POLICY STATEMENT

Laser Surgery

Policy
The quality of care for patients undergoing laser surgery is a concern of the American Academy of Ophthalmology. The quality of care should be safeguarded in the same way that it is safeguarded for patients undergoing any surgery, because the clinical complexities and potentially harmful consequences are similar. The Academy strongly supports the position that all laser surgery for medical purposes, including ophthalmic laser surgery, should be performed only by licensed doctors of medicine or osteopathy.

Background
Like other surgical procedures, laser surgery alters, removes, replaces, and reshapes human tissue, or it activates drugs for the purpose of treating disease and improving patient function and well-being. Because laser energy possesses remarkable strength, unlike ordinary light energy, lasers are used as sophisticated surgical instruments to produce definitive and precise surgical effects.

Lasers were originally used in ophthalmology in the early 1960s, soon after the laser effect was first successfully demonstrated. Since then, many benefits of laser surgery have since been demonstrated, including reducing visual loss from diabetic retinopathy, restoring vision for posterior capsular opacification after cataract surgery, and reducing intraocular pressure in glaucoma patients.

The excimer laser was approved by the FDA for use in refractive surgery under specific terms and conditions. Adverse effects of this surgery that have occurred include corneal haze, which can limit visual acuity; visually significant irregular astigmatism; and, rarely, infection or scarring. The femtosecond laser has FDA approval for the creation of a corneal flap in patients undergoing LASIK surgery or other treatment that requires initial lamellar resection of the cornea as well as for capsulotomy, lens fragmentation, and all corneal incisions. Another FDA-approved ophthalmic laser procedure is photodynamic therapy, which uses laser light to activate an intravenously administered drug that helps to close off abnormal blood vessels that interfere with normal retinal function.

Like other surgical instruments, lasers are potentially dangerous and can cause bleeding, edema, trauma, and tissue damage. Specific risks associated with lasers that are used for ophthalmic surgery include penetration of blood vessels, with resultant bleeding; an increase in intraocular pressure, with resultant damage to the optic nerve; retinal injury that includes damage to the area of central, fine vision; damage to the cornea; and cataract formation. Each of these complications could result in significant loss of vision. Because of the potentially harmful medical consequences of laser surgery, strict guidelines have been established for the use of lasers in patient care. The FDA regulates all medical instruments as prescription devices, including ophthalmic lasers.

In order to guard against potential proliferation of unsafe or inappropriate use of lasers in patient care, several surgical specialty societies have developed guidelines or policies that set forth criteria for the medical qualifications of surgeons who practice laser surgery. The guidelines also
Cataract Surgery
Cataract surgery is an intraocular procedure that comprises multiple steps, some of which can or may be performed by a laser. To date, there are no studies that show superiority of cataract surgery performed with femtosecond laser assistance when compared with standard phacoemulsification. Removal of a cataract involves surgery inside the eye and can be associated with damage to delicate intraocular structures, with potentially serious vision threatening complications. All steps of the procedure should be performed only by, or under the direct supervision of, an eye physician with surgical-training qualifications from a residency program accredited by the Accreditation Council for Graduate Medical Education (ACGME) or American Osteopathic Association (AOA). Eye physicians with these qualifications have the skill and knowledge to perform this procedure and handle potential surgical complications.

Evaluation
Ophthalmologists have been among the principal pioneers and innovators in the field of laser surgery. They learn and gain mastery of laser surgery techniques through residency and fellowship training, continuing educational courses, didactic courses, and preceptorship opportunities. The best possible outcome for a patient after laser surgery depends on the physician making an accurate diagnosis, considering a patient’s health status and visual needs, choosing the right treatment within the spectrum of alternatives, timing the treatment appropriately, and prescribing drugs postoperatively. As with any sophisticated surgery, patient outcome is also determined by the technical skill, dexterity, and coordination needed to control the laser system during treatment. Optimization of the outcome depends on timely recognition and management of both the anticipated and unforeseen complications.

Recommendation
The clinical complexities of ocular laser surgery, and the associated potential for laser-induced health problems, clearly justify adherence by regulatory authorities to a requirement that laser surgery is performed only by licensed doctors of medicine or osteopathy.

Approvals
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