OMIC

OPHTHALMIC MUTUAL INSURANCE COMPANY
(A Risk Retention Group)

MALPRACTICE CLAIM STUDIES

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DISCLOSURES

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- Dr. Abbott has no disclosures.
- Anne Menke has no disclosures.
- Greg Tiemeier has no disclosures.

Objectives

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- IMPROVE ABILITY TO:
- Review diagnostic tests performed by ophthalmic technicians
- Assess patients' vocation, avocations, and expectations as part of informed consent.
- Manage patient's failed expectations after poor outcomes.

Case 1:
Clinical Summary & Issues

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- 36 yo woman evaluated for LASIK surgery
- Soft contact lens wearer
- Refraction to 20/20 OU - moderate myopic astigmatism
- Appropriate testing completed 5 days prior to surgery (topography, corneal pachymetry, etc)
- Detailed informed consent reviewed by doctor, patient took home and signed on return to office

Case 1:
Clinical Summary & Issues

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- Surgery and immediate post-op period without complications or complaints
- 2 months post-op, patient started noticing decrease in vision OS.
- 6 months post-op “irregular astigmatism” documented
- 9 months post-op consultation requested with corneal specialist

Case 1:
Clinical Summary & Issues

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- One year post-op: **corneal ectasia** noted. Pt unable to wear contact lens OS
- INTACS placed (with no improvement)
- Six years later, had PKP OS with rigid contact lens for vision. Poor comfort.

Case 1:
Clinical Summary & Issues

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- ISSUES FOR DISCUSSION:
  - Pre-operative corneal topography not normal in appearance
  - Informed consent regarding abnormal test results?
  - Forme Fruste KC vs Pellucid Marginal Degeneration – what was known in literature at the time of patient evaluation?
  - Detailed informed consent documents – time to digest material by patient?
  - 2nd eye involvement?

Case 1:
Legal Perspective

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- Date of surgery is critical to defense – what was known in 2001 about ectasia?
- 2005 ASCRS Washington DC– majority of keynote speakers addressed ectasia
- 2007 ASCRS – Randleman presents research on risk factors for ectasia
- "What a reasonable surgeon would do, at the same time, same or similar circumstances.

Case 1:
Legal Perspective

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- 2001 – considered to be a screening issue, rather than informed consent.
- Today, ectasia known to occur in absence of risk factors – informed consent issue
- Asymmetry between OD, OS known risk factor in 2001?

Case 1:
Legal Perspective

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- "there are no established criteria for the topographic diagnosis of form fruste or 'preclinical' keratoconus, but we consider the pre-op inferior steepening to be relevant to patient's outcome"

- What year?

Case 1:
Legal Perspective

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- Published in *Ophthalmology* in 2000
- In *Cornea* in 2001, most common over-call is diagnosis of FFKC in cornea with mild inferior steepening and no other signs of disease.
- Knowledge changes rapidly – focus on the time of the event.

Case 1:
Risk Management Issues

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- Event analysis
  - Can recurrence be prevented?
  - Can defensibility be improved?
- Managing patient expectations following serious complications

Case 1:
Risk Management Issues

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- EVENT ANALYSIS
- Clinical knowledge not available at time
- Excellent care process and consent
- Responsive postoperative management
- Significant vision loss and unmet expectations
- Get risk management help early

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Case 1:
Risk Management Issues

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- Serious, vision-threatening complication deeply disturbing to physician and patient alike
- State that outcome unexpected and offer to review records to determine cause
- Schedule appointment to discuss review

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Case 1:
Risk Management Issues

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- Keep patient informed of current condition, prognosis, treatment options, including possibility of second opinion
- Consider phone call if long periods between follow-up appointments
- Ask patient is he/she has questions or concerns

Case 1:
Risk Management Issues

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- Watch for and recognize signs of grief in patient and yourself
  - Anger most common and enduring reaction in patient but also anxiety/depression
  - Empathy: keep focus on patient
  - Take care of yourself
    - Anxiety, depression, insomnia, relationship issues
    - Get help from your own physician

Case 1:
Risk Management Issues

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- If complication requires significant medical costs and/or time off work, ask patient if this poses problems
  - Refer if needed to social worker
- If you feel an error on your part contributed, get risk management input on how to manage

Case 2:
Clinical Summary & Issues

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- 29 yo male had bilateral EpiLASIK performed without complication
- Pupil size measured by employed COT with Covard pupillometer.
- Detailed informed consent obtained from patient on at least 2 occasions.
- Risk of large pupils specifically reviewed with patient
- Post-op complaints of double vision and night vision problems

Case 2:
Clinical Summary & Issues

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- ISSUES FOR DISCUSSION:
  - Correct performance of tests – Who is responsible?
  - Informed consent discussion regarding potential complications
  - Debate in medical literature regarding pupil size and cause of visual aberrations and double vision at night

Case 2:
Legal Perspective

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- Pupil zone size implicated in *Post v. University Physicians, Inc.* – alleged it was improperly measured
- United Airlines pilot claimed difficulty flying at night due to glare, halos
- $4.0 Million Arizona jury verdict
  - $3.9 Million in lost wages
  - $100,000 in pain and suffering

Case 2:
Legal Perspective

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- What does research show re: effect on night vision complaints after PRK, LASIK?
  - Haw, Manche
  - Pop
  - Schallhorn
  - Salz and Maguen
  - Trattler

Case 2:
Legal Perspective

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- Research to date by Haw, Manche, Pop, Schallhorn shows no correlation between large pre-op pupil size and night vision complaints after LASIK
- Research by Trattler showed positive correlation between pupil size and complaint of increased size of starburst (Larson Glareometer)
- Research (non-clinical) shows increase in higher-order aberrations with larger pupils
- Patients with high myopia or pre-op glare/halos are more likely to have them after LASIK

Pupil Size Trial in Denver

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- 2000 LASIK surgery, good refractive outcome, night vision complaints – running, driving at night
- Allegations that pupil size not properly measured pre-op
- Doctor claimed pupil size not shown to affect night vision complaints, in 2000.
- 1-Week trial to jury in Denver Dist. Ct., 11/15/04

Jury Thoughts re: Pupil Size

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- SOC in 2000 was to inform large pupil patients of increased risk of night vision complaints, research came later
- Disparity in pupil size measurements by different doctors – were they “large”?
- Didn’t matter, since patient would have had surgery anyway

Case 2:
Legal Perspective

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- Lessons Learned:
  - Pupil size is not the end of the inquiry as to post-LASIK night vision problems
  - Informed consent - need to tell patients about factors they have that may lead to problems
  - If you measure pupil size pre-op – consistent measurement technique and document it (Mesopic? Scotopic? Door open? Closed?)
  - If a defendant, educate your attorney on the pupil size research

Case 2:
Risk Management Issues

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- Event analysis
- Identifying and managing patients who need TLC/VIP attention
- Delegation to non-physician staff

Case 2:
Risk Management Issues

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- EVENT ANALYSIS
- Appropriate delegation of task
- Inconsistent test results
- Prevention & Defensibility
  - MD review of all results: do these results make sense? Check for inconsistencies (e.g., pupillometer vs. Orbscan results)
- Poor quality of vision = unhappy patient

Case 2:
Risk Management Issues

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- Far from the "wow" response: **25** postoperative visits without good outcome
- Frequent check-in on progress, prognosis, treatment options, reaction
  - "I can only imagine how disappointed you must be with the outcome so far, how long it is taking for your eye to heal, with the number of visits without the desired outcome
  - "I'm disappointed, too."

Case 2:
Risk Management Issues

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- Ask if help needed
  - "I know you are coming in for a lot of visits. Is this causing any problems at work? Would it help if I wrote a letter?"
  - "How is your eye condition impacting your life?

Case 2:
Risk Management Issues

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- Delegation and Supervision
  - Most office staff, even if certified, are not licensed and may not perform tasks for which a license is required
  - Physician and staff member could face allegations of violating state law (unauthorized practice of medicine, optometry, nursing, etc.)

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- What may I delegate to unlicensed staff?
  - Can staff receive certification in procedure from JCAHPO?
    - If "yes," then may train, delegate, and supervise
  - Could this task be considered the practice of medicine, optometry, or nursing?
    - If "yes," then **do not** delegate
      - Examples include administration of Botox, use of lasers, ordering prescription refill

Case 2:
Risk Management Issues

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- Cosmetic vs. medical procedure?
  - Are estheticians trained to perform this?
  - May they perform the procedure in a salon that has no affiliation with a physician?
    - If “yes” to both, cosmetic, so may delegate
    - If “no” to either, medical procedure
  - May the device only be purchased by a physician? Is the product labeled as a drug?
    - If “yes” to either, medical procedure

Case 2:
Risk Management Issues

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- Who may determine candidacy for a medical procedure?
  - Registered nurses with special training and written protocols
  - Treatment must be ordered by physician who also meets with patient and agrees that patient is candidate

Case 3:
Clinical Summary & Issues

- 67 yo woman had PHACO with IOL OD without complication
- Two weeks post-op had pain OD with corneal abrasion. Rx Predforte and Vigamox
- Two days later – abrasion larger in size and meds increased
- Three days later – severe pain. Seen by on-call MD and dx of endophthalmitis. Referred to retina surgeon for management. Vitreous tap and antibiotic injections given to patient.

Case 3:
Clinical Summary & Issues

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- Two weeks later – Perforating corneal ulcer requiring patch graft at site of clear corneal wound.
- Secondary glaucoma developed – controlled on meds.
- Visual acuity in 20/30-20/40 range

Case 3:
Clinical Summary & Issues

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- ISSUES FOR DISCUSSION:
  - Poor records: infection vs abrasion with hypopyon?
  - Poor records regarding treatment options
  - Informed consent – no documentation
  - Doctor's lack of concern towards patient's symptom of eye pain
  - Doctor's recommendation to "call office if not better" rather than a specific follow-up appointment

Case 3:
Legal Perspective

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- Main concern is CHARTING
- Insured adamant that pt had no infection at two weeks, and then 2 days later
- Chart, however, mentioned only evaluation of corneal surface – abrasion
- Notation of “no cells, flare in AC”?
- Notation of “Neg. Seidel”, “Good red reflex”

Case 3:
Legal Perspective

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- Pain after intraocular surgery – assume infection, prove otherwise
- Retrospectoscope is particularly harsh
- Be alert to unusual circumstances, and CHART your reasons for assuming a benign diagnosis vs. endophthalmitis

Case 3:
Risk Management Issues

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- EVENT ANALYSIS
- Worsening patient condition
- No change in diagnosis or treatment
- Poor documentation of decision-making process
- Patient confusion about medication
- Patient perception that MD doesn't care

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Case 3:
Risk Management Issues

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- Missed diagnostic due to inadequate skill/knowledge in only **4%** of cases
- Cognitive errors are the cause
  - Faulty data gathering and data synthesis
  - Shortcuts and “rules of thumb”
    - Framing technique
    - Obedience to hierarchy
    - Premature closure of diagnostic process

Case 3:
Risk Management Issues

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- Signs of a possible missed diagnosis
  - Findings unexpected
  - Condition not responding to treatment
  - Diagnosis does not account for all findings
  - Comorbidity explains some of the findings (premature closure of diagnostic process)
  - Multiple patient visits

Case 3:
Risk Management Issues

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- Cognitive strategies to improve decision-making process
  - Pause: What else could produce these findings?
  - Worst: What is the worst case scenario?
    - What tests are needed to rule this in or out?
  - **D^5:** Develop, disclose, document the differential diagnosis

Case 3:
Risk Management Issues

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- Patient education and follow-up
  - Include patient in the healthcare team
  - Patient needs to know if condition is serious and worsening
  - Written instructions for care and medications
  - Follow-up appointed scheduled before leaving office
  - Specific reasons to call before appointment

Case 4:
Clinical Summary & Issues

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- 56 yo woman complained of poor distance vision and occasional double vision.
- Cataracts noted OU. Vision 20/30 and 20/20- with Rx.
- Told about cataracts. Return when worse.
- Patient returned for evaluation several years later. Vision 20/60 and 20/25.

Case 4:
Clinical Summary & Issues

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- Cataract surgery recommended OD.
- Third visit with doctor and long discussion with patient regarding R/B/A/C.
- Patient complained mostly about poor driving vision.
- Doctor recommended slight under correction and better distance vision than reading vision.
- Told patient that reading glasses would be required.

Case 4:
Clinical Summary & Issues

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- Patient states that she did not want to wear reading glasses. Adamant that she told doctor this.
- Doctor testifies that pre-operative measurements performed to target -.58D
- Informed consent is signed prior to surgery
- Patient **wrote on consent form** that she did not want reading glasses and was “assured her wishes would be fulfilled”.
- Day of surgery – additional discussion with patient and necessity for reading glasses. Patient claims she told doctor that she would wake up and not need readers.

Case 4:
Clinical Summary & Issues

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- Surgery without complication.
- Severe post-operative eye pain. No findings or explanation for eye pain found.
- Patient requires glasses for reading
- Patient referred to experts for pain evaluation – no findings to support severe eye pain.
- Patient independently seeks 2nd opinions from multiple other doctors – no explanation for severe pain found.
- Finally lens removed by another doctor – new Rx -3.00 and eye pain gone. Patient satisfied. Able to read without glasses.

Case 4:
Clinical Summary & Issues

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- ISSUES FOR DISCUSSION:
  - "He said/she said" debate – documentation?
  - Patient selection issues
  - Informed consent – discussions with patient, witnesses, documentation
  - Second opinions selected by doctor vs patient

Case 4:
Legal Perspective

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- Patient wrote on consent form that she did not want reading glasses and was "assured her wishes would be fulfilled"
- Consent Form – memorialization of a PROCESS of exchange of information

Case 4:
Legal Perspective

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- Third visit with doctor and long discussion with patient regarding R/B/A/C.
- Told patient that reading glasses would be required
- CHARTED?
- Patient took the time to chart her impression of the discussion, why didn't the doctor?

Case 4:
Legal Perspective

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- What did medical staff tell doctor about the patient?
- “Don’t do surgery on her”?

Case 4:
Risk Management Issues

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- EVENT ANALYSIS
- Detailed preoperative counseling: “Spent more time with her than 99% of my patients”
- Patient fixated on particular, unlikely outcome of no glasses
- Surgeon and patient goals incompatible

Case 4:
Risk Management Issues

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- Recruit staff to watch for signs of demanding personality or unrealistic expectations
- “I want my patients to be satisfied with the outcome and I don’t think you will be.”
- Risk management means sometimes having to say **“I’m sorry, I can’t do your surgery”**

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Case 4:
Risk Management Issues

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- Patient with unexplained findings
  - "I believe that you are experiencing ____. I have examined you and conducted ____ tests but cannot find the cause. This is frustrating for both of us."
  - "Some conditions take time to declare themselves. Sometimes we can't find the cause."
  - Would you like to see another physician?

Questions?

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- FOLLOW-UP QUESTIONS
  - amenke@omic.com
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