

## Ask the Ethicist: "Femto-Ethics"

July 2015

*Q: I am considering adding femtosecond cataract surgery to my practice, but I have many questions, including: What training and skills are required? How should I prepare for my first case? Are there specific ethics or medico-legal issues that I should take into consideration?*

A: Each of these questions—not just the last one—has an ethics component. Before introducing femtosecond surgery into your practice, consider the applicable rules in the Academy's Code of Ethics. These include Rule 1, Competence; Rule 2, Informed Consent; Rule 6, Preoperative Assessment; and Rule 15, Conflict of Interest.

**Competence.** Rule 1 says, "An ophthalmologist should perform only those procedures in which the ophthalmologist is competent by virtue of specific training or experience or is assisted by one who is." In the case of femtosecond cataract surgery, a commitment to formal study is strongly recommended. Suggested resources include instruction courses and Skills Transfer sessions at AAO 2015, surgical simulators, slide scripts, video and self-assessment materials, assistance of a skilled mentor, and review of initial cases with a mentor.<sup>1</sup>

All the femtosecond cataract companies require certification. However, successful completion of training components or objectives does not necessarily signify an individual's clinical competence in a specific procedure. Components of competency or user proficiency include patient selection; preoperative evaluation and preparation; familiarity with instrumentation; surgical skills/judgment; safe, expeditious completion of the procedure; a postoperative plan; and avoidance of complications.<sup>2</sup> Furthermore, hospitals have stringent guidelines governing acquisition of new procedures, usually under the supervision of a senior staff member. Managed care entities may have their own guidelines, and these should also be reviewed carefully.

**Informed consent.** Rule 2 states, "The performance of medical or surgical procedures shall be preceded by appropriate informed consent." Most states set a higher standard than Rule 2 by requiring disclosure of all information that a reasonable patient would find significant in deciding to agree to the use of a femtosecond laser, such as whether other options are available, (e.g., manual corneal incisions and anterior capsulotomies), and the ophthalmologist's financial interests in the laser device. The Ophthalmic Mutual Insurance Company (OMIC) offers

an informed consent addendum for femtosecond laser use in cataract surgery:

<http://www.omic.com/cataract-femtosecond-laser-addendum/>.

It may also be prudent to contact your liability carrier about your coverage in using this new technology.

**Preoperative assessment.** The portion of Rule 6 that is most relevant to your situation is as follows, "Treatment shall be recommended only after a careful consideration of the patient's physical, social, emotional and occupational needs."

Ethical and quality-of-care standards are met only if the individual patient's needs are addressed. Your assessment of the patient should be based on what is in the patient's best interests - that may be femto, or it may be manual procedures. With femto, the patient's financial situation is a significant part of this assessment.

To give yourself the best chance of successful outcome with your first case, appropriate patient selection is a particularly important factor. Patient selection should initially be made on the basis of anticipated technical difficulty. The patient's personality should also be considered; anxiety, impatience, or a demanding nature may not make for a suitable candidate.

**Conflict of interest.** Rule 15 says, "A conflict of interest exists when professional judgment concerning the well-being of the patient has a reasonable chance of being influenced by other interests of the provider. Disclosure of a conflict of interest is required in communications to patients, the public, and colleagues."

When an ophthalmic surgeon has a professionally related commercial interest, such as the ownership or part ownership of a femtosecond laser device, the potential exists for a conflict of interest in patient care. It is essential that conflicting commercial interests related to the laser device be disclosed to the patient, unless it is apparent to a reasonable person that the device is an integral part of the ophthalmologist's practice facility and hence is likely to be owned in whole or in part by the ophthalmologist or the practice.

Most patients would likely be unaware that a laser device is owned by an individual or a practice and that each use of the laser produces income for the individual or practice, so it is wise to disclose this.

**For more information,** visit [www.aao.org/ethics](http://www.aao.org/ethics).

1 Sachdeva AK et al. *Surg Clin North Am*. 2007;87(4):853-866.

2 [www.sages.org/publications/guidelines/framework-for-post-residency-surgical-education-training](http://www.sages.org/publications/guidelines/framework-for-post-residency-surgical-education-training). Accessed February 25, 2016.