

Current European Guidelines for Refractive Surgery

Ophthalmologists from across Europe describe their countries' standards or accepted norms.

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France



By Damien Gatinel, MD, PhD

The practice of refractive surgery is accessible to any ophthalmic surgeon in France. In theory, no special certification is required besides an ophthalmology specialty diploma.

Conversely, ophthalmologists are the only physicians who are qualified to perform refractive surgery.

Ophthalmologists learn theory and gain surgical experience through daily hospital practice. Lectures given as part of the teaching residency program cover the entire field of ophthalmic pathology. Although refractive surgery represents a significant proportion of ocular surgical activity in France, this field is taught only in specific units and may not be available to some residents. As the field of medical knowledge widens, especially in ophthalmology, it is difficult for teaching units to remain versatile and provide as much emphasis on elective and, some would say, cosmetic procedures as on vision-threatening diseases. Additionally, public hospitals cannot always afford the heavy financial burdens of the costs and maintenance of the lasers used in refractive surgery.

The complexity of refractive surgery requires surgeons to possess specific skills to master several types of specialized laser units. To learn these skills, it is recommended that surgeons, particularly those interested in laser refractive surgery, including LASIK and PRK, follow specific courses, such as the Inter-University Diploma offered in partnership by the Université de Bordeaux, the Université de Toulouse, and the Université de Besançon.

Anterior segment and cataract surgeons already perform lens-based refractive surgery, using toric and multi-

focal IOLs to correct blurred vision, astigmatism, and presbyopia. In fact, many surgeons who perform lens-based refractive surgery regularly are now also mastering laser-based techniques. The introduction of femtosecond laser technology to the field of crystalline lens surgery will probably continue to strengthen this trend toward refractive lens surgery.

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Germany



By Suphi Taneri, MD, and Saskia Oehler, Dipl Ing

Germany does not have a regulatory agency like the FDA that approves refractive procedures. However, most surgeons in Germany adhere to the evaluation of indications for refractive surgery procedures outlined by the Commission of Refractive Surgery, a combined commission of the German Ophthalmological Society and the Professional Association of German Ophthalmologists.¹ These guidelines are designed to evaluate and safeguard the quality of refractive surgical procedures performed in Germany.

In the following review of these guidelines, the term *recommended range of application* refers to the range in which a procedure is considered eligible and side effects are rare. In this range, normal standards are sufficient for patients' education and the informed consent process. The *range of limited application* is the range in which the surgery may be performed but in which less predictable results and side effects may be anticipated. For procedures in this range, patients' education must be extensive. Surgeons are discouraged from performing surgery outside of these ranges.

Surface ablation. The recommended range of application for PRK, LASEK, and epi-LASIK is correction of myopia of up to -6.00 D and correction of astigmatism up to 5.00 D. If myopic astigmatism is to be corrected, the values for myopia and astigmatism must be added, not subtracted. The range of limited application for these procedures is correction of myopia up to -8.00 D and correction of astigmatism up to 6.00 D. If myopic astigmatism is to be corrected, the values for myopia and astigmatism must be added. Up to 4.00 D is the range of limited application for hyperopia.

Contraindications include chronic progressive corneal disease, surgery before the age of 18 years, symptomatic cataract, glaucoma with a marked loss of visual field, and exudative macular degeneration.

LASIK. The recommended range of application is correction of myopia up to -8.00 D and correction of astigmatism up to 5.00 D. If myopic astigmatism is to be corrected, the values for myopia and astigmatism must be added. The recommended range for correction of hyperopia is up to 3.00 D. The range of limited application for LASIK is correction of myopia up to -10.00 D and correction of astigmatism up to 6.00 D. If myopic astigmatism is to be corrected, the values for myopia and astigmatism must be added. Up to 4.00 D is the range of limited application for hyperopia.

Contraindications include preoperative corneal thickness less than 480 μm , predicted stromal thickness under the flap after ablation of less than 250 μm , chronic progressive corneal disease and forme fruste keratoconus, surgery before the age of 18 years, symptomatic cataract, glaucoma with a marked loss of visual field, and exudative macular degeneration.

Phakic IOLs. The recommended range of application for implantation of a phakic IOL is correction of myopia greater than -8.00 D and correction of hyperopia greater than 4.00 D. If astigmatism or ametropia remains after implantation, excimer laser surgery may be performed. The range of limited application is correction of myopia greater than -5.00 D and correction of hyperopia greater than 3.00 D.

Contraindications include surgery before the age of 18 years, symptomatic cataract, glaucoma with a marked loss of visual field, preexisting corneal disease with a low endothelial cell count, and insufficient anterior chamber depth.

Conductive keratoplasty. This procedure has never gained popularity in Germany and is almost never performed.

Refractive lens exchange (RLE). The recommended range of application for RLE is the correction of myopia and hyperopia in presbyopic patients. If astigmatism or ametropia remains after RLE, excimer laser surgery may be performed. The range of limited application is the correction of presbyopia in emmetropic eyes.

Patients should be informed of the potential long-term side effect of increased retinal detachment rates, especially in long myopic eyes.

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Italy



**By Simonetta Morselli, MD,
and Antonio Toso, MD**

Refractive surgery in Italy is considered aesthetic surgery. The government fully reimburses the health insurance system only for procedures that address diseases. Many patients who ask for refractive surgery abandon the idea when they discover that public insurance will not cover the cost. The government health system will reimburse refractive surgery on one condition: if the patient has a difference in refractive error of more than 4.00 D between his or her two eyes. Italy's health care system will cover expenses for the patient to correct anisometropia. For instance, if the patient's right eye is -8.00 D and left eye is -4.00 D, the right eye could be corrected to -4.00 D.

Although there are no official guidelines for refractive surgery in Italy, some refractive and anatomical considerations serve as guidelines in this country for practical purposes.

Corneal thickness. The corneal thickness must be sufficient to allow correction of the refractive error. If the indication is a corneal refractive procedure, whether LASIK or PRK, the postoperative residual pachymetry should not be less than 430 to 450 μm , regardless of the amount of myopia targeted. If the preoperative pachymetry is less than 480 μm , we do not recommend corneal refractive surgery for any amount of myopia, even -0.75 D, because this can be a sign of developing keratoconus.¹ Some surgeons perform corneal collagen cross-linking in conjunction with PRK or LASIK.² For the reasons listed above, the amount of myopia is not a determining factor for performing PRK, LASIK, or other corneal refractive surgical procedures.

Corneal curvature. It is important to consider preoperative corneal curvature before performing PRK or LASIK. We would like to obtain a postoperative curvature no flatter than 40.00 to 41.00 D when correcting myopia and no steeper than 48.00 to 49.00 D when correcting hyperopia. These guidelines must be taken into consideration because postoperative higher-order aberrations are important for the patient's quality of vision. The shape of the cornea is also important; PRK or LASIK is relatively contraindicated if the patient has keratoconus. Some surgeons perform collagen cross-linking at the time of PRK to correct refractive errors associated with keratoconus.² In these cases, the patient must be informed that the correction may not be permanent.

Presbyopia. Some patients with presbyopia are convinced that lasers must be able to correct their problem. Although some software has been designed for this purpose, we currently do not have a standardized refractive surgical procedure to offer to presbyopic patients.³⁻⁵

Hyperopia and hyperopic astigmatism. When treating these conditions, we take into consideration the patient's pachymetry, corneal curvature, and amount of hyperopia. For cases with up to 3.00 D spherical equivalent, PRK is suitable. For more than 4.00 D, we recommend LASIK with femtosecond laser flap creation (femto-LASIK). In our experience, PRK is not stable for more than 4.00 D of hyperopia; the cornea tends to revert to its original shape, causing a postoperative hyperopic shift that requires an enhancement.

Astigmatism. In the presence of more than 2.50 D of myopic or hyperopic astigmatism, we prefer to perform femto-LASIK to obtain good postoperative stability.

Age. For patients older than 40 to 45 years, we recommend femto-LASIK for reasons related to re-epithelialization and dry eye. These two conditions are related to the risk of postoperative infection and the delay of visual recovery.

LASIK versus PRK. We choose to perform femto-LASIK or PRK depending on the anatomy of the eye, the degree and type of refractive error, and the desire of the patient. If the patient does not want to feel pain after surgery or if he or she is a busy professional, then I recommend femto-LASIK if the anatomy of the eye is suitable for this procedure. For young patients, we recommend PRK because in Italy it is cheaper than femto-LASIK and it is free of intraoperative complications. The postoperative quality of vision is the same with PRK and femto-LASIK.⁶

If the anatomy of the eye does not match the requirements for a corneal procedure, we consider phakic IOL implantation for myopic prepresbyopic patients. In this case, we measure anterior chamber depth, endothelial cell count, and white-to-white distance. If these are appropriate, we implant the Acrysof Cachet IOL (Alcon Laboratories, Inc., Fort Worth, TX; not available in the United States), a foldable anterior chamber angle-supported IOL. We have been using this lens for 10 years and have not encountered any complications. Iridectomy is not needed, and the IOL is implanted through a 2.6-mm corneal incision. If the anatomy of the eye is not suitable for this IOL, we consider the Artisan phakic iris-supported IOL (Ophtec BV, Groningen, Netherlands; in the United States, Verisyse; Abbott Medical Optics Inc., Santa Ana, CA). If the endothelial cell count is not high enough in relation to the patient's age, we consider implanting a posterior chamber phakic IOL (toric if appropriate). If the patient is presbyopic, we consider performing clear lens extraction, especially in those with hyperopia. In some special cases, when early cataract is present, we consider implanting multifocal or bifocal IOLs.

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Spain



By Daniel Elies, MD

Although Spain does not have defined guidelines for refractive surgery, there is a general consensus that surgeons follow regarding preoperative workup, indications, and follow-up for various procedures. It is important to take into account that my country is covered by both public and private health services. The public health care system, which is universal and free, is responsible for approximately three-quarters of the cataract surgeries performed in Spain. The standard public coverage does not include premium IOLs or excimer lasers. Private ophthalmic centers have access to the leading technology in refractive surgery, such as lasers (excimer and femtosecond) and premium IOLs, and they offer a wider range of treatments than public centers.

Current refractive surgery trends in Spain show an increase in the use of surface ablation techniques, particularly advanced surface ablation and PRK; a rise in phakic IOL implantation, which makes up 4% to 5% of the total refractive surgery procedures performed on young patients; and an increase in the use of femtosecond lasers to create thin LASIK flaps. Refractive lens exchange (RLE) is becoming the technique of choice in patients older than 50 years. This may be due to the safety of the surgical technique, more accurate biometry, and the development of premium IOLs. In Spain, premium lens implantation represents approximately 10% to 12% of the 400,000 lenses implanted per year; of that, of those 40,000 to 48,000 premium lenses, 70% to 80% are multifocal, and 20% to 30% are toric IOLs (data on file with Alcon Laboratories, Inc., Fort Worth, TX, and Abbott Medical Optics, Inc., Santa Ana, CA). The percentage for premium IOLs is much higher if we consider only patients treated in the private setting.

The preoperative regimen for patients scheduled for refractive surgery requires a complete ophthalmic evaluation after discontinuation of contact lens use for at least 1 to 2 weeks. The evaluation includes subjective refraction under cycloplegia, slit-lamp examination with emphasis on the ocular surface and the quality of the tear film, mesopic and scotopic pupillary diameter, IOP, fundus examination, and corneal topography and pachymetry. In some cases, corneal hysteresis is also highly recommended. In Spain, the increasing use of customized laser surgery with aspheric ablations has made the pupillary diameter less relevant, provided that it exceeds 7.5 mm under scotopic conditions. Examining the tear film and the ocular surface has become more important, because it helps surgeons to decide whether the patient is a candidate for corneal refractive surgery.

Indications for surgical techniques vary according to the

patient's age. In Spain, refractive surgery is not approved in children, except in cases that cannot be managed with standard treatments such as high amblyopic anisometropia. Individuals must be at least 18 years of age to undergo corneal refractive surgery or phakic IOL implantation; however, surgeons generally prefer patients to be at least 20 years old. Corneal refractive surgery is the gold standard for all patients younger than 45 years who meet the accepted dioptric range. In older patients, the surgery of choice is RLE. Some exceptions can be made in terms of age limits. For example, RLE can be offered to younger (40-42 years old) high hyperopes and later (± 50 years) in high myopes.

Excimer laser techniques are considered the gold standard for myopic refractive errors up to -7.00 D and are widely used in this country, with approximately 180,000 procedures performed per year (data on file with Alcon Laboratories, Inc., and Abbott Medical Optics Inc.). Surface ablation procedures have recently become more popular among Spanish surgeons, now accounting for almost one-third of excimer laser procedures, mainly in patients with myopia up to -4.00 D. Mitomycin C is widely used, mostly in deep ablations, compound myopic astigmatism treatments, and enhancements. For patients with myopic errors greater than -7.00 D, the first option usually is implantation of a phakic IOL. A preoperative endothelial cell count of greater than 2,000 cells/mm² and an anterior chamber depth greater than 2.8 mm from the endothelium to the lens are required for phakic IOL implantation. In this country, 80% of phakic IOLs are posterior chamber models, and 20% are anterior chamber models.

In patients with hyperopia of up to 4.00 D, my first option is LASIK using an optical ablation zone of greater than 6.5 mm. When the hyperopic defect is greater than 4.00 D, implantation of a phakic IOL or, if presbyopia is present, a multifocal IOL is recommended.

The main surgical options for managing astigmatism in young patients include excimer laser ablation or implantation of toric phakic IOLs in those who are not LASIK candidates. For older, presbyopic patients, toric pseudophakic IOLs are the preferred approach. Incisional astigmatic surgery, such as limbal relaxing incisions, has practically been abandoned by surgeons in Spain; it is used only in patients undergoing cataract surgery with monofocal IOLs.

Intracameral cefuroxime is the intraoperative treatment used for infection prophylaxis in all intraocular refractive procedures (whether cataract surgery, phakic IOL implantation, or RLE). Topical antibiotics are prescribed postoperatively for 1 week and topical steroids for 2 to 4 weeks. For LASIK, I prescribe a combination of antibiotic and steroid drops three times daily for the first week and artificial tears five times daily for at least 2 months.

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United Kingdom



**By David P. S. O'Brart,
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There are no formal guidelines in the United Kingdom for refractive surgery. However, the Royal College of Ophthalmologists published its latest *Standards for Laser Refractive Surgery* in 2009.¹ These guidelines, which are reviewed annually, were developed in response to public concern about safety but are intended only to provide advice and assistance rather than definitive regulations in the following areas.

Experience and qualifications. Surgeons should be registered with the General Medical Council, maintain professional indemnity insurance, have a broad base of ophthalmic knowledge, ideally hold the Royal College of Ophthalmologists' certificate in laser refractive surgery, regularly audit their cases, undertake continuing medical education in refractive surgery, and be a member of a national or international refractive surgery association.

Laser facilities. Laser facilities must be appropriately registered. All equipment within the facility must be correctly maintained and calibrated with documented procedures for use. A back-up power supply for the laser is required. Staff must be adequately trained with demonstrated and documented competence, patient consultations must be conducted confidentially, and information outlining how to make a complaint or offer suggestions about the organization's services must be displayed.

Patient resources. Patient information should be in concise, nontechnical language and include the range of refractive surgery procedures offered along with their eligibility criteria, risks, benefits, and probability of achieving a desired goal. Surgeons' qualifications and previous substantive positions and a price list that explicitly details what is and is not included in each procedure fee should be available to patients. It is also recommended that all patients receive written postoperative directions with a 24-hour emergency contact number. They should also be given their preoperative keratometry and pachymetry readings, pre- and postoperative BCVA, refraction, and IOPs.

Informed consent. The consent process should follow General Medical Council and Department of Health guidelines. Written information must be given to patients

at least 24 hours before the procedure. Adequate time must be made before surgery to discuss the risks and benefits, to answer questions, and to confirm that patients understand the written and verbal information they have been given. It is recommended that patients have an appointment with a refractive surgeon prior to the day of the surgery. The consent form must reference the elective nature of the procedure and its specific risks and state that spectacles and contact lenses may still be required after the procedure. The surgeon is required to certify on the form that, in his or her opinion, the patient understands the risks and benefits of the procedure and alternative treatments.

Clinical governance. Surgeons must be responsible for patients' care and available to assess their suitability for surgery and must provide postoperative follow-up and emergency care (providing appropriate cover when on leave). Surgeons must undertake clinical audits and regularly review the results. They must also investigate, record, and collate all adverse events and report and discuss them with a Medical Advisory Committee or equivalent. There should be documented clinical protocols for all surgical procedures performed, including common variances from the care pathway, which have been made known to and agreed among all clinical staff. All entries in patients' notes should be clearly readable, signed, and dated.

Promotional materials. Advertising and marketing literature, which should be legal and adhere to the standards of the UK Advertising Standards Agency, must be factual, not misleading, and drafted and designed to prevent unrealistic patient expectations.

Postoperative evaluation. The refractive surgeon should be available at the first postoperative visit. He or she is responsible for ensuring that postoperative management is appropriate. Refractive surgeons should be fully trained in the management of postoperative complications and have facilities to provide microbiological and inpatient services if required. The patient's general practitioners should be informed of all procedures undertaken unless the patient requests otherwise. ■

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