

American Academy of Optometry  
Position Paper on Refractive Surgery  
Section on Cornea, Contact Lenses, and Refractive Technologies  
Information for Eye Care Practitioners  
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**What is Refractive Surgery?**

Refractive surgery is a category of treatments designed to induce structural change to the eye with the intent of altering its refractive status. There are two broad categories of refractive surgery: Keratorefractive, during which the physical architecture of the cornea is altered; and Intraocular, during which synthetic lenses are placed into the eye, with or without removal of the natural crystalline lens. Keratorefractive surgery comprises nearly 98% of the procedures performed in the United States (US).<sup>1</sup>

**What is the Market for Refractive Surgery?**

In the past two decades, increasing numbers of patients have been seeking permanent surgical change in their refractive status as an alternative to traditional spectacles and contact lenses. An estimated 1.4 million surgeries were performed in the United States in 2007.<sup>1</sup> The vast majority of patients seeking refractive surgery are myopic with or without astigmatism. The demand is driven by the incidence of refractive error in the country. The Beaver Dam Eye Study showed myopia present in 26.2% of participants.<sup>2</sup> A 2000 review of studies of US population data of patients over 40 showed nearly 30% with at least one diopter of myopia.<sup>3</sup> McCarty<sup>4</sup> found that the vast majority of myopes between the ages of 4 and 74 manifested less than five diopters. It has been estimated that 110 million Americans could or do achieve normal vision with proper refractive correction.<sup>5</sup> This results in a large potential patient base for these procedures.

## **Why Do Patients Choose Refractive Surgery?**

The primary reason given for considering refractive surgery is a desire for freedom from spectacles or contact lenses along with an intolerance and / or sense of inconvenience with these traditional forms of vision correction.<sup>6</sup> In its early years, refractive surgery was often perceived to be risky and unproven. Early adopters of the technology were thought to have psychological profiles consistent with dynamic personalities with risk-taking tendencies.<sup>7</sup> In the past 10 years there has been a significant increase in the number of patients undergoing refractive surgical procedures. With the evolution of treatment technology and an increased sophistication on the part of the industry to determine who is a highly qualified candidate for surgery, fewer complications and better outcomes have been reported resulting in refractive surgery becoming more mainstream.

Patient satisfaction is extremely high with refractive surgery.<sup>8-10</sup> The United States Army has stated that their experience shows “excellent outcomes and improved readiness” of service members.<sup>11</sup> A recent study by Bailey and colleagues<sup>12</sup> reported that 90% of patients who had undergone refractive surgery would recommend it to friends and family. The primary reasons given for the recommendation to others were elimination, or reduced need for spectacles and/or contact lenses and better visual acuity after surgery. These were very similar to the reasons given for initially considering surgery.

## **History of Keratorefractive Surgery**

Initially, there were two approaches to refractive surgery on the cornea: incisional and lamellar. For the treatment of myopia, a flattening of the central curvature of the cornea was necessary to decrease its effective convergent power. Incisional surgery, in which no tissue is removed from the cornea, was promoted by Fyodorov and others in the late 1970's and early 1980's based on the work of Sato in Japan. Dr. Sato noted that making incisions in the posterior stroma of keratoconus patients resulted in a flattening of the central cornea. Incisions through the endothelium were abandoned because of a very high rate of corneal decompensation.<sup>13</sup> Incisions made anterior-to-posterior through the cornea and up to 90% of the depth of the stroma was termed Radial Keratotomy (RK). With this technique, the

endothelium was left intact. The incisions were placed in a radial fashion in the paracentral and peripheral cornea. This weakened the structural integrity of the tissue allowing a forward bowing of the stroma in the area of the incision under the influence of the eye's natural intraocular pressure. The increase in peripheral curvature shorted the chord length of the surface resulting in a flattened central cornea. The flatter cornea had less dioptric power resulting in a decrease in myopia. The desired dioptric correction dictated the number, location and depth of these incisions. Perpendicular "T" cuts were made to correct astigmatism and circumferential cuts in a hexagonal pattern were applied for treatment of hyperopia.<sup>13-27</sup>

Initial refractive results with RK were positive but 10 year post-operative data showed refractive instability with nearly 40% of eyes showing a shift toward hyperopia.<sup>28</sup> Patients also complained of night vision problems as the incisions typically came within a few millimeters of the visual axis. When the pupil dilated under low light conditions, glare was created by the incision scars and aberrations increased. Due to the lack of dioptric accuracy, patient dissatisfaction and long-term loss of effect, RK has been more or less abandoned as a form of primary surgery. However, astigmatic keratotomy remains as a viable alternative for astigmatic correction in selected cases.

Lamellar surgery, which involves the removal of corneal tissue, had its genesis in the late 1940's with the work of Jose Barraquer, MD in Columbia. In the 1960's, he developed Keratomileusis, a technique for treatment of myopia that involved excising a button of corneal stroma with a microkeratome, freezing the tissue, reshaping it with a cryolathe and replacing the tissue in the patient's cornea. Automated Lamellar Keratoplasty (ALK) used a microkeratome to create a lamellar flap in the patient's cornea. A second pass of the instrument resected a disc of stroma to decrease the effective front surface curvature of the initial lamellar flap then sutured the lamellar tissue back into place. For treatment of hyperopia a deep lamellar cut was made to induce ectasia with resultant steepening of the cornea. All of these procedures were invasive and lacked a fine degree of control of the refractive outcome.

In 1983, Trokel et al<sup>29</sup> suggested the use of the 193nm excimer laser as a method to precisely alter the curvature of the cornea. Photorefractive Keratectomy (PRK) was its initial application. The epithelium was removed and the excimer energy applied to the stromal

collagen under computer control. The ultraviolet energy of the excimer laser broke carbon-carbon bonds in the collagen stroma vaporizing tissue. By accurate placement of the laser energy, a new shape could be imparted to the stroma. For myopic treatments, more stroma was removed centrally, decreasing the physical curvature of the cornea reducing its dioptric power. The epithelium then healed with a permanent change in the refractive power of the cornea. The first sighted eyes in the United States (US) were treated by Marguerite MacDonald, MD in 1988. Ionnis Pallikaris, MD from Crete suggested combining the excimer laser with a lamellar flap to maintain the integrity of the epithelium. He described this flap approach as Laser in situ Keratomileusis or LASIK.<sup>30,31</sup> The first excimer lasers were US Food and Drug Administration (FDA) approved for treatment of myopia in 1996 with approvals for treatment of astigmatism coming in 1997 and hyperopia in 1998.

Treatment of hyperopia presented challenges to treatment modalities like PRK and LASIK that involved the removal or ablation of the peripheral corneal stromal tissue. In a hyperopic eye, the effective curvature of the cornea needs to be increased to compensate for insufficient convergent power in the eye's optical system. The optical and geometric limitations of ablative surgery resulted in the development of other techniques to steepen the effective curvature of the central cornea by shrinking the peripheral stromal tissue. Stromal collagen is known to contract and shrink with the application of thermal energy in the range of 55° to 58°C. Application of thermal energy in a circular pattern to the peripheral cornea created a "purse string" effect inducing steepening of the central cornea.<sup>32,33</sup> This technique has evolved from use of a hot wire (Radial Thermokeratoplasty)<sup>33-35</sup> to use of a holmium laser (Laser Thermokeratoplasty – LTK)<sup>36,37</sup> to use of radio frequency energy (Conductive Keratoplasty – CK)<sup>38-42</sup> to alter the corneal shape. All of these procedures were fraught with inaccuracy and significant regression of outcomes. CK remains as a niche treatment for low degrees of hyperopia and for the induction of mild myopia in one eye of an emmetropic patient for a monovision-based treatment for presbyopia.<sup>43</sup>

In addition to "subtractive" surgeries like PRK and LASIK, "additive" surgeries exist for the treatment of high degrees of myopia. Phakic Intraocular Lenses (PIOL) were FDA-approved in 2004 and 2005 for the treatment of up to 20 diopters of myopia. This technique involves the placement of an artificial lens inside of the eye to alter the refractive state without removal of the natural crystalline lens. These lenses are either placed in the anterior

chamber attached to the iris or in the ciliary sulcus between the iris and the crystalline lens. They are a useful treatment in those eyes whose myopia cannot be addressed by subtractive technology for reasons that will be discussed. Some surgeons also suggest that removal of the crystalline lens, Clear Lens Extraction (CLE) with placement of a traditional Intraocular Lens (IOL) is a valid form of refractive surgery. As a class, invasive intraocular surgeries come with greater risk of inflammation, infection, retinal detachment, and elevated intraocular pressure than PRK and LASIK but may be appropriate in carefully selected patients. Currently, PIOL's and CLE are less than 2% of all refractive surgeries performed in the US.<sup>1</sup>

### **Keratorefractive Treatment Options**

Cornea-based ablative procedures can be broadly characterized under two categories: "Flap Surgery" or "Surface Surgery." The difference between techniques being the method used to expose the corneal stroma for treatment. Multiple acronyms exist for these approaches to the corneal stroma. Flap surgery is used to describe the surgery commonly known as Laser in situ Keratomileusis (LASIK). LASIK comprised over 84% of refractive surgeries performed in the US during the first quarter of 2008 (Q1-2008).<sup>1</sup> With LASIK, a lamellar corneal flap is created and reflected to expose the stromal collagen for ablation with the excimer laser. The corneal flap may be created with a mechanical microkeratome or a femtosecond laser. The microkeratome creates the flap with a rapidly oscillating blade passed across the cornea. This technology is based on the early work of Barraquer. Femtosecond lasers, FDA approved in 2002, use precisely focused bursts of non-excimer laser energy to create a cavitation bubble cleaving stroma.<sup>44, 45</sup> Accurate placement of millions of cavitation bubbles can create the lamellar flap. At question now is whether the accuracy of flap creation is better with use of the femtosecond laser as opposed to the microkeratome.<sup>46-49</sup> Both approaches have excellent outcomes and time will decide if one is safer or more efficacious than the other.

Once the hinged flap has been created and reflected, the excimer laser energy is applied under computer control to resculpt the collagen. For pure myopic treatment, tissue is removed in a uniform pattern, more centrally than peripherally, to decrease the radius of curvature and the dioptric power of the cornea. When treating astigmatism, differing amounts

of tissue are removed in different meridians. Treatment of hyperopia involves removal of tissue in a mid-peripheral circumferential fashion to increase the effective curvature and dioptric power of the central cornea. Following ablation, the flap is replaced onto the ablated stroma. There is stroma on the underside of the flap and, when replaced, an adhesion develops between the flap stroma and unaltered posterior corneal stromal bed. Chemical adhesion between the proteoglycans in the stromal ground substance and the inward osmotic gradient present in the cornea secondary to the endothelial pump mechanism holds the flap in place without the need for sutures.<sup>50</sup> Within hours the corneal epithelium seals the anterior-most edge of the flap incision. Although the seam, or interface, between the flap and residual corneal stroma never disappears with tissue knitting together, the flap is extremely stable within a matter of days. As there are no exposed nerves after flap replacement, there is little discomfort following LASIK. As the epithelial layer is not disrupted, vision is excellent within a matter of a day or two in most cases. The most active healing occurs in the first several weeks after treatment and LASIK eyes tend to be refractively stable within one to three months of surgery.<sup>51</sup>

Surface ablation surgery has many different acronyms, each of which represents a subtle difference in technique for removal of the corneal epithelium. PRK or Photorefractive Keratectomy is the traditional term for this procedure. To expose the collagen stroma for PRK, the corneal epithelium is removed via mechanical debridement with a blade, blunt instrument or rotating brush. For Laser Epithelial Keratomileusis (LASEK), the surgeon uses a dilute alcohol solution applied to the cornea to soften the basement membrane to assist with removal of the epithelium.<sup>52</sup> Epi-LASIK procedure uses a blunt-bladed microkeratome or epikeratome to push the epithelium aside.<sup>53</sup> With both LASEK and Epi-LASIK, the surgeon may elect to retain the epithelial flap replacing it at the end of the treatment or remove it prior to laser ablation. These various approaches to removal of the epithelium have been placed by many under the umbrella “Advanced Surface Ablation” or simply “Surface Ablation.” Surface surgeries were 13.2% of procedures performed in the US during Q1-2008.<sup>1</sup>

Following surface ablation, a bandage soft lens is placed on the treated eye to protect the healing epithelium. With LASEK or Epi-LASIK, the original epithelial layer may be replaced prior to insertion of the bandage lens. In either case, the cornea will re-epithelialize within two to three days. The original epithelial flap, if retained, will slough as the treated

cornea re-epithelializes.<sup>54</sup> During this period of time the patient may experience significant discomfort and require oral analgesia. After epithelial recovery, usually five to six days, the bandage lens is removed. As the newly healed epithelium is not smooth and regular, vision in the first few weeks after PRK may be reduced. As the surface smoothes and recovers optical quality, the clarity of vision improves. It is not uncommon for a surface treatment eye to require up to three months to achieve maximum acuity.

Refractive outcomes are virtually identical with LASIK and surface ablation surgery.<sup>55,56</sup> The process and time for visual recovery differentiate the procedures. The decision as to which procedure is most appropriate is based on several factors. Patient choice is always the first option, with all other factors being essentially equal. The primary reason for choosing surface surgery over flap surgery is the estimated residual stromal bed that will be left in the cornea after ablation. A rare, but devastating complication following keratorefractive surgery is keratectasia, a keratoconus-like progressive thinning and ectasia of the cornea.<sup>57-61</sup> Historically, and with no scientific evidence, 250 microns was chosen to be the minimum desired residual stromal bed thickness to prevent keratectasia.<sup>58, 62</sup> Simple calculations were suggested to predict safety (e.g. total corneal thickness - predicted flap thickness - ablation depth = residual stromal bed).<sup>63</sup> Although one could predict ablation depth with some accuracy, flap thickness was widely variable, especially with early generation microkeratomes. This made the calculation suspect. If the calculated residual stromal bed was less than 250 microns, surface surgery was chosen to leave more stromal tissue unablated. Although keratectasia is extremely rare with surface surgery, it had been reported as have LASIK cases where the residual stromal bed was documented to well above 250 microns.<sup>64-69</sup> Current literature suggests that the minimum residual stromal bed be at least 300 microns.<sup>70-72</sup> Much uncertainty exists between the “optimal” residual stromal bed thickness and the incidence of keratectasia. Residual stromal bed thickness is just one piece of the keratectasia risk puzzle and must be weighed in conjunction with other factors such as corneal topography and corneal architecture.<sup>73-80</sup> This uncertainty has led to the upswing in the number of surface surgeries being performed in the past five years, especially in the higher myopic population where ablation depths increase. Another reason to consider a surface surgery over a flap procedure is mechanical. Corneas that are very steep or very flat are at greater risk of complication while creating the lamellar flap with a microkeratome.<sup>81-83</sup>

Before the advent of femtosecond laser technology, many of these eyes were earmarked for surface treatment. The method of creation and the thinner femtosecond laser flap reduces some of these risks and allows otherwise ineligible patients to have LASIK.

Once the more appropriate laser treatment to the corneal stroma is determined, there are two ways to program the excimer laser to apply the necessary ablation. “Conventional” ablation uses the patient’s refractive data to treat sphere and cylinder, commonly referred to as “lower order aberrations.” Work performed by Liang, Williams and others in the late 1990’s showed that the optics of the eye also suffered from more subtle optical imperfections termed “higher order aberrations.”<sup>84-87</sup> These aberrations (e.g. trefoil, coma, spherical aberration, quadrafoil) tend to impact quality of vision by decreasing contrast acuity more than actual Snellen acuity.<sup>86, 88-90</sup> Higher order aberrations may be considered to represent an optical fingerprint and are unique to every eye. The presence and the induction of higher order aberrations (particularly spherical aberration and coma) by early excimer laser platforms was a prime cause of the night vision symptoms (glare, starbursts, halos) reported by refractive surgery patients.<sup>91, 92</sup> The development of wavefront sensors to quantify the amount of pre-operative higher order aberration and the ability to transfer this data to treatment platforms has reduced the risk of visual complications.<sup>87, 93-95</sup> “Customized” or “wavefront-guided” ablation limits the induction of higher order aberrations (particularly spherical aberration) and may reduce pre-existing aberrations during treatment. As a result, the reported subjective quality of vision is improved. “Wavefront optimized” platforms apply an adjustment for a population average of spherical aberration in an attempt to reduce the amount induced during treatment. Outside of the United States, customized platforms are available that are guided by corneal topographic data.

Some of the early problems observed with both LASIK and surface surgery were technology related. The first excimer lasers approved were “broad beam” devices. They applied the laser energy with relatively large area pulses resulting in a decrease in surgical precision. Interference with the laser beam by vaporized stromal tissue resulted in “central islands” where less tissue was ablated than intended. The early broad beam lasers also had very small effective treatment zones, which were found to decrease the optical quality of the ablation. Patient cooperation in being able to hold the eye still during treatment also decreased quality of outcomes, especially in astigmatic treatments where centration was

critical. Newer generation excimer lasers such as the flying spot class use a very small, accurate treatment spot that can be placed on the cornea in such a way as to avoid the interference that caused central islands. This degree of precision has also made it possible to treat higher degrees of astigmatism. Tracking systems are now standard and follow the subtle X/Y axis eye movements all patients exhibit during treatment, realigning the treatment beam to assure centration. Newer tracking systems are becoming available that can also follow cyclorotational movements of the eye. All of these technological advances have served to increase the accuracy and safety of treatment.

### **Is Refractive Surgery Safe?**

Many studies have been published reporting on the long-term results of keratorefractive surgery. Excellent outcomes have been reported for myopic LASIK<sup>96-99</sup> and PRK<sup>100-103</sup> as well as hyperopic LASIK<sup>104-107</sup> and PRK<sup>108-111</sup>. Nothing suggests that keratorefractive surgery, in an otherwise eligible patient, induces future harm to the physiology of the cornea, alters the development/progression of presbyopia or increases the risk of the development of cataracts, glaucoma (?? NOTE: Patients with advanced glaucoma are not good LASIK candidates due to elevated IOP produced by suction ring; also patients with steroid-induced glaucoma are high risk patients for PRK/PTK due to prolonged steroid use after the procedure) or macular degeneration. Until recently, it was more of a challenge calculating the appropriate intraocular lens power for use after cataract extraction in a patient who had undergone keratorefractive surgery, but the development of new IOL lens power calculation nomograms has significantly improved precision.

In a certain percentage of eyes treated, the intended refractive outcome will not be achieved. The eye may be undercorrected, overcorrected or may demonstrate regression in which there is loss of the refractive effect with time. During initial evaluation, calculation should be made to allow for repeat or enhancement surgery for residual refractive error. The risk of requiring retreatment increases with the degree and complexity of the refractive error. In particular, retreatment is more common with high degrees of hyperopia and/or astigmatism. Newer excimer laser technology has reduced the incidence of retreatments for all refractive errors.

Individuals expecting lifetime freedom from corrective lenses will be disappointed once they reach presbyopia, as they will begin to need glasses for clear vision from closer than arm's length. One option for the management of presbyopia is monovision. Monovision is a method of prescribing vision correction that attempts to provide far vision in one eye and near correction in the contralateral eye.<sup>112</sup> Monovision is a compromise: the vision for long distances is not always as good as it would be with both eyes having full correction, and the near vision may not necessarily be as good as it would be with reading glasses. It may, however, allow the patient to reduce overall dependence on glasses once they reach presbyopia.<sup>112-116</sup> Monovision has been successfully used for decades with contact lenses. Additionally, contact lenses offer the ability to continually adjust the corrective lens power to adjust focus that is not offered by refractive surgery. Trial use of contact lenses before surgery can help guide decisions regarding the advisability, laterality, and degree of monovision attempted by the procedure.<sup>112-116</sup>

### **Intraocular Lens Treatment Options**

Most refractive surgeons agree that safety and accuracy of keratorefractive surgery declines in eyes having more than 10 diopters of myopia or 4 diopters of hyperopia. For these patients, intraocular lens surgeries may be an option. First FDA approved in 2004, Phakic Intraocular Lenses (PIOLs) are available to treat myopic eyes up to 20 diopters. PIOLs are an additive concept procedure in which an artificial lens is placed in the eye in addition to the crystalline lens. Initial outcomes with PIOLs have been excellent.<sup>117-125</sup> As of this writing, there are two lenses available: the Verisyse lens from Advanced Medical Optics (AMO) and the Visian lens from Staar Surgical. The Verisyse is an anterior chamber iris-clip lens that is attached to the surface of the peripheral iris. It does not interfere with normal pupillary function and allows for normal dilation of the pupil. The Visian lens is placed in the ciliary sulcus between the iris and the crystalline lens. Currently neither lens is available to correct astigmatism or hyperopia. Patients being considered for PIOLs must have adequate depth in the anterior chamber to accommodate the lens without impinging upon the corneal endothelium. The FDA has also established age-specific standards for minimum safe endothelial cell densities to assess corneal health prior to implantation. These lenses are not

currently available for hyperopic correction. One reason is that the hyperopic eye tends to have shorter anterior-posterior axial lengths with a resultant shallow anterior chamber and inadequate physical space for placement of the lens.

For hyperopic refractive errors beyond the acceptable range for keratorefractive surgery, clear lens extraction (CLE) may be an option. The natural crystalline lens is removed using traditional cataract phacoemulsification techniques with an intraocular lens placed in the eye to significantly reduce or eliminate the refractive hyperopia. In younger patients, this approach results in the immediate loss of accommodative ability. The recent introduction of multifocal and pseudo-accommodating IOL's has made the procedure more acceptable. CLE is not considered a primary treatment for high myopes due to the increased risk of retinal detachment following the procedure.<sup>126, 127</sup>

### **Who May be Considered a Candidate for Cornea-based Refractive Surgery?**

The first determinant for candidacy is the degree of refractive error that must be corrected. As previously discussed, corneal treatment may be considered for eyes with a refractive error ranging from approximately 10 diopters of myopia to 4 diopters of hyperopia. Newer treatment software allows for up to 6 diopters of astigmatism to be considered for treatment. Minimum corneal pachymetry measurements are essential to demonstrate adequate residual corneal stromal bed thickness. Depending on the platform, FDA approvals require the patient to be either 18 years or 21 years old. Independent of age, with a younger patient, refractive stability should be confirmed. Many younger patients are seeking refractive surgery to reach a career goal (police, fire, military service) before their refraction has stabilized. These individuals must be counseled that treatment will not prevent further progression and they should have adequate residual stromal bed to permit retreatment if needed in the future.

Corneal health is paramount in determining safety for refractive surgery. Particular attention must be paid to the eye's corneal topography. Pre-existing ectatic disease such as keratoconus or pellucid marginal degeneration have been directly linked to post-operative keratectasia.<sup>128-130</sup> The pre-operative topography must be scrutinized for any asymmetry suggestive of this risk.<sup>69-72, 131, 132</sup> The cornea should be free from any form of progressive

dystrophy or degeneration that might compromise outcomes or increase risk of complication. For both ectatic disease and dystrophy/degeneration, a careful family history is required to assess potential for future risk. The eye must be examined for any pre-existing dry eye syndrome or ocular surface disease. This can compromise outcomes or result in an intractable dry eye.<sup>82, 83, 133-137</sup> Patients with Meibomian Gland Dysfunction or blepharitis should be treated prior to surgery. As LASIK surgery induces temporary dry eye due to loss of sensory innervation following creation of the lamellar flap,<sup>133</sup> surface pre-treatment should be considered for patients with marginal dry eye in which there is no demonstrable damage to the ocular surface.

Patients with glaucoma and retinal disease may be considered for refractive surgery if they have good best corrected visual acuity and otherwise stable eye health.<sup>138, 139</sup> With glaucoma, special attention must be given to the patient's pre- and post-operative intraocular pressure. It is known that central corneal thickness influences the measurement of intraocular pressure.<sup>140</sup> It has been demonstrated that post-operative intraocular pressures may be significantly lower following keratorefractive surgery.<sup>141</sup> It has been suggested that serial tonometry before and after surgery might be useful to establish new baseline pressures as there is no consensus on a formula to apply to pressure readings to adjust for the alteration induced by surgery.<sup>142</sup> There is also no consensus as to whether application of a suction ring during LASIK and the accompanying temporary increase in intraocular pressure could cause damage to the glaucomatous optic nerve head. Special attention should be paid to optic nerve head morphology and structure in post-refractive surgical patients with glaucoma.<sup>143</sup> Glaucoma patients with demonstrable visual field loss should be considered at additional risk when being considered for keratorefractive surgery. The eye care practitioner managing the patient's condition should be consulted prior to recommending surgery. For safety of the patient, truly monocular patients should not be considered for refractive surgery due to the risk of loss of best-corrected visual acuity in the treated eye. Patients who have strabismus are not excluded from refractive surgery unless they are also amblyopic. It is unwise to treat the non-amblyopic eye if the amblyopic eye has best corrected visual acuity of less than 20/40. Many surgeons will not treat if the worse eye is less than 20/25, again for risk of losing best-corrected visual acuity in the better eye.

Systemic health conditions may impact the outcomes of refractive surgery. The first FDA approvals for PRK came with recommended contraindications for surgery in patients with a broad spectrum of systemic disease from autoimmune disease to diabetes to the formation of keloids following skin wounds. The current literature is quite clear that patients with a systemic diagnosis who are well controlled and otherwise healthy, may be considered for surgery.<sup>144-148</sup> Absolute contraindications would include diabetes with eye signs or inadequate control due to the possibility of an unstable refraction or compromised corneal innervation<sup>149</sup> and rheumatoid arthritis with Sjögren Syndrome due to the pathologic dry eye that is part of the disease. Careful attention should be paid to the psychological state of patients taking medication for clinical depression as they may respond poorly should there be an unintended outcome or surgical complication. Patients taking medications with anticholinergic side effects should be carefully screened for tear film problems secondary to the medications. Patients with arthritis without Sjögren's Syndrome, lupus, HIV/AIDS, type 2 diabetes and other systemic diseases may be considered for refractive surgery on a case-by-case basis.<sup>145, 146</sup>

The goals and expectations of the refractive surgery candidate must be carefully considered prior to treatment. They must understand that presbyopia is inevitable and that some form of reading correction will be required. They must be perfectly comfortable that the benefits of refractive surgery outweigh the risks. They must realize that despite the best of care pre-, peri- and post-operatively, complications may occur and that those complications could lead to a permanent loss of best spectacle corrected vision. They must also understand they will be responsible, to some degree, for the success or failure of their surgery and must be willing to be an active participant in their care. A patient with unrealistic expectations, even if clinically appropriate for treatment, should be approached with great caution as they may never be satisfied with their outcome.

### **The Role of the Doctor of Optometry**

The doctor of optometry is often the first eye care professional that a refractive surgery candidate consults and is the first person to counsel these patients, particularly if he/she has followed and treated the patient over a number of years. It is extremely important

that the doctor of optometry be very familiar with all of the options for altering refractive error, so that the patient can be thoroughly counseled. The “family eye doctor”, a role that is commonly filled by the doctor of optometry, is in a unique position to advise the patient on the appropriateness of these procedures. In many cases doctors of optometry have long-term relationships with patients and their families which can give the doctor/patient relationship a level of confidence that is of great value to the patient. Although doctors of optometry may participate financially by managing the post-operative care of refractive surgery patients, this is balanced by a relatively large time commitment in educating and then monitoring the patient.

Very few doctors of optometry have been trained to perform laser-based refractive surgical procedures. Most procedures discussed thus far have been performed exclusively by ophthalmic surgeons. Due to legislative restriction, the role of the doctor of optometry in most states is that of case manager participating in patient education, counseling the patient concerning treatment options, identifying qualified ophthalmic surgeons, discussing monovision, and providing post-operative care.

Once the procedure has been performed, the doctor of optometry may resume care of the patient, monitoring the healing response of the treated eye(s). Patients are typically seen on the first post-procedure day by the operating surgeon. If stable, the patient’s care may be transferred for co-management to their family eye doctor. The doctor of optometry must understand the dynamics of the healing response of the cornea, be able to recognize potential problems and be capable of providing any necessary treatment to ensure the safety of his or her patient.

### **The American Academy of Optometry’s Position**

The American Academy of Optometry recognizes that refractive surgical procedures can have significant advantages for carefully selected patients. Prior to submitting to such procedures, patients must be fully informed of both the potential benefits and complications related to surgery. Realistic expectations on behalf of the patient are of paramount importance in obtaining a satisfactory outcome.

Optometric involvement in the process of evaluation, education and consent can be of particular value to the patient who must rely on the professional judgment of a practitioner in the choice of procedure and targeted refractive outcome. In order to fill that role, the doctor of optometry must be appropriately educated and willing to assist in the care of the patient. Where allowed by law, doctors of optometry who have obtained appropriate training and certification may perform the actual procedure. Following the procedure, optometric management and care of the patient should continue through the complete healing process.

The American Academy of Optometry realizes that refractive surgery is an important area in the field of vision and eye care. As new procedures are introduced and as the body of outcome data continues to grow, opinions regarding this group of procedures will necessarily be modified.

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