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REFRACTIVE SURGERY INFORMATION STATEMENT

Introduction

Refractive surgery encompasses a variety of technologies and procedures for correcting several common eye conditions such as myopia (nearsightedness) and hyperopia (farsightedness). The surgery changes the focusing characteristics of the eye to achieve a clearer image. These surgeries may change the shape of the cornea, implant an artificial lens, or alter the eye in other ways.

Refractive surgery offers millions of eyeglass and contact lens wearers new alternatives for improving their vision. While most of these people are accustomed to the benefits of eyeglasses or contact lenses, few understand the technology, benefits and risks associated with refractive surgery. Because of the large impact refractive surgery is likely to have on the visual well-being of so many Americans as well as on standards of eye care, Prevent Blindness America has set forth this statement which, in summary, suggests:

- Anyone considering refractive surgery should become well-informed about the various surgical alternatives.
- They should also carefully review the procedure's potential benefits and possible risks, including a thorough discussion of these and other facets of their surgery with their own doctor. Prevent Blindness America takes no position regarding the appropriateness or recommendation of refractive surgery for any given patient or under any given circumstances.
- Eye care professionals who provide refractive surgery should do so only within the prevailing standards of care and in the best interests of the patient. The instruments used in refractive surgery should be used only in accordance with applicable laws and regulations.
- Issues regarding the inclusion or exclusion of the various forms of refractive surgery within the legal scope of practice of any given eye care profession are best decided by appropriate state licensing entities. Prevent Blindness America takes no position regarding scope of practice matters.

Types of Refractive Surgeries

Three forms of refractive surgery are now commonly available in the U.S.:

Radial Keratotomy, or **RK** as it is often called, is one of the oldest forms of refractive surgery. In RK, an eye surgeon usually uses a scalpel to make from four to eight tiny cuts into the cornea. The cuts are arranged like spokes on a wheel. The cuts allow the cornea to flatten, lessening its focusing effect on the light entering the eye. This process is most commonly used to correct nearsightedness.

Photorefractive Keratectomy, **PRK**, is a more recent development in refractive surgery. Like RK, PRK changes the shape of the cornea to correct problems like nearsightedness. In PRK, however, a laser is used to remove the outer layers of the cornea to create a flatter shape. The laser instrument used in PRK can also re-shape the cornea to correct conditions like nearsightedness and astigmatism.

LASIK is an acronym for **Laser In Situ Keratomileusis**. LASIK is another type of refractive surgery that uses a laser to reshape the cornea. Rather than removing the outer layers of the cornea like PRK, a surgeon performing LASIK first uses a special cutting instrument to cut a thin flap into the top of the cornea. This outer flap is folded back and the exposed inner tissue of the cornea is then reshaped with the laser. Afterward, the flap is folded back into place. This preserves the outer layers of the cornea and helps to speed healing.

Several other forms of refractive surgery are under development but are not yet widely available. The safety and effectiveness of these procedures are under study. These include the following:

Intrastromal corneal ring segments are curved plastic strips that are surgically implanted into the cornea. The segments push outward on the cornea to flatten its shape to correct nearsightedness. Segments of different thicknesses can be used to create the right amount of change in the cornea. Segments can also be exchanged if the implanted ones do not produce the desired effect.

Intracorneal lenses are tiny lenses that can be surgically placed directly into the cornea. Like a contact lens, these can be shaped to correct most refractive error.

Implantable contact lenses function like the soft contact lenses many people place on the surface of their eye. These lenses, however, are implanted by a surgeon not on the cornea, but inside the eye in front of the natural lens using surgical techniques similar to those used to correct cataracts.

Undoubtedly, additional refractive procedures will be developed and these surgeries may soon offer even more choices for correcting common vision conditions.

Safety

By the time refractive surgeries are widely available to the public, they are generally performed thousands of times and are carefully studied to demonstrate their safety and effectiveness. In addition, instruments used by surgeons for many of these procedures are regulated by the U.S. Food and Drug Administration and have been approved for these uses.

Like any other surgery, however, refractive surgery also has potential risks. These risks fall into three broad categories: over-correction or under-correction of the vision problem being treated, complications after the surgery such as infections or scarring, and damage to the eye caused by problems that occur during the surgery.

The most common problem with refractive surgery is over- or under-correction. This simply means that the change created in the focusing power of the eye is too great or too small. Ideally, refractive surgery returns a person's vision to normal without the need for additional correction with eyeglasses. However, the amount of change created by the surgery can only be estimated by the surgeon. While the accuracy of these predictions is usually high, it is possible that a person will still need additional correction to see at 20/20 or some other acceptable level. RK in particular has been shown to cause a gradual shift toward over-correction a number of years after the surgery. Any long-term changes from other refractive surgeries will only become known after the surgeries have been available for ten or more years.

Complications that can occur after refractive surgery include infections and corneal scarring. Although uncommon, infections can cause problems ranging from discomfort and delayed healing to serious damage to the cornea and permanent loss of vision. Corneal scarring is also uncommon but can occur as a result of infection, the presence of diseases like rheumatoid arthritis, or other problems with the eye's natural healing process. Mild corneal scarring can result in poorer-than-expected visual acuity. Severe cases can reduce vision significantly and permanently, even to the point of blindness.

Damage to the eye resulting from problems that arise during surgery is rare, but can have serious results. In RK, for example, it is possible for the surgeon to cut too deeply and penetrate completely through the cornea, rupturing the eye. The instrument used to cut the flap in LASIK can cut too deeply or not deeply enough. Other problems can occur unrelated to the skill of the surgeon or the quality of the instruments used, such as unusual reactions to anesthesia.

It is impossible to discuss every possible complication of every refractive surgical procedure in this brief document. Your doctor should review with you the possible complications of the procedure you are considering and answer your questions about these.

Refractive Surgery Considerations

Prevent Blindness America takes no position regarding the appropriateness or recommendation of refractive surgery for any given patient or under any given circumstances.

Refractive surgery can offer a permanent alternative to glasses or contact lenses to many people with common vision problems. People with nearsightedness or astigmatism can benefit from the currently available forms of refractive surgery. Those with farsightedness may have to wait for new or refined refractive surgeries to arrive.

If you are counting on refractive surgery to free you from wearing glasses or contact lenses, you should be aware that there is no guarantee the surgery will accomplish this. As mentioned above, a small percentage of patients will continue to need their eyeglasses or contact lenses due to over- or under-correction. There is no way that an eye doctor can guarantee that you will no longer need glasses or contact lenses to reach the clearness of vision you desire after the surgery.

Cost is another factor to consider before seeking refractive surgery. The surgery can cost several thousand dollars per eye and is usually not covered by most medical insurance plans. If you are uncertain about your insurance coverage for refractive surgery, contact your insurance company.

In addition, as people get older, they find it increasingly difficult to change focus from seeing objects far away to seeing up close (for example, when reading). This condition is called presbyopia. In general, refractive surgery does not relieve this problem. Most people who have refractive surgery will need reading glasses as they get older. However, some people who have refractive surgery chose to have one eye corrected for seeing objects far away and the other eye corrected for seeing objects close up. If you are concerned about the future need for reading glasses, you should discuss this alternative with your doctor.

Also, as mentioned above, refractive surgery can have serious, if uncommon, risks. For example, blunt trauma to an eye that has had radial keratotomy can cause rupture and loss of the eye. It is very important that you understand and carefully consider these risks before consenting to surgery. Your doctor should describe these risks for you and you should make certain that all your questions regarding them have been answered before making your decision.

Finally, some people are simply not good candidates for refractive surgery because of the risks presented by their health status or other characteristics. For example, people with connective tissue diseases such as rheumatoid arthritis or lupus erythematosus may be more likely to suffer severe scarring as a result of refractive surgery. People with certain eye conditions like glaucoma, retinal disease or dry eye also may not be

good candidates for refractive surgery. People taking certain medications including immunosuppressants or corticosteroids are at greater risk of infection following surgery. Be sure to inform your doctor of any health problems you may have and any medications you may be taking.

Refractive Surgery Providers

In the United States, refractive surgery procedures can be performed only by a physician licensed to practice medicine and surgery, generally a medical doctor (M.D.) or a doctor of osteopathy (D.O.). Most frequently, this is an M.D. specializing in ophthalmology. Oklahoma is currently the only state that permits optometrists (O.D.) to perform “laser surgery” including PRK.

Individual state licensing agencies and legislatures determine which procedures the various eye care providers can perform. Prevent Blindness America believes issues regarding the legal scope of practice of any given eye care professions are best settled by appropriate state licensing authorities and/or legislatures and takes no position on scope of practice issues.

Both optometrists and ophthalmologists may be involved in the care of a refractive surgery patient before and after the surgery. Doctors who provide refractive surgery must also conduct the surgery within the prevailing standards of care and in the best interests of the patient. Since some of the instruments and lasers used in refractive surgery are regulated by the U.S. Food and Drug Administration, doctors should use these instruments only in accordance with applicable laws and regulations.

The Prevent Blindness America Scientific Advisory Committee Task Force on Refractive Surgery

This statement was prepared by members of Prevent Blindness America's refractive surgery task force. Prevent Blindness America gratefully acknowledges their contribution. The members of the task force are:

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Approval

This statement was approved by the Prevent Blindness America board of directors executive committee in September, 1998.

Founded in 1908, Prevent Blindness America is the nation's leading volunteer eye health and safety organization dedicated to fighting blindness and saving sight. Focused on promoting a continuum of vision care, Prevent Blindness America touches the lives of millions of people each year through public and professional education, advocacy, certified vision screening training, community and patient service programs and research. These services are made possible through the generous support of the American public. Together with a network of affiliates, divisions and chapters, it's committed to eliminating preventable blindness in America. For more information, or to make a contribution to the sight-saving fund, call 1-800-331-2020 or visit us on the web at www.preventblindness.org.

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