

# Eye Care Newsletter

Omni Eye Specialists • Madison Street Surgery Center  
Spivack Vision Center • MSFS, Inc. • Colorado Laser Surgeons

The doctrine of informed consent relates back to English common law. Common law refers to a judge using prior case precedents to determine a legal course as opposed to statutes which are legislated direction. Beginning in the late 18th century, doctors were charged with the tort of battery if they had not gained the consent of their patients prior to performing a surgery. A tort is a civil wrong intentional or not, not in the context of a contract or statute. Tort law terms, including “standard of care” and “negligence” are front and center in today’s medical malpractice environment.

Within the US, a seminal case involving the concept of consent for surgical procedures is *Scholendorff vs. Society of New York Hospital (1914)*. Mary Schloendorff consented to ether anesthesia to determine the source of an abdominal mass. The surgeon removed a tumor without her consent while she was under anesthesia. Unfortunately, infection, gangrene, and amputation of several fingers occurred following surgery. The courts found that “Every adult of sound mind has a right to determine what shall be done with his own body” and that a surgeon who performs an operation without his patient’s consent performs “assault.” Schloendorff goes against the concept and practice of Paternalism, common at that time.

The concept of informed consent had its birth with *Salgo vs. Leland Stanford University Board of Trustees (1957)*. Martin Salgo had symptoms of cramping in the legs. He became paralyzed after a diagnostic procedure, aortography. He sued indicating that he was not told that paralysis was a risk associated with aortography. The court found that though Mr. Salgo gave his consent for the procedure, the failure to disclose risks and alternatives was a cause for legal action on its own.

*Natanson vs. Kline (1960)* involved Irma Natanson, a 35 year old housewife who suffered burns as a result of cobalt irradiation treatment for breast cancer. Though the patient gave consent and some risks were discussed, the issue of whether something that happens less than 1 percent of the time needs to be told came up. This case set a precedent for the determining standards of what needs to be disclosed in the informed consent process. The court found and set the standard of disclosure to what “a reasonable practitioner” in the community would provide.

*Canterbury vs. Spence (1972)* set a different standard of disclosure. In this case, a 19 year old patient became partially paralyzed after thoracic spine surgery. A mitigating factor was that the patient fell out of bed while voiding early after surgery. Canterbury sued for both hospital negligence and lack of informed consent. An important element of this case is that the court found that the standard of disclosure of risks depends on what a “reasonable patient” would need to know to agree to proceed and not what a “reasonable practitioner” would think is important. This ruling avoids a perceived “code of silence” where it was difficult to find a practitioner who would testify against another practitioner.

Other precedents from subsequent case law reinforce the concept that patients need to receive sufficient infor-

mation upon which to make a sound decision to consent. Also, the patient doesn’t need to inquire about risks and alternatives but it is the physician’s duty to relay these risks. In addition, it is the physician’s duty to make sure the patient understands the information being relayed.

In the typical lack of informed consent malpractice scenario, the issue of informed consent arises when a patient suffers an injurious or harmful outcome from a treatment or surgery. The outcome is usually not the result of negligence. The complication is typically a foreseeable risk. However, the patient alleges that he or she was never informed of the possibility of the injury or the harm. The patient would claim that had he known of the particular risk or that an alternative treatment not disclosed was available, that the patient would have not opted for the chosen treatment. The patient would then have avoided the harm. The patient sues for the lack of being informed because if he were, would have avoided the complication.

According to the General Medical Council: Guidance for Doctors (6/08), our duties to the patient include:

- Make an assessment of the patient’s condition, taking into account the patient’s medical history
- Doctor uses specialist knowledge, experience, and clinical judgment to identify which treatments are likely to benefit the patient.
- Doctor explains options to patient, setting out potential benefits, risks, burdens and side effects of each option, including the option of no treatment
- Recommend a particular option but not put pressure on the patient to accept advice
- Patient weighs benefits, risks, and burdens of the various options as well as non-clinical issues relevant to them.
- Patient decides whether to accept any of the options. They have a right to accept or refuse an option for any or no reason.
- Disclose if a treatment might result in a serious adverse outcome, even if the likelihood is very small.
- Disclose less serious side effects if they occur frequently

Today, states are divided on the level of disclosure during the informed consent process legally obligated. Some states use the concept of the “prudent physician” a.k.a. “community” standard akin to the “reasonable practitioner” standard set forth by *Natanson vs. Kline*. This is a less stringent standard than the “prudent patient” or “materiality” standard as it is often called which is akin to the “reasonable patient” standard that was set forth by *Canterbury vs. Spence*.

States currently using the community standard include Arkansas, California, Delaware, Florida, Georgia, Idaho, Illinois, Iowa, Kentucky, Maine, Michigan, Missouri, Nebraska, New Hampshire, New York, North Carolina, Tennessee. Those adhering to the materiality

standard include Alaska, Hawaii, Indiana, Louisiana, Massachusetts, Ohio, Oregon, Pennsylvania, Texas, Utah, Vermont, Washington, West Virginia

The American Academy of Ophthalmology “Advisory Opinion of the Code of Ethics (6/2008)” advocates an ethical standard similar the materiality standard, regardless of state requirements. It recommends disclosing complications that are common or significant such they might reasonably influence the patient’s judgment to accept the proposed treatment. It states also that exclusions include very minor, rare, or inconsequential risks.

OMIC (Ophthalmic Mutual Insurance company) risk management data shows that the majority of malpractice claims reported to them are related to cataract surgery. This may be related to the fact that cataract surgery is the most frequently performed ophthalmic procedure in the US. More recently, allegations related to physician advertising overstating benefits can destroy the validity of consent forms. Patients are also using state consumer protection laws to claim physician fraud.

OMIC emphasizes the proper management of patient expectations, highlighting the importance of various factors and tailoring it to the individual patient.

- Determine role of cataract in vision loss
- Evaluate ocular and medical comorbidities that can affect the outcome of cataract surgery including:
  - Previous trauma
  - Very Large or small eyes
  - Weak zonules (pseudoxfoliation syndrome)
  - Anticoagulants, antiplatelets, Flomax
- Surgical and non-surgical options for near vision and astigmatism reduction need to be discussed
- Standard of care requires informing patients these options as part of informed consent, including referring out if those procedures not offered at the particular practice.

#### Data for success rates for cataract surgery include:

- ASCRS National cataract database: (3 months data) 5788 patients
  - 86% had 20/40 or better vision (BCVA, or vision with their best glasses after surgery)
  - 57% had 20/25 or better BCVA
  - 75% were within 1 diopter of anticipated refractive target.
- AAO National Eyecare Outcomes Network (NEON) 7626 patients 96-97 (2 year data)
  - 92% had an improvement in visual acuity
  - 90% had an improvement in VF-14, a subjective vision questionnaire
  - 89% had 20/40 or better BCVA
  - 96% had 20/40 or better BCVA (when no ocular comorbid conditions
  - 95% were satisfied with their results

**Complications of cataract surgery include:**

- Synthesis of literature prior to 1992, American Academy of Ophthalmology (AAO) preferred practice patterns:
  - Infectious endophthalmitis 0.13%
  - Cystoid macular edema 1.4%
  - Retinal detachment 0.7%
  - Corneal Edema (BK) 0.3%
  - IOL dislocation 1.1%
- National Cataract Surgery Survey, British Journal of Ophthalmology 1997-1998 with 18,000 patients:
  - Posterior capsule rupture 4.4%
  - Iris damage 0.77%
  - Wound leak 1.2%
  - Retained lens material 1.1%
- European Cataract Outcome Study, 1999 with 8646 patients (95-99)
  - Intraoperative complications 3.1%
  - Posterior capsule rupture 1.8%
  - Vitreous loss 1.3%

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There is an increased risk for developing **retinal detachments** following cataract surgery. Generalized long-term risk of RD after cataract surgery

*Seminars in Ophthalmology 17(3)206-21L;*

- Non post-surgical Retinal detachment:
  - Prevalence 5 per 100,000 per year
  - lifetime risk 1 in 300
  - 67% of RD's occur in nearsighted individuals with myopic lifetime risk (above 5-6 diopters) 1 in 20
  - Associated with cataract surgery: 5 to 16 per 1000 cataract surgeries

*Ophthalmology 106: 154-159*

- 0.36% retinal detachment at 2 years after surgery
  - 0.77% at 5 years
  - 1.29% at 10 years
- Because of this induced increased risk, counseling with regard to the symptoms of retinal detachment is indicated to cataract post-surgical patients, in particular those with myopia. These include the sudden onset of photopsias (multiple, split second, lightning-like flashes of light), a new shower of floaters, or a curtain-like veil covering part or all of a person's vision. Prompt treatment often lessens morbidity.

At OMNI Eye Specialists, we are committed to the principles of informed consent prior to cataract surgery. The presence alone of cataractous lens changes is not sufficient to require cataract surgery. The decision to go forward with cataract surgery depends on whether a patient experiences a functional loss of visual clarity related to cataract formation sufficient to impact his or her daily visual tasks. An appropriate level of disclosure including rates of success and complications provides the patient the basis from which he or she can make an informed decision.

**Chronic Open Angle Glaucoma**

*By Gary Belen, M.D.*

Glaucoma is an optic neuropathy that produces characteristic structural changes to the optic nerve head, often with correlating visual field defects. It is second only to cataracts as one of the leading causes of blindness in the world. However, as opposed to cataracts, the visual loss sustained from glaucoma is irreversible. In the United States, it is the most frequent cause of blindness in African-Americans, with a higher prevalence, earlier age of onset, and greater sensitivity of optic nerve damage than other conditions. It is the third most frequent cause in Caucasians, following only macular degeneration and diabetic retinopathy. Over two million Americans have glaucoma, with an additional one million people who are unaware that they have the disease. Due to the rapid aging population, the number of Americans with glaucoma is expected to rise to more than three million by the next ten years.

In the normal eye, aqueous humor is produced by the ciliary body and drained primarily through the trabecular meshwork (TM) to a canal leading to the venous system. Although the exact cause of chronic open angle glaucoma (COAG) is not known, it seems to be related to increased resistance to outflow of aqueous through the trabecular meshwork. The increased resistance results in a gradual increase in intraocular pressure (IOP), which may result in glaucomatous optic nerve damage in susceptible patients.

costeroid use. Other risk factors include myopia, Type II diabetes mellitus, hypertension, migraine, sleep apnea, and hypothyroidism.

Glaucoma affects almost 2% of the general population. The prevalence increases with age: approximately 1% in Caucasians younger than 40 and rising to 2-5% among those older than 75. African-Americans have respective values of 1% and 11%. There is a strong genetic tendency of glaucoma with the relative risk of having COAG is increased approximately 3.7 times for people who have a sibling with COAG. Corticosteroid use by any route is a risk factor for elevated IOP and cataract formation. An examination might be needed within several weeks of starting steroids if a patient has one or more other risk factors.

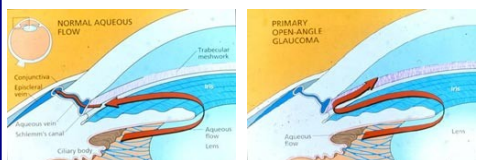
When performing an eye examination, the pupils should be checked for an afferent pupillary defect which is indicative of optic nerve damage. The most crucial part of the examination is assessment of the optic nerve, which can be accomplished with a direct ophthalmoscope. The optic nerve is typically round or oval. There is a yellowish center called the cup. Between the edge of the cup and the disc margin is an orange appearing neural rim. Notation of the cup to disc ratio is critical, as well as the contour of the neural rim. Glaucomatous damage, also called "cupping" occurs when the IOP is too high. This results in enlargement and excavation of the cup and an increased cup to disc ratio. Any enlargement of or asymmetry in the cup to disc ratio between a patient's eyes is suggestive of glaucoma. Optic nerve disc hemorrhages and notching of the neural rim are also signs of glaucoma damage.

Prompt treatment of risk factors in high-risk factors has been shown to reduce the development of glaucoma by 50%. However, the only risk factor that can currently be treated is IOP. Medical therapy with eye drops is usually the first line of treatment and the least invasive. They lower IOP either by reducing the ciliary body's production of aqueous humor or enhancing aqueous outflow through the TM or uveoscleral pathways. Laser and surgical treatments exist for progressive or advanced disease. The goal of treatment is to lower the IOP to a target range that hopefully halts progressive optic nerve damage and visual field loss.

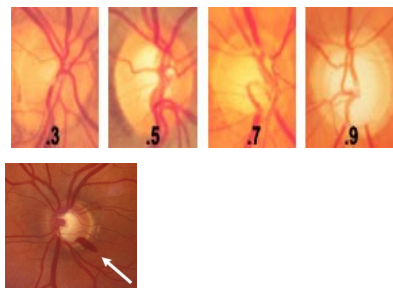
Eye drops come in several classes of medicines including beta-blockers (yellow or blue cap), carbonic anhydrase inhibitors (orange cap), alpha adrenergic agonists (purple cap), prostaglandin analogs (turquoise cap), and cholinergic agonists (green cap). Many patients do not know the name of their eye drops, but the class of medication can usually be identified by the cap color of the bottle.

Topical medications are generally well-tolerated, but they can have severe systemic side effects. It is helpful to be familiar with these systemic side effects as a patient might present to a primary care physician and not an eye specialist. Beta blockers can produce serious systemic side effects, including worsening of congestive heart failure and bronchospasm. Bradycardia, hypotension, syncope, CNS depression, and decreased libido are all also associated with beta blockers. Carbonic anhydrase inhibitors are structurally related to sulfonimides, and should be avoided in patients with sulfa allergies. Renal failure, blood dyscrasias, and severe dermatologic reactions can occur. Alpha adrenergic agonists are associated with drowsiness, fatigue, dry mouth, arrhythmias, and hypertension.

Any vision loss due to glaucoma is irreversible. Glaucoma is both under-diagnosed and under-treated, and patients are often unaware of their disease. Primary care physicians are vital in the diagnosis and management of glaucoma. By recognizing risk factors and clinical signs, high-risk patients can be directed towards appropriate care and diagnostic work-up; the end result of which will prevent blindness in patients and allow them to maintain their quality of life.



Because patients with glaucoma are usually asymptomatic, primary care physicians can play a vital role in recognizing this silent cause of blindness. By screening patients with major risk factors and examining the optic nerve with a direct ophthalmoscope, timely referral to an eye specialist can prevent the loss of vision in many patients. Major risk factors for glaucoma include advanced age, black race, family history of glaucoma, and history of long-term corti-



## Systemic Conditions and Medications Can Affect Lasik Surgery Candidacy and Outcome

By Ketty Lee, OD

LASIK (Laser Assisted In situ Keratomileusis) has become one of the most common and popular elective refractive surgery performed in the United States. The success of this procedure can be attributed to a combination of great technology in addition to a good sense today on who is considered to be a good candidate. Although most of the contributing factors to good candidacy are related to ocular findings, a careful review of a patient's systemic health and pertinent medications and their side effects is also crucial to assuring a predictable and successful outcome.

We will first summarize the key ocular findings and measurements currently used to determine candidacy for Lasik candidacy.

**Refractive Error:** The FDA has approved ranges of myopia (nearsightedness), hyperopia (farsightedness), and astigmatism that can be treated using the excimer laser. On average, the higher the degree of these refractive errors, the higher the chances that a full correction may not be achieved and/or that an enhancement may be needed.

**Corneal Thickness:** Pachymetry measurements of the cornea are key measurements to determine if the patient has enough corneal tissue to undergo Lasik surgery. The Lasik procedure typically entails removing tissue from the cornea to sculpt it to the appropriate curvature necessary to achieve emmetropia. With the availability of Femtosecond Laser keratomes and their ability to create very thin flaps, we have been able to expand the number of patients qualifying for Lasik surgery based on thickness values.

**Pupil Size:** The pupil size can be helpful in determining a patient's risk for night glare and halos, a potential side effect after Lasik surgery. Typically, the larger the pupils are, the higher the risk for these side effects. With the newer Custom Wavefront software, we are now able to potentially reduce some of the side effects significantly.

**Topographical Maps:** Detailed topography maps of the corneal curvature are evaluated to determine how regular the corneal anterior and posterior surfaces are. Irregularities on the cornea surfaces can sometimes lead to reduced predictability of the outcome from surgery. Corneal irregularities seen on topography maps can also indicate structural issues that may be a result from scars or corneal dystrophies. There are a few corneal dystrophies, such as Keratoconus and Pellucid Marginal Degeneration, that can rule out a patient's candidacy for Lasik surgery.

**Ocular Health:** Corneal irregularities (scars, dystrophies), cataracts, glaucoma, macular degenerations, retinal holes/tears, all need to be ruled out prior to considering Lasik Surgery.

**Dry eyes:** Dry eye testing is typically recom-

mended prior to Lasik surgery to help determine candidacy because another one of the more common side effects Lasik surgery is dryness. The creation of the Lasik flap severs corneal nerves creating a neurotrophic effect. Patients are typically most dry for the first 3-6 months after Lasik surgery and improve over the ensuing months. Dryness after Lasik can delay healing and affect overall visual outcome from surgery.

As with most surgeries, the statement "If you heal well, you will do well" certainly applies also to Lasik surgery. As healing well is certainly linked with health, systemic conditions and pertinent medications can affect whether we would consider a patient for Lasik surgery. Overall, we are looking for any condition or medication that can delay healing by suppressing the immune response, that can increase the risk for infections, that can cause more dry eyes, that can affect increase the chances for intraocular bleeding, and that can decrease predictability.

There are a few specific systemic conditions and medications that we feel need to be evaluated cautiously. The following are some of the more common conditions and medications we come across and the accompanying guidelines we consider prior to Lasik surgery:

**Acutane:** Patients need to be off Acutane for at least 12 months prior to considering Lasik surgery due to its very drying effects.

**Amiodarone:** Patients on Amiodarone and similar medications can have corneal whorl deposits which can affect how the excimer laser ablates the cornea. If the corneal deposits are present, the patient is not considered a candidate. Lasik can be considered if the patient is taken off the medication, if possible, and the corneal deposits resolve.

**Antihistamines:** Oral antihistamines can induce dry eyes. Ideally, patients should be off the antihistamines for at least a day prior to surgery and a few days after the surgery. It is understandable that sometimes this is not feasible, and in this case, Lasik can still be performed provided the patients are extra diligent with artificial tears.

**Chemotherapy:** Lasik can be considered at least 12 months after the last dose of chemotherapy.

**Connective Tissue Disease:** Recent studies and reports have demonstrated that Lasik surgery may be safe for patients with a diagnosis of a collagen vascular condition such as Rheumatoid Arthritis, Systemic Lupus Erythematosus, Scleroderma, Polymyositis, and Dermatomyositis. Lasik may be considered if the patient's condition is deemed stable by their treating physician. A careful consultation, education, and discussion with the Lasik surgeon needs to take place in order for the patient to understand the potential increased risks of Lasik surgery for patients with a collagen vascular condition.

**Coumadin:** Patients on Coumadin or any other blood thinners including daily aspirin, ideally need to discontinue taking this medication for 1 week prior to surgery with the consent of the

treating physician. Blood thinners not only increase the chances for subconjunctival hemorrhages after Lasik but also may place the patient at increased risks for uncontrolled retinal (macular hemorrhages), which has been reported in literature after the intraocular pressure increase during Lasik. If the patient is unable to be off blood thinners, other laser surgery techniques such as PRK (Photorefractive Keratectomy) can be considered.

**Diabetes:** Patients are candidates if the diabetes is controlled, ie blood sugar is stable, Hb A1c is normal, vision is stable, and no signs of Background Diabetic Retinopathy are present. They also need to be counseled on the potential unpredictability of refractive results due to the diabetes and also the higher risk for epithelial complications, and slower healing after surgery.

**Grave's Disease:** Patient is a Lasik candidate if the condition is stable and no ocular symptoms exist, such as dry eyes, and significant lagophthalmos. The corneal surface needs to be intact.

**Huntington's Disease:** Patient is a candidate if the condition is mild with no history of emotional fluctuations and no significant head and body tremors.

**HIV:** Lasik surgery can be considered if the condition is stable per the treating physician. T4 count should be preferably above 500.

**Immunosuppressive Meds:** Not a candidate.

**Leukemia:** Due to higher tendency for infections, patients with Leukemia are not candidates. If the Leukemia is on remission with normal blood work, Lasik can be considered provided the patient understands the risk factors involved.

**Mental Illness and Psychological Disorders:** Not a surgical concern, but expectations and compliance with the preop and postop medications of Lasik surgery can be an issue. Also, some of the medications for these disorders can induce dry eyes. Patients with any mental disorder need to be stable and evaluated cautiously.

**Multiple Sclerosis:** Lasik Surgery can be considered if there are: no visual field defects, no history of optic neuritis, clear color vision test, and normal nerve fiber layers. If patient has a history of optic neuritis, PRK may be considered.

**Pacemaker:** The excimer laser can affect a pacemaker. Clearance and confirmation of the extent of dependency on the pacemaker from the treating cardiologist needs to be considered.

**Seizure Disorders:** Surgery can be considered depending on the severity, the incidence and the stability of the disorder. A seizure episode during the procedure can result in a very unpredictable outcome.

As with any elective surgical procedure, we believe it is also important to have a thorough informed consent discussion of any potential risk factors due to a particular systemic condition or medication. An informed patient is a more reasonable and happier patient.

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