Refractive Surgery Part 2: Complications and Recent Advances

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Abstract

While LASIK and PRK have been used for two decades, there have been few long-term studies on refractive surgery. This study examined the long-term outcomes of LASIK and PRK and analyzed the risks, benefits, and technological breakthroughs of these procedures. Rates and causes of patient satisfaction are discussed in detail. Alternative techniques such as small-incision lenticule extraction (SMILE) and surgical options for presbyopia are also explored.

KEY WORDS:
PRK, LASIK, SMILE, KAMRA, ectasia

COMPLICATIONS & DISSATISFACTION

Although about 95% of patients in the available world literature are satisfied with LASIK surgery, as with any surgical procedure, not all candidates will be pleased.[10] In a literature review, 4.6% of patients were dissatisfied with surgery due to refractive error, night vision problems, dry eye and older age.[10] Some of the most frequent complaints of dissatisfied patients are uncorrected refractive error leading to poor distance vision, glare and haloes, dry eye, blurred near vision and night vision problems.[10,26,47]

With better appreciation and screening of pre-existing conditions along with improved guidelines for the upper limits of refractive error, as well as enhanced technology, satisfaction rates are likely higher today.[6,10]

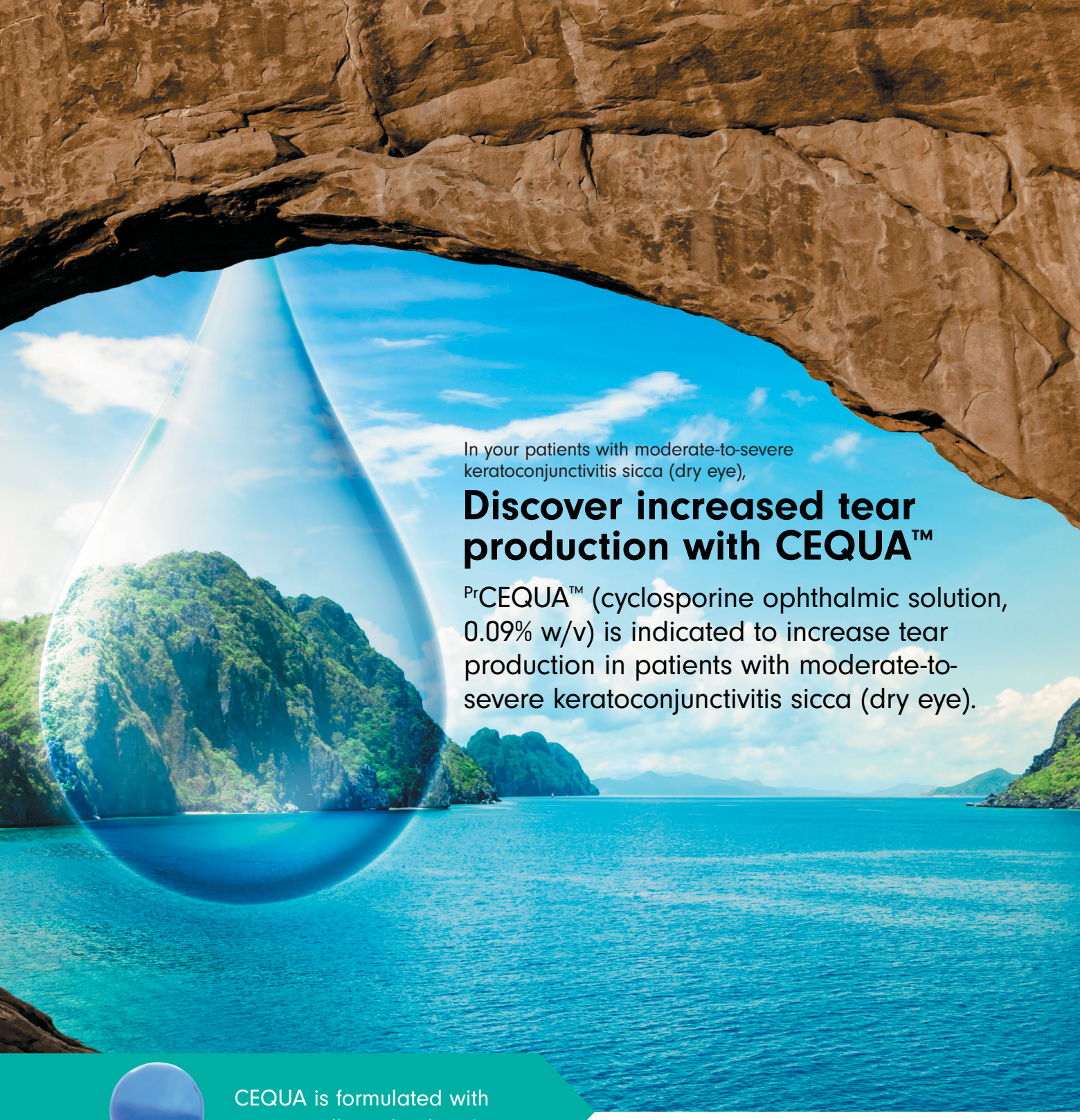
REGRESSION

Myopic regression with LASIK has been explained in terms of both corneal and non-corneal causes.[12,35] The extent to which each factor contributes to myopic regression over the long-term with LASIK is unclear.[12] Corneal changes are based on alterations to the biomechanics of the cornea.[12] Interestingly, non-corneal changes, such as increases in axial length secondary to vitreous chamber elongation, may increase myopia in adults.[12,35] Therefore, patients with high myopia and younger patients undergoing LASIK should be counseled that they may need retreatment in the future.[35]

Since the early days of refractive surgery, the possibility of regression and a reduction in biomechanical strength have been cited as potential progressive long-term complications.[3] Myopic regression can sometimes be perceived as a positive development as the patient reaches presbyopia and is therefore able to delay the need for reading glasses.[38]

PSYCHOLOGICAL FACTORS

Evaluations of the patient's motivations and expectations as well as their mental and physical well-being can be helpful.[26] Factors such as a history of anxiety and depression may negatively affect outcomes.[26] Post-operative complaints are also due to unrealistic expectations, personality[50] and psychopathological conditions.[18] Individuals suffering from depression are known to have worse outcomes after other surgical procedures, such as coronary bypass-grafting traumatological procedures.[18] Several psychi-



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atric procedures have been associated with a greater risk of post-LASIK complications, like flap dislocation from abnormal rubbing in OCD patients.[18] Patients with depression are more likely to experience dissatisfaction from unmet expectations.[50] The literature has shown decreased patient satisfaction with LASIK in patients who are depressed.[50] Of note, women are up to twice as likely to be depressed than men.[50]

As in other elective surgical procedures, LASIK carries a risk of litigation.[51] The most important predictor of a claim against a physician was having a high-volume clinic.[51] Such high-volume clinics that use aggressive marketing, portray refractive surgery as cosmetic rather than medical and fail to spend adequate chair time with patients are particularly likely to have decisions rendered against them.[51]

DRY EYE

The most common complication of LASIK is dry eye,[20,33] with up to 95% of patients experiencing some form of dryness post-surgically.[29] Dry eye is also the main complication of PRK.[8] Dry eye is one reason for patient dissatisfaction despite good visual outcomes.[10] The symptoms are most common immediately after surgery and are generally transient in nature.[11,33,52] Symptoms peak in the first few months after surgery and improve six-to-12 months thereafter.[8,29]

Roughly 20 to 40% of patients report dryness six months after surgery.[11] Dry eye symptoms generally return to preoperative levels by the one-year mark[8] Dry eye generally improves over time, but can persist in some cases for months or years.[26] Preoperative dryness and the sex of patients (female) may confer a higher risk.[11]

The pathophysiology of how LASIK contributes to dry eye is multifactorial.[20,29,53] However, it is thought to be chiefly rooted in iatrogenic corneal nerve damage to the sub basal nerve plexus[10,54] and stromal corneal nerves during anterior stromal flap creation and corneal laser ablation.[29,33,55] The interruption of sensory fibers of the cornea reduces the stimulus to tear production.[11,55] Tear quantity is reduced and osmolarity is increased with improvement at the three-month post-operative mark.[11] Dry eye may also be caused by alteration of the distribution of the tear film and the ensuing relationship of the ocular surface to the upper lid.[8]

Higher refractive error, deeper stromal ablation and preexisting dry eye are associated with increased severity of post-surgical dry eye.[29,33] In addition, patients over 40, females, patients of Asian descent (possibly because of higher refractive errors, extensive contact lens use and eye anatomy) and those who undergo a procedure in which a keratome is used to create the flap are also at greater risk.[20] Goblet cell damage and post-operative inflammatory changes may also be involved.[20,29] LASIK-induced

damage to the sensory nerve fibers of the cornea diminishes basal and reflex tearing, slows the blink rate and impairs the neurotrophic effect on corneal epithelial cells.[20,29,56] Corneal sensitivity is reduced after both PRK and LASIK.[20,29,52] While the exact timeline is still controversial, recovery from these issues as reflected by tear quality is observed at the six- to nine-month point.[29]

As PRK involves a shallower depth of the cornea, recovery from post-surgical dryness is quicker than that after LASIK.[52] PRK patients tend to complain of soreness or pain rather than dryness.[20] TBUT (tear break-up time) and tear secretion take longer to return to normal in North-East Asian patients than in Caucasian patients.[20]

Most studies have indicated that corneal sensation and clinical signs and symptoms of dry eye return to pre-operative levels within one year,[8,29] but corneal nerve morphology continues to be abnormal.[29] Unfortunately, a small percentage of patients may have the condition indefinitely.[52] As can be surmised, dry eye can substantially affect a patient's perception of their surgery and level of satisfaction.[29]

A recent study suggests a possible link between genetics and susceptibility to chronic post-surgical pain with LASIK (expressed as dry eye disease), offering a pathway to future screening of patients at risk.[53]

Identification of preoperative dryness could help predict chronic dry eye development in PRK and LASIK patients.[6,52] As one group framed it, "Dry eye disease (DED) is commonly encountered but poorly understood, difficult to define and lacks a unique diagnostic tool".[29] Most patients with post-LASIK dry eye fair well with standard treatments for dry eye.[29]

A history of contact lens intolerance may be a predictor of post-LASIK dryness and should be part of the preoperative discussion.[25] Interestingly, those who have never worn contact lenses (spectacle wearers) may be less aware of their tendency toward dry eye, which may manifest post-surgically.[25]

Chronic post-LASIK dry eye also increases the risk of myopic regression.[29,33] Careful preoperative screening and pre-emptive treatment of existing disorders, such as MGD or blepharitis, can aid in mitigating post-operative complications.[10] MGD can significantly contribute to ocular surface discomfort and inflammation.[29,57] Initial treatment includes warm compresses and lid scrubs along with gentle lid massage.[29,57] Cyclosporine can also be used to treat dry eye.[29,58] Autologous serum eye drops composed of a patient's own serum provide a unique source of growth factors and anti-inflammatory factors that could be effective for the post-LASIK dry eye sufferer.[29] Autologous serum eye drops, however, are not yet FDA approved. A comparison of serum and artificial tears demonstrated improved TBUT and less ocular staining in the serum tear group at six months post-operatively.[29]

In the future, treatments targeting nerve healing will hopefully improve post-LASIK dry eye.[29] Modern thin-flap LASIK has been associated with a reduced incidence of long-term dry eye.[10] With greater attention placed on conditions, such as blepharitis,[57] and novel artificial tear formulations, these issues are more manageable than before.[10,58] All patients should be educated on the importance of UV protection to avoid complications associated with such exposure.[59]

NIGHT VISION PROBLEMS

Night vision problems are one of the most frequent post-operative visual symptoms associated with LASIK.[9] In severe cases, this may result in driving impairments and medico-legal litigation.[9] LASIK is associated with haloes and glare, probably in part due to the dramatic change in corneal shape.[22]

Different forms of night vision disturbances (NVD) have been reported by patients who have undergone refractive surgery.[46] Starburst is thought to be caused by a transient loss of transparency in the post-operative period while halo phenomena are based on the margin of the corneal ablation within the pupillary area.[46] Pupil size on its own does not seem to be important for subjectively perceived night vision distortion.[46] Regardless of pupil size, patients should be aware of the potential for night vision issues with LASIK surgery.[26] Secondary astigmatism, coma and spherical aberration are higher-order aberrations (up to the sixth order) that are significantly correlated with the halo disturbance index.[46] Smaller treatment zone sizes can decrease nighttime visual performance (cause halo formation) after LASIK, particularly in high refractive conditions.[26] There is reason to believe that a significant proportion of NVD are simply the result of residual uncorrected refractive error as patients report these phenomena without the use of spectacles or contact lenses.[38] In one study, complaints of

NVD decreased by 90% once the residual refractive error was corrected.[38] The proportion of patients suffering from NVD in long-term studies varies considerably (from as low as 3% to as high as 80%). Proper pre-surgical patient education on potential complications could prevent these issues from being a cause of post-operative dissatisfaction.[22]

ECTASIA

Ectasia, while extremely rare, is a serious complication following LASIK.[22,60] LASIK reduces the biomechanical stability of the cornea by intersecting with structural lamellae in the anterior cornea and by removing structural lamellae during ablation.[60] Post-LASIK ectasia is a progressive structural corneal deformation leading to a refractive and optical instability after otherwise uneventful LASIK surgery.[61]

Post-LASIK corneal ectasia is characterized by a progressive thinning and steepening of the central and inferior portions of the cornea.[62] The main concern with corneal ectasia is the risk of varying degrees of permanent vision loss.[61]

A pre-operative keratoconus suspect topography is considered to be the most critical risk factor for ectasia.[61] Seventy-five percent of cases (of ectasia) in one study were considered keratoconus suspects, which is not surprising.[61]

Low corneal thickness, young age (under 25) [40] and high myopia have been regarded as risk factors for corneal ectasia.[61] The amount of tissue removed may be a better indication of corneal biomechanical destabilization.[61] A small percentage (from 0.4 to 0.6%) of patients will have corneal ectasia post-surgically.[26]

Biomechanical instability is of particular concern with iatrogenic keratectasia being recognized as a late risk refractive procedure.[17]

Corneal collagen cross-linking (CXL) using riboflavin in concert with ultraviolet A (UVA) is a new treatment for increasing corneal biochemical resistance by adding polymer bands between collagen fibers.[62,63] Over the past 10 years, CXL has been shown to be effective for delaying or arresting the progression of keratoconus.[62]

A study from China using CXL to treat post-LASIK corneal ectasia showed that the procedure stabilized or partially reversed progression without apparent complications.[62] The authors suggested that the procedure should be conducted as soon as the complication was identified in order to arrest progression.[62] CXL may offer a way to reduce long-term regression in high myopes undergoing LASIK.[60]

Prophylactic CXL for high-risk LASIK cases appears to be a safe and effective adjunct therapy for refractive regression and potential ectasia.[60] Prophylactic CXL may be particularly indicated in young patients with an unknown family history, especially in countries with a high incidence of keratoconus.[60] Long-term outcome data show the safety and efficacy of LASIK Xtra (combining LASIK with high fluence CXL) in stabilizing myopia and hyperopic LASIK results.[64]

The risk of ectasia is significantly lower than it was a decade ago based on modern keratoconus screening techniques and the availability of CXL.[37]

ADVANCES IN REFRACTIVE SURGERY

Femtosecond laser: A newer technique employs a femtosecond laser instead of a mechanical microkeratome to create a flap ("all–laser" LASIK).[11,33] The use of a femtosecond laser for LASIK flap creation was approved by the FDA in 2001.[29]

While it is more costly than the standard microkeratome, the femtosecond laser is potentially more accurate,[65] more reliable and safer.[26,29,66,67] Femtosecond lasers may also provide more predictable flap thickness,[54,67–69] less LASIK-induced dry eye, quicker recovery and better UDVA than a mechanical keratome.[15,70] One study showed that a femtosecond laser had a significantly higher TBUT than traditional LASIK with a mechanical microkeratome.[33]

While a femtosecond laser has been shown to decrease dry eye signs and symptoms in several studies, these newer lasers also decrease conjunctival goblet cell density.[20,29] The effect of goblet cells on LASIK-induced dry eye is not well understood.[29,52,58] Femtosecond LASIK flaps are typically associated with complications owing to a heightened inflammatory response, such as diffuse lamellar keratitis.[71] Distinct complications, such as transient light-sensitivity syndrome, opaque bubble layer, rainbow glare and vertical gas breakthrough have also been known to occur.[65,66]

The latest femtosecond units employ significantly lower energy delivery to cut the flap, decreasing the overall inflammatory response so that it is virtually indistinguishable from a mechanical microkeratome.[72] Femtosecond LASIK flaps have a lower incidence of complications, such as epithelial defect and flap dislocations, than microkeratomes.[71]

Further studies, including long-term follow up, are necessary to better understand the full implications of this technique.[65]

Wavefront: Technology has taken large leaps forward with customized surgery, personalized nomograms and femtosecond lasers for flap creation.[10] LASIK has become more effective with the introduction of newer equipment.[6,11,67] If a scanning laser with eye-tracking or a wavefront-guided laser is applied, more than 80% of patients achieve vision within half a dioptre of the target,[11] and more than 95% achieve vision within one dioptre of the target.[11] Almost all patients achieve at least 20/40, and most reach a UCVA of 20/20.[6,11]

Wavefront-guided LASIK tailors the laser correction to the particular pattern of corneal aberration of each patient.[11] Spherical aberration (SA) is the most significant consequence of refractive surgery apart from a prescription change.[9] Aspheric ablation techniques decrease SA and improve vision under dim lighting conditions.[10,26] Patients with night vision symptoms after myopic LASIK refractive surgery (glare, haloes and starbursts) have considerably higher SA than asymptomatic patients.[9] With the use of topographic corneal wavefront-guided customization, there is a significant improvement in night vision symptoms and decreased SA following retreatment.[9] Several studies have reported fewer post-operative complaints of glare and haloes at night with wavefront-guided LASIK.[26] Most North American surgeons choose wavefront-guided ablative corneal surgery.[11]

Retreatment: As wavefront-guided LASIK becomes more popular, retreatment may become more prevalent based on patients' higher expectations of visual outcomes. In one study, over 90% of patients were satisfied with their retreatment outcomes.[23] Myopic LASIK retreatment seems to carry fewer risks and is more effective than hyperopic retreatment.[23] Retreatment may sometimes be the only way to improve a patient's satisfaction.[23] Although LASIK can be repeated if necessary, the risks dictate that it should not be suggested for small changes in refraction.[72]

SMILE: Small incision lenticular extraction (SMILE) has attracted much attention as an alternative to LASIK and PRK because of its promising early results.[54,55,67,73–75]

SMILE is a minimally invasive surgery that uses femtosecond laser exclusively to create a intrastromal lenticule that is then extracted manually via a small corneal incision.[54,55,76] SMILE thus eliminates the need for both excimer laser ablation and flap creation.[54,76]

SMILE can reduce complications associated with flap creation in LASIK that often result in the severing of corneal nerves and lead to dryness (decreasing patient satisfaction).[54,55] Dry eye possibly caused by neurotrophic epitheliopathy because of damaged subbasal nerve plexus in refractive surgery may be diminished by SMILE.[54,76] The absence of a flap may preserve more corneal nerves in SMILE.[54] Corneal nerves also may heal faster after SMILE than after LASIK.[54] Further, TBUT,[55] osmolarity and dry eye severity score may be better with SMILE than with LASIK.[54] There is also evidence that SMILE may also induce less higher-order aberration than femtosecond LASIK.[67]

While multiple studies have compared SMILE and LASIK, neither technique is conclusively superior to the other.[55] However, there is some indication that SMILE may decrease dry eye symptoms and corneal sensitivity may be greater after SMILE than after LASIK (once again, probably because of the lack of flap creation that severs corneal nerves[55]).[67,76] The visual recovery of SMILE may be faster than that with PRK but slower than that with LASIK.[54] Some studies have found that corneal hysteresis and corneal resistance are far less stable with LASIK for myopic corrections over -6.00D than with SMILE, but the results are controversial.[54] Equally contentious is the idea that post-operative tensile strength is superior in SMILE.[54] Possible advantages of SMILE in maintaining biomechanical strength[67] and corneal nerves (over LASIK or PRK)[54] need further evaluation.

SMILE does have distinct complications, such as difficult or incomplete removal of the lenticule and slower visual recovery.[54] As with LASIK and PRK, high myopes appear to be at risk of significant regression with SMILE.[77] One study showed that the regression rate after five years was similar to the mean annual regression rate of LASIK.[54] Research is ongoing regarding the application of SMILE to hyperopic patients and preliminary results appear promising.[74] SMILE exhibits safety, efficacy, predictability and stability comparable to those in femtosecond LASIK.[54,55,67,75]

Studies regarding SMILE are still limited in scope and duration, and therefore there continues to be controversy.[55] Further research is needed to properly compare SMILE to existing procedures and evaluate the benefits of this novel technique.[55]

OPTIONS FOR PRESBYOPIA

Presbyopia is the most common refractive disorder, affecting 2 billion people worldwide.[69] It is defined as the inability to focus on nearby objects because of a loss of elasticity of the crystalline lens, which generally manifests after age 40.[16,78] Today, an increased number of patients who have had LASIK are becoming presbyopic.[15] Several treatments exist, such as multifocal or monovision contact lenses, monovision LASIK, multifocal LASIK (presbyLASIK), multifocal intraocular lenses (IOLs) and accommodating IOLs.[15,16]

Correcting presbyopia has been shown to significantly improve the patient's quality of life.[79]

Monovision: Monovision is a technique where the dominant eye is generally corrected for distance and the non-dominant eye is corrected for near vision.[78] In 2007, the FDA approved LASIK to achieve monovision.[80] Monovision LASIK successfully improved near vision in presbyopic patients.[78] Moreover, monovision has been associated with high rates of satisfaction, surpassing 90% in various studies.[81] While visual acuity was good, contrast sensitivity and stereoacuity were substantially decreased.[80,78] Patients with binocular vision anomalies or who require strong stereoacuity for their occupation should not undergo monovision LASIK.[80]

Multifocal ablation: In multifocal ablation, the same part of the cornea is corrected for distance and near vision.[80,81] While multifocal ablation does not substantially affect stereoacuity, it does decrease contrast sensitivity, increase coma and decrease spectacle-corrected visual acuity.[80] Several studies have confirmed the safety, predictability, stability and visual quality of multifocal LASIK techniques.[81] A detailed case history that takes into account the patient's demands (profession, hobbies, expectations, etc.) is critical.[81]

Despite the predictability of optical results, some patients find it difficult to adapt to the compromise between distance and near vision.[81]

Kamra: Artificial aperture stops can also be used as a solution for presbyopia by increasing the depth of focus.[81] Based on the pinhole effect, the depth of focus increases by artificially reducing the pupil's aperture size, leading to improved VA in near and intermediate tasks.[69]

A corneal inlay is placed within the cornea underneath the LASIK flap or via a corneal pocket.[79] The first inlays were implanted in the 1940s,[15,79] but failed because of several significant complications.[79] The Kamra corneal inlay has a 5-μm-thin microperforated artificial aperture made of biocompatible polymers with good long-term safety and patient satisfaction during follow-up for up to 4 years.[79] The procedure is also reversible,[69,79] can be combined with other refractive procedures and does not require neuroadaptation, as is necessary in monovision or multifocal LASIK.[79]

One study suggested that, after removal of the corneal inlay, corneal topography and corneal aberrometry are not permanently affected.[82] In more than 60% of patients, CNVA, CDVA, UNVA and UDVA were similar to pre-operative values.[82]

Kamra can also be performed on previous LASIK patients via a secondary interface (corneal pocket).[15] Symptoms similar to those experienced after LASIK (such as dry eye, glare, halo and night vision problems) have been reported after Kamra surgery in previous LASIK patients.[15]

As in all procedures, patients should be carefully counseled and their expectations managed.[15] The pocket technique damages significantly fewer corneal nerves than a conventional flap.[69] This may decrease the prevalence of post-surgery dry eye symptoms and preserve the biomechanical properties of the cornea.[69] Although the amount of light transmission through the inlay is diminished, there is no evidence of visual field constriction or a ring scotoma due to the position of the inlay.[69]

A long-term study of patients who underwent LASIK and Kamra simultaneously demonstrated the safety and effectiveness of using the techniques in concert. The procedures improved near vision with a minimal effect on distance acuity.[83]

Emerging Surgical Options for Presbyopia: Several clear inlays are emerging, such as the Raindrop Near Vision Inlay and Flexivue Microlens, both of which show a multifocal effect through various mechanisms of action.[84]

Intracor is a minimally invasive technique for addressing presbyopia where femtosecond laser pulses are used to restore the flexibility of the crystalline lens.[45] Isolated lens opacification is a potential side effect.[45]

Multifocal IOL are an alternative to laser procedures, though still presenting with a compromise to pre-presbyopic function (much like multifocal contact lenses).[84] In theory, an accommodating IOL would replicate the performance of a young eye, thereby allowing the patient to focus on distant and near targets. However, the current products on the market have not delivered consistent and effective results.[84]

Contact Lenses versus LASIK: Although both contact lens wear and LASIK possess risks, most assume that surgery is riskier than contact lens wear.[72] For lenses, the vision loss is due to contact lens-related microbial keratitis (CLMK).[63] CLMK is a potentially blinding complication that results predominantly from overnight contact lens wear.[63] With LASIK, the risks can involve several complications.[72] Notably, the risk of rigid gas-permeable (RGP) contact lenses never surpassed the risk associated with LASIK.[72]

Extended-wear soft contact lenses (intended for sleeping in contacts) had the highest risk of all contact lenses and exceeded the risk of vision loss associated with LASIK under most conditions.[72]

LASIK can sometimes provide better correction than contact lenses for patients with severe astigmatism whose vision may be affected by lens rotation.[72] Both LASIK and contact lenses have been associated with glare, haloes, starbursts, dry eye and eye irritation. For many patients with low to moderate myopia, long-term contact lens wear may actually be riskier than LASIK surgery.[72] Contact lenses, though they eliminate various problems associated with glasses, are difficult to maintain for soldiers under battle conditions in terms of hygiene.[4] In a Japanese study, 61.9% of soldiers did not change their contact lenses at all during military exercises.[39] Since Operation Iraqi Freedom began, over 200 cases of CLMK have been treated despite official policy forbidding the use of contact lenses.[4]

The notion that LASIK can cause dry eye is indeed well-documented.[4] This can be a particular concern under the extreme environmental conditions that a soldier may face because the symptoms tend to be aggravated.[4]

Although studies on monovision LASIK are rare, there is evidence to suggest that patients who have had surgery are more satisfied than those with contact lenses; 88 to 98% of those who underwent monovision LASIK were pleased with the procedure.[80]

Globally, evidence suggests that individuals who undergo LASIK enjoy a better quality of life than those who wear glasses or contact lenses.[22]

A three-year longitudinal survey that compared visual satisfaction with LASIK and contact lenses found that former contact lens wearers believed their night driving had improved after undergoing LASIK.[25] These patients did not report a significant increase in dry eye and reported higher levels of satisfaction than their counterparts who continued wearing contacts. Similarly, the incidences of serious complications, such as corneal ulcers, decreased significantly in those who had undergone LASIK as opposed to those who remained in contact lenses.[25]

CONCLUSION

Long-term studies worldwide confirm that refractive procedures are safe and effective for the correction of ametropia. While any surgery involves risks, proper counseling of patients can minimize the gap between expectations and results. ●

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