

A Risk Management Approach to Simultaneous Bilateral LASIK Surgery

by Sharon Koob, RN, BSBA, CPHRM, ARM
Princeton Insurance Healthcare Risk Consultant

Ophthalmic surgeons who do LASIK surgery are now frequently choosing to do the procedure on both eyes at the same time. This approach has apparently evolved to suit both patient and practice convenience. Simultaneous, bilateral procedures are not without risk, however, and the practitioner should proceed with patient safety and risk management in mind.

Minimizing error, complications, and liability rest on three fundamental issues: good informed consent, good pre-operative assessment of the patient, and appropriate equipment management.

Vice President of Healthcare Risk Services
Tom Snyder x5852

Manager, Healthcare Risk Services
Phyllis DeCola x5897

Phone: 609.452.9404

www.RiskReviewOnline.com

We welcome your feedback, comments and suggestions. Please feel free to contact us if you have a question or to send us your ideas for improving this site.



Informed Consent

As a fully developed process, informed consent involves:

- patient education about the proposed procedure
- discussions with the patient to ascertain their understanding of the information, answering any questions they may have, and determining whether they agree to the proposed surgery
- signing and witnessing of a clearly worded, comprehensive consent form
- documentation in the patient's record that this process took place

The presence of a signed consent form in the record is not, by itself, sufficient documentation. There should be a remark in the progress notes memorializing patient education, discussion, and any specifics which are important to that patient or to that procedure.

No physician wishes to scare their patient pre-operatively with dire news of possible serious complications during surgery or post-op, but patients who sue because of those same intra- or post-operative difficulties invariably say they were not aware that the complication could happen. It is not appropriate to minimize known risks and complications for the sake of

continued on page 2

patient ease of mind; and it is wise to document that you had a preoperative discussion of potential complications. Patients may not remember that conversation clearly when complications occur, making your note very important if a suit is filed. As an example: an ophthalmologist verbally advised a LASIK patient pre-operatively of potential risks; this information was not documented in the chart with any specificity. The patient suffered serious complications and significant vision loss. Postoperatively this patient only remembered the physician mentioning the possibility of dry eyes or the need for reading glasses.

When approaching consent for bilateral simultaneous LASIK, it is important that the patient understand they have an option to have their surgery on each eye in separate procedures (allowing time in between procedures for the first eye to heal). They should not get the impression through marketing materials, educational resources, the pre-operative discussion, or the wording of the consent form that bilateral simultaneous procedures are the only way this surgery is done.

The consent process must include a review of the material risks of the procedure and clearly state that the risks could affect both eyes. It also should explain the risks and benefits of LASIK done on one eye at a time and the documentation reflect whether the patient chooses or does not choose this approach. Both the chart note and the consent form itself should document that the patient was fully informed of these options. The consent form should have a place for the patient to indicate whether they choose individual surgeries or a bilateral simultaneous procedure. There should be a place for them to initial their choice along with their signature on the full form.

Pre-Operative Assessment of the Patient

A substantial number of post-operative complications of bilateral simultaneous LASIK surgery involved alleged inadequate pre-operative assessment, especially in taking and documenting crucial eye measurements. Whether measurement was done, the means used, and the care with which the determination was made were called into question during subsequent suits. To prevent surgical error and liability, the pre-operative assessment process used in each practice must include:

- a routine process for taking measurements, done on every potential pre-operative LASIK patient
- routine documentation of the measurements done on every patient considering LASIK
- careful explanations of the measurement process for the patient, answers to their questions, and documentation of this discussion

Equipment Management

Early LASIK equipment-related cases often involved the use of microkeratome blades. As these blades are being replaced by lasers, they figure less prominently in LASIK suits. But improvements in technology do not guarantee a reduction in claims.

Cases resulted from interruptions in routine protocols. For example, a patient arrived early and asked to be moved ahead on the surgical schedule. The practice was able to accommodate this request, the move was made, and involved staff members were notified. However, the technician from the laser company who was setting up the machine failed to confirm patient ID, and

planned surgical information as was required; information for the patient who was supposed to be there at that time, rather than the patient who had been moved up, was programmed into the machine.

In this, as in the majority of equipment-related cases, human error caused the complication. It is imperative that careful protocols be established, that those protocols be followed every time the procedure is done, and that there is documentation to substantiate adherence to protocol.

It is also imperative that practitioners be very familiar with the equipment before they use it with patients. Injuries from mishandled equipment occur as the result of inappropriate machine settings and simple misuse of a device.

Summary

Simultaneous bilateral LASIK procedures are now done with increasing frequency. Just because they are common, however, does not diminish their risk.

Patients must be informed that they have the right to have one eye done at a time. They must understand the risks and benefits of this approach as well as the risks and benefits of bilateral simultaneous LASIK. It is important that they understand that, in bilateral procedures, complications usually occur in both eyes.

To minimize error and liability, the physician and practice must have routine protocols which are followed every time and documented every time. This approach includes informed consent, pre-operative assessments, and equipment management.

With this approach, the physician and practice can exhibit good patient safety and risk management. ❖

This material is not to be construed as establishing professional practice standards or providing legal advice. Compliance with any of the recommendations contained herein in no way guarantees the fulfillment of your obligations as may be required by any local, state or federal laws, regulations or other requirements. Readers are advised to consult a qualified attorney or other professional regarding the information and issues discussed herein, and for advice pertaining to a specific situation. ❖



On the following page you will find a *Sample Consent Form for Lasik Surgery* that can be used in your office.

For you convenience, this form can also be downloaded at:

www.PrincetonInsurance.com/downloads/Risk_Review_Downloads/Spring.2010/SampleConsentForm_Lasik.pdf



SAMPLE CONSENT FORM FOR LASIK SURGERY

Explanation

LASIK surgery may be performed on the eyes one at a time, within three months of each other. The eyes may also be surgically corrected at the same time (simultaneously). However, simultaneous bilateral LASIK surgery can represent a level of risk that is not typically present when the eyes are corrected in separate procedures.

You should, therefore, understand both the benefits and risks before you choose a specific approach to LASIK surgery.

Simultaneous Bilateral LASIK

Risks

Complications in both eyes at the same time: There are risks of infection, clouding of the cornea, scars on the cornea, bleeding in the eye and retinal damage. These complications are not common, but when eyes are done simultaneously, the complications usually occur in both eyes. When they do occur, complications can cause diminished vision or even blindness (temporary or permanent).

It is appropriate to note that not all complications occur immediately. Some, such as scarring or cloudiness of the cornea, can take time to develop and time to resolve (get better). If this occurs in both eyes, the prolonged healing period can have a significant effect on a patient's lifestyle.

Inappropriate correction of vision: If, after healing, vision is noted to be over or under-corrected it will probably be inappropriately corrected in both eyes. This may require re-treatment and, if it does, the re-treatment will be needed for both eyes.

Length of recovery time: Though recovery is usually rapid, you may recover more slowly. In delayed recoveries, patients may have some blurred vision, glare at night, or 'ghost' images. If one or more of these symptoms occur during prolonged healing, they can interfere with your activities of daily life. This interference can be significant when both eyes are affected.

During LASIK surgery, a flap is created on the cornea which can become dislodged if the eye is traumatized during healing. When bilateral simultaneous LASIK is done, these flaps may become dislodged, requiring treatment.

Side effects: All surgery has potential for side effects. In LASIK, those effects are not common and not usually severe. However, when a patient with simultaneous bilateral LASIK experiences significant side effects such as glare, increased sensitivity to light, haze in the cornea, or ghost images, the effects usually occur in both eyes and can cause decreased vision and/or other problems.

Benefits

Ease: Having surgery done on both eyes during the same visit can reduce time loss from a job and is generally more convenient for you.

Length of recovery time: Vision in both eyes can be stabilized more quickly. This is more convenient when you have trouble wearing a contact in the eye which still has not been corrected.

Expense: Fees for simultaneous bilateral LASIK may be less than if each eye was done individually. This, along with less time off work, can represent a savings.

After you have read and understood this information on simultaneous bilateral LASIK surgery, please initial and date here: _____

LASIK Done on Each Eye at Different Times (Unilaterally)

Risks

LASIK done on each eye at different times poses the same kinds of risks as those specified in the preceding section of this document (under complications, side effects, inaccurate correction of vision, and possible slow recovery). As in bilateral simultaneous LASIK these risks can be as serious as loss of vision. However, if any of these complications occur during or following LASIK done on only one eye, the problem usually will happen in only that eye.

LASIK done on each eye at different times also has the following specific risks:

Inconvenience: Two surgeries require two of everything – two recovery periods, two sets of pre-operative and post-operative visits, and more time away from work or other responsibilities.

Having two surgeries may cost more; your insurance carrier could request a physician call or letter explaining this choice.

Benefits

Limits on complications: Though you still run the risk of experiencing a complication of the surgery (this is not common), it occurs in one eye, not both. The nature and severity of the complication allow you and your doctor to discuss whether you should go ahead with the second surgery or decide not to have it.

If the complication is a slowly developing and slowly healing one, such as cornea scarring or cloudiness, the second surgery can be delayed to accommodate this situation.

Correction of vision: Your physician can observe your recovery from the first surgery and adjust, if necessary, treatment for the second eye; this sometimes can lead to a more accurate correction in the second eye.

Ease of recovery: While the eye which was corrected is healing, you can continue to function with your other eye.

Your ability to determine how LASIK will best work for you: Having LASIK done on one eye at a time gives you the chance to evaluate the results before you continue on with the second eye. People over 40 can evaluate whether they are comfortable with the change in their close vision. Some decide to have the second eye corrected differently so that they do not need glasses for close vision.

After you have read and understood this information on unilateral LASIK surgery, please initial and date here: _____

Surgical Consent:
Simultaneous Bilateral or Each Eye at Different Times

I have read and understand the above explanation of the risks and benefits of:

- simultaneous bilateral LASIK, and
- LASIK done on each eye at different times.

I understand that this document does not contain all the possible risks, benefits or complications that might occur in either of these surgical choices.

I have discussed both surgical approaches with my physician, and my questions have been answered.

I wish to have Simultaneous Bilateral LASIK surgery

If I have chosen a bilateral procedure, my reason/s are as follows (*check all that apply*):

- Convenience
 - Faster recovery (not guaranteed)
 - Contact lens intolerance or difficulty wearing contacts
 - Less time away from work
 - Removal of possible vision imbalance between treated and untreated eyes
- I wish to have LASIK surgery done on only one eye at this time (check one)
- Right
 - Left

Patient Signature _____ Date _____

Physician Signature _____ Date _____

Witness Signature _____ Date _____