

Pearls for Handling Informed Consent

The final installment of this two-part article offers suggestions on how to properly discuss risks.

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In the June issue of *Advanced Ocular Care*, I suggested that you stop approaching informed consent as merely a legal chore and instead think of it as a great opportunity for marketing your practice and your skill as a surgeon. This article offers specific tips on how to properly inform your patients about the risks associated with ophthalmological procedures.

ACT EARLY

Give the consent form to your patients as early in the process as possible and have them take it home. Make a note in the chart as to (1) when the form was given to the patient, (2) when it was brought back and signed, and (3) whether questions were asked and answered. I have had trials at which the plaintiffs who were suing for malpractice claimed a lack of informed consent but had been given days or weeks to review the consent form. Jurors' reactions were strongly against the plaintiff, whom they saw as unbelievable. This reaction has a spillover effect to other areas of testimony, which makes a verdict in favor of the defense easier to obtain. It is much harder to defend a claim of a lack of informed consent when the patient did not see the consent form until the day of his or her surgery or saw it only briefly at a preoperative visit before he or she signed it.

Tell your patients about the risks associated with the procedure they are about to have. Do not wait for them to ask. If you are not a "people person," have a patient counselor do most of the talking and reinforce the basics afterward. Describe to patients the risks particular to their condition and needs. In the example I discussed last issue, an attorney with high myopia experienced "cracked mud" striae after LASIK. The greatest challenge in defending the case was the lack of any documentation (and perhaps any discussion) about the likelihood of this result from the significant ablation needed. Also, there was no documentation of (because there was no discussion of) the effect this outcome might have on someone who spends most of her time reading documents. Although this case was dismissed without payment 1 week after I took the plaintiff's deposition, the doctor had already "lost" because he had to endure almost

2 years of litigation, with the attendant emotional trauma and financial loss from time away from his practice.

TALK TO YOUR PATIENTS ABOUT EXPECTED SIDE EFFECTS

The difference between a complication and a side effect is in the eye of the beholder. Most surgeons I have talked to consider dry eyes to be a transient side effect. To most patients/plaintiffs I have talked to, however, dry eye at its worst significantly impairs vision and at its best is distractingly uncomfortable. Side effects are less anxiety provoking to the patient, however, if he or she has been forewarned of their possibility. Most LASIK patients expect to have perfect vision within days of the surgery. If they do not, they start wondering what went wrong, and the search for answers may lead them to an attorney's office. Providing answers to patients preemptively will lead them back to your office instead. You want to be the smart doctor who knows what is going to happen before it does, not the defensive one who backfills after a problem arises.

Providing answers up front is also particularly important with multifocal IOLs. The manufacturers of advanced-technology lenses like to portray them as returning the eyes of youth to the elderly patient; only reincarnation could do that. What these lenses offer is a compromise, and your patients should understand that. Telling your unhappy patient after surgery that it takes 6 months to adapt to a multifocal IOL, that it is best when both eyes have the procedure, and that decreased function in low light is common will be of little consolation. Ask Jim Palmer, the former major league baseball pitcher, about that. After receiving a multifocal IOL that was subsequently explanted, he suffered retinal tears that required re-attachment surgery; he sued his surgeon. Mr. Palmer was awarded \$890,000 by a Palm Beach, Florida, jury on February 4, 2008, for loss of income, pain, and suffering.

The duty to provide the patient with information regarding risks, benefits, and alternatives to the proposed surgery lies with the surgeon. In some states, the surgeon is the only person who may have the discussion with a patient. In

other states, the task, but not the responsibility, may be delegated. For example, the surgeon may tell a surgical scheduler to have an informed consent discussion with the patient, but the surgeon is still responsible if the scheduler fails to inform the patient of a substantial risk that occurred.

If you are a good communicator—be honest in this assessment—then do all the informing yourself. If not, have a well-spoken staff member help out. Always keep in mind that the rapport you establish, and your role as the patient's guide throughout the procedure, depends on the time and energy you have devoted to him or her before surgery.

DISCUSS THE RISKS

In most (if not all) jurisdictions, the surgeon must disclose the substantial risks of the procedure. This generally means risks that occur frequently or risks that, although infrequent, are severe. To quantify the risk, it may be helpful to use a diagram depicting what one-half of 1% is, for example. Charts depicting numerical probabilities can be found at www.riskcomm.com.

The risks specific to the person, because of his or her occupation or physical condition, should be discussed. In the *Post v. University Physicians* lawsuit, a plaintiff who was an airline pilot prevailed because of the risk of night vision problems inherent in LASIK. He claimed he had not been informed of the chance of decreased low-light vision or glare and halos. Although his refractive outcome was a nearly perfect 20/20, the jury awarded him \$4.0 million because the members did not feel that the patient had been adequately warned of the risks LASIK posed to his ability to perform his job. A LASIK patient with high myopia should be informed that he or she is more likely to experience all of the risks discussed—particularly nighttime or low-light visual problems, flap striae, and corneal ectasia.

Alternative treatments should be discussed, even if the patient does not ask about them. In today's environment of pervasive advertising, patients often come in inquiring about a specific procedure—LASIK or a multifocal instead of asking the physician what is best. What patients request may not always be what is best for them. For example, a high myope should be informed of the option of PRK due to risk of flap-bed mismatch after ablation, resulting striae, or postoperative ectasia. Whether the patient selects that option is another matter. One thing is certain: if this patient sues and you did not discuss the alternative procedure, the patient will claim he or she would have chosen whatever option you did not offer. In the case of the previously mentioned highly myopic attorney, PRK was an option, yet nothing in the chart or consent form indicated it

was ever discussed. In that case, the plaintiff's expert witness pointed out that mitomycin C was widely used and that a flap-bed mismatch, and resultant striae, was likely given the size of the ablation.

Be sure you cover the basics in your informed consent discussions. I receive countless calls from people who are contemplating eye surgery, and the risks not disclosed to them are remarkable. Examples include pain after PRK (the patient was a nurse, and she was listening carefully), the need for reading glasses for a 50-something presbyope who is scheduled for a full distance correction, and night vision problems (glare and halos) for a high myope who is receiving excimer ablation without wavefront technology. I also hear from the surgeons who tell me they are adequately informing their patients but that these individuals just do not listen or remember. If your message is not getting across, perhaps the communication process needs to be re-evaluated.

Whether it is yours or a competitor's, your patients are likely exposed to pervasive advertising of LASIK that does not mention the risks and usually does not even stipulate that it is a surgical procedure. Consequently, patients walking in for their initial consultation may not understand that they are considering surgery that carries attendant uncertainties and perils. Perhaps your first reaction to this is, "Good, I don't want patients to be scared away." You may also be tempted to mention the procedure's risks only in passing during the consultation so the patient is more inclined to have LASIK. The result is a patient who has an unrealistic understanding of the safety and risks. The advertisements did not discuss the risks, friends who had LASIK and raved about it did not discuss risks, and the doctor and his or her staff did not discuss them.

Most of the time, this situation will be of little consequence, as LASIK has a very high rate of success. It is not a perfect procedure, however, and every LASIK surgeon has had dissatisfied patients. Some patients with an objectively good result will seek out an attorney because they may be surprised by a transient side effect such as dry eye or halos.

CONCLUSION

Informed consent is much more than a legal chore. You are missing out if you do not approach this task as an opportunity to promote both your practice and your surgical skills. The amount of time you spend with your patient before surgery and the conversation you have with him or her can ultimately be profitable. Not handling this discussion may cost you. ■

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