Financial Disclosure

• John Banja has served 3 years as the public member of the ASCRS governing board, for which he has received compensation. He rotated off the board on April 24, 2014.  

By the end of this presentation, learners should be able to:

• List key informed consent requirements as they might apply to offering patients premium intraocular lenses and FEMTO second laser technology
• Describe common patient complaints sometimes leading to malpractice litigation involving post-surgical communications between physicians and PIOL patients
• Discuss problematic and nonproblematic advertisements for ophthalmology services per Federal Trade Commission and Federal Drug Administration guidelines

PIOL Informed Consent

Near vision may not be sufficient to see very small print (stock quotes, phone book entries, medicine labels)

Eye fatigue may occur 25% of patients note glare, haloes, and starbursts which might interfere with driving at night (although most patients get used to it; 7-8% of patients with standard monofocal lenses also note glare and halos)
Additional Informed Consent
Elements for PIOLs

• Patient must pay the difference: $2K - $4K per eye
• After lens insertion, at least 5 percent of PIOL patients will need refractive surgery, which is usually not needed after standard IOLs (Eric Donnenfield, MD)
• FDA: Up to 20 percent of patients, depending on the brand of premium lens, will still need glasses some of the time

Barriers

• Language is too technical; informational overload
• Outcome uncertainty is irritating and difficult to discuss
• Worry over alarming patients
• Stressed by workload – not enough time
• The hcp doesn’t like to converse and is a poor communicator

• Patients are worried, excited, not listening well, in denial, uncomprehending
• Patients believe the decision is in the professional’s hands or patients have already decided
• We don’t teach hcps how to conduct emotionally difficult communications

“Accepting an unsatisfactory outcome requires more resiliency than some patients possess or can develop.” (Anne Menke, PhD, Ophthalmic Mutual Insurance Company, 2011)
Considerations

• Patients might be too optimistic, or engaging in magical thinking, or just have unreasonably high expectations. By nature, they might be very intolerant of anything that doesn’t meet their expectations. While not all will blame the surgeon when that happens, some will. Consider having patients evaluate themselves on a “Perfectionist Scale.”

• The physician must develop a communicational style that realistically acknowledges these possibilities and informs the patient of them

More

• Talk slowly; use visual or phonetic aids or family members; have patients repeat what you just said; be very wary of patients who don’t seem to or refuse to understand you; beware of the “I’m in your hands, Doctor” or “You’re the boss, Doctor” patient.

• Do not become defensive, angry, hostile, or self-protective to patients who are very upset with you. Stay calm. Learn how to absorb their anger and offer other corrective strategies

Sticker Shock

It’s probably a good idea to give the patient as good an idea of the costs of the procedure before the surgery including additional costs that might be required for refractive error. If you’re unable to implant a PIOL, refund the extra fee ASAP.

Ethics, PIOLs and Physician Fears?

• Continued observation that PIOLs have not penetrated enough of the market (10% of the cataract market when maybe should be up to 30% - 50%): Aren’t enough patients being informed about PIOLs?

• 25% of cataract surgeons do not offer either presbyopia-correcting or toric IOLs (David Harmon of Market Scope)
SM2 2009 Strategic Survey (reported by Shareef Mahdavi)

- 279 cataract patients surveyed
- Awareness of PIOLs is low
- Once informed about PIOLs, interest is high
- Majority of patients would like unaided vision for all distances
- 47% reported a willingness to pay at least $1,000 more per eye for unaided vision
- 25% reported that “money is no object”

“The only thing I cannot resist is temptation.” Oscar Wilde

- Do you as a practitioner become more aggressive in trying to get more of your patients to select a premium IOL in order to offset some of the loss of revenue from codes 66984 and 66982? (Contributed by Brock Bakewell)

References

- OMIC Digest, Summer 2011, Volume 21, Number 3 (Menke quotations)
- Multifocal Intraocular Lens Implants—Premium IOLs at http://www.mastereyeassociates.com
- Surgeons considering premium IOLs must overcome fear of change, challenge, Ocular Surgery news, Oct. 25, 2009 at http://www.healio.com/opthalmology
FEMTO Advantages/Benefits

- More reproducible procedure, doesn’t require as much manipulation
- Allows superior removal of lens chunks (maybe)
- Need less phacoenergy, improved safety
- Enables virtually perfect capsulorhexis (that might enable improvement in effective lens positioning)
- Recommended for hypermature lens, weak zonules, endothelial dystrophies

More........

- Pupil might not stay dilated
- Potential for posterior capsule tears
- Atrophy of manual skills (!)
- Cataract refractive surgery has become so refined and safe that FEMTO benefits seem marginal
- NO REIMBURSEMENT from Medicare; Medicare pays for corneal incision, capsulorhexis, lens fragmentation and removal, and insertion of IOL. Medicare only pays its standard rate for these procedures regardless of how they are technologically performed

Fraud or Abuse?

- 70 year-old Medicare beneficiary has significant bilateral cataract formation and desires surgery. You have FS laser and the patient wants it. However, the patient wants a monofocal IOL OU. The only way for you to get compensated for the cost of the laser is to charge for LRIs. However, the patient only has 0.12 D of astigmatism in OD and 0.0 D OS. Patient says she is willing to pay for “astigmatism” so that you can use the laser. What do you think about charging for the patient’s zero to trace astigmatism, so that you can use the laser, knowing that if Medicare or OIG audits this chart, the auditor might question why astigmatism was treated and charged when the patient doesn’t have any? (Contributed by Brock Bakewell, MD)
Training Considerations

• Premium IOL/Refractive Surgery and Training Programs:
  – Should trainees be performing premium surgeries?
  – How to teach these procedures?
  – What is the proper informed consent procedure, especially bearing on the trainees’ “first time”?
  – If there is a complication, who is responsible or legally liable?
  – What happens when the trainee finishes? Who follows the patient?

Thanks very much.