MEDICOLEGAL RISKS IN THE EUROPEAN OPHTHALMOLOGY ENVIRONMENT

Adequately informing patients about potential complications and treatment alternatives is key to avoiding legal consequences.

BY MICHAEL ZACH

It is up to the surgeon to choose which surgical approach is most appropriate for a given patient. As a basic principle, the safest and most efficacious treatment option should be chosen. Opinions can vary from region to region, however, regarding what is safe.

In Germany, for example, the Kommission Refraktive Chirurgie (Commission for Refractive Surgery) assesses the risks associated with treatment approaches such as LASIK, refractive lens exchange (RLE), and phakic lens implantation and, based on these findings, formulates indications and provides general recommendations for these surgeries. This committee advises German ophthalmologists against simultaneous bilateral surgical treatment. At the same time, however, in Finland, almost one out of two cataract surgeries is performed as a simultaneous bilateral procedure.[1] (Editor's note: For more on this subject, see *Informed Consent Considerations for ISBCS*, pg 38.) This illustrates how difficult it can be to agree on an analysis and assessment of treatment risks on a general basis in Europe.

RISK ASSESSMENT: GENERAL VERSUS INDIVIDUAL

Deviation from the general recommendations of a professional body may be acceptable and even necessary in specific cases. It is the responsibility of the surgeon to prove that such deviation is justified. If the surgeon cannot prove this justification, the existence of a signed informed consent document will not help avoid legal ramifications because informed consent to a nonstandard medical procedure is invalid and will not protect the surgeon from risk.

If the surgeon deviates from the general recommendation based on objectively justified medical considerations, he or she must disclose all available treatment options to the patient before surgery. German civil law states that alternatives to the selected treatment must be discussed if several equally medically indicated methods could lead to significantly different outcomes, risks, or chances of recovery. Otherwise, the question of liability arises in the event of incomplete explanation of treatment alternatives, even if no risk or complication occurs, simply because the patient was deprived of freedom of choice due to the lack of sufficient information.

PATIENT-TAILORED RISK INFORMATION

A proper informed consent process aims to provide all relevant information the patient needs to make a decision about treatment, including information regarding specific risk factors such as comorbidities, a thin cornea, or elevated IOP. The possibility of developing complications due to macular changes or surgically induced progression of age-related macular degeneration should be explained to the patient. The patient should also be informed that the intended outcome of cataract surgery can be affected by physiologic developments that cannot be foreseen. When an RLE is planned, if the surgery will increase the risk of retinal detachment, this should be disclosed to the patient preoperatively.

In terms of liability, if a surgeon neglects to disclose a treatment risk to a patient, it is only relevant if this complication actually occurs. If complications do not occur, there would be no legal consequence.

The physician should perform a preoperative evaluation to determine whether an intended surgery is indicated for medical or aesthetic reasons. For example, the Bundesärtzekammer (the German Medical Association) stated in 2002 that myopia of more than -6.00 D (myopia magna) is a disease, and thus surgical treatment is medically indicated. In lower degrees of nearsightedness, refractive surgery would be elective, leading to its qualification as an aesthetic procedure. In this case, the risks of the operation must be disclosed to the patient, as there is no medical justification for the treatment.

If an elective procedure is chosen, the informed consent process must be detailed and precise. Before

cataract surgery is performed, the patient must be informed about the possibility of postoperative halos, glare, and reflections. Before RLE, the patient should be asked if he or she comprehends the possibility of undesirable outcomes and side effects, and whether he or she fully recognizes that these effects—regarding his or her specific profession—could lead to an occupational disability. The answers should be documented on a written and signed informed consent form.

OTHER CONSIDERATIONS

Adequate risk and treatment information. If a patient is told factually incorrect information (eg, "All patients will develop a cataract at some point."), the patient could be entitled to a claim for fee reimbursement and compensation. Giving an inaccurate initial diagnosis to the patient and his or her insurance provider is strictly discouraged.

Treatment and medical device risks. The physician must provide adequate information about risks associated with the intended treatment but not necessarily about risks resulting from a medical device involved in the procedure.

Informed consent documents do not commonly refer to the possible clouding of IOLs and the consequent need for removal and reimplantation. The general risk of opacification should still be discussed, however. The patient should understand that, in the case that a reimplantation is required, it will entail at least the same level of risk as the initial implantation, and possibly an increased risk due to the tissue damage caused by the previous surgery.

If the physician decides to use a medical device in an off-label manner, this should also be explained to the patient, and the reasons for this deviation should be noted in the patient record. According to a decision by the Court of First Instance of Athens, Greece, the use of an off-label medicine amounts to malpractice when an on-label product exists and the physician fails to prove that there is no increased risk of complications with the off-label product.

CONCLUSION

The rate of physician liability is smaller in ophthalmic surgery than it is in other surgical specialties.[2] However, failure to adequately inform patients of related risks is of high importance in ophthalmic surgery because ophthalmology offers a high proportion of elective treatments with a broad scope of treatment alternatives.

Thus, good communication skills, proper patient education, and documentation of informed consent are of paramount importance for ophthalmologists who wish to avoid medicolegal entanglements. ■

1. Sarikkola AU, Uusitalo RJ, Hellstedt T, et al. Simultaneous bilateral versus sequential bilateral cataract surgery: Helsinki simultaneous bilateral cataract surgery study report 1. *J Cataract Refract Surg*. 2011;37(6):992-1002.
2. Spaniol K, Thanos S, Weber B, et al. Medical malpractice in ophthalmology [article in German]. *Ophthalmologe*. 2013;110(4):339-345.

MICHAEL ZACH
- Lawyer for Medical Law, Mönchengladbach, Germany
- info@rechtsanwalt-zach.de
- Financial disclosure: None acknowledged