w/q
 P: 1.2log RAPD
 EOM: full
 SLE: tr NS
 Ta: 16 OU
 Fundus:

The image displays visual field plots for both eyes, showing normal results. Below the plots are two fundus photographs showing the optic disc and retinal vessels. To the right is a grid of 12 small eye photographs showing different views of the eyes.

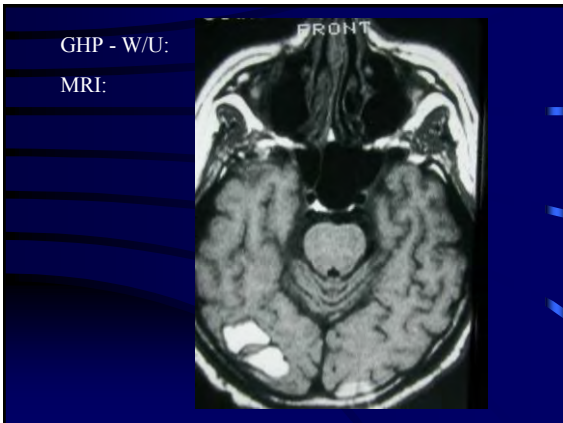
MKE – W/U
 OCT NFL (2/07):


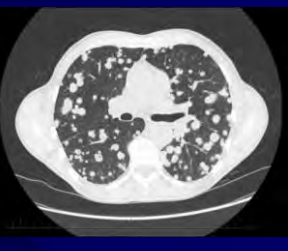
The image shows an OCT scan of the retina and a detailed RNFL thickness average analysis. The analysis includes graphs for the right eye (OD) and left eye (OS), showing the thickness of the retinal nerve fiber layer across different sectors. A table below the graphs provides numerical data for various parameters.

Parameter	OD (µm)	OS (µm)	Diff (µm)
Mean	111.5	127.3	-15.8
SD	12.7	12.1	0.6
CV	11.4	9.5	1.9
Max	130.0	140.0	-10.0
Min	80.0	90.0	-10.0
Mean	111.5	127.3	-15.8
SD	12.7	12.1	0.6
CV	11.4	9.5	1.9
Max	130.0	140.0	-10.0
Min	80.0	90.0	-10.0



GHP 35yo male
2/88: 1wk h/o HA + blurred Va
Va: 20/20 OU; N: 3pt OU; 10/10 HRR plates OU
No APD; EOM: symmetric OKN



GHP - W/U:
CXR:  CT: 

Lymph node bx: Germ cell tumor; Rx: chemotherapy

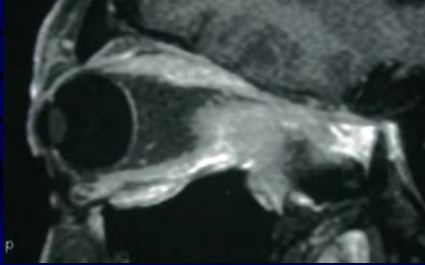
When to Image Diplopia

- With evidence of orbital pathology
 - Proptosis
 - Injection
 - Bruit
 - Sensory changes
- Skew deviation
- Atypical ocular motor palsies

JTC 48yo male
3/97: 7mo h/o "numbness" R cheek; 2mo diplopia
Va: 20/20 OU; N: 4pt OU;
Ext: H 23.5/17.5, ↓sensation R V2

JTC - W/U:

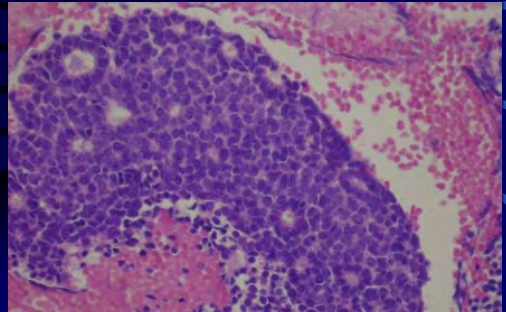
MRI:



JTC - W/U:

FNAB:

Open bx:

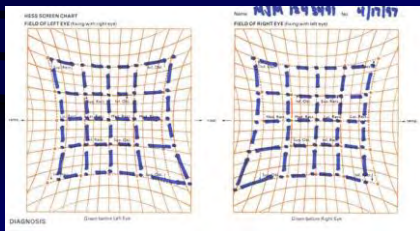


MJM 26yo male

4/97: 3-4yr h/o "problems w/ tracking"

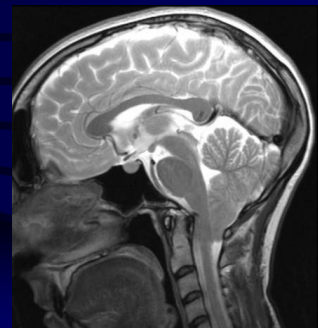
Va: 20/20 OU; N: 3pt,4pt; VF: full; no APD

EOM: abnormal pursuit at zero velocity, E



MJM W/U:

MRI:

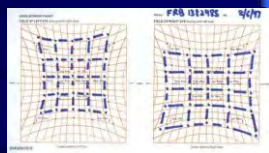


FRB 42yo male

8/97: 4wk h/o "blurred Va"

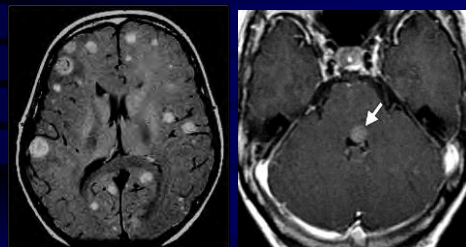
Va: 20/20,20/30; N: 5pt,6pt; VF: full

EOM: LHT ↑ on down gaze, ET ↑ on L gaze



FRB - W/U:

MRI:



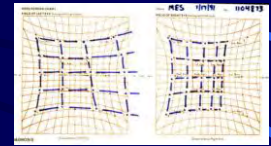
When to Image Ocular Motor Palsy

- When it is not isolated
- When it is progressive
- Pupil involvement III
- When there is evidence of aberrant regeneration III

MES 66yo female

1/91: 1mo h/o diplopia

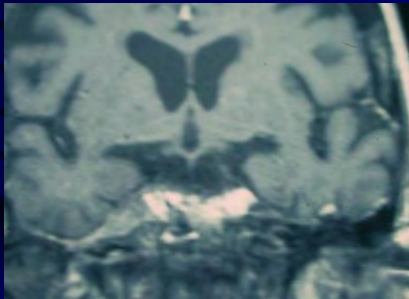
Va: 20/40,20/200; N: 3pt,5pt; VF: diffuse depression



Ext: ↓sensation V1&2

MES - W/U:

MRI:



DJH 37yo male

7/97: 2wk h/o diplopia

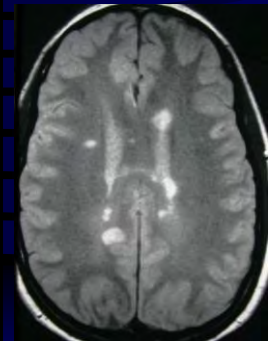
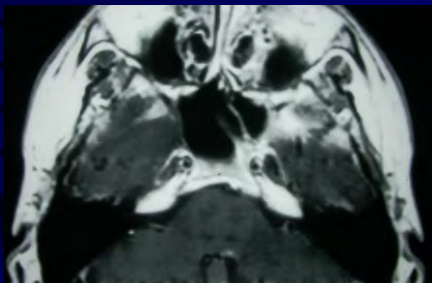
Va: 20/15 OU; N: 3pt OU; VF: full

Ext: w/q; EOM: ET ↑ on L gaze

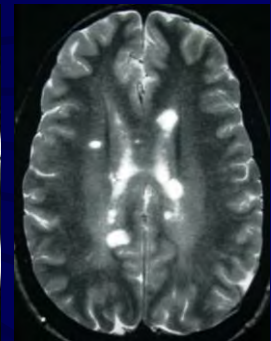


DJH - W/U:

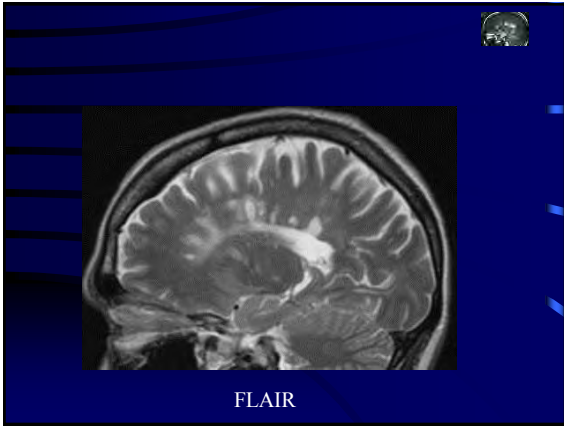
MRI:



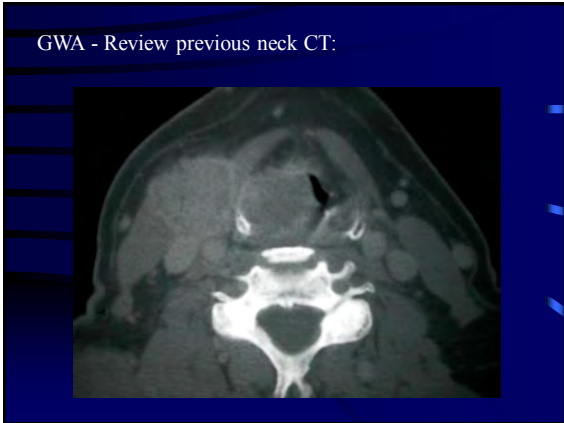
Proton Density



T2



GWA 58yo male PMH: squamous cell Ca neck
 9/93: 1wk h/o diplopia + lid droop
 Va: 20/50,20/40; N: 3pt OU; VF: full
 Ext: 4mm L ptosis; P: 4.2/4 w/o APD
 EOM: ↓ elevation, depression, adduction OS



GWA - W/U:
 MRI:

Bx: squamous cell Ca Rx: RT

GWA - F/U (2mo):
 "Double better"
 Va: 20/20,20/25; N: 3pt OU

When You Don't Image

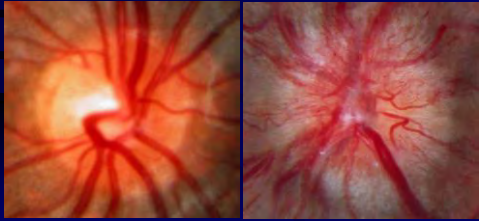
- You must follow the patient
 - Is the natural history expected?
 - Does the microvascular CN palsy entirely resolve?
 - Does the disc edema resolve w/ residual VF defect?
- Reconsider imaging if atypical features
- "Peace of mind"

BOC 9yo female

3/97: 1wk h/o pain and decreased Va OS

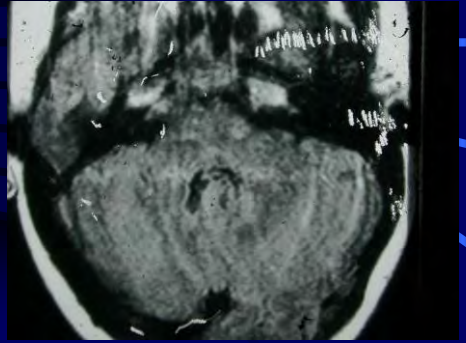
Va: 20/20,20/400; N: 4pt,20/400

2.1log LAPD



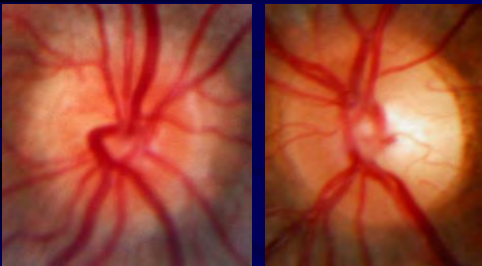
BOC - W/U:

MRI:



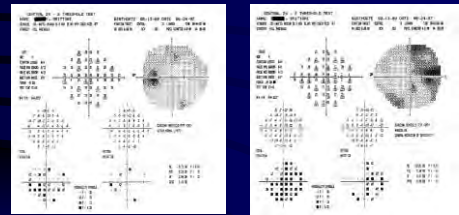
BOC - F/U (2mo): "Initially worse than better"

Va: 20/15,20/20; N: 3pt OU; no APD



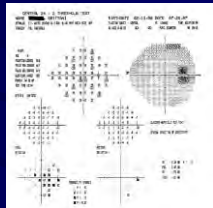
BOC - F/U (1mo 6/97): "Worsen on the right"

Va: 20/20 OU; N: 4pt,3pt; no APD



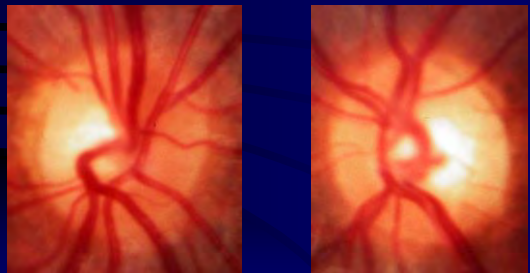
BOC - F/U (7/97): "Better"

Va: 20/15 OU; N: 3pt OU; .3log RAPD



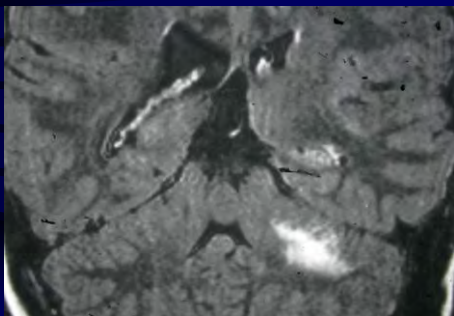
BOC - F/U (7/00): 2wk h/o pain and blurred vision OD

Va: 20/25,20/20; N: 3pt OU; .3log RAPD



BOC - W/U:

MRI:



BOC - F/U (10/00): "Vision back to normal"

Va: 20/15,20/20; N: 3pt OU; <.3log LAPD

Localization

- Suggested by history
- Confirmed by physical examination

Localization

- Orbit
 - Globe
 - Anterior segment
 - Retina/choroid
 - Retrobulbar space
- Intracranial
 - Parasellar/superior orbital fissure
 - Supratentorial/infratentorial

Localization - Intracranial

- Parasellar
 - Optic chiasm
 - Cavernous sinus/superior orbital fissure/clivus
- Middle cranial fossa
 - Visual pathways (tract/geniculate/radiations/cortex)
- Posterior cranial fossa
 - Brainstem (midbrain/pons/medulla)
 - Cerebellum

Pathophysiology

- Neoplastic
- Vascular
- Inflammatory
- Traumatic
- Toxic
- Metabolic
- Hereditary

Clinical History

- Onset
- Associated findings
- Course
- Residual

Onset

- Acute
- Subacute
- Slow
- Indeterminate

Associated Symptoms

- Other cranial nerve palsy (V, VII)
- Long tract signs
- Cerebellar signs
- Higher cortical dysfunction
- Mentation changes

Course

- Static
- Progressive
- Fluctuating
- Recovery
- Transient
- Duration

Information from Imaging

- Localization
- Characteristics
- Definitive diagnosis
- Change over time or with treatment

Intracranial Information

- Intra- vs extra-axial
- Relationship to visual pathways
- Relationship to vascular structures
- Relationship to ventricular system
- Relationship to the paranasal sinuses

Intraorbital Information

- Intraocular
- Relationship to the optic nerve
- Intra- vs extra-conal
- Relationship to the bones of the orbit
- Relationship to the lacrimal gland/sac

What to Order

- Plain films
- CT
- MRI
- Angiography
 - MRA/CTA
- Functional MR/MR spectroscopy
- Positron emission tomography (PET)

Imaging – General Principles

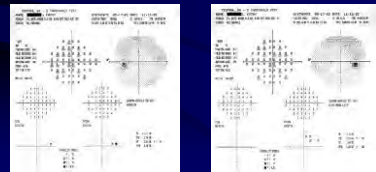
- CT superior for bone and acute trauma
- CT superior for FB (except wood)
- MRI superior for intracranial pathology
- CT & MRI often complementary
 - Both useful in the orbit

KLS 32yo female

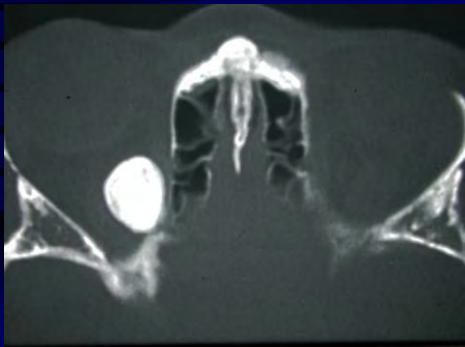
12/95: "Difficulty focusing"

Va: 20/20,20/15; N: 3pt OU

Ext: H 15 OU, palpebral
fissures 10 OU



KLS - W/U: CT scan done to evaluate galactorrhea:



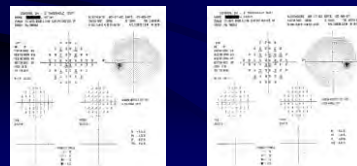
KLS - Rx: ?

Followed w/o Rx

F/U (5/97): no change

Va: 20/20 OU; N 3pt OU

Ext: H 16 OU



HMP 4mo female

2/90: 6wk h/o intermittent ET

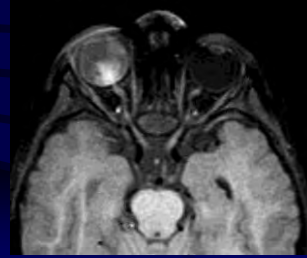
Va: FFM OS, w/o central fixation OD

EOM: 20Δ RET



HMP - W/U:

CT:

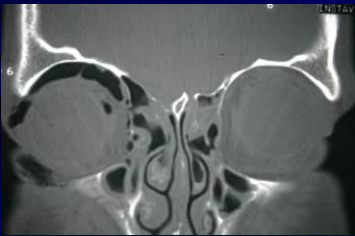


AJS 27yo male

4/97: Periocular swelling after blowing his nose

Va: 20/20 OU; VF: full

Ext: H 23/21, crepitus; ↓ elevation OD



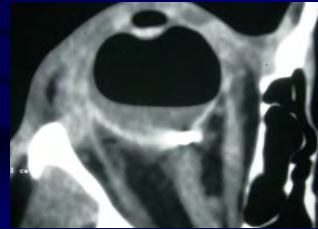
CT:

ECG 54yo male

12/96: Hammering

Va: HM, 20/25

Ext: 2+ injection OD; SLE: formed AC



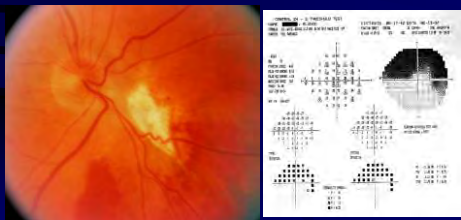
CT:

ECG - Rx: Vitrectomy + PFP bubble

F/U (1wk): "Vision blurry"

Va: 20/50, 20/25

RAPD Fundus:

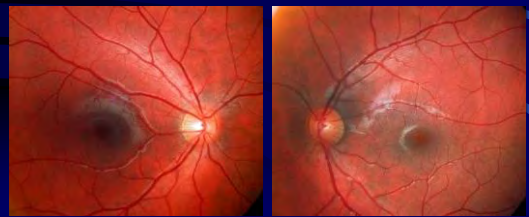


JRD 13yo male

1/97: Shot L eye w/ BB-gun

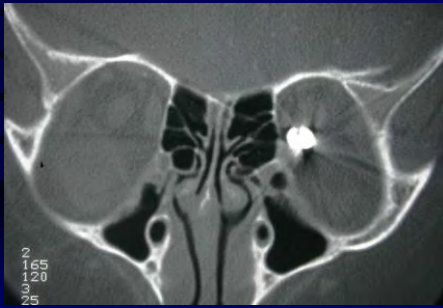
Va: 20/20 OU; N: 3pt OU

No APD



JRD - W/U:

CT:

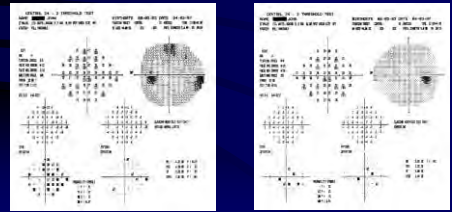


JRD - F/U (3mo): No problems

Va: 20/15,20/25; N: 3pt,4pt

Ext: H 15 OU; w/o APD

EOM: full



CRM 3yo male

4/02: Fell while climbing a tree

Va: CF OD, unobtainable OS

Ext: 2+ edema OS; EOM: absent abduction OS

“Air in orbit”



CRM - Rx: Taken to OR



CRM - F/U (10d):

Va: 20/30 OU; VF: full

Ext: w/q; EOM: full

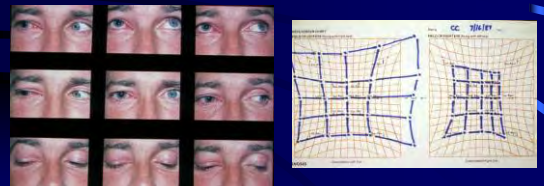


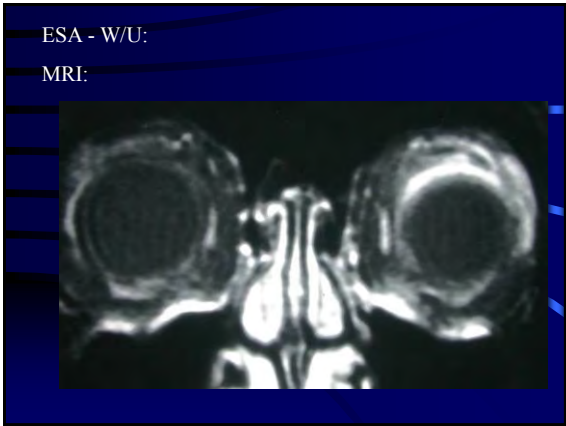
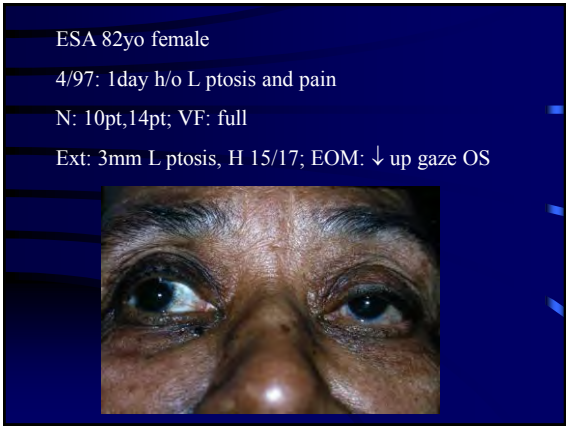
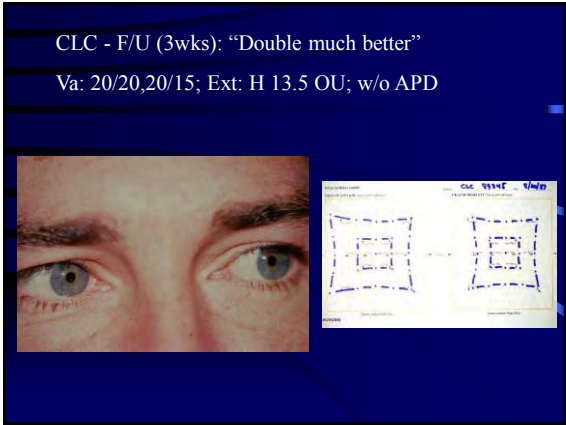
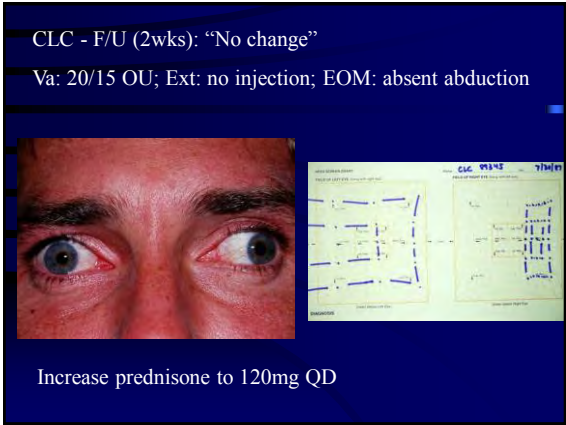
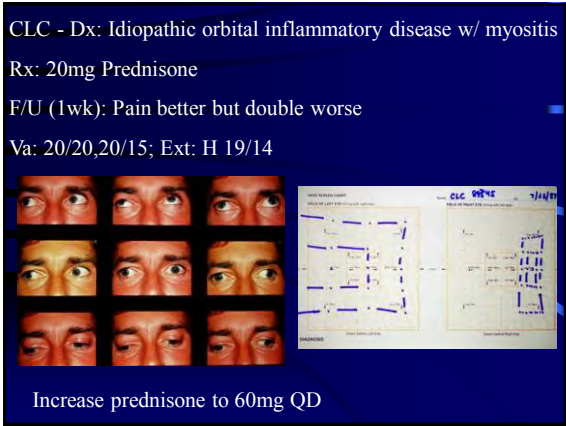
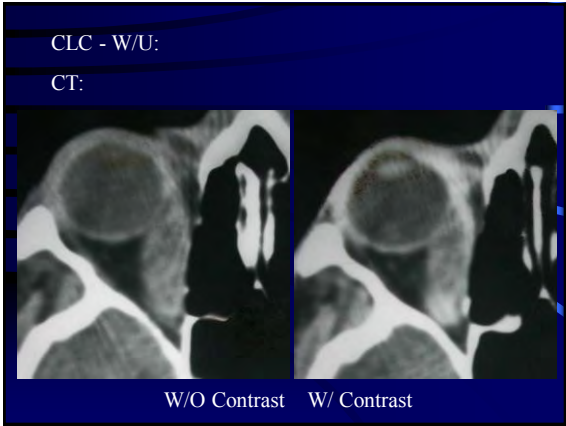
CLC 30yo male

7/87: 1wk h/o painful swelling OD

Va: 20/20,20/15; N: 3pt OU; VF: full

Ext: 1+injection OD, H 17.5/13; w/o APD





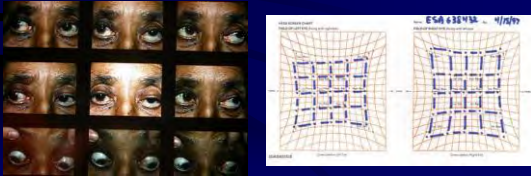
ESA - Dx: Idiopathic orbital inflammatory disease

Rx: Indocin

F/U (1wk): Resolved pain, decrease diplopia

Va: 20/40,20/30; N: 5pt,4pt

Ext: H14/16, 2mm L ptosis; EOM: ↓ up gaze OS



ELB 52yo female

5/97: 6yr h/o "orbital pain"

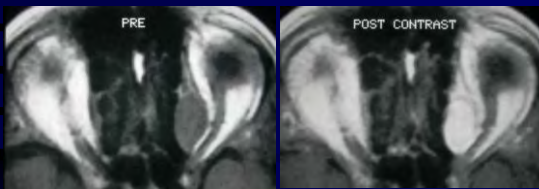
Va: 20/20 OU; N: 4pt OU; VF: full

Ext: palpebral fissures 6 OU, H 12 OU; EOM: full



ELB - W/U:

MRI:



CT Limitations

- Low but cumulative radiation dose
- Poor resolution at orbital apex
- Beam hardening artifact in posterior fossa
- Possible allergic reaction to contrast

22yo male

4/96: 3mo h/o "lump" R brow

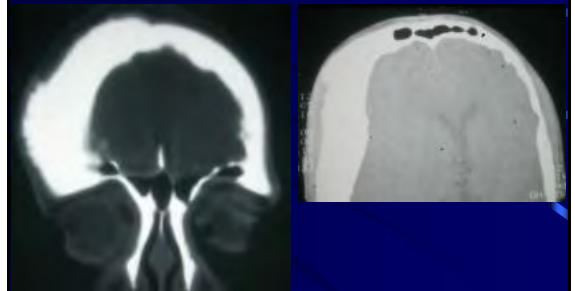
Va: 20/20,20/15; N: 3pt OU; VF: full

Ext: H 20.5/16, sensation intact; P: w/o APD



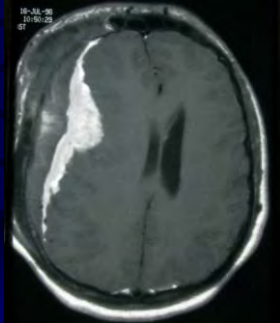
JWC - W/U:

CT:

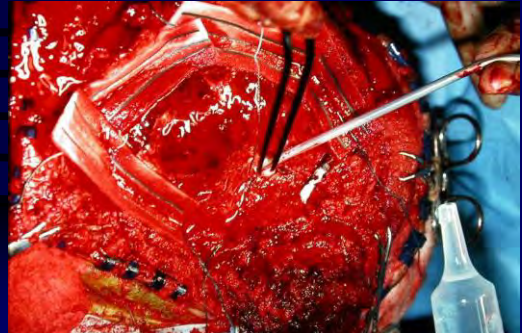


JWC -W/U: Calvarial bone biopsy: meningioma

MRI:



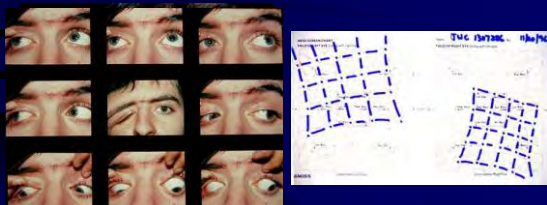
JWC - Rx: Craniotomy and excision



JWC - F/U (4mo): "Double vision"

Va: 20/50,20/15; N: 6pt,3pt

Ext: swelling R forehead; EOM: limitation elevation OD



JWC - Rx: Cranioplasty 11/96 (subgaleal shunt 12/96)

3/97: LIO extirpation

F/U (1mo 4/97): "Double only w/ up gaze"

Va: 20/25,20/20



Indications for CT

- Question fracture
- Question metallic foreign body
- Acute hemorrhage
 - Subarachnoid hemorrhage
 - Pituitary apoplexy
- Orbital infectious process
- Bone detail (pre-op planning)
- Contraindication to MRI

Contraindications to MRI

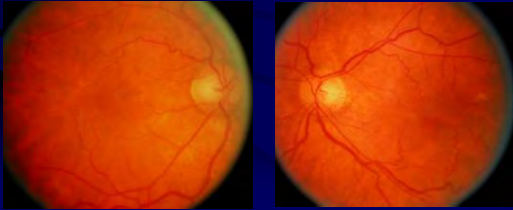
- Implanted ferromagnetic device (cochlear implant, pacemaker, retained FB)
- Relative contraindications
 - Weight
 - Claustrophobia
 - Risks of sedation when uncooperative

CGR 75yo male

4/88: 6mo h/o distortion OS

Va: 20/25,20/30; N: 3pt,10pt; Amsler: metamorphopsia OS

EOM: 4ΔRHT ↑ R gaze; Fundus: epiretinal membrane OS



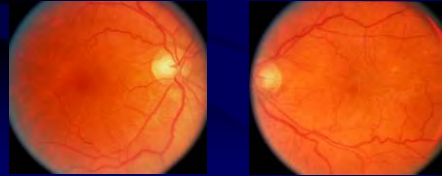
CGR - Dx: L IVth nerve palsy + epiretinal membrane

Rx: Vitrectomy + membrane peel 1992

F/U (6/92): Persistent diplopia

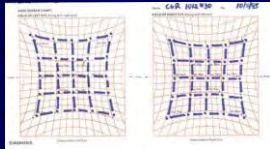
Va: 20/25,20/60; N: 4pt OU

EOM: 12 Δ LHT; SLE: 1-2+NS



CGR - Rx: R inferior rectus recession

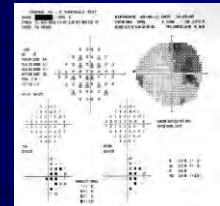
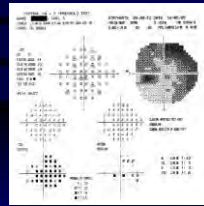
Inflammatory nodule treated with excision + Maxitrol



CGR - F/U (10/95): ↑difficulty w/ reading

Va: 20/25,20/200; N: 4pt,8pt; no APD

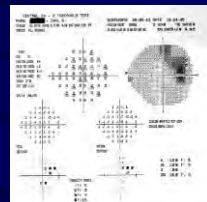
EOM: 3Δ LH; SLE: 2+NS



CGR - W/U: MRI scan order

Cancelled due to pacemaker

Return 3 wks for repeat VF



CGR - F/U: 12/95: Phaco OS

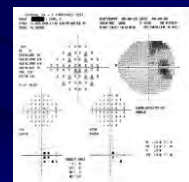
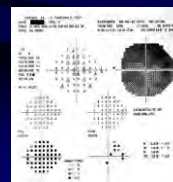
2/96: Persistent visual distortion OS

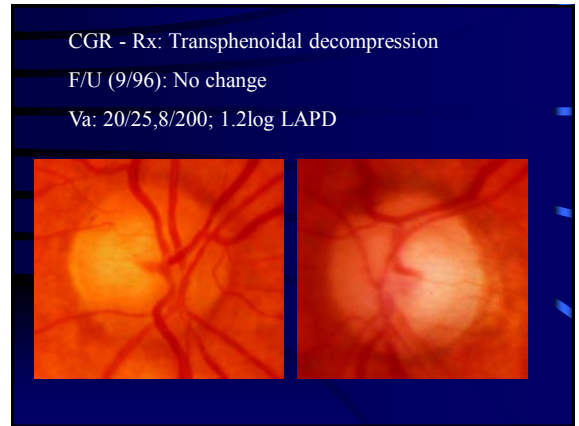
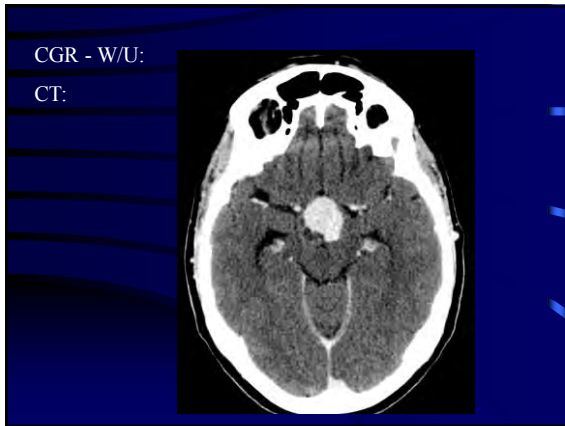
Va: 20/25,20/70; epiretinal membrane OS

Rx: repeat vitrectomy + peel OS

8/96: Episodes of confusion

Va: 20/25,20/400





Nonradiologist & MRI

- T1: localization (best anatomy)
 - Gadolinium (identifies abn blood/brain barrier)
 - Fat Sat (T1 w/ fat signal suppressed)
- T2: identification abnormal tissue
 - FLAIR (T2 image suppress ↑CSF signal; not orbit)
- DWI: detects early infarct
- Perfusion: detects gross blood flow abnormalities

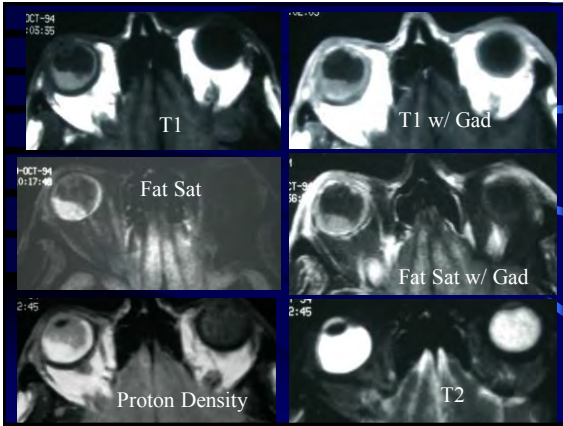
MRI Type & Parameters

Image	TR (repetition)	TE (time echo)
T1	Short (200-700)	Short (20-25)
T2	Long (1500-3000)	Long (75-250)
Proton density	Long (>1000)	Short (<35)
FLAIR	Long (>6000)	Long (>75)

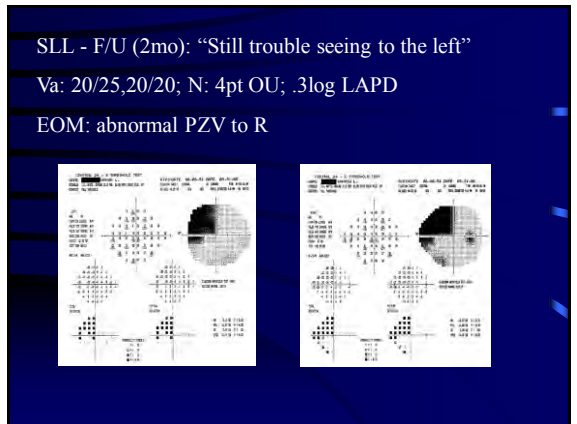
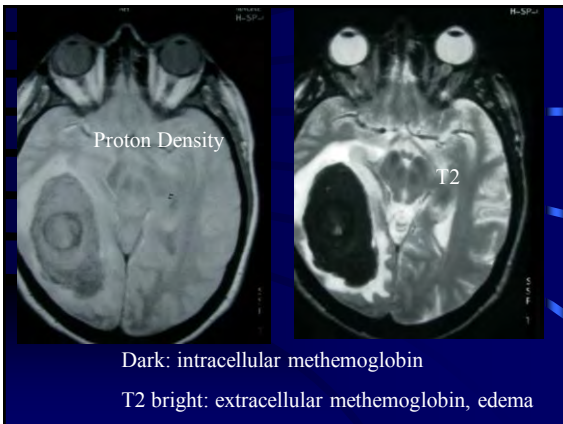
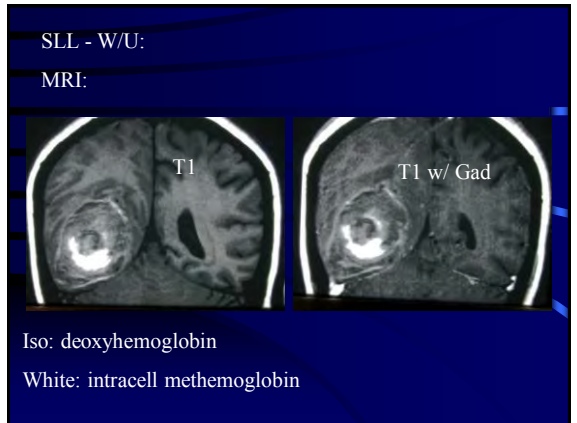
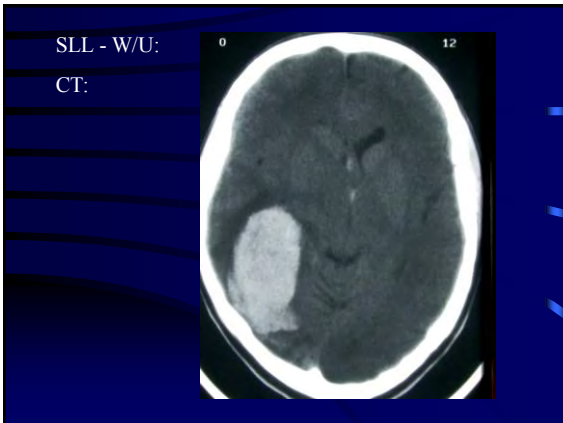
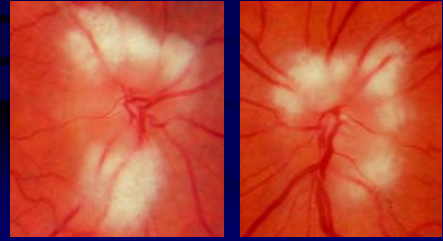
Nonradiologist & MRI

- T1: Fat>>white>gray>vitreous/CSF>air
- T2: Vitreous/CSF>>gray>white>fat>air
- Proton: Vitreous/CSF>gray=white>fat>air
- FLAIR: Fat>gray>white>vitreous/CSF>air

69yo male
10/94: 6mo h/o "lump" R eye
Va: HM, 20/30; N: 20/800, 5pt
3log RAPD



SLL 44yo female w/ chronic atrial fibrillation
 3/96: Sudden onset HA
 Va: 20/20 OU; N: 3pt OU; .3log LAPD
 EOM: ↓ pursuit to the right

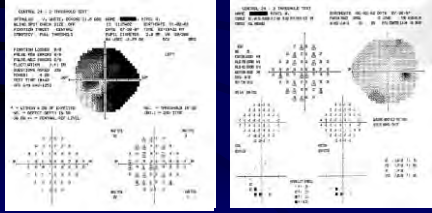


MAD 35yo male

7/97: 1day h/o pain w/ eye movement; Va 20/20

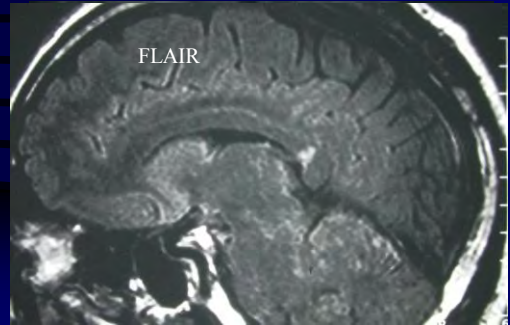
2days later "Vision dim"

Va: 20/20,20/200; N: 3pt,26pt; 1.8log LAPD



MAD - W/U:

MRI:



Angiography

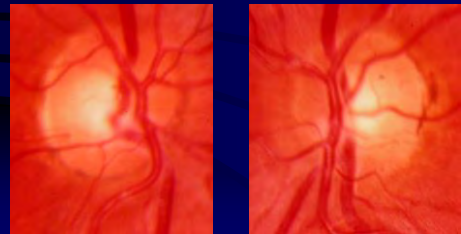
- Presence of a Fistula or AVM
- Detection of aneurysm
 - CTA/MRA: >95% over 4mm
- Pretreatment embolization

CWW 25yo male

12/89: F/U of visual complaints

Va: 20/20 OU; N: 3pt OU

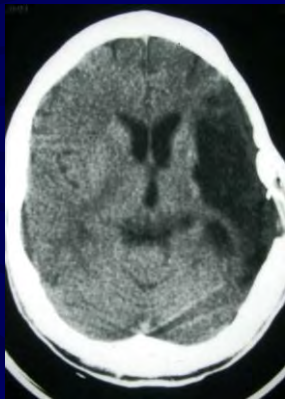
.3log RAPD



CWW - PMH: 2/82: MVA

L traumatic carotid occlusion:

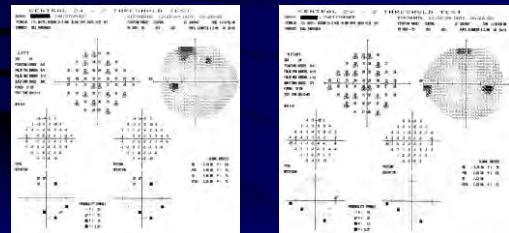
CT:



ECW 23yo male

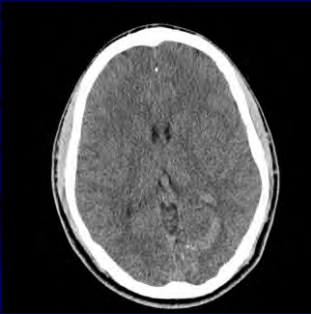
6/88: "Blurred vision R eye"

Va: 20/15 OU; N: 3pt OU; no APD



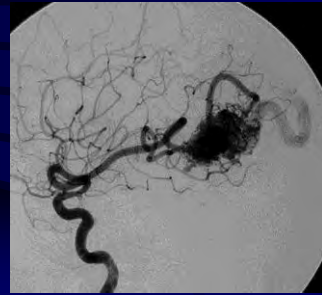
ECW - W/U:

CT:



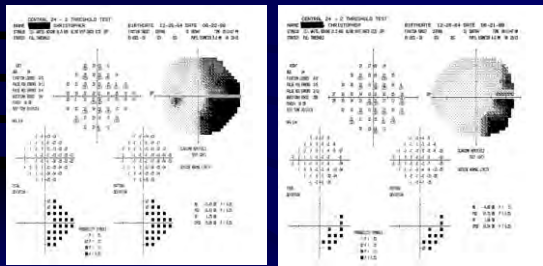
ECW - W/U:

Angio:



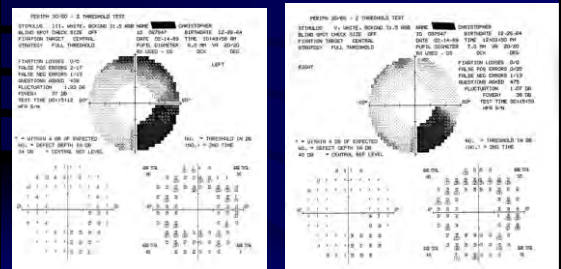
ECW - Rx: embolization

VF (3days post embolization):



ECW - F/U (8mo 2/89): "No change"

Va: 20/20 OU; N: 3pt OU



How to Order

- As much information as possible
- Suspected location
- Differential diagnosis
- Discuss personally with radiologist if possible

How to Interpret Results

- Neuro-ophthalmology: "The reinterpretation of previously negative imaging studies"
- Importance of reviewing films
- The risk of "Image Worship"

PAC 19yo male

4/84: MVA w/ "double vision"

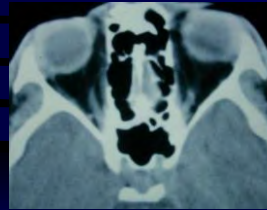
CT: "normal"

Va: 20/15 OU; N: 3pt OU; VF: full

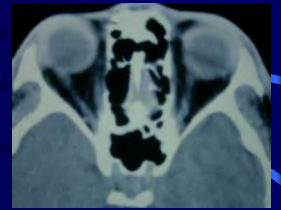
EOM: limitation adduction & adduction OS



PAC W/U: Review of negative CT:



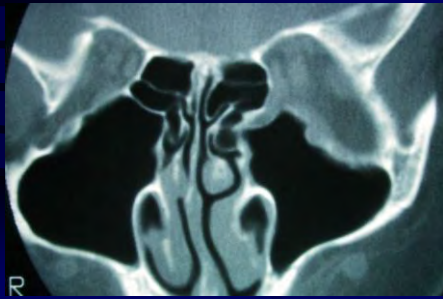
Look straight



Look left

PAC - W/U: IOP OS \uparrow 17 \rightarrow 30 w/ attempt abduction

Repeat CT:



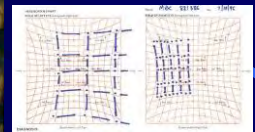
MBC 60yo female

7/96: 6wk h/o "red eyes," 5wk h/o double vision

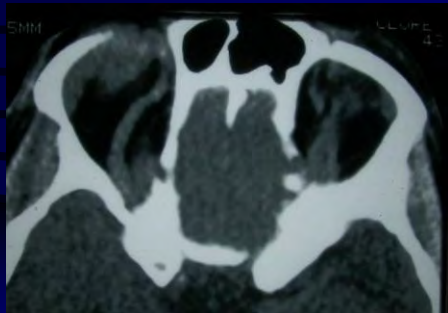
CT: "negative" Rx: prednisone

Va: 20/15, 20/20; N: 3pt OU; VF: nl 24-2

Ext: 2+ inj, mod chemosis; Ta: 40/26



MBC - W/U: Review CT scan:

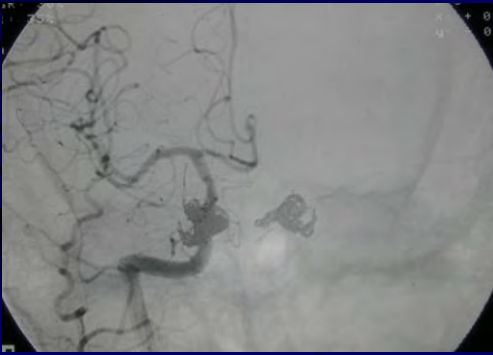


MBC - W/U:

Angio:

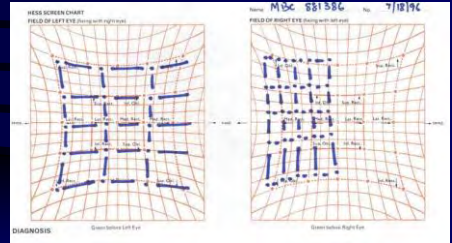


MBC - Rx: Transvenous embolization dural cavernous fistula



MBC - F/U (3days post Rx): "May be a little better"

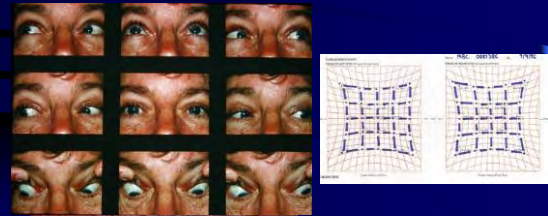
Va: 20/20 OU; N: 3pt OU



MBC - F/U (2mo): "No double"

Va: 20/20 OU; N: 3pt OU

EOM: min abducting delay; Ta: 17/18



TB 41yo female

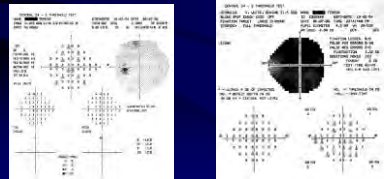
1989: "Flashing lights" OD; "Swollen nerve"

"Couple of MRI's & 2 LP's

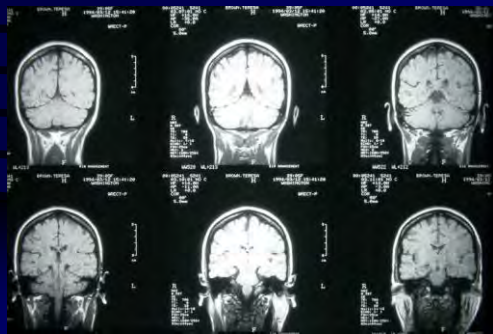
Told she had "mild MS"

8/96: Progressive visual loss OD

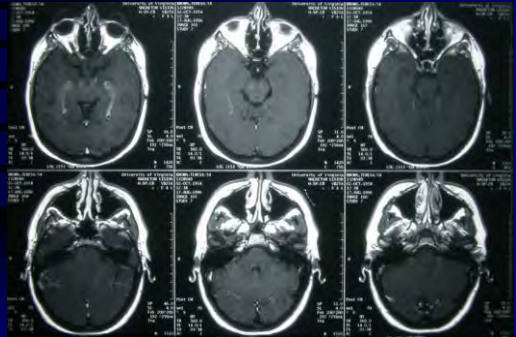
Va: 2/200,20/20; N: 3pt OS; 1.2log RAPD



TB - Review MRI (3/94):



TB - W/U: 8/96: Repeat MRI:



OUT PATIENT RADIOLOGY CONSULTATION FORM
UNIVERSITY OF VIRGINIA

IMPORTANT: All information requested on this form is essential and must be completed to proceed with the exam.

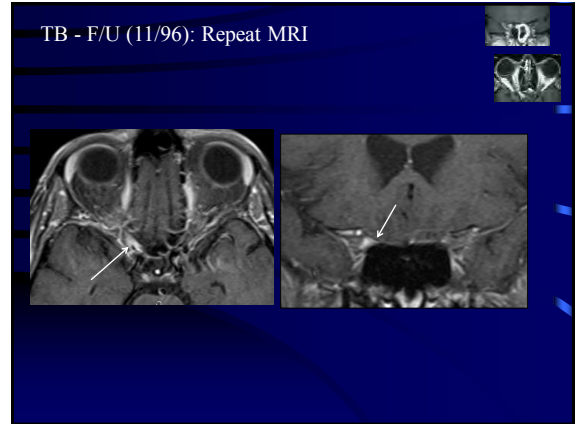
Patient Name: T. W. NEUM
 History Number: 1320217 OR 1320217
 Attending MD: (Required) DR. J. K. WILSON
 Ordering MD: (Required) DR. J. K. WILSON
 Address/Clinic: UNIVERSITY OF VIRGINIA MEDICAL CENTER
 Phone and/or Fax: 703-256-1111
 Fax: 703-256-1111
 Exam Date: 8-12-96

Phase Check	Type of Exam Requested
Phase I	<u>MR</u>
CT	<u>2 T1 w/ gadolinium</u>
MRI	
Phase II	
Angiogram	
Other	

Clinical Indications: facial numbness
h/o optic nerve sheath meningioma
h/o optic neuritis

ARE FILMS TO RETURN DIRECTLY TO CLINIC WITH THE PATIENT? YES NO

Additional Information (agent, Pa, authorization #, Workman's Comp., etc.):



DCJ 63yo male

3/03: 13mo h/o L facial numbness

2mo h/o diplopia

PMH:

8/01: during dental work lesion noted L cheek

9/01: Punch bx: squamous cell CA

Moh's surgery scheduled

2nd biopsy "negative"

2/01: numbness L cheek

DCJ - PMH

Dx: "Trigeminal problem"

MRI suggested

Neurology consult: normal

7/02 MRI: normal

8/02: "Second opinion"

8/02: 2nd MRI negative; Dx: "trigeminal neuralgia"

Rx: Trileptal - no improvement

10/02: Spread of numbness to L upper face

DCJ - PMH

2/03: onset of oblique diplopia

1 diopter L hyper

2/03: 3rd MRI: ? abnormal L trigeminal

Rx: Imitrex

Referred to Emory

3/03: 4th MRI: "normal"

Review of the MRI: enhancement V in floor CS

Craniotomy suggested

DCJ - F/U

Referred to UVA

Review of PMH

BCE removed from face in past

Face lift

H/o anxiety & depression

DCJ – PE

Va 20/20, 20/25

N 3pt, 5pt

VF: nl 24-2

Color: 10/10 HRR OU

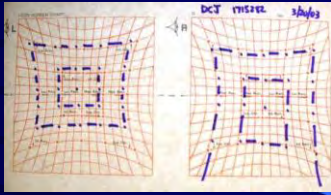
Ext: absent sens LV1,2; H 14.5/14

P: 5/4.5 w/o APD

EOM: 8Δ LHT, 5Δ X

SLE: 1+ NS, SPK OS

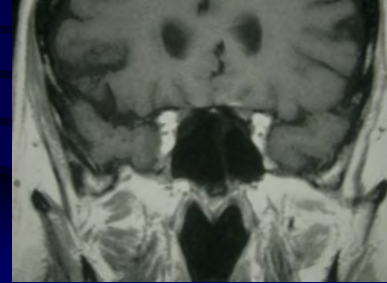
Fundus: nl DMV



DCJ – W/U

Cocaine test: no dilatation OS

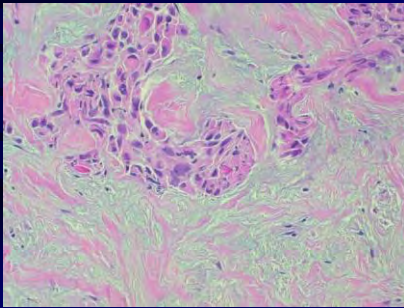
Review MRI:



DCJ – W/U

Transmaxillary biopsy L inferorbital nerve

Path:



DCJ – Rx

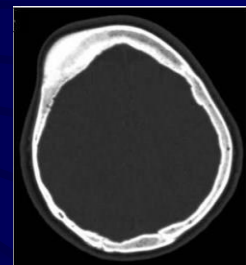
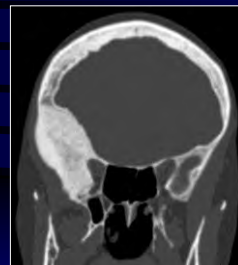
Referred for IMRT fractionated RT

Conclusion

- When: don't order if it won't matter
- What:
 - MRI for intracranial pathology
 - CT for trauma/orbit
- How: as much information as possible
 - Localization based on history/physical

JWC - W/U:

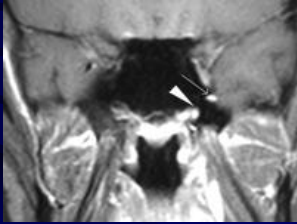
CT:



DCJ – W/U

Cocaine test: no dilatation OS

Review MRI:



Edward Buckley, MD

Dr. Buckley is a native of Cincinnati, Ohio. He graduated from Duke University in 1972 with a BSE in Electrical Engineering. He received his MD degree from Duke in 1977 followed by a residency in ophthalmology. He then completed two fellowships, one in pediatric ophthalmology and the other in neuro-ophthalmology, both at the University of Miami Bascom Palmer Eye Institute returning to the faculty at Duke in 1983. He is currently the Banks Anderson, Sr. Distinguished Professor of Ophthalmology and Pediatrics. He was the Chief of both the Pediatric and Neuro-ophthalmology services for many years and is now the Vice Dean for Education for the School of Medicine, overseeing all of the student education programs including the PA, DPT, Path Assistant and Masters of Clinical Research, Biostatistics, and Clinical Leadership. He has been involved with the development of the Duke-National University of Singapore Medical School (Duke-NUS) education program since 2001 and currently Co-Chairs the Duke-NUS Academic Committee. He is the director of the pediatric ophthalmology fellowship program at Duke and has trained over 45 clinical and 10 research fellows.

Dr. Buckley has served as President of the American Association of Pediatric Ophthalmology (AAPOS) and Strabismus, Chair of the American Board of Ophthalmology, Chair of the Section of Ophthalmology of the American Academy of Pediatrics, President of the American Orthoptic Society, and is the current Editor-in-Chief of the Journal of AAPOS. He has received the Life Time Achievement Award from the American Academy of Ophthalmology (AAO) and AAPOS. He has published/edited eight books, 40 book chapters, and over 120 peer-reviewed articles. He has given many prestigious named lectures including the Marshall Parks Lecture at the AAO, the Costenbader lecture at AAPOS and the Richard Scobee Memorial Lecture for the AACO. Although he is considered an expert in multiple aspects of pediatric ophthalmology, Dr. Buckley, is perhaps best known for his research and clinical innovations involving the treatment of complicated strabismus and congenital cataracts.

Orbital Mass in a Child



Edward G. Buckley, MD
 Banks Anderson Professor of Ophthalmology
 Duke University

Orbital Tumors/Lesions in Children



- Malformations
- Choristomas - Hemangioma, Lymphangioma, Varix, Neurofibroma
- Primary Neoplasms - Glioma, Rhabdomyosarcoma, fibrous dysplasia
- Secondary tumors - Astrocytoma, medulloepithelioma
- Metastatic tumors - Neuroblastoma, Wilm's, Ewing's sarcoma
- Leukemias / Lymphoma - Burkitt's
- Histiocytoses/Xanthogranuloma- eosinophilic granuloma
- Inflammations- Pseudotumor, myositis
- Infections - orbital cellulitis

How to evaluate a child with orbital mass?



Neuro-imaging !

Which neuro-imaging test is best ?



CT scans are superior in most cases



MRI may be desirable in certain cases
 when optic nerve dysfunction is present

How to evaluate an orbital mass in a child?



Ways to:

- Classify ?
- Categorize ?
- Compartmentalize ?

How to determine:

- Seriousness ?
- Urgency ?
- Morbidity ?

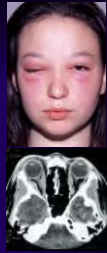
Is it Rapidly Expanding ?



- Cellulitis/abscess
- Pseudotumor/myositis
- Hemangioma
- Rhabdomyosarcoma
- Neuroblastoma
- Lymphoma
- Eosinophilic granuloma

Bilateral ?

- Optic nerve glioma
- Neuroblastoma
- Leukemia
- Lymphoma
- Pseudotumor/myositis
- Eosinophilic granuloma



Eyelid echymosis ?

- Neuroblastoma
- Ewing's sarcoma
- Leukemia
- Eosinophilic granuloma
- Lymphoma



Present at birth ?

- | | |
|--------------------------|--------------------------|
| Microphthalmos with cyst | Varix |
| Teratoma | Optic nerve glioma |
| Capillary hemangioma | Retinoblastoma |
| Lymphangioma | Neuroblastoma |
| Dermoid cyst | Neurofibroma |
| Meningoencephalocele | Juvenile xanthogranuloma |



Intermittent ?

- Lymphangioma
- Dermoid cyst
- Varix
- Inflammatory Pseudotumor
- Mucocele



An illusion ? ...

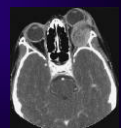
1. Unilateral high axial myopia
2. Actual enophthalmos of other eye
3. Upper lid retraction



By appearance ?

Tumors that are well circumscribed on neuroimaging

- Cavernous hemangioma
- Schwannoma
- Fibrohistiocytoma
- Neurofibroma
- Hemangiopericytoma
- Dermoid cyst



Simple approach to Orbital Mass in Children

Age - young vs. older



Speed of growth -

fast: days to week(s)



slow: months to year(s)



Simple approach to Orbital Masses in Children

		AGE	
		Young	Older
Growth	Fast	Infection Leukemia Neuroblastoma	Infection Myositis Rhabdomyosarcoma Lymphoma
	Slow	Dermoid cyst Glioma Hemangioma Lymphangioma Eosinophilic granuloma	Ewing's sarcoma Fibrous dysplasia Mucocoele

Fast/young.....

15 month old
2 week history of proptosis
No other complaints

Normal birth
No childhood illnesses
Normal development

Fast/young



Vision – CSM, localizes 1mm bead OU easily

Pupils – no afferent defect

External - 6mm proptosis OS

EOM – slight decrease OS

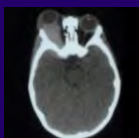
Fundus – Venous engorgement OS

Normal nerve



Fast/young

WBC – 150,000



Diagnosis: Chloroma

Fast/young



Post Chemotherapy

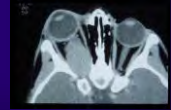
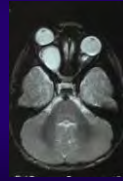
Slow/Young



- 6 month old
- ? Proptosis OD
- Mid optic atrophy



Slow/Young



Slow/Young



Child < 6 y.o. with gradual, painless, progressive, unilateral axial proptosis with visual loss

Optic nerve glioma (juvenile pilocytic astrocytoma)

- slow-growing tumor
- Decreased visual acuity with a RAPD
- CT scan or MRI - "fusiform" enlargement of the ON
- associated with NF1 Dx if bilateral
- Systemic evaluation and genetic counselling for NF is essential

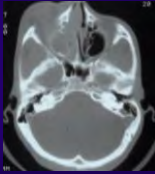
NF 1 - Optic Nerve Glioma



Fast/young.....



Fast/young,



Fast/young,



Unilateral proptosis, pain, fever, decreased ocular motility, erythema, and edema of the eyelids

Infectious orbital cellulitis

- usually bacterial
- extended posterior to orbital septum
- meningitis
- cavernous sinus thrombosis
- staphylococci, streptococci, anaerobes, and *Haemophilus influenza* (in children under 5 years of age)
- most common source -- ethmoid sinusitis
- intravenous antibiotics

Fast/older,



- 15 year old female
- 2 week history of ? Diplopia
- Mild ? eye pain on movement
- No other symptoms

Doesn't want to go to school --- Exam week !

Fast/older,

Motility



Ow! It hurts. Doesn't want to move her eyes !

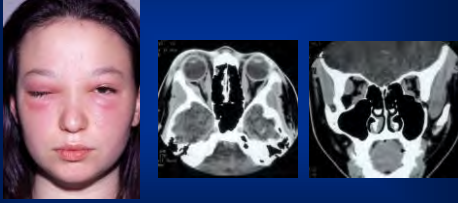
Fast/older,

Motility



Fast/older

I told you I had an eye problem !!



Orbital Myositis

Lessons Learned

Pain

- Uncommon in benign strabismus
- Pain on movement = myositis/inflammatory

Incomitance



Fast/older.....

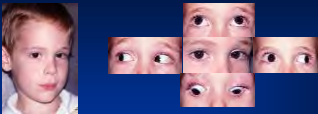


- 8 year old
- Notes “funny” right eye x 2 weeks
- Head position to left
- Otherwise fine !

Motility

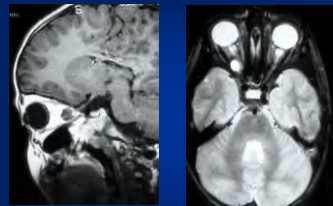


Case Report



Diagnosis ?

- a) Right Duane's syndrome
- b) Right internuclear ophthalmoplegia
- c) Myasthenia gravis
- d) Right orbital mass



Radiology: “probable hemangioma / lymphangioma”

Case Report



Management ?

- a) Excisional Biopsy
- b) Oral Steroids
- c) Observation
- d) External beam radiation

Case Report

2 weeks later.....



Rhabdomyosarcoma

Child with rapidly progressive unilateral proptosis, displacement of the globe inferiorly, and edema of upper eyelid?

Rhabdomyosarcoma

- > most common primary orbital malignancy of childhood
- > malignant growth of striated muscle tissue
- > rapidly progressive mass in the superior orbit with proptosis, globe displacement, and eyelid swelling
- > average age of presentation is 7 years
- > Prompt diagnosis with orbitotomy and biopsy is crucial
- > **overall mortality is 60%** once the disease has extended to orbital bones
- > Current Rx with radiation + chemo have lowered mortality rates to 5 to 10%

Fast/older.....



Fast/older.....

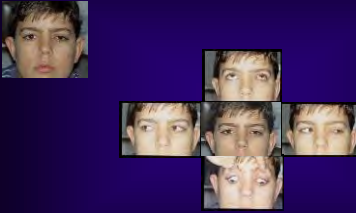


Persistent proptosis or progression of infection despite adequate antibiotic Rx

Orbital subperiosteal abscess

- CT scan
 - > confirm diagnosis
 - > locate the abscess
- surgical drainage and continued intravenous antibiotics

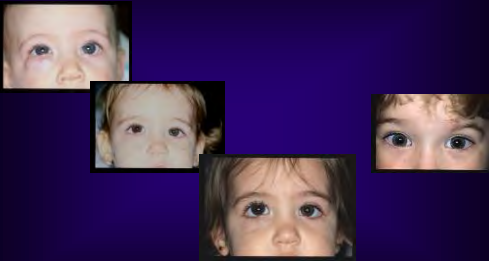
Fast/older.....



Slow/young.....

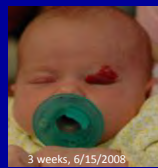


Slow/young.....



Capillary Hemangioma

Systemic corticosteroids



The NEW ENGLAND JOURNAL of MEDICINE

Propranolol for Severe Hemangiomas of Infancy

Article • Study Article • Case • Letter

To the Editor:

Despite their self-limited course, inflexible capillary hemangiomas can impair vital eye function. Because of their histogenetic characteristics, our first case of infantile capillary hemangioma¹ (other entities include rubeoma infantis and nevus) was treated with propranolol that achieved complete resolution of these hemangiomas. Our previous study from 11 children are summarized in Table 1 in the Supplemental Appendix available with this issue of the issue at www.nejm.org.

The first child had a raised capillary hemangioma. Despite corticosteroid treatment, the lesion was unresponsive to intravenous heparin, topically treated, or the patient was treated with propranolol. Two days after the initiation of propranolol, the hemangioma changed from convex to the eye and flattened. The corticosteroids were tapered, but the hemangioma continued to regress. When the corticosteroids were discontinued, no regrowth of the hemangioma occurred. Until the child was 14 months of age, the hemangioma remained flat.

The second child had a plaque-like elevated capillary hemangioma involving the entire right upper lip and part of the face (Fig 1). At 7 months of age, a subcutaneous component developed, and despite corticosteroid treatment, the hemangioma continued to enlarge.

Magnetic resonance imaging revealed intracranial and intracanalicular extension, as well as an elevated degree of vascularity compared with the normal and hyperplastic vessels of the capillary hemangioma. Ultrasonography showed increased color Doppler and treatment with propranolol. At 18 months of age, the child was able to open his eye.

Our study of 11 children with the typical infantile hemangioma was initiated 6 weeks after the child was able to open his eye independently, and the study was the typical infantile hemangioma, which is self-limited. Propranolol was discontinued at 8 months of age, and the majority of the hemangiomas at 8 months of age, the eye opening was

Propaganolol in Infantile Hemangioma

Mechanism of Action?

- **Early (1-3 days):** vasoconstriction due to decreased release of nitric oxide
 - Inhibit vasodilation by adrenaline via beta receptors → vasoconstriction → reduction of blood flow to the hemangioma
- **Intermediate:** blocking of pro-angiogenic signals (VEGF, bFGF, MMP2/9) → growth arrest
 - MMP 2/9 regulated via beta receptors
- **Late:** induction of apoptosis in proliferating endothelial cells → tumor regression
 - Disengage inhibition of apoptosis caused by beta agonists

Storch HJ, Hooser PJ. Propranolol for infantile haemangiomas: insights into the molecular mechanisms of action. *Br J Dermatol.* 2010 Aug;163(2):269-74. Epub 2010 May 8.

Safety

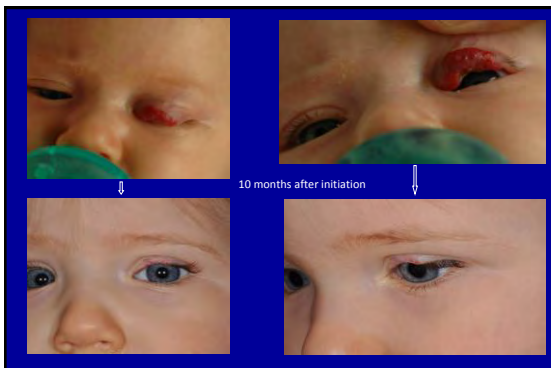
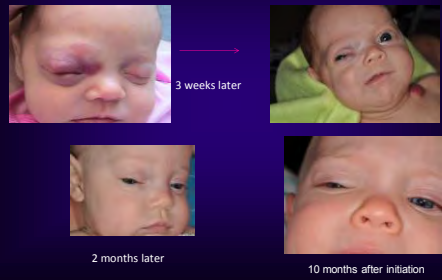
- > 40 years of clinical experience in infants and young children
- No documented case of death or serious cardiovascular morbidity <6 yrs
- BUT... among beta blockers- high risk of side effects
 - Bradycardia
 - Hypotension
 - Bronchospasm (ask about asthma or episodes of wheezing)
 - **Hypoglycemia (stop if decreased food intake for ANY reason)**
 - Check other medications (salicylates, sulfonyleureas, quinine)
 - Preoperative & nighttime fasting
 - Give during day, followed by feeding
 - Hyperkalemia
 - Sweats
 - Cold & mottled extremities
 - Diarrhea



After propranolol



Orbital Hemangioma



Timolol



Guo S, Ni N. Topical treatment for capillary hemangioma of the eyelid using beta-blocker
 ointment. Arch Ophthalmol. 2010;Feb;128(2):255-6.

Propranolol & injections



My experience with propranolol

- Treated > 75 patients since February 2009
- Reflux: mild to extremely severe
- Sleepy 1st 2 weeks → normal activity
- Ulceration: both helpful & harmful
- Younger children usually have a better outcome

Summary

Simple approach to Orbital Mass in Children

		AGE	
		Young	Older
Growth	Fast	Infection Leukemia Neuroblastoma	Infection Myositis Rhabdomyosarcoma Lymphoma
	Slow	Dermoid cyst Glioma Hemangioma Lymphangioma Eosinophilic granuloma	Ewing's sarcoma Fibrous dysplasia Mucocoele

Final comment



You got to be very careful because.....
 if you don't know where you are going,
 you might not get there !!

Karl G. Stonecipher, MD

Karl G. Stonecipher, MD is a cornea and refractive trained surgical specialist and the Director of The Laser Center in Greensboro, North Carolina, which he joined in 2005. Prior to that appointment he had been the director of the Southeastern Laser and Refractive Center in Greensboro, North Carolina from 1991-2005. He is a Clinical Assistant Professor at the University of North Carolina and assists in the refractive surgery training of the residents in the department of Ophthalmology.

Dr. Stonecipher received his undergraduate degrees in Biology and Chemistry from Southern Methodist University. His medical degree was obtained from the University of Oklahoma Health Sciences Center and his residency in Ophthalmology was at Tulane University from 1987 through 1990. He spent 18 months in a cornea and refractive surgery fellowship with Dr. J. James Rowsey at the McGee Eye Institute. Dr. Stonecipher has additional basic science education from Stanford University prior to starting in practice at Southeastern Eye Center. He has performed over 65,000 refractive surgical procedures and over 25,000 cataract surgical procedures.

With more than 100 book chapters, abstracts and articles published, Dr. Stonecipher speaks both nationally and internationally on refractive, cataract, presbyopic and corneal surgery.

Dr. Stonecipher has been certified by the American Board of Ophthalmology since 1992. His memberships include the American Academy of Ophthalmology, the International Society for Refractive Surgeons, and the American Society of Cataract and Refractive Surgery. He is currently involved in FDA trials for the Study of Cornea, Cataract, Presbyopic and Refractive Surgery. He recently received the Achievement Award from the American Academy of Ophthalmology and is listed as one of the Top Fifty Ophthalmologist by Cataract and Refractive Surgery Today, registered with Who's Who in Ophthalmology, and picked as one of Americas Top Ophthalmologists.

Born and raised in Oklahoma City, Oklahoma, Dr. Stonecipher and his wife, Lynne, have two children, Megan and Kody, and live in Greensboro, North Carolina.

Solutions for Presbyopia Past & Future: Surgical Treatment Options

Karl Stonecipher, MD
Clinical Assistant Professor of
Ophthalmology, University of North
Carolina
Medical Director TLC Greensboro

“If you keep talking sooner or later
something you say will sound intelligent”
Anonymous

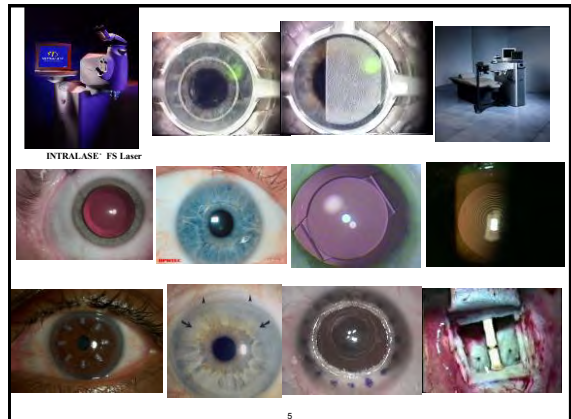
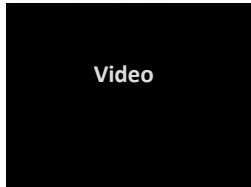


Number 10

10. Expect the unexpected...

“My first night on call at
Charity I spent the night at the
hospital. After clinic one of
the third years told me I had to
the ER to see a patient that
had been hit by a Mac Truck.....

When I arrived there he
was.....”



Effective Presbyopia Treatment Remains a “Holy Grail” of Ophthalmology

WHY?

- Almost 1/3 of the population of developed nations is 35-65 years old
- 1% of the population joins them each year
- Few individuals escape the onset of presbyopia
- By age 50, the average patient needs a 1.50D reading add
- Today's 50 year olds are a demanding group
- The market potential is HUGE

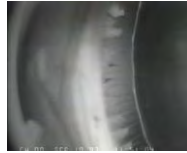
The characteristics of any focusing system include:

- The range of distances (vergences) over which it can operate
- The ambient light conditions under which it can operate efficiently
- The accuracy of focus within its operating range
- The stability of its focus on a fixed object
- The speed with which it can attain its position of focus
- **When we consider the eye as a focusing system, how do these characteristics change with age?**



To Potentially Restore 'Dynamic' Accommodation

- *Make the spherical aberration of the crystalline lens very negative (increased depth of field, not true accommodation)*
- *Increase efficiency of the ciliary muscles*
- *Increase sclera viscoelasticity*
- *Increase lens-ciliary body space*
- *Increase lens mobility in some other fashion*
- *Design a viscoelastic intraocular lens*

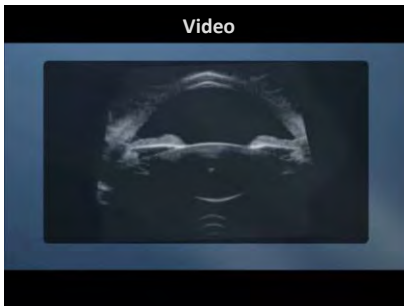


New Thoughts

Video

Real Footage

Video



Number 9

9. Patients say the darndest things...

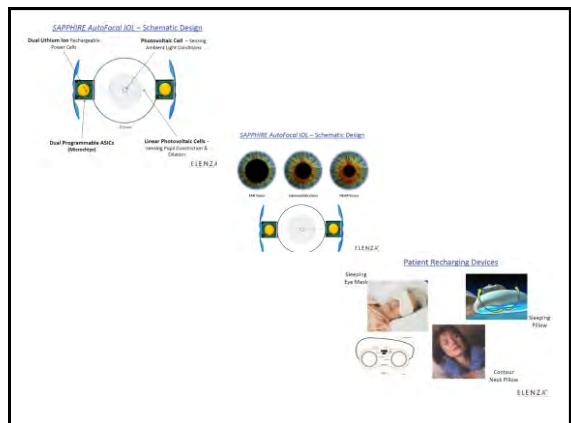
As I second year I was called in to room 4 in the ER. I began with my history of how this had happened when he said, "Have you guys changed the ceiling tiles in here?"

Charity taught me to believe in God because it always seemed that Evolution and "Survival of the Fittest" was not applicable to New Orleans.



Desirable Attributes of an Effective Technology Solution

- Continuously variable addition up to perhaps 3 or 4 D
- No loss in image contrast at any distance
- Rapid response – ideally no need for intervention by patient.
- No restrictions in viewing direction for objects at any distance



Number 8

8. I never could understand Dr. Caldwell's teaching as it was happening but I certainly figured it out as time went along.....



Do what it takes.....

Surgical Presbyopia Solutions

Pseudo Accommodation True Accommodation

- Multifocal
 - Cornea or IOL
 - Monovision
 - Cornea or IOL
 - Increased Asphericity
 - Cornea or IOL
 - Corneal inlays for increased depth of field
- Accommodating IOLs
 - Mechanical
 - Electro-optical
 - Scleral techniques
 - Scleral laser micro-excisions
 - Scleral implants

Surgical procedures for presbyopia "treatment"-correction

CORNEA

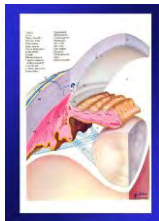
- Conductive Keratoplasty:
Monovision CK, Near Vision CK
- Excimer Laser Corneal TPG Change:
LASIK Monovision, Multi-focal cornea, PRESBYLASIK
- Corneal Inlays Insertion:
(Acufocus Inc., Biovision Inc.Revitavision, iNC.)

Lens

- Surgical Lens Exchange:
Accommodating IOL's, Multifocal IOLs, Phakic IOLs

Sclera

- *Scleral bands implantation, ACS, Laser Scleral Ablation Expansion (LAPR), LaserACE®.*



Number 7

7. If thine eye offend thee then pluck it out.....



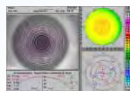
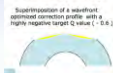
CORNEAL PRESBYOPIA "TREATMENT"

May Not Be Ideal.

- **POTENTIAL DECREASE** in Contrast Sensitivity
- **POTENTIAL DECREASE** in Distance VA
- **INDUCED Aberrations** - Difficulties for further IOL choice & IOL power calculation when cataract surgery will be needed.
- Progression of presbyopia-reading glasses may be needed again over time



Custom Q: profile design:



One Femtosecond Laser for both Cataract and Refractive Applications

Cataract



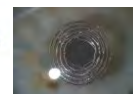
Flap



Arcuate Incisions



Therapeutic



INTRACOR
(Presbyopia Treatment)

Presbyopia Treatment Options Cataract Surgery

1. Monofocal IOLs (monovision)
2. Multifocal IOLs
3. Presbyopia Correcting IOLs

• Limitations/drawbacks:

- Not ideal for patients with...
 - No Cataract
 - No Distance prescription
- Optical challenges
 - Ghosting, glare, halo, depth of focus
- Risks
 - Intraocular surgery (invasive)
 - Retinal detachment



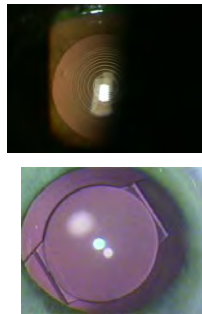
Other Surgical Alternatives Intraocular lenses

- Cataract surgery with monofocal monovision may be a successful option
 - Some binocularity is sacrificed
 - Some patients will not tolerate monovision – test with a contact lens before surgery to avoid later lens exchange
 - The difference that most patients will accept is limited to 1.5D, which may be insufficient



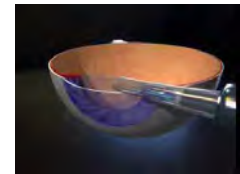
Other Surgical Alternatives Intraocular lenses

- **Multifocal IOLs demonstrate good near and distance acuity**
 - Increased likelihood of visual disturbances relative to a monofocal IOL
 - Intermediate vision may be compromised
 - Patients will have a fixed distance where near vision is optimized – lenses are not dynamic
- **Accommodating IOLs have failed to meet expectations**
 - Poor predictability
 - Challenges of lens position, stability, capsule fibrosis



Multifocal IOL's May Not Be Ideal

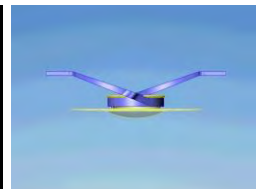
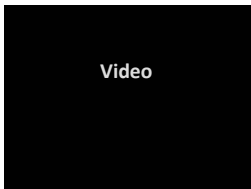
- Splitting of light may increase the potential for glare and halos
- There is no true accommodating IOL
- Range of Pseudo-accommodation or accommodation may be limited.



New Designs

Synchrony

NuLens



New Designs

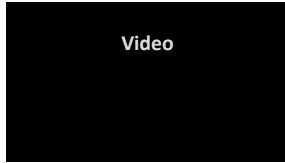
Fluid Vision

Smart Lens



Number 6

6. You get by with a little help from your friends.....

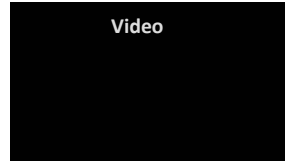


Yes we still keep in touch....

CLEAR LENS EXCHANGE

PRO

- Progressive change of lens optical power ceases
- New Multifocal, Accommodative & Aspheric IOLs for better quality of vision
- Suitable treatment for high myopes



CON

- Potential Loss of Contrast Sensitivity
- Inside Eye procedure
- Infection risk
- Risk of IOL Power miscalculation
- Surgical Complications
- Secondary cataract

Contact lenses for the presbyope

(In principle can also be achieved through excimer laser on cornea or an implanted IOL but those cannot be changed easily if patient is unhappy)

- Single-vision contact lens distance correction, spectacles for near addition (**convenience?**)
- Monovision, usually dominant eye far, non-dominant near (**loss of stereopsis and binocularity?**)
- Alternating or translating/ multifocal IOL (**difficult to achieve adequate relative lens movement**)
- Simultaneous bifocals, varifocals etc (**loss of image contrast, since both in- and out-of-focus images always superimposed**)
- Modified monovision etc
- General problem of interaction of light-dependent changes in pupil diameter with lens design

Charman et al, Vision Res 38, 2841-2853, 1998 W.Neil Charman University of Manchester

Number 5

5. Never believe the ER is telling you the whole story....



I got something in my eye.....

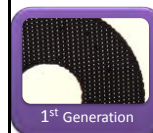


Surgical Presbyopia Solutions

Three different non-IOL approaches

- Corneal Inlays
- Intrastromal corneal ablation
- Dynamic "Active" restoration of Accommodation" (SSP, LaserACE®, Lens fillers)

Refinements by Generation

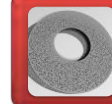


1st Generation



Generation 2 & 3

- Thinner
- Medical grade film
- Easier to produce



Generation 4 & 5

- Improved light transmission
- Improved hole pattern
- Not susceptible to UV light



Final Design

- Optimized hole pattern
- Optimized light transmission
- Even thinner

Corneal Inlays

Aperture to increase depth of field

- Small diameter aperture to increase depth of field
- Centration is challenging
 - Pupil position changes with light levels
 - Axis of incoming light will change
- Small apertures will reduce overall light entering the eye
 - May present challenges in dim light

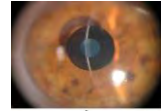


Yilmaz OF, Alagöz N, Pekel G, Azman E, Aksoy EF, Cakir H, Bozkurt E, Demirok A. Intracorneal inlay to correct presbyopia: Long-term results. J Cataract Refract Surg. 2011 Jul;37(7):1275-81.

US FDA IDE - Study Design

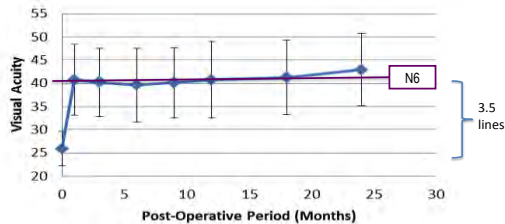
Emmetropic Presbyopes

- 24 Sites (US, Europe & Asia-Pacific)
- Prospective, non-randomized
- Subjects:
 - 507 enrolled and implanted
 - Naturally occurring presbyopic emmetropes
 - Spherical equivalent between +0.50 to -0.75



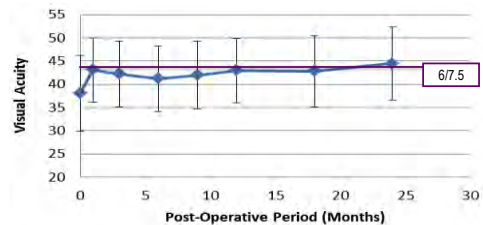
Uncorrected Near Visual Acuity at 40cm

- On average patients experienced a gain of 3.5 lines of near acuity between pre-op and the 24 month follow-up



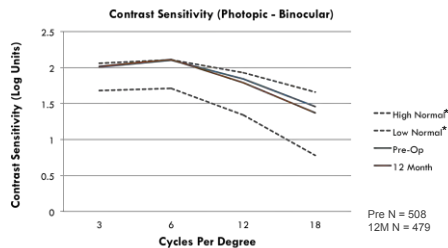
Uncorrected Intermediate Visual Acuity

- Mean uncorrected intermediate visual acuity improved to 6/7.5 post-op in the inlay implanted eye.



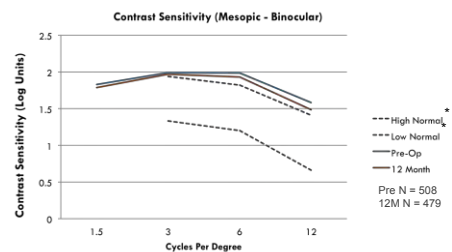
Binocular Photopic Contrast Sensitivity

- Binocular photopic contrast sensitivity remains within normal limits at 12 months post-op



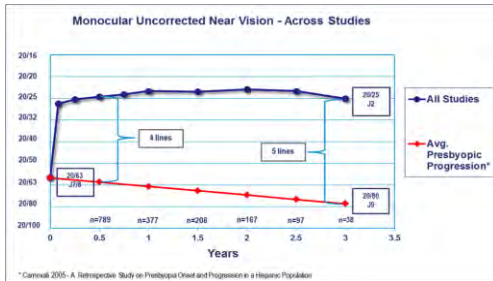
Binocular Mesopic Contrast

- Binocular photopic contrast sensitivity remains within normal limits at 12 months post-op



Long-Term Results

- Over a 3 year time period a presbyopic patient on average can expect to lose a line of vision
- Patients with a KAMRA Inlay, over the same time period, do not experience a loss of near vision



Long-Term Results

Emmetropic Presbyopes

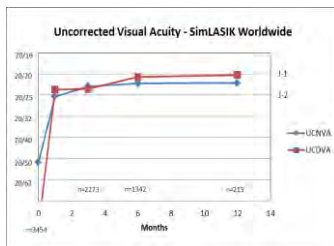
- Grabner et al presented 4 year results at ESCRS:
 - Mean UCNVA (inlay eye): **J2 at 40cm**
 - Mean UCDVA (inlay eye): **6/6**
- Yilmaz et al*, reported 4 years data in JCRS:
 - Mean UNVA (inlay eye): **J1**
 - Mean UDVA (inlay eye): **6/7.5**

Global Sim-LASIK Registry Results

Ametropic Presbyopes

- Sim-LASIK Mean acuities at 1 year across multiple practices:

- N=3,454 enrolled
- N=215 at 1 year
- UNVA: **J1-J2***
- UDVA: **6/6**



*Some sites measured UNVA at 40cm and others at 30cm.

Number 4

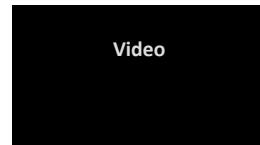
4. The Staff....

I had the opportunity to operate with over 40 great surgeons.....

I'm still learning from them today.....

"Even while men teach they learn."

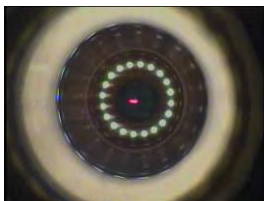
Seneca



Corneal Stromal Ablation

Intracor

- Concentric ring pattern of corneal stromal ablation
- Spares endothelium, epithelium
- Localized curvature changes produce an increase in spherical aberration, increasing depth of focus



Corneal Stromal Ablation

Intracor

- Clinical results demonstrate a significant improvement in near vision
 - 89% 20/25 distance and J2 or better near¹
 - 2 year mean UCDVA of 20/30, UCNVA of 20/30²
- Central steepening of the cornea is documented
- A mean myopic shift (0.5-0.9D) is reported, which may account for some of the near VA increase
- 2.5% of eyes lost 2 or more lines of BCDVA

1. Ruiz LA, Cepeda LM, Fuentes VC. Intrastromal correction of presbyopia using a femtosecond laser system. J Refract Surg. 2009 Oct;25(10):847-54.
 2. Holzer, MP, Tomalla, M, Neuhann, TH., Knorz, MC. Two-Year Follow-up of Femtosecond Intrastromal Presbyopic Laser Treatments; ASCRS Annual Meeting, 2011, Abstract # 984579

Presbyopia “treatment”- correction

No current Corneal or Lens method really restores accommodation:

- Surgically induced refraction change
- Pseudo-accommodation



Possible methods of surgically restoring “active” accommodation

- Remove lens and replace with “accommodating” IOL - limited power change (What if capsule is no longer elastic or circumlental gap is insufficient?) ****Not yet available**
- Remove too-hard lens, refill capsule with suitable material to mimic youthful lens (Affected by capsular fibrosis?) ****Not yet available**
- Increase circumlental gap - scleral expansion, Ultra-SEB etc. (Alteration of the globe may change refractive status?) ****Available in Clinicals**
- Increase Scleral Plasticity without altering the globe, Laser Micro excisions to improve ciliary muscle efficiency, LaserACE® (What if the lens is too hard?) ****Available in Clinicals**
- True accommodating implants (switchable power, e.g. by electrical power). (Numerous challenges but may hold promise for the future) **** Futuristic**

Number 3

Charity Hospital



Scleral Spacing Procedure

PresVIEW Scleral Implants (PSI)
(Refocus Group Inc. formerly PresbyCorp)



Imaging scleral expansion bands for presbyopia with optical coherence tomography.

www.knk-augen.de & www.refocus.de

Klinik für Augenheilkunde, Vivantes Klinikum Neukölln, Berlin, Germany. knk.augen@vivantes.de | J Cataract Refract Surg. 2003 Dec;29(12):2435-8.

The OCT method provided precise images of the segment depth and thickness, the scleral thickness at the scleral spur, the anterior chamber angle, and the angle-opening distance.



Presbyopia Treatment Options SSP Clinical Trial

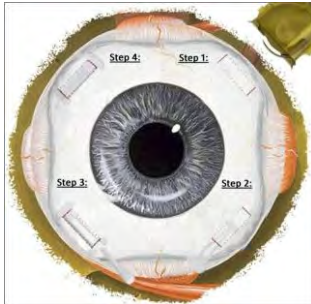
- Being conducted by Refocus Group, Inc.
 - Founded in 1996
 - US Research (FDA)
 - Final phase of FDA trial
 - 14 physician sites
 - 330 surgeries targeted
 - International Research (non-FDA)
 - On-going studies



SSP Implant



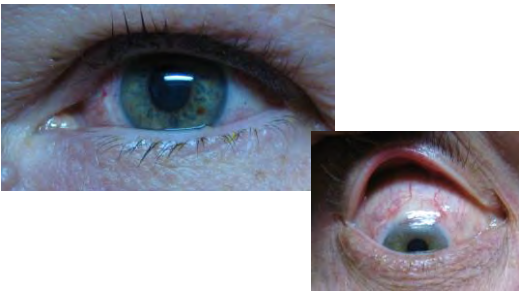
SSP implant procedure steps



Surgical Procedure

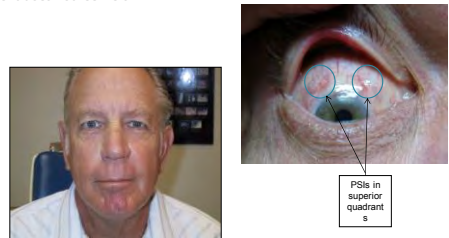
Video

SSP Implant Position Behind Eyelids



PresVIEW™ Scleral Implants (PSIs) in a Patient

Hidden during normal eye position
Only visible when pull down eyelids
Patient does not feel PSIs



What to Expect after SSP

- Near activities to strengthen focusing system
 - Practice using your near vision
 - Do not wear reading glasses
 - Allow more time to read
 - Be patient



Ssp Procedure

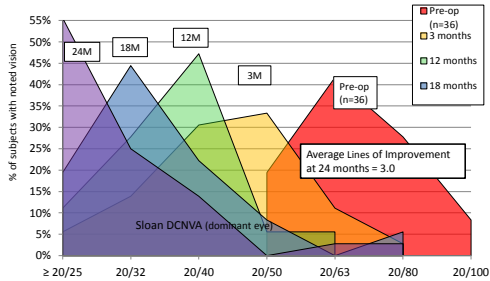
- Pros
 - Implants
 - Removable
 - Outside visual axis
 - Not monovision
- Cons
 - Cosmetic
 - Short term redness
 - Risk of rare complication, possibly severe*
 - Not an overnight solution
 - Rehabilitation of the focusing system
 - 2 year follow-up period



*see research study informed consent document for detailed information

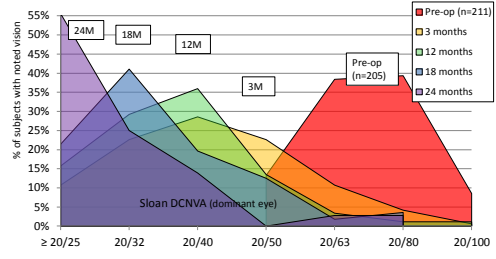
Individual Subjects' Vision Continues to Improve After the PresVIEW™ Procedure

Results from all 36 patients that have reached 24 months



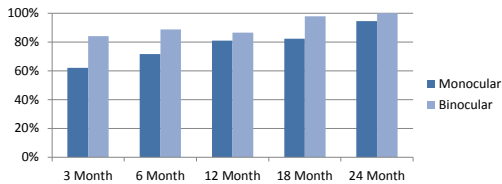
Results from Overall PresVIEW™ Procedure Study

Primary eye



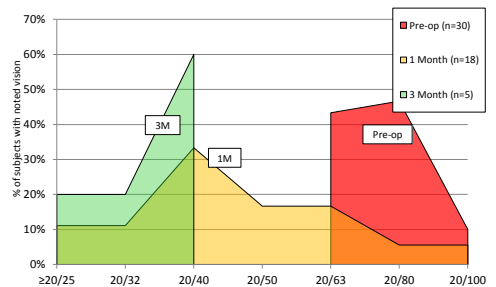
Post-Operative DCNVA of 20/40 or Better

	Monocular	Binocular
3 Month	62% (n=168)	84% (n=44)
6 Month	71% (n=123)	89% (n=97)
12 Month	82% (n=89)	86% (n=74)
18 Month	82% (n=56)	98% (n=44)
24 Month	94% (n=36)	100% (n=28)



Lines of Improvement from Baseline

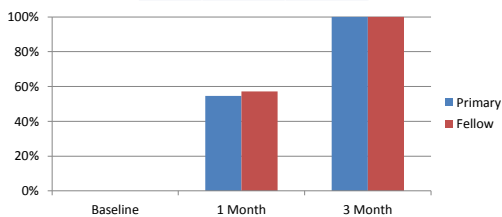
Distance Corrected Near Visual Acuity (DCNVA) @ 40cm – Sloan EDTRS Chart
Primary and Fellow Eyes (as of 5/29/2012)



Post-operative 20/40 or Better Primary vs. Fellow

Distance Corrected Near Visual Acuity (DCNVA) @ 40cm – Sloan EDTRS Chart (as of 5/29/2012)

	Primary	Fellow
Baseline	0% (n=18)	0% (n=12)
1 Month	55% (n=11)	57% (n=7)
3 Month	100% (n=4)	100% (n=1)



Conclusions

- The PresVIEW™ Procedure improves near acuity over time
 - An average of 3 lines of improvement at 24 months
 - 100% of subjects at 24 months are 20/40 or better at near
 - Pattern of continual improvement over 24 months
- The IDE study is expected to be fully enrolled by Fall 2012

Am I a Candidate?

- 50-60 years old
- Generally healthy
- No glasses for distance vision
- Need reading glasses
- No prior eye surgery (i.e. – LASIK)
- No prior study participation
- Willing to return for follow-up exams



Number 2

2. There are foreign bodies and then there are foreign bodies....

Don't just pull it out.....



The LaserACE® Procedure

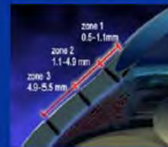
- Use of a laser to create regions of increased plasticity on the sclera.
- NO attempt to alter the shape of the sclera, the cornea or the crystalline lens.
- Increased plasticity is presumed to increase the mechanical advantage of the ciliary muscle, facilitating accommodation where it might otherwise have been lost (e.g., after age 45).



LaserACE® Procedure

Theory:

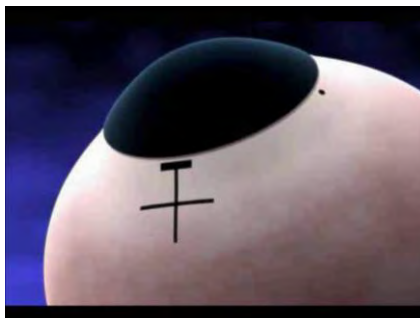
Excisions in the sclera in critical zones restores in part the biomechanics of the accommodative system. Procedure objective: to restore the mechanical efficiency of the natural accommodation mechanism. It improves Biomechanical mobility to achieve accommodative power.



- 600um spot size in Mathematical Diamond Matrix Pattern in made with a Er:Yag laser with fiber optic probe
- The Excisions are in 3 Critical Zones of physiological importance
- Performed in the 4 oblique quadrants
- 9 Excisions per quadrant

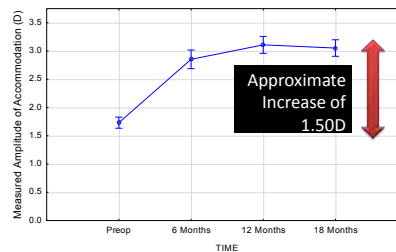
*VisioDynamic Theory, Hignley 2003

LaserACD



Statistically Significant Increase in Objective Amplitude of Accommodation was Observed

Change in Measured Amplitude of Accommodation Over Time
74 eyes of 37 patients
Statistically significant improvement, $p < 0.01$



LaserACE® Summary

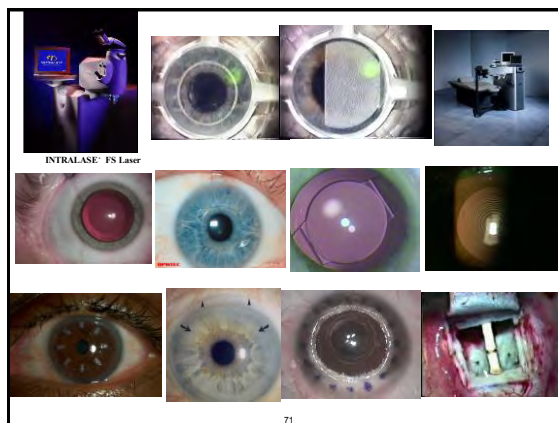
- Scleral procedure, spares the optical elements of the eye
- No change in Rx, no change in asphericity
- Preserves existing eye geometry
- Produces a stable, objectively measurable increase in accommodative amplitude
- True dynamic accommodation, not multifocality
- Potential to be combined with other lens/corneal solutions to improve dynamic range of vision
- Potential to serve as a rescue procedure for other failed accommodating IOL's .
- Potential to serve as a dynamic vision enhancer for complications created by other technologies (corneal or lens)

Surgical Presbyopia Treatments: Summary Table

	IOL	Kamra Acufocus	Intracor	LaserACE
ADVANTAGES				
True accommodation				+
Minimally invasive			+	+
Preserves best-corrected distance vision	+	+		+
Compatible with additional technologies				+
DISADVANTAGES				
Increases potential for visual disturbances	+	+	+	
Alters the optical elements of the eye (cornea, lens)	+	+	+	
May complicate future surgeries (e.g. cataract)		+	+	
Alters normal eye geometry			+	

The Lens Solution

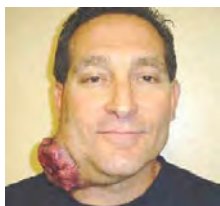
Video



71

Number 1

1. I just wanted to see one of every thing....



Thank You





Florida Society of Ophthalmology
6816 Southpoint Parkway, Suite 1000
Jacksonville, FL 32216
Phone: 904-998-0819 Fax: 904-998-0855
www.ophmasters.com