Glaucoma 2014
Integrating New Technologies and Approaches Into Your Daily Practice

Under Pressure®

Program Directors
David S Friedman MD MPH PhD
James D Brandt MD

In conjunction with the American Glaucoma Society

McCormick Place
Chicago, Illinois
Saturday, Oct. 18, 2014

Presented by:
The American Academy of Ophthalmology

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2014 Glaucoma Subspecialty Day Planning Group

On behalf of the American Academy of Ophthalmology and the American Glaucoma Society (AGS), it is our pleasure to welcome you to Chicago and Glaucoma 2014: Integrating New Technologies and Approaches Into Your Daily Practice.

David S Friedman MD MPH PhD
Program Director
Alcon Laboratories, Inc.: C
Allergan, Inc.: C
Carl Zeiss, Inc.: S
For Sight Vision 5: C
Merck & Co., Inc.: C, L
Nidek, Inc.: C
Quark Bio Tech: C
Valiant: C

James D Brandt MD
Program Director
Alcon Laboratories, Inc.: C, L
Allergan, Inc.: C, L
Apple Computer, Inc.: O
Carl Zeiss Meditec: C
Glaukos Corp.: C, O

Anjali M Bhorade MD
None

Yvonne M Buys MD
Alcon Laboratories, Inc.: C, L
Allergan, Inc.: L

Teresa C Chen MD
None
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CME Credit

Academy's CME Mission Statement
The purpose of the American Academy of Ophthalmology’s Continuing Medical Education (CME) program is to present ophthalmologists with the highest quality lifelong learning opportunities that promote improvement and change in physician practices, performance or competence, thus enabling such physicians to maintain or improve the competence and professional performance needed to provide the best possible eye care for their patients.

2014 Glaucoma Subspecialty Day Meeting Learning Objectives
Upon completion of this activity, participants should be able to:

- Describe innovations in the diagnosis and management of glaucoma within their historical context
- Manage complex cases of glaucoma when other eye diseases are present
- Evaluate the current status of optic disc and retinal nerve fiber layer imaging and their role in diagnosing and managing glaucoma
- Demonstrate familiarity with current issues in medical and surgical therapy for glaucoma
- Identify and manage glaucoma surgical complications

2014 Glaucoma Subspecialty Day Meeting Target Audience
This activity has been designed to meet the educational needs of general ophthalmologists, glaucoma specialists and other ophthalmologic subspecialists, and allied health personnel who are involved in the management of glaucoma patients.

2014 Glaucoma Subspecialty Day CME Credit
The American Academy of Ophthalmology is accredited by the Accreditation Council for Continuing Medical Education to provide CME for physicians. The American Academy of Ophthalmology designates this live activity for a maximum of 7 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Self-Assessment Credit
This activity meets the Self-Assessment CME requirements defined by the American Board of Ophthalmology (ABO). Please be advised that the ABO is not an accrediting body for purposes of any CME program. The ABO does not sponsor this or any outside activity, and the ABO does not endorse any particular CME activity. Complete information regarding the ABO Self-Assessment CME Maintenance of Certification requirements is available at http://abop.org/maintain-certification/part-2-lifelong-learning-self-assessment/cme/. NOTE: Credit designated as “self-assessment” is AMA PRA Category 1 Credit™ and is also preapproved by the ABO for the Maintenance of Certification (MOC) Part II CME requirements.

Teaching at a Live Activity
Teaching instruction courses or delivering a scientific paper or poster is not an AMA PRA Category 1 Credit™ activity and should not be included when calculating your total AMA PRA Category 1 Credits™. Presenters may claim AMA PRA Category 1 Credits™ through the American Medical Association. Please contact the AMA to obtain an application form at www.ama-assn.org.

Scientific Integrity and Disclosure of Financial Interest
The American Academy of Ophthalmology is committed to ensuring that all CME information is based on the application of research findings and the implementation of evidence-based medicine. It seeks to promote balance, objectivity and absence of commercial bias in its content. All persons in a position to control the content of this activity must disclose any and all financial interests. The Academy has mechanisms in place to resolve all conflicts of interest prior to an educational activity being delivered to the learners.

Attendance Verification for CME Reporting
Before processing your requests for CME credit, the Academy must verify your attendance at Subspecialty Day and/or AAO 2014. In order to be verified for CME or auditing purposes, you must either:

- Register in advance, receive materials in the mail and turn in the Final Program and/or Subspecialty Day Syllabus exchange voucher(s) onsite;
- Register in advance and pick up your badge onsite if materials did not arrive before you traveled to the meeting or
- Register onsite.

CME Credit Reporting
South, Level 2.5; Academy Resource Center, Booth 508
Attendees whose attendance has been verified (see above) at AAO 2014 can claim their CME credit online during the meeting. Registrants will receive an email during the meeting with the link and instructions on how to claim credit.

Onsite, you may report credits earned during Subspecialty Day and/or AAO 2014 at the CME Credit Reporting booth.

Academy Members: The CME credit reporting receipt is not a CME transcript. CME transcripts that include AAO 2014 credits entered onsite will be available to Academy members on the Academy’s website beginning Nov. 13, 2014.

NOTE: CME credits must be reported by Jan. 15, 2015. After AAO 2014, credits can be claimed at www.aao.org.
The Academy transcript cannot list individual course attendance. It will list only the overall credits spent in educational activities at Subspecialty Day and/or AAO 2014.

Nonmembers: The Academy will provide nonmembers with verification of credits earned and reported for a single Academy-sponsored CME activity, but it does not provide CME credit transcripts. To obtain a printed record of your credits, you must report your CME credits onsite at the CME Credit Reporting booths.

Proof of Attendance

The following types of attendance verification will be available during AAO 2014 and Subspecialty Day for those who need it for reimbursement or hospital privileges, or for nonmembers who need it to report CME credit:

- CME credit reporting/proof-of-attendance letters
- Onsite Registration Form
- Instruction Course Verification Form

Visit the Academy’s website for detailed CME reporting information.
The American Glaucoma Society (AGS)
Subspecialty Day Lecture
The Quarter Century’s Progress in the Treatment of Open-Angle Glaucoma
Saturday, Oct. 18, 2014
11:27 AM – 11:57 AM

Henry D Jampel, MD MHS

Henry D. Jampel, M.D., M.H.S., Odd Fellows Professor of Ophthalmology, was raised in the home of an academic ophthalmologist, and hence was exposed to ophthalmology at an early age. After graduating from Harvard summa cum laude in Biology, he attended the Yale University School of Medicine where he met his wife Risa, a dermatologist who has been part of the Johns Hopkins community for almost 30 years. They have three children, Catherine, a PhD candidate in Geography at Clark University, Joseph, a Harvard graduate, and Sarah, who is a senior at Yale. The decision to enter the field of ophthalmology came late during medical school, and when he sought his father, Dr. Robert Jampel’s, advice about where he should train, he was told “Wilmer, if you can get in.”

After completing his residency at Wilmer, Dr. Jampel was encouraged to stay at Wilmer for an extended glaucoma fellowship with Harry Quigley, M.D., A.E. Maumenee Professor of Ophthalmology, and Irvin Pollack, M.D., Professor Emeritus. Dr. Quigley doubled the faculty of the Glaucoma Service in 1988 by adding Dr. Jampel as his colleague. Dr. Jampel went back to school as an Associate Professor and obtained a Master’s degree in Health Finance and Management in 1996.

Dr. Jampel’s research career has encompassed both laboratory and clinical research. He was a principal investigator on the Collaborative Initial Glaucoma Treatment Study, a multi-center study comparing medical and surgical treatment for glaucoma in newly diagnosed patients. He was also an investigator, along with fellow faculty member Don Zack, M.D., Ph.D., Guerrieri Family Professor of Ophthalmology, in the Ocular Hypertension Treatment Study. He actively collaborated with Dr. David Friedman, M.D., MPH, Alfred Sommer Professor of Ophthalmology, and Dr. Michael Boland on a government funded project assessing the value of screening and treating glaucoma. Dr. Jampel has collaborated with the team of Ran Zeimer, Ph.D., Morton F. Goldberg Professor of Ophthalmology, and Susan Vitale, Ph.D., M.H.S., on imaging devices for the detection of glaucoma and its progression. Throughout all of his endeavors, Dr. Jampel has been assisted by his study coordinator and administrator, Rhonda Miller, C.O.A. He observes “The opportunity to collaborate with brilliant vision scientists at Wilmer is what really makes the research enjoyable.”

Jampel’s interests in ophthalmology are broad and his service to the field considerable. Since 2003, he has been the Deputy Editor-in-Chief of Ophthalmology, one of the most prestigious clinical journals in the field. He chairs the American Academy of Ophthalmology’s Ophthalmic Technology Assessment Panel, which evaluates the role of devices in the diagnosis and management of glaucoma. Closer to home at Wilmer, for the past 8 years, Dr. Jampel has served as medical director of Wilmer’s Green Spring Station satellite office, where he oversees an outpatient clinic with 35,000 visits a year, the Laser Vision Center, and the Ambulatory Surgery Center.

Endurance athletics are Dr. Jampel’s main extracurricular activity. He has completed two Ironman distance triathlons, in Hawaii in 1999 and in Lake Placid in 2004, and 6 marathons, including Boston in 2009. In September of 2014 he completed his fourth annual 3 mile open water swim as part of a fundraiser for the Kimmel Cancer Center at Johns Hopkins.
Faculty

Iqbal K Ahmed MD
Mississauga, ON, Canada
Assistant Professor
University of Toronto
Clinical Assistant Professor
University of Utah

Keith Barton MD
London, England
Consultant Ophthalmic Surgeon
Moorfields Eye Hospital

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Professor of Ophthalmology
University of Iowa

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and Chairman of Ophthalmology
University of North Carolina

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Glaucoma
Singapore National Eye Centre
Professor of Ophthalmology
National University of Singapore

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University
Assistant Professor
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Johns Hopkins University

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Chair, Continuing Professional
Development / Annual Meeting
Planning Committee
Canadian Ophthalmological Society
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Glaucoma Service
Massachusetts Eye and Ear Infirmary

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Physician
Spokane Eye Clinic

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Baltimore, MD
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Dana Center for Preventive Ophthalmology
Wilmer Eye Institute, Johns Hopkins University
Professor of Epidemiology and International Health
Johns Hopkins Bloomberg School of Public Health

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Director, Glaucoma/Cataract Moran Eye Center
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Director, Division of Ophthalmic and ENT Devices
FDA / Center for Devices and Radiological Health / Office of Device Evaluation

Ivan Goldberg MBBS FRANZCO
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Surgical Eye Specialists

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Director, Glaucoma Service
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Director, UPMC Eye Center

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Jefferson Medical College

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and Visual Sciences
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Assistant Professor of Ophthalmology
and Visual Sciences
Institute for Healthcare Policy and Innovation

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Vice Chair and Associate Professor of Ophthalmology
Northwestern University Feinberg School of Medicine

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Aristotle University of Thessaloniki
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Associate Professor of Ophthalmology
Duke Eye Center
Career Development Awardee
VA Health Services Research and Development

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Distinguished Professor of Ophthalmology
University of California, San Diego
Chair, Department of Ophthalmology, and Director, Hamilton Glaucoma Center
University of California, San Diego

Derek S Welsbie MD
Baltimore, MD
# Glaucoma 2014: Integrating New Technologies and Approaches Into Your Daily Practice

*In conjunction with the American Glaucoma Society*

**SATURDAY, OCT. 18**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>7:00 AM</td>
<td>CONTINENTAL BREAKFAST</td>
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<tr>
<td>8:00 AM</td>
<td>Welcome and Introductions</td>
<td>David S Friedman MD MPH PhD*</td>
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<tr>
<td>8:02 AM</td>
<td>American Glaucoma Society Introduction</td>
<td>Kuldev Singh MD MPH*</td>
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<tr>
<td>8:04 AM</td>
<td>Announcements</td>
<td>James D Brandt MD*</td>
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## Section I: Pseudoexfoliation—The Worst of the Open-Angle Glaucomas

Moderator: Jody R Piltz-Seymour MD*

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<tr>
<th>Time</th>
<th>Event</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>8:06 AM</td>
<td>Introduction and Self-assessment</td>
<td>Jody R Piltz-Seymour MD*</td>
</tr>
<tr>
<td>8:08 AM</td>
<td>Pseudoexfoliation—it’s Not Just a Scandinavian Disease</td>
<td>Louis R Pasquale MD*</td>
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<tr>
<td>8:16 AM</td>
<td>What Is the Natural History of Pseudoexfoliation?</td>
<td>Fotis Topouzis MD*</td>
</tr>
<tr>
<td>8:24 AM</td>
<td>Genetics: What Do We Now Know and How Should You Counsel Your Patients With Pseudoexfoliation?</td>
<td>John Fingert MD PhD</td>
</tr>
<tr>
<td>8:32 AM</td>
<td>Is There Evidence to Support Cataract Surgery Alone in Pseudoexfoliation?</td>
<td>Karim F Damji MD</td>
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<tr>
<td>8:40 AM</td>
<td>Panel Discussion: What I Do Differently With Patients With Pseudoexfoliation</td>
<td>Panelists: Iqbal K Ahmed MD*, Alan S Crandall MD*, Bradford J Shingleton MD*</td>
</tr>
</tbody>
</table>

## Section II: Challenging Surgical Cases

Moderators: Teresa C Chen MD, Pradeep Y Ramulu MD PhD*

Virtual Moderator: Thomas W Samuelson MD*

Panelists: F Jane Durcan MD, Marlene R Moster MD*, Paul F Palmberg MD PhD*, Lisa Fran Rosenberg MD, Prithvi S Sankar MD

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<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>9:06 AM</td>
<td>Introduction and Self-assessment</td>
<td>Teresa C Chen MD</td>
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<tr>
<td>9:08 AM</td>
<td>Case Presentation of Choroidals</td>
<td>Teresa C Chen MD</td>
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<tr>
<td>9:10 AM</td>
<td>When and If to Drain Choroidals</td>
<td>Keith Barton MD*</td>
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<tr>
<td>9:16 AM</td>
<td>Panel Discussion and Summary</td>
<td>Pradeep Y Ramulu MD PhD*</td>
</tr>
<tr>
<td>9:19 AM</td>
<td>Case Presentation of Uncontrolled Angle Closure</td>
<td>Pradeep Y Ramulu MD PhD*</td>
</tr>
<tr>
<td>9:21 AM</td>
<td>High Eye Pressures and Angle Closure: Should We Take Out the Clear Lens?</td>
<td>Tin Aung FRCS PhD*</td>
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<tr>
<td>9:27 AM</td>
<td>Panel Discussion and Summary</td>
<td>Teresa C Chen MD</td>
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<tr>
<td>9:30 AM</td>
<td>Case Presentation of a Bleb Leak</td>
<td>Teresa C Chen MD</td>
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<tr>
<td>9:32 AM</td>
<td>What to Do With Bleb Leaks After Trabeculectomy?</td>
<td>Yao Liu MD</td>
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<tr>
<td>9:38 AM</td>
<td>Panel Discussion and Summary</td>
<td>Pradeep Y Ramulu MD PhD*</td>
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<tr>
<td>9:41 AM</td>
<td>Case Presentation of a Patient Needing Trabeculectomy</td>
<td>Pradeep Y Ramulu MD PhD*</td>
</tr>
<tr>
<td>9:43 AM</td>
<td>Patient Needs a Trab—Do You Use an Ex-Press?</td>
<td>Davinder S Grover MD*</td>
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* Indicates that the presenter has financial interest.
No asterisk indicates that the presenter has no financial interest.
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<th>Time</th>
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<tbody>
<tr>
<td>9:49 AM</td>
<td>Panel Discussion and Summary</td>
<td>Teresa C Chen MD</td>
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<tr>
<td>9:52 AM</td>
<td>Case Presentation of a Failing Trabeculectomy</td>
<td>Teresa C Chen MD</td>
<td>9</td>
</tr>
<tr>
<td>9:54 AM</td>
<td>What to Do When Blebs Start to Fail?</td>
<td>Keith R Martin MD*</td>
<td>18</td>
</tr>
<tr>
<td>10:00 AM</td>
<td>Panel Discussion, Summary and Self-assessment</td>
<td>Pradeep Y Ramulu MD PhD*</td>
<td></td>
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<tr>
<td>10:05 AM</td>
<td>REFRESHMENT BREAK and AAO 2014 EXHIBITS</td>
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**Section III: Confound It! Interpreting Glaucoma Testing in the Presence of Other Eye Diseases**

Moderator: Yvonne M Buys MD*
Virtual Moderator: Thomas W Samuelson MD*
Panelists: David S Greenfield MD*, Ronald L Gross MD*, Kouros Nouri-Mahdavi MD*, Kelly Walton Muir MD*

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<th>Time</th>
<th>Event</th>
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<tr>
<td>10:45 AM</td>
<td>Introduction and Self-assessment</td>
<td>Yvonne M Buys MD*</td>
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<tr>
<td>10:47 AM</td>
<td>Case 1: High Myope Getting Worse</td>
<td>Shan C Lin MD*</td>
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<tr>
<td>10:50 AM</td>
<td>Panel Discussion</td>
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<tr>
<td>10:56 AM</td>
<td>Case 2: AMD and Glaucoma</td>
<td>Jeffrey M Liebmann MD*</td>
<td>22</td>
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<tr>
<td>10:59 AM</td>
<td>Panel Discussion</td>
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<tr>
<td>11:05 AM</td>
<td>Case 3: Optic Nerve Head Drusen, Low IOP, and Field Loss—Do You Treat?</td>
<td>Richard P Mills MD MPH*</td>
<td>23</td>
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<tr>
<td>11:08 AM</td>
<td>Panel Discussion</td>
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<tr>
<td>11:14 AM</td>
<td>Case 4: Diabetes</td>
<td>Young H Kwon MD PhD*</td>
<td>24</td>
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<tr>
<td>11:17 AM</td>
<td>Panel Discussion</td>
<td></td>
<td></td>
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<tr>
<td>11:23 AM</td>
<td>Conclusion and Self-assessment</td>
<td>Yvonne M Buys MD*</td>
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**The American Glaucoma Society Subspecialty Day Lecture**

Introduction of the Lecturer: Kuldev Singh MD MPH*
The Quarter Century’s Progress in the Treatment of Open-Angle Glaucoma: Henry D Jampel MD*
Presentation of the Award: Kuldev Singh MD MPH*
LUNCH and AAO 2014 EXHIBITS

**Section IV: Empowering Our Patients With Better Information**

Moderator: Anthony D Realini MD*

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<tbody>
<tr>
<td>1:07 PM</td>
<td>Introduction and Self-assessment</td>
<td>Anthony D Realini MD*</td>
<td></td>
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<tr>
<td>1:09 PM</td>
<td>Paging Dr. Google: What Do Our Patients Learn on the Internet?</td>
<td>Ivan Goldberg MBBS FRANZCO*</td>
<td>26</td>
</tr>
<tr>
<td>1:17 PM</td>
<td>Scamming for Dollars: What Are Our Patients Buying From Alternative Glaucoma Providers?</td>
<td>Derek S Welsbie MD</td>
<td>27</td>
</tr>
<tr>
<td>1:25 PM</td>
<td>Glaucoma Neuroprotection in 2014: A Reality Check</td>
<td>Robert N Weinreb MD*</td>
<td>29</td>
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* Indicates that the presenter has financial interest.
No asterisk indicates that the presenter has no financial interest.
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<td>Michele C Lim MD*</td>
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<td>Should You Rebuild Your Office: The Ergonomics of Using an EMR</td>
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<td>How I Came to Believe That EMR Is Good for My Practice and Good for Patients: A Converted Skeptic</td>
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**Section V: How EMR and IT Advancements Are Changing the Practice of Medicine**
Moderators: Michael V Boland MD PhD*, Michele C Lim MD*

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Pseudoexfoliation—It’s Not Just a Scandinavian Disease

Louis R Pasquale MD

I. Introduction

A. Terminology: “exfoliation syndrome” vs. “pseudoexfoliation syndrome”

The term “true exfoliation of the lens capsule” refers to anterior lens capsular delamination that occurs in response to very high ambient temperatures. In contrast, “pseudoexfoliation syndrome” refers to a more generalized ocular process that may start in the anterior uveal tract blood vessels, culminating in the addition/precipitation of disorganized basement membrane material at cell-surface interfaces. In pseudoexfoliation syndrome, this disorganized macromolecular material (also known as exfoliation material or pseudoexfoliation material) admixes or replaces existing basement membrane to varying degrees depending on local anatomic and other factors. This process of extracellular deposition recapitulates itself in tissues other than the anterior uveal tract to varying degrees.

B. Ocular manifestations of exfoliation syndrome (XFS)

Table 2. Exfoliation Syndrome: A Panocular Condition That Transcends Glaucoma

<table>
<thead>
<tr>
<th>Tissue</th>
<th>Sign</th>
<th>Consequence</th>
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<tbody>
<tr>
<td>Cornea</td>
<td>Guttae endothelial changes</td>
<td>Corneal decompensation</td>
</tr>
<tr>
<td>Iris</td>
<td>Peripupillary atrophy</td>
<td>Poor exposure for cataract extraction</td>
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<tr>
<td></td>
<td>Poor pupil dilation</td>
<td>Uveitis; Pronounced inflammation after anterior</td>
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<td></td>
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<td>segment surgery</td>
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<tr>
<td>Trabecular meshwork (TM)</td>
<td>Pigment and fibrillar</td>
<td>Elevated IOP via open-angle or closed-angle</td>
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<td>deposition in the TM</td>
<td>mechanisms</td>
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<td></td>
<td>Scalloped pigment anterior</td>
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<td></td>
<td>to Schwalbe line (Sampaolesi line)</td>
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<tr>
<td></td>
<td>Narrow angle</td>
<td></td>
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<tr>
<td>Lens / zonule</td>
<td>Nuclear cataract</td>
<td>Need for cataract surgery</td>
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<td></td>
<td>Frosted zonular fibers</td>
<td>Vitreous loss during cataract extraction</td>
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<tr>
<td></td>
<td>Phacodonesis</td>
<td>Subluxation of lens/IOL</td>
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<tr>
<td>Posterior segment</td>
<td>Optic nerve cupping</td>
<td>Visual loss from optic nerve or retinal disease</td>
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<td>Venous occlusive disease</td>
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II. Epidemiological Features

A. Prevalence rates for XFS vary widely, from < 1% to 25% and higher.

B. Age: XFS is a strongly age-related disease.

C. Sex: Studies are mixed with regard to disease predisposition based on sex.

D. Race: No racial group is immune, although the disease is relatively rare among the Greenland Inuit and Peruvian people.

Asians: XFS is not rare in Asians. The prevalence of XFS in Northern China was surprisingly high (5.8%), although an association between XFS and glaucomatous optic neuropathy could not be demonstrated. Furthermore, XFS is common in Japanese (3.4%) and other Asian populations.

Africans: Interestingly XFS is likely more common in African-derived people residing in South Africa (6%-7.7% prevalence in a population-based survey) than among African Americans from the southern United States (0.5% in a clinic-based survey).

Hispanics: The prevalence of XFS in Hispanics has not been well studied, but the condition is not rare in this population.

Europeans: The rates of XFS vary widely among whites, but the highest prevalence rates are generally seen in Scandinavian populations.

E. Geographic features: Using a health-care relational database representative of the continental United States, which spans 15 degrees of latitude, XFS and exfoliation glaucoma (XFG) cases were identified with ICD-9 coding. The continental United States was stratified into northern, middle, and southern tiers. In multivariable analysis controlling for age, sex, race, and other factors, the risk of XFS was higher in the northern U.S. tier relative to the middle tier. Also the relative risk of disease in the southern tier was lower compared to the middle tier. While Scandinavians may be more likely to populate the northern U.S. tier, this did not account for the relation between U.S. tier and XFS. The propensity for XFS to developed in the northern tier remained when only people of African, Hispanic, and Asian heritage were considered in the analysis.

Stein et al used a de-identified database to demonstrate the trend of increasing XFS risk with higher latitude. Kang et al sought to determine whether the result could be duplicated in 2 U.S. population-based studies, the Nurses Health Study (NHS) and the Health Professionals Follow-up Study (HPFS), where more detailed residential history information was available. In multivariable analysis, compared to lifetime living in the northern continental U.S. tier, lifetime residence in the middle tier was associated with a 47% reduced risk of XFG. Furthermore, lifetime residence in the southern tier was associated with a 75% reduced risk of XFG compared to lifetime residence in the northern tier.

III. Other Determinants of XFS

A. Stein et al implicated colder ambient temperature with increased risk of XFS.

B. Stein et al found that increased number of sunny days was associated with XFS in climatic analysis. Ocular solar exposure from reflective surfaces is an excellent candidate determinant of the latitude effect. While solar exposure to the horizon is clearly highest at the equator, the sun is highest in the sky in this location, creating less opportunity for solar rays to reflect off surfaces into the eye. Further away from the equator, there are more opportunities for sunlight to reflect off surfaces and become incident with the eye. Water is good reflector of solar radiation and snow is the best reflector of UV radiation. Obviously snow pack increases as a function of latitude.

Several studies found an association between increased time spent outdoors, which is a surrogate for ocular solar exposure, and XFS. A study on the island of Rab found that fishermen had much more XFS than inland urban dwellers, probably because of higher ocular solar exposure from reflection off the water. Several studies find associations between pterygium and climatic keratopathy—conditions where ocular UV radiation is implicated—and XFS.

C. Low dietary folate results in high serum homocysteine levels. Elevated homocysteine levels could contribute to dysregulation of extracellular matrix metabolism in XFS. There is a trend between lower dietary folate intake and incident XFG in the NHS and HPFS.

D. Coffee consumption increases homocysteine levels. Higher coffee consumption was associated with increased risk of XFG.

IV. Speculation Regarding Why Scandinavians Have a High Burden of XFS

A. The near 24-hour sun in summer combined with solar reflection from glaciers creates considerable ocular UV exposure.

B. Scandinavians are the highest coffee consumers in the world.

NB: The frequency of XFS-related LOXL1 variants in Scandinavian countries is no different than in other parts of the world. Scandinavian heritage was not a risk factor for XFS in a large U.S.-based study.

References


**What Is the Natural History of Pseudoexfoliation?**

**Fotis Topouzis MD**

Pseudoexfoliation (PEX) syndrome is a systemic age-related condition affecting the eye and presenting with the deposition of a fibrillar material in various ocular structures like the anterior lens capsule, the iris, and the lens zonules.

There has been a lot of research on the genetic aspect of the condition, as PEX has been strongly associated with single nucleotide polymorphisms (SNPs) of the lysyl oxidase-like 1 (LOXL1) gene on chromosome 15q24.1, which is one of the group of enzymes involved in the crosslinking of collagen and elastin in the extracellular matrix.

Pseudoexfoliation is considered to be the most common identifiable cause of open-angle glaucoma (OAG) worldwide. However, the majority of subjects with PEX do not have glaucoma. The reported rates of prevalence of PEX/pseudoexfoliation glaucoma (PEX-G) differ in various populations, which could have to do either with population-related factors or with the methodology followed in the specific studies; for example, the age range of the studied population plays a critical role in the prevalence results since the condition is age related. Some of the variation may also be attributable to differences in examination techniques and criteria used to diagnose PEX. Prevalence of PEX has been found to be 16.9% and 17.9% in the Norwegian and Swedish population, respectively, aged over 65. For the age group of over 50 years, PEX prevalence in Australia and the United States has been found to be around 2%; and in Japan, those that were 70-79 years at baseline, 71% of clinically unilat-

incidence for either eye increased with increasing age, from 6.5% in an Icelandic sample to increase from 2.4% in those aged 50 to 59 years to 40.6% in those 80 years and older.

The 5-year incidence of PEX in the same Icelandic population was found to be 5.2% in either eye, while the overall 12-year incidence for either eye increased with increasing age, from 6.5% in those participants aged 50-59 years at baseline to 10.6% in those that were 70-79 years at baseline; 71% of clinically unilateral cases had converted to bilateral over 12 years.

A retrospective community-based study of newly diagnosed cases of PEX syndrome in all residents of Olmsted County, Minnesota, showed that of all PEX patients, 16% were placed on therapy at the time of initial diagnosis of PEX, while in the remaining PEX patients, the probability of being placed on therapy was 44% at 15 years.

The Early Manifest Glaucoma Trial (EMGT) gave interesting results on the natural history of PEX and PEXG. After a mean of 8.7 years without treatment, glaucoma conversion rate was twice as high in patients with ocular hypertension (OH) and PEX as in control patients (OH without PEX) matched for IOP, age, and gender. Thus, PEX was shown to be a strong independent risk factor for glaucoma in patients with OH. They also found that PEX is a risk factor for progression of glaucoma, with a hazard ratio of 2.22 for the total 253 enrolled patients in the study. Moreover, with regards to OAG progression, the same study after 6 years follow-up showed that progression rate and thus time to progression varied considerably among OAG groups in untreated participants; rates of progression were highest in patients with PEX-G (93%). Time to progression was shown to be shorter in PEX-G compared to other types of OAG in the same report.

In the Thessaloniki Eye Study (TES), a population-based study, participants with PEX compared with non-PEX participants had higher IOP, larger vertical cup-to-disc ratio (V-CDR), and higher percentage with IOP ≥ 22 mmHg, V-CDR ≥ 0.7, V-CDR asymmetry > 0.2, and optic disc damage. This finding is mainly explained by the higher proportion with glaucoma among PEX participants (15.2%) than that for glaucoma among non-PEX participants (4.7%). When participants with glaucoma were excluded from the analysis, the only statistically significant difference was the 0.6 mmHg higher IOP in participants with PEX than in those without.

In relation to visual field (VF) defect, most studies show that eyes with PEX-G present with greater damage at diagnosis in clinical settings. In contrast to the clinical setting findings, the TES showed that PEX-G was not associated with more advanced disease at population level, including undiagnosed cases in the community. Lower rates of undiagnosed PEX-G compared to POAG may explain this difference in findings between clinical and population-based settings. In TES, POAG was found to be 4 times more likely to remain undiagnosed than was PEX-G. In addition, in undiagnosed and untreated cases mean IOP was higher in PEX-G compared to POAG (24.3 ± 8.0 in PEXG vs. 19.8 ± 5.8 in POAG, P value 0.023), while when all treated and untreated cases were included, IOP was not statistically significantly different between PEX-G and POAG (21.3 ± 7.2 in PEX-G vs. 19.2 ± 5.2 in POAG, P value .175). This could be indicative of a more aggressive IOP-lowering treatment in PEX-G. More aggressive management in PEX-G in conjunction with higher rates of PEX-G being diagnosed and treated could explain similar stages of damage between POAG and PEX-G at population level. TES also showed that the likelihood of having glaucoma was 3 times higher among those with PEX at the same screening IOP. This finding might indicate that apart from high IOP, there might be additional factors contributing to the vulnerability of the optic nerve at the same IOP level in subjects with PEX.

**References**

Section I: Pseudoexfoliation—The Worst of the Open-Angle Glaucomas


Genetics: What Do We Now Know and How Should You Counsel Your Patients With Pseudoexfoliation?

*John H Fingert MD PhD*

I. Pseudoexfoliation (PXF) is heritable.
   A. Familial clustering
   B. Different prevalence in different ethnic groups

II. PXF has a complex genetic basis.
   A. Combined action of many genes
   B. Environmental factors

III. Genetic Studies of Pseudoexfoliation Syndrome (XFS)
   A. Population-based studies (genome-wide association studies) have identified genetic risk factors for XFS.
      1. Lysl oxidase-like 1 (*LOXL1*) gene
         a. Encodes an enzyme that is involved in elastin synthesis
         b. Major risk factor for PXF
         c. *LOXL1* variants are extremely common.
            i. Carried by most healthy individuals
            ii. Higher frequency in PXF patients
            iii. Poor positive predictive value
      2. Other factors remain to be discovered.
      3. Ongoing (larger) genome-wide association studies will likely identify more factors.
   B. Candidate genes that encode components of PXF material (eg, elastin, tropoelastin, fibronec tin, laminin, vitronectin, fibrillin-1, clusterin)
      1. No current consensus
      2. Ongoing research

IV. Commercial Tests for XFS Genes
   A. *LOXL1* risk alleles
   B. Guidelines from the American Academy of Ophthalmology on genetic testing
   C. Testing is not warranted in 2014.

V. Counseling Patients
   A. PXF has a genetic component.
   B. A good clinical examination is the best test in 2014.
   C. Future discovery of more genetic, epigenetic, and environmental factors will likely improve the utility of genetic testing.

Selected Readings
Is There Evidence to Support Cataract Surgery Alone in Pseudoexfoliation?

Karim F Damji MD, Lisa Heckler MD

I. Pseudoexfoliation Syndrome (XFS) and Glaucoma
   A. Most common identifiable cause of open-angle glaucoma worldwide
   
   B. Progression to glaucoma varies, overall about 40% over 10 years.
   
   C. Usually an open-angle mechanism, but can also involve occludable angles and angle-closure glaucoma (ACG)
      1. Biometric study of XFS patients showing thicker and more anteriorly placed lenses, and shallower anterior chamber depth
      2. Predisposed to pupillary block from iridolenticular adhesion, zonular weakness, cataract formation

II. Cataract Surgery in XFS and Pseudoexfoliation Glaucoma (XFG)
   A. Several studies demonstrate an IOP-lowering effect following cataract surgery, particularly in patients with XFS.
   
      1. Purpose: To determine mid-term (2 years) IOP response to phacoemulsification in patients with and without XFS
      2. Subgroups: XFS, XFG, primary open-angle glaucoma (POAG), cataract controls. All had open angles by gonioscopy.
      3. Baseline variables: Similar among groups, but mean baseline IOP was higher in XFS compared to control eyes: 17.60 (SD 3.23) mmHg vs. 16.08 (3.18) mmHg ($P = .002$).
      4. Results: 183 patients were enrolled, 71 with and 112 without XFS. IOP reduction was significantly greater in pseudoexfoliation groups (XFS and XFG) than non-XFS groups (POAG, cataract) at all time points to 2 years (−2.51 vs. −0.89 mmHg, respectively, $P = .0015$). The percentage of patients with a postoperative IOP spike was similar and relatively high in both XFS and control groups (34% vs. 25%, $P = .54$).

      
   5. Main predictors of IOP reduction: presence of pseudoexfoliation, preoperative IOP, irrigation volume used at time of cataract surgery
   
   6. Theories for greater reduction in IOP in pseudoexfoliation groups: washing out of pseudoexfoliation material and pigment, decrease in iridolenticular friction, deepening of anterior chamber angle, inflammation leading to enhanced aqueous outflow (ie, laser trabecuoplasty-like effect)
   
   7. Implication: Cataract surgery provides a margin of comfort for better IOP control in the short to medium term for XFS patients with relatively well-controlled IOP and without advanced glaucoma.

III. Our Current Surgical Approach to Patients With XFS and Cataract
   A. Guided by mechanism (open vs. closed angle), stage of glaucoma, degree of IOP elevation, ocular and systemic factors, patient and care partner preference(s)
   
   B. Open angle
      1. No glaucoma or early glaucoma: phacoemulsification alone ± pretreatment with SLT. Follow closely postop for IOP spikes and every 6 months thereafter for unpredictable loss of IOP control.
      2. Early or moderate glaucoma: IOP well controlled or slightly higher than target – phacoemulsification combined with microinvasive glaucoma surgery (MIGS)
3. Advanced glaucoma and/or IOP > 30 mmHg: Optimize preoperative IOP, then phacoemulsification combined with trabeculectomy (including antimetabolite)

C. Angle closure
1. Phacoemulsification combined with goniosynechialysis
2. May combine with MIGS or trabeculectomy based on degree of IOP elevation and stage of glaucoma

D. General ocular and systemic considerations for choice of glaucoma surgery
1. Poor conjunctiva/sclera: Favor MIGS
2. Cornea not clear: Favor trabeculectomy
3. Risk factors for overfiltration or suprachoroidal hemorrhage: Favor MIGS
4. Use of anticoagulants: If cannot be stopped for surgery, favor MIGS

E. Involve patients/care partners in discussion of risks/benefits and decision making.

F. Postoperative management: Aggressive anti-inflammatory treatment with steroids and nonsteroidal agents due to weak blood-aqueous barrier

References
Case Presentations

Case Presentation of Choroidals
Teresa C Chen MD

Case Presentation of Uncontrolled Angle Closure
Pradeep Y Ramulu MD PhD

Case Presentation of a Bleb Leak
Teresa C Chen MD

Case Presentation of a Patient Needing Trabeculectomy
Pradeep Y Ramulu MD PhD

Case Presentation of a Failing Trabeculectomy
Teresa C Chen MD
When and If to Drain Choroidals?
Keith Barton MD

I. Causes of choroidal swelling in patients may be the result of:
   A. Effusion
      1. Transudate from hypotony (eg, glaucoma surgery), ophthalmic venous obstruction (eg, thick sclera [nanophthalmos]), vortex vein obstruction during scleral buckling, superior ophthalmic vein, cavernous sinus thrombosis or carotid-cavernous fistula, severe anterior capsular / zonular contraction after cataract surgery
      2. Exudate or other mechanism from inflammatory disease or drugs
         a. Posterior scleritis, Vogt-Koyanagi-Harada (VKH)
         b. Topiramate, acetazolamide, methazolamide, pergolide, hydrochlorothiazide
   B. Hemorrhage
      1. Drugs (eg, anticoagulants)
      2. Trauma – choroidal rupture
      3. Surgery – retina, cataract, glaucoma (filtration or cyclophotocoagulation), penetrating keratoplasty
      4. Spontaneous, subarachnoid hemorrhage
      5. Rarer – melanoma, disseminated intravascular coagulation eg, thrombotic thrombocytopenic purpura, polyoidal choroidal vasculopathy, laser to retinal vascular disorders

II. Risk Factors
   A. Sturge-Weber
   B. Hypotony
   C. Myopia
   D. Coagulation disorders (eg, hemophilia)

III. Diagnosis
   A. Clinical appearance
   B. Ultrasonography

IV. Differential Diagnoses
   Choroidal hemorrhage may be misdiagnosed as malignant melanoma or vice versa.

V. Management
   A. Effusions in the presence of hypotony resolve quickly on correction of the hypotony, avoiding the need for drainage.
   B. Effusions that have resulted from a period of hypotony occasionally persist after the hypotony has been corrected. Drainage of the effusion is then indicated.
   C. Effusions in the presence of high IOP from secondary angle closure are usually small and more easily detected by imaging than clinical examination. Drainage is not usually a practical consideration. Treatment:
      1. Aqueous suppressants for the IOP, avoiding acetazolamide and other sulphas if secondary to topiramate.
      2. Treat the cause, eg, effusion with inflammatory disease – VKH, scleritis – treat inflammation, effusion with drugs (eg, topiramate) – withdraw.
   D. Choroidal hemorrhage – correct hypotony, corticosteroid treatment to minimize inflammation and drain.
      Timing of drainage is very important. Traditional teaching is to drain immediately before the hemorrhage clots or after 7-10 days when the clot has lysed. Unless the hemorrhage occurs in the operating room, it is usually not possible to drain immediately. On the other hand, delaying drainage in a hemorrhage involving the macula may result in a very poor visual outcome. Good results have been reported from drainage as early as 5 days, and the author will illustrate this talk with a good result from drainage after 6 days.
   E. Intraocular gas tamponade is often recommended when draining choroidal effusions or hemorrhage. The author prefers to use an anterior chamber infusion in combination with correction of the cause of hypotony, resorting to gas when the IOP cannot be successfully maintained.
   F. Vitrectomy / silicone oil if vitreous hemorrhage / retinal breaks or failure of previous drainage
   G. Tissue plasminogen activator has been used to lyse subretinal and suprachoroidal hemorrhages in isolated reports.

VI. Drainage Techniques
   A. Identify area of largest effusion / hemorrhage, usually by B-scan ultrasonography, before surgery. This will usually be an inferior quadrant.
   B. In the operating room, first correct the hypotony (eg, close over-draining trabeculectomy flap or ligate overdraining aqueous shunt).
   C. Use an anterior-chamber infusion to maintain the IOP and provide tamponade.
D. Create a sclerostomy at the lower-most point of the globe that is surgically accessible. This will have to be either inferonasal or inferotemporal to avoid inferior rectus and should also avoid the vortex veins.

E. A V-shaped sclerostomy, with the apex of the V pointing anteriorly, is easier to fashion and drain fluid from than a slit. Begin with partial thickness grooves and deepen slowly until the sclera is just breached. Then lengthen with the blade upward, away from choroid.

F. At the point when the suprachoroidal space is entered, there should be a gush of fluid / blood. In the case of hemorrhage, the blood will be a dark dusky color in contrast to any bleeding from the scleral wound.

G. Gently depress choroid just at the scleral entry with a flat blunt instrument (eg, iris repository), repetitively. It is worth continuing this activity repetitively for a significant period of time (eg, 15-20 minutes) to ensure that all blood has drained.

H. Leave the scleral wound unsutured.

I. Close conjunctiva with sutures or fibrin glue.

J. Repeat the procedure in the contralateral inferior quadrant.

K. An alternative method of drainage has been suggested using 23-gauge or other vitrectomy cannulas as a method of avoiding the risk of choroidal and retinal incarceration in the scleral wound.
High Eye Pressures and Angle Closure: Should We Take Out the Clear Lens?

Tin Aung FRCS PhD

Angle closure occurs because of obstruction of the trabecular meshwork by the iris, resulting in impaired aqueous outflow, causing an increase in IOP. While pupil block is considered to be the primary mechanism for angle closure,1,2 however, recent studies have shown that non-pupil block mechanisms may also play a significant role in pathogenesis of angle closure.3 Laser peripheral iridotomy (LPI) remains the first-line therapy of angle closure management,4,5 as it relieves pupil block and widens the angle.

Post-Laser Iridotomy: Why is the IOP still high?

Studies have shown that LPI alone does not open up the angles in all cases, and persistent elevations in IOP in the presence of a patent iridotomy have been reported.2,6 Plausible reasons for the persistence of angle closure and/or high IOP have been attributed to the presence of extensive peripheral anterior synechiae (PAS) that prevents aqueous outflow and mechanisms other than pupil block, such as plateau iris syndrome or a lens-related element. The angle may also be damaged and not functioning.

The Role of the Lens in Angle Closure

The lens plays an important role in the pathogenesis of primary angle-closure glaucoma (PACG). There is a greater tendency for eyes with angle closure to have thicker and more anteriorly placed lens, with a corresponding shallow anterior chamber.7-9 Another lens parameter associated with angle closure is the lens vault (LV).10 This is a measurement of the amount of lens that is located anterior to the plane of the scleral spurs, and it has been found to better quantify the relationship of the lens with respect to the anterior chamber angles.10

Factors to be Assessed if the IOP Is Still High After LPI

For those angle closure subjects with persistently elevated IOP despite a patent LPI, the following factors should be assessed to determine the next procedure to perform:

1. The extent of optic disc/visual field damage
2. The extent of PAS and residual angle closure
3. Magnitude of IOP (untreated) and number of glaucoma medications
4. Magnitude of the LV and/or lens thickness: In the presence of a large LV and/or a thick lens, lens extraction (possibly combined with trabeculectomy) should be considered, as removal of the lens would deepen the anterior chamber and relieve crowding of the angle.
5. Degree of hyperopia: Lens extraction in angle closure subjects with hyperopia would help improve visual function by correcting the refractive error.
6. Visual acuity: If there is reduced visual acuity due to cataract, lens extraction should be performed. However in the presence of a clear lens, the option of lens extraction is controversial but should be considered if there is increased lens thickness and/or lens vault.

Surgical Procedures

Depending on the magnitude of the reduction in IOP that is needed, several studies have shown that either lens extraction, alone or combined with a trabeculectomy procedure, or trabeculectomy alone, can be considered as treatment options in eyes with angle closure for the control of IOP.

A randomized controlled trial (RCT) on medically controlled PACG13 with coexisting cataract found that phacoemulsification alone was comparable to phacotrabeculectomy in terms of decreasing IOP and reducing the requirements of postoperative glaucoma medications. There were no significant differences in terms of visual acuity and progression of glaucomatous optic neuropathy and visual fields between the 2 treatment groups at 2 years. The phacotrabeculectomy group required 0.80 fewer topical medications in the 2-year period than did the phaco-alone group. Similar results were obtained from the counterpart RCT in medically uncontrolled PACG.14 The combined phacotrabeculectomy group resulted in greater absolute reduction in IOP, but the difference was significant in only a few time points. In both trials, postoperative complications were higher in the combined phacotrabeculectomy group and were related to the trabeculectomy part of the surgery.

The effect of lens extraction compared to LPI in eyes after acute primary angle closure (APAC) were evaluated in another RCT.15 Phacoemulsification resulted in a significantly greater reduction in the risk of IOP rise after abortion of the acute attack. This was attributed to the wider opening of the drainage angles, thereby providing more outflow facility and a lower IOP. Moreover, lens extraction was also effective in relieving the residual angle closure following LPI.
Risks

When considering / deciding on the optimal surgical procedure, it is important to consider the risks of surgery. In particular, one needs to gauge the risk of a transient IOP spike that is commonly seen following lens extraction alone. The other important aspect to consider is the likelihood of pre-existing irreversible structural trabecular damage in PACG eyes. Lens extraction alone in such eyes may not be adequately effective in controlling IOP. Furthermore, the risks of surgical complications vary, depending on the nature of the surgical procedure. In published studies, the intraoperative complications of phacoemulsification and phacotrabeculectomy were similar, and were essentially related to the cataract surgery. Postoperative complications, however, were higher in the combined phacotrabeculectomy group and were related to the trabeculectomy part of the surgery.

Surgical Options Depending on the Stage of Glaucoma and Angle Closure

1. Mild glaucoma and minimal PAS: Phacoemulsification alone
2. Mild glaucoma and extensive PAS: Phacoemulsification with goniosynechialysis
3. Advanced glaucoma: Trabeculectomy or phacotrabeculectomy

Conclusions

While data from the RCTs suggests that lens extraction alone is a feasible option for control of IOP in some eyes, the risks associated with phacoemulsification alone should be considered. In those eyes that require greater IOP reduction, phacoemulsification can be combined with trabeculectomy. The removal of a clear lens in PACG is controversial but may be considered if there is increased lens thickness and/or lens vault.

References

What to Do With Bleb Leaks After Trabeculectomy?

Yao Liu MD

I. Introduction to Bleb Leaks
A. Prevalence and natural history
   1. Occur in approximately 4%-30% of trabeculectomies with antimetabolites1-5
   2. Majority occur within the first 3 months after surgery

B. Clinical diagnosis
   1. Symptoms
      a. Can be asymptomatic
      b. May present with ocular discomfort, tearing, and/or decreased acuity from maculopathy, hyperopic shift, or increased astigmatism
   2. Hypotony with corneal striae, shallow anterior chamber, disc edema, and maculopathy may be present.

II. Early Bleb Leaks
A. Definition: Leak occurring within 1 month following trabeculectomy
B. Prevalence: Reported rate varies widely.
C. Location
   1. Wound site or other site of surgical trauma (ie, conjunctival buttonhole)
   2. May be more common in fornix-based than limbal-based trabeculectomies3
D. Impact on surgical outcome: Conflicting reports as risk factor for bleb failure3,5,6
E. Prevention
   1. Meticulous attention to wound closure and careful assessment for leaks at the end of case
      a. Incorporation of Tenon capsule into wound closure (single- or double-layer closure)
      b. Check with Weck-cell sponges or fluorescein strip
   2. Verify ability to elevate / maintain formed bleb with deep anterior chamber by applying gentle pressure or by instilling BSS into anterior chamber through paracentesis.
   3. Close buttonholes with 9-0 poly-glactin suture on tapered needle (BV or VAS) using purse-string suture.
   4. Use lower concentrations of mitomycin, 5-fluorouracil, or no antimetabolite in patients with very thin conjunctiva.
F. Management
   1. Nonsurgical7
      a. Observation
      b. Medications
         i. Prophylactic antibiotic use controversial; may not be effective in preventing blebitis8
         ii. Aqueous suppressant (ie, timolol, dorzolamide, or brimonidine)
         iii. Gentamicin to promote scarring
   2. Surgical
      Wound closure / bleb revision

III. Late Bleb Leaks
A. Definition: Leak occurring 1-3 months or more following trabeculectomy
B. Prevalence: 3.7%-9% of patients undergoing trabeculectomy with mitomycin C1,2
C. Location: avascular, cystic thin-walled area of bleb
D. Risk factor: use of mitomycin-C
E. Recurrence3: 36% represent recurrent leaks
F. Frequency of infection
   1. 22% had blebits upon diagnosis of leak.
2. 5% had endophthalmitis upon diagnosis of leak.
3. 5% had subsequent endophthalmitis following diagnosis of leak despite initiation of antibiotic prophylaxis.

G. Management

1. Goal: resolution of leak
   a. 77% resolved with conservative, office-based management.
   b. 18% resolved after surgical revision.
   c. 5% had a persistent leak with conservative therapy.

2. Nonsurgical
   a. As above (ie, observation, medications, mechanical treatments, and procedures)
   b. Needle bleb to expand filtration area in localized bleb (can be done in the office or OR)

3. Surgical
   a. Approaches: Prospective, comparative data is lacking (only 1 randomized, controlled trial in recent Cochrane Review); data are primarily retrospective.
      i. Conjunctival advancement or transplantation
      ii. Scleral or corneal patch
      iii. Amniotic membrane transplantation
      iv. Bleb closure with implantation of glaucoma drainage device
   b. Success rates of surgical intervention
      i. 65%-77% at 2 years in largest studies when success is defined as resolution of bleb leak, IOP < 21 mmHg with or without glaucoma medications, and no additional glaucoma surgery or postoperative complications such as recurrent leak or blebitis
      ii. Success rate may be lower over longer time frames.
   c. Factors favoring surgical intervention
      i. Recurrent bleb leak
      ii. Previous history of blebitis in either eye
      iii. High risk for infection (ie, blepharitis, poor hygiene, immunocompromised, diabetes)
      iv. Brisk leak
      v. Flat or very shallow anterior chamber
      vi. Hypotony maculopathy
      vii. Likelihood of being lost to follow-up

IV. Bleb-Related Infections

A. Prevalence: Reported to occur in 0.2%-9.6% of patients after filtering surgery

B. Common organisms: Staphylococcus, Streptococcus, Haemophilus influenzae

C. Risk factors
   1. Bleb leak
   2. Prior history of blebitis
   3. Blepharitis
   4. Nasolacrimal duct obstruction
   5. Contact lens use
   6. Use of antimetabolites
   7. Inferior bleb placement
   8. Pediatric patients

D. Management
   First aggressively treat infection, then plan surgical revision following complete resolution of infection.
   1. Blebitis: mucopurulent material in or around bleb with mild anterior chamber inflammation
      a. Hourly or every 30 min alternating topical antibiotics (ie, fluoroquinolone and/or fortified antibiotics)
      b. Topical steroids added once there are signs/symptoms of improvement
      c. Tap and inject if no improvement or worsening over the first 24-48 hours following initiation of topical antibiotics
   2. Endophthalmitis: moderate-severe anterior chamber inflammation, hypopyon, or the presence of vitritis
      a. Tap and inject with intravitreal antibiotics
      b. Vitrectomy in severe cases (may have lower threshold compared to Endophthalmitis Vitrectomy Study (EVS) guidelines, which evaluated endophthalmitis following cataract surgery)
      c. Topical steroids

V. Future Areas for Consideration

A. Impact of changes in trabeculectomy techniques on late bleb leak and blebitis risk
   1. Mitomycin C injection vs. sponge application
   2. Biodegradable collagen matrix implant

B. Possibility of bleb imaging (ie, ultrasound biomicroscopy or anterior segment OCT) to prognosticate likelihood of bleb leak resolution with conservative therapy vs. surgical intervention
References

Patient Needs a Trab—Do You Use an Ex-PRESS?

Davinder S Grover MD

Introduction

- Overview of Ex-PRESS shunt
- Indications

Review of Surgical Procedure

- Important landmarks

Review of Clinical Data


Economic Analysis of the Ex-PRESS Shunt vs. Trabeculectomy

- Patel HY, et al. J Glaucoma. 2012.6

Clinical Implications: I use an Ex-PRESS shunt:

- If patient cannot be taken off blood thinners or bleeding diathesis
- If I want to avoid intraoperative shallowing of the AC (large capsulotomy with worry of vitreous prolapse or nearby vitreous prolapse
- If I need to aggressively avoid intraoperative hypotony (history of suprachoroidal hemorrhage or vitrectomized eye)
- If IOL is unstable
- If patient is concerned about episodes of coughing, sneezing, or other uncontrolled exertion intraoperatively or postoperatively
- If I am placing a toric lens and am concerned about inducing astigmatism

Complications and Their Management

- Bleb failure
- Device erosion/exposure
- Ab externo removal
- Ab interno removal

Conclusion

- There is a definite role for the Ex-PRESS shunt in the surgical management of glaucoma. Limited to a select group of patients (listed above) where the device may allow a more favorable risk benefit surgical profile.
- The economic impact of the Ex-PRESS shunt may not justify the minimal (if any) benefit of the implant in low-risk filtration patients. The patient is not only at a life-long risk for infection (blebitis) following an Ex-PRESS shunt but is also at a life-long risk for device exposure.

References and Selected Readings

Managing the failing trabeculectomy bleb is a key skill for all ophthalmologists managing patients after trabeculectomy. The key to success is understanding where the site of resistance is that has caused the failure so that the most effective treatment strategy can be deployed.

**Keys to Success**

1. **Prevention is better than cure.**
   Careful trabeculectomy surgery with appropriate use of antiscarring agents and meticulous surgical techniques can reduce the risk of bleb failure. The Moorfields Safer Surgery System\(^1\) is a useful strategy that emphasizes the importance of a wide treatment area with antiscarring drugs combined with trabeculectomy flap design and watertight closure at the limbus to encourage controlled posterior drainage of aqueous. Careful management of postoperative inflammation is also crucial. We use hourly preservative-free dexamethasone 0.1% drops for the first week after trabeculectomy, maintaining patients on topical steroid treatment at least 4 times daily for 2-3 months after surgery and adjusting the frequency according to the observed vascularization and scarring response.

2. **Intervene sooner rather than later.**
   Careful observation of patients in the weeks after a trabeculectomy enables the detection of early failure, which can often be addressed easily and effectively. Adjustment, laser lysis, or removal of trabeculectomy flap sutures is usually most effective in the first few weeks after surgery. Bleb massage can also be helpful in some patients but is not a substitute for the identification and treatment of the site of resistance to aqueous outflow.

3. **Identify the site of failure.**
   Failure may occur due to:
   - Obstruction of the internal ostium
   - Scarring of the scleral flap
   - Episcleral scarring
   Careful examination of the bleb combined with gonioscopic examination of the ostium can often help distinguish these different etiologies and aid the planning of intervention. A flat bleb may occur due to any of the mechanisms above, alone or in combination. A formed bleb, even if encysted, will usually exclude the ostium or the scleral flap as the site of greatest resistance.
   Gonioscopic examination is a key, but often neglected, part of the assessment of the failing bleb. If the ostium is occluded on gonioscopy, then conventional bleb needling is highly unlikely to be successful. Gonioscopy also frequently allows for the identification of the relative position of the scleral flap. If the scleral flap is flat rather than elevated, it is unlikely that bleb needling that does not involve manipulation under the flap will succeed.

4. **Plan the intervention.**
   If a needling is to be attempted, following careful assessment as above, then the following factors should also be considered:

   a) **Clinic or operating room?**
   This decision will depend on a number of variables, including the experience of the surgeon, the tolerance of the patient, the chosen antiscarring regime, and the risk of complications. If it is likely that needling under the flap and into the anterior chamber will be required when a previous needling has been technically difficult or has failed or when topical application of mitomycin C is to be used, then we often prefer to perform the procedure in the operating room.

   b) **Which antiscarring regime?**
   Both 5-fluorouracil (FU; often 0.1 ml of 25 mg/ml) and mitomycin C (0.01%–0.04%) have been shown to increase the success of bleb needling in clinical studies. 5-FU has been more widely used, but multiple injections are often required and corneal toxicity can be a significant problem in a proportion of patients. Use of subconjunctival viscoelastic at the time of needling can help to reduce the efflux of 5-FU onto the cornea in the aftermath of needling, and there is also evidence to suggest that this approach can facilitate “slow release” of 5-FU from the viscoelastic and thus extended efficacy compared to conventional 5-FU injections.\(^2\) Subconjunctival viscoelastic can also help to maintain the separation of tissue planes after needling.
   Subconjunctival injection of mitomycin C is has been advocated, but it is associated with an increased risk of complications, including hypotony and scleral melt.\(^3\) However, recent evidence has suggested that external topical application of mitomycin C 0.04% to the conjunctiva for 3 minutes achieved therapeutic concentrations of mitomycin in the Tenon layer in 36 of 41 patients treated, while minimizing complication risk.\(^4\) We find this approach very useful in many patients, particularly if 5-FU toxicity has been an issue in the past.
   Alternative approaches such as the use of anti-VEGF agents in bleb needling have also been reported, and larger studies would be of interest.\(^5\)

   c) **Needling technique**
   Many different needling techniques have been described, and the following description represents our current preferred approach. A drop of apraclonidine 1% given 15 minutes preoperatively can help reduce the risk of subconjunctival bleeding.\(^6\) We favor topical anesthesia with proximetacaine followed by application of an amethocaine-soaked swab to the area to be treated. We use povidone iodine 5% topically, aseptic technique, and a lid speculum in all cases. We avoid subconjunctival injection of anesthetics where possible, as this can make it more difficult to determine when sufficient aqueous drainage has been achieved. If mitomycin C is to be used, we favor topical application to a wide treatment area using a sponge soaked in the drug at a concentration of 0.02%–0.04% for 3 minutes. The conjunctiva is thoroughly irrigated after treatment.
For the needling procedure itself we use a bent 30-gauge tuberculin syringe containing viscoelastic, approaching the bleb from approximately 1 cm away, lysing scar tissue with the edge of the bevel and watching carefully for the establishment of aqueous flow. If the flap is flat and no flow is established by episcleral needling, then we will attempt to elevate the back edge of the flap. If this fails to achieve aqueous flow then needling under the flap and into the anterior chamber can be considered, taking care to avoid lens damage in phakic patients. Once aqueous flow has been established, subconjunctival viscoelastic injection can be helpful to separate tissue planes, identify further tissue adhesions for lysis, facilitate slow release of 5-FU (if used), and reduce 5-FU related corneal toxicity due to reflux from the conjunctival entry site.

In challenging cases, particularly where a previous needling has failed, we frequently perform needling in the operating room using an anterior chamber maintainer (anterior chamber cannula connected to a BSS infusion via a 3-way tap). This approach can allow a clearer demonstration that appropriate aqueous flow from the anterior chamber to the subconjunctival space has been re-established. In addition, varying the infusion bottle height can allow confirmation that aqueous flow will occur at an IOP relevant to the patient (10 mmHg = 13.6 cm H₂O).

5. Post-needling treatment
We use preservative-free dexamethasone drops after needling treatment at a frequency of 4-6 times daily, tapering according to clinical signs of inflammation and scarring.

Outcome of Bleb Needling
Since the early 1990s, multiple case series of trabeculectomy bleb needling have been reported, with and without antiscarring treatment, and with quoted success rates (usually as defined by IOP < 21 mmHg) of 75%–94%. Studies are difficult to compare directly because of the differences in case mix, surgical technique, and follow-up time, but there is evidence that the success of needling may be higher in patients who had mitomycin C treatment at the time of their initial trabeculectomy. Broadway et al reported a long-term success rate for needling augmented with 5-FU of 59.4%, with immediate reduction in IOP to < 11 mmHg the best predictor of long-term efficacy. Perhaps surprisingly, the correlation between bleb morphology and needling success appears to be relatively poor.

References
Case 1: High Myope Getting Worse

Shan C Lin MD

Myopia case of 46-year-old female software engineer from Taiwan
- Past medical history: mitral valve prolapse, hypotension (systolic blood pressure as low as 90 mmHg), sleep apnea
- Family history: Glaucoma in mother
- Medications: Bimatoprost
- Exam
  - Visual acuity 20/20 O.U.
  - IOP 14, 15 (maximum documented IOP: 22 O.U.)
  - Refraction -6.00, -6.25
  - Central corneal thickness: 534, 532
- Discs: See Figure 1.
- OCT: See Figure 2.
- Visual fields: See Figures 3 and 4.
- Visual fields: Progressed
- Further treatment? Patient refuses surgery. Alternative therapies?

Figure 1.
AMD and Glaucoma
Glaucoma and the Macula

Jeffrey M Liebmann MD

The macula is defined as the region of the retina where the retinal ganglion cell (RGC) layer contains more than a single monolayer of cells. While this region surrounding the fovea represents only 8% of the retinal surface area, it contains almost 50% of all RGCs. Although not normally thought of as a macular disease, loss of macular RGCs is a common feature of glaucoma and significant cause of functional impairment (eg, loss of contrast sensitivity, reading ability) and diminished quality of life in glaucoma patients.

Glaucomatous injury to RGC axons occurs at the level of the lamina cribrosa and causes irreversible axonal damage, leading to RGC death. This results in the characteristic structural features of glaucoma damage that can be assessed during clinical examination and imaging evaluation. These features include ganglion cell complex loss, retinal nerve fiber layer (RNFL) defect, and loss of neuroretinal rim tissue (eg, notch, disc hemorrhage). Functional deficits associated with the loss of RGCs in glaucoma follow the arcuate pattern of the RNFL, respect the horizontal raphe, and can occur at almost location in the visual field (VF).

Spectral domain OCT (SD-OCT) has greatly advanced our ability to evaluate the RNFL and macular ganglion cell complex structural changes in glaucoma and confirm that RGC damage occurs throughout the retina, resulting in both peripheral and central VF deficits. Since structural and functional damage in glaucoma are spatially consistent, this RNFL pattern of axonal loss results in an arcuate pattern of VF damage. In the periphery, this is often seen as a nasal step or arcuate scotoma; in the central field, these defects appear as small paracentral arcuate scotomata that can be detected in the regions surrounding fixation.

The VF corresponding to the macula is insufficiently tested during conventional perimetry and can be more effectively evaluated with a denser central VF test grid. For example, 2-degree stimulus spacing in the central field (10-2 program) can more effectively identify small paracentral scotomata when compared to traditional 6-degree spacing grids (24-2 or 30-2 programs). It is imperative that we not miss central VF loss because of its relationship to quality of life with respect to reading, contrast sensitivity, driving, and falls.

It is important to differentiate glaucomatous from nonglaucomatous causes of central visual dysfunction. In contrast to other retinal and optic nerve causes of visual impairment, glaucoma subjects usually have excellent acuity, and the remaining neuroretinal rim should not be pale. Clinical examination of the macular region and SD-OCT assessment can also be utilized to confirm that retinal disease (eg, AMD, diabetic retinopathy, retinovascular accident) are not contributing factors to loss of vision.

Selected Readings
Case 3: Optic Nerve Head Drusen, Low IOP, and Field Loss—Do You Treat?

Richard P Mills MD MPH

This 56-year-old male physician was visually asymptomatic when bilateral optic disc drusen were discovered on routine eye examination. The disc appearance was typical, with visible drusen and no central cup, and color vision was 1/11 Ishihara plates correct O.U. Visual field and OCT changes were compatible with the diagnosis. Initial IOP was 15 right and 16 left.

Should IOP-lowering therapy be used? Would the situation be different if visual field progression were documented?
Case 4: Diabetes
Glaucoma Progression in Proliferative Diabetic Retinopathy

Young H Kwon MD PhD

The patient is a 62-year-old white woman with type II diabetes. She has history of neovascular glaucoma (NVG) O.U. secondary to proliferative diabetic retinopathy (PDR) in 2008. She presented with progressive visual field and OCT changes with IOP of 16 mmHg O.S. in 5/2014. The following is her clinical history and exam (O.S. only).

Past Ocular History (O.S.)
- NVG 2008-10. Treated as above. Status post (s/p) phaco/IOL/Ahmed tube shunt 2010
- Pseudophakia 2010, s/p YAG posterior capsulotomy 2013
- History of diabetic macular edema (DME) since 2013, s/p bevacizumab (Avastin) injections 2014, focal macular laser in 5/2014
- History of dry eyes, s/p punctual plug 2014

Most Recent Ocular Exam in 5/2014 (O.S.)
- Vision (corrected) 20/150 (pinhole to 20/60)
- IOP 16 mmHg on timolol/dorzolamide b.i.d. (Max IOP of 30 mmHg prior to tube shunt in 2010, range of 14–25 since 2010)
- Pachymetry 558 microns
- Cornea diffuse punctate epitheliopathy
- Anterior chamber deep and quiet with tube in good position
- Iris: no iris neovascularization
- Lens: PCL in the capsular bag, good position
- Gonioscopy mostly open to scleral spur, focal peripheral anterior synechiae temporally, no angle neovascularization
- Fundus: no cupping, moderate pallor of optic disc 2-3+ arteriolar narrowing and sclerotic vessels dot/blot hemorrhage, microaneurysms, dense PRP scars

Ancillary Testing in 5/2014 (O.S.)
- Visual field: Progressive nasal field loss since 2010, now with absolute nasal defect threatening central fixation in 5/2014
- Cirrus OCT: Progressive thinning of peripapillary nerve fiber layer (NFL) since 2011. Ganglion cell analysis shows thinning temporally

Summary and Clinical Dilemma (O.S.)
This 62-year-old woman has a history of NVG secondary to PDR with fluctuating IOPs (14–25) since Ahmed tube shunt in 2010. Are the visual field and OCT progression due to glaucoma or diabetic retinopathy?

Selected Readings
A Quarter Century’s Progress in the Treatment of Open-Angle Glaucoma

Henry D Jampel MD MHS

1989: We had not proven to others that glaucoma could be successfully treated.

There were 3 small randomized trials involving medical treatment of ocular hypertension to reduce the incidence of development of glaucoma.

1. Epstein, et al.: Beneficial effect
2. Kass et al.: Beneficial effect

These reports were not enough to convince the U.S. Preventive Health Services Task Force from stating in their 1988 monograph that the evidence that lowering IOP to either prevent glaucoma or prevent worsening of glaucoma was not convincing.

The glaucoma community was formulating a response in the form of 3 multicenter RCTs:

1. Collaborative Normal Tension Glaucoma Study
2. Ocular Hypertension Treatment Study
3. Early Manifest Glaucoma Study

2014: We have proven that glaucoma treatment works.

- The Collaborative Normal Tension Glaucoma Study results appeared in 1998 and demonstrated a beneficial effect of IOP-lowering in terms of less visual field worsening in eyes with unremarkable IOPs and established glaucoma damage.
- The Ocular Hypertension Treatment Study (2001) demonstrated that lowering IOP was effective in preventing the development of glaucoma in eyes with elevated IOP.
- The Early Manifest Glaucoma Study (2001) showed us that lowering IOP reduced glaucoma worsening in eyes with pre-existing glaucoma.

1989-2014: Advances in Medical Therapy

- Topical prostaglandins
- Generics
- Combination eye drops
- Topical carbonic anhydrase inhibitors
- Alpha adrenergic agonist
- Alternative preservatives

Wish List for Future Advances in Medical Therapy

- Controlled release delivery system
- Convention outflow drug
- Neuroprotective medication

1989-2014: Advances in Laser Therapy

1989-2014: Advances in Surgical Therapy

- Refinement of trabeculectomy, especially the addition of mitomycin C
- Proof of efficacy and safety of aqueous drainage devices
- FDA approval of first minimally invasive glaucoma surgery (MIGS) device, and continued investigation of conjunctival sparing surgery
- Proof that phacoemulsification lowers IOP

Wish List for Future Advances in Surgical Therapy

- Surgery that does not involve the conjunctiva
- Surgery that can achieve lower IOPs, not just 15-17 mmHg
- Less invasive, more elegant surgery

1999-2014: New Concepts in Glaucoma Treatment

- Palmberg and “target pressure” appears in the PPP for POAG.
- Central corneal thickness widely accepted to influence applanation tonometry measurements.
- Although treating ocular hypertension works, not all eyes with elevated IOP need to be treated.
- Need to distinguish between slowly and rapidly worsening glaucoma.
- Reincarnation of “compliance” as “adherence”
Paging Dr. Google: What Do Our Patients Learn on the Internet?

Ivan Goldberg MBBS FRANZCO

In 2002, in a survey of 1000 primary care patients, 53.5% accessed medical information on the Web, 60% of these patients reported that the information they obtained was “the same or better” than that provided by their physician, and about 60% of them did not discuss this information with their doctor. More educated patients with higher incomes searched the Internet more frequently.

Use of the Internet to access medical information has increased exponentially over the past decade, with the overwhelming abundance of online information, the availability of decision aids and Web health applications (eg, the Ocular Hypertension Treatment Study risk calculator: http://ohts.wustl.edu/risk/calculator.html), and the accessibility and pervasiveness of information technologies in daily life.

In a chronic, generally progressive disease like glaucoma, which causes irreversible visual damage, there are many overt daily barriers to self-administered care combined with covert disease progression. Not surprisingly, nonadherence to medications and missed appointments, poor persistence with long-term treatment, and unrecognized physical barriers to drop instillation are all too common.

A health professional’s time and ability cannot realistically control the out-of-consultation behavior of consumers; we cannot expect consumers to rely entirely on written and verbal information provided by their regular practitioner. Physicians need to recognize the common and increasing use of Internet resources by patients seeking information and understanding. We should embrace this opportunity to guide them proactively and to welcome their efforts to engage with their health management. Such guidance includes improving their assessment of the quality of the information obtained and its incorporation into their individual management needs.

To date most approaches have been didactic: patients have been taught how to use a computer, how to access the Internet and how to find credible websites. Most assessment of the successes of these interventions have been subjective: self-reported pre-/postintervention knowledge and skills of computer/Internet use and access to reliable health information. There is great opportunity for further research into other strategies to assist patients to find reliable online health information and to assess outcomes of these strategies with objective measures.

References
Scamming for Dollars: What Are Our Patients Buying From Alternative Glaucoma Providers?

Derek S Welsbie MD

I. Prevalence of Complementary and Alternative Medicine (CAM) Usage

A. All medicine
   1. As of 2007, Americans spent $34B on CAM, ~12% of all out-of-pocket health-care expenditures.
   2. Evenly split between nonvitamin natural products and massage, chiropractic, acupuncture, and homeopathy

B. Glaucoma
   1. Rhee et al (2002) showed a 5% utilization rate among glaucoma patients already being treated at U.S. hospital-based practices.
   2. Wan et al (2012) reported nearly 14% past or present CAM usage at Canadian hospital-based practices.

II. Types of CAM Used by Glaucoma Patients

A. Most common forms of CAM
   1. Herbal medications
   2. Dietary changes
   3. Vitamins

B. Top herbal medications
   1. Bilberry
   2. Lutein
   3. Fish oil
   4. Ginkgo biloba
   5. Chinese herbs

C. Marijuana self-reported usage is between 0% and 2%.

D. Chiropractic, meditation, acupuncture, and faith healing were relatively infrequently used.

III. How Glaucoma Patients Learn of CAM

A. Two-thirds of patients learned of their CAM treatment from the media, Internet, or friends/family.

B. Gunasekera et al (2007) studied the quality of websites returned when patients search for “CAM and glaucoma.”
   1. Two-thirds have a commercial bias.
   2. 10% discourage the use of conventional treatments.

C. Only 25% of patients disclose all their CAM treatments to their ophthalmologist.

D. Internet
   1. Over 90% of search engine traffic comes from page 1.
   2. Page 1 of a Google search for “alternative medicine” and “glaucoma”:
      a. www.glaucoma.org/treatment/alternative-medicine.php (“Alternative Medicine,” Glaucoma Research Foundation): Balanced article noting the only evidence is for aerobic exercise
      d. www.umm.edu/health/medical/altmed/condition/glaucoma (“Glaucoma,” University of Maryland Medical Center): Eliminate allergens, caffeine and refined foods; increase antioxidant, healthy fat and water intake; exercise; consume lutein, ginkgo, and bilberry.
   3. Page 1 of a Bing search for “alternative medicine” and “glaucoma”
      c. www.livestrong.com (“Alternative treatments for glaucoma,” Livestrong): Reduce stress, vitamins and nutrition, marijuana (although a balanced view of the latter)
      e. www.walgreens.com: Same info/text as UMaryland site
      f. http://ezinearticles.com: Bright Eyes (N-acetylcarnosine)
IV. Evidence for CAM

A. Caffeine
1. Multiple groups have shown that caffeinated coffee leads to a small, but detectable, short-term (60-90 min) increase in IOP (~1 mmHg) compared to decaffeinated drinks.
2. The short-term increase may be slightly greater in patients with glaucoma.
3. One study found higher baseline IOP levels in caffeine consumers compared to controls (Chandrasekaran et al, 2005).
4. Caffeine intake did not increase the risk of glaucoma in the Nurses’ Health Study/Health Professionals Follow-up study (> 170,000 patients, Kang et al, 2008).

B. Lutein/zeaxanthin
1. No randomized controlled trials (RCTs)
2. Antioxidant intake did not decrease the risk of glaucoma in the Nurses’ Health Study/Health Professionals Follow-up study (> 170,000 patients, Kang et al, 2003).

C. N-acetylcarnosine
1. No RCTs

D. Vitamin C
1. No RCTs showing a benefit
2. Only evidence for IOP-lowering comes in the setting of osmotic agents.
3. Little evidence that ascorbic acid is reduced in the aqueous of glaucoma patients (Lee et al, 1977)

E. Ginkgo biloba
1. Quaranta et al (2003) found an improvement in mean deviation in normal-tension glaucoma patients who consumed 120 mg daily of Ginkgo.
2. A similar study by Guo et al (2014) was unable to detect an improvement.

F. Bilberry/anthocyanins
1. Small RCT (Ohguro et al, 2012) showed lessened visual field progression in patients taking black currant anthocyanins.
2. More evidence required

References
Glaucoma is now recognized as a progressive neurodegeneration, rather than merely a condition relating to only IOP.1,2 The etiology is likely to be multifactorial, with several hypothesized contributing factors. It also is a progressive optic neuropathy in which there is irreversible visual loss as the result of neuronal death within the central visual pathway.

What is glaucoma neuroprotection?

By definition, glaucoma neuroprotection is an IOP-lowering independent therapy3,4 that targets neurons within the central visual pathway, particularly retinal ganglion cells (RGCs), and enhances their function and survival.

Glaucoma neuroprotection offers potential as a complementary therapy to IOP lowering for those patients in whom lowering of IOP does not adequately ameliorate the progressive loss of visual function. It also offers potential as an alternative therapy for those patients in whom pressure-lowering agents are not used, not tolerated, or ineffective.

Rationale for Glaucoma Neuroprotection

IOP lowering is currently the only therapy approved by regulatory agencies for the treatment of glaucoma. Reducing IOP prevents glaucoma in individuals at risk, including those with ocular hypertension, and also prevents progression of glaucoma in individuals with existing disease. However, reduction of IOP is not always effective. Moreover, achieving adequate pressure lowering may not be possible or may be associated with adverse effects.

Why is it so difficult to translate experimental models of glaucoma to human disease?5

- Animal models often are developed by increasing the IOP of healthy and young animals. The IOP is increased acutely; in many cases, it is increased to higher levels than are measured in human glaucoma. The resulting damage occurs in days or weeks rather than in the many months or years typically found in human glaucoma.
- The anatomy and pathophysiology of most animals are quite different from those of humans. There are differences in the retina / optic disc / optic nerve.
- There are major differences in study design between preclinical and clinical glaucoma studies. These include doses and timing of intervention, methods and endpoints, age of study groups, and absence vs. presence of IOP-lowering treatment.

Why is it so difficult to demonstrate glaucoma neuroprotection?6

Neuroprotection therapies have been investigated to treat other disorders of the central nervous system (eg, stroke, head trauma, amyotrophic lateral sclerosis, Parkinson and Alzheimer disease). Only a minority of these investigations has led to approved therapies, including the use of memantine for Alzheimer disease.

The detection of progressive glaucomatous injury and the definition of study endpoints are problematic. At the present time, regulatory agencies equate glaucoma progression with standard achromatic visual field (ie, functional) injury and have not embraced structural alterations in optic nerve or retinal nerve fiber layer to serve as primary endpoints. Visual field testing is subjective, with considerable variability.

As glaucoma is slowly and variably progressive in most patients, clinical trials require more than 1 year to measure change. In addition, neuroprotective agents must be evaluated in glaucoma patients who have already been treated to lower IOP. Therefore, the duration of clinical trials of neuroprotection are necessarily much longer than is required for determining IOP-lowering effects. In addition, large numbers of patients are needed.

Clinical Trials of Glaucoma Neuroprotection

There still has not yet been definitive proof of clinical efficacy for any neuroprotective agent in glaucoma.

References

Do-It-Yourself Genetic Testing for Glaucoma: Is There Any Value?

Wallace LM Alward MD

I. Current Known Glaucoma Genes

There are several known genes that cause some forms of glaucoma.

A. Aniridia (PAX6)
B. Axenfeld-Rieger syndrome (PITX2, FOXC1)
C. Juvenile open-angle glaucoma (MYOC [myocilin])
D. Normal-tension glaucoma (OPTN [optineurin] and TBK1)
E. Primary congenital glaucoma (CYP1B1 and LTBP2)
F. Primary open-angle glaucoma (MYOC [myocilin])

II. Available Genetic Testing

A. There are commercially available tests for most of these:
   1. CYP1B1
   2. FOXC1
   3. LTBP2
   4. MYOC
   5. OPTN
   6. PAX6
   7. PITX2

B. To find a laboratory that tests for these consult: www.genetests.org

C. Because these genes collectively cause about 5% of glaucoma, routine genetic testing is not justified.

III. Direct to Consumer Genetic Testing

A. Direct to consumer genetic testing (such as 23andMe) gave individuals genetic risk information for diseases such as glaucoma.

B. For example, it might tell a patient that he or she was at a 2.9-fold increased risk of exfoliation glaucoma. But what does the patient or their ophthalmologist do with this information?

C. The FDA felt that this testing was a medical device, and as of December 5, 2013, 23andMe provides only raw genetic information and ancestry information.

IV. Direct to Consumer Genetic Testing as a Research Tool

A. Direct to consumer testing companies have the potential to advance genetic research by the huge amount of data that can be analyzed.

B. 23andMe asked 45,000 customers whether they were near-sighted and, if so, at what age. They found 22 associations with the age of onset of myopia (2 previously published and 20 novel associations).

Selected Readings


Medicinal Cannabis for Glaucoma: Science, Smoke, or Mirrors?
Marc F Lieberman MD

I. Clinical Dimensions of Marijuana (MJ) and Glaucoma
A. Anecdotal reports of lowered IOP with MJ first appeared in 1971 and sporadically that decade.1-3
B. Further investigations substantiated short duration of IOP-lowering effect, and distinction among MJ’s many components.4-6
C. Ocular effects
1. In approximately 2/3 of users, smoking MJ joints with 2% delta-9-tetrahydrocannabinol (THC) decreases IOP by 25%-30%, with duration of 3-4 hours (translating into a need to smoke over 3000 joints/year!).
2. Though smoking maximizes THC absorption, variable THC concentrations plus risk of carcinogens plus long-term pulmonary damage make it a “nonviable” delivery route; tolerance-effects for extent of IOP reduction often seen
3. Equivalent or reduced efficacy of alternative administration routes (cf. IV and oral effects > topical)
D. Systemic side effects
1. Psychotropic (euphoria/anxiety); impaired coordination; altered spatial/temporal perception; impaired cognition and short-term memory
2. Lowers blood pressure, often with compensatory increased heart rate ± palpitations
E. Marijuana chemistry
1. Over 480 distinctive chemicals in MJ: cannabinoids, terpenoids, and flavonoids that produce singular and/or interactive and/or entourage effects. (Still needs to be unraveled)
2. Strains are now grown with > 11% THC, the identified agent for IOP effect.
3. Intriguing identification of endocannabinoids and their pervasive CNS receptors (including retinal cells): neuroprotective potential? (7 references)
F. Broad consensus for inappropriateness of marijuana in glaucoma management!
1. Federal Drug Administration (FDA)
2. National Institutes of Health-National Eye Institute / Institute of Medicine
3. American Glaucoma Society
4. Canadian Ophthalmological Society
5. American Academy of Ophthalmology
Complimentary Therapy Assessment (2014): “There is no scientific evidence demonstrating increased benefit and/or diminished risk of marijuana use in the treatment of glaucoma compared with the wide variety of pharmaceutical agents now available.”

II. America Emerges From the “Drug Wars” of 1970-2012:
A. Phobic and racist origins of U.S. Government’s Stigmatization of MJ
1. A bigot’s official testimony to Congress, 1930: “Marijuana is the most violence-causing drug in the history of mankind. . . . Most marijuana smokers are Negroes, Hispanics, Filipinos and entertainers. Their satanic music, jazz and swing, result from marijuana usage. . . . Reefer makes darkies think they’re as good as white men—the primary reason to outlaw marijuana is its effect on the degenerate races.” Henry J. Anslinger, First Director, Federal Bureau Narcotics
B. Controlled Substance Act of 1970
1. “Politicized” classification of MJ as Schedule I (eg, heroin, cardio-toxic toad venom) vs. Schedule II (eg, cocaine and methamphetamine)
2. Total distortion and exaggeration of marijuana’s potential health risks when contrasted with the incalculable social calamities of alcohol and tobacco use vs. marijuana use
C. Devastating social costs of “marijuana prohibition”
1. Over 20 million Americans arrested for MJ violations
2. Profound racial disparity of arrests: blacks 4-30 x likelier to be arrested (despite parity usage rates of whites and blacks); plus blacks 10 times likelier to be incarcerated.
3. Costs of over $100 billion dollars for courts, prisons, enforcement, etc. (eg, $45,000/year of incarceration)
D. The pendulum swings: By August 2014, 37 states liberalized marijuana law into 3 kinds:
1. Medical access (MJ or THC) with physician’s prescription
2. Decriminalization (± fines for usage)
3. Legalization (medicinal and recreational . . . )

III. American Medicalization of Marijuana

A. As of May 2014, “medical marijuana” was authorized by nearly half the states for glaucoma, Crohn disease, post-traumatic stress, epilepsy, Alzheimer disease, chemotherapy-induced nausea, AIDS- or cancer-related cachexia, spasticity in multiple sclerosis, and neuropathic or rheumatoid arthritis pain management. Much “evidence” is testimonial, with no randomized, clinically controlled trials.

B. “Pushback” from various medical societies has revolved predominantly around issues involving the inexplicable deviations from prescription-drug standards historically and routinely required by the FDA.19,21

1. No standardization for ascertaining the potency, purity, or composition of MJ exists.
2. No optimal dosage schedules have been established.
3. Although many chronic diseases are designated as appropriate for treatment, no information regarding MJ tolerance or dependence is available.
4. Unlike standard prescription medications with single active compounds, MJ contains several hundred distinctive components.
5. No other prescription medication is smoked—raising concerns regarding long-term respiratory effects and possible fungal or herbicidal contaminants (especially placing immune-compromised AIDS or cancer patients at risk).
6. Current systems of dispensing do not adequately safeguard against potential for diversions and abuse, possibly facilitating MJ’s availability to minors.
7. Paralleling trends in legalization is a growing public perception that marijuana is not associated with significant or lasting harm. This is patently at odds with reports of a 9% dependency rate among users—especially worrisome in young adolescents, who are at risk after chronic usage for long-term, permanent IQ reduction of approximately 10 points by their twenties.

IV. Recent Safety Assessments of MJ Use

A. Marijuana’s “safety profile” is disturbingly reminiscent of those of the largest, legal recreational drugs in the U.S.: alcohol and tobacco. And as with tobacco, young people are the primary targets: they will be “customers for life.”

1. Lessons from alcohol: Currently alcohol’s costs to American society—in terms of lost productivity, crime, and damage to health—have been calculated to be higher than those of all illegal drugs combined. Availability is price-sensitive, especially in regard to teenagers.22 Thus extrapolating from evidence showing that hikes in alcohol taxes having reduced alcohol-related deaths in Alaska, it has been calculated that a 10% drop in the price of MJ would correlate with a 3%-5% increase in the number of minors who start smoking. In other words, if taxes and regulations can keep legal marijuana costs high, it may well help reduce adolescent exposure to long-term dependency and neurological impairment.

2. Driving safety: Marijuana use has been implicated in doubling the risk of automobile-driver accidents. Drivers in accidents who had smoked MJ within three hours of the crash or who tested positive for its use were twice as likely as nonusers to be involved.20

3. Tobacco’s influence: Antismoking epidemiologists are alarmed that although the 9% rate of dependency among MJ smokers is less than the 32% rate among tobacco users, the nonfatal effects of respiratory damage, cardiovascular disease, impaired cognitive development, and mental illness remain formidable. Increasing THC potency and smoke-reducing vaporizers permit greater amounts of drug delivery than in the past. And “warnings” won’t work! Despite decades of alarming health warnings and education, 20% of American adults continue to smoke tobacco. There are apprehensions that the emerging marijuana industry will follow the tobacco industry’s “road map to profits”: by denying addiction potential; by downplaying known adverse health effects; by creating as large a market as rapidly as possible; and by protecting their market through aggressive lobbying, campaign contributions, and other advocacy efforts.23

B. The long-term psychiatric risks of marijuana use, especially among adolescents, are a serious concern with MJ’s increasing availability and affordability from competitive, legal drug sources.

1. In over 1000 New Zealander adolescents followed26 prospectively for 38 years from birth, cannabis usage was assessed at regular intervals from age 18 to 38, with neuropsychological tests at age 13 (prior to usage) and age 38, after a pattern of persistent use was acknowledged. Independent of education, direct correlation was found between persistent usage and neuropsychological decline across 5 domains of functioning (eg, executive functioning and verbal IQ) in direct proportion to reported use; cessation for more than 1 year still did not result in recovery. Similar findings were not seen in adult users. Determined, creative efforts to delay adolescent access and usage are essential!

2. An extensive review of the association between both natural and synthetic cannabinoids in susceptible individuals has revealed an alarming conversion rate from cannabis-induced psychosis to irreversible schizophrenia.24 Vulnerable individuals include a history of child abuse and a familial
history of psychotic disorders. There are more frequent negative effects of cannabis use with prolonged and early exposure in adolescence. It remains unclear whether these psychiatric findings are related to reports of detectable alterations in the brain’s reward/aversion regions implicated in addiction—the nucleus accumbens and amygdala—in young adult recreational users.26

References and Selected Readings

Ophthalmology Studies


Cannabinoid Studies


Official Medical Position Statements

14. Laura D. Volkow MD, National Institute on Drug Abuse, NIH. Letter from the Director: Marijuana. Available at: www.drugabuse.gov/publications/research-reports/marijuana/letter-director


Medical Overview and Sociological Sources


Medically Current Books


Web Sources

31. Laura D. Volkow MD, National Institute on Drug Abuse, NIH. Letter from the Director: Marijuana. Available at: www.drugabuse.gov/publications/research-reports/marijuana/letter-director
32. Lester Grinspoon, M.D. (Prof. Psychiatry, Harvard): Marijuana the forbidden medicine. Available at www.rxmarijuana.com. Also see Dr. Lester Grinspoon’s Marijuana uses. Available at: www.marijuana-uses.com
Improving Adherence in Glaucoma Patients: The Role of Social Media and New Technology

Robert M Schertzer MD
Adherence to any medication is a daunting task. It requires the recognition that a medication might provide a benefit (acceptance), the administration of the medication at the correct time(s) of day (compliance), and the continued administration over time (persistence).

A factor that is commonly overlooked is the ability to correctly administer the medication (execution). For oral medications, this commonly is not an important concern as it is relatively simple to put a pill in one’s mouth and swallow it unless one has dysphagia. For medications such as eye drops, however, this can be a daunting task.

Challenges with eye drop administration begin with packaging. Bottles are not only difficult to open but difficult to squeeze. The ease of getting a single drop rather than a stream of drops may be due to the bottle type as well as the type of plastic the container is made from. We have found that bottle design can potentially influence execution.

Drop size is important. Smaller drops are often associated with comparable if not superior outcomes, in terms of both efficacy and safety profile.

The skills associated with successful drop administration are the ability to get a drop on the eye and to do so without contamination and without wasting too many drops. The latter is especially important now, with pharmacy benefit managers limiting the refill rate. Fewer than half of patients can do all three successfully.

We have found a significant correlation between ophthalmologist-patient communication and both adherence and the ability to instill a drop correctly. Currently fewer than two-thirds of doctors provide any education about glaucoma and only one-sixth educate their patients in how to use their medications or discuss the subject with them.

Finally, can you teach an old dog new tricks? Can patients who have difficulties instilling drops improve their techniques? We still are not sure what the best or preferred techniques are for drop instillation.
The KISS Principle: Simple Things to Improve the Daily Life of Glaucoma Patients

Anjali M Bhorade MD

As clinicians, we often focus on a patient’s IOP, optic nerve exam, or visual field tests, and we may overlook factors that have a greater impact on a patient’s daily function and quality of life. The following 5 D’s are simple things to discuss with your patient to improve their daily life:

I. Daily Activities

Many glaucoma patients have difficulty with activities of daily living, such as reading, writing, and paying bills.1,2

A. Inquire about difficulty with activities of daily living and lighting in the home.

B. Recommend increased lighting in the home.3

C. Refer to an occupational therapist specialized in low vision for an in-home evaluation:
   1. Recommendations for optimal levels of lighting and type/position of lighting fixtures.
   2. Strategies to maximize reading skills (eg, eccentric viewing, scanning).
   3. Environmental modifications (eg, organization and marking strategies, contrasting colors).

D. Refer to low vision clinics for low vision optical devices (eg, magnifiers, CCTV).

E. Refer to low vision services (eg, books on tape, MindsEye)

F. Recommend iPhone/iPad applications for low vision patients (eg, Magnifier, Ariadne GPS, LookTel Money Reader, Voice Brief, VoCal) and electronic reading books with white lettering on dark background.

II. Driving

Patients with glaucoma are at an increased risk of motor vehicle collisions compared to drivers without glaucoma.4 Some glaucoma patients, however, may be safe drivers but self-restrict or stop driving, thus suffering from negative social and psychological consequences of driving cessation.

A. Refer for an on-road driving evaluation to assess driving safety.

B. Refer potentially safe drivers to a driver rehabilitation clinic to improve driving skills or to a low vision clinic for driving aids (eg, Bioptic lenses, prisms).

C. Consider restricted driving for select patients (eg, daytime driving only).

D. Refer unsafe drivers to driving cessation programs to help provide support groups and resources for alternative modes of transportation.

III. Disability from Falls

Falls are the leading cause of injury-related death and a significant cause of morbidity in older adults in the United States.5 Glaucoma patients have almost a 4-fold increased risk of a fall.6

A. Inquire about recent falls and injuries from falls.

B. Consider changing bifocal or progressive corrective lenses to separate distance and reading glasses.

C. Refer to an occupational therapist for an in-home evaluation and modifications to reduce risk of falls.

D. Refer to an orientation and mobility specialist to improve mobility.

E. Refer to physical therapy for strength training and assistive devices for ambulation (eg, walkers, canes).

IV. Dual Sensory Loss

In the United States, 26.7 million adults > 50 years of age have clinically significant hearing loss, yet less than 15% use hearing aids.7 The compounded effects of hearing and vision impairment increase a patient’s risk for depression and poor overall well-being compared to single sensory loss alone.8

A. Inquire about hearing impairment to both the patient and their family.

B. Refer for a hearing evaluation / hearing aids to optimize hearing.

C. Maximize visual potential with recommendations from #1 above.

V. Depression

Patients with glaucoma are at increased risk of depression.9,10 Many glaucoma patients have additional risk factors for depression, including older age, chronic comorbidities, disability, retirement, and bereavement of loved ones.9,11

A. Inquire about depressive symptoms or use a screening questionnaire (eg, Geriatric Depression Scale).

B. Refer to a mental health professional for evaluation and treatment.

C. Refer to social support groups.

References


IRIS Registry: Update on What Has to Happen by When

Cynthia Mattox MD FACS

The IRIS Registry and Physician Quality Reporting System / Meaningful Use / Quality Clinical Data Registry: Introduction

The IRIS Registry (Intelligent Research in Sight) is the nation’s first EHR-based comprehensive eye disease and condition registry. It is a centralized data repository and reporting tool that uses observational study methods to collect and perform statistical analysis of patient data to produce easy-to-interpret national and interpractice benchmark reports. The reports can validate the quality of care ophthalmologists provide and pinpoint opportunities for improvement.

Eligible physicians who sign up and meet the reporting requirements can use the IRIS Registry to report clinical quality data to the Physician Quality Reporting System (PQRS) and the Medicare Electronic Health Record Incentive Program. The IRIS Registry will automatically extract and submit data for PQRS measures to the Center for Medicare and Medicaid Services (CMS) on a practice’s behalf. Please go to the following link for an extensive list of frequently asked questions about the basics of the IRIS Registry: www.aao.org/iris-registry/faq.cfm

IRIS as a Quality Clinical Data Registry

IRIS is approved as a Quality Clinical Data Registry (QCDR), which allows the American Academy of Ophthalmology to create additional quality measures in addition to the existing PQRS measures. New measures in the QCDR must be approved by CMS and outcome measures are preferred, but it is understood that there are important process of care measures that will enhance patient care that will be included in the IRIS Registry, even if not approved for use by CMS.

Currently the rules allow for an additional 20 measures for all of ophthalmology to be included in the QCDR. In 2015, physicians utilizing IRIS will be able to use any of these measures or the existing PQRS measures to qualify for the quality reporting requirements of PQRS or for purposes of the value-based modifier (VBM) quality component.

The Academy’s Clinical Data Registry Workgroup has worked with the subspecialty societies to develop important, clinically meaningful measures that will be submitted to CMS for approval to be used during calendar year 2015. These measures are currently undergoing testing within the IRIS Registry, and modifications may be made before the final submission to CMS.

2014: Requirements for Successful Participation

In 2014, IRIS can be used to report the current 2014 PQRS measures only. This will allow you to avoid the PQRS/VBM penalty (by reporting 3 measures), may also allow for a bonus through the PQRS (by reporting 9 measures), and also help you get a bonus in the 2016 VBM (if your practice has 10 or more eligible professionals). See below for more details on the VBM.

2015: Requirements for Successful Participation

In 2015, IRIS can be used to report participation using the QCDR measures or the existing PQRS measures approved for 2015. There will be no public reporting about how well you perform on each measure in 2015.

2015 is important for all eligible professionals (EPs), all M.D.s and O.D.s in your practice, not only to avoid penalties for PQRS, but also because all EPs will now be subject to the VBM to be applied to 2017 Medicare payments. The VBM is calculated from both a quality component and a cost-of-care component, and depending on the cost/quality combination, an upward, downward, or neutral adjustment to ALL your Medicare payments will be applied to 2017 payments based on your performance in 2015.

For successful quality reporting, an EP must report on at least 1 approved outcome measure, plus 8 additional measures (across 6 “quality domains”) from the 20 approved measures or PQRS measures available in the QCDR. We expect that the cost component of the VBM will compare your average cost of care to that of your peers (all other ophthalmologists participating in Medicare in your region) and then stratify it if your cost is greater than 1 standard deviation from the mean, higher or lower. We do not yet have final rules on the exact 2017 VBM calculations or amount of adjustments.

Conclusion

One goal of the IRIS Registry is to enable easier participation and the ability to navigate this complex regulatory environment, which has potential for significant financial impact on your practice.

The “home-grown” Academy and subspecialty quality measures will be meaningful and able to enhance your clinical practice, identify best practices, and improve patient outcomes. The measures will be modifiable and enhanced with appropriate risk adjustment as time goes on, with the potential for important analysis and benchmarking of such a large aggregate patient database.

As of June 9, 2014:

-IRIS Registry is mapped to 20 different EHR systems.
-277 practices and 1595 physicians are mapped with their EHR to the IRIS Registry
-Including the above, there are 653 practices and 3100 physicians contracted with the IRIS Registry
-So far, there is access to 7.06 million patient encounters, representing 2.34 million unique patients.
Resources


How EHRs Will Evolve Into Real-time Expert Systems

Joshua D Stein MD MS

Current Paradigm

EHRs are simply serving as electronic file cabinets for medical information. Instead of capturing patient data on paper records, the data is being captured electronically. Advantages over paper records: It easier to read and share notes. But beyond that, little is being done with the plethora of data that is captured.

Future Paradigm

Harvesting data from EHRs to help guide real-time clinical decision making, to incorporate patient preferences into the decision-making process, and to assess patient outcomes.

I. What is an Expert System?

An expert system is a computer system that emulates the decision-making ability of a human expert.

II. How an Expert System Works

A. User interface
B. Knowledge base
C. Inference engine

III. Examples of Ways Expert Systems Can Be Helpful in Medicine

A. To assist medical personnel with determining which patients require immediate treatment and which can be otherwise triaged
B. To aid clinicians whose clinical knowledge may be out of date or those whose knowledge base may be limited because of lack of time to read journals or attend conferences
C. To guide clinicians in emergency situations when they may not have access to test results before having to decide on how to best treat a given patient
D. To aid clinicians who lack experience in managing particular rare conditions and therefore may not recognize them or not know how to treat them
E. To facilitate access to subspecialists whom the clinician might like to consult who may reside in a different part of the country or world
F. To aid clinicians who may be unsure about the diagnosis and want to check it with someone more experienced or those who may be under time pressure and unable to fully think through a complex case
G. To aid clinicians who may not be aware of modern drugs, drug interactions, guidelines on drug usage, or contraindications for the use of certain medications

IV. Potential Benefits of Expert Systems Using EHRs

A. Ability to assimilate past information quickly and efficiently and incorporate it into real-time decision making
B. Improve efficiency of clinical care, workflow
   1. No need for manual data calculations
   2. Provide real-time advice
C. Ability to generate a longer list of differential diagnoses / prioritize them than can humans
D. Incorporate patient preferences into decision-making process. This can be set up so that patient can see the impact of modifying certain risk factors.
E. Assist generalists with determining which patients would benefit from receiving care by specialist or subspecialist (can be integrated with telemedicine)

V. Drawbacks / Limitations of Use of EHRs as Expert Systems

A. Limiting physician’s ability to think; “cookbook medicine”
B. Lack of common sense
C. Inability of EHR to adequately capture selected parameters
D. Lack of standardization of data collection in EHRs
E. Garbage in → Garbage out / Missing data in EHR records
   1. Data entered as free text rather than in discrete fields
   2. Inconsistency in data entry
F. Difficulty with expert system adapting to new circumstances

VI. Examples of Use of EHRs as Expert Systems

A. Determining risk of cardiovascular disease
B. Pediatric medication dosing
C. Point of care for obesity management
D. Sepsis control at University of California, Davis
E. Reminders to nurses to turn patients at high risk for pressure ulcers; reduced ulcer rates from 3.5% to 1%
F. Identifying eligible patients for clinical trial recruitment
VII. Ideas for Use of EHRs as Expert Systems in Ophthalmology

A. Forecasting of glaucoma progression
B. Diabetic retinopathy risk calculator
C. Risk of hospitalization following cataract surgery

References


How I Use My EMR to See Glaucoma Patients

Joel S Schuman MD

I. Barriers to EHR Implementation, AAO 2006 Member Survey
   A. Concern about lack of capital resources to invest in EHR and insufficient return on investment
   B. Concern about loss of productivity during implementation
   C. Concern about ability to draw in EHR
   D. But . . .
      1. 76% of the respondents to the AAO 2006 survey of EHR adoption would recommend the EHR to another ophthalmologist.
      2. 79% would not go back to paper records.

II. EHR Implementation, AAO 2013 Member Survey
   A. Of 17,839 AAO members, 1500 AAO members were surveyed, 492 responded.
      1. 32% of practices had implemented an EHR.
      2. 15% had implemented an EHR for some of their physicians or were in the process of implementation, and another 31% had plans to do so within 2 years.
      3. 49% were satisfied or extremely satisfied with their system.
      4. 42% reported increased or stable overall productivity.
      5. 19% reported decreased or stable overall costs.
      6. 55% would recommend an EHR to a fellow ophthalmologist.
   B. For those with an electronic image management system, only 15% had all devices integrated, 33% had images directly uploaded into their system, and 12% had electronic association of patient demographics with the image.
   C. Adoption of EHRs by ophthalmology practices more than doubled from 2007 to 2011, but satisfaction declined.
   D. The percentage of physicians actually receiving meaningful use incentive payments is low.
      1. 1906 of 17,839 AAO members
      2. Received $33.9 million compared to 74,035 doctors of medicine or osteopathy receiving a total of $1.38 billion
      3. Penalties for not using EHR/lack of meaningful use begin 2015
   E. Shortcomings in image management systems must be addressed.

III. EHR Financial Benefits
   A. Implementation of EHR can be costly, but research shows that return on investment can be achieved.
   B. AAO 2006 survey: Average cost of implementation for ophthalmologists was $49,712/physician, with average monthly maintenance costs of $1066/physician.
   C. Research in primary care outpatient clinics
   D. $44,000/provider implementation costs
   E. $8,500 maintenance costs / provider / year
   F. 2.5 years to pay for implementation
   G. Afterwards, $23,000 in net benefits / provider / year

IV. UPMC
   A. 20 hospitals
   B. 4200 licensed beds
   C. 200,000+ inpatient admissions and observation cases per year
   D. 4.5 million outpatient appointments annually
   E. Nearly 60,000 employees
   F. 3400 employed physicians
   G. 11,000 nurses
   H. 1.4 million members UPMC Health Plan
   I. $11 billion in revenue

V. 2010 and 2011 Surveys
   A. Web-based, with email link
   B. Anonymous
   C. 2010: 181 clinical support staff; 477 physicians
   D. 2011: 1051 clinical support staff; 356 physicians
   E. Physicians’ appraisal of EpicCare
   F. EpicCare and clinician workload
   G. Physician commitment to EpicCare by duration of use

VI. Satisfaction: Quality of Patient Care, UC Davis
   A. Satisfaction: UC Davis
   B. EpicCare ROI Project
   C. Purpose
      1. To assess the financial impact of implementation of an ambulatory EHR in an academic ophthalmology practice based upon quantifiable clinical productivity measures
2. Design
3. 4-year longitudinal study
4. 2 years pre-implementation (July 2004 – June 2006)
5. 2 years post-implementation (July 2006 – June 2008)
6. Includes only faculty employed during study period

VII. The Case for EHR
A. The records are always instantly available–even from home or on the road.
B. Notes are always legible, and everything is always in the same place and standardized.
C. While clinic may end slightly later, charts and letters are completely done.
D. Letters go out the same day or the next.
E. Postoperative notes are very fast and easy.
F. E-prescribing

VIII. EHR Shortcomings and Possible Solutions
A. It is much harder to draw . . . but photos and imaging are much more accessible, making drawing less critical.
B. Typing is tedious . . . “smart phrases,” scribe

IX. OHSU Experience
Twenty-three faculty providers completed 120,490 clinical encounters during a 3-year study period.
A. Postimplementation volume was essentially back to baseline by Year 1.
B. 75% of encounters were completed within 1.7 days after visit.
C. Mean total time per patient was 6.8 minutes longer with EHR than paper ($P < .01$).
D. EHR documentation more text based than graphical

X. Personal Health Records (PHRs)
A. Center for Information Technology Leadership (CITL)
B. Have the potential to dramatically change health care over the coming years
C. Enable patients to become more involved and engaged in their care
D. Allow patient to authorize stakeholders access to information that was not previously available
E. PHR systems could have a significant, positive impact on the efficiency of administrative and clinical processes within health care.
F. Resulting in considerable cost savings

XI. Patient Self-Service
A. UPMC HealthTrak is a patient’s window to his or her personal medical record.
B. Patients can access their
   1. Medical record
   2. Allergies
   3. Medications
   4. Health problems
   5. Lab and test results
C. Schedule, confirm, and cancel appointments
D. Exchange secure messages with physicians and staff
E. Request a prescription renewal
F. Have a virtual, online visit (eVisit) with a physician for common conditions

XII. HealthTrak and eVisit Growth
A. Over 50,000 registered users (patients)
B. 77 medical practices
C. 44 primary care
D. 23 specialty
E. 989 active physicians
F. 941 eVisits total in 2010
G. 100 mobility features
H. Data access
   I. Capturing vital signs
   J. Image capture
   K. Input into EMR
   L. Identification
   M. Single-Sign On (SSO)
   N. RFID user authentication and proximity
   O. Patient and medication identification using barcode
   P. Information delivery
   Q. Image (x-ray) review at bedside (PACS)
   R. Communication
   S. Care team collaboration (communication using VoIP)
   T. Mobile messaging
   U. CPOE
   V. Bedside device ordering and patient transport request
   W. Blood transfusion verification
   X. Mobile eRx and CPOE
   Y. Resource tracking
Z. Assets
AA. Patient

XIII. Future Opportunities
A. Patient mobile access
B. New eVisit content
C. Online payment
D. Text message alerts and reminders
E. Chat
F. Web calls
G. Images
H. Patient data capture
I. Biometrics
J. Education/informed consent
K. Cost data/cost estimaters
L. Lifestyle management

XIV. What Is Health Information Technology All About?
A. Access to information
B. Ubiquitous
C. Instantaneous
D. Unlimited
E. Reliable
F. Secure
G. Intuitive
H. Multimedia
I. Effortless

References
Key Issues to Consider When Choosing Your EMR

Michael V Boland MD PhD

Introduction

The move to electronic health records (EHRs) by U.S. ophthalmology practices has accelerated, largely due to incentive payments for adoption of EHRs provided by the Centers for Medicare and Medicaid Services. Given the complexity of this transition, it is important for practices to thoroughly prepare themselves both before and after the decision to convert to electronic records. History has shown that large information technology (IT) projects are at high risk of failure and that careful project planning is required to mitigate that risk.

Preparation

Before your practice can make a decision regarding an EHR, it is first necessary to take some time and evaluate the current state of your practice. This process should include writing down in some fashion all of the work that occurs in your practice:

■ What steps does a new patient take to get through a visit? (scheduling, registration, intake, testing, examination, education, surgical scheduling, etc.)
■ What steps does a return patient take to get through a visit?
■ How are telephone calls handled?

The process should also include collection of all of the documents (paper or electronic) you currently use to run the practice. The forms used to document your examinations are only the most obvious; make sure to include paperwork used to document procedures, order tests, result tests, schedule surgery, and so forth.

Your initial practice assessment should include a careful study of the roles played by all of the physicians and staff within your practice. One person may serve both as a technician and a scribe or handle both registration and billing, for example. This step is important to make sure that your new system can provide the appropriate access and security to accommodate users.

Also as part of your planning, make note of how ophthalmology practices are different than other specialties of medicine. The American Academy of Ophthalmology (Academy) Medical IT Committee has produced a list of these, and you can confirm that they apply to your practice.2

Don’t forget to include all of your ancillary testing as part of your evaluation. Whether or not you already have digital image management available in your practice, you will need to document which systems will need to be integrated. For newer devices, the best approach is to use the Digital Imaging and Communications in Medicine (DICOM) standard as the means of connecting your imaging and testing devices to your EHR. Through the work of the Academy, ophthalmology now has DICOM standards for our most common testing devices.3 This process can become complicated with older devices which may not be able to be networked to other systems or can only produce output in a proprietary format. Stop by the Integrating the Healthcare Enterprise (IHE) Electronic Office booth this week to see how device integration can work to improve your practice.

Once you have defined the current state of your practice, you should carefully review everything you found or produced in the steps above and take the opportunity to consider ways to upgrade or “fix” your practice. You may find inefficiencies you did not know about, think of better ways to accomplish some tasks, or delete some tasks altogether. After you are happy with your reconsidered practice, you can then move on to the process of looking for a vendor.

Vendor Selection

The most important comment to be made about vendor selection is that there is no vendor that is best for everyone. This is why it is essential that you understand your practice and then actively work with potential vendors to see which one(s) will best serve your needs.

After completing the evaluation of your practice, you can then create a document that specifies for your potential vendors what you need their system to do for you. This is generally referred to as a request for proposals (RFP). You can find an example of this document on the Academy’s EHR Central website (http://aao.org/ehr)4. Also on EHR Central, you can find additional resources for selecting a vendor:

■ The AAO EHR checklist: Which vendors provide features important to ophthalmology?
■ The AAO/AAOE EHR satisfaction survey
■ Online reviews from peers

Once you have identified candidate vendors, you can approach them with your RFP, ask them for a response, and begin your evaluation.

Technical Considerations

The selection of an EHR system for your practice clearly comes with the need to evaluate technical details. If you do not have someone in your practice capable of discussing these, consider hiring someone from outside who can help.

One issue that is increasingly important is to decide where your EHR will physically live. Traditionally, you had to set aside space somewhere in your practice for servers, backup equipment, and power supplies. Like much of the rest of the digital world, some vendors are offering the model of housing your servers and data for you (in the “cloud”). There are clear tradeoffs between these two approaches, including the convenience of not having to support your own EHR server hardware, the need to deploy redundant networks to reduce the risk of not being able to access your cloud-based system, the question of who “owns” your data, and so on. Again, there is no one correct answer for every practice.

Also important is whether you purchase a single system to provide all of your electronic needs (registration, scheduling, documentation, image management, and billing) or whether you end up with multiple systems to meet your needs. If, like most practices, you end up with multiple systems, you will need
to carefully consider how you will integrate them all. There are standards to help you, including the DICOM standard mentioned above and the Health Level 7 (HL7) standard that allows systems to communicate demographics and other administrative data between one another.

References


5. ONE® Network. Integrating EHR success with EHE Eyecare. (AAO Medical IT Resources). Available at: http://aao.org/mit
Should You Rebuild Your Office: The Ergonomics of Using an EMR

Donald L Budenz MD MPH

Introduction

The use of electronic medical records is rapidly transforming the way in which we interact with patients. Doctors’ biggest concern seems to be a slowing of work flow, causing reductions in the volume of patients seen, thus resulting in reduced revenue. Patients and doctors are concerned that there is less face-to-face interaction, resulting in degradation of the doctor-patient relationship. The purpose of this talk is to discuss the ergonomics of the environment in which we see patients and how that can minimize the negative imposed by the use of an EMR system.

I have no financial interest in the topic of this presentation, but I do have experience dating back 15 years using 4 different EMRs—2 Ophthalmology-specific and 2 that are used by multiple specialties—so I believe I am qualified to advise you based on my experiences. I also have experience with 2 different image storage systems, which are separate from the EMR but need to be considered.

Outside the Office

Most of us are used to reviewing a patient’s chart prior to seeing the patient. Typically, we grab the patient’s written medical record from a bin on or by the exam room door and leaf through it to remind ourselves of who the patient is and why they are there to see us. With EMR, it is very uncomfortable to walk into an exam room “cold” and have to bring up the patient’s electronic record in front of them to familiarize ourselves with their personal and medical situation. Many doctors develop friendly relationships with our patients, particularly glaucoma patients, whom we tend to see multiple times per year for their entire life. In fact, we may be the doctor that glaucoma patients see most frequently. For the patient, they have only one glaucoma doctor to keep track of, whereas we have hundreds of glaucoma patients. So we are at a disadvantage when it comes to refreshing our memories, both because of the number of patients we have to keep track of and now because we can’t leaf through the record outside the room.

That’s why I strongly recommend adding computer stations outside your exam rooms or nearby so that you can bring up the patient’s record for review before entering the room. If you cannot add computer viewing stations outside the room, then consider staying in the previous exam room and looking up the patient in the next room. Many EMRs (such as Epic) allow you to view which patient is in which room so you can just click on the next patient after you finish seeing the previous one.

Another extremely important issue to consider is printer location. We are required to provide an after-visit summary (AVS) for Meaningful Use metrics, and, while many patients have emails that they will let you send it to and many EMRs have a MyChart (Epic) function allowing patients to go into their own record and view the AVS, elderly patients in a glaucoma practice may prefer a printed AVS. In addition, while e-prescribing is supposed to be a paperless activity, my 4 years of experience with it suggests that printed prescriptions or confirmations of prescriptions are still frequently needed.

Alternate locations for printer locations include inside the exam room, outside the exam room in the hallway or nearby work area, or at the check-out desk. Practices that have placed printers inside every exam room have regretted it because printers need constant attention due to paper running out, paper jams, toner cartridges being empty, etc. There are just too many problems with printers to keep them maintained in every room for the occasional patient who needs something. A central printer that serves multiple exam lanes nearby or at the check-out desk seems to be better; however, we have had HIPAA issues when the front desk is used and a patient is given part or all of another patient’s AVS or e-prescription by overworked administrative staff who are trying to also schedule the next appointment and collect payment, etc. at check-out. So placing printers nearby exam rooms that serve multiple rooms may be the best option.

Doctor/staff work areas are another important feature to consider. If you are fortunate enough to have enough space for doctors’ offices right near your clinical space, then perhaps this isn’t as important, but others who do not have this luxury need somewhere to finish and sign notes. We have created shared desks for staff and doctors, each with computer stations. Just make sure everyone is aware they are “shared” since doctors can be very territorial about such things.

Inside the Office

In this age of smart phones, tablets, and laptops, it can be tempting to try to get away from desktop computers and monitors to save space and money. I strongly recommend against this, as the screens on such devices are not big enough and the devices are too easily stolen. I recommend a small but powerful CPU and at least two 24” monitors with moveable arms, mounted on the wall. The monitors need to be mounted in such a way that both you and the patient can see them at eye level. Otherwise, musculoskeletal strain in the doctor can result. The moveable arms are used because not all doctors are the same height and you need to be able to turn them so the patient can view the images. It can be extremely helpful to show patients’ their OCT or VF images as an educational tool. You’ll need two monitors because you will be running at least two programs, the EMR and the image storage program. Sure, you can get by with one monitor by minimizing and maximizing windows, but this will get old fast and takes time. You’ll want to walk into the room with the EMR opened on one monitor and the images on the other to improve efficiency and functionality.

The design of the room is essential in maintaining the doctor-patient interaction. You never want to have your back to the patient, but many of our exam lanes that are retrofitted for the EMR leave you doing just that. You will need wall space to mount the monitors on and under-counter space to sit the CPU in. The cords need to be long and flexible enough to reach you (seems simple but it must be planned), and the keyboard should be built in under the cabinet and retractable as well. Make sure the cabinetry is not so low that the keyboard holder is at your knees, though! We use a keyboard holder with a side table for the mouse, so you don’t need to have this on the cabinet table.
Final Note

Before changing or building your rooms, set up a prototype for doctors and staff to try. Important suggestions will come out of this exercise, and there will be things you haven’t thought of that others will. Plus, you will get better buy-in and fewer complaints once the project is completed.
How I Came to Believe That EMR Is Good for My Practice and Good for Patients: A Converted Skeptic

Jonathan S Myers MD

I. Early Fears and Concerns
A. Cost: Tens of thousands of dollars, minimum
B. Diversion of focus from medical care to technology hurdles
C. Time, pain, and effort of switch, with uncertain benefits
D. Daily fear of crashes and glitches interfering with office function and care of patients
E. Doctor talking to monitor, patient staring at back of doctor’s head
F. Slower, less efficient way to document exam
G. Garbage in, garbage out: Abuse of cut/paste/copy forward, creating meaningless records and audit or malpractice risk

II. Mid- and Long-term Experience
A. Cost: Significant. But offset in part by:
   1. Reduced transcription costs ($65,000 per year pre-EMR)
   2. Reduced staffing of chart room
   3. Meaningful Use bonus (for now . . . )
B. Diversion of focus from medical care
   1. This is a significant issue, but we came to the realization that better records are part of care.
      a. Increased legibility and greater understanding by others
      i. Critical for patient care
      ii. Critical for billing audits or malpractice cases
   b. No more lost charts
      i. Reduced manpower spent searching for charts
      ii. Immediate availability of charts when patients or colleagues call
      iii. Access to charts when on call/at home.
      End of refills of old prescriptions on evenings/weekends by on-call docs for patients who stopped coming years ago but just refill meds.
C. Time and pain vs. uncertain benefits
   1. The time and effort were real and significant, but are largely past.
   2. The benefits have become manifest and continue.
D. Fear of crashes and glitches: Generally overblown
   1. Rare downtime
   2. Switching back to paper for an hour every 3-9 months is not the end of the world in a nonemergency specialty. The surprising thing is that now staff dislike return to paper.
   3. If your EMR has downtime and glitches more than rarely, it must be fixed or ditched.
      a. Life is just too short.
      b. You wouldn’t commute to work in a car that left you on the side of the road on a regular basis.
E. Doctor talking to monitor, patient staring at back of doctor’s head
   1. This is a human issue, not just an EMR issue.
      People, once aware of the issue, can learn and adapt.
   2. Better ergonomics in room setup, simpler EMR charting facilitate change, as do awareness and reminders
F. Slower, less efficient way to document exam
   1. This has the potential to be a huge issue but not definitely worse overall.
      a. Every click takes time away from either your patients or your family. Many EMR companies do not understand this.
      b. Customization and adaptation of EMR to your needs is important.
   2. Reduced dictation is a big payback in time.
   3. Used with judgment, copying last exam (cut/paste or copy forward) saves time and effort on meaningless tasks (eg, documenting every time that there are 2 tube shunts and an IOL), allowing more effort to be put into more important impression/plan.
G. Abuse and liability of poorly used copy/paste
   1. A real concern
   2. However, if you trust yourself and your partners to use a knife in the OR, you probably should be able to educate them and trust them to use this appropriately.

III. Subsequent Benefits
A. Patient perceptions
   Computers are used for everything else. At this point, paper charts do not convey that your practice utilizes state-of-the-art technology. Would you keep...
your money in a bank that kept track of it on paper records?

B. Security

Fire and flood won’t destroy my records: Multiple, offsite backups. However, data encryption and Internet security are absolutely critical.

C. Coding compliance

1. Legible
2. Templates are updated to comply with directives and help encourage, or force, better documentation.⁵

D. Summarizing and tracking data

1. Track last VF, dilated exam, and remind me when out of expected range
2. IOP etc. may be graphed, tracked, etc.
3. Can search for study patients
4. Can search for patients failing to follow up, etc.

E. E-prescribing

1. Saves time for my techs
2. Allows better tracking of refills.

Some systems allow detailed viewing of patient refills, allowing identification of adherence issues.

F. Letters

1. Letters to physicians go out within 24 hours.
2. What is lost in the “personal touch” is gained in the timely receipt of valuable information.

G. Time savings for billing department:

Electronic charge entry is time neutral for doc, but then does not need re-entry (with risk of mistakes) by billing staff.

H. More direct and efficient communication in office:

“Tasks” and messages generated within EMR are quick to send and don’t get lost.

I. Ability to reduce effort for the repeated task (eg, postop or medication instructions), while still allowing individualization of care (postop instructions can be modified for the exception before printing for that patient).

IV. Choice of EMR

A. Not all EMRs are similar or equal.

1. The EMR that works for the LASIK or retina specialist may not work for a glaucoma specialist.
2. A field trip to see it work in a similar practice is invaluable.
3. Due diligence in researching purchase cannot be overemphasized.

B. EMR must match needs and orientation of individual doctor and practice.

1. Workflow must match practice, or practice must change to match EMR workflow.
2. Doctor must be committed to master EMR to determine suitability and find out how to make it work or what must be changed.

V. EMR Conversion Suggestions

A. Research vendor choice exhaustively. Go see it in a practice like yours.

B. Consider all the ramifications of the switch by involving staff of every type in your office to think about EMR’s impact on every task their job entails.

C. Test and train exhaustively before going live. Physicians especially need training and practice.

D. Reduce patient volume more than you think necessary for 1-4 weeks minimum.

E. Make sure vendor is fiscally viable, that long-term users think its support services are good, and that it is ready for every level of Meaningful Use requirements.

F. Make sure that the time savers are set up for your practice: automatic letter generation, patient instructions, e-prescribing defaults or shortcuts, etc.

G. Software vendor, hardware vendor, and local IT group must all be competent and experienced in your specific needs: Never be their “first.”

H. Keep a list in your pocket of things that need to be improved. Add to it daily; empower someone to work through it weekly.

I. Remember there is no perfect EMR. They all have strengths and weaknesses in clinical practice.

J. Remember EMR is a tool for health care, not an end in itself.

References


Medico-Legal Risks

Paul Lee MD JD

I. Legal Context in the United States
   A. U.S. and state constitutions
   B. Federal legislation and regulations
   C. State legislation and regulations
   D. Case law
      1. Precedents in case law
      2. Interpretation of legislation and regulations

II. Topics for Discussion
   A. Malpractice / tort
   B. Communications
   C. Office issues

III. Basics of Malpractice
   A. State by state rules and standards
      1. Traditionally, set by court decisions
      2. Increasingly, state legislative involvement
   B. Four essential elements
      1. Duty: Doctor-patient relationship
      2. Breach of standard of care (target pressure)
      3. Proximately causes (“but for”)
      4. Actionable damage to patient (vision loss)

IV. When Is a Duty Established?
   A. Advice over telephone, even if never seen
   B. Certainly, after a patient is seen
   C. Possibly, after an appointment has been scheduled

V. Breach of Duty Occurs When You Do Not Provide Adequate Care.
   A. Standard of care varies
      1. State case law
      2. Comprehensive vs. specialist
      3. Statutory and regulatory
   B. “Vicarious” liability – for your employees and staff

VI. Breach must “cause” an “injury” under the law.
   A. Loss of vision
   B. Economic damages
   C. Emotional trauma
   D. Pain or other suffering

VII. Procedural Steps
   A. Plaintiff’s attorney reviews records.
   B. Filing of notice of claim/claim
   C. Panel review or arbitration (if required)
   D. Discovery via documents and depositions
   E. Negotiations
   F. Trial
   G. Verdict
   H. Appeals

VIII. Closed Paid Claims (see Table 1)


<table>
<thead>
<tr>
<th>Stage of Claim</th>
<th>Percent</th>
<th>Mean $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presuit period</td>
<td>20</td>
<td>147 K</td>
</tr>
<tr>
<td>After arbitration</td>
<td>6</td>
<td>174 K</td>
</tr>
<tr>
<td>After suit</td>
<td>69</td>
<td>258 K</td>
</tr>
<tr>
<td>Pre-verdict trial</td>
<td>2</td>
<td>454 K</td>
</tr>
<tr>
<td>After trial verdict</td>
<td>2</td>
<td>Higher</td>
</tr>
</tbody>
</table>

IX. Ophthalmic Malpractice (Smith HE, Ophthalmology 1990.)
   A. Of cases in 1981, closed in 1994, eye MDs:
   B. 3% of total liability claims
   C. 33% of claims settled with payment
   D. 15% of ophthalmologists involved in claims

   A. Glaucoma constitutes 6% of eye claims.
   B. Leading allegations (* = also highest rates of paid claims)
      1. Improper performance*
      2. Errors in diagnosis*
      3. Failure to monitor*
      4. Improper treatment
      5. Highest average $
      6. Failure to supervise
Section V: How EMR and IT Advancements Are Changing Medicine

C. Cases with highest likelihood of closed claims with payment
   1. Steroid induced
   2. Angle closure
   3. Secondary glaucoma

XI. Claims Details (see Table 2)

Table 2. Ophthalmic Mutual Insurance Company (OMIC) and Physician Insurers Association of America (PIAA) Ophthalmology: Claims Over 17 years

<table>
<thead>
<tr>
<th></th>
<th>OMIC</th>
<th>PIAA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closed eye claims</td>
<td>1663</td>
<td>5556</td>
</tr>
<tr>
<td>Total paid claims</td>
<td>21%</td>
<td>29%</td>
</tr>
<tr>
<td>Avg. indemnity paid</td>
<td>$130,112</td>
<td>$164,905</td>
</tr>
<tr>
<td>Expenses paid</td>
<td>$37,667</td>
<td>$26,693</td>
</tr>
<tr>
<td>Avg. exp w/o indemnity paid</td>
<td>$11,329</td>
<td>$11,884</td>
</tr>
</tbody>
</table>

XII. Principal Allegation: Glaucoma Malpractice Claims (Courtesy of OMIC, 2011)
   A. Surgical misadventure: 24%
   B. Failure to diagnosis: 17%
   C. Improper medical management: 13%
   D. Medication errors: 7%
   E. Surgery not warranted: 7%
   F. Failure/delay in consultation: 5%
   G. Surgery not performed: 4%
   H. Failure to instruct/communicate: 3%

XIII. Associated Allegations: Glaucoma Malpractice Claims
   A. Problem with records/billing: 23%
   B. Consent issues/breach of contract: 12%
   C. Vicarious liability: 11%
   D. Poor compliance: 5%
   E. Lack of equipment or malfunction: 4%
   F. Abandonment: 3%

XIV. Keys to Avoiding Malpractice Liability
   A. Adequate quality care
   B. Communications
   C. Documentation

XV. Keys in Communications
   A. Don’t assume; ask.
   B. Listen and pay attention.
   C. Acknowledge.
   D. Understand lack of comprehension.

XVI. Communicating Bad Outcomes
   A. Maloccurrence is not the same as malpractice.
   B. Prior informed consent and education
   C. Honest communications of situation
      1. Disclose complications
      2. Apology movement gaining momentum
   D. See the patient as often as needed.
   E. Communicate with partners on call.
   F. Second opinion / referral
   G. Careful comanagement

XVII. Office Issues
   A. Safety around office: falls, parking lot, OHSA
   B. Patient abandonment – system for documentation of contacts
   C. Failure to follow-up, especially after surgery
   D. Reusing single-use instruments
   E. Billing compliance / whistleblower lawsuits
   F. HR issues

XVIII. Summary / Conclusions
   A. Malpractice claims in ophthalmology are relatively uncommon among all medical specialties.
      1. Compounded by documentation / billing issues
      2. Less than a third are closed with payment.
      3. Paid claims are settled prior to trial verdict (>90%).
   B. Avoid claims by communications with patient and family members.
   C. Be aware of general office / business issues.

Additional Information Regarding Documentation

XIX. Informed Consent: How Much to Discuss?
   A. Varies by state. Most use “reasonable person” standard (no longer “typical MD”).
      1. More common than 1/1000
      2. Serious (life, disability, stroke)
      3. More information with elective and cosmetic procedures
   B. New, minority rule is “specific patient.”

XX. Elements of Typical Discussion
   A. Diagnosis
   B. Indication
   C. Nature of treatment
   D. Benefits
   E. Probability of success
F. Risks
G. Alternatives
H. Consequences of doing nothing

XXI. How Does Consent Get Documented?
A. Usually in writing, usually via a form
B. Usually inclusive and complete, but general
C. Usually includes use of assistants and explicit consent to other procedures if needed
D. Patients retain only 5% to 35% of what they are told in typical interaction.

XXII. “It wasn’t done if it wasn’t documented …”
A. Note all phone calls.
B. Who and what at a minimum.
C. And office response
D. And file in patient’s chart
E. Record all phone calls regarding lab results and advice in chart.

XXIII. Documenting “No-Shows”
A. Document “no show” and follow-up phone call or letter.
B. If serious condition or multiple no-shows, send return receipt / registered letter and file in chart.
C. Withdrawal if continued noncompliance or if circumstances warrant

XXIV. Documenting Billing and Non-Care Related Disputes
A. Do not put billing / financial or any nonclinical care disputes in medical chart.
B. When patients are angry or hostile, document what happened without judgmental or emotional terms. (Eg, use “appeared angry, shouted at staff” instead of “stupid.”)
2014 Advocating for Patients

Thomas A Graul MD

Ophthalmology’s goal in protecting quality patient eye care remains a key priority for the American Academy of Ophthalmology (the Academy). All Eye M.D.s should consider their contributions to the following three funds as (a) part of their costs of doing business and (b) their individual responsibility in advocating for patients:

- Surgical Scope Fund (SSF)
- OPHTHPAC® Fund
- State Eye PAC

Your Eye M.D. colleagues serving on the Academy’s Secretariat for State Affairs commit many hours on your behalf while strategizing and collaborating with state ophthalmology society leaders to ensure the success of Surgery by Surgeons. Their ultimate goal—protecting quality patient eye care in the states—requires a robust Surgical Scope Fund, and we need every single Eye M.D. to step up to the plate and deliver with their checkbooks.

The Academy’s federal advocacy arm works to protect ophthalmology practices from payment cuts, burdensome regulations, and scope of practice threats, as well as to advance the profession by promoting funding for vision research and expanded inclusion of ophthalmology in public and private programs. It is critical for our OPHTHPAC Fund to also be strong.

Surgical Scope Fund

The Surgical Scope Fund (SSF) provides grants to state ophthalmology societies to support their legislative, regulatory and public education efforts. Since its inception, the Surgery by Surgeons campaign, in partnership with state ophthalmology societies and with support from the SSF, has helped 31 state/territorial ophthalmology societies reject optometric surgery proposals.

2014 has proved to be a challenging year, with several battleground states facing major optometric surgery initiatives. A number of state ophthalmic societies benefited from SSF disbursements and were able to successfully implement patient safety advocacy campaigns to defeat attempts by optometry to expand its scope of practice to include surgery. The Nebraska Academy of Eye Physicians and Surgeons was successful in its patient advocacy and public education efforts to derail legislation that would have granted optometrists the authority to perform eyelid surgery and injections. Additionally, the Arizona Ophthalmological Society succeeded in protecting patients by stopping legislation that would have allowed optometrists to gain authority to perform injections. The SSF is also at work assisting ophthalmic societies with their efforts to protect patients in California, Delaware and Massachusetts.

Proactively, the Georgia Society of Ophthalmology introduced a bill that would establish a formal definition of “surgery” into state law. While the legislative session expired before the bill could advance, Georgia ophthalmologists will be back in 2015 in an effort to pass this important safeguard for their patients.

2014 was certainly not without its challenges. Despite a vigorous battle for patient safety on the part of the Tennessee Academy of Ophthalmology, the Tennessee Medical Association and the Academy, the legislature passed a bill allowing optometrists to inject anesthesia into the eyelids. Previously, optometrists were authorized to perform only therapeutic injections and any surgical procedure that required no more than a topical anesthetic. And in Louisiana, the Academy, the Louisiana Ophthalmology Association, and the Louisiana State Medical Society vigorously opposed legislation that would authorize optometrists to perform certain scalpel and laser surgeries and injections. On June 1, 2014, Louisiana Governor Bobby Jindal signed into law a laser surgery bill that will allow optometrists to perform scanning laser trabeculoplasty and argon laser trabeculoplasty glaucoma surgery procedures, as well as YAG capsulotomy surgery procedures, with the completion of as little as 32 hours coursework. The Academy’s Secretariat for State Affairs knows from past experience that with this success in Louisiana, organized optometry will push hard in 2015 to see if they can gain additional surgery states. This is why everyone must “advocate for patients,” engage in the state political process, and aggressively support the SSF.

California, Delaware, and Massachusetts remain “in play” and are still faced with active O.D. surgery legislation. When it comes to state legislation of any kind, California and Massachusetts are often considered bellwether states for the rest of the nation. Now more than ever, your contribution to the SSF is needed as a critical tool of the Surgery by Surgeons campaign to protect quality surgical care for our patients. The Academy relies not only on the financial contributions to the SSF from individual Eye M.D.s and their business practices, but also on the contributions made by ophthalmic state, subspecialty and specialized interest societies. The American Glaucoma Society (AGS) contributed to the Surgical Scope Fund in 2013, and the Academy counts on its contributions in 2014.

OPHTHPAC® Fund

OPHTHPAC is a crucial part of the Academy’s strategy to protect and advance ophthalmology’s interests in key areas, including physician payments from Medicare as well as protecting ophthalmology from federal scope-of-practice threats. Established in 1985, today OPHTHPAC is one of the largest and most successful political action committees in the physician community. In the past, Politico highlighted OPHTHPAC as one of the most successful health PACs in strategic giving. By making strategic election campaign contributions and independent expenditures, OPHTHPAC helps us elect friends of ophthalmology to federal leadership positions, ultimately resulting in beneficial outcomes for all Eye M.D.s. For example, in the 2012 election cycle, OPHTHPAC was able to help retain 20 physicians in Congress. Among the significant impacts of OPHTHPAC are the following:

- Prevented onerous national patient prescription requirements for compounded drugs and preserved access to most ophthalmic compounded drugs for office use
- Averted significant cuts to Medicare payments due to the Sustainable Growth Rate (SGR) formula
Protected practice expense increases for ophthalmology when other specialties sought legislative carve-outs

Protected ophthalmologists’ ability to provide in-office diagnostic testing without triggering self-referral violation

Prompted congressional action that helped reduce ophthalmology’s multiple procedure payment reduction

Secured appointment of full-time ophthalmology national program director in the U.S. Department of Veterans Affairs

Provided further exemptions from both the Electronic Prescribing and Meaningful Use EHR penalties

Leaders of the AGS are part of the Academy’s Ophthalmic Advocacy Leadership Group (OALG), which has met for the past seven years in January in the Washington, D.C., area to provide critical input and to discuss and collaborate on the Academy’s advocacy agenda. The topics discussed at the 2014 OALG meeting included a focus on the collaboration needed among the Academy and its OALG partners on the issue of compounding. As a 2014 Congressional Advocacy Day (CAD) partner, the AGS ensured a strong presence of glaucoma specialists to support ophthalmology’s priorities as nearly 400 Eye M.D.s had scheduled CAD visits to members of Congress in conjunction with the Academy’s 2014 Mid-Year Forum in Washington, D.C. The AGS remains a crucial partner with the Academy in its ongoing federal and state advocacy initiatives.

State Eye PAC

We all must also support our respective State Eye PACs, because state ophthalmology societies cannot count on the Academy’s SSF alone. The presence of a strong State Eye PAC providing financial support for campaign contributions and legislative education to elect ophthalmology-friendly candidates to the state legislature is also critical. The Secretariat for State Affairs strategizes with state ophthalmology societies on target goals for state eye PAC levels.

ACTION REQUESTED: Advocate for your patients!!

Academy Surgical Scope Fund contributions are used to support the infrastructure necessary in state legislative / regulatory battles and for public education. PAC contributions are necessary at the state and federal level to help elect officials who will support the interests of our patients. Contributions to each of these three funds are necessary and should be considered the costs of doing business. Surgical Scope Fund contributions are completely confidential and may be made with corporate checks or credit cards, unlike PAC contributions, which must be made by individuals and are subject to reporting requirements.

Please respond to your Academy colleagues who are volunteering their time on your behalf to serve on the OPHTHPAC* and Surgical Scope Fund** Committees, as well as your state ophthalmology society leaders, when they call on you and your subspecialty society to contribute. Advocate for your patients now!

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Microinvasive Glaucoma Surgery Is a Routine Part of My Practice Because . . .
Incorporating MIGS Into Your Practice

Richard A Lewis MD

I. Microinvasive Glaucoma Surgery (MIGS): Here to Stay
   A. Impact of iStent (Glaukos) since launch in 2012
   B. Understand the strength and limitations of each MIGS procedure
   C. Role of cataract surgery alone in glaucoma

II. Incorporating MIGS Into Your Practice
   A. Optimal patients to implant and those to avoid with MIGS procedures
   B. Gonioscopy: Practice, practice, practice – in office and in OR
   C. Prepare the OR staff and obtain necessary equipment
   D. Initial procedures will take longer; there is a learning curve!
   E. Postoperative care

III. MIGS: Where Are We Going With MIGS, and Its Impact On Glaucoma

IV. Summary
I Have Not Started Using Microinvasive Glaucoma Surgery Because . . .

Harry A Quigley MD

In deciding whether to utilize a new procedure for the glaucoma patient, we should consider a group of attributes that would recommend it over present practice. Chief among these features would be that a new procedure should be more effective, applicable to many surgical candidates, safer, more acceptable to the patient, rapid to learn, easy to perform, of lower cost to surgeon and care system, and without disadvantage to subsequent surgery.

While there are debates over what features constitute “MIGS” surgery, I will discuss endocyclophotocoagulation (ECP), canaloplasty, iStent, and Trabectome. Some of these procedures are being utilized in dramatically greater numbers, with ECP surpassing all but trabeculectomy by 2009 in Medicare data to be the second most frequently performed glaucoma operation.1 Others are under investigation, but until they can be done by the majority of those in glaucoma practice, their assessment should wait.

In 1 of 2 meta-analyses on newer glaucoma surgeries, written by academic authors with no financial associations to particular techniques,2,3 Budenz and Gedde conclude: “Studies evaluating these new glaucoma procedures combined with phacoemulsification generally include retrospective case series without a comparison group. Because cataract surgery alone is associated with IOP reduction,[4] the relative contribution of the glaucoma procedure in lowering IOP cannot be determined in these studies. Randomized clinical trials are needed to better evaluate the efficacy and safety of newer glaucoma procedures in combination with cataract surgery. . . . The newer glaucoma procedures appear less effective than trabeculectomy, but they are associated with a lower risk of surgical complications.”3

I would add to their assessment that laser trabeculoplasty and eye drop treatment are alternatives to trabeculectomy that also have lower risk, and in fact, based on the Advanced Glaucoma Intervention Study and Collaborative Initial Glaucoma Treatment Study controlled clinical trials, both of these are equally effective in lowering IOP and maintaining visual field status compared to trabeculectomy. Despite the fact that ECP has been used for 20 years and the Trabectome for over 10 years, their effectiveness and that of the newer approved iStent have never been subjected to a controlled clinical trial against trabeculectomy (in the absence of concurrent IOL surgery). Canaloplasty has never undergone a randomized, controlled trial of any kind. These facts alone should raise questions in the mind of every ophthalmologist as to whether the procedures are justified.

As to effectiveness, IOP lowering is the only outcome ever utilized for these procedures. Since many of the studies compare the new procedure combined with phacoemulsification to phaco alone, it is difficult to determine what the actual effectiveness is. Certainly, nearly all published studies of any procedure will show IOP lowering, otherwise they would not be published. The original iStent 1-year result at least showed promise that the device would produce more lowering combined with IOL surgery than the IOL surgery alone. Unfortunately, the additional effect seems to have waned at 2 years,5 with less than a 1-mmHg difference and no difference in needed eye drops. Since none of the other procedures has ever been tested in a randomized, controlled trial, their effectiveness is essentially unknown. Furthermore, inspection of the final IOP in nearly every study of these procedures finds that none is as low as 15 mmHg and in many it is greater than 17 mmHg. The target IOP for many glaucoma patients is therefore lower than likely to be achieved by these newer operations, especially by comparison with trabeculectomy or tube-shunt surgery. One group experienced with Trabectome, for example, concluded: “This surgery is appropriate for patients requiring a target IOP of 21 mmHg or above.”6 In my clinical experience, this would be a small proportion of all my glaucoma patients. In fact, in a review of over 700 surgical operations at Wilmer from 2002 to 2009, none had a target IOP as high as 21 mmHg.

As to relative safety, certainly iStent seems least likely to have significant complications, while late effects such as hypotony and infection are clearly infrequent or nonexistent with the other 3 procedures. If they were demonstrated to be effective as free-standing procedures independent of phacoemulsification, this would be a significant advantage.

Acceptability to the patient would be an advantage of any procedure that was effective and had better outcomes and fewer side effects. But even the medium-term outcomes of these procedures have not been assessed. If the IOP is not lowered sufficiently, the need for subsequent trabeculectomy or tube shunt surgery will give the impression to the patient that inadequate surgery was done before the definitive operation.

These newer procedures require substantial new surgical skills for the surgeon who attempts them. Some are done in a new patient position through gonioscopy, while ECP is performed by viewing in 2 dimensions on a TV screen instead of directly through the microscope stereoscopically. Experienced surgeons admit that there is a need to perform dozens of procedures before the outcomes will achieve their optimal result with minimal complication.

The cost of the procedures is worth consideration. Let’s take as example the cost to fee-for-service Medicare of all reimbursement for each procedure listed in 2009.1 While ECP had a relatively low reimbursement ($467), it has the highest cost for the equipment needed for the physician / surgicenter / hospital. Trabeculectomy reimbursement was $1256, canaloplasty = $1789, tube shunt including scleral graft = $2467, and iStent is estimated to be $2500 in addition to the 50% reduced reimbursement for phaco performed with it. As we move to newer models of care (accountable care organizations), it will increasingly be important for physicians to take account of the cost-benefit ratio of procedures.

Newer procedures hopefully do not reduce the later opportunity to do more surgery. This is clearly an advantage of the iStent, Trabectome, and ECP. Canaloplasty, on the other hand, utilizes conjunctiva and a site that would otherwise be available for filtering or tube surgery.

Since I practice in a large, academic Glaucoma Center of Excellence, our choice has been to both evaluate new procedures before their FDA approval as part of sponsored research and to evaluate our own experience and the specific usefulness of any
new procedure. We have participated in research or carried out a large number of procedures with 3 of the 4 surgeries discussed here. The approach we have taken is to have one surgeon train and carry out all procedures for something new. In this way, we avoid multiple learning curves and can maximize the chance that patients benefit. By continuously evaluating which procedure is potentially advantageous for each patient, we hope to add to both our knowledge and the literature on surgery.

As a surgical innovator, I have participated in early studies of laser iridotomy, trabeculectomy, laser angle treatment outcomes, and YAG laser capsulotomy complications as each of these entered our field. We should encourage new approaches and actively assist in their evaluation. But peer-reviewed, controlled observations should dictate our behavior, not marketing hype. It is far easier to claim a potential advantage of something new than to prove its value.

**References and Selected Readings**


So You’ve Decided to Introduce Microinvasive Glaucoma Surgery—How Do You Talk to Your First Patient About It?

George L Spaeth MD

What do you say to a person you hope will allow you to do a MIGS?

I. Basic Principles
   A. Autonomy
   B. Beneficence/nonmaleficence
   C. Justice

II. Regarding Autonomy
   A. Patient decides on the basis of what the patient wants to know.
   B. You may think and patients may think that they are making the decision.
   C. But your recommendations will rarely be challenged.
   D. So you are making the decision.

III. Regarding Beneficence/Nonmaleficence
   A. “First, do no harm”
      1. An unwise primary guiding principle
      2. Every treatment always involves some harm.
   B. Better: Do that which benefits more than harms.

IV. Regarding Justice
   A. Are costs justified?
      1. Resources are limited.
      2. Health/disease care as presently practiced cannot be sustained.
      3. There must be reductions in cost.
   B. There is a need to improve quality of care.
      This requires research, and that requires costs and risks. These costs and risks may be justified.
   C. Quality of care in a research trial is never optimal because it is never personalized.
   D. A lie is an attempt to deceive.
   E. It is wrong to lie to patients. Lying totally removes patients’ ability and right to make informed decisions.
   F. The most powerful type of lie is a truth used to deceive.
   G. Truthful lies
      1. “New surgeries work better than older ones.”
      2. “This procedure has fewer side effects than that one.”

H. Improperly leading words / phrases
   1. Expected to . . .
   2. Safe
   3. Proven
   4. Widely accepted
   5. Less invasive
   I. These are all lies.

J. Proper words to use
   1. “We hope . . .” instead of “We expect . . .”
   2. “Margin of safety (risk / benefit ratio)” instead of “safe”
   3. “Studied” instead of “proven”
   4. “Some surgeons recommend (others do not)” instead of “widely accepted”
   5. “Less invasive, but less effective in lowering pressure” instead of only “less invasive”

K. We are all seducible.
   1. The more we love something, the more easily do we become biased in its favor.
   2. Those who are most passionate about wanting a better glaucoma procedure are the ones who most need to be distrusted.

L. Those who are most passionate about wanting a better glaucoma procedure are the ones who most need to be distrusted because they have the greatest propensity to be biased. Those who believe they are unbiased are the most dangerous of all, because they have proven that they lack insight.

V. So, what to say?
   A. Do not say . . . “I’m going to recommend a (__________) because it is newer and reduces side effects.”
      1. It is true. But it “forces” the patient into choosing your decision.
      2. That is a leading lie.
B. Do say:

1. “I’m going to recommend a (____) because for you my opinion is that the balance of risk and benefits favor this. The procedure is still under development. If it works as well as we hope, it will benefit not only you but others as well. You must understand that the long-term effects are not known, although we do know that (____) worked well in most people like you.”

2. “We will ask you to do some things that are not routine for patients having glaucoma surgery. For example, we will want you to have some extra visits, and perhaps some extra tests, so that we can develop information that will allow us to decide just how well this procedure does or does not work.”

C. If you are disappointed because the patient chooses not to have the MIGS, you know you are improperly biased.

D. We have an ethical responsibility to develop better treatments.

1. But not for our benefit
2. The procedure is for the benefit of the patient.
How the FDA Evaluates New Surgical Technologies

Malvina Eydelman MD

All medical devices are regulated via a risk-based paradigm, which gives the FDA the flexibility to calibrate its regulatory approach to the level of potential risk posed by new products. This risk-based paradigm is implemented through a device classification system. Class I categorization is used for simple, low-risk devices that are generally exempt from any application to the FDA prior to marketing in the United States. Class II devices are typically more complex, with greater potential risk than Class I devices. Most Class II devices require the submission and clearance of a premarket notification (510(k)) before being introduced into the U.S. market. Finally, Class III devices are those considered to have the greatest potential risk, thus requiring submission and approval of a premarket approval application (PMA) prior to marketing in the United States.

When evaluating devices, the FDA considers both safety and effectiveness for the intended population with regard to disease severity and prior therapy, as well as the proposed conditions for use (eg, implantation of proposed device with or without concomitant cataract surgery) that will impact the final approved labeling. For Class III devices, the FDA carefully evaluates the benefit/risk profile and the reliability of these devices in making regulatory decisions and may require postmarket studies to obtain additional confirmatory data regarding device-specific questions.

Therapeutic glaucoma devices are categorized as either Class II or Class III. An implantable glaucoma device is considered Class II if it meets the definition identified in 21 Code of Federal Regulations (CFR) 886.3920, Aqueous Shunt, which states, “An aqueous shunt is an implantable device intended to reduce intraocular pressure in the anterior chamber of the eye in patients with neovascular glaucoma or with glaucoma when medical and conventional surgical treatments have failed.” Implantable glaucoma devices, which are intended to treat patients who do not meet this definition, are regulated as Class III.

To evaluate medical devices, the Center for Devices and Radiological Health (CDRH) employs an extensive internal cadre of scientific expertise, via our scientists, engineers, and clinicians. Despite these internal resources, CDRH staff expertise cannot encompass all of the applicable knowledge and experience necessary to fulfill our mission, given the rapidly growing variety and complexity of medical devices. This is particularly true when it comes to new and rapidly emerging fields of science and pioneering technologies, such as that seen in the development of glaucoma devices. In these areas, it is often necessary for our experts to obtain further scientific understanding from external sources.

CDRH scientists, clinicians, and engineers often supplement their knowledge base by reading scientific literature and attending conferences, holding public workshops with experts, reaching out to other federally employed scientists, convening advisory panel meetings with special government employees (SGEs), or utilizing the newly formed Network of Experts. Partnership with external clinical experts in academia, research, and in community practice allows CDRH to achieve our vision of providing patients in the United States with access to high-quality, safe, and effective medical devices first in the world.

References

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5. CDRH network of experts. FDA website. Updated Aug. 12, 2014. Available at: www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/ucm289534.htm
Pipes in the Pipeline: Current Clinical Trials of Microinvasive Glaucoma Surgery

Angelo P Tanna MD

It is clear that IOP reduction meaningfully slows the progression of glaucomatous vision loss. Medical and laser therapy are ineffective or insufficient in a substantial proportion of patients with glaucoma, necessitating incisional surgical intervention. Trabeculectomy, though very effective in lowering IOP, is associated with a high risk of sight-threatening complications and a high risk of failure at 5 years after surgery. Tube shunt surgery is increasingly being favored over trabeculectomy and is even being investigated as a first-line surgical intervention. Recent clinical trials of tube shunt surgery, which primarily recruit patients at high risk of surgical complications and failure, have disclosed a low 5-year unqualified success rate and a high risk of serious postoperative complications.

In our continued quest for improved surgical procedures to safely lower IOP in eyes with glaucoma, the focus has been on 3 different strategies: (1) the use of devices to bypass the trabecular meshwork, diverting aqueous directly to the Schlemm canal, (2) the use of devices to shunt aqueous to the suprachoroidal space, and (3) the use of short tubes to shunt aqueous to the subconjunctival space.

In this presentation we will critically review the available information on the following novel devices that are in various stages of clinical investigation in the United States.

I. Intracanalicular Shunt: Schlemm Canal Scaffold

Hydrus Microstent

The so-called intracanalicular scaffold (Ivantis, Inc.; Irvine, Calif.) is an 8-mm long device made of a highly elastic biocompatible material called Nitinol, which has already been used in other implantable medical devices. The scaffold is placed inside the Schlemm canal during cataract surgery.

II. Suprachoroidal Shunts

A. CyPass Micro-Stent (Transcend Medical, Inc.; Menlo Park, Calif.)

The CyPass is a supraciliary tube designed to create a controlled outflow from the anterior chamber to the suprachoroidal space. It is made from polyamide and has a length of 6.35 mm and a diameter (largest) of 0.51 mm. Currently, the device is for investigational use only, and 3 clinical trials are registered.

B. SOLX Gold Microshunt (SOLX, Inc.; Waltham, Mass.)

C. Glaukos iStent Supra shunt (Glaukos Corporation; Laguna Hills, Calif.)

III. Shunts to Subconjunctival Space

A. AqueSys XEN Gel Stent (AqueSys, Inc.; Aliso Viejo, Calif.)

B. InnFocus Microshunt (originally called the MIDI Arrow; InnFocus, Inc.; Miami, Fla.)
<table>
<thead>
<tr>
<th>Study Id</th>
<th>Status</th>
<th>Study Title</th>
<th>Condition(s)</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Completed</td>
<td>A Dose Evaluation Study of the Effect of Plug Placement on the Efficacy and Safety of the Latanoprost Punctal Plug Delivery System (L-PPDS) in Subjects With Ocular Hypertension or Open-Angle Glaucoma</td>
<td>Glaucoma; ocular hypertension (OH)</td>
<td>Drug: Latanoprost-PPDS</td>
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<tr>
<td>2</td>
<td>Recruiting</td>
<td>Multicenter Study Using Glaukos® Trabecular Micro-Bypass Stent Model GTS400 Using the G2-M-IS Injector System in Conjunction With Cataract Surgery</td>
<td>Primary open-angle glaucoma</td>
<td>Device: iStent inject; Procedure: cataract surgery</td>
</tr>
<tr>
<td>3</td>
<td>Recruiting</td>
<td>InnFocus MicroShunt Versus Trabeculectomy Study</td>
<td>Primary open-angle glaucoma</td>
<td>Procedure: Glaucoma Surgery; device: InnFocus Micro-Shunt</td>
</tr>
<tr>
<td>4</td>
<td>Recruiting</td>
<td>AqueSys XEN 45 Glaucoma Implant in Refractory Glaucoma</td>
<td>Glaucoma; Glaucoma, open angle</td>
<td>Device: AqueSys XEN 45 Glaucoma implant</td>
</tr>
<tr>
<td>5</td>
<td>Active, not recruiting</td>
<td>SOLX Gold Shunt for Refractory Glaucoma</td>
<td>Glaucoma; Glaucoma, open angle</td>
<td>Device: SOLX Gold Shunt</td>
</tr>
<tr>
<td>6</td>
<td>Recruiting</td>
<td>Multicenter Investigation of the Glaukos® Suprachoroidal Stent Model G3 In Conjunction With Cataract Surgery</td>
<td>Primary open-angle glaucoma</td>
<td>Device: iStent supra; Procedure: cataract surgery</td>
</tr>
<tr>
<td>7</td>
<td>Active, not recruiting</td>
<td>AqueSys Microfistula Implant in Refractory Glaucoma</td>
<td>Glaucoma; Glaucoma, open-angle</td>
<td>Device: AqueSys Microfistula implant</td>
</tr>
<tr>
<td>8</td>
<td>Recruiting</td>
<td>Subjects With Open-angle Glaucoma, Pseudoexfoliative Glaucoma, or Ocular Hypertension Naïve to Medical and Surgical Therapy, Treated With Two Trabecular Micro-bypass Stents (iStent Inject) or Travoprost</td>
<td>Open-angle glaucoma</td>
<td>Device: iStent inject; Drug: travoprost</td>
</tr>
<tr>
<td>9</td>
<td>Recruiting</td>
<td>Open-Angle Glaucoma Subjects With One Prior Trabeculectomy Treated Concurrently With One Suprachoroidal Stent and Two Trabecular Micro-bypass Stents</td>
<td>Open-angle glaucoma</td>
<td>Device: iStent and iStent Supra</td>
</tr>
</tbody>
</table>
How I Use Microinvasive Glaucoma Surgery in My Practice

Thomas W Samuelson MD

The surgical management of glaucoma is varied and highly individualized to specific patients and surgeons. As the title of my assigned topic implies, the following discussion reflects my personal approach to glaucoma surgery and not the correct or definitive approach.

My glaucoma surgical practice has evolved considerably over the past two decades. In the 1990s, combined phacoemulsification and trabeculectomy was my most common surgical procedure. In that era, cataracts were removed from a scleral approach and combining both procedures seemed highly synergetic. Two developments changed my approach rather dramatically: the advent of clear corneal cataract surgery and the realization that cataract surgery itself has a favorable effect on IOP for many patients with ocular hypertension or early to moderate glaucoma.1-3 Accordingly, cataract surgery and filtration surgery were decoupled in favor of phacoemulsification alone for most individuals with early to moderate glaucoma.

Microinvasive glaucoma surgery (MIGS) has produced yet another major change in my strategy for managing glaucoma in phakic eyes, resulting in a resurgence of combined cataract and glaucoma surgery. However, unlike combined surgery of the past, contemporary combined cataract and glaucoma surgery is much more individualized, the risk of the procedure closely matched to the severity of the disease and the risk of functional impairment to the patient. While several procedures might be included in an inclusive MIGS definition, my preferred MIGS procedure involves placing a stenting device within the Schlemm canal via an ab-interno approach. In the United States, the only approved such device is the iStent,4,5 although the Ivantis canal via an ab-interno approach. In the United States, the procedure involves placing a stenting device within the Schlemm canal. Some surgeons prefer and include in an inclusive MIGS definition, these patients have altered outflow systems, and several late complications can become problematic years later with a late bleb leak, hypotony, or worse, bleb-related endophthalmitis. Perhaps no statistic bears this out more poignantly than the “return to operating room to manage complications” data in the landmark Trabeculectomy vs. Tube Shunt Trial (TVT). The reoperation rate for complications at 1, 3, and 5 years respectively was 5%, 9%, and 18% for trabeculectomy and 7%, 14%, and 22% for tube surgery.6-8 Few other surgical procedures generate complications years following the original intervention. Further, these late complications are directly attributable to the surgery itself rather than the disease process.

I then explain that the second option (phacoemulsification + iStent) will not lower IOP to the same degree and may require the use of 1 or 2 medications postoperatively but has a much quicker and more predictable visual recovery and far fewer potential complications. I explain further that a more definitive glaucoma surgery may be required in the future in the event that the IOP remains too high, but future surgery is not compromised by the previous MIGS procedure. Despite a neutral presentation of the options by me, most of the time the patient chooses the procedure with less risk.

Postop Care: Not Business as Usual

While the surgical outcomes with MIGS procedures are far less dependent on postoperative decisions or timely interventions (suture lysis, etc.) than is filtration surgery, careful proper postoperative surveillance is mandatory. Patients eligible for iStent and other microinvasive procedures are at significant risk for an IOP spike following cataract surgery, for several reasons. By definition, these patients have altered outflow systems, and several perioperative “stressors” can trigger a transient IOP spike. Candidates for MIGS procedures have a higher chance of being steroid responders than do nonglaucoma patients. Retained viscoelastic material, inflammation, or pigment release inherent to cataract surgery can also cause increased IOP in a compromised patient. Finally, although a significant hyphema is rare with iStent, placement of any device within the Schlemm canal can result in reflux of red blood cells, which can further compromise outflow.

For all these reasons, it is important to monitor the IOP carefully following surgery and to take preventive steps, some of which are outlined below. In my experience, the percentage of patients who have dangerous pressure spikes is low, assuming these precautions are taken.
Preventive Measures for Postoperative IOP Elevation Following Phacoemulsification With Trabecular-Microbypass

Several steps can be taken to help minimize IOP spikes. Perhaps most importantly, all of the viscoelastic material should be evacuated from the anterior chamber and from the capsular bag. I prefer to use a long-acting miotic agent such as carbachol at the end of the case after the cataract has been removed, the IOL and the iStent have been placed, and all ophthalmic viscosurgical device (OVD) has been removed. If a miotic agent is used prior to placing the iStent, care should be taken to remove viscoelastic from behind the IOL and from the retropupillary space prior to instilling the miotic as complete evacuation of OVD from the capsular bag is more difficult once the pupil has been constricted. Suffice it to say that patients with glaucoma in general and patients receiving MIGS procedures in particular should have thorough evacuation of all viscoelastic material following completion of the case. Adequate OVD removal is the most important step to mitigate IOP spikes. Later in the postoperative period, steroid response becomes an important contributing factor to increased IOP, and anticipation of a steroid response with subsequent, timely withdrawal of steroid is critical.

Managing Postoperative IOP Elevation Following iStent Surgery

While these preventive measures reduce significant IOP spikes following MIGS surgery, it is not uncommon to encounter elevated IOP early in the postoperative period. When faced with increased pressure following MIGS surgery, I generally tap the paracentesis if the IOP is in the upper thirties or higher and treat medically for a more modest rise in IOP. I tell patients that it will take 6-8 weeks to determine the new baseline IOP and that adding a medication in the early postoperative period does not mean that they will need the medication chronically. Quite often, the IOP is lower once all inflammation has resolved, all OVD has left the eye, and the patient is off steroid. One or more medications may be needed to get through the first 6 weeks but might be subsequently discontinued 6 or 8 weeks postop. As mentioned, a common cause of high pressure is steroid response, especially during the second or third postoperative week. I generally use a more rapid steroid taper when using canal stenting devices, for example 4 times daily prednisolone acetate for 1 week, twice daily for 1 week, then discontinue. I generally continue the nonsteroidal anti-inflammatory for the first postoperative month. Again, it is not until the viscoelastic is completely gone from the eye, all inflammation has resolved, and the patient is off topical steroid that the new postoperative IOP baseline can be determined.

Definition of “Success” in Glaucoma Surgery

Traditionally, “surgical success” in glaucoma has been defined in terms of IOP and whether or not patients require glaucoma medications following the procedure. “Complete success” has traditionally meant that the IOP is controlled without the need for medication. For instance, a patient with a pale, ischemic bleb and IOP of 08 mmHg off of medications is usually considered a complete success by this definition. While this definition may hold true for a patient at high risk for significant functional impairment from glaucoma, the risks inherent to ischemic blebs, whether intraoperative, perioperative, or ongoing, in my opinion, exceed the risk of functional impairment for most patients with mild to moderate glaucoma. In such patients, I would hesitate to claim “complete success” by creating a pale ischemic bleb because I believe such an approach subjects the patient to more risk than is necessary.

MIGS procedures combined with the phacoemulsification platform offer a new and evolving definition of glaucoma surgical success. In such patients, complete success might be defined as IOP within the target range, the highest quality vision, rapid visual recovery, a more favorable and stable refractive outcome, a realistic and manageable medical regimen of 1 or 2 medications, and most importantly, limited exposure to surgical risk intraoperatively, perioperatively, and ongoing — risk that is commensurate with the disease risk, all the while reassured by the knowledge that additional surgical options remain unaltered by the MIGS procedure.

Summary

The glaucoma surgical landscape has changed as a result of the confluence of several developments. In particular, the advent of MIGS and increased awareness of the favorable effect of phacoemulsification on IOP has provided an opportunity to rethink the surgical approach to glaucoma, especially when combined with cataract surgery. The availability of alternative glaucoma procedures with varying degrees of risk and efficacy provide the potential to individualize the surgical approach more completely than ever before. Undoubtedly, as surgeons become more familiar with the various MIGS procedures, their utility for use in pseudophakic glaucoma and phakic eyes without cataract will be further clarified as well.

References


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