

MEDICAL NON-CANDIDATES FOR REFRACTIVE SURGERY:
A STATISTICAL ANALYSIS

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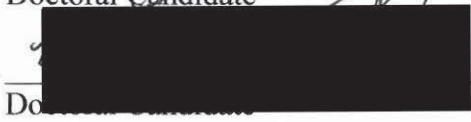
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Non-Surgical Candidates of LASIK Surgery; a Statistical Analysis

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ABSTRACT

Introduction: Thousands of patients each year are referred to LASIK surgeons for a consultation to determine their candidacy for the procedure. This retrospective study will evaluate the medical records of hundreds of non-surgical candidates in a metropolitan population with the goal of helping to guide practitioners when recommending LASIK surgery. *Methods* The medical records of all medical non-candidates who presented between October 2011 and January 2015 for an evaluation for LASIK surgery at the Lasik Vision Institute in Brookfield, Wisconsin were selected for the analysis. *Results:* The sample size was 573 non-surgical candidates, which represented 7.9% of all patients seen for a consult in the specified time period. All non-surgical candidates were categorized into groups identifying the medical reason for denial of surgery as well as the percentage of candidates relative to the total number of candidates. *Conclusions:* Data has shown that patients consult with optometrists prior to seeking a refractive surgery consultation, and therefore optometrists should be knowledgeable and serve as a resource to the patient. This study has shown that the most frequent cause of rejection is related to refractive error which is outside of FDA parameters. As the gatekeepers of eyecare, optometrists should advise patients accordingly. The success rate of patients achieving visual acuity of 20/40 or better is 97%, and furthermore, 90% of all patients achieve visual acuity of 20/20 or better. In order to keep the success rate so high, appropriate selection of candidates is imperative.

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CHAPTER 1

INTRODUCTION OF REFRACTIVE SURGERY

Every day there are thousands of patients inquiring about refractive surgery, such as Laser-Assisted in Situ Keratomileusis (LASIK) or Photorefractive Keratectomy (PRK). These patients are referred to LASIK surgeons for a consultation to determine their candidacy for the procedure. Many are denied the opportunity to have the procedure done due to many reasons, some of the more common reasons being ocular surface disorders, excessively high or unstable refractive errors, and the presence of systemic or ocular disease that may adversely affect the surgical outcome. This retrospective study will evaluate the medical records of hundreds of non-surgical candidates in a metropolitan population with the goal of helping to guide practitioners when recommending LASIK surgery. The results of this study will be used to educate optometrists on the indications, relative contraindications, and absolute contraindications of LASIK candidates.

During the late 1980s, theoretic applications using the 193-nm Argon-Fluoride (ArF) excimer laser on humans were postulated^{1,2}. One application was to reshape the cornea with the laser causing a refractive change. In 1988, Munnerlyn, Kroons, and Marshall developed an algorithm correlating diameter and depth of the ablation to the required desired dioptric change in the human cornea². Dr. McDonald performed the first

excimer laser surgery on a human myopic eye¹. This type of procedure would eventually be called Photorefractive Keratectomy (PRK). Following the successful application of correcting myopia, the Food and Drug Administration (FDA) organized a 3-phase trial to demonstrate the safety, predictability, and stability of laser technology on eyes that concluded in 1996³. Following the advent of PRK, LASIK became a more convenient and popular alternative because the patient obtains improved acuity faster with less pain and faster healing. Figure 1 summarizes the process of LASIK surgery.

The mechanism of treatment is known as photochemical ablation because every photon produced by the excimer laser has 6.4 eV of energy, thus being enough to break covalent bonds of the corneal tissue¹. The length of treatment is typically 30 seconds or less. The laser pulses many times per second.

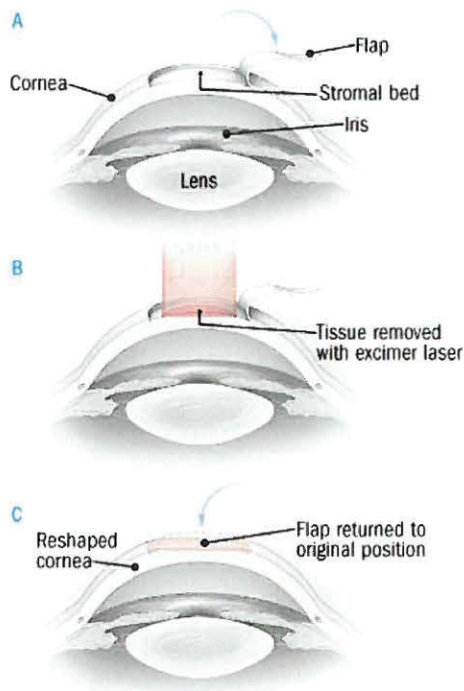


Figure 1: A) Flap is created and retracted to expose the stromal bed. B) Treatment is delivered via an excimer laser. C) Flap is returned to original position with treatment zone underneath².

A study comparing PRK and LASIK found that both procedures offer effective correction of myopia, hyperopia, and astigmatism^{3,4}. However, that same study found LASIK resulted in less discomfort and faster wound healing. Similar benefits and risks exist between LASIK and PRK. The benefits of PRK over LASIK are refractive correction on corneas that otherwise are not suitable for LASIK such as thin or steep corneas with less risk of regression^{3,4}.

Patient eligibility is one of the most important factors in selecting any refractive surgery patient. Contraindications can be separated into two categories: relative and absolute. The relative contraindications must be carefully evaluated on a case by case basis. Examples include cataract formation, monocularly, patients under the age of 25, diabetics without retinopathy, history of herpes simplex, corneal dystrophies and degenerations, moderate dry eye, and early glaucoma patients⁴⁻⁷. Absolute contraindications are conditions, where under no circumstances, should surgery be performed. Examples include pregnancy, acquired immune deficiency syndrome (AIDS), lupus, rheumatoid arthritis, keratoconus, keloid scarring disorders, and severe dry eye⁴⁻⁷.

The pre-operative exam should include measuring corneal thickness, eye dominance, manifest and wet refraction, corneal topography, intra-ocular pressure, anterior and posterior segment evaluation. If dry eye is suspected, additional testing should be considered such as Shirmer's testing, tear lab, or the phenyl red thread test. After all testing, the patient must be counseled regarding the risks, benefits, and realistic

expectations of any cosmetic refractive surgery procedure. All of these tests help to determine whether or not a patient is a candidate for refractive surgery.

CHAPTER 2

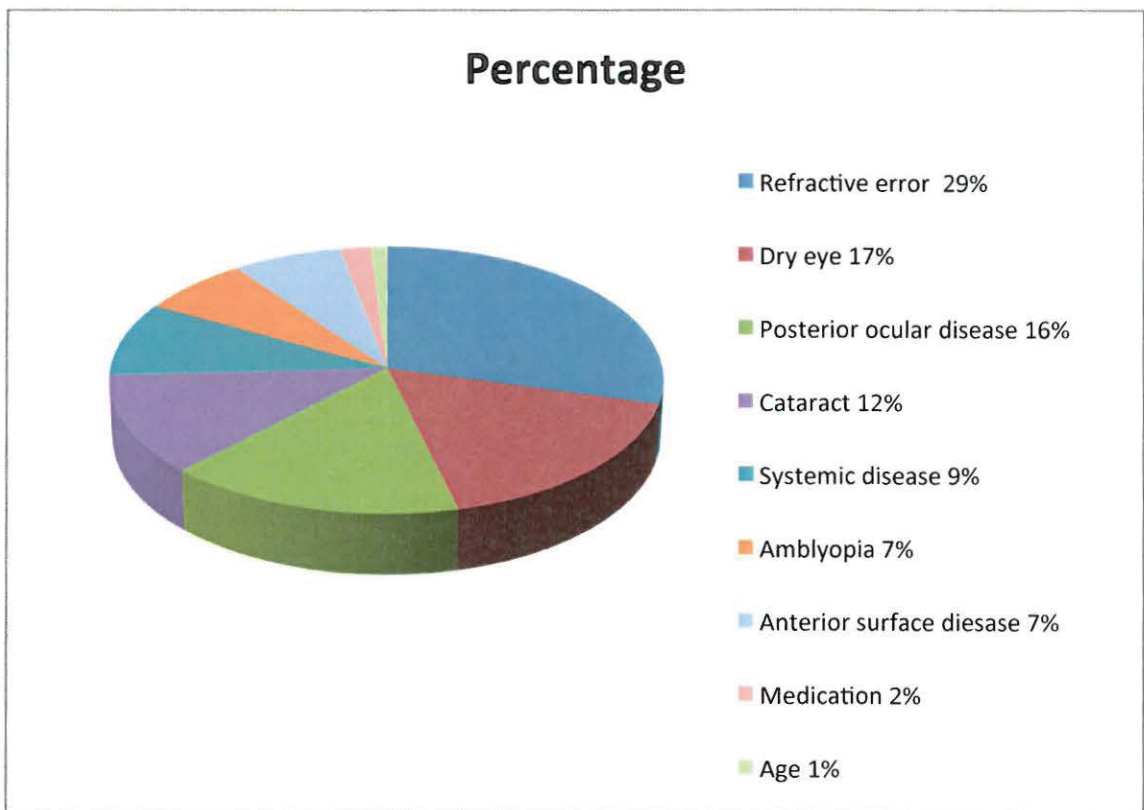
METHOD OF COLLECTION OF DATA

The information was gathered from a database at the Lasik Vision Institute located in Brookfield, Wisconsin. The majority of patients live within a 50 mile radius, however, patients desiring surgery come from up to 300 miles away. This center recruits patients from multiple states outside of Wisconsin including Michigan, Illinois, Indiana, Minnesota, and Iowa. There are approximately nine new patient evaluations each day. Over the course of one year, approximately 2,200 new patients present for a consultation for refractive surgery. During the pre-operative exam, each patient is categorized as a candidate for LASIK, a candidate for PRK, or a medical non-candidate. The medical non-candidates can be classified into subcategories based on refractive error, anterior surface disease, posterior segment ocular disease, or for systemic medical reasons.

Every new patient is required to complete a lifestyle survey including information about hobbies, occupation, medical history, and other analytics. When each patient completes the lifestyle survey, the data is collected and used for future analysis. During the course of this project, no new paperwork was requested to be completed by the patient. All the data was gathered from pre-existing paperwork. No personal information was collected for use in this project.

The medical records of all medical non-candidates who presented between October 2011 and January 2015 for an evaluation for LASIK surgery were selected for the analysis. Patients that underwent refractive surgery were not selected for the analysis. The sample size was 573 patients with no prejudice to race, ethnicity, gender, age, or lifestyle. The documented medical reason for not performing surgery was selected for further statistical and qualitative analysis.

Chart 1: Percentage of Non-candidates for each Category.



CHAPTER 3

RESULTS OF MEDICAL NON-CANDIDANCY

The 573 non-surgical candidates represented 7.9% of all candidates that underwent a consultation during the stated time period. According to our sample population, the most common reason for denial was related to refractive error. The LASIK Vision Institute uses the Visx 4 laser with FDA recommended refractive error parameters of up to -10.00 diopters sphere, +4.00 diopters sphere, and 4.00 diopters cylinder^{6,9-12}. We defined our sample using the FDA parameters as the cutoff. A total of 168 patients of 573 fall into this category and represent 29.32% of the total population.

Specifically within the refractive error category, we subdivided it further. The most common subcategory was excessive myopic spherical refractive error; 57 patients (9.95%) of the 573 patients total fall into this category. This is classified as more than -10.00 diopters according to the FDA guidelines. This type of refractive error is common in patients with diseases like posterior staphyloma or diseases that are lenticular in nature^{8,11}. Figure 2 details an example of posterior staphyloma.

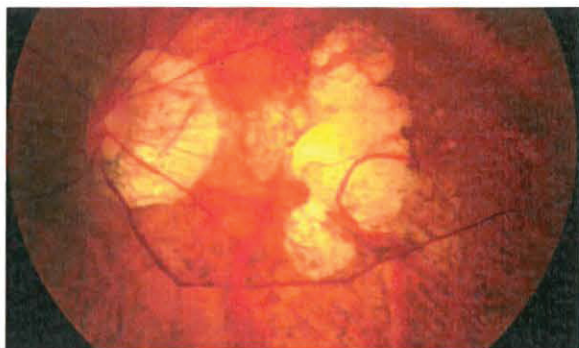


Figure 2: Posterior staphyloma with significant peripapillary atrophy, tilted optic disc, and large Fuch's spot revealing underlying choroid¹³.

The second leading subcategory was hyperopic spherical refractive error; 39 patients (6.81%) of the 573 total patients fall into this category. This is classified as more than +4.00 diopters according to the FDA guidelines. If patients were treated with greater than 4.00 diopters of hyperopia, they would experience excessive aberrations¹². These excessive aberrations would cause symptoms of light halos and the patients would subjectively dislike their vision.

The third leading subcategory is unstable refractive error; 34 patients (5.93%) of the 573 patients total fall into this category. Typically this is associated with younger patients, however, it is not always limited to younger patients. An example of an older patient with unstable refractive error is a newly diagnosed diabetic without any visible retinopathy. Literature varies on which specific age refractive error stabilizes; some literature suggests the age of 21 while others suggest waiting until the age of 25 to check for stability^{5,8}. The surgeon used the age of 25 at this surgery center. In order to verify a stable refractive error, the surgeon requires all patients under 25 to show a previous eye exam or prescription. If the refractive error is significantly changed, the surgeon will

recommend waiting on surgery however if the refractive error is similar, the surgeon will perform surgery.

The fourth leading subcategory was too high of cylinder power; 31 patients (5.41%) of the 573 patients total fall into this category. This is classified as more than 4.00 diopters of astigmatic power according to the FDA guidelines. Often such irregular astigmatism is lenticular in origin and thus is difficult to treat with refractive surgery.¹⁴

The laser treatment is only performed on the cornea and would not correct any lenticular irregularity. Figure 3 displays retinoscopy of such a patient with irregular lenticular astigmatism.

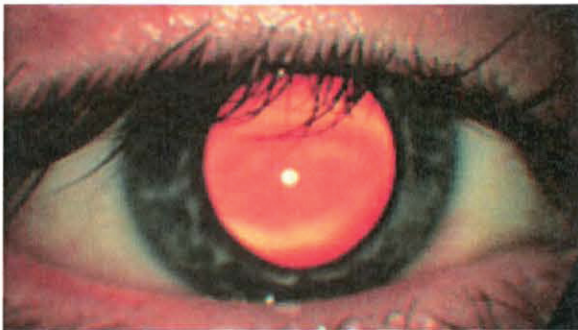


Figure 3: Large irregular astigmatism revealing the irregular bending of light¹⁵.

The last subcategory was patients with refractive error which was too low. Only 7 patients (1.22%) of the 573 patients total fall into this category. Although rare, some patients desire better vision even though they have 20/20 uncorrected visual acuity. The surgeon typically will only treat patients with uncorrected visual acuity of 20/30 or worse. The benefits do not outweigh the risks when the patient's uncorrected visual

acuity is better than 20/30. The goal of any elective medical treatment is to act in the best interest of the patient by weighing the risks and the benefits.

The next main category of medical non-candidates was dry eye representing 97 patients (16.92 %). Like the refractive error category, we subdivided this large group into two groups: those who failed dry eye therapy and those who never initiated therapy. If the dry eye treatment was successful the patient was considered a candidate and ultimately received laser treatment. Dry eye is one of most significant postoperative complaints¹⁶. Dry eye will be exacerbated by surgery and is often difficult to treat. It degrades the quality of vision and the patient is subjectively dissatisfied¹⁶⁻¹⁸. Figure 4 describes an example of a Keratoconjunctivitis Sicca (KCS), or dry-eye, patient with fluorescein staining. The first subcategory of the dry eye patients were patients that tried and ultimately failed with a three month trial of dry eye therapy. Seventy-one patients (12.39% of total sample, 73.19% of dry eye sample) fall into this category. Therapy could have included but was not limited to Restasis, fish oil capsules, artificial tears, or punctal plug insertion. The second subcategory were patients that elected to not try therapy, into which 26 patients (4.54% of total sample, 26.80% of dry eye sample) were classified. Some reasons for this decision may have been the cost of therapy, no guarantee of successful cure of dryness, or lack of desire.

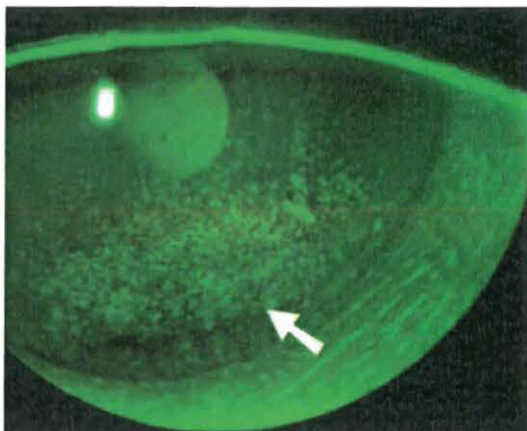


Figure 4: Patient with severe Keratoconjunctivitis Sicca. The white arrow shows areas of epithelial staining with fluorescein¹⁹.

Posterior segment disease was represented by 91 patients (15.99%) of the total population. This group was further classified into two subcategories based on location of disease: optic nerve and retina. Optic nerve disease is an example of vision loss that is not refractive in origin representing 18 patients (3.14%). Examples of optic nerve disease are glaucoma suspects, hypoplastic optic nerves, and ischemic neuropathy. Treating any refractive error in this type of patient would not improve best corrected visual acuity. Figure 5 shows the difference between a normal optic nerve and one which is glaucomatous. The other subcategory is retinal disease representing 73 patients (12.74%). Examples include previous macular holes, ischemic retinopathy, diabetic retinopathy, or hypertensive retinopathy. Figure 6 shows examples of some forms of retinopathy.

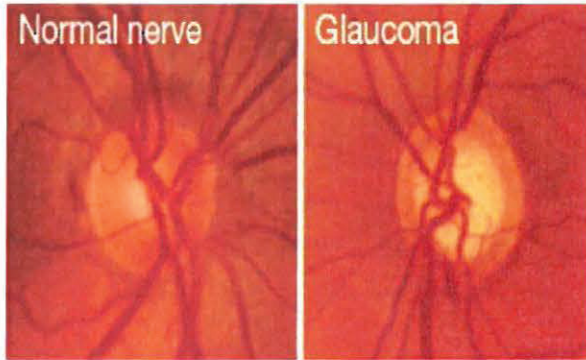


Figure 5: The difference between a normal optic nerve appearance and glaucomatous nerve appearance. Note the narrowing of the rim tissue, large cup to disc ratio, and disc hemorrhage²⁰.

Similar to posterior disease processes, cataracts are a non-refractive type of vision loss. Sixty-nine patients (12.04%) represented this group of candidates. The difference between the age group and cataract group was the age group had previous cataract surgery. All patients with visually significant cataracts are advised against refractive surgery because cataract formation often results in a mild refractive shift and reduction in best corrected visual acuity. All patients with cataracts are advised to seek cataract surgery or advised surgery may be warranted in the near future.

Many patients do not realize the effect of systemic disease on the eyes. In our sample, 51 patients (8.90%) were reported to have a systemic disease. It is important to note in this category, patients with retinopathy secondary to a systemic disease were not included in this category, but rather were included in the retinopathy group. Excluded from this group are the two main systemic causes for ocular pathology: diabetes and hypertension. Examples of systemic disease that are included in this category are multiple sclerosis, rheumatoid arthritis, lupus, and collagen disorders. Patients with advanced multiple sclerosis and myasthenia gravis are contraindicated because of poor

eyelid function²¹. Dryness is a major concern postoperatively so a poor functioning eyelid would not be able to properly spread tears^{21,22}. Patients with collagen disorders can form irregular scarring in the cornea resulting in less than optimal vision. The final deciding factor or question to ask in patients with complex systemic disease is whether refractive surgery would act in the best interest of the patient.

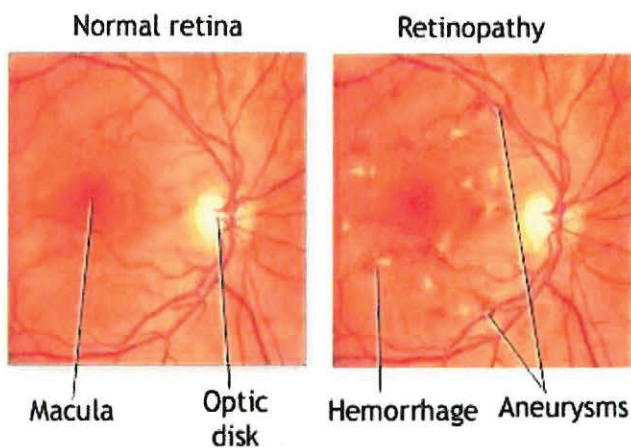


Figure 6: The difference between normal retina and retinopathy depicting hemorrhages, aneurysms, and cotton wool spots²³.

Patients with amblyopia represent 40 patients or about 7% of our sample population. Similar to the above cases regarding non-refractive vision loss, amblyopia is neurological vision loss. The brain's neural processing did not properly develop in these cases. The surgeon involved in this project allows refractive surgery for amblyopes with visual acuity better than 20/40. Best corrected visual acuity worse than 20/40 is considered a non-candidate. Different surgeons may have different parameters regarding amblyopes depending upon individual philosophies.

Corneal disease represents 40 patients or about 7% of the sample population in this project. Similar to categories above, this group was subdivided into three subcategories. The largest subcategory was corneal ectasia suspect representing 27 patients (4.71%). This decision was made based on ORBscan of the posterior corneal plane²⁴. It appears as steepening of 3.00 diopters or more in either a regular or irregular pattern. The ORBscan was the diagnostic factor used to distinguish between keratoconus and ectasia. If a circular pattern was visible on the anterior surface, it was classified as keratoconus. The keratoconus suspect group consisted of 7 patients (1.22%). However, if visible on the posterior plane, it was classified as ectasia suspect. The last subcategory was other corneal surface disease representing 6 patients (1.04%). This subcategory could be conditions like anterior basement membrane dystrophy or Fuchs dystrophy^{22,24,25,26}.

There is a list of medications that are contraindicated for relative surgery. Patients using contraindicated medications accounted for 11 non-candidates or about 2% of the sample. Some medications may require the patient to discontinue use for an extended period of time. In the case of a patient not electing to discontinue use, the patient is considered to be a medical non-candidate. Specific medications such as Imitrex, Accutane, and Topamax all require one month stoppage prior to refractive surgery.

The last category of the project is age representing 6 cases or about 1%. Age is similar to unstable refractive error in the fact that most surgeons have their own parameters. The surgeon involved in this project used a maximum age of 72. In order for surgery to be performed, the patient must have had previous cataract surgery and no

history of dry eye. As the data shows, expected peak visual acuity declines as age increases. As age increases, healing is more difficult and dryness is more prevalent. As age increases, the benefits do not typically outweigh the risks.

Figure 7: Summary of data gathered including percentages and subcategories

Medical Reason	# of Patients
Refractive Error Outside of FDA Parameters	168 (29.32%)
Minus Sphere Too High	57
Plus Sphere Too High	39
Prescription Unstable	34
Cylinder Too High	31
Prescription Too Low	7
Dry Eye	97 (16.92%)
Three Month Failed Therapy	71
No Therapy	26
Posterior Ocular Disease	91 (15.88%)
Retinal Disease	73
Optic Nerve Disease	18
Cataracts	69 (12.04%)
Systemic Disease	51 (8.90%)
Amblyopia	40 (6.98%)
Anterior Surface Disease	40 (6.98%)
Corneal Ectasia Suspect	27
Keratoconus Suspect	7
Other Surface Disease	6
Medications	11 (1.92%)
Age (greater than 72 years)	6 (1.05%)

CHAPTER 4

DISCUSSION OF IMPORTANCE IN OPTOMETRY

Optometrists routinely encounter primary eye care patients interested in LASIK surgery. Optometrists are often referred to as the “gatekeepers of eye care” because the majority of eye care patients are examined by optometrists. Optometrists must know and serve as a knowledgeable resource to the patient. Although different surgeons have different specific parameters and tolerances, the optometrist should be able to consult the patient regarding general indications and contraindications. Data has shown that many patients consult with optometrists prior to seeking a refractive surgery consultation. In some cases, the optometrist can recommend a specific surgeon with a history of successful results. As the frequency of refractive surgery increases, optometrists can play a vital role in co-management. Co-management can open a new revenue source as the patient can seek preoperative and postoperative care with the optometrist.

As shown in the table above, the most frequent cause of rejection is related to refractive error being outside of FDA parameters. As the gatekeepers of eyecare, optometrists should advise patients with refractive errors outside the FDA recommendation accordingly. In addition, optometrists can advise those patients about alternatives to refractive surgery such as clear lens exchange or corneal rings.

The profession of optometry has grown over the past 25 years. With the growth of medical optometry, therapeutic prescribing, and diagnostic topical pharmaceuticals, optometrists diagnose, treat, and manage ocular disease. Optometrists need to be cognizant of the specific diseases that are contraindicated for refractive surgery. Optic nerve and macular diseases are contraindicated because the reduction in vision is not refractive in origin. Non-refractive vision reduction will not be improved with refractive surgery. Amblyopia is a relative contraindication because vision in the amblyopic eye cannot be corrected to a visual acuity equivalent to the other eye. Some corneal dystrophies and degenerations may not manifest in visual acuity loss but can be exacerbated by the laser treatment to the cornea. Examples of contraindicated corneal dystrophies include Fuch's dystrophy and anterior basement membrane dystrophy.

Refractive surgery is an elective form of cosmetic surgery and an estimated 1.5 million procedures are performed each year. As an elective procedure, time must be spent to consult the patient about the benefits and risks and to set realistic expectations for the patient. Refractive surgery is a proven method for treating myopia, astigmatism, and hyperopia. The success rate of patients achieving visual acuity of 20/40 or better is 97%, and furthermore, 90% of all patients achieve visual acuity of 20/20 or better^{2,9}. In order to keep the success rate at this level, appropriate selection of candidates is necessary. The importance of knowing the factors involved in not performing refractive surgery are arguably just as important as knowing the reasons for performing it.

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